MANNKIND CORP
Form 10-K
March 18, 2013
Table of Contents

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, 2012

or

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

Commission file number: 000-50865.

MannKind Corporation

(Exact name of registrant as specified in its charter)

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

Registrant s telephone number, including area code

(661) 775-5300

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

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

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

None

(Title of Class)

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

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

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

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

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

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

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

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

As of June 29, 2012, 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 $264,556,791.

As of March 13, 2013, there were 289,350,125 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 2013 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.

Table of Contents

MANNKIND CORPORATION

Annual Report on Form 10-K

For the Fiscal Year Ended December 31, 2012

TABLE OF CONTENTS

Table of Contents

Forward-Looking Statements

Statements in this report that are not strictly historical in nature are forward-looking statements. These statements include, but are not limited to, statements about: the progress or success of our research, development and clinical programs, including the application for and receipt of regulatory clearances and approvals, and the timing or success of the commercialization of AFREZZA, if approved, or any other products or therapies that we may develop; our ability to market, commercialize and achieve market acceptance for AFREZZA, or any other products or therapies that we may develop; our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; our estimates for future performance; our estimates regarding anticipated operating losses, future revenues, capital requirements and our needs for additional financing; and scientific studies and the conclusions we draw from them. In some cases, you can identify forward-looking statements by terms such as anticipates, believes, could, estimates, expects, goal, intends, may, plans, predicts, projects, should, will, would, and similar expressions intended to identify forward-looking statements. These statements are only predictions or conclusions based on current information and expectations and involve a number of risks and uncertainties. The underlying information and expectations are likely to change over time. Actual events or results may differ materially from those projected in the forward-looking statements due to various factors, including, but not limited to, those set forth under the caption Risk Factors and elsewhere in this report. Except as required by law, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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

PART I

Item 1. ***Business***

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

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

PRODUCT CANDIDATES

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

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

Table of Contents

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

The AFREZZA clinical development program was designed to demonstrate that the efficacy of insulin administered as AFREZZA inhalation powder is comparable to the most effective standard of care rapid-acting insulin analogs as measured by the reduction in levels of glycosylated hemoglobin, or A1c, which is a measure of average blood glucose. We have also demonstrated that the comparable reductions in A1c seen with AFREZZA powder are associated with a lower risk of hypoglycemia for both subjects with type 1 and type 2 diabetes. For example:

- In a completed Phase 3 clinical study, insulin-dependent subjects with type 2 diabetes were randomized to either injected premixed insulin or mealtime AFREZZA in combination with insulin glargine (an injected basal insulin). This study demonstrated that the reduction in A1c levels over 52 weeks of therapy with the combination of AFREZZA and insulin glargine was non-inferior to premixed insulin. Moreover, the combination of AFREZZA and insulin glargine achieved these results with significantly less hypoglycemia and weight gain than the premixed treatment group. These differences in rates of hypoglycemia and weight gain were not due to differences in glycemic control.

- In a completed Phase 3 clinical study involving subjects with type 1 diabetes, we compared the efficacy and safety of AFREZZA in combination with insulin glargine versus insulin lispro (an injected rapid-acting analog) in combination with insulin glargine over a 16-week treatment period. The results of this study demonstrated that AFREZZA in combination with insulin glargine is non-inferior to insulin lispro in combination with insulin glargine. The subjects treated with AFREZZA in combination with insulin glargine also had significantly lower rates of total and mild or moderate hypoglycemia than the insulin lispro-treated group. This difference in the rates of hypoglycemia was not due to differences in glycemic control.

There are no assurances, however, that the US Food and Drug Administration, or FDA, will agree that the advantages of AFREZZA shown in these studies are sufficient to support approval or will otherwise be included in final product labeling or advertising.

To date, our clinical trials have indicated that AFREZZA has a favorable safety profile. The most common adverse event associated with AFREZZA therapy was a transient, mild and non-productive cough, which occurred early in about 25-30% of subjects and diminished within the first few weeks after initiation of AFREZZA therapy. The occurrence of mild cough is well recognized with inhaled medications. In our studies, the number of subjects withdrawing due to cough was very low: 3.2% of subjects with type 1 diabetes and 2.6% of subjects with type 2 diabetes.

After a two-year Phase 3 safety trial of AFREZZA, we determined that the use of AFREZZA in patients with diabetes was non-inferior to traditional 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.

Table of Contents

Our completed Phase 3 clinical studies utilized our first-generation inhaler, known as MedTone. As part of ongoing development activities, we developed a next-generation inhaler, known as Dreamboat. Both the MedTone and Dreamboat devices are breath-powered, re-usable, high resistance inhalers that rely on air flow to empty the cartridge and deagglomerate the powder, but the Dreamboat inhalation system incorporates cosmetic improvements and removes non-essential elements. The resulting device is smaller, can be operated in fewer steps, requires only one inhalation per cartridge, and needs no cleaning because it is replaced after 15 days of use. The same AFREZZA powder is used in both the MedTone and Dreamboat inhalation systems.

In March 2009, we submitted a new drug application, or NDA, for AFREZZA to the FDA, in which we sought approval of the product with the MedTone inhaler. In March 2010, we received a Complete Response letter from the FDA that requested additional information about the clinical utility of AFREZZA and about the commercial version of the MedTone inhaler. After meeting with the FDA in June 2010, we determined that the best way to address the agency s inhaler-related questions was to submit information regarding the bioequivalence of the MedTone inhaler and the Dreamboat inhaler, the latter of which had by that time become our preferred device from a clinical and commercial perspective. In June 2010, we submitted to the FDA the available bioequivalency data for the two devices along with additional evidence of efficacy of AFREZZA as part of our response to the 2010 Complete Response letter.

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

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

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

We are conducting these clinical studies at sites in the United States, Eastern Europe and South America. We finished recruiting patients in early October 2012 and expect to complete the studies in the second quarter of 2013. Upon completion, we expect to submit the results of these studies to the FDA as an amendment to our NDA during the fourth quarter of 2013. However, the data collected from these clinical trials may not reach statistical significance or may not otherwise be sufficient to support an amendment to our NDA, or FDA approval. Moreover, there can be no assurance that we will satisfy all of the FDA s requirements with these two clinical studies or that the FDA will ultimately find our proposed approach to these clinical studies acceptable. The FDA could also request that we conduct additional clinical studies beyond studies 171 and 175 in order to provide sufficient data for approval of AFREZZA.

Table of Contents

Other Product Opportunities

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

Prior to the receipt of the Complete Response letters relating to AFREZZA, we had additional development programs aimed at developing products for treating different forms of cancer. During 2012, we out-licensed two of these programs and conducted only a limited amount of research with respect to a third program. Given our current resource constraints, we do not expect to allocate any significant funds to oncology product development activities for at least the next year.

OUR STRATEGY

The following are key elements of our strategy:

Complete the requested clinical studies and gain FDA approval of AFREZZA. We finished recruiting patients in early October 2012 and expect to complete the studies in the second quarter of 2013. Upon completion, we expect to submit the results to the FDA as an amendment to our NDA during the fourth quarter of 2013.

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

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

SALES AND MARKETING

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

In order to commercially market any of our product candidates, we would either need to develop an internal sales team and 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 organization in North America would have substantial advantages, we recognize that this may not be practical for some of our product candidates 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 Technosphere-based 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.

Table of Contents

MANUFACTURING AND SUPPLY

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

Currently, our insulin inventory is from two sources. Between November 2007 and July 2011, we received a quantity of insulin pursuant to an insulin supply agreement with N.V. Organon, a subsidiary of Merck & Co., Inc. In June 2009, we acquired a quantity of bulk insulin from Pfizer Manufacturing Frankfurt GmbH, a subsidiary of Pfizer Inc., as well as Pfizer s rights under a license to manufacture insulin for pulmonary delivery. In addition, we acquired an option to purchase from Pfizer additional insulin inventory, in whole or in part, at a specified price, to the extent it remains available. Once we have used our existing supply of insulin, we will need to secure additional insulin from market sources.

The contract manufacturer that has been producing our clinical supplies of the Dreamboat inhaler and the corresponding cartridges is currently performing qualification of the various cartridge and inhaler molds for commercial purposes. We may also seek to qualify an additional vendor.

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 we intend to use as a back-up facility. Like us, our third-party manufacturers are subject to extensive governmental regulation. We rely on our manufacturers to comply with relevant regulatory requirements, including compliance with Quality System Regulations, or QSRs.

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.

Our Technosphere drug delivery platform, including AFREZZA, enjoys patent protection relating to the particles, their manufacture, and their use for pulmonary delivery of drugs. We have additional patent coverage relating to the treatment of diabetes using AFREZZA. We have been granted patent coverage for our inhaler and cartridges in the form in which we expect our insulin product to be sold to the consumer, if and when approved by the FDA. We have additional pending patent applications, and expect to file further applications, relating to the drug delivery platform, methods of manufacture, the AFREZZA product and its use, and other Technosphere-based products, inhalers and inhaler cartridges. Overall, AFREZZA is protected by over 300 issued patents, and we also have over 300 pending applications in the United States and selected jurisdictions around the world related to our Technosphere platform. These include composition and method of treatment patents providing protection for AFREZZA that have terms extending into 2020 and 2031. In addition, patents providing protection for our inhaler and cartridges have terms extending into 2023 and 2030, and we have certain treatment claims that have terms extending into 2026 and 2029.

Table of Contents

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

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

Although we own a number of domestic and foreign patents and patent applications relating to our Technosphere-based investigational products, 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 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 was 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

Table of Contents

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 major international pharmaceutical companies, and other institutions that have substantially greater financial, research and development, marketing and sales capabilities and have substantially greater experience in undertaking preclinical and clinical testing of products, obtaining regulatory approvals and marketing and selling biopharmaceutical products. We will face competition based on, among other things, product efficacy and safety, the timing and scope of regulatory approvals, product ease of use and price.

Diabetes Treatments

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

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

Rapid-acting (Injected) Insulin

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

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

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

Biodel, Inc. is developing ultra-rapid acting insulin formulations, one of which has advanced to a Phase 2 clinical trial.

Inhaled Insulin Delivery Systems

In January 2006, Exubera®, developed by Pfizer in collaboration with Nektar Therapeutics, Inc., 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.

Table of Contents

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

In January 2011, Dance Pharmaceuticals, Inc. announced that it would pursue development of an inhaled insulin product based on aerosol technology licensed to Dance Pharmaceuticals by Aerogen Ltd.

Non-insulin Medications

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

- GLP-1 agonists, such as exenatide or liraglutide, which mimic a naturally occurring hormone that stimulates the pancreas to secrete insulin when blood glucose levels are high.

- Inhibitors of dipeptidyl peptidase IV, such as sitagliptin or saxagliptin, are a class of drugs that work by blocking the enzyme that normally degrades GLP-1.

- Sulfonylureas and meglitinides, which are classes of drugs that act on the pancreatic cells to stimulate the secretion of insulin.

- Thiazolidinediones, such as pioglitizone, and biguanides, such as metformin, which lower blood glucose by improving the sensitivity of cells to insulin, or diminishing insulin resistance.

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

- SGLT-2 inhibitors, which are a new class of medications that lower blood glucose by increasing glucose excretion in urine. Examples include dapagliflozin, which was recently approved in Europe but not in the United States and canagliflozin, which is currently under review by the FDA.

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 any of our subsequently approved products are marketed abroad, they will also be 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.

Table of Contents

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

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

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

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

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

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

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

Submission to the FDA of an NDA, or a 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, 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.

Table of Contents

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

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

Table of Contents

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

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

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

Product development and approval within this regulatory framework may 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.

Moreover, if our product candidates are approved by the FDA, government coverage and reimbursement policies will both directly and indirectly affect our ability to successfully commercialize our product candidates,

Table of Contents

and such coverage and reimbursement policies will be affected by future healthcare reform measures. Government health administration authorities, private health insurers and other organizations generally decide which drugs they will pay for and establish reimbursement levels for healthcare. In particular, in the United States, private health insurers and other third-party payors often provide reimbursement for products and services based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. In the United States, the European Union and other potentially significant markets for our product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

The United States and some foreign jurisdictions have enacted or are considering a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives, including, most recently, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, PPACA, enacted in March 2010.

Further, if a drug product is reimbursed by Medicare, Medicaid or other federal or state healthcare programs, we, including our sales, marketing and scientific/educational grant programs must comply with the False Claims Act, as amended, the federal Anti-Kickback Statute, 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, PPACA substantially changes the way healthcare is financed by both governmental and private insurers. Among other cost containment measures, 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.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA s privacy and security standards directly applicable to business associates independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Table of Contents

We may incur significant costs to comply with these laws and regulations now or in the future. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion of products from reimbursement under government programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

RESEARCH AND DEVELOPMENT EXPENSES; LONG-LIVED ASSETS

A significant portion of our operating expenses relates to research and development. Our research and development expenses totaled $112.3 million, $100.0 million and $101.5 million for the years ended December 31, 2010, 2011 and 2012, respectively.

Our long-lived assets located in the United States totaled $202.4 million, $193.0 million and $184.0 million as of December 31, 2010, 2011 and 2012, respectively.

EMPLOYEES

As of December 31, 2012, we had 246 full-time employees. Ten of these employees were engaged in basic research and development, 93 in manufacturing, 81 in clinical research and development, regulatory affairs and quality assurance and 62 in administration, finance, management, information systems, marketing, corporate development and human resources. 33 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.

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

SCIENTIFIC ADVISORS

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

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

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

Name	Primary Affiliation
Geremia Bolli	University of Perugia

Steven Edelman, MD	University of California, San Diego
Brian Frier, MD, FECP, BS	Edinburgh Royal Infirmary
Lois Jovanovic, MD	Sansum Medical Research Institute
Mark Peyrot, MD	Loyola College Center
Daniel Porte, MD	University of California, San Diego
Julio Rosenstock, MD	Dallas Diabetes and Endocrinology Center
Jay Skyler, MD, MACP	University of Miami, Diabetes Research Institute

Table of Contents

EXECUTIVE OFFICERS OF THE REGISTRANT

The following table sets forth our current executive officers and their ages as of December 31, 2012:

Name	Age	Position(s)
Alfred E. Mann	87	Chairman of the Board of Directors and Chief Executive Officer
Hakan S. Edstrom	62	President, Chief Operating Officer and Director
Matthew J. Pfeffer	55	Corporate Vice President and Chief Financial Officer
Juergen A. Martens, Ph.D.	57	Corporate Vice President, Technical Operations and Chief Technical Officer
Diane M. Palumbo	59	Corporate Vice President, Human Resources
David B. Thomson, Ph.D., J.D. .	46	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 holds bachelor s and master s degrees in Physics from the University of California at Los Angeles, honorary doctorates from Johns Hopkins University, the University of Southern California, Western University and the Technion-Israel Institute of Technology and is a member of the National Academy of Engineering.

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

Matthew J. Pfeffer has been our Corporate Vice President and Chief Financial Officer since April 2008. Previously, Mr. Pfeffer served as Chief Financial Officer and Senior Vice President of Finance and Administration of VaxGen, Inc. from March 2006 until April 2008, with responsibility for finance, tax, treasury, human resources, IT, purchasing and facilities functions. Prior to VaxGen, Mr. Pfeffer served as CFO of Cell Genesys, Inc. During his nine year tenure at Cell Genesys, Mr. Pfeffer served as Director of Finance before being named CFO in 1998. Prior to that, Mr. Pfeffer served in a variety of financial management positions at other

Table of Contents

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 is a member of the board of directors of DS Healthcare Group, Inc. (NASDAQ: DSKX). Mr. Pfeffer graduated 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 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.

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

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

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

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

RISKS RELATED TO OUR BUSINESS

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

To date, we have not commercialized any product candidates. We have expended significant time, money and effort in the development of our lead product candidate, AFREZZA, which has not yet received regulatory approval and which may not be approved by the FDA in a timely manner, or at all. Our other product candidates are generally in early clinical or preclinical development. We anticipate that in the near term, our ability to generate revenues will depend solely on the successful development and commercialization of AFREZZA.

In January 2011, the FDA issued a Complete Response letter and requested that we conduct additional clinical studies of AFREZZA using our next-generation inhaler, Dreamboat. Over the next eight months, we participated in a number of written and verbal exchanges with the FDA in order to clarify the FDA s requirements for

Table of Contents

approval of AFREZZA, culminating in an in-person meeting in August 2011 in which we confirmed with the FDA the designs of the two requested studies. There can be no assurance that we will satisfy all of the FDA s requirements with our current clinical studies. The FDA could also again request that we conduct additional clinical trials to provide sufficient data for approval of the NDA. There can be no assurance that we will obtain approval of the NDA in a timely manner or at all.

We must receive the necessary approvals from the FDA before AFREZZA can be marketed and sold in the United States and must receive the necessary approvals from similar foreign regulatory agencies before AFREZZA can be marketed outside of the United States. 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 lack of coverage or adequate reimbursement. 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 and our Technosphere platform technology. Even if our research programs identify candidates that initially show promise, these candidates may fail to progress to clinical development for any number of reasons, including discovery upon further research that these candidates have adverse effects or other characteristics that indicate they are unlikely to be effective. In addition, the clinical results we obtain at one stage are not necessarily indicative of future testing results. If we fail to successfully complete the development and commercialization of AFREZZA or develop or expand our other product candidates, or are significantly delayed in doing so, our business and results of operations will be harmed and the value of our stock could decline.

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

We are a development stage company with no commercial products. All of our product candidates are still being developed, and all but AFREZZA are still in the early stages of development. Our product candidates will require significant additional development, clinical trials, regulatory clearances and additional investment before they can be commercialized. We cannot be certain when AFREZZA may be approved or if it will be approved.

We have never been profitable or generated positive cash flow from operations and, as of December 31, 2012, we had incurred a cumulative net loss of $2.1 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, 2012, we had a stockholders deficit of $110.7 million. Our ability to achieve and sustain positive cash flow from operations and profitability primarily depends upon obtaining regulatory approvals for and successfully commercializing AFREZZA, either alone or with third parties. We do not currently have the required approvals to market any of our product candidates, and we may not receive them. We may not generate positive cash flow from operations or be profitable even if we succeed in commercializing any of our product candidates. As a result, we cannot be sure when we will generate positive cash flow from operations or become profitable, if at all.

Table of Contents

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

Based upon our current expectations, we believe that our existing capital resources including the available borrowings under our loan arrangement with The Mann Group LLC, an entity controlled by our principal stockholder will enable us to continue planned operations through at least the third quarter of 2013. However, we cannot assure you that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. We will need to raise additional funds, whether through the sale of equity or debt securities, the entry into strategic business collaborations, the establishment of other funding facilities, licensing arrangements, asset sales or other means, or an increase in the borrowings available under the loan arrangement with The Mann Group, 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, 2012, we had a stockholders deficit of $110.7 million which may raise concerns about our solvency and affect our ability to raise additional capital. The amount of additional funds we need will depend on a number of factors, including:

- the election of any or all of the holders of our 3.75% Senior Convertible Notes due 2013, or 2013 notes, or of any or all of the holders of our 5.75% Senior Convertible Notes due 2015, or 2015 notes, to require us to repay or repurchase such notes when required;
- our ability to refinance existing indebtedness, including indebtedness under the 2013 notes or 2015 notes which mature in December 2013 and August 2015, respectively;
- 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 or other sales or licensing of assets, and the timing and amount of any payments we might receive from any such transactions;
- the costs of preparing applications for regulatory approvals for our product candidates, including AFREZZA;
- actions taken by the FDA and other regulatory authorities affecting our product candidates and competitive products;
- our degree of success in commercializing AFREZZA assuming receipt of required regulatory approvals;
- the emergence of competing technologies and products and other market developments;
- the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights or defending against claims of infringement by others;
- the level of our legal expenses;
- the costs associated with litigation; and

the costs of discontinuing projects and technologies, and/or decommissioning existing facilities, if we undertake any such activities.

We have raised capital in the past primarily through the sale of equity and debt securities. We may in the future pursue the sale of additional equity and/or debt securities, or the establishment of other funding facilities including asset based borrowings. There can be no assurances, however, that we will be able to raise additional capital through such an offering on acceptable terms, or at all. Issuances of additional debt or equity securities, or the conversion of any of our currently outstanding convertible debt securities into shares of our common stock or the exercise of our currently outstanding warrants for shares of our common stock could impact the rights of the holders of our common stock and may dilute their ownership percentage. Moreover, the establishment of other funding facilities may impose restrictions on our operations. These restrictions could include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to

Table of Contents

create liens, pay dividends, redeem our stock or make investments. We also may seek to raise additional capital by pursuing opportunities for the licensing or sale of certain intellectual property and other assets. We cannot offer assurances, however, that any strategic collaborations, sales of securities or sales or licenses of assets will be available to us on a timely basis or on acceptable terms, if at all. We may be required to enter into relationships with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop independently, and any such relationships may not be on terms as commercially favorable to us as might otherwise be the case.

In the event that sufficient additional funds are not obtained through strategic collaboration opportunities, sales of securities, funding facilities, licensing arrangements and/or asset sales on a timely basis, we will be required to reduce expenses through the delay, reduction or curtailment of our projects, including AFREZZA development activities, or further reduction of costs for facilities and administration. Moreover, if we do not obtain such additional funds, there will be substantial doubt about our ability to continue as a going concern and increased risk of insolvency and loss of investment to the holders of our securities. As of the date hereof, we have not obtained a solvency opinion or otherwise conducted a valuation of our properties to determine whether our debts exceed the fair value of our property within the meaning of applicable solvency laws. If we are or become insolvent, investors in our stock may lose the entire value of their investment.

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

We have a substantial amount of convertible debt and may be unable to make required interest payments in the future or to refinance or repay this debt before it becomes due.

In December 2006, we completed the sale of $115.0 million aggregate principal amount of 2013 notes, which mature in December 2013, and in August 2010, we completed the sale of $100.0 million aggregate principal amount of 2015 notes, which mature in August 2015. As of March 13, 2013, all $115.0 million principal amount of the 2013 notes remained outstanding, and all $100.0 million principal amount of the 2015 notes remained outstanding. As of December 31, 2012, we did not have sufficient cash and cash equivalents to repay the 2013 notes or the 2015 notes. In addition, as of December 31, 2012, the effective conversion prices of the 2013 notes and 2015 notes were approximately $22.47 per share and $6.80 per share, respectively, subject to adjustment, which are substantially above the closing price of our common stock on March 13, 2013. We may therefore need to refinance our 2013 notes and/or 2015 notes before such notes mature, or raise additional funds to repay such notes, and there can be no assurance that we will be able to do so on favorable terms by the applicable repayment dates, or at all. In addition, if we undergo a fundamental change, as that term is defined in the indentures governing the terms of the 2013 notes and the 2015 notes, each holder of 2013 notes or 2015 notes will have the option to require us to repurchase all or any portion of such holder s notes at a repurchase price of 100% of the principal amount of such notes to be repurchased plus accrued and unpaid interest, if any. The 2013 notes bear interest at the rate of 3.75% per year on the outstanding principal amount, payable in cash semi-annually in arrears on June 15 and December 15 of each year, and the 2015 notes bear interest at the rate of 5.75% per year on the outstanding principal amount, payable in cash semiannually in arrears on February 15 and August 15 of each year. While we have been able to timely make our required interest payments to date, we cannot guarantee that we will be able to do so in the future. If we fail to pay interest on the 2013 notes or 2015 notes or repay or repurchase the 2013 notes or 2015 notes when required, we will be in default under the applicable indenture(s)

Table of Contents

for such note(s), and may also suffer an event of default under the terms of other borrowing arrangements that we may enter into from time to time. Any of these events could have a material adverse effect on our business, results of operations and financial condition, up to and including the noteholders initiating bankruptcy proceedings or causing us to cease operations altogether.

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

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

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

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

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

In addition, if we do not obtain sufficient additional funds through sales of securities, strategic collaborations or the license or sale of certain of our assets on a timely basis, we will be required to reduce expenses by delaying, reducing or curtailing our development of AFREZZA. If we fail to commence or complete, or experience delays in or are forced to curtail, our proposed clinical programs or otherwise fail to adhere to our projected development goals in the timeframes we announce and expect (or within the timeframes expected by analysts or investors), our business and results of operations will be harmed and the market price of our common stock may decline.

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

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.

Table of Contents

Many of our existing or potential competitors have, or have access to, substantially greater financial, research and development, production, and sales and marketing resources than we do and have a greater depth and number of experienced managers. As a result, our competitors may be better equipped than we are to develop, manufacture, market and sell competing products. In addition, gaining favorable reimbursement is critical to the 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 will 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. Our product candidates are intended to be used by a large number of healthcare professionals who will require substantial education and support. For example, a broad base of physicians, including primary care physicians and endocrinologists, treat patients with diabetes. A large sales force would be required in order to educate these physicians about the benefits and advantages of AFREZZA and to provide adequate support for them. With respect to the commercialization of AFREZZA, if 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, many of whom have substantially more resources and experience than we do. For example, several other companies selling products to treat diabetes have existing sales forces in excess of 1,500 sales representatives. We, acting alone, would not initially be able to field a sales force as large as our competitors or provide the same degree of marketing support. Also, we would not be able to match our competitors spending levels for pre-launch marketing preparation, including medical education. We cannot assure you that we will succeed in entering into acceptable collaborations, that any such collaboration will be successful or, if not, that we will successfully develop our own sales, marketing and distribution capabilities.

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 efforts.

Table of Contents

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

- safety and efficacy results for AFREZZA obtained in our nonclinical and previous clinical testing may be inconclusive or may not be predictive of results that we may obtain in our future clinical trials or following long-term use, and we may as a result be forced to stop developing AFREZZA;
- the data collected from clinical trials of AFREZZA or our other product candidates may not reach statistical significance or otherwise be sufficient to support FDA or other regulatory approval;
- after reviewing test results, we or any potential collaborators may abandon projects that we previously believed were promising; and
- our product candidates may not produce the desired effects or may result in adverse health effects or other characteristics that preclude regulatory approval or limit their commercial use if approved.

Forecasts about the effects of the use of drugs, including AFREZZA, over terms longer than the clinical trials or in much larger populations may not be consistent with the clinical results. If use of AFREZZA results in adverse health effects or reduced efficacy or both, the FDA or other regulatory agencies may terminate our ability to market and sell AFREZZA, may narrow the approved indications for use or otherwise require restrictive product labeling or marketing, or may require further clinical trials, which may be time-consuming and expensive and may not produce favorable results.

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

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

For AFREZZA to be commercially viable, we need access to sufficient, reliable and affordable supplies of insulin, our AFREZZA inhaler, the related cartridges and other materials. We must rely on our suppliers to comply with relevant regulatory and other legal requirements, including the production of insulin in accordance with the FDA s current Good Manufacturing Practices, or cGMP for drug products, and the production of the AFREZZA inhaler and related cartridges in accordance with Quality System Regulations, or QSRs. The supply

21

Table of Contents

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 encounter delays or difficulties in our relationships with manufacturers or suppliers, the development or manufacturing of AFREZZA may be delayed. Any such events could delay market introduction and subsequent sales of AFREZZA and, if so, our business and results of operations will be harmed and the market price of our common stock may decline.

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

We use our Danbury, Connecticut facility to formulate AFREZZA inhalation powder, fill plastic cartridges with the powder, package the cartridges in blister packs, and place the blister packs into foil pouches. We will utilize a contract packager to do the final kitting and cartoning of foil pouched blisters containing cartridges, as well as inhalers and the package insert. Although the Danbury facility has been qualified and undergone an inspection by the FDA in connection with our original NDA submission that sought approval of AFREZZA using our MedTone inhaler, we anticipate that our facility will need to undergo further inspection related to our ability to fill and package cartridges for our next-generation Dreamboat inhaler before we can be approved to distribute AFREZZA 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.

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.

If any product that we develop does not become widely accepted by physicians, patients, third-party payors 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 payors and the healthcare community. Failure to achieve market acceptance would limit our ability to generate revenue and would adversely affect our results of operations.

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

- claims for which FDA approval can be obtained, including superiority claims;
- effectiveness of our or our third party collaborator(s) efforts to educate physicians about the benefits and advantages of AFREZZA or our other products and to provide adequate support for them, and the 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 payors, regarding the safety, efficacy and benefits compared to competing products or therapies;

Table of Contents

convenience and ease of administration relative to existing treatment methods;

coverage and 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 payors do not cover any products for which we receive regulatory approval or adequately reimburse consumers for any such products, our products might not be used or purchased, which would adversely affect our revenues.

Our future revenues and ability to generate positive cash flow from operations may be affected by the continuing efforts of governments and third-party payors 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 payors 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 payors, such as governmental and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. The market for our product candidates for which we may receive regulatory approval will depend significantly on access to third-party payors drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. In addition, because each third-party payor individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement 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 payor separately with no assurance that approval would be obtained. This process could delay the market acceptance of any product and could have a negative effect on our future revenues and operating results. Even if we succeed in bringing one or more products to market, we cannot be certain that any such products would be considered cost-effective or that coverage and adequate reimbursement to the consumer would be available. Patients will be unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. We may face competition for our product candidates from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, there may be importation of foreign products that compete with our own products, which could negatively impact our profitability.

Table of Contents

If we are unable to obtain coverage of, and adequate payment levels for, our product candidates from third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them and patients may decline to purchase them. This in turn could affect our ability to successfully commercialize our products and impact our profitability, results of operations, financial condition, and future success.

Healthcare legislation may make it more difficult to receive revenues, even if we have products that are approved.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals in recent years to change the healthcare system in ways that could impact our ability to sell our products profitably. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, PPACA, became law in the United States. PPACA substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the healthcare industry. Among the provisions of PPACA of importance to our potential product candidates are the following:

an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, beginning in 2011;

a 2.3% medical device excise tax on certain transactions, including many U.S. sales of medical devices, which currently includes and we expect will continue to include U.S. sales of drug-device combination products;

an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23% and 13% of the average manufacturer price for most branded and generic drugs, respectively;

expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;

a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer s outpatient drugs to be covered under Medicare Part D;

extension of manufacturers Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in 2014 and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers Medicaid rebate liability;

expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

new requirements to report certain financial arrangements with physicians and teaching hospitals, as defined in PPACA and its implementing regulations, including reporting any payments or transfers of value made or distributed to prescribers, teaching hospitals and other healthcare providers and reporting any ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations during the preceding calendar year, with data collection to be required beginning August 1, 2013 and reporting to the Centers for Medicare & Medicaid Services, or CMS, to be required by March 31, 2014 and by the 90th day of each subsequent calendar year;

a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and

a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Table of Contents

In addition, other legislative changes have been proposed and adopted since PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

We expect that PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

If we fail to comply with federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

As a biopharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which constrains our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and

- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exceptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. To the extent that any of our product candidates is ultimately sold in a foreign country, we may be subject to similar

25

Table of Contents

foreign laws and regulations. If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, imprisonment, exclusion of products from reimbursement under U.S. federal or state healthcare programs, and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could materially adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management s attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

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 $10.0 million. In addition, we carry local policies per trial in each country in which we conduct clinical trials that require us to carry coverage based on local statutory requirements. We intend to obtain product liability coverage for commercial sales in the future if AFREZZA is approved. However, we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise, and because insurance coverage in our industry can be very expensive and difficult to obtain, we cannot assure you that we will be able to obtain sufficient coverage at an acceptable cost, if at all. If losses from such claims exceed our liability insurance coverage, we may ourselves incur substantial liabilities. If we are required to pay a product liability claim our business and results of operations would be harmed and the market price of our common stock may decline.

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

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. In addition, in order to commercialize our product candidates successfully, we may be required to expand our work force, particularly in the areas of manufacturing, and, if we are unable to enter into collaborations with third parties to commercialize AFREZZA or any other approved products, sales and marketing. These activities will require the addition of new personnel, including management, and the development of additional expertise by existing personnel, and we cannot assure you that we will be able to attract or retain any such new personnel 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

Table of Contents

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

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

Alfred Mann, our Chairman and Chief Executive Officer, is involved in many other business and charitable activities. As a result, the time and attention Mr. Mann devotes to the operation of our business varies, and he may not expend the same time or focus on our activities as other, similarly situated chief executive officers. If Mr. Mann is unable to devote the time and attention necessary to running our business, we may not be able to execute our business strategy and our business could be materially harmed.

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

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

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.

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. In addition, we are headquartered in Valencia, California. This facility contains our principal executive offices and is used to provide support for the development of our AFREZZA programs. We depend on our facilities and on collaborators, contractors and vendors for the continued operation of our business, some of whom are located in Europe. Natural disasters or other catastrophic events, including interruptions in the supply of natural resources, political and governmental changes, severe weather conditions, wildfires and other fires, explosions, actions of animal rights activists, terrorist attacks, volcanic eruptions, earthquakes and wars could disrupt our operations or those of our collaborators, contractors and vendors. We might suffer losses as a result of business interruptions that exceed the coverage available under our and our contractors insurance policies or for which we or our contractors do not have coverage. For example, we are not insured against a terrorist attack. Any natural disaster

Table of Contents

or catastrophic event could have a significant negative impact on our operations and financial results. Moreover, any such event could delay our research and development programs and adversely affect, which may include stopping, our readiness for commercial production.

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

Our research and development work involves the controlled storage and use of hazardous materials, including chemical and biological materials. In addition, our manufacturing operations involve the use of a chemical that may form an explosive mixture under certain conditions. Our operations also produce hazardous waste products. We are subject to federal, state and local laws and regulations (i) governing how we use, manufacture, store, handle and dispose of these materials (ii) imposing liability for costs of cleaning up, and damages to natural resources from past spills, waste disposals on and off-site, or other releases of hazardous materials or regulated substances, and (iii) regulating workplace safety. Moreover, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated, and in the event of an accident, we could be held liable for any damages that may result, and any liability could fall outside the coverage or exceed the limits of our insurance. Currently, our general liability policy provides coverage up to $1.0 million per occurrence and $2.0 million in the aggregate and is supplemented by an umbrella policy that provides a further $4.0 million of coverage; however, our insurance policy excludes pollution liability coverage and we do not carry a separate hazardous materials policy. In addition, we could be required to incur significant costs to comply with environmental laws and regulations in the future. Finally, current or future environmental laws and regulations may impair our research, development or production efforts or have an adverse impact on our business, results of operations and financial condition.

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

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

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;

Table of Contents

product storage and shipping;

pre-market clearance or approval;

advertising and promotion; and

product sales and distribution.

Clinical testing can be costly and take many years, and the outcome is uncertain and susceptible to varying interpretations. We cannot be certain if or when the FDA might request additional studies, under what conditions such studies might be requested, or what the size or length of any such studies might be. The clinical trials of our product candidates may not be completed on schedule, the FDA or foreign regulatory agencies may order us to stop or modify our research, or these agencies may not ultimately approve any of our product candidates for commercial sale. The data collected from our clinical trials may not be sufficient to support regulatory approval of our various product candidates, including AFREZZA. Even if we believe the data collected from our clinical trials are sufficient, the FDA has substantial discretion in the approval process and may disagree with our interpretation of the data. Our failure to adequately demonstrate the safety and efficacy of any of our product candidates would delay or prevent regulatory approval of our product candidates, which could prevent us from achieving profitability.

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

The process of obtaining FDA and other required regulatory approvals, including foreign approvals, is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. We are not aware of any precedent for the successful commercialization of products based on our technology. In January 2006, the FDA approved the first pulmonary insulin product, Exubera. This approval has had an impact on, and notwithstanding the voluntary withdrawal of the product from the market by its manufacturer could still impact, the development and registration of AFREZZA in different ways. For example, Exubera may be used as a reference for safety and efficacy evaluations of AFREZZA, and the approval standards set for Exubera may be applied to other products that follow, including AFREZZA.

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

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

Table of Contents

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

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

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

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

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

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

The manufacture, marketing and sale of any of our product candidates will be subject to stringent and ongoing government regulation. The FDA may also withdraw product approvals if problems concerning the safety or efficacy of a product appear following approval. We cannot be sure that FDA and United States Congressional initiatives or actions by foreign regulatory bodies pertaining to ensuring the safety of marketed drugs or other developments pertaining to the pharmaceutical industry will not adversely affect our operations.

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

Table of Contents

injunctions and/or criminal prosecution of responsible individuals and us. Any such actions would have a material adverse effect on our business and results of operations.

Our suppliers will be subject to FDA inspection before the agency approves an NDA for AFREZZA.

When we are required to find a new or additional supplier of insulin, we will be required to evaluate the new supplier s ability to provide insulin that meets regulatory requirements, including cGMP requirements as well as our specifications and quality requirements, which would require significant time and expense and could delay the manufacturing and future commercialization of AFREZZA. We also depend on suppliers for other materials that comprise AFREZZA, including our AFREZZA inhaler and cartridges. Each supplier must comply with relevant regulatory requirements including QSR, and is subject to inspection by the FDA. There can be no assurance, in the conduct of an inspection of any of our suppliers, that the agency would find that the supplier substantially complies with the QSR or cGMP requirements, where applicable. If we or any potential third-party manufacturer or supplier fails to comply with these requirements or comparable requirements in foreign countries, regulatory authorities may subject us to regulatory action, including criminal prosecutions, fines and suspension of the manufacture of our products.

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

At present, there are a number of clinical trials being conducted by us and other pharmaceutical companies involving insulin delivery systems. If we discover that AFREZZA is associated with a significantly increased frequency of adverse events, or if other pharmaceutical companies announce that they observed frequent adverse events in their trials involving insulin therapies, we could encounter delays in the timing of our clinical trials, difficulties in obtaining approval of AFREZZA or be subject to class warnings in the label for AFREZZA, if approved. In addition, the public perception of AFREZZA might be adversely affected, which could harm our business and results of operations and cause the market price of our common stock to decline, even if the concern relates to another company s products or product candidates.

There are also a number of clinical trials being conducted by other pharmaceutical companies involving compounds similar to, or competitive with, our other product candidates. Adverse results reported by these other companies in their clinical trials could delay or prevent us from obtaining regulatory approval or negatively impact public perception of our product candidates, which could harm our business and results of operations and cause the market price of our common stock to decline.

RISKS RELATED TO INTELLECTUAL PROPERTY

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

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

Moreover, the term of a patent is limited and, as a result, the patents protecting our products expire at various dates. For example, some patents providing protection for our AFREZZA inhalation powder expired in 2012. Other patents providing similar protection have terms extending into 2020 and 2031. In addition, patents providing protection for our inhaler and cartridges have terms extending into 2023 and 2030, and we have

Table of Contents

method of treatment claims that extend into 2026 and 2029. As and when these different patents expire, AFREZZA could become subject to increased competition. As a consequence, we may not be able to recover our development costs.

Moreover, the issuance of a patent is not conclusive as to its validity or enforceability and it is uncertain how much protection, if any, will be afforded by our patents. A third party may challenge the validity or enforceability of a patent after its issuance by various proceedings such as oppositions in foreign jurisdictions or re-examinations in the United States. If we attempt to enforce our patents, they may be challenged in court where they could be held invalid, unenforceable, or have their breadth narrowed to an extent that would destroy their value.

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

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

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

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

Interference proceedings brought by the United States Patent and Trademark Office, or USPTO, may be necessary to determine the priority of inventions with respect to our patent applications or those of our collaborators or licensors. Additionally, the Leahy-Smith Act has greatly expanded the options for post-grant review of patents that can be brought by third parties. Litigation, post-grant review, 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, post-grant review, 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

Table of Contents

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.

Biotechnology patents are numerous and may, at times, conflict with one another. 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 may be manufactured outside the United States and imported into the United States. As such, third parties could file complaints under 19 U.S.C. Section 337(a)(1)(B), or a 337 action, with the International Trade Commission, or the ITC. A 337 action can be expensive and would consume time and other resources. There is a risk that the ITC would decide that we are infringing a third party s patents and either enjoin us from importing the infringing products or parts thereof into the United States or set a bond in an amount that the ITC considers would offset our competitive advantage from the continued importation during the statutory review period. The bond could be up to 100% of the value of the patented products. We may not prevail in any legal action, and a required license under the patent may not be available on acceptable terms, or at all, resulting in a permanent injunction preventing any further importation of the infringing products or parts thereof into the United States. We also may not be able to develop a non-infringing product design on commercially reasonable terms, or at all.

Although we own a number of domestic and foreign patents and patent applications relating to AFREZZA, 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. If a court were to determine that AFREZZA was 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

Table of Contents

this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, the market price of our common stock may decline.

In addition, patent litigation may divert the attention of key personnel and we may not have sufficient resources to bring these actions to a successful conclusion. At the same time, some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. An adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our products or result in substantial monetary damages, which would adversely affect our business and results of operations and cause the market price of our common stock to decline.

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

We have not selected trade names for some of our product candidates; therefore, we have not filed trademark registrations for all of our potential trade names for our product candidates in all jurisdictions, nor can we assure that we will be granted registration of those potential trade names for which we have filed. No assurance can be given that any of our trademarks will be registered in the United States or elsewhere or that the use of any of our trademarks will confer a competitive advantage in the marketplace. Furthermore, even if we are successful in our trademark registrations, the FDA has its own process for drug nomenclature and its own views concerning appropriate proprietary names. It also has the power, even after granting market approval, to request a company to reconsider the name for a product because of evidence of confusion in the marketplace. We cannot assure you that the FDA or any other regulatory authority will approve of any of our trademarks or will not request reconsideration of one of our trademarks at some time in the future.

RISKS RELATED TO OUR COMMON STOCK

Our stock price is volatile.

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

- the progress and results of our clinical trials;
- general economic, political or stock market conditions;
- legislative developments;
- announcements by us or our competitors concerning clinical trial results, acquisitions, strategic alliances, technological innovations, newly approved commercial products, product discontinuations, or other developments;
- the availability of critical materials used in developing and manufacturing AFREZZA or other product candidates;
- developments or disputes concerning our patents or proprietary rights;
- the expense and time associated with, and the extent of our ultimate success in, securing regulatory approvals;

announcements by us concerning our financial condition or operating performance;

changes in securities analysts estimates of our financial condition or operating performance;

general market conditions and fluctuations for emerging growth and pharmaceutical market sectors;

sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;

Table of Contents

the status of any legal proceedings against us or any of our executive officers and directors, including the legal proceedings described under Item 3 of this Annual Report;

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

the conversion of any of our 2013 notes or 2015 notes into shares of our common stock; and

discussion of AFREZZA, our other product candidates, competitors products, or our stock price by the financial and scientific press, the healthcare community and online investor communities such as chat rooms. In particular, it may be difficult to verify statements about us and our investigational products that appear on interactive websites that permit users to generate content anonymously or under a pseudonym and statements attributed to company officials may, in fact, have originated elsewhere.

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

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

Public companies in general and companies included on the NASDAQ Global Market in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. There has been particular volatility in the market prices of securities of biotechnology and other life sciences companies, and the market prices of these companies have often fluctuated because of problems or successes in a given market segment or because investor interest has shifted to other segments. These broad market and industry factors may cause the market price of our common stock to decline, regardless of our operating performance. We have no control over this volatility and can only focus our efforts on our own operations, and even these may be affected due to the state of the capital markets.

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

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

At December 31, 2012, Mr. Mann beneficially owned 48.2% 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.

Table of Contents

The future sale of our common stock, the conversion of our senior convertible notes into common stock or the exercise of our warrants for common stock could negatively affect our stock price.

As of December 31, 2012, we had 286,035,082 shares of common stock outstanding. Substantially all of these shares are available for public sale, subject in some cases to volume and other limitations or delivery of a prospectus. If our common stockholders sell substantial amounts of common stock in the public market, or the market perceives that such sales may occur, the market price of our common stock may decline. Likewise the issuance of additional shares of our common stock upon the conversion of some or all of our senior convertible notes, or upon the exercise of some or all of the warrants we issued in February 2012 and October 2012, could adversely affect the trading price of our common stock. In addition, the existence of these notes and warrants may encourage short selling of our common stock by market participants. Furthermore, if we were to include in a company-initiated registration statement shares held by our stockholders pursuant to the exercise of their registration rights, the sale of those shares could impair our ability to raise needed capital by depressing the price at which we could sell our common stock.

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

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.

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

None.

Table of Contents

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 2014. The facility houses our medical, regulatory affairs, clinical operations and administrative staff.

Item 3. ***Legal Proceedings***

We are subject to legal proceedings and claims which arise in the ordinary course of our business. As of the date hereof, we believe that the final disposition of such matters will not have a material adverse effect on our financial position, results of operations or cash flows. We maintain liability insurance coverage to protect our assets from losses arising out of or involving activities associated with ongoing and normal business operations.

The Securities Action. Beginning January 31, 2011, several complaints were filed in the U.S. District Court for the Central District of California against us and four of our officers Alfred E. Mann, Hakan S. Edstrom, Dr. Peter C. Richardson (a former officer) and Matthew J. Pfeffer on behalf of certain purchasers of our common stock. The complaints include claims asserted under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and were brought as purported shareholder class actions. In general, the complaints alleged that the defendants violated federal securities laws by making materially false and misleading statements regarding our business and prospects for AFREZZA, thereby artificially inflating the price of our common stock. The U.S. District Court for the Central District of California consolidated the pending actions for all purposes. The consolidated action is referred to as the Securities Action.

On July 23, 2012, we, while continuing to deny all allegations of wrongdoing or liability whatsoever arising out of the Securities Action, and without in any way admitting fault or liability, entered into a stipulation of settlement to resolve the Securities Action. The current and former officers and directors named as individual defendants in the consolidated lawsuits also entered into the stipulation of settlement.

In exchange for a release of all claims by the class members, among others, and a dismissal of the consolidated lawsuits, we agreed (i) to cause our insurers to pay class members and their attorneys a total of $16.0 million; and (ii) to issue to class members and their attorneys 2,777,778 shares of our common stock. On December 21, 2012, the U.S. District Court issued the Order and Final Judgment, providing final approval of the settlement for the Securities Action. As of December 31, 2012, the Securities Action was concluded.

The Derivative Actions. Beginning in February 2011, several shareholder derivative complaints were filed in the Superior Court of California for the County of Los Angeles and in the U.S. District Court for the Central District of California against all of our directors and certain of our officers. The complaints in the shareholder derivative actions allege breaches of fiduciary duties by the defendants and other violations of law. In general, the complaints allege that the defendants caused or allowed for the dissemination of materially false and misleading statements regarding our business and prospects for AFREZZA, thereby artificially inflating the price of our common stock. The Superior Court of California for the County of Los Angeles consolidated the actions pending before it. The consolidated state derivative actions are referred to as the State Derivative Action. The U.S. District Court for the Central District of California also consolidated the derivative actions pending before

Table of Contents

it. The consolidated federal derivative actions are referred to as the Federal Derivative Action. The State Derivative Action and the Federal Derivative Action are collectively referred to as the Derivative Actions.

On August 3, 2012, we, while continuing to deny all allegations of wrongdoing or liability whatsoever arising out of the Derivative Actions and without in any way admitting fault or liability, entered into a stipulation of settlement to resolve the Derivative Action. In an exchange for a release of all claims by the plaintiffs, among others, and a dismissal of the Derivative Actions, we agreed (i) to adopt certain corporate governance measures, (ii) to cause our insurers to pay the plaintiffs attorneys a total of $800,000, and (iii) to issue plaintiffs attorneys 225,000 shares of our common stock. On November 19, 2012, the U.S. District Court issued the Order and Final Judgment, providing final approval of the settlement for the derivative action. As of December 31, 2012, the Derivative Actions were concluded.

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

Not applicable.

Table of Contents

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, 2011		
First quarter	$ 10.05	$ 3.40
Second quarter	$ 4.75	$ 3.48
Third quarter	$ 3.99	$ 2.20
Fourth quarter	$ 3.87	$ 2.45
Year ended December 31, 2012		
First quarter	$ 3.48	$ 2.14
Second quarter	$ 2.49	$ 1.57
Third quarter	$ 3.11	$ 2.02
Fourth quarter	$ 2.91	$ 1.82

The closing sales price of our common stock on the NASDAQ Global Market was $3.56 on March 13, 2013 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, except to the extent we specifically incorporate this section by reference.

Table of Contents

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, 2007, 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 sets forth information regarding all securities sold by us during the fiscal year ended December 31, 2012 without registration under the Securities Act (excluding those previously disclosed in a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K):

On December 6, 2012, following final approval of the settlement of the Securities Action, we transferred the 225,000 shares of our common stock into an investment brokerage account established by the plaintiffs attorneys. The shares were issued pursuant to an exemption from registration provided by Section 3(a)(10) of the Securities Act of 1933, as amended.

Table of Contents

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:	**2008**	**2009**	**2010**	**2011**	**2012**
	(In thousands, except per share amounts)				
Revenue	$ 20	$	$ 93	$ 50	$ 35
Operating expenses:					
Research and development	250,442	156,331	112,279	99,959	101,522
General and administrative	55,343	53,447	40,312	40,630	45,473
Total operating expenses	305,785	209,778	152,591	140,589	146,995
Loss from operations	(305,765)	(209,778)	(152,498)	(140,539)	(146,960)
Other income (expense)	(62)	51	(725)	1,541	(1,191)
Interest expense on note payable to principal stockholder	(12)	(5,679)	(10,249)	(10,883)	(10,491)
Interest expense on senior convertible notes	(2,327)	(4,768)	(7,128)	(10,941)	(11,139)
Interest income	5,129	70	40	18	7
Loss before provision for income taxes	(303,037)	(220,104)	(170,560)	(160,804)	(169,774)
Income taxes	(2)				(408)
Net loss applicable to common stockholders	$ (303,039)	$ (220,104)	$ (170,560)	$ (160,804)	$ (169,366)
Basic and diluted net loss per share	$ (2.98)	$ (2.07)	$ (1.50)	$ (1.32)	$ (.94)
Shares used to compute basic and diluted net loss per share	101,561	106,534	113,672	121,817	180,855

	December 31,				
Balance Sheet Data:	**2008**	**2009**	**2010**	**2011**	**2012**
	(In thousands)				
Cash and cash equivalents	$ 27,648	$ 30,019	$ 66,061	$ 2,681	$ 61,840
Total assets	282,459	247,397	277,256	199,553	251,314
Senior convertible notes	112,253	112,765	209,335	210,642	212,026
Note payable to related party	30,000	165,000	235,319	277,203	119,635
Deficit accumulated during the development stage	(1,384,078)	(1,604,182)	(1,774,742)	(1,935,546)	(2,104,912)
Total stockholders equity (deficit)	86,734	(59,221)	(185,532)	(313,652)	(110,679)

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

41

Table of Contents

We are a development stage enterprise and have incurred significant losses since our inception in 1991. As of December 31, 2012, we have incurred a cumulative net loss of $2.1 billion and a stockholders deficit of $110.7 million. To date, we have not generated any product revenues and have funded our operations primarily through the sale of equity securities and convertible debt securities and borrowings under a loan arrangement provided by our principal stockholder. As discussed below in Liquidity and Capital Resources, if we are unable to obtain additional funding in the future, there will continue to be substantial doubt about our ability to continue as a going concern.

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

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

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

RESEARCH AND DEVELOPMENT EXPENSES

Our research and development expenses consist mainly of costs associated with the clinical trials of our product candidates that have not yet received regulatory approval for marketing and for which no alternative future use has been identified. This includes the salaries, benefits and stock-based compensation of research and development personnel, raw materials, such as insulin purchases, laboratory supplies and materials, facility costs, costs for consultants and related contract research, licensing fees, and depreciation of 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.

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

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

At this time, due to the risks inherent in the clinical trial process and given the early stage of development of our product candidates other than AFREZZA, we are unable to estimate with any certainty the costs that we will incur in the continued development of our product candidates for commercialization. The costs required to complete the development of AFREZZA will be largely dependent on the cost and efficiency of our clinical trial operations and discussions with the FDA regarding its requirements.

During the first quarter of 2011, we implemented a restructuring to streamline operations, reduce operating expenses, extend our cash runway and focus our resources on securing FDA approval of the NDA for AFREZZA. In connection with the restructuring, we recorded charges to research and development expenses of approximately $4.7 million for employee severance and other related termination benefits. The restructuring

42

Table of Contents

resulted in research and development operating cost savings of approximately $9.5 million in 2011. These savings were partially offset by increased costs associated with the additional trials required by the FDA.

GENERAL AND ADMINISTRATIVE EXPENSES

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

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

CRITICAL ACCOUNTING POLICIES

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

Impairment of long-lived assets

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

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

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

43

Table of Contents

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*. 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. As of December 31, 2012, there was $107,000 and $3.7 million of unrecognized expenses related to performance-based options and restricted stock units, respectively, for milestones where achievement was not considered probable.

Forward contracts

In February and October 2012, we entered into agreements with The Mann Group whereby we agreed to sell and The Mann Group agreed to purchase common stock and/or warrants. These agreements have been accounted for as forward contracts, having met the definition of derivative instruments in accordance with the provisions of ASC 815 *Derivatives and Hedging*. We determine the fair value of the forward contract upon its issuance, record fair value adjustments of the forward contract to Other income (expense) during the reporting period and through the settlement of the forward contract, and reclassify the forward contract to equity upon settlement of the forward contract. The fair value of the forward purchase contract is highly sensitive to the discount applied for lack of marketability and the stock price, and changes in this discount and/or the stock price could cause the value of the forward purchase contract to change significantly**.**

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, 2012, we have established a valuation allowance of $750.2 million against all of our net deferred tax asset balance, due to uncertainties related to the realizability of 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.

Table of Contents

RESULTS OF OPERATIONS

Years ended December 31, 2011 and 2012

Revenues

During the years ended December 31, 2011 and December 31, 2012, we recognized $50,000 and $35,000, respectively, in 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, 2011 and 2012 (dollars in thousands):

	Year Ended December 31,			
	2011	2012	$ Change	% Change
Clinical	$ 25,280	$ 47,936	$ 22,656	90%
Manufacturing	58,523	40,094	(18,429)	(31)%
Research	11,399	7,614	(3,785)	(33)%
Research and development tax credit	(609)	(289)	320	(53)%
Stock-based compensation expense	5,366	6,167	801	15%
Research and development expenses	$ 99,959	$ 101,522	$ 1,563	2%

The increase in research and development expenses for the year ended December 31, 2012 compared to the year ended December 31, 2011, was primarily due to $24.9 million of increased clinical trial related expenses in connection with studies 171 and 175 conducted in 2012 and increased clinical distribution costs in support of our clinical trials, offset by the non-recurring $16.0 million expense recorded in 2011 related to our termination of the supply agreement with Organon and receipt of insulin, decreased salary related expenses of $8.6 million due to the February 2011 restructuring as well as the positive effect of our cost cutting measures on operating expenses.

In 2012, clinical trial related expenses increased $24.9 million in connection with studies 171 and 175 subsequent to completion of enrollment in the end of September and early October of 2012, partially offset by $2.1 million in salary related cost savings resulting from the February 2011 reduction in force. In 2012, manufacturing expenses decreased as no insulin purchases were made subsequent to the termination of our supply agreement in 2011. In 2011, we paid $16.0 million in connection with the settlement of the dispute arising from us terminating our supply agreement. Additionally, the February 2011 reduction in force resulted in $4.3 million in salary related manufacturing cost savings partially offset by increased clinical distribution costs in support of our clinical trials. Decreased salary related expenses of $2.2 million resulting from the February 2011 reduction in force and $0.9 million in reduced purchased services primarily contributed to decreased research expenses in 2012.

We anticipate that our overall research and development expenses will decrease in 2013 as we complete our clinical trials and prepare our resubmission for regulatory approval of AFREZZA.

General and Administrative Expenses

The following table provides a comparison of the general and administrative expense categories for the years ended December 31, 2011 and 2012 (dollars in thousands):

	Year Ended December 31,			
	2011	2012	$ Change	% Change
Salaries, employee related and other general expenses	$ 34,792	$ 38,348	$ 3,556	10%
Stock-based compensation expense	5,838	7,125	1,287	22%

General and administrative expenses	$ 40,630	$ 45,473	$ 4,843	12%

Table of Contents

General and administrative expenses for the year ended December 31, 2012 increased as compared to the same period in the prior year primarily due to a litigation settlement charge of $6.5 million, increased stock-based compensation expense of $1.3 million resulting from special awards issued to employees, partially offset by decreased salary related costs of $2.6 million as a result of the February 2011 reduction in force.

We expect general and administrative expenses to be lower in 2013 due to reduced legal expenses and the effect of our cost cutting measures on operating expenses.

Other Income (Expense)

Other expense for the year ended December 31, 2012 was $1.2 million as compared to other income of $1.5 million for the year ended December 31, 2011. In 2012, other expense reflects the adjustment in fair value of forward purchase contracts with a related party. In 2011, other income is primarily comprised of realized gains of $1.3 million on the termination of foreign exchange hedging contracts related to our supply agreement with Organon. We terminated these contracts in the first quarter of 2011.

Interest Income and Expense

Interest expense for the year ended December 31, 2012 increased compared to the year ended December 31, 2011, primarily due to the interest expense associated with additional principal drawn down and conversion of accrued and unpaid interest to principal in 2012 on our note payable to our principal stockholder.

Years ended December 31, 2010 and 2011

Revenues

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

Research and Development Expenses

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

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

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

The research and development tax credit recognized for the years ended December 31, 2011 and 2010 partially offsets our research and development expenses. The State of Connecticut provides an opportunity to exchange certain research and development income tax credit carry-forwards 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

Table of Contents

research and development expenses. During the years ended December 31, 2011 and 2010, research and development expenses were offset by $0.6 million and $0.4 million, respectively, in connection with the program.

General and Administrative Expenses

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

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

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

Other Income (Expense)

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

Interest Income and Expense

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

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 $350.0 million loan arrangement with our principal stockholder. 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. Until January 1, 2013, interest on outstanding principal amounts accrued at a fixed rate equal to the one-year London Interbank Offered Rate (LIBOR) rate as reported by the *Wall Street Journal* on the date of such advance plus 3% per annum. The borrowing rate was 4.5% at December 31, 2012. We amended the promissory note underlying the loan arrangement at various dates during 2012. The most recent amendment occurred in October 2012 to extend the maturity date to January 1, 2014, extend the date through which we can borrow under the promissory note to

47

Table of Contents

September 30, 2013, and adjust the annual interest rate on all outstanding principal to the one-year LIBOR rate on December 31, 2012 plus 5%, effective beginning on January 1, 2013.

As of December 31, 2012, the total principal amount outstanding under the credit facility was $119.6 million, and the amount available for future borrowings was $125.4 million. Interest is due and payable quarterly in arrears on the first day of each calendar quarter for the preceding quarter, or at such other time as we and The Mann Group mutually agree. All or any portion of accrued and unpaid interest that becomes due and payable may be paid-in-kind and capitalized at any time upon mutual agreement of both parties. 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 (see discussion regarding letter agreement below).

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 its working capital resources. 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. There are no warrants associated with the loan arrangement.

On February 8, 2012, we sold $86.3 million worth of units in an underwritten public offering, with each unit consisting of one share of common stock and a warrant to purchase 0.6 of a share of common stock, and reflects the full exercise of an over-allotment option granted to the underwriters. Net proceeds from this offering were approximately $80.6 million (excluding discounts and commissions to the underwriters and offering expenses), excluding any warrant exercises. Concurrent with this public offering, The Mann Group LLC agreed to purchase $77.2 million worth of restricted shares of common stock which were issued on June 27, 2012 in exchange for cancellation of principal indebtedness of $77.2 million. In connection with this purchase, we and The Mann Group agreed that the cancelled principal amount related to the common stock purchase would be permanently retired and not available for re-borrowing and accrued and unpaid interest that becomes due and payable under the note to be paid-in-kind and capitalized into new principal indebtedness upon agreement of the parties under the amended and restated promissory note dated June 27, 2012. We capitalized into new principal indebtedness an aggregate of approximately $11.9 million of accrued and unpaid interest due and payable as of June 27, 2012.

In October 2012, we sold in an underwritten public offering 40,000,000 shares of its common stock, together with 40,000,000 warrants to purchase up to an aggregate of 30,000,000 shares of our common stock. In addition, we sold pursuant to the full exercise of an over-allotment option granted to the underwriters, an additional 6,000,000 shares of common stock, together with 6,000,000 warrants to purchase up to an aggregate of 4,500,000 shares of common stock. The shares of common stock were sold together with a warrant for a combined purchase price of $2.00. Net proceeds from the offering were approximately $86.3 million (after deducting discounts and commissions to the underwriters and offering expenses), excluding any future proceeds from the exercise of the warrants. Each warrant entitles the holder to purchase 0.75 of a share of common stock. The warrants are exercisable at $2.60 per share and will expire in October 2013.

Concurrently with the underwritten public offering, The Mann Group agreed to purchase $107.4 million worth of restricted shares of common stock and restricted warrants to purchase restricted shares of common stock in exchange for cancellation of principal under the amended and restated promissory note held by The Mann Group. On October 18, 2012, we amended and restated the existing promissory note evidencing the loan arrangement with The Mann Group to extend the maturity date from March 31, 2013 to January 1, 2014, extend the date through which we can borrow under the note to September 30, 2013, adjust the annual interest rate on all outstanding principal to the one-year LIBOR rate on December 31, 2012 plus 5%, effective beginning on January 1, 2013. Following the approval by our stockholders in December 2012 to increase our authorized shares of common stock, we completed the closing under The Mann Group Common Stock and Warrant Purchase Agreement. Following the cancellation of the principal amount and the capitalization of the accrued and unpaid interest, the total principal amount outstanding under the amended and restated promissory note was $119.6 million, and we had $125.4 million available for borrowing under such note.

Table of Contents

During the year ended December 31, 2012, we used $119.9 million of cash for our operations and had a net loss of $169.4 million, which included $36.2 million of non-cash charges primarily consisting of depreciation and amortization, stock-based compensation, fair value of forward purchase contracts and common stock issued pursuant to litigation settlement. By comparison, during the year ended December 31, 2011, we used $123.9 million of cash for our operations and had a net loss of $160.8 million, which included $27.1 million of non-cash charges primarily consisting of depreciation and amortization, and stock-based compensation. The operating cash flow increased by $3.4 million primarily due to increased accrued expenses associated with the clinical trials. Cash used for our operations for the year ended December 31, 2012 decreased by $4.0 million compared to cash used for our operations for the year ended December 31, 2011 primarily due to the non-recurring payment related to the termination of our insulin supply agreement during 2011, offset by increased clinical trial expenditures during 2012. We expect our negative operating cash flow to continue at least until we obtain regulatory approval and achieve commercialization of AFREZZA.

We used $560,000 of cash for investing activities during the year ended December 31, 2012, as compared to $2.9 million of cash used for the year ended December 31, 2011. Cash used for investing activities for the year ended December 31, 2012 compared to the same period in the prior year decreased $2.4 million, primarily due to a $6.2 million decrease in purchases of machinery and equipment, offset by the non-recurrence of $3.8 million in proceeds received in 2011 from the early termination of certificates of deposit that were previously held as collateral for foreign exchange hedging instruments. In 2011, we purchased $6.9 million of machinery and equipment to expand our manufacturing operations and our quality systems that support clinical trials for AFREZZA as compared to $0.6 million of machinery and equipment purchased in 2012.

Our financing activities generated $179.6 million of cash for the year ended December 31, 2012, as compared to $63.4 million for the same period in 2011. For the year ended December 31, 2012, cash provided by financing activities was primarily from $166.8 million in net aggregate proceeds received from the sale of stock and warrants pursuant to two underwritten public offerings and $12.8 million in borrowings from The Mann Group loan arrangement. In February 2012, we received net proceeds of $80.6 million from the sale of 35,937,500 units in an underwritten public offering, including 4,687,500 units sold pursuant to the full exercise of an over-allotment option granted to the underwriters, with one unit consisting of one share of common stock and a warrant to purchase 0.6 of a share of common stock, for a combined price of $2.40 per unit to the public and $2.256 per unit to the underwriters. In October 2012, we received net proceeds of $86.3 million from the sale of 46,000,000 shares of our common stock, together with 46,000,000 warrants to purchase 34,500,000 shares of our common stock, for a combined purchase price of $2.00 per share and warrant. For the year ended December 31, 2011, cash from financing activities was primarily from $53.0 million of related party borrowings and $10.9 million related to the sale of common stock during the first quarter of 2011 as well as exercise of stock options, and shares purchased through the employee stock purchase plan.

As of December 31, 2012, we had $61.8 million in cash and cash equivalents. We believe our existing cash resources, including the amount available to borrow under our loan arrangement with The Mann Group, as amended, will be sufficient to fund our anticipated cash requirements through at least the third quarter of 2013. The $115.0 million aggregate principal amount of 2013 notes mature in December 2013, and our cash and cash equivalents as of December 31, 2012 were insufficient to repay these notes. Accordingly, we will need to raise additional capital, either through the sale of equity or debt securities, the entry into a strategic business collaboration with a pharmaceutical or biotechnology company, the establishment of other funding facilities, licensing arrangements, asset sales or other means, and/or refinance our indebtedness under the 2013 notes, in order to continue the development and commercialization of AFREZZA and other product candidates and to support our other ongoing activities. There can be no assurance that we will be able to do so on favorable terms by the applicable repayment date, or at all. In addition, if we undergo a fundamental change, as that term is defined in the indentures governing the terms of the 2013 notes, each holder of 2013 notes will have the option to require us to repurchase all or any portion of such holder s notes at a repurchase price of 100% of the principal amount of such notes to be repurchased plus accrued and unpaid interest, if any. Any of these events could have a material adverse effect on our business, results of operations and financial condition, up to and including the noteholders initiating bankruptcy proceedings or causing us to cease operations altogether. This raises substantial doubt about our ability to continue as a going concern.

Table of Contents

We intend to use our capital resources to continue the development and commercialization of AFREZZA, if approved. 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 continue to be substantial doubt about our ability to continue as a going concern.

Off-Balance Sheet Arrangements

As of December 31, 2012, 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, the senior convertible notes, and open purchase order and supply commitments consisted of the following at December 31, 2012 (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)	$ 34,527	$ 900	$	$	$ 35,427
Senior convertible notes(2)	125,086	111,532			236,618
Note payable to principal stockholder(3)		123,974			123,974
Operating lease obligations	21				21
Total contractual obligations	$ 159,634	$ 236,406	$	$	$ 396,040

(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.

Table of Contents

(2) The senior convertible notes obligations include the 2013 notes and the 2015 notes. 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 $119.6 million of borrowings as of December 31, 2012. Interest is paid based on a fixed rate equal to the one-year LIBOR rate on December 31, 2012 plus 5% and the principal payment is due on January 1, 2014.

RELATED PARTY TRANSACTIONS

For a description of our related party transactions see Note 6 Related-Party Arrangements in the notes to our financial statements.

RECENT ACCOUNTING PRONOUNCEMENTS

In June 2011, the FASB issued Accounting Standards Update (ASU) No. 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income* . This update improves the comparability, consistency and transparency of financial reporting and increases the prominence of items reported in other comprehensive income. This update is effective for interim and annual periods beginning after December 15, 2011. In December 2011, the FASB issued ASU No. 2011-12, *Comprehensive Income (Topic 220): Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in ASU No. 2011-05.* This update deferred only those changes in ASU No. 2011-05 that related to the presentation of reclassification adjustments. In February 2013, the FASB issued ASU 2013-02, *Comprehensive Income (Topic 220) Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income.* These amendments do not change the current requirements for reporting net income or other comprehensive income in the financial statements. These amendments provide for additional disclosure requirements for amounts reclassified out of accumulated other comprehensive income. These amendments are effective prospectively for interim and annual periods beginning after December 15, 2012. Early adoption is permitted. Effective January 1, 2012, we adopted the new requirements as set forth in ASU No. 2011-05 in the disclosure of comprehensive income on our consolidated financial statements. We are evaluating the impact, if any, of the adoption of ASU No. 2013-02 will have on our consolidated financial statements.

In May 2011, the FASB issued ASU No. 2011-04 for Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs . This update addresses how to measure fair value and requires new disclosures about fair value measurements. The amendments in this update are effective for interim and annual periods beginning after December 15, 2011. Effective the quarter ended March 31, 2012, we adopted the new requirements in the disclosure of financial instruments on our consolidated financial statements.

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

We are exposed to market risk related to changes in interest rates impacting our short-term investment portfolio as well as the interest rate on the promissory note underlying our revolving credit facility with The Mann Group. The interest rate on amounts borrowed under our credit facility with The Mann Group for the year ended December 31, 2012 was 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. Pursuant to an amendment to the promissory note in October 2012, as of January 1, 2013 the interest rate on all outstanding principal amounts under our credit facility with The Mann Group was adjusted to the one-year LIBOR on December 31, 2012 plus 5%. As of December 31, 2012, the total principal amount outstanding under the credit facility was $119.6 million. In addition, all borrowings under the credit facility for periods on and after January 1, 2013 bear interest at the one-year LIBOR on December 31, 2012 plus 5%. 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

Table of Contents

invested through highly rated financial institutions in North America. We continue to utilize our $350.0 million revolving credit facility with The Mann Group to fund operations. As of December 31, 2012, the amount available for borrowing under our revolving credit facility with The Mann Group was $125.4 million. If a 10% change in interest rates were to have occurred on December 31, 2012, this change would not have had a material effect on the value of our short-term investment portfolio or on our interest expense obligations with respect to outstanding borrowed amounts under our revolving credit facility.

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 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, 2012. Based on that evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Management s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework set forth in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework set forth in *Internal Control Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2012. Deloitte & Touche LLP, the independent registered public accounting firm that audited the financial statements included in this 2012 Form 10-K, has issued an attestation report on our internal control over financial reporting as of December 31, 2012, which is included herein.

Changes in Internal Control Over Financial Reporting

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of any change in our internal control over financial reporting that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting during the fiscal quarter ended December 31, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

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, 2012, 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, 2012, 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, 2012 of the Company and our report dated March 18, 2013 expressed an unqualified opinion on those financial statements and includes an explanatory paragraph relating to the Company s ability to continue as a going concern.

/s/ DELOITTE & TOUCHE LLP

Los Angeles, California

March 18, 2013

Table of Contents

Item 9B. ***Other Information.***

On March 18, 2013, we entered into an At-The-Market Issuance Sales Agreement with MLV & Co. LLC, or MLV, and an At-The-Market Issuance Sales Agreement with Brinson Patrick Securities Corporation, or Brinson Patrick. We refer to the foregoing agreements as the sales agreements. Under each sales agreement, we may issue and sell shares of our common stock having an aggregate offering price of up to $50.0 million (provided that in no event may we issue and sell more than $50.0 million of our common stock under both agreements in the aggregate) from time to time through MLV or Brinson Patrick, as applicable, as our sales agent. We will issue and sell shares under only one sales agreement at any one time.

MLV and Brinson Patrick may each sell the common stock by any method that is deemed to be an at-the-market equity offering as defined in Rule 415 promulgated under the Securities Act, including sales made directly on or through The NASDAQ Global Market or to or through a market maker. MLV and Brinson Patrick may each also sell the common stock in negotiated transactions, subject to our approval. Subject to the terms and conditions of the respective sales agreements, MLV and Brinson Patrick will use commercially reasonable efforts consistent with their respective normal trading and sales practices and applicable laws, rules and regulations to sell the our common stock from time to time, based upon our instructions (including any price, time or size limits or other parameters or conditions we may impose). We are not obligated to make any sales of common stock under either of the sales agreements. The offering of shares of our common stock pursuant to either sales agreement will terminate upon the earlier of (1) the sale of all common stock subject to the applicable sales agreement, (2) March 18, 2016 and (3) termination of the applicable sales agreement. Each sales agreement may be terminated by us or by MLV or Brinson Patrick, as applicable, at any time upon 10 days notice to the other party, or by MLV or Brinson Patrick, as applicable, at any time in certain circumstances, including but not limited to the occurrence of a material adverse change in us. We will pay MLV and Brinson Patrick a commission of up to 3.0% of the gross proceeds of the sales price per share of any common stock sold through MLV or Brinson Patrick, respectively, under their respective sales agreements. We have also provided MLV and Brinson Patrick with customary indemnification rights and reimbursement for up to $25,000 of legal expenses each.

The foregoing description of the sales agreements is not complete and is qualified in its entirety by reference to the full text of such agreements, copies of which are filed herewith as Exhibits 10.38 and 10.39 to this Annual Report on Form 10-K.

The foregoing description of the sales agreements shall not constitute an offer to sell or the solicitation of an offer to buy the securities discussed above in this Item 9B, nor shall there be any offer, solicitation or sale of the securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

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 2013 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.

Table of Contents

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, to the extent any such waiver is required to be disclosed pursuant to the rules and regulations of the SEC.

Item 11. ***Executive Compensation***

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

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

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

Item 13. ***Certain Relationships, Related Transactions and Director Independence***

The information under the caption Certain Transactions and Corporate Governance Principles and Board and Committee Matters in the Proxy Statement is incorporated herein by reference.

Item 14. ***Principal Accounting Fees and Services***

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

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

PART IV

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

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

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

Table of Contents

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:

Table of Contents

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(14)	Certificate of Amendment of Amended and Restated Certificate of Incorporation.
3.3(20)	Certificate of Amendment of Amended and Restated Certificate of Incorporation.
3.4(9)	Amended and Restated Bylaws.
4.1(10)	Indenture, by and between MannKind and Wells Fargo Bank, N.A., dated November 1, 2006.
4.2(3)	First Supplemental Indenture, by and between MannKind and Wells Fargo Bank, N.A., dated December 12, 2006.
4.3(3)	Form of 3.75% Senior Convertible Note due 2013.
4.4	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(16)	Indenture, by and between MannKind and Wells Fargo Bank, N.A., dated August 24, 2010.
4.7(16)	Form of 5.75% Senior Convertible Note due 2015.
4.8(18)	Form of Warrant to Purchase Common Stock issued February 8, 2012.
4.9(19)	Form of Warrant to Purchase Common Stock issued October 23, 2012.
4.10	Form of Warrant to Purchase Common Stock issued December 21, 2012.
5.1	Opinion of Cooley LLP.
10.1(19)	Amended and Restated Promissory Note made by MannKind in favor of The Mann Group LLC, dated October 18, 2012.
10.3(19)	Common Stock and Warrant Purchase Agreement by and between MannKind and The Mann Group LLC, dated October 18, 2012.
10.4(12)	Agreement, dated September 13, 2006, between MannKind and Torcon, Inc.
10.5(2)	Securities Purchase Agreement, dated August 2, 2005 by and among MannKind and the purchasers listed on Exhibit A thereto.
10.6**(4)	Supply Agreement, dated December 31, 2004, between MannKind and Vaupell, Inc.
10.7*(1)	Form of Indemnity Agreement entered into between MannKind and each of its directors and officers.
10.8*(8)	Description of Officers Incentive Program.
10.9*(11)	Executive Severance Agreement, dated October 10, 2007, between MannKind and Hakan Edstrom.
10.10*(11)	Executive Severance Agreement, dated October 10, 2007, between MannKind and David Thomson.
10.11*(17)	Employment Agreement, dated June 27, 2011, between MannKind and Peter Richardson.
10.12*(11)	Executive Severance Agreement, dated October 10, 2007, between MannKind and Juergen Martens.

Table of Contents

Exhibit Number	Description of Document
10.13*(11)	Executive Severance Agreement, dated October 10, 2007, between MannKind and Diane Palumbo.
10.14*(11)	Executive Severance Agreement, dated April 21, 2008, between MannKind and Matthew J. Pfeffer.
10.15*(11)	Change of Control Agreement, dated October 10, 2007, between MannKind and Hakan Edstrom.
10.16*(11)	Change of Control Agreement, dated October 10, 2007, between MannKind and David Thomson.
10.18*(11)	Change of Control Agreement, dated October 10, 2007, between MannKind and Juergen Martens.
10.19*(11)	Change of Control Agreement, dated October 10, 2007, between MannKind and Diane Palumbo.
10.20*(11)	Change of Control Agreement, dated April 21, 2008, between MannKind and Matthew J. Pfeffer.
10.22*(7)	2004 Equity Incentive Plan, as amended.
10.23*(1)	Form of Stock Option Agreement under the 2004 Equity Incentive Plan.
10.24*(6)	Form of Phantom Stock Award Agreement under the 2004 Equity Incentive Plan.
10.25*(8)	2004 Non-Employee Directors Stock Option Plan and form of stock option agreement there under.
10.26*(1)	2004 Employee Stock Purchase Plan and form of offering document there under.
10.28*(1)	Pharmaceutical Discovery Corporation 1999 Stock Plan and form of stock option plan there under.
10.29*(1)	AlleCure Corp. 2000 Stock Option and Stock Plan.
10.30*(1)	CTL Immunotherapies Corp. 2000 Stock Option and Stock Plan.
10.31*(1)	2001 Stock Awards Plan.
10.32**(20)	Letter Agreement, dated June 4, 2011, between MannKind and N.V. Organon.
10.33**(13)	Insulin Maintenance and Call-Option Agreement, dated June 19, 2009, by and among Pfizer Manufacturing Frankfurt GmbH, Pfizer Inc. and MannKind.
10.34(16)	Purchase Agreement, dated August 18, 2010, by and between MannKind and Merrill Lynch, Pierce, Fenner & Smith Incorporated, as representative for the initial purchasers named therein.
10.35(16)	Share Lending Agreement, dated August 18, 2010, by and between MannKind and Bank of America, N.A.
10.36(15)	Letter Agreement, dated August 10, 2010, by and between MannKind and Omni Capital Corporation.
10.37(18)	Common Stock Purchase Agreement by and between MannKind and The Mann Group LLC, dated February 2, 2012.
10.38	At-The-Market Issuance Sales Agreement, dated March 18, 2013, by and between MannKind and MLV & Co. LLC.
10.39	At-The-Market Issuance Sales Agreement, dated March 18, 2013, by and between MannKind and Brinson Patrick Securities Corporation.
23.1	Consent of Independent Registered Public Accounting Firm
23.2	Consent of Cooley LLP (included as Exhibit 5.1).
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.

Table of Contents

Exhibit Number	Description of Document
32	Certifications of the Chief Executive Officer and Chief Financial Officer pursuant to Rules 13a-14(b) and 15d-14(b) of the Securities Exchange Act of 1934, as amended and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350)
101	Interactive Data Files pursuant to Rule 405 of Regulation S-T.

* Indicates management contract or compensatory plan.

** 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.

(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 proxy statement on Schedule 14A (File No. 000-50865), filed with the SEC on April 6, 2012.

(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 17, 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 May 4, 2009.

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

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

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

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

(18) Incorporated by reference to MannKind s current report on Form 8-K (File No. 000-50865), filed with the SEC on February 6, 2012.

(19) Incorporated by reference to MannKind s current report on Form 8-K (File No. 000-50865), filed with the SEC on October 19, 2012.

Table of Contents

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 18, 2013

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 18, 2013
/s/ Hakan S. Edstrom Hakan S. Edstrom	President, Chief Operating Officer and Director	March 18, 2013
/s/ Matthew J. Pfeffer Matthew J. Pfeffer	Corporate Vice President and Chief Financial Officer (*Principal Financial and Accounting Officer)*	March 18, 2013
/s/ Ronald J. Consiglio Ronald J. Consiglio	Director	March 18, 2013
/s/ Michael Friedman Michael Friedman, M.D.	Director	March 18, 2013
/s/ Kent Kresa	Director	March 18, 2013

Kent Kresa		
/s/ David H. MacCallum	Director	
David H. MacCallum		March 18, 2013
/s/ Henry L. Nordhoff	Director	
Henry L. Nordhoff		March 18, 2013

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

INDEX TO FINANCIAL STATEMENTS

Table of Contents

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, 2011 and 2012 and the related consolidated statements of operations, comprehensive loss, stockholders equity (deficit), and cash flows for each of the three years in the period ended December 31, 2012 and for the period from February 14, 1991 (date of inception) to December 31, 2012. 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 consolidated financial statements present fairly, in all material respects, the financial position of MannKind Corporation and subsidiaries as of December 31, 2011 and 2012, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2012 and for the period from February 14, 1991 (date of inception) to December 31, 2012, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements for the years ended December 31, 2011 and 2012 have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company s existing cash resources and its operating losses since inception raise substantial doubt about its ability to continue as a going concern. Management s plans concerning these matters are also described in Note 1 to the financial statements. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company s internal control over financial reporting as of December 31, 2012, 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 18, 2013 expressed an unqualified opinion on the Company s internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Los Angeles, California

March 18, 2013

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONSOLIDATED BALANCE SHEETS

	December 31, 2011	2012
	(In thousands, except share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,681	$ 61,840
State research and development credit exchange receivable current		450
Prepaid expenses and other current assets	3,140	4,520
Total current assets	5,821	66,810
Property and equipment net	193,029	183,961
State research and development credit exchange receivable net of current portion	473	313
Other assets	230	230
Total	$ 199,553	$ 251,314
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 4,624	$ 4,555
Accrued expenses and other current liabilities	20,736	25,777
Senior convertible notes		114,443
Total current liabilities	25,360	144,775
Senior convertible notes	210,642	97,583
Note payable to related party	277,203	119,635
Total liabilities	513,205	361,993
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, 2011 and 2012		
Common stock, $0.01 par value 250,000,000 and 550,000,000 shares authorized at December 31, 2011 and 2012, respectively; 131,522,945 and 286,035,082 shares issued and outstanding at December 31, 2011 and 2012, respectively	1,315	2,860
Additional paid-in capital	1,620,535	1,991,379
Accumulated other comprehensive income (loss)	44	(6)
Deficit accumulated during the development stage	(1,935,546)	(2,104,912)
Total stockholders deficit	(313,652)	(110,679)
Total	$ 199,553	$ 251,314

See notes to consolidated financial statements.

63

Table of Contents

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, 2012
	2010	2011	2012	
	(In thousands, except per share data)			
Revenue	$ 93	$ 50	$ 35	$ 3,166
Operating expenses:				
Research and development	112,279	99,959	101,522	1,467,573
General and administrative	40,312	40,630	45,473	425,704
In-process research and development costs				19,726
Goodwill impairment				151,428
Total operating expenses	152,591	140,589	146,995	2,064,431
Loss from operations	(152,498)	(140,539)	(146,960)	(2,061,265)
Other income (expense)	(725)	1,541	(1,191)	(2,267)
Interest expense on note payable to related party	(10,249)	(10,883)	(10,491)	(38,825)
Interest expense on senior convertible notes	(7,128)	(10,941)	(11,139)	(39,933)
Interest income	40	18	7	36,996
Loss before benefit for income taxes	(170,560)	(160,804)	(169,774)	(2,105,294)
Income tax benefit			(408)	(382)
Net loss	(170,560)	(160,804)	(169,366)	(2,104,912)
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	$ (170,560)	$ (160,804)	$ (169,366)	$ (2,128,124)
Net loss per share applicable to common stockholders basic and diluted	$ (1.50)	$ (1.32)	$ (0.94)	
Shares used to compute basic and diluted net loss per share applicable to common stockholders	113,672	121,817	180,855	

See notes to consolidated financial statements.

64

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Year ended December 31,			Cumulative Period from February 14, 1991 (Date of Inception) to December 31, 2012
	2010	2011	2012	
	(In thousands)			
Net Loss	$ (170,560)	$ (160,804)	$ (169,366)	$ (2,104,912)
Other comprehensive loss:				
Cumulative translation (loss) gain	(6)	(3)	(2)	(6)
Unrealized gain (loss) on investments:				
Unrealized holding gain (loss) during the period	361	(27)		48
Less: reclassification adjustment for gains (losses) included in net loss			(48)	(48)
Net unrealized gain (loss) on investments	361	(27)	(48)	
Comprehensive loss	$ (170,205)	$ (160,834)	$ (169,416)	$ (2,104,918)

See notes to consolidated financial statements.

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)

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

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (Continued)

(In thousands)	Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series C Convertible Preferred Stock Issuable	Series C Convertible Preferred Stock Subscriptions Receivable	Common Stock		Additional Paid-In Capital	Notes Receivable from Stockholders	Notes Receivable from Officers	Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total
	Shares	Amount	Shares	Amount			Shares	Amount						
Conversion of notes payable							63	1	1,073					1,074
Issuance of Series B preferred stock for cash	193	15,000												15,000
Issuance of common stock for cash, services and notes							4,690	46	33,945	(2,358)				31,633
Discount on notes below market rate										241				241
Accrued interest on notes										(117)				(117)
Purchase of Series A redeemable convertible preferred stock									(993)					(993)
Amount in excess of redemption obligation									999					999
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 feature of Series B convertible preferred stock					(1,421)			(1,421)
Accretion to redemption value on Series A redeemable convertible preferred stock					(251)			(251)
Stock-based compensation					268			268
Put option redemption by stockholder					1,921			1,921
Net loss							(206,265)	(206,265)
BALANCE, DECEMBER 31, 2002	193	15,000	16,464	165	378,010	(1,310)	(301,092)	90,773

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (Continued)

(In thousands)	Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series C Convertible Preferred Stock Issuable	Series C Convertible Preferred Stock Subscriptions Receivable	Common Stock		Additional Paid-In Capital	Notes Receivable from Stockholders	Notes Receivable from Officers	Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total
	Shares	Amount	Shares	Amount			Shares	Amount						
Issuance of Series C convertible preferred stock subscriptions					50,000	(50,000)								
Cash collected on Series C convertible preferred stock subscriptions						31,847								31,847
Issuance of common stock for cash							3,494	35	49,965					50,000
Non-cash compensation expense of officer resulting from stockholder contribution									70					70
Issuance of common stock for cash already received							17							
Notes receivable by stockholder issued to officers									225		(225)			
Accrued interest on notes										(102)	(3)			(105)
Beneficial conversion feature of Series B convertible preferred stock									1,017					1,017
Deemed dividend related to									(1,017)					(1,017)

beneficial conversion feature of Series B convertible preferred stock												
Accretion to redemption value on Series A redeemable convertible preferred stock									(253)			(253)
Stock-based compensation									4,501			4,501
Put shares sold to majority stockholder									623			623
Net loss											(65,879)	(65,879)
BALANCE, DECEMBER 31, 2003	193	15,000			50,000	(18,153)	19,975	200	433,141	(1,412)	(228)	(366,971)	111,577
Issuance of Series C convertible preferred stock for cash			356	18,153	(18,153)	18,153							18,153
Issuance of Series C convertible preferred stock for cash already received			624	31,847	(31,847)								
Exercise of stock options							86		1,079				1,079
Exercise of warrants							4		46				46
Accrued interest on notes										(107)			(107)
Repayment of notes receivable by stockholder issued to officers									(225)		228		3
Repayment of stock note receivable							(90)	(1)	(1,518)	1,519			
Conversion of Series A convertible preferred stock to common stock							891	9	5,239				5,248
Conversion of Series B convertible preferred stock to common stock	(193)	(15,000)					811	8	14,992				
Conversion of Series C convertible preferred			(980)	(50,000)			4,464	45	49,955				

stock to common stock					
Issuance of common shares in exchange for warrants	22				
Issuance of common shares under Employee Stock Purchase Plan	36		430		430
Net proceeds from initial public offering	6,557	66	83,110		83,176
Beneficial conversion feature of Series B convertible preferred stock			19,822		19,822
Deemed dividends related to beneficial conversion feature of Series B and Series C convertible preferred stock			(19,822)		(19,822)
Accretion to redemption value on Series A redeemable convertible preferred stock			(60)		(60)
Stock-based compensation			6,810		6,810
Net loss				(75,992)	(75,992)
BALANCE, DECEMBER 31, 2004	32,756	327	592,999	(442,963)	150,363

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (Continued)

(In thousands)	Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series C Convertible Preferred Stock Issuable	Series C Convertible Preferred Stock Subscriptions Receivable	Common Stock		Additional Paid-In Capital	Notes Receivable from Stockholders	Notes Receivable from Officers	Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total
	Shares	Amount	Shares	Amount			Shares	Amount						
Issuance of common shares in exchange for warrants							24		245					245
Issuance of common shares under Employee Stock Purchase Plan							58	1	494					495
Exercise of stock options							304	3	1,948					1,951
Issuance of stock awards to consultants							40	1	(146)					(145)
Issuance of stock and warrants for cash							17,132	171	170,063					170,234
Stock-based compensation									(1,828)					(1,828)
Net loss													(114,338)	(114,338)
BALANCE, DECEMBER 31, 2005							50,314	503	763,775				(557,301)	206,977
Exercise of warrants							339	3	2,691					2,694
Issuance of common shares under Employee Stock Purchase Plan							86	1	980					981
Exercise of stock options							263	3	2,309					2,312
Cancellation of common shares for stock notes receivable							(844)	(8)	8					
Issuance of stock for cash							23,000	230	384,440					384,670
Issuance of common shares from the release of restricted stock units							102	1	(341)					(340)
Issuance of common shares pursuant to research agreement							100	1	2,073					2,074
Stock-based compensation									14,667					14,667
Net loss													(230,548)	(230,548)
BALANCE, DECEMBER 31, 2006							73,360	734	1,170,602				(787,849)	383,487
Issuance of common shares under Employee Stock Purchase Plan							124	1	1,064					1,065

Exercise of stock options	607	6	4,917		4,923
Issuance of stock awards to consultants	30		123		123
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

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (Continued)

(In thousands)	Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series C Convertible Preferred Stock Issuable	Series C Convertible Preferred Stock Subscriptions Receivable	Common Stock		Additional Paid-In Capital	Notes Receivable from Stockholders	Notes Receivable from Officers	Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total
	Shares	Amount	Shares	Amount			Shares	Amount						
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)
Stock-based compensation									24,811					24,811
Unrealized gain on available-for-sale securities												295		295
Net loss													(303,039)	(303,039)
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
Unrealized loss on available-for-sale securities												(581)		(581)
Unrealized gain on foreign currency translation												5		5
Net loss													(220,104)	(220,104)
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
							2,100	21	14,314					14,335

Issuance of stock for cash						
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
Unrealized gain on available-for-sale securities				361		361
Unrealized loss on foreign currency translation				(6)		(6)
Net loss					(170,560)	(170,560)
BALANCE, DECEMBER 31, 2010	127,793	1,278	1,587,858	74	(1,774,742)	(185,532)

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT) (Continued)

(In thousands)	Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series C Convertible Preferred Stock Issuable	Series C Convertible Preferred Stock Subscriptions Receivable	Common Stock		Additional Paid-In Capital	Notes Receivable from Stockholders	Notes Receivable from Officers	Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total
	Shares	Amount	Shares	Amount			Shares	Amount						
Issuance of common shares under Employee Stock Purchase Plan							283	3	766					769
Issuance of stock for cash							1,400	14	9,526					9,540
Issuance of stock in exchange for cancelling an equal amount of note payable to related party							1,400	14	11,102					11,116
Issuance of common shares from the release of restricted stock units							433	4	(547)					(543)
Exercise of stock options							214	2	626					628
Stock-based compensation									11,204					11,204
Unrealized loss on available-for-sale securities												(27)		(27)
Unrealized loss on foreign currency translation												(3)		(3)
Net loss													(160,804)	(160,804)
BALANCE, DECEMBER 31, 2011							131,523	1,315	1,620,535			44	(1,935,546)	(313,652)
Exercise of stock options							3		9					9
Issuance of common shares from the release of restricted stock units							886	9	(915)					(906)
Issuance of common shares pursuant to underwritten public offerings							81,938	819	166,045					166,864
Issuance of common shares in exchange for cancelling equal amounts of note payable to related party							71,250	713	183,824					184,537
Fair value of forward purchase contracts									1,237					1,237
Issuance of common shares pursuant to litigation settlement							225	2	436					438
									6,056					6,056

Commitment to deliver common shares pursuant to litigation settlement to additional paid-in capital										
Issuance of common shares under Employee Stock Purchase Plan			211	2	860					862
Stock-based compensation					13,292					13,292
Cumulative translation (loss) gain								(2)		(2)
Reclassification adjustment for gains (losses) included in net loss								(48)		(48)
Net loss									(169,366)	(169,366)
BALANCE, DECEMBER 31, 2012	$	$	286,035	$ 2,860	$ 1,991,379	$	$	$ (6)	$ (2,104,912)	$ (110,679)

See notes to consolidated financial statements.

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,			Cumulative Period from February 14, 1991 (Date of Inception) to December 31, 2012
	2010	2011	2012	
	(In thousands)			
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net loss	$ (170,560)	$ (160,804)	$ (169,366)	$ (2,104,912)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and accretion	17,324	15,912	14,402	126,777
Stock-based compensation expense	13,580	11,204	13,292	137,918
Stock expense for shares issued pursuant to research agreement				3,018
Loss (gain) on sale, abandonment/disposal or impairment of property and equipment		(4)	682	24,253
Accrued interest on investments, net of amortization of premiums (discounts)				(191)
In-process research and development				19,726
Goodwill impairment				151,428
Loss on available-for-sale securities	644		117	990
Fair value of forward purchase contract			1,237	1,237
Common shares issued pursuant to litigation settlement			438	438
Commitment to deliver common shares pursuant to litigation settlement			6,056	6,056
Other, net	(6)	(3)	(2)	1,099
Changes in assets and liabilities:				
State research and development credit exchange receivable	1,115	830	(290)	(763)
Prepaid expenses and other current assets	823	224	(1,545)	(2,570)
Other assets	267	87		(230)
Accounts payable	(4,287)	2,672	44	4,418
Accrued expenses and other current liabilities	(7,554)	6,045	15,075	35,049
Other liabilities				(2)
Net cash used in operating activities	(148,654)	(123,837)	(119,860)	(1,596,261)
CASH FLOWS FROM INVESTING ACTIVITIES:				
Purchase of marketable securities	(4,178)			(796,779)
Sales and maturities of marketable securities	2,000	3,828		796,393
Purchase of property and equipment	(9,542)	(6,858)	(637)	(327,746)
Proceeds from sale of property and equipment		93	77	454
Net cash used in investing activities	(11,720)	(2,937)	(560)	(327,678)
CASH FLOWS FROM FINANCING ACTIVITIES:				
Issuance of common stock and warrants for cash	17,025	10,941	167,735	1,397,756
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	87,000	53,000	12,750	387,750
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	(3,392)	(547)	(906)	(13,027)
Net cash provided by financing activities	196,416	63,394	179,579	1,985,779

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)

	Year Ended December 31,			Cumulative Period from February 14, 1991 (Date of Inception) to December 31, 2012
	2010	2011	2012	
		(In thousands)		
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	$ 36,042	$ (63,380)	$ 59,159	$ 61,840
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	30,019	66,061	2,681	
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 66,061	$ 2,681	$ 61,840	$ 61,840
SUPPLEMENTAL CASH FLOWS DISCLOSURES:				
Cash paid for income taxes	$	$	$	$ 26
Interest paid in cash, net of amounts capitalized to Construction in progress	13,662	17,248	9,755	59,152
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	1,742	250	4,072	4,072
Capitalization of interest on note payable to related party			14,219	14,219
Reduction of principal on note payable to related party upon issuance of common stock and warrants	16,681	11,116	184,537	212,334
Forward purchase contracts contribution to additional paid-in capital			29,317	29,317
Reclassification of forward purchase contracts to additional paid-in capital			28,080	28,080

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.

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED STATEMENTS

1. Description of business and basis of presentation

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

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 and since incorporation has been establishing its facilities, recruiting personnel, conducting research and development, business development, business and financial planning, and raising capital. It is costly to develop therapeutic products and conduct clinical trials for the Company s products. Since its inception through December 31, 2012, the Company has reported accumulated net losses of $2.1 billion, which include a goodwill impairment charge of $151.4 million (see Note 2), and cumulative negative cash flow from operations of $1.6 billion. At December 31, 2012, the Company s capital resources consisted of cash and cash equivalents of $61.8 million.

In October 2007, the Company entered into a $350.0 million loan arrangement with its principal stockholder, The Mann Group, LLC (The Mann Group). In December 2012, the Company amended and restated the promissory note underlying the loan arrangement to, among other things, extend the maturity date of the promissory note to January 1, 2014, extend the date through which the Company can borrow under the promissory note to September 30, 2013, and adjust the annual interest rate on all outstanding principal to the one-year London Interbank Offered Rate (LIBOR) on December 31, 2012 plus 5%, effective January 1, 2013 (see Note 6 Related-party arrangements).

In October 2012, concurrently with an underwritten public offering (see Note 10 Common and preferred stock), The Mann Group agreed to purchase $107.4 million worth of restricted shares of common stock and restricted warrants in exchange for cancellation of principal under the $350.0 million amended and restated promissory note, the closing of which was completed in December 31, 2012. Following the cancellation of the principal amount and the capitalization of the accrued and unpaid interest, the total principal amount outstanding under the amended and restated promissory note was $119.6 million, and the Company had $125.4 million available for borrowing under the amended and restated promissory note (see Note 6 Related-party arrangements). On December 15, 2013, $115.0 million aggregate principal will be due under the 3.75% Senior Convertible Notes for unconverted securities on that date (see Note 7 Senior convertible notes).

Based upon the Company s current expectations, management believes the Company s existing capital resources, including the available borrowings under our loan arrangement with The Mann Group, as amended, will enable it to continue planned operations through at least the third quarter of 2013. 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. The Company 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, in order to continue the development and commercialization of AFREZZA and other product candidates and to support its other ongoing activities. However, the Company cannot provide assurances that such additional capital will be available 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. This raises substantial doubt about the Company s ability to continue as

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

a going concern. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

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.

Principles of Consolidation The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. Intercompany balances and transactions have been eliminated.

Segment Information In accordance with Accounting Standards Codification (ASC) 280-10-50 *Segment Reporting*, 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.

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 (GAAP) 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. The more significant estimates reflected in these accompanying financial statements involve assessing long-lived assets for impairment, accrued expenses, including clinical trial expenses, valuation of forward purchase contracts, valuation of stock-based compensation and the determination of the provision for income taxes and corresponding deferred tax assets and liabilities and any valuation allowance recorded against net deferred tax assets.

Cash and Cash Equivalents The Company considers all highly liquid investments with original or remaining maturities of 90 days or less at the time of purchase, that are readily convertible into cash 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. Cash and cash equivalents consist primarily of interest-bearing accounts and are regularly monitored by management and held in high credit quality institutions.

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

75

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 ASC 350-10 *Intangibles- 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 sheets.

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.* 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;

76

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 2010, 2011 and 2012, respectively.

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 15).

Income tax positions are considered for uncertainty in accordance with ASC 740-10-25 *Income Taxes,* 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 liabilities for uncertain income tax positions have been recorded. 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, if any. Penalties, if probable and reasonably estimable, are recognized as a component of income tax expense.

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 the realization of the Company s deferred tax assets as a result of its 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.* 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, 2012, the Company had three active stock-based compensation plans, which are described more fully in Note 12. 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). 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

77

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 estimates 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 within 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.

Forward Contracts The Company has entered into agreements with The Mann Group whereby the Company agreed to sell and The Mann Group agreed to purchase common stock and/or warrants. These agreements have been accounted for as forward contracts, having met the definition of derivative instruments in accordance with the provisions of ASC 815 *Derivatives and Hedging*. The Company determines the fair value of the forward contract upon its issuance, records fair value adjustments of the forward contract to Other income (expense) during the reporting period and through the settlement of the forward contract, and reclassifies the forward contract to equity upon settlement of the forward contract.

Comprehensive Income (Loss) Other comprehensive income (loss) (OCI) is recorded in accordance with ASC 220-10-45 *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.*

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, 2010, 2011 and 2012 was $17.4 million, $21.8 million and $21.6 million,

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

respectively. Interest costs capitalized was not significant for the year ended December 31, 2010 and were $0.4 million and $0.3 million for the years ended December 31, 2011 and 2012, respectively.

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.

Exit or Disposal Activities The obligations related to exit or disposal activities, including reductions in force, are accounted for in accordance with ASC 420-10-30 *Exit or Disposal Cost Obligations,* (ASC 420-10-30). 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 June 2011, the FASB issued Accounting Standards Update (ASU) No. 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income.* This update improves the comparability, consistency and transparency of financial reporting and increases the prominence of items reported in other comprehensive income. This update is effective for interim and annual periods beginning after December 15, 2011. In December 2011, the FASB issued ASU No. 2011-12, *Comprehensive Income (Topic 220): Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in ASU No. 2011-05.* This update deferred only those changes in ASU No. 2011-05 that related to the presentation of reclassification adjustments. In February 2013, the FASB issued ASU 2013-02, *Comprehensive Income (Topic 220) Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income.* These amendments do not change the current requirements for reporting net income or other comprehensive income in the financial statements. These amendments provide for additional disclosure requirements for amounts reclassified out of accumulated other comprehensive income. These amendments are effective prospectively for interim and annual periods beginning after December 15, 2012. Early adoption is permitted. Effective January 1, 2012, the Company adopted the new requirements as set forth in ASU No. 2011-05 in the disclosure of comprehensive income on the Company s consolidated financial statements. The Company is evaluating the impact, if any, of the adoption of ASU No. 2013-02 will have on the Company s consolidated financial statements.

In May 2011, the FASB issued Accounting Standards Update No. 2011-04 for Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs . This update addresses how to measure fair value and requires new disclosures about fair value measurements. The amendments in this update are effective for interim and annual periods beginning after December 15, 2011. Effective the quarter ended March 31, 2012, the Company adopted the requirements as set forth in this guidance.

3. 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, 2010, 2011 and 2012, research and development expenses were offset by $385,000, $609,000 and $289,000, respectively, in connection with the program.

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. Property and equipment

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

	Estimated Useful Life (Years)	December 31, 2011	December 31, 2012
Land		$ 5,273	$ 5,273
Buildings	39-40	54,948	54,948
Building improvements	5-40	114,247	114,245
Machinery and equipment	3-15	83,476	81,382
Furniture, fixtures and office equipment	5-10	5,249	5,239
Computer equipment and software	3	13,049	11,840
Leasehold improvements		53	17
Construction in progress		8,498	12,266
		284,793	285,210
Less accumulated depreciation and amortization		(91,764)	(101,249)
Property and equipment net		$ 193,029	$ 183,961

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, 2010, 2011 and 2012, and the cumulative period from February 14, 1991 (date of inception) to December 31, 2012 was $16.5 million, $14.6 million, $13.0 million and $121.8 million, respectively.

No asset impairment was recognized during the years ended December 31, 2010, 2011 and 2012.

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.

5. Accrued expenses and other current liabilities

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

	December 31, 2011	December 31, 2012
Salary and related expenses	$ 8,997	$ 10,074
Research and clinical trial costs	2,383	5,995
Accrued interest	8,262	4,533

Construction in progress		3,878
Other	1,094	1,297
Accrued expenses and other current liabilities	$ 20,736	$ 25,777

6. Related-party arrangements

In October 2007, the Company entered into a $350.0 million loan arrangement with its principal stockholder. In February 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. Until January 1, 2013, interest on outstanding principal amounts accrued

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

at a fixed rate equal to the one-year London Interbank Offered Rate (LIBOR) rate as reported by the *Wall Street Journal* on the date of such advance plus 3% per annum. The borrowing rate was 4.5% at December 31, 2012. The promissory note underlying the loan arrangement was amended at various dates during 2012. The most recent amendment occurred in October 2012 to extend the maturity date to January 1, 2014, extend the date through which the Company can borrow under the promissory note to September 30, 2013, and adjust the annual interest rate on all outstanding principal to the one-year LIBOR rate on December 31, 2012 plus 5%, effective beginning on January 1, 2013.

As of December 31, 2012, the total principal amount outstanding under the credit facility was $119.6 million, and the amount available for future borrowings was $125.4 million. Interest is due and payable quarterly in arrears on the first day of each calendar quarter for the preceding quarter, or at such other time as the Company and The Mann Group mutually agree. All or any portion of accrued and unpaid interest that becomes due and payable may be paid-in-kind and capitalized at any time upon mutual agreement of both parties. 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 (see discussion regarding letter agreement below).

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 prepayment would require the Company to use its working capital resources. 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. There are no warrants associated with the loan arrangement.

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 was required to issue and sell, and The Mann Group was obligated to purchase, the same number of shares of the Company s common stock that Seaside 88, LP (Seaside) purchased on each closing date under its agreement with the Company. The price of the shares that the Company sold to The Mann Group under the agreement was 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 issued and sold to The Mann Group was 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 was cancelled. The common stock purchase agreement with The Mann Group terminated upon termination of the Seaside agreement in the quarter ended September 30, 2011.

In the fourth quarter of 2010, the Company issued and sold a total of 2,100,000 shares of common stock to Seaside for net proceeds of $14.1 million in accordance with the Company s common stock purchase agreement with Seaside. During the quarter ended March 31, 2011, the Company issued and sold a total of 1,400,000 shares of common stock to Seaside for net proceeds of $9.7 million. No additional shares of common stock were sold to Seaside under this agreement subsequent to the quarter ended March 31, 2011. As of December 31, 2011, the Company had issued and sold a total of 3,500,000 shares of common stock to Seaside for net proceeds of $23.8 million in accordance with the agreement. The agreement with Seaside terminated during the quarter ended September 30, 2011. Concurrently, with the sales to Seaside, the Company issued and sold a total of 2,100,000

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

and 1,400,000 shares of common stock to The Mann Group, an entity controlled by the Company s principal stockholder, in 2010 and 2011, respectively, for a total purchase price of $16.7 million and $11.1 million, respectively, which was paid by the cancellation of outstanding principal under the Company s amended and restated promissory note with The Mann Group.

On February 8, 2012, the Company sold $86.3 million worth of units in an underwritten public offering, with each unit consisting of one share of common stock and a warrant to purchase 0.6 of a share of common stock. Concurrent with this public offering, The Mann Group agreed to purchase $77.2 million worth of restricted shares of common stock to be paid, at the discretion of the Company, by cash or by cancellation of principal indebtedness under the amended loan arrangement, subject to stockholder approval to increase the number of authorized shares. In May 2012, the Company s stockholders approved an increase in the authorized shares of common stock from 250,000,000 to 350,000,000. On June 27, 2012, the Company completed the closing of the sale of 31,250,000 share of its common stock through the cancellation of outstanding indebtedness under the loan agreement (see Note 10 Common and preferred stock).

In October 2012, the Company sold $92.0 million worth of units in an underwritten public offering, with each unit to purchase one share of common stock and a warrant to purchase at 0.75 of a share of common stock. Concurrent with the underwritten public offering, the Company entered into a Common Stock and Warrant Purchase Agreement on October 18, 2012, in which the Company was required to issue and sell and The Mann Group was obligated to purchase 40,000,000 restricted shares of the Company s common stock at a purchase price of $2.59 per share (the consolidated closing bid price of the Company s common stock on October 17, 2012), and 40,000,000 warrants to purchase up to an aggregate of 30,000,000 restricted shares of the Company s common stock at a purchase price of $0.125 for each share of the Company s common stock underlying the warrants, in exchange for cancellation of outstanding principal under the $350 million amended and restated promissory note with The Mann Group.

The restricted shares sold to The Mann Group may not be sold, pledged, assigned or transferred unless (i) the shares have been registered with the Securities and Exchange Commission (SEC) or (ii) the restricted shares are exempt from SEC registration requirements and the company has obtained an opinion from the company s counsel that the shares may be sold lawfully without registration.

As a result of the special meeting of the Company s stockholders held on December 20, 2012 in which the Company s stockholders approved an amendment to its Amended and Restated Certificate of Incorporation to increase the authorized shares of its common stock from 350,000,000 shares to 550,000,000 shares, the Company completed the closing of the Common Stock and Warrant Purchase Agreement entered into with The Mann Group on October 18, 2012. The aggregate purchase price for the shares and warrants that the Company issued to The Mann Group was approximately $107.4 million and was paid for by cancelling principal indebtedness owed to The Mann Group under the amended and restated promissory note. The cancelled principal amount became available for reborrowing. Additionally, in accordance with the terms of the note, the Company elected to capitalize the accrued and unpaid interest on the cancelled principal amount that became due upon the closing (see Note 10 Common and preferred stock).

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The principal amount outstanding under the loan arrangement as of December 31, 2011 and 2012, respectively, subsequent to the completion of the common stock purchase agreements was as follows (in thousands):

Principal amount outstanding at December 31, 2011	$ 277,203
Borrowings	12,750
Capitalization of accrued and unpaid interest due and payable as of June 27, 2012	11,876
Reduction of principal indebtedness related to the issuance of common stock pursuant to common stock purchase agreement completed on June 27, 2012	(77,187)
Capitalization of accrued and unpaid interest due and payable as of October 18, 2012	2,343
Reduction of principal indebtedness related to the issuance of common stock pursuant to common stock purchase agreement completed on October 18, 2012	(107,350)
Principal amount outstanding at December 31, 2012	$ 119,635

As of December 31, 2011, the Company had accrued and unpaid interest of $5.9 million related to the amount outstanding and had $45.0 million of available borrowings under the loan agreement. As of December 31, 2012, the Company had accrued and unpaid interest of $2.2 million related to the amount outstanding and had $125.4 million of available borrowings. Interest expense on the Company s note payable to a related party for the years ended December 31, 2010, 2011 and 2012 was $10.2 million, $10.9 million and $10.5 million, respectively.

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 $230,000, $111,000 and $200,000, respectively, for the years ended December 31, 2010, 2011 and 2012 on the basis of the corresponding cost of commercial airfare.

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 13).

7. Senior convertible notes

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

	December 31, 2011	2012
2013 notes		
Principal amount	$ 115,000	$ 115,000
Unaccreted debt issuance expense	(1,140)	(557)
Net carrying amount	113,860	114,443
2015 notes		
Principal amount	$ 100,000	$ 100,000
Unaccreted debt issuance expense	(3,218)	(2,417)

Net carrying amount	96,782	97,583
Senior convertible notes	$ 210,642	$ 212,026

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 2015 notes). The 2015 notes are governed by the terms of an indenture dated as of August 24, 2010 (the 2015 Note Indenture). The 2015 notes 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. The Company had accrued interest of $2.2 million as of December 31, 2011 and 2012 related to the 2015 notes. The 2015 notes 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 2015 notes is August 15, 2015 and payment is due in full on that date for unconverted securities. Holders of the 2015 notes 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 2015 notes 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 2015 notes 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 2015 notes 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 2015 notes 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 2015 notes 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. Under the terms of the 2015 Note Indenture, the conversion option can be net-share settled and the maximum number of shares that could be required to be delivered under the contract, including the make-whole shares, is fixed and less than the number of authorized and unissued shares less the maximum number of shares that could be required to be delivered during the contract period under existing commitments. Applying the Company s sequencing policy, the Company performed an analysis at the time of the offering of the 2015 notes and each reporting date since and concluded that the number of available authorized shares at the time of the offering and each subsequent reporting date was sufficient to deliver the number of shares that could be required to be delivered during the contract period under existing commitments.

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

On December 12, 2006, the Company completed an offering of $115.0 million aggregate principal amount of 3.75% Senior Convertible Notes due 2013 (the 2013 notes), including $15.0 million aggregate principal amount of the 2013 notes sold pursuant to the underwriters over-allotment option that was exercised in full. The 2013 notes 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 2013 Note Indenture). The 2013 notes 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 as of December 31, 2011 and 2012. The 2013 notes 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

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

debt, and to the debt and all other liabilities of the Company. The maturity date of the 2013 notes 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 2013 notes into shares of the Company s common stock at an initial conversion rate of 44.5002 shares per $1,000 principal amount of 2013 notes, 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 2013 notes converted in connection with a fundamental change by increasing the conversion rate on such 2013 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 the 2013 notes will have the option to require the Company to repurchase all or any portion of such holder s 2013 notes at a repurchase price of 100% of the principal amount of the 2013 notes to be repurchased plus accrued and unpaid interest, if any. Under the terms of the 2013 Note Indenture, the conversion option can be net-share settled and the maximum number of shares that could be required to be delivered under the contract, including the make-whole shares, is fixed and less than the number of authorized and unissued shares less the maximum number of shares that could be required to be delivered during the contract period under existing commitments. Applying the Company s sequencing policy, the Company performed an analysis at the time of the offering of the 2013 notes and each reporting date since and concluded that the number of available authorized shares at the time of the offering and each subsequent reporting date was sufficient to deliver the number of shares that could be required to be delivered during the contract period under existing commitments.

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 charged to interest expense using the effective interest method over the term of the 2013 notes.

Accretion of debt issuance expense in connection with the Notes offerings during the years ended December 31, 2011 and 2012 were $1.3 million and $1.4 million, respectively.

8. Restructuring charges

On February 10, 2011, the Company announced that following receipt of the Complete Response letter from the United States Food and Drug Administration (FDA) regarding the new drug application (NDA) for AFREZZA, it implemented a restructuring to streamline operations, reduce operating expenses, extend the cash runway and focus its resources on securing the FDA s approval of the NDA for AFREZZA. In connection with the restructuring, the Company reduced its total workforce by approximately 41% to 257 employees. The Company recorded charges of approximately $6.7 million for employee severance and other related termination benefits and recognized an initial liability of $6.7 million in February 2011, which approximated fair value.

	Workforce Reduction
Restructuring Balance, February 10, 2011	$ 6,659
Cash payments	(6,189)
Adjustment	(403)
Restructuring Balance, December 31, 2011	$ 67
Adjustment	(67)
Restructuring Balance, December 31, 2012	$

During the year ended December 31, 2011, the Company adjusted the restructuring balance based on the election of certain termination benefits by a portion of the terminated employees.

85

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The remaining restructuring balance as of December 31, 2011 consists of severance and related termination benefits for employees still to be terminated.

The net $6.3 million of costs associated with the restructuring are included in Research and development and General and administrative operating expenses in the consolidated statements of operations as $4.7 million and $1.6 million, respectively, for the year ended December 31, 2011.

9. Fair Value of Financial Instruments

The carrying amounts of financial instruments, which include cash equivalents 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, 2011 and 2012, the Company held $2.7 million and $61.8 million, respectively of cash and cash equivalents, consisting of money market funds of $0.6 million and $60.8 million, respectively, and the remaining funds in non-interest bearing checking accounts. The fair value of these money market funds was determined by using quoted prices for identical investments in an active market (Level 1 in the fair value hierarchy).

The following is a summary of the carrying values and estimated fair values of the Company s senior convertible notes due in 2013 and 2015 (in millions).

	December 31, 2011		December 31, 2012	
	Carrying value	Estimated fair value	Carrying value	Estimated fair value
2013 notes	$ 113.9	$ 61.0	$ 114.4	$ 81.9
2015 notes	$ 96.8	$ 60.8	$ 97.6	$ 63.2

The estimated fair value of the senior convertible notes due 2013 was calculated based on quoted prices in an active market (Level 1 in the fair value hierarchy). The estimated fair value of the senior convertible notes due 2015 was calculated based on model derived valuations whose inputs were observable, such as the Company s stock price, and non-observable, such as the Company s long-term historical volatility (Level 3 in the fair value hierarchy). As there is no current observable market for the senior convertible notes due 2015, the Company determined the estimated fair value using a convertible bond valuation model within a lattice framework. The convertible bond valuation model combined expected cash outflows with market-based assumptions regarding risk-adjusted yields, stock price volatility and recent price quotes and trading information regarding Company issued debt instruments and shares of common stock into which the notes are convertible.

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 quarterly purchases on 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 was considered minimal and was 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

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

operations. The Company entered into foreign exchange hedging contracts with notional amounts totaling $25.5 million and zero at December 31, 2010 and 2011, respectively. The Company recorded an unrealized loss on the foreign exchange hedging contracts of $0.2 million at December 31, 2010. The Company recorded a realized loss of $1.6 million and a realized gain of $1.3 million for the years ended December 31, 2010 and 2011, respectively, on the execution of quarterly foreign exchange hedging contracts. The Company terminated these contracts during the quarter ended March 31, 2011.

The estimated fair values in connection with the February 2012 The Mann Group Common Stock Purchase Agreement (The February 2012 Forward Purchase Contract) and the October 2012 The Mann Group Common Stock and Warrant Purchase Agreement (The October 2012 Forward Purchase Contract) was based on forward purchase contract valuations (Level 3 in the fair value hierarchy). See Note 10 Common and preferred stock for further discussion.

The following roll-forward provides a summary of the changes in fair value of the Company s Level 3 forward purchase contracts during the year ended December 31, 2012 (in thousands) :

	The February 2012 Forward Purchase Contract	The October 2012 Forward Purchase Contract	Total
Beginning Balance	$	$	$
Issuance	1,080	28,237	29,317
Adjustments to fair value included in other income (expense)	12,011	(13,248)	(1,237)
Transfers to additional paid-in-capital	(13,091)	(14,989)	(28,080)
Ending Balance	$	$	$

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 Offerings 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.

Included in the common stock outstanding as of December 31, 2010, 2011 and 2012 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 $100.0 million aggregate principal amount of 2015 notes (see Note 7). 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.

87

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 was below $6.50 per share, then that closing did not occur and the aggregate number of shares to be purchased was reduced by 700,000 shares. The purchase price per share at each closing was equal to 92% of that 10-day volume weighted average price. During the years ended December 31, 2010 and 2011, the Company issued and sold a total of 2,100,000 and 1,400,000 shares of common stock, respectively, to Seaside for net proceeds of $14.1 million and $9.7 million, respectively, in accordance with the agreement. The agreement with Seaside terminated during the quarter ended September 30, 2011. During the agreement, the Company issued and sold a total of 3,500,000 shares of common stock to Seaside for net proceeds of $23.8 million. 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 was required to issue and sell, and The Mann Group was 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 purchased on each closing date under its agreement with the Company (see Note 6). Concurrently with the Seaside closing, the Company issued and sold 2,100,000 and 1,400,000 shares to The Mann Group as of December 31, 2010 and 2011, respectively, for a total purchase price of $16.7 million and $11.1 million, respectively, which was paid by the cancellation of outstanding principal under the Company s loan agreement with The Mann Group. The agreement with The Mann Group terminated during the quarter ended September 30, 2011. During the agreement, the Company issued and sold a total of 3,500,000 shares of common stock to The Mann Group that had resulted in total reduction in the note payable to related party of $27.8 million.

On February 8, 2012, the Company sold 35,937,500 units in an underwritten public offering, including 4,687,500 units sold pursuant to the full exercise of an over-allotment option granted to the underwriters, with each unit consisting of one share of common stock and a warrant to purchase 0.6 of a share of common stock. All of the securities were offered by the Company at a combined price to the public of $2.40 per unit and the underwriters purchased the units at a price of $2.256 per unit. Net proceeds from this offering were approximately $80.6 million, excluding any warrant exercises. The 21,562,500 shares of common stock underlying the warrants are exercisable at $2.40 per share and expire four years from the date of the issuance. The shares of common stock and warrants are immediately separable and were issued separately. Concurrent with the February 2012 underwritten public offering, the Company entered into a common stock purchase agreement with The Mann Group, pursuant to which the Company agreed to sell and The Mann Group agreed to purchase 31,250,000 shares of the Company s restricted common stock at a price of $2.47 per share, the closing of which was subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (HSR Clearance), and the Company s receipt of stockholder approval to increase the authorized number of shares of our common stock. In June 2012, following HSR Clearance and the Company s receipt of such stockholder approval, The Mann Group purchased $77.2 million worth of restricted shares of common stock which were paid through the cancellation of principal indebtedness under the revolving amended loan arrangement with The Mann Group (see Note 6 Related-party arrangements).

The Company concluded that The Mann Group common stock purchase agreement represented a contingent forward purchase contract that met the definition of a derivative instrument in accordance with ASC 815 *Derivatives and Hedging (ASC 815).* Of the 31,250,000 shares issuable pursuant to the common stock purchase agreement, the portion of the derivative instrument representing 14.7 million shares were recorded as equity (Equity Portion) as they met the criteria for equity classification under ASC 815-40 *Derivatives and*

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Hedging, Contracts in an Entity s Own Stock. The remaining 16.5 million shares (Non-Equity Portion) required classification outside of equity as the Company did not have sufficient available shares at the time of issuance. The Company revalued the Non-Equity Portion of the forward purchase contract at each reporting date and recorded a fair value adjustment within Other income (expense) . At the time of issuance, the fair value of the forward purchase contract was $2.0 million. The Equity Portion of $0.9 million was classified as equity, and the Non-Equity Portion of $1.1 million was initially recorded to Prepaid expenses and other current assets.

On May 17, 2012, the Company s stockholders approved an increase in its authorized shares of common stock from 250,000,000 to 350,000,000. Accordingly, the shares of common stock needed to consummate The Mann Group common stock purchase agreement dated February 2, 2012 became available. As of May 17, 2012, the fair value of the Non-Equity Portion was $13.1 million. As of result of receiving stockholder approval of the increase in authorized shares, the Non-Equity Portion met the criteria for equity classification. Consequently, the Company reclassified the $13.1 million from Prepaid expenses and other current assets to Additional paid-in capital.

The fair value of the forward purchase contract is highly sensitive to the discount applied for lack of marketability and the stock price, and changes in this discount and/or the stock price caused the value of the forward purchase contract to change significantly. As of and for the year ended December 31, 2012, the Company recognized the change in fair value of $12.0 million in Other income (expense). The Company revalued the Non-Equity Portion using a forward contract valuation formula, in which the forward contract was estimated to be equal to the valuation date stock price of $2.40 at issuance and $1.69 at May 17, 2012 minus the strike price discounted to the valuation date using a risk-free rate of 0.08% at issuance and 0.18% at May 17, 2012. As the shares which would be received upon settlement were unregistered, the Company applied a discount for lack of marketability of 2.57% at issuance and 0.42% at May 17, 2012 based on quantitative put models, adjusted to take into account qualitative factors, including the fact that the Company s stock was publicly traded and the fact that there was no contractual restriction on the unregistered shares being registered.

In October 2012, pursuant to a previously filed Shelf Registration, which was declared effective by the SEC on September 24, 2012, the Company sold in an underwritten public offering 40,000,000 shares of its common stock, together with warrants to purchase up to 30,000,000 shares of the Company s common stock. In addition, the Company sold pursuant to the full exercise of an over-allotment option granted to the underwriters, an additional 6,000,000 shares of common stock , together with warrants to purchase up to an aggregate of 4,500,000 shares of common stock. All of the securities were sold together with a warrant for a combined purchase price of $2.00 per unit. The shares of common stock and warrants are immediately separable and were issued separately. Net proceeds from this offering were approximately $86.3 million (after deducting discounts and commissions to the underwriters and offering expenses), excluding any future proceeds from the exercise of the warrants. Each warrant entitles the holder to purchase 0.75 of a share of common stock. The warrants are exercisable at $2.60 per share and will expire in October 2013. The Company performed an analysis of the warrants to determine their appropriate classification and concluded that the warrants should be classified within equity.

Concurrent with the underwritten public offering, the Company entered into a Common Stock and Warrant Purchase agreement, in which the Company was required to issue and sell and The Mann Group was obligated to purchase 40,000,000 restricted shares of the Company s common stock and 40,000,000 warrants to purchase up to an aggregate of 30,000,000 restricted shares of the Company s common stock in a separate private placement. The restricted shares were sold to The Mann Group at $2.59 per share (the consolidated closing bid price of the Company s common stock on October 17, 2012), and the warrants were sold to The Mann Group at a purchase price of $0.125 for each share of the Company s common stock underlying the warrants, in exchange for cancellation of outstanding principal under the $350 million amended and restated promissory note with The

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Mann Group. The restricted shares and warrants were sold to The Mann Group for an aggregate purchase price of $107.4 million. Following receipt of stockholder approval, in December 2012, to increase the Company s authorized shares of common stock from 350,000,000 to 550,000,000, the Common Stock and Warrant Purchase agreement was consummated, and the shares of common stock and warrants were issued to The Mann Group.

On the date the Common Stock and Warrant Purchase agreement was entered into with The Mann Group, the Company did not have a sufficient number of authorized, unissued and available common shares to satisfy their commitments under this agreement. The Company characterized the Common Stock and Warrant Purchase agreement as a forward contract, in accordance with ASC 815-40, to deliver a single unit comprising 40,000,000 shares of restricted common stock and 40,000,000 warrants to purchase 30,000,000 shares of restricted common stock that should be classified as assets or liabilities accounted for at fair value.

At the time of issuance, the Company determined the fair value of the forward contract to be $28.2 million and recorded a current asset. On December 20, 2012, the date at which a sufficient number of authorized and unissued common shares became available following approval by the stockholders to increase its authorized shares of common stock, the Company re-valued the forward contract and recorded a fair value adjustment to Other income (expense) of $13.2 million expense. Therefore, having met the criteria for equity classification, the Company reclassified the remaining balance of the forward contract of $15.0 million to additional paid in capital. In addition, the Company performed an analysis of the warrants to determine their appropriate classification once the forward contract settled and concluded that the warrants should be classified within equity.

The fair value of the forward purchase contract is highly sensitive to the discount applied for lack of marketability and the stock price, and changes in this discount and/or the stock price caused the value of the Forward Contract to change significantly. The value of the derivative instrument was calculated using a forward contract valuation formula in which the forward contract is estimated to be equal to the valuation date stock price minus the strike price discounted to the valuation date using a risk-free rate of 0.11% at issuance on October 18, 2012 and 0.00% at closing on December 20, 2012. As the shares which would be received upon settlement are currently unregistered, the Company applied a discount for lack of marketability of 2.3% at October 18, 2012 and 1.5% at December 20, 2012 to reflect this lack of marketability based on quantitative put models, adjusted to take into account qualitative factors, including the fact that the Company s stock is publicly traded and the fact that there is no contractual restriction on the unregistered shares being registered.

The Company then determined that upon the settlement of the forward contracts, the common stock and warrants represent freestanding financial instruments and should be initially recorded at their relative fair values based on the total consideration received. The total consideration received equaled the $107.4 million principal amount of indebtedness cancelled less the recorded value of the forward contracts on December 20, 2012, the date immediately before settlement.

The Company is authorized to issue 550,000,000 shares of common stock, par value $0.01 per share, and 10,000,000 shares of undesignated preferred stock, par value $0.01 per share, issuable in one or more series designated by the Company s board of directors. No other class of capital stock is authorized. As of December 31, 2011 and 2012, 131,522,945 and 286,035,082 shares of common stock, respectively, were issued and outstanding and no shares of preferred stock were 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,

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2011 and 2012, 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 30,858,590 shares, 34,048,852 and 128,324,123 shares of the Company s common stock as of December 31 2010, 2011 and 2012, respectively, and exclude the 9,000,000 shares of the Company s common stock loaned under the share lending arrangement as of December 31, 2011 and 2012.

Potentially dilutive securities outstanding are summarized as follows:

	December 31,		
	2010	2011	2012
Exercise of common stock options	7,760,833	10,082,351	18,674,539
Conversion of senior convertible notes into common stock	19,826,113	19,826,113	19,826,113
Exercise of common stock warrants			86,062,440
Vesting of restricted stock units	3,271,644	4,140,388	3,761,031
	30,858,590	34,048,852	128,324,123

12. Stock award plans

As of December 31, 2012, 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. The following table summarizes information about the Company s stock-based award plans as of December 31, 2012:

	Outstanding Options	Outstanding Restricted Stock Units	Shares Available for Future Issuance
2004 Equity Incentive Plan	17,983,708	3,761,031	6,521,347
2004 Non-Employee Directors Stock Option Plan	690,831		109,169
Total	18,674,539	3,761,031	6,630,516

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 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. Performance-based awards

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

vest upon achieving pre-determined performance milestones which are expected to occur over periods ranging from 13 months to 96 months from the date of grant. All but one of the milestones is considered probable as of December 31, 2012. 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 May 17, 2012, the Compensation Committee also approved a management proposal designed to encourage employee retention. The proposal involved the grant of stock options and restricted stock units to employees, including executive officers of the Company. 3,942,500 options were granted with vesting terms subject to MannKind Corporation s achievement of specified regulatory and business development milestones related to AFREZZA. 3,892,500 options were granted with time-based vesting terms of 25% every 6 months beginning November 1, 2012, to be fully vested on May 1, 2014. The performance-based options and time-based stock options had a grant date fair value of $0.60 and $1.12, respectively and stock compensation expense associated with these grants will be approximately $6.7 million over the award period.

On March 3, 2011, the Compensation Committee approved a management proposal designed to encourage employee retention. The proposal involved the issuance of restricted stock units and stock options to the majority of employees and executive officers of the Company. A total of 1,177,300 restricted stock units and 1,467,500 stock options were granted under the Plan. These units vest 50% annually for two years and will be fully vested on March 3, 2013. Stock compensation expense associated with these grants will be recorded on a straight line basis from March 3, 2011 through March 3, 2013 and will be approximately $8.2 million over the award period.

On May 21, 2009, June 2, 2011, and May 17, 2012 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, 6,000,000, and 10,000,000 shares, respectively.

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, 2010, 2011 and 2012 the ESPP share reserve was increased by 700,000, 700,000 and 700,000 shares, respectively. As of December 31, 2012, 2,674,003 shares were available for issuance under the ESPP. For the years ended December 31, 2010, 2011 and 2012 the Company sold 287,597, 282,816 and 422,260 shares, respectively, of its common stock to employees participating in the ESPP. The ESPP purchase for the period ending December 31, 2012 was initiated prior to year end but did not settle until January 3, 2013. As a result, the shares sold are reflected in the ESPP share reserves but is excluded from common stock outstanding as of December 31, 2012.

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, which is determined using the Black-Scholes option valuation model and amortizes such expense on a straight-line basis over the service period for time-based awards and over the expected dates of achievement for performance-based awards. These awards are subject to re-measurement until service is complete. As of December 31, 2012, there were options to purchase 243,033 shares of common stock outstanding to consultants.

During the years ended December 31, 2010, 2011 and 2012 the Company recorded stock-based compensation expense related to its stock award plans and the ESPP of $13.6 million, $11.2 million, and $13.3 million, respectively.

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

	Year Ended December 31,		
	2010	2011	2012
Employee-related	$ 13,478	$ 11,202	$ 13,224
Consultant-related	102	2	68
Total	$ 13,580	$ 11,204	$ 13,292

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

	Year Ended December 31,		
	2010	2011	2012
Research and development	$ 7,926	$ 5,366	$ 6,167
General and administrative	5,654	5,838	7,125
Total	$ 13,580	$ 11,204	$ 13,292

The Company uses the Black-Scholes option valuation model to estimate the grant date fair value of employee stock options. The expected term of an option granted is based on combining historical exercise data with expected weighted time outstanding. Expected weighted time outstanding is calculated by assuming the settlement of outstanding awards is at the midpoint between the remaining weighted average vesting date and the expiration date.

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 granted during the years ended December 31, 2010, 2011 and 2012 using the following assumptions:

	Year Ended December 31,

	2010		2011		2012	
Risk-free interest rate	0.74%	3.14%	0.10%	2.43%	0.32%	1.16%
Expected lives	2.6	6.1 years	1.1	6.1 years	1.4	6.1 years
Volatility	78%	102%	76%	83%	70%	84%
Dividends						

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table summarizes information about stock options outstanding:

	Number of Shares	Weighted Average Exercise Price per Share	Aggregate Intrinsic Value ($000)
Outstanding at January 1, 2012	10,082,351	5.67	$ 168
Granted	9,795,600	1.81	
Exercised	(3,216)	2.86	
Forfeit	(715,131)	3.96	
Expired	(485,065)	15.17	
Outstanding at December 31, 2012	18,674,539	3.46	$ 4,867
Vested and expected to vest at December 31, 2012	17,546,663	3.53	$ 4,867
Exercisable at December 31, 2012	7,199,768	5.26	$ 602

The weighted average grant date fair value of the stock options granted during the years ended December 31, 2010, 2011 and 2012 was $4.06, $2.04, and $0.99 per option, respectively. The total intrinsic value of options exercised during the years ended December 31, 2010, 2011 and 2012 was $1.6 million, $443,000, and $1,000, 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.

Cash received from the exercise of options during the years ended December 31, 2010, 2011 and 2012 was approximately $924,000, $625,000, and $9,200, respectively. The weighted-average remaining contractual terms for options outstanding, vested and expected to vest, and exercisable at December 31, 2012 was 8.1 years, 8.0 years and 6.5 years, respectively.

A summary of restricted stock unit activity for the year ended December 31, 2012 is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value per Share
Outstanding at January 1, 2012	4,137,688	$ 4.47
Granted	1,371,455	$ 2.25
Vested	(1,277,572)	$ 4.25
Forfeited	(470,540)	$ 4.49
Outstanding at December 31, 2012	3,761,031	$ 3.73

The total restricted stock units expected to vest as of December 31, 2012 was 3,254,819 with a weighted average grant date fair value of $3.74. The total intrinsic value of restricted stock units expected to vest as of December 31, 2012 was $7.5 million. Intrinsic value of restricted stock units expected to vest is measured using the closing share price at December 31, 2012.

Total intrinsic value of restricted stock units vested during the years ended December 31, 2010, 2011 and 2012 was $10.5 million, $1.7 million, and $2.9 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 fair value of restricted stock units vested during the years ended December 31, 2010, 2011 and 2012 was $11.4 million, $1.6 million, and $3.0 million, respectively.

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

As of December 31, 2012, there was $12.2 million and $7.8 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 2.3 years. The Company evaluates stock awards with performance conditions as to the probability that the performance conditions will be met and estimates the date at which the performance conditions will be met in order to properly recognize stock-based compensation expense over the requisite service period. As of December 31, 2012, there was $107,000 and $3.7 million of unrecognized expenses related to performance-based options and restricted stock units, respectively, for milestones not considered probable of achievement.

13. Commitments and contingencies

Operating Leases The Company leases certain facilities and equipment under various operating leases, which expire at various dates through 2013. As of December 31, 2012, future minimum rental payments required under operating leases consist of $21,000 for the year ending December 31, 2013.

Rent expense under all operating leases for the years ended December 31, 2010, 2011 and 2012 was approximately $1.2 million, $766,000 and $675,000, respectively.

Capital Leases The Company s capital leases were not material for the years ended December 31, 2010, 2011 and 2012.

Supply Agreement In November 2007, the Company entered into a long-term supply agreement (the Supply Agreement) with N.V. Organon (Organon), now a subsidiary of Merck & Co., Inc., pursuant to which Organon manufactured and supplied specified quantities of recombinant human insulin to the Company. In June 2011, the Company entered into a letter agreement (the Letter Agreement) with Organon to settle a dispute that arose between the Company and Organon in connection with the termination by the Company of the Supply Agreement. Under the terms of the Letter Agreement, the Company paid Organon an aggregate of $16.0 million in two installments, each of which was paid after the Company received certain quantities of recombinant human insulin manufactured and supplied by Organon. The Letter Agreement is in full and final settlement of, and the Company and Organon agreed to release each other from, any and all actions and claims that the Company and Organon had or may have against each other in connection with the dispute regarding the Supply Agreement and related matters. The Company has concluded that the Letter Agreement represents a multiple element arrangement consisting of two elements representing the purchase of insulin and a contract cancellation fee. The Company has allocated the $16.0 million settlement in the following manner: first to the fair value of the insulin received, which was recorded as expense of $8.4 million and the remaining $7.6 million to the contract cancellation fee. These charges were recorded to Research and development operating expenses in the consolidated statements of operations.

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.

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Litigation The Company is subject to legal proceedings and claims which arise in the ordinary course of its business. As of the date hereof, the Company believes that the final disposition of such matters will not have a material adverse effect on the financial position, results of operations or cash flows of the Company. The Company maintains liability insurance coverage to protect the Company s assets from losses arising out of or involving activities associated with ongoing and normal business operations. In accordance with ASC 450 *Contingencies*, the Company records 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. The Company s policy is to accrue for legal expenses in connection with legal proceeding and claims as they are incurred.

The Securities Action. Beginning January 31, 2011, several complaints were filed in the U.S. District Court for the Central District of California against us and four of our officers Alfred E. Mann, Hakan S. Edstrom, Dr. Peter C. Richardson (a former officer) and Matthew J. Pfeffer on behalf of certain purchasers of our common stock. The complaints include claims asserted under Sections 10(b) and 20(a) of the Exchange Act and were brought as purported shareholder class actions. In general, the complaints alleged that the defendants violated federal securities laws by making materially false and misleading statements regarding our business and prospects for AFREZZA, thereby artificially inflating the price of the Company s common stock. The U.S. District Court for the Central District of California consolidated the pending actions for all purposes. The consolidated action is referred to as the Securities Action.

On July 23, 2012, the Company, while continuing to deny all allegations of wrongdoing or liability whatsoever arising out of the Securities Action, and without in any way admitting fault or liability, entered into a stipulation of settlement to resolve the Securities Action. The current and former officers and directors named as individual defendants in the consolidated lawsuits also entered into the stipulation of settlement.

In exchange for a release of all claims by the class members, among others, and a dismissal of the consolidated lawsuits, the Company agreed (i) to cause the Company s insurers to pay class members and their attorneys a total of $16.0 million; and (ii) to issue to class members and their attorneys 2,777,778 shares of the Company s common stock. The Company also agreed that if the consolidated closing bid price for the Company s common stock is below $1.00 per share on the date the U.S. District Court enters an order of final judgment, then the Company will issue into the Escrow Account an additional 1,000,000 shares of its common stock. On September 12, 2012, the U.S. District Court preliminarily approved the settlement.

On December 21, 2012, the U.S. District Court issued the Order and Final Judgment, providing final approval of the settlement for the securities action. The Order and Final Judgment consisted of requiring the Company to cause its insurers to pay $16.0 million and to issue the 2,777,778 shares of its common stock in accordance with the stipulation of settlement. The Order and Final Judgment did not include the requirement of the Company to issue the additional 1,000,000 shares of its common stock. In late September and in early October, following the preliminary approval of the settlement, the Company s insurers remitted payment of the $16.0 million into the Escrow Account. On December 31, 2012, following final approval of the settlement, the Company initiated the transfer of the 2,777,778 shares of its common stock into the Escrow Account. The stock transfer settled on January 2, 2013. The shares were issued pursuant to an exemption from registration provided by Section 3(a)(10) of the Securities Act of 1933, as amended. As of December 31, 2012, the Securities Action was concluded.

The Derivative Actions. Beginning in February 2011, several shareholder derivative complaints were filed in the Superior Court of California for the County of Los Angeles and in the U.S. District Court for the Central District of California against all of the Company s directors and certain of its officers. The complaints in the shareholder derivative actions allege breaches of fiduciary duties by the defendants and other violations of law. In general, the complaints allege that the defendants caused or allowed for the dissemination of materially false and misleading statements regarding its business and prospects for AFREZZA, thereby artificially inflating the price of its common stock. The Superior Court of California for the County of Los Angeles consolidated the

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

actions pending before it. The consolidated state derivative actions are referred to as the State Derivative Action. The U.S. District Court for the Central District of California has also consolidated the derivative actions pending before it. The consolidated federal derivative actions are referred to as the Federal Derivative Action. The State Derivative Action and the Federal Derivative Action are collectively referred to as the Derivative Actions.

On August 3, 2012, the Company, while continuing to deny all allegations of wrongdoing or liability whatsoever arising out of the Derivative Actions and without in any way admitting fault or liability, entered into a stipulation of settlement to resolve the Derivative Action. Subject to preliminary and final approval of the settlement by the U.S. District Court and notice to shareholders, and in an exchange for a release of all claims by the plaintiffs, among others, and a dismissal of the Derivative Actions, the Company agreed (i) to adopt certain corporate governance measures, (ii) to cause the Company s insurers to pay the plaintiffs attorneys a total of $800,000, and (iii) to issue plaintiffs attorneys 225,000 shares of the Company s common stock. On September 12, 2012, the U.S. District Court preliminarily approved the settlement.

On November 19, 2012, the U.S. District Court issued the Order and Final Judgment, providing final approval of the settlement for the derivative action. The Order and Final Judgment consisted of requiring the Company to cause its insurers to pay $800,000 and to issue the 225,000 shares of its common stock in accordance with the stipulation of settlement. In late September and in early October, following the preliminary approval of the settlement, the Company s insurers remitted payment of the $800,000 into an account established by the plaintiffs attorneys. In December 2012, following final approval of the settlement, the Company transferred the 225,000 shares of its common stock into an investment brokerage account established by the plaintiffs attorneys. The shares were issued pursuant to an exemption from registration provided by Section 3(a)(10) of the Securities Act of 1933, as amended. As of December 31, 2012, the Derivative Actions were concluded.

As a result of settlement discussions with the plaintiffs taking place in the latter part of the quarter ended June 30, 2012 and entering into the stipulation of settlement for the Securities Action on July 23, 2012 and for the Derivative Action on August 3, 2012, the Company determined that the liabilities pertaining to both the securities and derivative lawsuits were probable as of June 30, 2012. The Company s financial statements as of and for the three months ended June 30, 2012 reflect the following accruals:

(i) *Cash consideration*. The Company recorded a current liability of $16.8 million under Accrued expense and other current liabilities and a corresponding current asset under Prepaid expenses and other current asset to reflect a receivable from the Company s insurers. The Company has determined that the collectability of the receivable from the insurers is probable. The cash obligation resulted in no charge to the Company s Condensed Consolidated Statements of Operations for the period.

(ii) *Stock consideration*. The Company recorded a charge to General and administrative expenses and an estimated current liability under Accrued expense and other current liabilities of $7.7 million representing the estimated fair value of the 3,002,778 common shares to be issued in the aggregate subject to court approval.

(iii) *Additional stock consideration*. The Company concluded that the contingent obligation to issue an additional 1,000,000 shares of its common stock, as defined in the stipulation of settlement agreement for the Securities Action, met the definition of a derivative instrument in accordance with ASC 815 *Derivatives and Hedging*. The Company estimated the fair value of the derivative instrument using the Monte Carlo simulation model to forecast the contingent obligation applying probabilities that the stock price will be lower than $1.00 based on the following assumptions: expected volatility of 60%, risk free interest rate of 0.16% and final judgment dates ranging from four to six months. As a result, the Company estimated the fair value of this contingent obligation to be immaterial.

97

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

As of September 30, 2012, the Company estimated the aggregate fair value of the stock consideration at $8.6 million and recognized an increase in the contingent liability of $901,000 during the quarter ended September 30, 2012. During the quarter ended September 30, 2012, the Company remeasured the additional stock consideration using the Monte Carlo simulation model to forecast the contingent obligation applying probabilities that the stock price will be lower than $1.00 based on the following assumptions: expected volatility of 54%, risk free interest rate of 0.1% and final judgment date on or before December 31, 2012. As a result, the Company estimated the fair value of this contingent obligation related to the additional stock consideration to be immaterial.

The Company considered the following in its financial statements as of and for the year ended December 31, 2012:

(i) *Cash consideration*. Upon satisfying the conditions of cash payment during the fourth quarter of 2012 and receiving final approvals of settlement, the Company relieved from its balance sheet the $16.8 million of current liability and current receivable from insurers as of December 31, 2012.

(ii) *Stock consideration*. As of December 31, 2012, the Company satisfied the conditions of issuing 225,000 shares of its common stock on the Derivative Action. With respect to the Securities Action, the issuance of 2,777,778 shares was initiated prior to year end and subsequently settled after year end. The Company concluded that the requirement to deliver these shares of common stock met the definition of a financial instrument representing a contingent forward contract in accordance with ASC 815 *Derivatives and Hedging* and that the forward contract met the criteria for equity classification, and further remeasurement through settlement was not required. The forward contract to issue shares settled on January 2, 2013, upon consummation of the delivery of these shares. The final fair values of the stock consideration are summarized in the following table:

	Number of Shares	Closing Price Per Share on Final Approval Date	Final Fair Value of Stock Consideration
Derivative Action	225,000	$ 1.94	$ 436,500
Securities Action	2,777,778	$ 2.18	6,055,556
Total	3,002,778		$ 6,492,056

In recognizing the fair value of the total stock consideration to equity on the date of final approval of the respective settlements, the Company released the previously recorded litigation accrual of $8.6 million, recognized the fair value of the total stock consideration of $6.5 million to equity, and recorded an adjustment to decrease legal expense by $2.1 million in the fourth quarter of 2012.

14. 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, 2010, 2011 and 2012, the Company contributed $752,000, $777,000 and $571,000 respectively, to the MannKind Retirement Plan.

98

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15. 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, 2011 and 2012 are approximately as follows (in thousands):

	December 31,	
	2011	2012
Deferred tax assets:		
Net operating loss carryforwards	$ 557,427	$ 609,471
Research and development credits	59,848	65,315
Capitalized research	32,440	31,490
Accrued expenses	2,827	2,922
Non-qualified stock option expense	27,964	30,928
Depreciation	8,906	10,025
Total net deferred tax assets	689,412	750,151
Valuation allowance	(689,412)	(750,151)
Net deferred tax assets	$	$

The Company s net deferred tax assets as of December 31, 2011, consist of $718.2 million of gross deferred tax assets and $28.8 million of gross deferred tax liabilities. The Company s net deferred tax assets as of December 31, 2012, consist of $784.6 million of gross deferred tax assets and $34.4 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, 2010, 2011 and 2012:

	December 31,		
	2010	2011	2012
Federal tax benefit rate	35.0%	35.0%	35.0%
State tax benefit, net of federal benefit			
Permanent items			
Intercompany transfer of intellectual property	(5.0)	(5.0)	(4.0)
Valuation allowance	(30.0)	(30.0)	(31.0)
Effective income tax rate	0.0%	0.0%	0.0%

As required by ASC 740 *Income Taxes* (ASC 740), 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 due to net losses since inception. 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, 2010, 2011 and 2012, the change in the valuation allowance was $56.5 million, $57.2 million and $60.7 million, respectively, for income taxes.

At December 31, 2012, the Company had federal and state net operating loss carryforwards of approximately $1.6 billion and $1.1 billion available, respectively, to reduce future taxable income and which will expire at various dates beginning in 2013 and 2014, 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

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 2012, the Company had research and development credits of $77.4 million that expire at various dates through 2033.

The Company has evaluated the impact of ASC 740 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 liabilities for uncertain income tax positions have been recorded. Tax years since 1993 remain subject to examination by the major tax jurisdictions in which the Company is subject to tax.

16. 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)			
2011				
Net loss	$ (41,525)	$ (44,480)	$ (38,402)	$ (36,397)
Net loss applicable to common stockholders	$ (41,525)	$ (44,480)	$ (38,402)	$ (36,397)
Net loss per share applicable to common stockholders basic and diluted	$ (0.34)	$ (0.37)	$ (0.31)	$ (0.30)
Weighted average common shares used to compute basic and diluted net loss per share applicable to common stockholders	121,057	121,708	122,130	122,357

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	March 31	June 30	September 30	December 31
	(In thousands, except per share data)			
2012				
Net loss	$ (38,173)	$ (36,578)	$ (42,834)	$ (51,781)
Net loss applicable to common stockholders	$ (38,173)	$ (36,578)	$ (42,834)	$ (51,781)
Net loss per share applicable to common stockholders basic and diluted	$ (0.27)	$ (0.23)	$ (0.22)	$ (0.23)
Weighted average common shares used to compute basic and diluted net loss per share applicable to common stockholders	143,154	159,859	190,534	229,234

17. Subsequent Event

On March 18, 2013, the Company entered into at-the-market issuance sales agreements (the ATM Agreements) with two sales agents, under which the Company may issue and sell shares of its common stock having an aggregate offering price of up to $50.0 million under each ATM Agreement (provided that in no event may the Company issue and sell more than $50.0 million of shares of its common stock under both ATM Agreements in the aggregate) from time to time through either of the sales agents. Neither the Company nor either of the sales agents has any obligation to sell shares of the Company s common stock under the ATM Agreements. Any sales of common stock made under the ATM Agreements will be made in at the market offerings as defined in Rule 415 of the Securities Act of 1933, as amended.