

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**Form 10-K**

**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**

*(State or other jurisdiction of incorporation or organization)*

**28903 North Avenue Paine**

**Valencia, California**

*(Address of principal executive offices)*

**13-3607736**

*(I.R.S. Employer Identification No.)*

**91355**

*(Zip Code)*

**Registrant's telephone number, including area code**

**(661) 775-5300**

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

<u>Title of Class</u>	<u>Name of Each Exchange on Which Registered</u>
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

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

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  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  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  Non-accelerated filer  Smaller reporting company

*(Do not check if a 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

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.

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## Forward-Looking Statements

Statements in this report that are not strictly historical in nature are forward-looking statements. These statements include, but are not limited to, statements about: the progress or success of our research, development and clinical programs, including the application for and receipt of regulatory clearances and approvals, and the timing or success of the commercialization of AFREZZA, if approved, or any other products or therapies that we may develop; our ability to market, commercialize and achieve market acceptance for AFREZZA, or any other products or therapies that we may develop; our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; our estimates for future performance; our estimates regarding anticipated operating losses, future revenues, capital requirements and our needs for additional financing; and scientific studies and the conclusions we draw from them. In some cases, you can identify forward-looking statements by terms such as “anticipates,” “believes,” “could,” “estimates,” “expects,” “goal,” “intends,” “may,” “plans,” “potential,” “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,

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such as insulin, can be loaded onto these particles by combining an acidic solution of the drug with a suspension of Technosphere material, which is then dried to 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 FEV<sub>1</sub>, 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.

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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.

## **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.

## **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.

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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

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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.

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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 pioglitazone, 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.

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- 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.

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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

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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,

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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.

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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):

<u>Name</u>	<u>Primary Affiliation</u>
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

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### EXECUTIVE OFFICERS OF THE REGISTRANT

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

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>
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

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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

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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.

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### ***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

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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)

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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.

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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.

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***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

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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;

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- 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.

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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.

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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

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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

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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

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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;

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- 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.

***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,

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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

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

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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

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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;

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- 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.

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### ***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.

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### **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

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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.

**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.

	<u>High</u>	<u>Low</u>
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

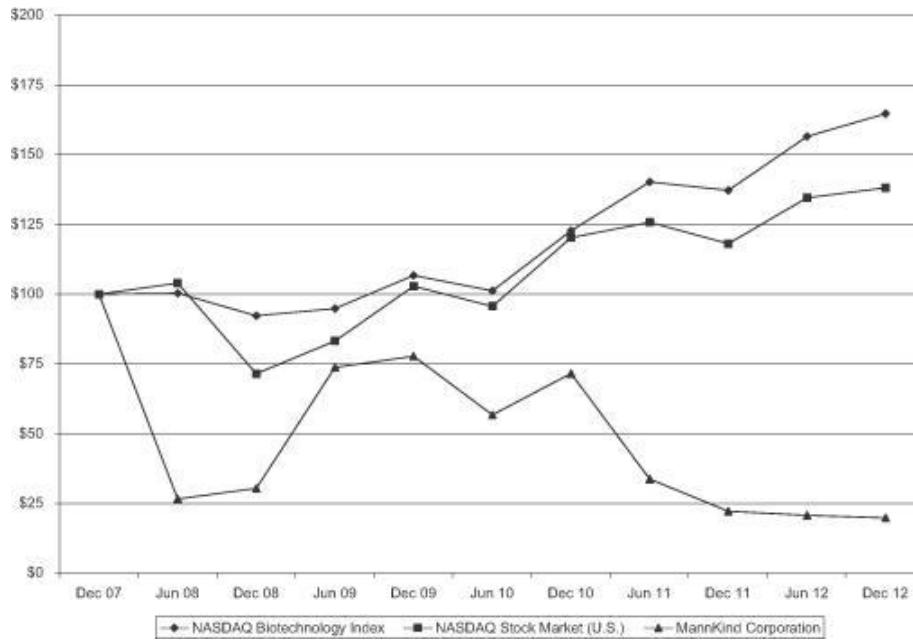
The closing sales price of our common stock on the NASDAQ Global Market was \$3.56 on March 13, 2013 and there were 192 registered holders of record as of that date.

**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.*

**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.

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### Item 6. Selected Financial Data

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

Statement of Operations Data:	Year Ended December 31,				
	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,		
			(In thousands)		
Balance Sheet Data:	2008	2009	2010	2011	2012
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.

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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

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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.

### **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.

**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,		\$ Change	% Change
	2011	2012		
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,		\$ Change	% Change
	2011	2012		
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%

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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,		\$ Change	% Change
	2010	2011		
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

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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,		\$ Change	% Change
	2010	2011		
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

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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.

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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.

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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):

<u>Contractual Obligations</u>	<u>Payments Due in</u>				<u>Total</u>
	<u>Less Than One Year</u>	<u>1-3 Years</u>	<u>3- 5 Years</u>	<u>More Than 5 Years</u>	
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
<b>Total contractual obligations</b>	<b>\$ 159,634</b>	<b>\$ 236,406</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 396,040</b>

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

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- (2) The senior convertible notes obligations include the 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

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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.

## 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

**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.

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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](http://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:

<a href="#">Report of Independent Registered Public Accounting Firm</a>	62
<a href="#">Consolidated Balance Sheets</a>	63
<a href="#">Consolidated Statements of Operations</a>	64
<a href="#">Consolidated Statements of Comprehensive Loss</a>	65
<a href="#">Consolidated Statements of Stockholders' Equity (Deficit)</a>	66
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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: 56

**Exhibit Index**

<b><u>Exhibit Number</u></b>	<b><u>Description of Document</u></b>
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.

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<u>Exhibit Number</u>	<u>Description of Document</u>
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.

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<u>Exhibit Number</u>	<u>Description of Document</u>
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.

## 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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Alfred E. Mann</u> Alfred E. Mann	Chief Executive Officer and Chairman of the Board of Directors <i>(Principal Executive Officer)</i>	March 18, 2013
<u>/s/ Hakan S. Edstrom</u> Hakan S. Edstrom	President, Chief Operating Officer and Director	March 18, 2013
<u>/s/ Matthew J. Pfeffer</u> Matthew J. Pfeffer	Corporate Vice President and Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>	March 18, 2013
<u>/s/ Ronald J. Consiglio</u> Ronald J. Consiglio	Director	March 18, 2013
<u>/s/ Michael Friedman</u> Michael Friedman, M.D.	Director	March 18, 2013
<u>/s/ Kent Kresa</u> Kent Kresa	Director	March 18, 2013
<u>/s/ David H. MacCallum</u> David H. MacCallum	Director	March 18, 2013
<u>/s/ Henry L. Nordhoff</u> Henry L. Nordhoff	Director	March 18, 2013

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**MANKIND CORPORATION AND SUBSIDIARIES**  
**(A Development Stage Company)**

**INDEX TO FINANCIAL STATEMENTS**

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**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of MannKind Corporation  
Valencia, California

We have audited the accompanying consolidated balance sheets of MannKind Corporation and subsidiaries (a development stage company) (the "Company") as of December 31, 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

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

	December 31,	
	2011	2012
	(In thousands, except share data)	
<b>ASSETS</b>		
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	<u>\$ 199,553</u>	<u>\$ 251,314</u>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
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	<u>513,205</u>	<u>361,993</u>
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	<u>(313,652)</u>	<u>(110,679)</u>
Total	<u>\$ 199,553</u>	<u>\$ 251,314</u>

See notes to consolidated financial statements.

**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	<u>152,591</u>	<u>140,589</u>	<u>146,995</u>	<u>2,064,431</u>
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	<u>(170,560)</u>	<u>(160,804)</u>	<u>(169,774)</u>	<u>(2,105,294)</u>
Income tax benefit	—	—	(408)	(382)
Net loss	<u>(170,560)</u>	<u>(160,804)</u>	<u>(169,366)</u>	<u>(2,104,912)</u>
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	<u><u>\$ (170,560)</u></u>	<u><u>\$ (160,804)</u></u>	<u><u>\$ (169,366)</u></u>	<u><u>\$ (2,128,124)</u></u>
Net loss per share applicable to common stockholders — basic and diluted	<u><u>\$ (1.50)</u></u>	<u><u>\$ (1.32)</u></u>	<u><u>\$ (0.94)</u></u>	
Shares used to compute basic and diluted net loss per share applicable to common stockholders	<u><u>113,672</u></u>	<u><u>121,817</u></u>	<u><u>180,855</u></u>	

See notes to consolidated financial statements.

**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	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	<u>\$(170,205)</u>	<u>\$(160,834)</u>	<u>\$(169,416)</u>	<u>\$(2,104,918)</u>

See notes to consolidated financial statements.

**MANKIND 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)
<b>BALANCE, FEBRUARY 29, 1992</b>	—	—	—	—	—	—	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)
<b>BALANCE, FEBRUARY 28, 1993</b>	—	—	—	—	—	—	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)
<b>BALANCE, FEBRUARY 28, 1994</b>	—	—	—	—	—	—	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)
<b>BALANCE, DECEMBER 31, 1994</b>	—	—	—	—	—	—	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)
<b>BALANCE, DECEMBER 31, 1995</b>	—	—	—	—	—	—	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)
<b>BALANCE, DECEMBER 31, 1996</b>	—	—	—	—	—	—	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)
<b>BALANCE, DECEMBER 31, 1997</b>	—	—	—	—	—	—	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)
<b>BALANCE, DECEMBER 31, 1998</b>	—	—	—	—	—	—	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)
<b>BALANCE, DECEMBER 31, 1999</b>	—	—	—	—	—	—	4,496	46	21,129	—	—	—	(21,921)	(746)

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**MANKIND 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	—	—	—			—	—						
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)
<b>BALANCE, DECEMBER 31, 2000</b>	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)
<b>BALANCE, DECEMBER 31, 2001</b>	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	—	—	—	—	—	—	—	—	(1,421)	—	—	—	—	(1,421)

conversion feature of Series B convertible preferred stock															
Accretion to redemption value on Series A redeemable convertible preferred stock	—	—	—	—	—	—	—	—	(251)	—	—	—	—	(251)	
Stock-based compensation	—	—	—	—	—	—	—	—	268	—	—	—	—	268	
Put option redemption by stockholder	—	—	—	—	—	—	—	—	1,921	—	—	—	—	1,921	
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(206,265)	(206,265)	
<b>BALANCE, DECEMBER 31, 2002</b>	<b>193</b>	<b>15,000</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>16,464</b>	<b>165</b>	<b>378,010</b>	<b>(1,310)</b>	<b>—</b>	<b>—</b>	<b>(301,092)</b>	<b>90,773</b>	

**MANKIND 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 beneficial conversion feature of Series B convertible preferred stock	—	—	—	—	—	—	—	—	(1,017)	—	—	—	—	(1,017)
Accretion to redemption value on Series A redeemable convertible preferred stock	—	—	—	—	—	—	—	—	(253)	—	—	—	—	(253)
Stock-based compensation	—	—	—	—	—	—	—	—	4,501	—	—	—	—	4,501
Put shares sold to majority stockholder	—	—	—	—	—	—	—	—	623	—	—	—	—	623
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(65,879)	(65,879)
<b>BALANCE, DECEMBER 31, 2003</b>	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	—	—	—	—	—	—	891	9	5,239	—	—	—	—	5,248

Series A convertible preferred stock to common stock														
Conversion of Series B convertible preferred stock to common stock	(193)	(15,000)	—	—	—	—	811	8	14,992	—	—	—	—	—
Conversion of Series C convertible preferred stock to common stock	—	—	(980)	(50,000)	—	—	4,464	45	49,955	—	—	—	—	—
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)
<b>BALANCE, DECEMBER 31, 2004</b>	—	—	—	—	—	—	32,756	327	592,999	—	—	—	(442,963)	150,363

**MANKIND 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)
<b>BALANCE, DECEMBER 31, 2005</b>	—	—	—	—	—	—	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)
<b>BALANCE, DECEMBER 31, 2006</b>	—	—	—	—	—	—	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)
<b>BALANCE, DECEMBER 31, 2007</b>	—	—	—	—	—	—	101,381	1,014	1,444,125	—	—	—	(1,081,039)	364,100



**MANKIND 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)
<b>BALANCE, DECEMBER 31, 2008</b>	—	—	—	—	—	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)
<b>BALANCE, DECEMBER 31, 2009</b>	—	—	—	—	—	113,025	1,130	1,544,112	—	—	—	(281)	(1,604,182)	(59,221)
Issuance of common shares under Employee Stock Purchase Plan	—	—	—	—	—	288	3	1,602	—	—	—	—	—	1,605
Issuance of stock for cash	—	—	—	—	—	2,100	21	14,314	—	—	—	—	—	14,335
Issuance of stock in exchange for cancelling an equal amount of note payable to related party	—	—	—	—	—	2,100	21	16,660	—	—	—	—	—	16,681
Issuance of stock under share lending agreement	—	—	—	—	—	9,000	90	71	—	—	—	—	—	161
Issuance of common shares from the release of restricted stock units	—	—	—	—	—	962	10	(3,402)	—	—	—	—	—	(3,392)
Exercise of stock options	—	—	—	—	—	318	3	921	—	—	—	—	—	924
Stock-based compensation	—	—	—	—	—	—	—	13,580	—	—	—	—	—	13,580
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)

**MANKIND 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)
<b>BALANCE, DECEMBER 31, 2011</b>	—	—	—	—	—	—	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
Commitment to deliver common shares pursuant to litigation settlement to additional paid-in capital	—	—	—	—	—	—	—	—	6,056	—	—	—	—	6,056
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)
<b>BALANCE, DECEMBER 31, 2012</b>	—	\$ —	—	\$ —	—	—	286,035	\$ 2,860	\$ 1,991,379	\$ —	\$ —	\$ (6)	\$ (2,104,912)	\$ (110,679)

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See notes to consolidated financial statements.

**MANKIND 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	2012
	(In thousands)			
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>				
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	<u>(148,654)</u>	<u>(123,837)</u>	<u>(119,860)</u>	<u>(1,596,261)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>				
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	<u>(11,720)</u>	<u>(2,937)</u>	<u>(560)</u>	<u>(327,678)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>				
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	<u>196,416</u>	<u>63,394</u>	<u>179,579</u>	<u>1,985,779</u>

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**CONSOLIDATED STATEMENTS OF CASH FLOWS — (Continued)**

	Year Ended December 31,			Cumulative Period from
	2010	2011	2012	February 14, 1991 (Date of Inception) to December 31, 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	<u>\$ 66,061</u>	<u>\$ 2,681</u>	<u>\$ 61,840</u>	<u>\$ 61,840</u>
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.

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**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

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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

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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;

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- 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

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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,

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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.

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**4. Property and equipment**

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

	Estimated Useful Life (Years)	December 31,	
		2011	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
		<u>284,793</u>	<u>285,210</u>
Less accumulated depreciation and amortization		(91,764)	(101,249)
Property and equipment — net		<u>\$ 193,029</u>	<u>\$ 183,961</u>

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	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	<u>\$20,736</u>	<u>\$25,777</u>

**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

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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

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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).

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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	<u>\$ 119,635</u>

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):

	<u>December 31,</u>	
	<u>2011</u>	<u>2012</u>
<b>2013 notes</b>		
Principal amount	\$ 115,000	\$ 115,000
Unaccreted debt issuance expense	(1,140)	(557)
Net carrying amount	<u>113,860</u>	<u>114,443</u>
<b>2015 notes</b>		
Principal amount	\$100,000	\$100,000
Unaccreted debt issuance expense	(3,218)	(2,417)
Net carrying amount	<u>96,782</u>	<u>97,583</u>
Senior convertible notes	<u>\$210,642</u>	<u>\$212,026</u>

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On August 18, 2010, the Company completed a Rule 144A offering of \$100.0 million aggregate principal amount of 5.75% Senior Convertible Notes due 2015 (the "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

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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.

	<b>Workforce Reduction</b>
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.

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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

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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	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

**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 45<sup>th</sup> 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.

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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*

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*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

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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,

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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
	<u>30,858,590</u>	<u>34,048,852</u>	<u>128,324,123</u>

## 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	<u>18,674,539</u>	<u>3,761,031</u>	<u>6,630,516</u>

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

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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.

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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
<b>Total</b>	<b>\$13,580</b>	<b>\$11,204</b>	<b>\$13,292</b>

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
<b>Total</b>	<b>\$ 13,580</b>	<b>\$ 11,204</b>	<b>\$ 13,292</b>

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	—	—	—

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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	<u>18,674,539</u>	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	<u>3,761,031</u>	\$ 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.

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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.

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*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

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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.

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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	<u>2,777,778</u>	\$ 2.18	<u>6,055,556</u>
Total	<u>3,002,778</u>		<u>\$ 6,492,056</u>

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.

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**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	<u>\$ —</u>	<u>\$ —</u>

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	<u>0.0%</u>	<u>0.0%</u>	<u>0.0%</u>

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

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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)			
<b>2011</b>				
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

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

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

**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.

014288

COMMON STOCK

PAR VALUE \$.01

MC



MannKind Corporation

INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE

THIS CERTIFICATE IS TRANSFERABLE IN NEW YORK, NY AND RIDGEFIELD PARK, NJ

CUSIP 56400P 20 1  
SEE REVERSE FOR CERTAIN DEFINITIONS

THIS CERTIFIES THAT

SPECIMEN

IS THE OWNER OF

FULLY PAID AND NON-ASSESSABLE SHARES OF THE COMMON STOCK, PAR VALUE \$.01 PER SHARE, OF

MANKIND CORPORATION

transferable on the books of the Corporation in person or by duly authorized attorney upon surrender of this Certificate properly endorsed. This Certificate is not valid unless duly countersigned by the Transfer Agent and registered by the Registrar.  
IN WITNESS WHEREOF, the said Corporation has caused this Certificate to be signed in facsimile by its duly authorized officers and its facsimile corporate seal to be duly affixed hereto.

Dated:

06 +2004  
*[Signature]*  
0001 0000



SECRETARY

06 +2004  
*[Signature]*  
0001 0000

PRESIDENT

DOWNLOADED AND REGISTERED BY  
MELLON INVESTMENT SERVICES LLC  
INCORPORATED IN NEW YORK

ALPHANUMERIC SEQUENCE

# MANKIND CORPORATION

The Corporation will furnish to any stockholder upon request and without charge a full statement of the powers, designations, preferences and relative, participating, optional or other special rights of each authorized class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights, to the extent that the same have been fixed, and of the authority of the board of directors to designate the same with respect to any shares. Such request may be made to the Corporation or to its Transfer Agent.

The following abbreviations, when used in the inscription on the face of this Certificate, shall be construed as though they were written out in full according to applicable laws or regulations:

TEN COM— as tenants in common  
TEN ENT — as tenants by the entireties  
JT TEN — as joint tenants with right of survivorship and not as tenants in common

UNIF GIFT MIN ACT — \_\_\_\_\_ Custodian \_\_\_\_\_  
(Cust) (Minor)  
Under Uniform Gifts to Minors  
Act \_\_\_\_\_  
(State)

Additional abbreviations may also be used though not in the above list.

FOR VALUE RECEIVED, \_\_\_\_\_ hereby sell, assign and transfer unto

PLEASE INSERT SOCIAL SECURITY OR OTHER IDENTIFYING NUMBER OF ASSIGNEE

(PLEASE PRINT OR TYPEWRITE NAME AND ADDRESS, INCLUDING ZIP CODE, OF ASSIGNEE)

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_ Shares  
of the stock represented by the within Certificate and do hereby irrevocably constitute and appoint

\_\_\_\_\_ Attorney  
to transfer the said stock on the books of the within-named Corporation, with full power of substitution in the premises.

Dated \_\_\_\_\_

X \_\_\_\_\_

X \_\_\_\_\_  
NOTICE: THE SIGNATURE(S) TO THIS ASSIGNMENT MUST CORRESPOND WITH THE NAME(S) AS WRITTEN UPON THE FACE OF THE CERTIFICATE IN EVERY PARTICULAR, WITHOUT ALTERATION OR ENLARGEMENT OF ANY KIND OR ANY CHANGE WHATSOEVER.

Signature(s) Guaranteed

By \_\_\_\_\_  
THE SIGNATURE(S) MUST BE GUARANTEED BY AN ELIGIBLE GUARANTOR INSTITUTION (BANKS, STOCKBROKERS, SAVINGS AND LOAN ASSOCIATIONS AND CREDIT UNIONS WITH MEMBERSHIP IN AN APPROVED SIGNATURE GUARANTEE MEDALLION PROGRAM), PURSUANT TO S.E.C. RULE 17Ad-15.

THIS WARRANT AND THE UNDERLYING SECURITIES HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED OR THE SECURITIES LAWS OF ANY STATE OF THE UNITED STATES. THE SECURITIES MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED, HYPOTHECATED, TRANSFERRED OR ASSIGNED IN THE ABSENCE OF AN EFFECTIVE REGISTRATION STATEMENT FOR THE SECURITIES UNDER APPLICABLE SECURITIES LAWS OR UNLESS OFFERED, SOLD, PLEDGED, HYPOTHECATED OR TRANSFERRED PURSUANT TO AN AVAILABLE EXEMPTION FROM THE REGISTRATION REQUIREMENTS OF THOSE LAWS. THE COMPANY SHALL BE ENTITLED TO REQUIRE AN OPINION OF COUNSEL SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED TO THE EXTENT THAT AN OPINION IS REQUIRED PURSUANT TO THE AGREEMENT UNDER WHICH THE SECURITIES WERE ISSUED.

MANKIND CORPORATION

WARRANT TO PURCHASE COMMON STOCK

Warrant No.: 2012-CW122112—1

Number of Warrants: 40,000,000

Date of Issuance: December 21, 2012 (“**Issuance Date**”)

Expiration Date: December 27, 2013 (“**Expiration Date**”)

MannKind Corporation, a Delaware corporation (the “**Company**”), certifies that, for good and valuable consideration, the receipt and sufficiency of which are acknowledged, The Mann Group LLC, the registered holder hereof or its permitted assigns (the “**Holder**”), is entitled, subject to the terms set forth below, to purchase from the Company, at the Exercise Price (as defined below) then in effect, upon surrender of this Warrant to Purchase Common Stock (including any Warrants to Purchase Common Stock issued in exchange, transfer or replacement hereof, the “**Warrant**”), at any time or times on or after the date hereof (the “**Exercisability Date**”), but not after 5:30 p.m., New York Time, on the Expiration Date, thirty million (30,000,000) fully paid and nonassessable shares of Common Stock (as defined below) (the “**Warrant Shares**”). Except as otherwise defined herein, capitalized terms in this Warrant shall have the meanings set forth in Section 15.

1. EXERCISE OF WARRANT.

(a) Mechanics of Exercise. Subject to the terms and conditions hereof (including, without limitation, the limitations set forth in Section 1(d)), this Warrant may be exercised by the Holder on any day on or after the Exercisability Date, in whole or in part (but not as to fractional shares), by (i) delivery of a written notice, in the form attached hereto as Exhibit A (the “**Exercise Notice**”), of the Holder’s election to exercise this Warrant and (ii) if both (A) the Holder is not electing a Cashless Exercise (as defined below) pursuant to Section 1(c) of this Warrant and (B) a registration statement registering the issuance of the Warrant Shares under the Securities Act of 1933, as amended (the “**Securities Act**”), is effective and available for the issuance of the Warrant Shares, or an exemption from registration under the Securities Act is available for the issuance of the Warrant Shares, payment to the Company of an amount equal to the applicable Exercise Price multiplied by the number of Warrant Shares as to which this Warrant is being exercised (the “**Aggregate Exercise Price**”) in cash or wire transfer of immediately available funds (a “**Cash Exercise**”). The Holder shall not be required to surrender this Warrant in order to effect an exercise hereunder, provided that in the event of an exercise of this Warrant for all Warrant Shares then issuable hereunder, this Warrant is surrendered to the Company by the second (2nd) Trading Day following the date on which the Company has received each of the Exercise Notice and, if this Warrant is being exercised pursuant to a Cash Exercise, the Aggregate Exercise Price (the “**Exercise Delivery Documents**”). On or before the first (1st) Trading Day following the date on which the Company has received the Exercise Delivery Documents, the Company shall transmit by email or facsimile an acknowledgment of receipt of the Exercise Delivery Documents to the Holder and the Company’s transfer agent for the Common Stock (the “**Transfer Agent**”).

The Company shall deliver any objection to the Exercise Delivery Documents on or before the first (1st) Trading Day following the date on which the Company has received all of the Exercise Delivery Documents. In the event of any discrepancy or dispute, the records of the Company shall be controlling and determinative in the absence of manifest error. On or before the third (3rd) Trading Day following the date on which the Company has received the Exercise Notice duly completed and executed by the Holder, and in the case of a Cash Exercise, the Aggregate Exercise Price (the "**Share Delivery Date**"), the Company shall, upon the request of the Holder, instruct the Transfer Agent to issue and dispatch by overnight courier to the address as specified in the Exercise Notice, a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of shares of Common Stock to which the Holder is entitled pursuant to such exercise. Upon delivery of the Exercise Delivery Documents and surrender of this Warrant, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the certificates evidencing such Warrant Shares. If this Warrant is submitted in connection with any exercise pursuant to this Section 1(a) and the number of Warrant Shares represented by this Warrant submitted for exercise is greater than the number of Warrant Shares being acquired upon an exercise, then the Company shall as soon as practicable and in no event later than five (5) Trading Days after any exercise and at its own expense, issue a new Warrant (in accordance with Section 7(e)) representing the right to purchase the number of Warrant Shares purchasable immediately prior to such exercise under this Warrant, less the number of Warrant Shares with respect to which this Warrant is exercised. The Company shall pay any and all taxes that may be payable with respect to the issuance and delivery of Warrant Shares upon exercise of this Warrant; provided, however, that the Company shall not be required to pay any tax which may be payable based on the income of the Holder or in respect of any transfer involved in the registration of any certificates for Warrant Shares or Warrants in a name other than that of the Holder or an affiliate thereof. The Holder shall be responsible for all other tax liability that may arise as a result of holding or transferring this Warrant or receiving Warrant Shares upon exercise hereof.

In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder certificates representing the Warrant Shares or to credit the Holder's balance account with The Depository Trust Company for such number of Warrant Shares to which the Holder is entitled upon the Holder's exercise pursuant to an exercise on or before the Share Delivery Date, and if after such date the Holder purchases (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "**Buy-In**"), then the Company shall within five (5) Trading Days after the Holder's request and in the Holder's discretion, either (i) pay cash to the Holder in an amount equal to the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased (the "**Buy-In Price**"), at which point the Company's obligation to deliver such certificate and to issue such Warrant Shares shall terminate, or (ii) promptly honor its obligation to deliver to the Holder a certificate or certificates representing such Warrant Shares or credit such Holder's balance account with DTC and pay cash to the Holder in an amount equal to the excess (if any) of the Buy-In Price over the product of (A) such number of shares of Common Stock, times (B) the Weighted Average Price of a share of Common Stock on the date of exercise.

(b) Exercise Price. For purposes of this Warrant, "**Exercise Price**" means \$2.60 per share of Common Stock, subject to adjustment as provided herein.

(c) Cashless Exercise. Notwithstanding anything contained herein to the contrary, if a registration statement registering the issuance of the Warrant Shares under the Securities Act is not effective or available for the issuance of the Warrant Shares and an exemption from registration under the Securities Act is not available for the issuance of the Warrant Shares, the Holder may, in its sole discretion, exercise this Warrant in whole or in part and, in lieu of making the cash payment otherwise contemplated to be made to the Company upon such exercise in payment of the Aggregate Exercise Price, elect instead to receive upon such exercise the "Net Number" of shares of Common Stock determined according to the following formula (a "**Cashless Exercise**"):

$$\text{Net Number} = \frac{(A \times B) - (A \times C)}{B}$$

For purposes of the foregoing formula:

A= the total number of shares with respect to which this Warrant is then being exercised.

B= the Weighted Average Price of the shares of Common Stock (as reported by Bloomberg) on the date immediately preceding the date of the Exercise Notice.

C= the Exercise Price then in effect for the applicable Warrant Shares at the time of such exercise.

(d) No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share that the Holder would otherwise be entitled to purchase upon such exercise, the Company shall pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price.

2. ADJUSTMENT OF EXERCISE PRICE AND NUMBER OF WARRANT SHARES. The Exercise Price and the number of Warrant Shares shall be adjusted from time to time as follows:

(a) Adjustment upon Subdivision or Combination of Shares of Common Stock. If the Company at any time on or after the Issuance Date subdivides (by any stock split, stock dividend, recapitalization or otherwise) one or more classes of its outstanding shares of Common Stock into a greater number of shares, the Exercise Price in effect immediately prior to such subdivision will be proportionately reduced and the number of Warrant Shares will be proportionately increased. If the Company at any time on or after the Issuance Date combines (by combination, reverse stock split or otherwise) one or more classes of its outstanding shares of Common Stock into a smaller number of shares, the Exercise Price in effect immediately prior to such combination will be proportionately increased and the number of Warrant Shares will be proportionately decreased. Any adjustment under this Section 2(a) shall become effective at the close of business on the date the subdivision or combination becomes effective.

(b) Other Events. If any event occurs of the type contemplated by the provisions of Section 2(a) but not expressly provided for by such provisions (including, without limitation, the granting of stock appreciation rights, phantom stock rights or other rights with equity features to the holders of the Company's equity securities), then the Company's Board of Directors will make an appropriate adjustment in the Exercise Price and the number of Warrant Shares so as to protect the rights of the Holder; provided, that no such adjustment pursuant to this Section 2(b) will increase the Exercise Price or decrease the number of Warrant Shares as otherwise determined pursuant to this Section 2.

(c) Par Value. Notwithstanding anything to the contrary in this Warrant, in no event shall the Exercise Price be reduced below the par value of the Company's Common Stock.

3. RIGHTS UPON DISTRIBUTION OF ASSETS. If the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction, but excluding any event resulting in an adjustment pursuant to Section 2 or Section 4(a) of this Warrant) (a "**Distribution**"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled upon exercise of this Warrant for the purchase of any or all of the Warrant Shares, to receive the amount of distributed property which would have been payable to the Holder had the Holder been the holder of such Warrant Shares on the record date for the determination of stockholders entitled to participate in the Distribution.

#### 4. PURCHASE RIGHTS; FUNDAMENTAL TRANSACTIONS

(a) Purchase Rights. In addition to any adjustments pursuant to Section 2 above, if at any time prior to the Expiration Date the Company grants, issues or sells any Options, Convertible Securities or rights to purchase stock, warrants, securities or other property pro rata to all of the record holders of any class of

shares of Common Stock (the "**Purchase Rights**"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of shares of Common Stock acquirable upon complete exercise of this Warrant (without regard to any limitations on the exercise of this Warrant) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights.

(b) Fundamental Transactions. Upon the occurrence of any Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Warrant referring to the "Company" shall refer instead to the Successor Entity), and may exercise every right and power of the Company and shall assume all of the obligations of the Company under this Warrant with the same effect as if such Successor Entity had been named as the Company herein. Upon consummation of the Fundamental Transaction, the Successor Entity shall deliver to the Holder confirmation that there shall be issued upon exercise of this Warrant at any time after the consummation of the Fundamental Transaction, in lieu of the shares of the Common Stock (or other securities, cash, assets or other property purchasable upon the exercise of the Warrant prior to such Fundamental Transaction), such shares of stock, securities, cash, assets or any other property whatsoever (including warrants or other purchase or subscription rights), if any, that the Holder would have been entitled to receive upon the happening of such Fundamental Transaction had this Warrant been exercised immediately prior to such Fundamental Transaction, as adjusted in accordance with the provisions of this Warrant. In addition to and not in substitution for any other rights hereunder, prior to the consummation of any Fundamental Transaction pursuant to which holders of shares of Common Stock are entitled to receive securities or other assets with respect to or in exchange for shares of Common Stock (a "**Corporate Event**"), the Company shall make appropriate provision to insure that the Holder will thereafter have the right to receive upon exercise of this Warrant within 90 days after the consummation of the Fundamental Transaction but, in any event, prior to the Expiration Date, in lieu of the shares of the Common Stock (or other securities, cash, assets or other property) purchasable upon the exercise of the Warrant prior to such Fundamental Transaction, such shares of stock, securities, cash, assets or any other property whatsoever (including warrants or other purchase or subscription rights) which the Holder would have been entitled to receive upon the happening of such Fundamental Transaction had the Warrant been exercised immediately prior to such Fundamental Transaction.

5. RESERVATION OF WARRANT SHARES. The Company covenants that it will at all times reserve and keep available out of the aggregate of its authorized but unissued and otherwise unreserved Common Stock, solely for the purpose of enabling it to issue Warrant Shares upon exercise of this Warrant as herein provided, the number of shares of Common Stock which are then issuable and deliverable upon the exercise of this entire Warrant, free from preemptive or any other contingent purchase rights of Persons other than the Holder (taking into account the adjustments and restrictions in Section 2). Such reservation shall comply with the provisions of Section 1. The Company covenants that all shares of Common Stock so issuable and deliverable shall, upon issuance and the payment of the applicable Exercise Price in accordance with the terms hereof, be duly and validly authorized, issued and fully paid and nonassessable. The Company will take all such actions as may be reasonably necessary to assure that such shares of Common Stock may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of any securities exchange or automated quotation system upon which the Common Stock may be listed.

#### 6. REPRESENTATIONS AND ACKNOWLEDGMENTS OF HOLDER.

(a) Acquisition of Warrant for Personal Account. The Holder represents and warrants that it is acquiring this Warrant and the Warrant Shares solely for its account for investment and not with a present view toward the public distribution of this Warrant or Warrant Shares or any part thereof and has no present intention of selling or distributing this Warrant or Warrant Shares or any arrangement or understanding with any other persons regarding the sale or distribution of this Warrant or the Warrant Shares. The Holder will not, directly or indirectly, offer, sell, pledge, transfer or otherwise dispose of (or solicit any offers to buy, purchase or otherwise

acquire or take a pledge of) this Warrant or the Warrant Shares except in accordance with the Securities Act. The Holder represents and warrants that (i) it is aware of the Company's business affairs and financial condition and has acquired sufficient information about the Company to reach an informed and knowledgeable decision regarding its investment in this Warrant and, upon exercise of this Warrant, any Warrant Shares and (ii) it is experienced in making investments of this type and has such knowledge and background in financial and business matters that the Holder is capable of evaluating the merits and risks of this investment and protecting the Holder's own interests.

(b) Securities Not Registered.

(i) The Holder understands that the offer and sale of this Warrant and the Warrant Shares have not been registered under the Securities Act on the basis that no distribution or public offering of the stock of the Company is to be effected. The Holder realizes that the basis for the exemption may not be present if, notwithstanding its representations, the Holder has a present intention of acquiring the securities for a fixed or determinable period in the future, selling (in connection with a distribution or otherwise), granting any participation in, or otherwise distributing the securities. The Holder has no such present intention.

(ii) The Holder recognizes that this Warrant and the Warrant Shares must be held indefinitely unless they are subsequently registered under the Securities Act or an exemption from such registration is available. The Holder recognizes that the Company has no obligation to register this Warrant or the Warrant Shares.

(c) Disposition of Warrant Shares.

(i) The Holder further agrees not to make any disposition of all or any part of this Warrant or Warrant Shares in any event unless and until:

(A) The Company shall have received a letter secured by the Holder from the United States Securities and Exchange Commission ("**SEC**") stating that no action will be recommended to the SEC with respect to the proposed disposition;

(B) There is then in effect a registration statement under the Securities Act covering such proposed disposition and such disposition is made in accordance with said registration statement; or

(C) The Holder shall have notified the Company of the proposed disposition and shall have furnished the Company with a detailed statement of the circumstances surrounding the proposed disposition, and if reasonably requested by the Company, the Holder shall have furnished the Company with an opinion of counsel, reasonably satisfactory to the Company, for the Holder to the effect that such disposition will not require registration of this Warrant or Warrant Shares under the Securities Act or any applicable state securities laws; *provided*, that no opinion shall be required for any disposition made or to be made in accordance with the provisions of Rule 144.

(ii) The Holder understands and agrees that all certificates evidencing the Warrant Shares to be issued to the Holder may bear a legend in substantially the following form:

THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES LAWS OF ANY STATE OF THE UNITED STATES. THE SECURITIES MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED, HYPOTHECATED, TRANSFERRED OR ASSIGNED IN THE ABSENCE OF AN EFFECTIVE REGISTRATION STATEMENT FOR THE SECURITIES UNDER APPLICABLE SECURITIES LAWS, OR UNLESS OFFERED, SOLD, PLEDGED, HYPOTHECATED OR TRANSFERRED PURSUANT TO AN AVAILABLE EXEMPTION FROM THE REGISTRATION REQUIREMENTS OF THOSE LAWS. THE COMPANY SHALL BE ENTITLED TO REQUIRE AN OPINION OF COUNSEL SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED TO THE EXTENT THAT SUCH OPINION IS REQUIRED PURSUANT TO THAT CERTAIN SECURITIES PURCHASE AGREEMENT UNDER WHICH THE SECURITIES WERE ISSUED.

(d) Holder Not Deemed a Stockholder. Except as otherwise specifically provided herein, the Holder, solely in such Person's capacity as a holder of this Warrant, shall not be entitled to vote or receive dividends or be deemed the holder of share capital of the Company for any purpose, nor shall anything contained in this Warrant be construed to confer upon the Holder, solely in such Person's capacity as the Holder of this Warrant, any of the rights of a stockholder of the Company or any right to vote, give or withhold consent to any corporate action (whether any reorganization, issue of stock, reclassification of stock, consolidation, merger, conveyance or otherwise), receive notice of meetings, receive dividends or subscription rights, or otherwise, prior to the issuance to the Holder of the Warrant Shares which such Person is then entitled to receive upon the due exercise of this Warrant. In addition, nothing contained in this Warrant shall be construed as imposing any liabilities on the Holder to purchase any securities (upon exercise of this Warrant or otherwise) or as a stockholder of the Company, whether such liabilities are asserted by the Company or by creditors of the Company.

## 7. REGISTRATION AND REISSUANCE OF WARRANTS.

(a) Registration of Warrant. The Company shall register this Warrant, upon the records to be maintained by the Company for that purpose (the "**Warrant Register**"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary. The Company shall also register any transfer, exchange, reissuance or cancellation of any portion of this Warrant in the Warrant Register.

(b) Transfer of Warrant. This Warrant may be offered for sale, sold, transferred or assigned without the consent of the Company, subject to Section 6(c) and except as may otherwise be required by applicable securities laws. Subject to applicable securities laws, if this Warrant is to be transferred, the Holder shall surrender this Warrant to the Company or its Transfer Agent, as directed by the Company, together with all applicable transfer taxes, whereupon the Company will, or will cause its Transfer Agent to, forthwith issue and deliver upon the order of the Holder a new Warrant (in accordance with Section 7(e)), registered as the Holder may request, representing the right to purchase the number of Warrant Shares being transferred by the Holder and, if less than the total number of Warrant Shares then underlying this Warrant is being transferred, a new Warrant (in accordance with Section 7(e)) to the Holder representing the right to purchase the number of Warrant Shares not being transferred. The acceptance of the new Warrant by the transferee thereof shall be deemed the acceptance by such transferee of all of the rights and obligations in respect of the new Warrant that the Holder has in respect of this Warrant.

(c) Lost, Stolen or Mutilated Warrant. Upon receipt by the Company of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Warrant, and, in the case of loss, theft or destruction, of any indemnification undertaking by the Holder to the Company in customary form or the provision of reasonable security by the Holder to the Company and, in the case of mutilation, upon surrender and cancellation of this Warrant, the Company or its Transfer Agent, as directed by the Company, shall execute and deliver to the Holder a new Warrant (in accordance with Section 7(e)) representing the right to purchase the Warrant Shares then underlying this Warrant.

(d) Exchangeable for Multiple Warrants. This Warrant is exchangeable, upon the surrender hereof by the Holder at the principal office of the Company or its Transfer Agent, as directed by the Company, together with all applicable transfer taxes, for a new Warrant or Warrants (in accordance with Section 7(e)) representing in the aggregate the right to purchase the number of Warrant Shares then underlying this Warrant, and each such new Warrant will represent the right to purchase such portion of such Warrant Shares as is designated by the Holder at the time of such surrender; provided, however, that the Company or its Transfer Agent, as directed by the Company, shall not be required to issue Warrants for fractional shares of Common Stock hereunder.

(e) Issuance of New Warrants. Whenever the Company or its Transfer Agent, as directed by the Company, is required to issue a new Warrant pursuant to the terms of this Warrant, such new Warrant shall (i) be of like tenor with this Warrant, (ii) represent, as indicated on the face of such new Warrant, the right to purchase the Warrant Shares then underlying this Warrant (or in the case of a new Warrant being issued pursuant to Section 7(b) or Section 7(c), the Warrant Shares designated by the Holder which, when added to

the number of shares of Common Stock underlying the other new Warrants issued in connection with such issuance, does not exceed the number of Warrant Shares then underlying this Warrant), (iii) have an issuance date, as indicated on the face of such new Warrant which is the same as the Issuance Date and (iv) have the same rights and conditions as this Warrant.

8. NOTICES. Whenever notice is required to be given under this Warrant, unless otherwise provided herein, such notice shall be given in accordance with the information set forth in the Warrant Register. The Company shall give written notice to the Holder (i) reasonably promptly following any adjustment of the Exercise Price, setting forth in reasonable detail, and certifying, the calculation of such adjustment and (ii) at least ten (10) days prior to the date on which the Company closes its books or takes a record (A) with respect to any dividend or distribution upon the shares of Common Stock, (B) with respect to any grants, issuances or sales of any Options, Convertible Securities or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock or (C) for determining rights to vote with respect to any Fundamental Transaction, dissolution or liquidation; provided, that in each case, such information shall be made known to the public prior to or in conjunction with such notice being provided to the Holder.

9. AMENDMENT AND WAIVER. Except as otherwise provided herein, the provisions of this Warrant may be amended and the Company may take any action herein prohibited, or omit to perform any act herein required to be performed by it, only if the Company has obtained the written consent of the Holder.

10. LIMITATION OF LIABILITY. No provision hereof, in the absence of any affirmative action by Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of Holder, shall give rise to any liability of Holder for the purchase price of any Warrant Shares or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

11. GOVERNING LAW. This Warrant shall be governed by and construed and enforced in accordance with, and all questions concerning the construction, validity, interpretation and performance of this Warrant shall be governed by, the internal laws of the State of New York, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of New York or any other jurisdictions) that would cause the application of the laws of any jurisdictions other than the State of New York.

12. CONSTRUCTION; HEADINGS. This Warrant shall be deemed to be jointly drafted by the Company and the Holder and shall not be construed against any person as the drafter hereof. The headings of this Warrant are for convenience of reference and shall not form part of, or affect the interpretation of, this Warrant.

13. DISPUTE RESOLUTION. In the case of a dispute as to the determination of the Exercise Price or the arithmetic calculation of the Warrant Shares, the Company shall submit the disputed determinations or arithmetic calculations via email or facsimile within two (2) Trading Days of receipt of the Exercise Notice giving rise to such dispute, as the case may be, to the Holder. If the Holder and the Company are unable to agree upon such determination or calculation of the Exercise Price or the Warrant Shares within five (5) Trading Days of such disputed determination or arithmetic calculation being submitted to the Holder, then the Company shall, within two (2) Trading Days submit via email or facsimile (a) the disputed determination of the Exercise Price to an independent, reputable investment bank selected by the Company and approved by the Holder or (b) the disputed arithmetic calculation of the Warrant Shares to the Company's independent, outside accountant. The Company shall cause the investment bank or the accountant, as the case may be, to perform the determinations or calculations and notify the Company and the Holder of the results no later than ten (10) Trading Days from the time it receives the disputed determinations or calculations. Such investment bank's or accountant's determination or calculation, as the case may be, shall be binding upon all parties absent demonstrable error. The expenses of the investment bank and accountant will be borne by the Company unless the investment bank or accountant determines that the determination of the Exercise Price or the arithmetic calculation of the Warrant Shares by the Holder was incorrect, in which case the expenses of the investment bank and accountant will be borne by the Holder.

14. REMEDIES, OTHER OBLIGATIONS, BREACHES AND INJUNCTIVE RELIEF. The remedies provided in this Warrant shall be cumulative and in addition to all other remedies available under this Warrant, at law or in equity (including a decree of specific performance and/or other injunctive relief), and nothing herein shall limit the right of the Holder to pursue actual damages for any failure by the Company to comply with the terms of this Warrant. The Company acknowledges that a breach by it of its obligations hereunder may cause irreparable harm to the Holder and that the remedy at law for any such breach may be inadequate. The Company therefore agrees that, in the event of any such breach or threatened breach, the holder of this Warrant shall be entitled, in addition to all other available remedies, to seek an injunction restraining any breach. Notwithstanding the foregoing or anything else herein to the contrary, if the Company is for any reason unable to issue and deliver Warrant Shares upon exercise of this Warrant as required pursuant to the terms hereof, the Company shall have no obligation to pay to the Holder any cash or other consideration or otherwise "net cash settle" this Warrant.

15. CERTAIN DEFINITIONS. For purposes of this Warrant, the following terms shall have the following meanings:

(a) "**Bloomberg**" means Bloomberg Financial Markets.

(b) "**Change of Control**" means any Fundamental Transaction other than (i) any reorganization, recapitalization or reclassification of the Common Stock in which holders of the Company's voting power immediately prior to such reorganization, recapitalization or reclassification continue after such reorganization, recapitalization or reclassification to hold publicly traded securities and, directly or indirectly, the voting power of the surviving entity or entities necessary to elect a majority of the members of the board of directors (or their equivalent if other than a corporation) of such entity or entities, or (ii) pursuant to a migratory merger effected solely for the purpose of changing the jurisdiction of incorporation of the Company.

(c) "**Common Stock**" means (i) the Company's shares of Common Stock, \$0.01 par value per share, and (ii) any share capital into which such Common Stock shall have been changed or any share capital resulting from a reclassification of such Common Stock.

(d) "**Convertible Securities**" means any stock or securities (other than Options) directly or indirectly convertible into or exercisable or exchangeable for shares of Common Stock.

(e) "**Eligible Market**" means the Principal Market, The New York Stock Exchange, Inc., the NYSE Amex LLC, The Nasdaq Stock Market, or the OTC Bulletin Board®.

(f) "**Fundamental Transaction**" means that (A) the Company shall, directly or indirectly, in one or more related transactions, (i) consolidate or merge with or into (whether or not the Company is the surviving corporation) another Person, or (ii) sell, assign, transfer, convey or otherwise dispose of all or substantially all of the properties or assets of the Company to another Person, or (iii) allow another Person providing to make a purchase, tender or exchange offer that is accepted by the holders of more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the Person or Persons making or party to, or associated or affiliated with the Persons making or party to, such purchase, tender or exchange offer), or (iv) consummate a stock purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person whereby such other Person acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock purchase agreement or other business combination), or (v) reorganize, recapitalize or reclassify the Common Stock or (B) any "person" or "group" (as these terms are used for purposes of Sections 13(d) and 14(d) of the Exchange Act) is or shall become the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of 50% of the aggregate ordinary voting power represented by issued and outstanding Common Stock.

(g) "**Options**" means any rights, warrants or options to subscribe for or purchase shares of Common Stock or Convertible Securities.

(h) **“Parent Entity”** of a Person means an entity that, directly or indirectly, controls the applicable Person and whose common stock or equivalent equity security is quoted or listed on an Eligible Market, or, if there is more than one such Person or Parent Entity, the Person or Parent Entity with the largest public market capitalization as of the date of consummation of the Fundamental Transaction.

(i) **“Person”** means an individual, a limited liability company, a partnership, a joint venture, a corporation, a trust, an unincorporated organization, any other entity and a government or any department or agency thereof.

(j) **“Principal Market”** means the Nasdaq Global Market.

(k) **“Successor Entity”** means the Person (or, if so elected by the Holder, the Parent Entity) formed by, resulting from or surviving any Fundamental Transaction or the Person (or, if so elected by the Holder, the Parent Entity) with which such Fundamental Transaction shall have been entered into.

(l) **“Trading Day”** means any day on which the Common Stock is traded on the Principal Market, or, if the Principal Market is not the principal trading market for the Common Stock, then on the principal securities exchange or securities market on which the Common Stock is then traded; provided that “Trading Day” shall not include any day on which the Common Stock is scheduled to trade on such exchange or market for less than 4.5 hours or any day that the Common Stock is suspended from trading during the final hour of trading on such exchange or market (or if such exchange or market does not designate in advance the closing time of trading on such exchange or market, then during the hour ending at 4:00:00 p.m., New York Time).

(m) **“Weighted Average Price”** means, for any security as of any date, the dollar volume-weighted average price for such security on the Principal Market during the period beginning at 9:30:01 a.m., New York City time, and ending at 4:00:00 p.m., New York City time, as reported by Bloomberg through its “Volume at Price” function or, if the foregoing does not apply, the dollar volume-weighted average price of such security in the over-the-counter market on the electronic bulletin board for such security during the period beginning at 9:30:01 a.m., New York City time, and ending at 4:00:00 p.m., New York City time, as reported by Bloomberg, or, if no dollar volume-weighted average price is reported for such security by Bloomberg for such hours, the average of the highest closing bid price and the lowest closing ask price of any of the market makers for such security as reported in the “pink sheets” by Pink OTC Markets Inc. If the Weighted Average Price cannot be calculated for such security on such date on any of the foregoing bases, the Weighted Average Price of such security on such date shall be the fair market value as mutually determined by the Company and the Holder. If the Company and the Holder are unable to agree upon the fair market value of such security, then such dispute shall be resolved pursuant to Section 13 with the term “Weighted Average Price” being substituted for the term “Exercise Price.” All such determinations shall be appropriately adjusted for any share dividend, share split or other similar transaction during such period.

***[Signature Page Follows]***

IN WITNESS WHEREOF, the Company has caused this Warrant to Purchase Common Stock to be duly executed as of the Issuance Date set out above.

**MANKIND CORPORATION**

By: \_\_\_\_\_  
David Thomson, Corporate Vice President,  
General Counsel and Secretary

EXERCISE NOTICE

TO BE EXECUTED BY THE REGISTERED HOLDER TO EXERCISE THIS  
WARRANT TO PURCHASE COMMON STOCK

MANKIND CORPORATION

The undersigned holder hereby exercises the right to purchase of the shares of Common Stock ("**Warrant Shares**") of MannKind Corporation, a Delaware corporation (the "**Company**"), evidenced by the attached Warrant to Purchase Common Stock (the "**Warrant**"). Capitalized terms used herein and not otherwise defined shall have the respective meanings set forth in the Warrant.

1. Exercise Price. The Holder intends that payment of the Exercise Price shall be made as (check one):

- Cash Exercise under Section 1(a).
- Cashless Exercise under Section 1(c).

2. Cash Exercise. If the Holder has elected a Cash Exercise, the Holder shall pay the sum of \$ \_\_\_\_\_ to the Company in accordance with the terms of the Warrant.

3. Delivery of Warrant Shares. The Company shall deliver to the holder \_\_\_\_\_ Warrant Shares in accordance with the terms of the Warrant.

4. Representations and Warranties. By its delivery of this Exercise Notice, the undersigned represents and warrants to the Company that the representations set forth in Section 6 are true and correct on the date hereof, and acknowledges and agrees to the transfer limitations with respect to the Warrant Shares set forth in Section 6.

DATED:

(Signature must conform in all respects to name of the Holder as specified on the face of the Warrant)

\_\_\_\_\_  
Registered Holder

Address: \_\_\_\_\_  
\_\_\_\_\_

ACKNOWLEDGMENT

The Company hereby acknowledges this Exercise Notice.

MANKIND CORPORATION

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

Sean M. Clayton  
T: +1 858 550 6034  
sclayton@cooley.com

March 18, 2013

MannKind Corporation  
28903 North Avenue Paine  
Valencia, CA 91355

Ladies and Gentlemen:

You have requested our opinion with respect to certain matters in connection with the offering by MannKind Corporation, a Delaware corporation (the "**Company**"), of the lesser of (i) \$50,000,000 of shares or (ii) 25,000,000 shares of the Company's common stock, par value \$0.01 (the "**Shares**"), pursuant to a Registration Statement on Form S-3 (No. 333-183679) (the "**Registration Statement**"), filed with the Securities and Exchange Commission (the "**Commission**") under the Securities Act of 1933, as amended (the "**Act**"), the prospectus included within the Registration Statement (the "**Base Prospectus**"), and the prospectus supplement dated March 18, 2013, filed with the Commission pursuant to Rule 424(b) of the Rules and Regulations of the Act (the "**Prospectus Supplement**"). The Base Prospectus and the Prospectus Supplement are collectively referred to as the "**Prospectus**." The Shares are to be sold by the Company in accordance with (i) an At-The-Market Issuance Sales Agreement, dated March 18, 2013, between the Company and MLV & Co. LLC (the "**MLV Agreement**") and (ii) an At-The-Market Issuance Sales Agreement, dated March 18, 2013, between the Company and Brinson Patrick Securities Corporation (the "**Brinson Patrick Agreement**"), as described in the Prospectus.

In connection with this opinion, we have examined and relied upon the Registration Statement and the Prospectus, the MLV Agreement, the Brinson Patrick Agreement, the Company's Amended and Restated Certificate of Incorporation, as amended, its Amended and Restated Bylaws, and the originals or copies certified to our satisfaction of such records, documents, certificates, memoranda and other instruments as in our judgment are necessary or appropriate to enable us to render the opinion expressed below. In rendering this opinion, we have assumed the genuineness and authenticity of all signatures on original documents; the genuineness and authenticity of all documents submitted to us as originals; the conformity to originals of all documents submitted to us as copies; the accuracy, completeness and authenticity of certificates of public officials; and the due authorization, execution and delivery of all documents where due authorization, execution and delivery are prerequisites to the effectiveness of such documents.

Our opinion herein is expressed solely with respect to the federal laws of the United States of America and the General Corporation Law of the State of Delaware. Our opinion is based on these laws as in effect on the date hereof. We express no opinion as to whether the laws of any particular jurisdiction other than those identified above are applicable to the subject matter hereof.

4401 EASTGATE MALL, SAN DIEGO, CA 92121 T: (858) 550-6000 F: (858) 550-6420 WWW.COOLEY.COM

MannKind Corporation

March 18, 2013

Page Two

On the basis of the foregoing, and in reliance thereon, we are of the opinion that the Shares, when sold and issued against payment therefor in accordance with the MLV Agreement or the Brinson Patrick Agreement, as applicable, the Registration Statement and the Prospectus, will be validly issued, fully paid and nonassessable.

We consent to the reference to our firm under the caption "Legal Matters" in the Prospectus and to the filing of this opinion as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2012 to be filed with the Commission for incorporation by reference into the Registration Statement.

Very truly yours,

Cooley LLP

By: /s/ Sean M. Clayton

Sean M. Clayton

4401 EASTGATE MALL, SAN DIEGO, CA 92121 T: (858) 550-6000 F: (858) 550-6420 WWW.COOLEY.COM

## MANKIND CORPORATION

Common Stock  
(par value \$0.01 per share)

## At-The-Market Issuance Sales Agreement

March 18, 2013

MLV & Co. LLC  
1251 Avenue of the Americas  
41st Floor  
New York, NY 10020

Ladies and Gentlemen:

MannKind Corporation, a Delaware corporation (the "Company"), confirms its agreement (this "Agreement") with MLV & Co. LLC ("MLV"), as follows:

1. Issuance and Sale of Shares. The Company agrees that, from time to time during the term of this Agreement, on the terms and subject to the conditions set forth herein, it may issue and sell through MLV, shares (the "Placement Shares") of the Company's common stock, par value \$0.01 per share (the "Common Stock"), up to an aggregate offering price of \$50,000,000 less the aggregate offering price of any Common Stock sold pursuant to the Concurrent Facility Agreement (as defined below), *provided however*, that in no event shall the Company issue or sell through MLV such number of Placement Shares that (a) would cause the Company to not satisfy the eligibility requirements for use of Form S-3 (including Instruction I.B.6. thereof), (b) exceeds the number of shares of Common Stock registered on the effective Registration Statement (as defined below) pursuant to which the offering is being made or (c) exceeds the number of authorized but unissued shares of the Company's Common Stock (the lesser of (a), (b) and (c), the "Maximum Amount"). Notwithstanding anything to the contrary contained herein, the parties hereto agree that compliance with the limitations set forth in this Section 1 on the amount of Placement Shares issued and sold under this Agreement shall be the sole responsibility of the Company and that MLV shall have no obligation in connection with such compliance. The issuance and sale of Placement Shares through MLV will be effected pursuant to the Registration Statement filed by the Company and declared effective by the Securities and Exchange Commission (the "Commission"), although nothing in this Agreement shall be construed as requiring the Company to use the Registration Statement to issue any Placement Shares.

The Company has filed, in accordance with the provisions of the Securities Act of 1933, as amended (the "Securities Act"), and the rules and regulations thereunder (the "Securities Act Regulations"), with the Commission a registration statement on Form S-3 (File No. 333-183679), including a base prospectus, relating to certain securities, including the Placement Shares to be issued from time to time by the Company, and which incorporates by reference

documents that the Company has filed or will file in accordance with the provisions of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the rules and regulations thereunder. The Company has prepared a prospectus supplement specifically relating to the Placement Shares (the "Prospectus Supplement") to the base prospectus included as part of such registration statement. The Company will furnish to MLV, for use by MLV, copies of the prospectus included as part of such registration statement, as supplemented by the Prospectus Supplement, relating to the Placement Shares. Except where the context otherwise requires, such registration statement, including all documents filed as part thereof or incorporated by reference therein, and including any information contained in a Prospectus (as defined below) subsequently filed with the Commission pursuant to Rule 424(b) under the Securities Act Regulations or deemed to be a part of such registration statement pursuant to Rule 430B of the Securities Act Regulations, is herein called the "Registration Statement." The base prospectus, including all documents incorporated therein by reference, included in the Registration Statement, as it may be supplemented by the Prospectus Supplement, in the form in which such prospectus and/or Prospectus Supplement have most recently been filed by the Company with the Commission pursuant to Rule 424(b) under the Securities Act Regulations, is herein called the "Prospectus." Any reference herein to the Registration Statement, the Prospectus or any amendment or supplement thereto shall be deemed to refer to and include the documents incorporated by reference therein, and any reference herein to the terms "amend," "amendment" or "supplement" with respect to the Registration Statement or the Prospectus shall be deemed to refer to and include the filing after the execution hereof of any document with the Commission deemed to be incorporated by reference therein (the "Incorporated Documents").

For purposes of this Agreement, all references to the Registration Statement, the Prospectus or to any amendment or supplement thereto shall be deemed to include the most recent copy filed with the Commission pursuant to its Electronic Data Gathering Analysis and Retrieval System, or if applicable, the Interactive Data Electronic Application system when used by the Commission (collectively, "EDGAR").

2. Placements. Each time that the Company wishes to issue and sell Placement Shares hereunder (each, a "Placement"), it will notify MLV by email notice (or other method mutually agreed to in writing by the parties) of the proposed terms of such Placement, which shall include at a minimum the number of Placement Shares to be issued, the time period during which sales are requested to be made, any limitation on the number of Placement Shares that may be sold in any one day and any minimum price below which sales may not be made (a "Placement Notice"), the form of which is attached hereto as Schedule 1. The Placement Notice shall originate from any of the individuals from the Company set forth on Schedule 3 (with a copy to each of the other individuals from the Company listed on such schedule), and shall be addressed to each of the individuals from MLV set forth on Schedule 3, as such Schedule 3 may be amended from time to time. The Placement Notice shall be effective unless and until (i) MLV declines to accept the terms contained therein for any reason, in its sole discretion by email notice to the Company within one Business Day (as defined below) from the time the Placement Notice is received, (ii) the entire amount of the Placement Shares thereunder have been sold, (iii) the Company suspends or terminates the Placement Notice or (iv) this Agreement has been terminated under the provisions of Section 13. The amount of any discount, commission or other compensation to be paid by the Company to MLV in connection with the sale of the Placement

Shares shall be calculated in accordance with the terms set forth in Schedule 2. It is expressly acknowledged and agreed that neither the Company nor MLV will have any obligation whatsoever with respect to a Placement or any Placement Shares unless and until the Company delivers a Placement Notice to MLV and MLV does not decline such Placement Notice pursuant to the terms set forth above, and then only upon the terms specified therein and herein. In the event of a conflict between the terms of this Agreement and the terms of a Placement Notice, the terms of the Placement Notice will control.

### 3. Sale of Placement Shares by MLV.

(a) Subject to the terms and conditions of this Agreement, for the period specified in the Placement Notice, MLV will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of the NASDAQ Global Market (the "Exchange"), to sell the Placement Shares up to the amount specified, and otherwise in accordance with the terms of such Placement Notice. MLV will provide written confirmation to the Company no later than the opening of the Trading Day (as defined below) immediately following the Trading Day on which it has made sales of Placement Shares hereunder setting forth the number of Placement Shares sold on such day, the compensation payable by the Company to MLV pursuant to Section 2 with respect to such sales, and the Net Proceeds (as defined below) payable to the Company, with an itemization of the deductions made by MLV (as set forth in Section 5(b)) from the gross proceeds that it receives from such sales. Subject to the terms of the Placement Notice, MLV shall sell Placement Shares only by methods deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act Regulations, including without limitation sales made directly on the Exchange, on any other existing trading market for the Common Stock or to or through a market maker. Subject to the terms of the Placement Notice and only with the Company's prior written consent, MLV may also sell Placement Shares by any other method permitted by law, including but not limited to in negotiated transactions. "Trading Day" means any day on which shares of Common Stock are purchased and sold on the Exchange.

(b) During the term of this Agreement, neither MLV nor any of its affiliates or subsidiaries shall engage in (i) any short sale of any security of the Company, (ii) any sale of any security of the Company that MLV does not own or any sale which is consummated by the delivery of a security of the Company borrowed by, or for the account of, MLV or (iii) any market making bidding, stabilization or other trading activity with respect to the Common Stock or related derivative securities if such activity would be prohibited under Regulation M or other anti-manipulation rules under the Securities Act. Neither MLV nor any of its affiliates or subsidiaries shall engage in any proprietary trading or trading for MLV's (or its affiliates' or subsidiaries') own account.

4. Suspension of Sales. The Company or MLV may, upon notice to the other party in writing (including by email correspondence to each of the individuals of the other party set forth on Schedule 3, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply) or by telephone (confirmed immediately by verifiable facsimile transmission or email correspondence to each of the individuals of the other party set forth on Schedule 3), suspend any sale of Placement Shares;

provided, however, that such suspension shall not affect or impair any party's obligations with respect to any Placement Shares sold hereunder prior to the receipt of such notice. Each of the parties agrees that no such notice under this Section 4 shall be effective against any other party unless it is made to one of the individuals named on Schedule 3 hereto, as such Schedule may be amended from time to time.

#### 5. Sale and Delivery to MLV; Settlement.

(a) Sale of Placement Shares. On the basis of the representations and warranties herein contained and subject to the terms and conditions herein set forth, unless MLV declines to accept the terms of a Placement Notice, and unless the sale of the Placement Shares described therein has been declined, suspended, or otherwise terminated in accordance with the terms of this Agreement, MLV, for the period specified in the Placement Notice, will use its commercially reasonable efforts consistent with its normal trading and sales practices to sell such Placement Shares up to the amount specified in, and otherwise in accordance with, the terms of such Placement Notice. The Company acknowledges and agrees that (i) there can be no assurance that MLV will be successful in selling Placement Shares, (ii) MLV will incur no liability or obligation to the Company or any other person or entity if it does not sell Placement Shares for any reason other than a failure by MLV to use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable law and regulations to sell such Placement Shares as required under this Agreement and (iii) MLV shall be under no obligation to purchase Placement Shares on a principal basis pursuant to this Agreement, except as otherwise agreed by MLV and the Company.

(b) Settlement of Placement Shares. Unless otherwise specified in the applicable Placement Notice, settlement for sales of Placement Shares will occur on the third (3rd) Trading Day (or such earlier day as is industry practice for regular-way trading) following the date on which such sales are made (each, a "Settlement Date"). The amount of proceeds to be delivered to the Company on a Settlement Date against receipt of the Placement Shares sold (the "Net Proceeds") will be equal to the aggregate sales price received by MLV, after deduction for (i) MLV's commission, discount or other compensation for such sales payable by the Company pursuant to Section 2 hereof, and (ii) any transaction fees imposed by any governmental or self-regulatory organization in respect of such sales.

(c) Delivery of Placement Shares. On or before each Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Placement Shares being sold by crediting MLV's or its designee's account (provided MLV shall have given the Company written notice of such designee a reasonable period of time prior to the Settlement Date) at The Depository Trust Company through its Deposit and Withdrawal at Custodian System or by such other means of delivery as may be mutually agreed upon by the parties hereto which in all cases shall be freely tradable, transferable, registered shares in good deliverable form. On each Settlement Date, MLV will deliver the related Net Proceeds in same day funds to an account designated by the Company on, or prior to, the Settlement Date. If the Company, or its transfer agent (if applicable), defaults in its obligation to deliver Placement Shares on a Settlement Date through no fault of MLV, the Company agrees that in addition to and in no way limiting the rights and obligations set forth in Section 11(a) hereto, it will (i) hold MLV harmless

against any loss, claim, damage, or expense (including reasonable legal fees and expenses), as incurred, arising out of or in connection with such default by the Company or its transfer agent (if applicable) and (ii) pay to MLV (without duplication) any commission, discount, or other compensation to which it would otherwise have been entitled absent such default.

(d) Limitations on Offering Size. Under no circumstances shall the Company cause or request the offer or sale of any Placement Shares if, after giving effect to the sale of such Placement Shares, the aggregate gross sales proceeds of Placement Shares sold pursuant to this Agreement would exceed the lesser of (A) together with all sales of Placement Shares under this Agreement, the Maximum Amount and (B) the amount authorized from time to time to be issued and sold under this Agreement by the Company's board of directors, a duly authorized committee thereof or a duly authorized executive committee, and notified to MLV in writing. Under no circumstances shall the Company cause or request the offer or sale of any Placement Shares pursuant to this Agreement at a price lower than any minimum price authorized from time to time by the Company's board of directors, a duly authorized committee thereof or a duly authorized executive committee, and notified to MLV in writing.

6. Representations and Warranties of the Company. Except as disclosed in the Registration Statement or the Prospectus (including Incorporated Documents), the Company represents and warrants to, and agrees with MLV that as of the date of this Agreement and as of each Applicable Time (as defined below), unless such representation, warranty or agreement specifies a different time:

(a) Registration Statement and Prospectus. The Company and, assuming no act or omission on the part of MLV that would make such statement untrue, the transactions contemplated by this Agreement meet the requirements for and comply with the conditions for the use of Form S-3 under the Securities Act. The Registration Statement has been filed with the Commission and has been declared effective under the Securities Act. The Prospectus Supplement will name MLV as an agent in the section entitled "Plan of Distribution." The Company has not received, and has no notice of, any order of the Commission preventing or suspending the use of the Registration Statement, or threatening or instituting proceedings for that purpose. The Registration Statement and the offer and sale of Placement Shares as contemplated hereby meet the requirements of Rule 415 under the Securities Act and comply in all material respects with said Rule. Any statutes, regulations, contracts or other documents that are required to be described in the Registration Statement or the Prospectus or to be filed as exhibits to the Registration Statement have been so described or filed. Copies of the Registration Statement, the Prospectus, and any such amendments or supplements and all documents incorporated by reference therein that were filed with the Commission on or prior to the date of this Agreement have been delivered, or are available through EDGAR, to MLV and its counsel. The Company has not distributed and, prior to the later to occur of each Settlement Date and completion of the distribution of the Placement Shares, will not distribute any offering material in connection with the offering or sale of the Placement Shares other than the Registration Statement and the Prospectus and any Issuer Free Writing Prospectus (as defined below) to which MLV has consented, such consent not to be unreasonably withheld, conditioned or delayed. The Common Stock is currently quoted on the Exchange under the trading symbol "MNKD". The Company has not, in the 12 months preceding the date hereof, received notice

from the Exchange to the effect that the Company is not in compliance with the listing or maintenance requirements and the Company has no reason to believe that it will not in the foreseeable future continue to be in compliance with all such listing and maintenance requirements.

(b) No Misstatement or Omission. The Registration Statement, when it became effective, and the Prospectus, and any amendment or supplement thereto, on the date of such Prospectus or amendment or supplement, conformed and will conform in all material respects with the requirements of the Securities Act. At each Settlement Date, the Registration Statement and the Prospectus, as of such date, will conform in all material respects with the requirements of the Securities Act. The Registration Statement, when it became effective, did not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. The Prospectus and any amendment and supplement thereto, on the date thereof and at each Applicable Time (defined below), did not or will not include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in light of the circumstances under which they were made, not misleading. The documents incorporated by reference in the Prospectus or any Prospectus Supplement did not, and any further documents filed and incorporated by reference therein will not, when filed with the Commission, contain an untrue statement of a material fact or omit to state a material fact required to be stated in such document or necessary to make the statements in such document, in light of the circumstances under which they were made, not misleading. The foregoing shall not apply to statements in, or omissions from, any such document made in reliance upon, and in conformity with, information furnished to the Company by MLV specifically for use in the preparation thereof.

(c) Conformity with Securities Act and Exchange Act. The Registration Statement, the Prospectus, or any amendment or supplement thereto, and the documents incorporated by reference in the Registration Statement, the Prospectus or any amendment or supplement thereto, when such documents were or are filed with the Commission under the Securities Act or the Exchange Act or became or become effective under the Securities Act, as the case may be, conformed or will conform in all material respects with the requirements of the Securities Act and the Exchange Act, as applicable.

(d) Financial Information. The consolidated financial statements of the Company included or incorporated by reference in the Registration Statement and the Prospectus, together with the related notes and schedules, present fairly, in all material respects, the consolidated financial position of the Company and the Subsidiaries (as defined below) as of the dates indicated and the consolidated results of operations, cash flows and changes in stockholders' equity of the Company for the periods specified (subject, in the case of unaudited statements, to normal year-end audit adjustments) and have been prepared in compliance with the requirements of the Securities Act and Exchange Act, as applicable, and in conformity with GAAP (as defined below) applied on a consistent basis (except for such adjustments to accounting standards and practices as are noted therein and except in the case of unaudited financial statements to the extent they may exclude footnotes or may be condensed or summary statements) during the periods involved; the other financial and statistical data with respect to the Company and the Subsidiaries contained or incorporated by reference in the Registration

Statement and the Prospectus are accurately and fairly presented and prepared on a basis consistent with the financial statements and books and records of the Company; there are no financial statements (historical or pro forma) that are required to be included or incorporated by reference in the Registration Statement or the Prospectus that are not included or incorporated by reference as required; the Company and the Subsidiaries do not have any material liabilities or obligations, direct or contingent (including any off-balance sheet obligations), not described in the Registration Statement (including the exhibits thereto and Incorporated Documents) and the Prospectus which are required to be described in the Registration Statement or the Prospectus (including exhibits thereto and Incorporated Documents); and all disclosures contained or incorporated by reference in the Registration Statement and the Prospectus regarding “non-GAAP financial measures” (as such term is defined by the rules and regulations of the Commission) comply in all material respects with Regulation G of the Exchange Act and Item 10 of Regulation S-K under the Securities Act, to the extent applicable;

(e) Conformity with EDGAR Filing. The Prospectus delivered to MLV for use in connection with the sale of the Placement Shares pursuant to this Agreement will be identical to the versions of the Prospectus created to be transmitted to the Commission for filing via EDGAR, except to the extent permitted by Regulation S-T.

(f) Organization. The Company and each of its Subsidiaries are, and will be, duly organized, validly existing as a corporation and in good standing under the laws of their respective jurisdictions of organization. The Company and each of its Subsidiaries are, and will be, duly licensed or qualified as a foreign corporation for transaction of business and in good standing under the laws of each other jurisdiction in which their respective ownership or lease of property or the conduct of their respective businesses requires such license or qualification, and have all corporate power and authority necessary to own or hold their respective properties and to conduct their respective businesses as described in the Registration Statement and the Prospectus, except where the failure to be so qualified or in good standing or have such power or authority would not, individually or in the aggregate, have a material adverse effect or would reasonably be expected to have a material adverse effect on the assets, business, operations, earnings, properties, condition (financial or otherwise), prospects, stockholders' equity (as set forth on the Company's most recent balance sheet included in the Incorporated Documents) or results of operations of the Company and the Subsidiaries (as defined below) taken as a whole (a “Material Adverse Effect”).

(g) Subsidiaries. Schedule 4 hereto sets forth each of the Company's significant subsidiaries (as such term is defined in Rule 1-02 of Regulation S-X promulgated by the Commission), if any (each such significant subsidiary, a “Subsidiary” and collectively, the “Subsidiaries”). Except as set forth in the Registration Statement and in the Prospectus, the Company owns, directly or indirectly, all of the equity interests of the Subsidiaries free and clear of any lien, charge, security interest, encumbrance, right of first refusal or other restriction, and all the equity interests of the Subsidiaries are validly issued and are fully paid, nonassessable and free of preemptive and similar rights.

(h) No Violation or Default. Neither the Company nor any of its Subsidiaries is (i) in violation of its charter or by-laws or similar organizational documents; (ii) in default, and

no event has occurred that, with notice or lapse of time or both, would constitute such a default, in the due performance or observance of any term, covenant or condition contained in any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company or any of its Subsidiaries is a party or by which the Company or any of its Subsidiaries is bound or to which any of the property or assets of the Company or any of its Subsidiaries are subject; or (iii) in violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority, except, in the case of each of clauses (ii) and (iii) above, for any such violation or default that would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. To the Company's knowledge, no other party under any material contract or other agreement to which it or any of its Subsidiaries is a party is in default in any respect thereunder where such default would have a Material Adverse Effect.

(i) No Material Adverse Change. Subsequent to December 31, 2012, and other than the Company's execution of this Agreement and the sale of any Placement Shares hereunder and the Company's execution of an At-The-Market Issuance Sales Agreement substantially similar to this Agreement with Brinson Patrick Securities Corporation (the "Concurrent Facility Agreement") and the sale of any shares of the Company's common stock thereunder, there has not been (i) any Material Adverse Effect, (ii) any transaction which is material to the Company and the Subsidiaries taken as a whole, (iii) any obligation or liability, direct or contingent (including any off-balance sheet obligations), incurred by the Company or any Subsidiary, which is material to the Company and the Subsidiaries taken as a whole, (iv) any material change in the capital stock or outstanding long-term indebtedness of the Company or any of its Subsidiaries or (v) any dividend or distribution of any kind declared, paid or made on the capital stock of the Company or any Subsidiary, other than in each case above (A) in the ordinary course of business, (B) as otherwise disclosed in the Registration Statement or Prospectus (including any document deemed incorporated by reference therein) or (C) where such matter, item, change or development would not make the statements in the Registration Statement or the Prospectus contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading.

(j) Capitalization. The issued and outstanding shares of capital stock of the Company have been validly issued, are fully paid and non-assessable and, other than as disclosed in or contemplated by the Registration Statement or the Prospectus, and are not subject to any preemptive rights, rights of first refusal or similar rights. The Company has an authorized, issued and outstanding capitalization as set forth in the Registration Statement and the Prospectus as of the dates referred to therein (other than the grant of additional options or other equity awards under the Company's existing stock option plans, or changes in the number of outstanding shares of Common Stock of the Company due to the issuance of shares upon the exercise or conversion of securities exercisable for, or convertible into, shares of Common Stock outstanding on the date hereof or described in the Registration Statement and the Prospectus (including any document deemed incorporated by reference therein) or as a result of the issuance of Placement Shares or shares of the Company's common stock under the Concurrent Facility Agreement) and such authorized capital stock conforms in all material respects to the description thereof set forth in the Registration Statement and the Prospectus. The description of the

Common Stock in the Registration Statement and the Prospectus (including any document deemed incorporated by reference therein) is complete and accurate in all material respects. Other than as set forth or described in the Registration Statement and the Prospectus, as of the dates referred to therein, the Company did not have outstanding any options to purchase, or any rights or warrants to subscribe for, or any securities or obligations convertible into, or exchangeable for, or any contracts or commitments to issue or sell, any shares of capital stock or other securities.

(k) Authorization; Enforceability. The Company has full legal right, power and authority to enter into this Agreement and perform the transactions contemplated hereby. This Agreement has been duly authorized, executed and delivered by the Company and is a legal, valid and binding agreement of the Company enforceable against the Company in accordance with its terms, except to the extent that (i) enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally and by general equitable principles and (ii) the indemnification and contribution provisions of Section 11 hereof may be limited by federal or state securities laws and public policy considerations in respect thereof.

(l) Authorization of Placement Shares. The Placement Shares, when issued and delivered pursuant to the terms approved by the board of directors of the Company or a duly authorized committee thereof, or a duly authorized executive committee, against payment therefor as provided herein, will be duly and validly authorized and issued and fully paid and nonassessable, free and clear of any pledge, lien, encumbrance, security interest or other claim (other than any pledge, lien, encumbrance, security interest or other claim arising from an act or omission of MLV or a purchaser), including any statutory or contractual preemptive rights, resale rights, rights of first refusal or other similar rights, and will be registered pursuant to Section 12 of the Exchange Act. The Placement Shares, when issued, will conform in all material respects to the description thereof set forth in or incorporated into the Prospectus.

(m) No Consents Required. No consent, approval, authorization, order, registration or qualification of or with any court or arbitrator or any governmental or regulatory authority is required for the execution, delivery and performance by the Company of this Agreement, and the issuance and sale by the Company of the Placement Shares as contemplated hereby, except for the registration of the Placement Shares under the Securities Act and such consents, approvals, authorizations, orders and registrations or qualifications as may be required under applicable state securities laws or by the by-laws and rules of the Financial Industry Regulatory Authority ("FINRA") or the Exchange in connection with the sale of the Placement Shares by MLV.

(n) No Preferential Rights. Except as set forth in the Registration Statement and the Prospectus, (i) no person, as such term is defined in Rule 1-02 of Regulation S-X promulgated under the Securities Act (each, a "Person"), has the right, contractual or otherwise, to cause the Company to issue or sell to such Person any shares of Common Stock or shares of any other capital stock or other securities of the Company (other than upon the exercise of options or warrants to purchase Common Stock or upon the exercise of options or stock awards that may be granted from time to time under the Company's stock option plans), (ii) no Person

has any preemptive rights, rights of first refusal, or any other rights (whether pursuant to a “poison pill” provision or otherwise) to purchase any shares of Common Stock or shares of any other capital stock or other securities of the Company from the Company which have not been duly waived with respect to the offering contemplated hereby, (iii) except as may be disclosed to MLV in writing, no Person has the right to act as an underwriter or as a financial advisor to the Company in connection with the offer and sale of the Common Stock, and (iv) no Person has the right, contractual or otherwise, to require the Company to register under the Securities Act any shares of Common Stock or shares of any other capital stock or other securities of the Company, or to include any such shares or other securities in the Registration Statement or the offering contemplated thereby, whether as a result of the filing or effectiveness of the Registration Statement or the sale of the Placement Shares as contemplated thereby or otherwise.

(o) Independent Public Accountants. Deloitte & Touche LLP, whose report on the consolidated financial statements of the Company is filed with the Commission as part of the Company’s most recent Annual Report on Form 10-K filed with the Commission and incorporated into the Registration Statement, is and, during the periods covered by its reports, was an independent public accounting firm within the meaning of the Securities Act and the Public Company Accounting Oversight Board (United States). To the Company’s knowledge, Deloitte & Touche LLP is not in violation of the auditor independence requirements of the Sarbanes-Oxley Act of 2002 (the “Sarbanes-Oxley Act”) with respect to the Company.

(p) Enforceability of Agreements. To the Company’s knowledge, all agreements between the Company and third parties expressly referenced in the Prospectus, other than such agreements that have expired by their terms or whose termination is disclosed in documents filed by the Company on EDGAR, are legal, valid and binding obligations of the Company enforceable in accordance with their respective terms, except to the extent that (i) enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors’ rights generally and by general equitable principles and (ii) the indemnification provisions of certain agreements may be limited by federal or state securities laws or public policy considerations in respect thereof, except for any unenforceability that, individually or in the aggregate, would not reasonably be expected to have a Material Adverse Effect.

(q) No Litigation. There are no legal, governmental or regulatory actions, suits or proceedings pending, nor, to the Company’s knowledge, any legal, governmental or regulatory investigations, to which the Company or a Subsidiary is a party or to which any property of the Company or any of its Subsidiaries is the subject that, individually or in the aggregate, if determined adversely to the Company or any of its Subsidiaries, would reasonably be expected to have a Material Adverse Effect or materially and adversely affect the ability of the Company to perform its obligations under this Agreement; to the Company’s knowledge, no such actions, suits or proceedings are threatened or contemplated by any governmental or regulatory authority or threatened by others that, individually or in the aggregate, if determined adversely to the Company or any of its Subsidiaries, would reasonably be expected to have a Material Adverse Effect; and (i) there are no current or pending legal, governmental or regulatory actions, suits or proceedings or, to the Company’s knowledge, investigations that are required under the Securities Act to be described in the Prospectus that are not described in the

Prospectus including any Incorporated Document; and (ii) there are no contracts or other documents that are required under the Securities Act to be filed as exhibits to the Registration Statement that are not so filed.

(r) Licenses and Permits. The Company and each of its Subsidiaries possess or have obtained, all licenses, certificates, consents, orders, approvals, permits and other authorizations issued by, and have made all declarations and filings with, the appropriate federal, state, local or foreign governmental or regulatory authorities that are necessary for the ownership or lease of their respective properties or the conduct of their respective businesses as described in the Registration Statement and the Prospectus (the "Permits"), except where the failure to possess, obtain or make the same would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. Neither the Company nor any of its Subsidiaries have received written notice of any proceeding relating to revocation or modification of any such Permit or has any reason to believe that such Permit will not be renewed in the ordinary course, except where the failure to obtain any such renewal would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(s) Market Capitalization. As of the close of trading on the Exchange on the Trading Day immediately prior to the date of this Agreement, the aggregate market value of the outstanding voting and non-voting common equity (as defined in Securities Act Rule 405) of the Company held by persons other than affiliates (as defined in Securities Act Rule 405) was \$75 million or more (calculated in accordance with Instruction 1.B.1 of Form S-3). The Company is not a shell company (as defined in Rule 405 under the Securities Act) and has not been a shell company for at least 12 calendar months previously and if it has been a shell company at any time previously, has filed current Form 10 information (as defined in Instruction 1.B.6 of Form S-3) with the Commission at least 12 calendar months previously reflecting its status as an entity that is not a shell company. To enable MLV to rely on Rule 5110(b)(7)(C)(i) of FINRA, the Company represents that, as of the date of this Agreement, the Company (i) has a non-affiliate, public common equity float of at least \$150 million or a non-affiliate, public common equity float of at least \$100 million and annual trading volume of at least three million shares and (ii) has been subject to the Exchange Act reporting requirements for a period of at least 36 months.

(t) No Material Defaults. Neither the Company nor any of the Subsidiaries has defaulted on any installment on indebtedness for borrowed money or on any rental on one or more long-term leases, which defaults, individually or in the aggregate, would reasonably be expected to have a Material Adverse Effect. The Company has not filed a report pursuant to Section 13(a) or 15(d) of the Exchange Act since the filing of its last Annual Report on Form 10-K, indicating that it (i) has failed to pay any dividend or sinking fund installment on preferred stock or (ii) has defaulted on any installment on indebtedness for borrowed money or on any rental on one or more long-term leases, which defaults, individually or in the aggregate, would reasonably be expected to have a Material Adverse Effect.

(u) Certain Market Activities. Neither the Company, nor any of the Subsidiaries, nor, to the Company's knowledge, any of their respective directors, officers or controlling persons has taken, directly or indirectly, any action designed, or that has constituted or might reasonably be expected to cause or result in, under the Exchange Act or otherwise, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Placement Shares.

(v) Broker/Dealer Relationships. Neither the Company nor any of the Subsidiaries or any related entities (i) is required to register as a “broker” or “dealer” in accordance with the provisions of the Exchange Act or (ii) directly or indirectly through one or more intermediaries, controls or is a “person associated with a member” or “associated person of a member” (within the meaning set forth in the FINRA Manual).

(w) No Reliance. The Company has not relied upon MLV or legal counsel for MLV for any legal, tax or accounting advice in connection with the offering and sale of the Placement Shares.

(x) Taxes. The Company and each of its Subsidiaries have filed all federal, state, local and foreign tax returns which have been required to be filed and paid all taxes shown thereon through the date hereof, to the extent that such taxes have become due and are not being contested in good faith, except where the failure to do so would not reasonably be expected to have a Material Adverse Effect. Except as otherwise disclosed in or contemplated by the Registration Statement or the Prospectus, no tax deficiency has been determined adversely to the Company or any of its Subsidiaries which has had, or would reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect. The Company has no knowledge of any federal, state or other governmental tax deficiency, penalty or assessment which has been asserted or threatened against it which would have a Material Adverse Effect.

(y) Title to Real and Personal Property. The Company and its Subsidiaries have good and marketable title in fee simple to all items of real property and good and valid title to all personal property (excluding Intellectual Property) described in the Registration Statement or Prospectus as being owned by them that are material to the businesses of the Company or such Subsidiary, in each case free and clear of all liens, encumbrances and claims, except those that (i) do not materially interfere with the use made of such property by the Company and any of its Subsidiaries or (ii) would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. Any real property described in the Registration Statement or Prospectus as being leased by the Company and any of its Subsidiaries is held by them under valid, existing and enforceable leases, except those that (A) do not materially interfere with the use made or proposed to be made of such property by the Company or any of its Subsidiaries or (B) would not be reasonably expected, individually or in the aggregate, to have a Material Adverse Effect.

(z) Intellectual Property. To its knowledge, the Company and its Subsidiaries own or possess adequate rights to use all patents, patent applications, trademarks (both registered and unregistered), service marks, trade names, trademark registrations, service mark registrations, copyrights, licenses and know-how (including trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures) (collectively, the “Intellectual Property”), necessary for the conduct of their respective businesses as conducted as of the date hereof, except to the extent that the failure to own or possess adequate rights to use such Intellectual Property would not, individually or in the aggregate, reasonably be expected to

have a Material Adverse Effect; except as disclosed in writing to MLV, the Company and any of its Subsidiaries have not received any written notice of any claim of infringement or conflict which asserted Intellectual Property rights of others, which infringement or conflict, if the subject of an unfavorable decision, would result in a Material Adverse Effect; there are no pending, or to the Company's knowledge, threatened judicial proceedings or interference proceedings against the Company or its Subsidiaries challenging the Company's or its Subsidiaries' rights in or to or the validity of the scope of any of the Company's or its Subsidiaries' owned material patents, patent applications or proprietary information; no other entity or individual has any right or claim in any of the Company's or its Subsidiaries' owned material patents, patent applications or any patent to be issued therefrom by virtue of any contract, license or other agreement entered into between such entity or individual and the Company or a Subsidiary or by any non-contractual obligation of the Company or a Subsidiary, other than by written licenses granted by the Company or a Subsidiary and other than such rights or claims that would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect; the Company and its Subsidiaries have not received any written notice of any claim challenging the rights of the Company or a Subsidiary in or to any Intellectual Property owned, licensed or optioned by the Company or such Subsidiary which claim, if the subject of an unfavorable decision, would result in a Material Adverse Effect.

(aa) Environmental Laws. The Company and its Subsidiaries (i) are in compliance with any and all applicable federal, state, local and foreign laws, rules, regulations, decisions and orders relating to the protection of human health and safety, the environment or hazardous or toxic substances or wastes, pollutants or contaminants (collectively, "Environmental Laws"); (ii) have received and are in compliance with all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses as described in the Registration Statement and the Prospectus; and (iii) have not received notice of any actual or potential liability for the investigation or remediation of any disposal or release of hazardous or toxic substances or wastes, pollutants or contaminants, except, in the case of any of clauses (i), (ii) or (iii) above, for any such failure to comply or failure to receive required permits, licenses, other approvals or liability as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(bb) Disclosure Controls. The Company and each of its Subsidiaries maintain systems of internal accounting controls designed to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company is not aware of any material weaknesses in its internal control over financial reporting (other than as set forth in the Prospectus). Since the date of the latest audited financial statements of the Company included in the Prospectus, there has been no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting (other than as set forth in the Prospectus). The Company has established disclosure controls and procedures (as

defined in Exchange Act Rules 13a-15 and 15d-15) for the Company and designed such disclosure controls and procedures to ensure that material information relating to the Company and each of its Subsidiaries is made known to the certifying officers by others within those entities, particularly during the period in which the Company's Annual Report on Form 10-K or Quarterly Report on Form 10-Q, as the case may be, is being prepared. The Company's certifying officers have evaluated the effectiveness of the Company's controls and procedures as of a date within 90 days prior to the filing date of the Form 10-K for the fiscal year most recently ended (such date, the "Evaluation Date"). The Company presented in its Form 10-K for the fiscal year most recently ended the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there have been no significant changes in the Company's internal controls (as such term is defined in Item 307(b) of Regulation S-K under the Securities Act) or, to the Company's knowledge, in other factors that could significantly adversely affect the Company's internal controls. To the knowledge of the Company, the Company's "internal controls over financial reporting" and "disclosure controls and procedures" are effective.

(cc) Sarbanes-Oxley. There is and has been no failure on the part of the Company or, to the knowledge of the Company, any of the Company's directors or officers, in their capacities as such, to comply with any applicable provisions of the Sarbanes-Oxley Act and the rules and regulations promulgated thereunder. Each of the principal executive officer and the principal financial officer of the Company (or each former principal executive officer of the Company and each former principal financial officer of the Company as applicable) has made all certifications required by Sections 302 and 906 of the Sarbanes-Oxley Act with respect to all reports, schedules, forms, statements and other documents required to be filed by it or furnished by it to the Commission. For purposes of the preceding sentence, "principal executive officer" and "principal financial officer" shall have the meanings given to such terms in the Sarbanes-Oxley Act.

(dd) Finder's Fees. Neither the Company nor any of the Subsidiaries has incurred any liability for any finder's fees, brokerage commissions or similar payments in connection with the transactions herein contemplated, except as may otherwise exist with respect to MLV pursuant to this Agreement.

(ee) Labor Disputes. No labor disturbance by or dispute with employees of the Company or any of its Subsidiaries exists or, to the knowledge of the Company, is threatened which would reasonably be expected to result in a Material Adverse Effect

(ff) Investment Company Act. Neither the Company nor any of the Subsidiaries is or, after giving effect to the offering and sale of the Placement Shares, will be an "investment company" or an entity "controlled" by an "investment company," as such terms are defined in the Investment Company Act of 1940, as amended (the "Investment Company Act").

(gg) Operations. The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial record keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all jurisdictions to which the Company or its

Subsidiaries are subject, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency having jurisdiction over the Company or its Subsidiaries (collectively, the “Money Laundering Laws”), except as would not reasonably be expected to result in a Material Adverse Effect; and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its Subsidiaries with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(hh) Off-Balance Sheet Arrangements. There are no transactions, arrangements and other relationships between and/or among the Company, and/or, to the knowledge of the Company, any of its affiliates and any unconsolidated entity, including, but not limited to, any structured finance, special purpose or limited purpose entity (each, an “Off Balance Sheet Transaction”) that would reasonably be expected to affect materially the Company’s liquidity or the availability of or requirements for its capital resources, including those Off Balance Sheet Transactions described in the Commission’s Statement about Management’s Discussion and Analysis of Financial Conditions and Results of Operations (Release Nos. 33-8056; 34-45321; FR-61), in each case that are required to be described in the Prospectus which have not been described as required.

(ii) Underwriter Agreements. The Company anticipates being a party to the Concurrent Facility Agreement simultaneous with this Agreement, but will not have an open sales order in force with more than one agent or underwriter under such agreements at any given time, provided, however, that nothing in this Agreement shall prohibit the Company from entering into the Concurrent Facility Agreement, a committed equity financing facility or similar transaction.

(jj) ERISA. To the knowledge of the Company, (i) each material employee benefit plan, within the meaning of Section 3(3) of the Employee Retirement Income Security Act of 1974, as amended (“ERISA”), that is maintained, administered or contributed to by the Company or any of its affiliates for employees or former employees of the Company and any of its Subsidiaries has been maintained in material compliance with its terms and the requirements of any applicable statutes, orders, rules and regulations, including but not limited to ERISA and the Internal Revenue Code of 1986, as amended (the “Code”); (ii) no prohibited transaction, within the meaning of Section 406 of ERISA or Section 4975 of the Code, has occurred with respect to any such plan excluding transactions effected pursuant to a statutory or administrative exemption; and (iii) for each such plan that is subject to the funding rules of Section 412 of the Code or Section 302 of ERISA, no “accumulated funding deficiency” as defined in Section 412 of the Code has been incurred, whether or not waived, and the fair market value of the assets of each such plan (excluding for these purposes accrued but unpaid contributions) equals or exceeds the present value of all benefits accrued under such plan determined using reasonable actuarial assumptions, other than, in the case of (i), (ii) and (iii) above, as would not reasonably be expected to have a Material Adverse Effect.

(kk) Forward Looking Statements. No forward-looking statement (within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act) (a “Forward Looking Statement”) contained in the Registration Statement and the Prospectus has been made

or reaffirmed without a reasonable basis or has been disclosed other than in good faith. The Forward Looking Statements incorporated by reference in the Registration Statement and the Prospectus from the Company's Annual Report on Form 10-K for the fiscal year most recently ended (i) except for any Forward Looking Statement included in any financial statements and notes thereto, are within the coverage of the safe harbor for forward looking statements set forth in Section 27A of the Securities Act, Rule 175(b) under the Securities Act or Rule 3b-6 under the Exchange Act, as applicable, (ii) were made by the Company with a reasonable basis and in good faith and reflect the Company's good faith commercially reasonable best estimate of the matters described therein, and (iii) have been prepared in accordance with Item 10 of Regulation S-K under the Securities Act.

(ll) Margin Rules. Neither the issuance, sale and delivery of the Placement Shares nor the application of the proceeds thereof by the Company as described in the Registration Statement and the Prospectus will violate Regulation T, U or X of the Board of Governors of the Federal Reserve System or any other regulation of such Board of Governors.

(mm) Insurance. The Company and each of its Subsidiaries carry, or are covered by, insurance in such amounts and covering such risks as the Company and each of its Subsidiaries reasonably believe are adequate for the use of their properties and as is customary for companies of similar size engaged in similar businesses in similar industries.

(nn) No Improper Practices. (i) Neither the Company nor, to the Company's knowledge, the Subsidiaries, nor to the Company's knowledge, any of their respective executive officers has, in the past five years, made any unlawful contributions to any candidate for any political office (or failed fully to disclose any contribution in violation of law) or made any contribution or other payment to any official of, or candidate for, any federal, state, municipal, or foreign office or other person charged with similar public or quasi-public duty in violation of any law or of the character required to be disclosed in the Prospectus; (ii) no relationship, direct or indirect, exists between or among the Company or, to the Company's knowledge, any Subsidiary or any affiliate of any of them, on the one hand, and the directors, officers and stockholders of the Company or, to the Company's knowledge, any Subsidiary, on the other hand, that is required by the Securities Act to be described in the Registration Statement and the Prospectus that is not so described; (iii) no relationship, direct or indirect, exists between or among the Company or any Subsidiary or any affiliate of them, on the one hand, and the directors, officers, stockholders or directors of the Company or, to the Company's knowledge, any Subsidiary, on the other hand, that is required by the rules of FINRA to be described in the Registration Statement and the Prospectus that is not so described; (iv) except as described in the Prospectus, there are no material outstanding loans or advances or material guarantees of indebtedness by the Company or, to the Company's knowledge, any Subsidiary to or for the benefit of any of their respective officers or directors or any of the members of the families of any of them; (v) the Company has not offered, or caused any placement agent to offer, Common Stock to any person with the intent to influence unlawfully (A) a customer or supplier of the Company or any Subsidiary to alter the customer's or supplier's level or type of business with the Company or any Subsidiary or (B) a trade journalist or publication to write or publish favorable information about the Company or any Subsidiary or any of their respective products or services; and (vi) neither the Company nor any Subsidiary nor, to the Company's knowledge, any employee or

agent of the Company or any Subsidiary has made any payment of funds of the Company or any Subsidiary or received or retained any funds in violation of any law, rule or regulation (including, without limitation, the Foreign Corrupt Practices Act of 1977), which payment, receipt or retention of funds is of a character required to be disclosed in the Registration Statement or the Prospectus.

(oo) Status Under the Securities Act. The Company was not and is not an ineligible issuer as defined in Rule 405 under the Securities Act at the times specified in Rules 164 and 433 under the Securities Act in connection with the offering of the Placement Shares.

(pp) No Misstatement or Omission in an Issuer Free Writing Prospectus. Each Issuer Free Writing Prospectus, as of its issue date and as of each Applicable Time (as defined in Section 24 below), did not, does not and will not include any information that conflicted, conflicts or will conflict with the information contained in the Registration Statement or the Prospectus, including any incorporated document deemed to be a part thereof that has not been superseded or modified. The foregoing sentence does not apply to statements in or omissions from any Issuer Free Writing Prospectus based upon and in conformity with written information furnished to the Company by MLV specifically for use therein.

(qq) No Conflicts. Neither the execution of this Agreement by the Company, nor the issuance, offering or sale of the Placement Shares, nor the consummation by the Company of any of the transactions contemplated herein and therein, nor the compliance by the Company with the terms and provisions hereof and thereof will conflict with, or will result in a breach of, any of the terms and provisions of, or has constituted or will constitute a default under, or has resulted in or will result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company pursuant to the terms of any contract or other agreement to which the Company may be bound or to which any of the property or assets of the Company is subject, except (i) such conflicts, breaches or defaults as may have been waived and (ii) such conflicts, breaches, defaults, liens, charges or encumbrances that would not reasonably be expected to have a Material Adverse Effect; nor will such action result (x) in any violation of the provisions of the certificate of incorporation or bylaws of the Company, or

(y) in any material violation of the provisions of any statute or any order, rule or regulation applicable to the Company or of any court or of any federal, state or other regulatory authority or other government body having jurisdiction over the Company, except where such violation would not reasonably be expected to have a Material Adverse Effect.

(rr) Clinical Studies. The clinical, pre-clinical and other studies and tests conducted by or, to the knowledge of the Company, on behalf of the Company were, and, if still pending, are being, conducted in accordance in all material respects with all applicable statutes, laws, rules and regulations (including, without limitation, those administered by the United States Food and Drug Administration (the "FDA") or by any foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA), except where the failure do so would not have a Material Adverse Effect. The Company has not received any written notices or other written correspondence from the FDA or any other foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA requiring the Company to terminate or suspend any ongoing clinical or pre-clinical studies or tests.

(ss) Compliance Program. The Company has established and administers a compliance program applicable to the Company, to assist the Company and the directors, officers and employees of the Company in complying with applicable regulatory guidelines (including, without limitation, those administered by the FDA and any other foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA); except where such noncompliance would not reasonably be expected to have a Material Adverse Effect.

(tt) OFAC. (i) Neither the Company nor any of its Subsidiaries (collectively, the "Entity") or, to the Company's knowledge, any director, officer, employee, agent, affiliate or representative of the Entity, is a government, individual, or entity (in this paragraph (tt), "Person") that is, or is owned or controlled by a Person that is:

(A) the subject of any sanctions administered or enforced by the U.S. Department of Treasury's Office of Foreign Assets Control ("OFAC"), the United Nations Security Council ("UNSC"), the European Union ("EU"), Her Majesty's Treasury ("HMT"), or other relevant sanctions authority (collectively, "Sanctions"), nor

(B) located, organized or resident in a country or territory that is the subject of Sanctions (including, without limitation, Burma/Myanmar, Cuba, Iran, North Korea, Sudan and Syria).

(ii) The Company represents and covenants that the Entity will not, directly or indirectly, knowingly use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other Person:

(A) to fund or facilitate any activities or business of or with any Person or in any country or territory that, at the time of such funding or facilitation, is the subject of Sanctions; or

(B) in any other manner that will result in a violation of Sanctions by any Person (including any Person participating in the offering, whether as underwriter, advisor, investor or otherwise).

(iii) The Company represents and covenants that, except as detailed in the Prospectus, for the past five years, the Entity has not knowingly engaged in, is not now knowingly engaged in, and will not knowingly engage in, any dealings or transactions with any Person, or in any country or territory, that at the time of the dealing or transaction is or was the subject of Sanctions.

(uu) Stock Transfer Taxes. On each Settlement Date, all stock transfer or other taxes (other than income taxes) which are required to be paid in connection with the sale and transfer of the Placement Shares to be sold hereunder will be, or will have been, fully paid or provided for by the Company and all laws imposing such taxes will be or will have been fully complied with in all material respects.

Any certificate signed by an officer of the Company and delivered to MLV or to counsel for MLV pursuant to or in connection with this Agreement shall be deemed to be a representation and warranty by the Company, as applicable, to MLV as to the matters set forth therein.

**7. Covenants of the Company.** The Company covenants and agrees with MLV that:

(a) **Registration Statement Amendments.** After the date of this Agreement and during any period in which a Prospectus relating to any Placement Shares is required to be delivered by MLV under the Securities Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act) (the "Prospectus Delivery Period"), (i) the Company will notify MLV promptly of the time when any subsequent amendment to the Registration Statement, other than documents incorporated by reference, has been filed with the Commission and/or has become effective or any subsequent supplement to the Prospectus (other than documents incorporated by reference therein) has been filed and of any request by the Commission for any amendment or supplement to the Registration Statement or Prospectus or for additional information, (ii) the Company will not file any amendment or supplement to the Registration Statement or Prospectus (except for documents incorporated by reference therein) unless a copy thereof has been submitted to MLV at least two Business Days before the filing and MLV has not reasonably and in good faith objected thereto within two Business Days of receiving such copy (provided, however, that (A) the failure of MLV to make such objection shall not relieve the Company of any obligation or liability hereunder, or affect MLV's right to rely on the representations and warranties made by the Company in this Agreement, (B) the Company has no obligation to provide MLV any advance copy of such filing or to provide MLV an opportunity to object to such filing if such filing does not name MLV or does not relate to the transactions contemplated by this Agreement, and (C) the only remedy MLV shall have with respect to the failure by the Company to provide MLV with such copy or the filing of such amendment or supplement despite MLV's objection shall be to cease making sales under this Agreement) and the Company will furnish to MLV at the time of filing thereof a copy of any document that upon filing is deemed to be incorporated by reference into the Registration Statement or Prospectus, except for those documents available via EDGAR; and (iii) the Company will cause each amendment or supplement to the Prospectus to be filed with the Commission as required pursuant to the applicable paragraph of Rule 424(b) of the Securities Act or, in the case of any document to be incorporated therein by reference, to be filed with the Commission as required pursuant to the Exchange Act, within the time period prescribed (the determination to file or not file any amendment or supplement with the Commission under this Section 7(a), based on the Company's reasonable opinion or reasonable objections, shall be made exclusively by the Company).

(b) **Notice of Commission Stop Orders.** The Company will advise MLV, promptly after it receives notice or obtains knowledge thereof, of the issuance or threatened issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement, of the suspension of the qualification of the Placement Shares for offering or sale in any jurisdiction, or of the initiation or threatening of any proceeding for any such purpose; and it

will promptly use its commercially reasonable efforts to prevent the issuance of any stop order or to obtain its withdrawal if such a stop order should be issued. The Company will advise MLV promptly after it receives any request by the Commission for any amendments to the Registration Statement or any amendment or supplements to the Prospectus or any Issuer Free Writing Prospectus or for additional information related to the offering of the Placement Shares or for additional information related to the Registration Statement, the Prospectus or any Issuer Free Writing Prospectus.

(c) Delivery of Prospectus; Subsequent Changes. During the Prospectus Delivery Period, the Company will use commercially reasonable efforts to comply in all material respects with all requirements imposed upon it by the Securities Act, as from time to time in force, and to file on or before their respective due dates all reports and any definitive proxy or information statements required to be filed by the Company with the Commission pursuant to Sections 13(a), 13(c), 14, 15(d) or any other provision of or under the Exchange Act. If the Company has omitted any information from the Registration Statement pursuant to Rule 430A under the Securities Act, it will use its best efforts to comply with the provisions of and make all requisite filings with the Commission pursuant to said Rule 430A and to notify MLV promptly of all such filings. If during the Prospectus Delivery Period any event occurs as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances then existing, not misleading, or if during such period it is necessary to amend or supplement the Registration Statement or Prospectus to comply with the Securities Act, the Company will promptly notify MLV to suspend the offering of Placement Shares during such period and the Company will promptly amend or supplement the Registration Statement or Prospectus (at the expense of the Company) so as to correct such statement or omission or effect such compliance; provided, however, that the Company may delay any such amendment or supplement if, in the judgment of the Company, it is in the best interests of the Company to do so.

(d) Listing of Placement Shares. During the Prospectus Delivery Period, the Company will use its commercially reasonable efforts to cause the Placement Shares to be listed on the Exchange and to qualify the Placement Shares for sale under the securities laws of such jurisdictions as MLV reasonably designates and to continue such qualifications in effect so long as required for the distribution of the Placement Shares; provided, however, that the Company shall not be required in connection therewith to qualify as a foreign corporation or dealer in securities or file a general consent to service of process in any jurisdiction.

(e) Delivery of Registration Statement and Prospectus. The Company will furnish to MLV and its counsel (at the expense of the Company) copies of the Registration Statement, the Prospectus (including all documents incorporated by reference therein) and all amendments and supplements to the Registration Statement or Prospectus that are filed with the Commission during the Prospectus Delivery Period (including all documents filed with the Commission during such period that are deemed to be incorporated by reference therein), in each case as soon as reasonably practicable and in such quantities as MLV may from time to time reasonably request and, at MLV's request, will also furnish copies of the Prospectus to each exchange or market on which sales of the Placement Shares may be made; provided, however, that the Company shall not be required to furnish any document (other than the Prospectus) to MLV to the extent such document is available on EDGAR.

(f) Earnings Statement. The Company will make generally available to its security holders as soon as practicable, but in any event not later than 15 months after the end of the Company's current fiscal quarter, an earnings statement covering a 12-month period that satisfies the provisions of Section 11(a) and Rule 158 of the Securities Act.

(g) Use of Proceeds. The Company will use the Net Proceeds as described in the Prospectus in the section entitled "Use of Proceeds."

(h) Notice of Other Sales. Without the prior written consent of MLV, the Company will not, directly or indirectly, offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any Common Stock (other than the Placement Shares offered pursuant to this Agreement) or securities convertible into or exchangeable for Common Stock, warrants or any rights to purchase or acquire, Common Stock during the period beginning on the second (2nd) Trading Day immediately prior to the date on which any Placement Notice is delivered to MLV hereunder and ending on the second (2nd) Trading Day immediately following the final Settlement Date with respect to Placement Shares sold pursuant to such Placement Notice (or, if the Placement Notice has been terminated or suspended prior to the sale of all Placement Shares covered by a Placement Notice, the date of such suspension or termination); and, at any time during which a Placement Notice is pending and for two (2) Trading Days after the last sale of Placement Shares under such Placement Notice, will not directly or indirectly in any other "at the market" or continuous equity transaction offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any shares of Common Stock (other than the Placement Shares offered pursuant to this Agreement) or securities convertible into or exchangeable for Common Stock, warrants or any rights to purchase or acquire, Common Stock prior to the termination of this Agreement with respect to Placement Shares sold pursuant to such Placement Notice; provided, however, that such restrictions will not be required in connection with the Company's issuance or sale of (i) Common Stock, options to purchase Common Stock or stock awards or Common Stock issuable upon the exercise of options or vesting of stock awards, pursuant to any employee or director stock option or benefits plan, stock ownership plan or dividend reinvestment plan (but not Common Stock subject to a waiver to exceed plan limits in its dividend reinvestment plan) of the Company whether now in effect or hereafter implemented; (ii) Common Stock issuable upon conversion of securities or the exercise of warrants, options or other rights in effect or outstanding, and disclosed in filings by the Company available on EDGAR or otherwise in writing to MLV and (iii) Common Stock, or securities convertible into or exercisable for Common Stock, offered and sold in a privately negotiated transaction to vendors, customers, investors, strategic partners or potential strategic partners and conducted in a manner so as not to be integrated with the offering of Common Stock hereby.

(i) Change of Circumstances. The Company will, at any time during the pendency of a Placement Notice advise MLV promptly after it shall have received notice or obtained knowledge thereof, of any information or fact that would alter or affect in any material respect any opinion, certificate, letter or other document required to be provided to MLV pursuant to this Agreement.

(j) Due Diligence Cooperation. The Company will cooperate with any reasonable due diligence review conducted by MLV or its representatives in connection with the transactions contemplated hereby, including, without limitation, providing information and making available documents and senior corporate officers, during regular business hours and at the Company's principal offices or such other location mutually agreeable by the parties, as MLV may reasonably request.

(k) Required Filings Relating to Placement of Placement Shares. The Company agrees that on such dates as the Securities Act shall require, the Company will (i) file a prospectus supplement with the Commission under the applicable paragraph of Rule 424(b) under the Securities Act (the date of each and every such filing under Rule 424(b), a "Filing Date"), which prospectus supplement will set forth, within the relevant period, the amount of Placement Shares sold through MLV, the Net Proceeds to the Company and the compensation payable by the Company to MLV with respect to such Placement Shares, and (ii) deliver such number of copies of each such prospectus supplement to each exchange or market on which such sales were effected as may be required by the rules or regulations of such exchange or market.

(l) Representation Dates; Certificate. On the date of this Agreement and each time during the term of this Agreement the Company:

(i) files the Prospectus relating to the Placement Shares or amends or supplements (other than a prospectus supplement relating solely to an offering of securities other than the Placement Shares) the Registration Statement or the Prospectus relating to the Placement Shares by means of a post-effective amendment, sticker, or supplement but not by means of incorporation of documents by reference into the Registration Statement or the Prospectus relating to the Placement Shares;

(ii) files an annual report on Form 10-K under the Exchange Act (including any Form 10-K/A containing restated financial statements or a material amendment to the previously filed Form 10-K);

(iii) files its quarterly reports on Form 10-Q under the Exchange Act; or

(iv) files a current report on Form 8-K containing amended audited financial information (other than information "furnished" pursuant to Items 2.02 or 7.01 of Form 8-K or to provide disclosure pursuant to Item 8.01 of Form 8-K relating to the reclassification of certain properties as discontinued operations in accordance with Statement of Financial Accounting Standards No. 144) under the Exchange Act;

(Each date of filing of one or more of the documents referred to in clauses (i) through (iv) shall be a "Representation Date")

the Company shall furnish MLV (but in the case of clause (iv) above only if MLV reasonably determines that the information contained in such Form 8-K is material) with a certificate, in the

form attached hereto as Exhibit 7(l). The requirement to provide a certificate under this Section 7(l) shall be automatically waived for any Representation Date occurring at a time at which no Placement Notice is pending, which waiver shall continue until the date the Company delivers a Placement Notice hereunder (which for such calendar quarter shall be considered a Representation Date); provided, however, that such waiver shall not apply for any Representation Date on which the Company files its annual report on Form 10-K. Notwithstanding the foregoing, if the Company subsequently decides to sell Placement Shares following a Representation Date when the Company relied on such waiver and did not provide MLV with a certificate under this Section 7(l), then before the Company delivers the Placement Notice or MLV sells any Placement Shares, the Company shall provide MLV with a certificate, in the form attached hereto as Exhibit 7(l), dated the date of the Placement Notice.

(m) Legal Opinion. On or prior to the date of the first Placement Notice given hereunder, the Company shall cause to be furnished to MLV a written opinion and letter of Cooley LLP ("Company Counsel"), or such other counsel reasonably satisfactory to MLV, covering opinions and statements substantially in the forms attached hereto as Exhibits 7(m)(1) and 7(m)(2). Thereafter within five (5) Trading Days of each Representation Date with respect to which the Company is obligated to deliver a certificate in the form attached hereto as Exhibit 7(l) for which no waiver is applicable, the Company shall cause to be furnished to MLV a letter of Company Counsel, or other counsel reasonably satisfactory to MLV, covering statements substantially in the form attached hereto as Exhibits 7(m)(2), modified, as necessary, to relate to the Registration Statement and the Prospectus as then amended or supplemented; provided, however, the Company shall be required to furnish to MLV no more than one letter hereunder per calendar quarter and the Company shall not be required to furnish letter if the Company does not intend to deliver a Placement Notice in such calendar quarter until such time as the Company delivers its next Placement Notice; provided, further, that in lieu of such letters for subsequent periodic filings under the Exchange Act, counsel may furnish MLV with a letter (a "Reliance Letter") to the effect that MLV may rely on a prior letter delivered under this Section 7(m) to the same extent as if it were dated the date of such letter (except that statements in such prior letter shall be deemed to relate to the Registration Statement and the Prospectus as amended or supplemented as of the date of the Reliance Letter).

(n) Comfort Letter. On or prior to the date the first Placement Notice is given hereunder and thereafter within five (5) Trading Days after each Representation Date referred to in Section 7(l)(ii), the Company shall cause its independent accountants to furnish MLV letters (the "Comfort Letters"), dated the date the Comfort Letter is delivered, which shall meet the requirements set forth in this Section 7(n); provided, that if requested by MLV, the Company shall cause a Comfort Letter to be furnished to MLV prior to the tenth (10th) Trading Day after the date of occurrence of any material transaction or event (including the restatement of the Company's financial statements) requiring the filing of a current report on Form 8-K containing material financial information and the date the first Placement Notice is given hereunder following such a material transaction or event, whichever is later. The Comfort Letter from the Company's independent accountants shall be in a form and substance reasonably satisfactory to MLV, (i) confirming that they are an independent public accounting firm within the meaning of the Securities Act and the PCAOB, (ii) stating, as of such date, the conclusions and findings of such firm with respect to the financial information and other matters ordinarily covered by

accountants' "comfort letters" to underwriters in connection with registered public offerings (the first such letter, the "Initial Comfort Letter") and (iii) updating the Initial Comfort Letter with any information that would have been included in the Initial Comfort Letter had it been given on such date and modified as necessary to relate to the Registration Statement and the Prospectus, as amended and supplemented to the date of such letter.

(o) Market Activities. The Company will not, directly or indirectly, (i) take any action designed to cause or result in, or that constitutes or might reasonably be expected to constitute, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of Common Stock or (ii) sell, bid for, or purchase Common Stock in violation of Regulation M, or pay anyone any compensation for soliciting purchases of the Placement Shares other than MLV.

(p) Investment Company Act. The Company will conduct its affairs in such a manner so as to reasonably ensure that neither it nor any of its Subsidiaries will be or become, at any time prior to the termination of this Agreement, an "investment company," as such term is defined in the Investment Company Act.

(q) Sarbanes-Oxley Act. The Company and the Subsidiaries will maintain and keep accurate books and records reflecting their assets and maintain internal accounting controls in a manner designed 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 and including those policies and procedures that (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company, (ii) provide reasonable assurance that transactions are recorded as necessary to permit the preparation of the Company's consolidated financial statements in accordance with generally accepted accounting principles, (iii) that receipts and expenditures of the Company are being made only in accordance with management's and the Company's directors' authorization, and (iv) 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 its financial statements. The Company and the Subsidiaries will maintain such controls and other procedures, including, without limitation, those required by Sections 302 and 906 of the Sarbanes-Oxley Act, and the applicable regulations thereunder that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms, including, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure and to ensure that material information relating to the Company or the Subsidiaries is made known to them by others within those entities, particularly during the period in which such periodic reports are being prepared.

8. Representations and Covenants of MLV. MLV represents and warrants that it is duly registered as a broker-dealer under FINRA, the Exchange Act and the applicable statutes and regulations of each state in which the Placement Shares will be offered and sold, except such states in which MLV is exempt from registration or such registration is not otherwise required. MLV shall continue, for the term of this Agreement, to be duly registered as a broker-dealer under FINRA, the Exchange Act and the applicable statutes and regulations of each state in which the Placement Shares will be offered and sold, except such states in which MLV is exempt from registration or such registration is not otherwise required, during the term of this Agreement. MLV will comply with all applicable laws and regulations (including, without limitation, Regulation M) in connection with performing its obligations under this Agreement.

9. Payment of Expenses.

(a) The Company will pay all expenses incident to the performance of its obligations under this Agreement, including (i) the preparation, filing, including any fees required by the Commission, and printing of the Registration Statement (including financial statements and exhibits) as originally filed and of each amendment and supplement thereto and each Issuer Free Writing Prospectus, in such number as MLV shall reasonably deem necessary, (ii) the printing and delivery to MLV of this Agreement and such other documents as may be required in connection with the offering, purchase, sale, issuance or delivery of the Placement Shares, (iii) the preparation, issuance and delivery of the certificates, if any, for the Placement Shares to MLV, including any stock or other transfer taxes and any capital duties, stamp duties or other duties or taxes payable upon the sale, issuance or delivery of the Placement Shares to MLV, (iv) the fees and disbursements of the counsel, accountants and other advisors to the Company, (v) the reasonable fees and disbursements of counsel to MLV, up to a maximum amount of \$25,000, (vi) the fees and expenses of the transfer agent and registrar for the Common Stock, (vii) the filing fees incident to any review by FINRA of the terms of the sale of the Placement Shares, and (viii) the fees and expenses incurred in connection with the listing of the Placement Shares on the Exchange.

(b) If this Agreement is terminated by MLV in accordance with the provisions of Section 13(a) hereof as a result of a material breach by the Company of its obligations hereunder, the Company shall reimburse MLV for all of its reasonable out-of-pocket expenses, including reasonable fees and disbursements of counsel for MLV (less any amounts paid under clause (a)(v) above) up to a maximum of \$25,000.

10. Conditions to MLV's Obligations. The obligations of MLV hereunder with respect to a Placement will be subject to the continuing accuracy and completeness of the representations and warranties made by the Company herein, to the due performance by the Company of its obligations hereunder, to the completion by MLV of a due diligence review satisfactory to it in its reasonable judgment, and to the continuing satisfaction (or waiver by MLV in its sole discretion) of the following additional conditions:

(a) Registration Statement Effective. The Registration Statement shall have become effective and shall be available for the sale of all Placement Shares contemplated to be issued by any Placement Notice.

(b) No Material Notices. None of the following events shall have occurred and be continuing: (i) receipt by the Company of any request for additional information from the Commission or any other federal or state governmental authority during the period of effectiveness of the Registration Statement, the response to which would require any post-effective amendments or supplements to the Registration Statement or the Prospectus; (ii) the issuance by the Commission or any other federal or state governmental authority of any stop order suspending the effectiveness of the Registration Statement or the initiation of any proceedings for that purpose; (iii) receipt by the Company of any notification with respect to the suspension of the qualification or exemption from qualification of any of the Placement Shares for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose; or (iv) any event that makes any material statement made in the Registration Statement or the Prospectus or any material document incorporated or deemed to be incorporated therein by reference untrue in any material respect or that requires the making of any changes in the Registration Statement, the Prospectus or documents so that, in the case of the Registration Statement, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading and, that in the case of the Prospectus, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(c) No Misstatement or Material Omission. MLV shall not have advised the Company that the Registration Statement or Prospectus, or any amendment or supplement thereto, contains an untrue statement of fact that in MLV's reasonable opinion is material, or omits to state a fact that in MLV's opinion is material and is required to be stated therein or is necessary to make the statements therein not misleading.

(d) Material Changes. Except as contemplated in the Prospectus, or disclosed in the Company's reports filed with the Commission, there shall not have been any material adverse change, on a consolidated basis, in the authorized capital stock of the Company or any Material Adverse Effect, or any development in the business or affairs of the Company that could reasonably be expected to cause a Material Adverse Effect.

(e) Legal Opinion. MLV shall have received the opinions of Company Counsel required to be delivered pursuant Section 7(m) on or before the date on which such delivery of such opinions are required pursuant to Section 7(m).

(f) Comfort Letter. MLV shall have received the Comfort Letter required to be delivered pursuant Section 7(n) on or before the date on which such delivery of such letter is required pursuant to Section 7(n).

(g) Representation Certificate. MLV shall have received the certificate required to be delivered pursuant to Section 7(l) on or before the date on which delivery of such certificate is required pursuant to Section 7(l).

(h) No Suspension. Trading in the Common Stock shall not have been suspended on the Exchange and the Common Stock shall not have been delisted from the Exchange.

(i) Other Materials. On each date on which the Company is required to deliver a certificate pursuant to Section 7(l), the Company shall have furnished to MLV such appropriate further information, certificates and documents as MLV may have reasonably requested in writing prior to such date and which are usually and customarily furnished by an issuer of securities in connection with the underwritten public offering thereof. All such opinions, certificates, letters and other documents will be in compliance with the provisions hereof. The Company will furnish MLV with such conformed copies of such opinions, certificates, letters and other documents as MLV shall reasonably request.

(j) Securities Act Filings Made. All filings with the Commission required by Rule 424 under the Securities Act to have been filed prior to the issuance of any Placement Notice hereunder shall have been made within the applicable time period prescribed for such filing by Rule 424.

(k) Approval for Listing. The Placement Shares shall either have been approved for listing on the Exchange, subject only to notice of issuance, or the Company shall have filed an application for listing of the Placement Shares on the Exchange at, or prior to, the issuance of any Placement Notice.

(l) No Termination Event. There shall not have occurred any event that would permit MLV to terminate this Agreement pursuant to Section 13(a).

#### 11. Indemnification and Contribution.

(a) Company Indemnification. The Company agrees to indemnify and hold harmless MLV, its partners, members, directors, officers, employees and agents and each person, if any, who controls MLV within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act as follows:

(i) against any and all loss, liability, claim, damage and expense whatsoever, as incurred, joint or several, arising out of or based upon any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement (or any amendment thereto), or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading, or arising out of any untrue statement or alleged untrue statement of a material fact included in the any related Issuer Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto), or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading;

(ii) against any and all loss, liability, claim, damage and expense whatsoever, as incurred, joint or several, to the extent of the aggregate amount paid in settlement of any

litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or of any claim whatsoever based upon any such untrue statement or omission, or any such alleged untrue statement or omission; provided that (subject to Section 11(d) below) any such settlement is effected with the written consent of the Company, which consent shall not unreasonably be delayed or withheld; and

(iii) against any and all expense whatsoever, as incurred (including the reasonable fees and disbursements of counsel), reasonably incurred in investigating, preparing or defending against any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever based upon any such untrue statement or omission, or any such alleged untrue statement or omission, to the extent that any such expense is not paid under (i) or (ii) above, provided, however, that this indemnity agreement shall not apply to any loss, liability, claim, damage or expense to the extent arising out of any untrue statement or omission or alleged untrue statement or omission made solely in reliance upon and in conformity with written information furnished to the Company by MLV expressly for use in the Registration Statement (or any amendment thereto) or in any related Issuer Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto).

(b) MLV Indemnification. MLV agrees to indemnify and hold harmless the Company and its directors and each officer of the Company who signed the Registration Statement, and each person, if any, who (i) controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act or (ii) is controlled by or is under common control with the Company against any and all loss, liability, claim, damage and expense described in the indemnity contained in Section 11(a), as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions, made in the Registration Statement (or any amendments thereto) or any Issuer Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto) in reliance upon and in conformity with information furnished to the Company in writing by MLV expressly for use therein.

(c) Procedure. Any party that proposes to assert the right to be indemnified under this Section 11 will, promptly after receipt of notice of commencement of any action against such party in respect of which a claim is to be made against an indemnifying party or parties under this Section 11, notify each such indemnifying party of the commencement of such action, enclosing a copy of all papers served, but the omission so to notify such indemnifying party will not relieve the indemnifying party from (i) any liability that it might have to any indemnified party otherwise than under this Section 11 and (ii) any liability that it may have to any indemnified party under the foregoing provision of this Section 11 unless, and only to the extent that, such omission results in the forfeiture or material impairment of substantive rights or defenses by the indemnifying party. If any such action is brought against any indemnified party and it notifies the indemnifying party of its commencement, the indemnifying party will be entitled to participate in and, to the extent that it elects by delivering written notice to the indemnified party promptly after receiving notice of the commencement of the action from the indemnified party, jointly with any other indemnifying party similarly notified, to assume the defense of the action, with counsel reasonably satisfactory to the indemnified party, and after notice from the indemnifying party to the indemnified party of its election to assume the defense,

the indemnifying party will not be liable to the indemnified party for any legal or other expenses except as provided below and except for the reasonable costs of investigation subsequently incurred by the indemnified party in connection with the defense. The indemnified party will have the right to employ its own counsel in any such action, but the fees, expenses and other charges of such counsel will be at the expense of such indemnified party unless (1) the employment of counsel by the indemnified party has been authorized in writing by the indemnifying party, (2) the indemnified party has reasonably concluded (based on advice of counsel) that there may be legal defenses available to it or other indemnified parties that are different from or in addition to those available to the indemnifying party, (3) a conflict or potential conflict exists (based on advice of counsel to the indemnified party) between the indemnified party and the indemnifying party (in which case the indemnifying party will not have the right to direct the defense of such action on behalf of the indemnified party) or (4) the indemnifying party has not in fact employed counsel to assume the defense of such action within a reasonable time after receiving notice of the commencement of the action, in each of which cases the reasonable fees, disbursements and other charges of counsel will be at the expense of the indemnifying party or parties. It is understood that the indemnifying party or parties shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable fees, disbursements and other charges of more than one separate firm admitted to practice in such jurisdiction at any one time for all such indemnified party or parties. All such fees, disbursements and other charges will be reimbursed by the indemnifying party promptly after the indemnifying party receives a written invoice relating to fees, disbursements and other charges in reasonable detail. An indemnifying party will not, in any event, be liable for any settlement of any action or claim effected without its written consent. No indemnifying party shall, without the prior written consent of each indemnified party, settle or compromise or consent to the entry of any judgment in any pending or threatened claim, action or proceeding relating to the matters contemplated by this Section 11 (whether or not any indemnified party is a party thereto), unless such settlement, compromise or consent (1) includes an unconditional release of each indemnified party from all liability arising out of such litigation, investigation, proceeding or claim and (2) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party.

(d) Contribution. In order to provide for just and equitable contribution in circumstances in which the indemnification provided for in the foregoing paragraphs of this Section 11 is applicable in accordance with its terms but for any reason is held to be unavailable from the Company or MLV, the Company and MLV will contribute to the total losses, claims, liabilities, expenses and damages (including any investigative, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claim asserted, but after deducting any contribution received by the Company from persons other than MLV, such as persons who control the Company within the meaning of the Securities Act, officers of the Company who signed the Registration Statement and directors of the Company, who also may be liable for contribution) to which the Company and MLV may be subject in such proportion as shall be appropriate to reflect the relative benefits received by the Company on the one hand and MLV on the other hand. The relative benefits received by the Company on the one hand and MLV on the other hand shall be deemed to be in the same proportion as the total net proceeds from the sale of the Placement Shares (before deducting expenses) received by the Company bear to the total compensation received by MLV (before

deducting expenses) from the sale of Placement Shares on behalf of the Company. If, but only if, the allocation provided by the foregoing sentence is not permitted by applicable law, the allocation of contribution shall be made in such proportion as is appropriate to reflect not only the relative benefits referred to in the foregoing sentence but also the relative fault of the Company, on the one hand, and MLV, on the other hand, with respect to the statements or omission that resulted in such loss, claim, liability, expense or damage, or action in respect thereof, as well as any other relevant equitable considerations with respect to such offering. Such relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or MLV, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and MLV agree that it would not be just and equitable if contributions pursuant to this Section 11(d) were to be determined by pro rata allocation or by any other method of allocation that does not take into account the equitable considerations referred to herein. The amount paid or payable by an indemnified party as a result of the loss, claim, liability, expense, or damage, or action in respect thereof, referred to above in this Section 11(d) shall be deemed to include, for the purpose of this Section 11(d), any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim to the extent consistent with Section 11(c) hereof. Notwithstanding the foregoing provisions of this Section 11(d), MLV shall not be required to contribute any amount in excess of the commissions received by it under this Agreement and no person found guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 11(d), any person who controls a party to this Agreement within the meaning of the Securities Act, and any officers, directors, partners, employees or agents of MLV, will have the same rights to contribution as that party, and each officer and director of the Company who signed the Registration Statement will have the same rights to contribution as the Company, subject in each case to the provisions hereof. Any party entitled to contribution, promptly after receipt of notice of commencement of any action against such party in respect of which a claim for contribution may be made under this Section 11(d), will notify any such party or parties from whom contribution may be sought, but the omission to so notify will not relieve that party or parties from whom contribution may be sought from any other obligation it or they may have under this Section 11(d) except to the extent that the failure to so notify such other party materially prejudiced the substantive rights or defenses of the party from whom contribution is sought. Except for a settlement entered into pursuant to the last sentence of Section 11(c) hereof, no party will be liable for contribution with respect to any action or claim settled without its written consent if such consent is required pursuant to Section 11(c) hereof.

12. Representations and Agreements to Survive Delivery. The indemnity and contribution agreements contained in Section 11 of this Agreement and all representations and warranties of the Company and MLV herein or in certificates delivered pursuant hereto shall survive, as of their respective dates, regardless of (i) any investigation made by or on behalf of MLV, any controlling persons, or the Company (or any of their respective officers, directors or controlling persons), (ii) delivery and acceptance of the Placement Shares and payment therefor or (iii) any termination of this Agreement.

### 13. Termination.

(a) MLV may terminate this Agreement, by notice to the Company, as hereinafter specified at any time (1) if there has been, since the time of execution of this Agreement or since the date as of which information is given in the Prospectus, any Material Adverse Effect, or any development that has occurred that is reasonably likely to have a Material Adverse Effect has occurred or in the sole judgment of MLV makes it impractical or inadvisable to market the Placement Shares or to enforce contracts for the sale of the Placement Shares, (2) if there has occurred any material adverse change in the financial markets in the United States or the international financial markets, any outbreak of hostilities or escalation thereof or other calamity or crisis or any change or development involving a prospective change in national or international political, financial or economic conditions, in each case the effect of which is such as to make it, in the sole judgment of MLV, impracticable or inadvisable to market the Placement Shares or to enforce contracts for the sale of the Placement Shares, (3) if trading in the Common Stock has been suspended or limited by the Commission or the Exchange, or if trading generally on the Exchange has been suspended or limited, or minimum prices for trading have been fixed on the Exchange, (4) if any suspension of trading of any securities of the Company on any exchange or in the over-the-counter market shall have occurred and be continuing for at least ten (10) Trading Days, (5) if a major disruption of securities settlements or clearance services in the United States shall have occurred and be continuing, or (6) if a banking moratorium has been declared by either U.S. Federal or New York authorities. Any such termination shall be without liability of any party to any other party except that the provisions of Section 9 (Payment of Expenses), Section 11 (Indemnification and Contribution), Section 12 (Representations and Agreements to Survive Delivery), Section 18 (Governing Law and Time; Waiver of Jury Trial) and Section 19 (Consent to Jurisdiction) hereof shall remain in full force and effect notwithstanding such termination. If MLV elects to terminate this Agreement as provided in this Section 13(a), MLV shall provide the required notice as specified in Section 14 (Notices).

(b) The Company shall have the right, by giving ten (10) days notice as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 9, Section 11, Section 12, Section 18 and Section 19 hereof shall remain in full force and effect notwithstanding such termination.

(c) MLV shall have the right, by giving ten (10) days notice as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 9, Section 11, Section 12, Section 18 and Section 19 hereof shall remain in full force and effect notwithstanding such termination.

(d) Unless earlier terminated pursuant to this Section 13, this Agreement shall automatically terminate upon the earlier to occur of (i) the third (3<sup>rd</sup>) year anniversary of the date hereof and (ii) the issuance and sale of all of the Placement Shares through MLV on the terms and subject to the conditions set forth herein except that the provisions of Section 9, Section 11, Section 11, Section 12, Section 18 and Section 19 hereof shall remain in full force and effect notwithstanding such termination.

(e) This Agreement shall remain in full force and effect unless terminated pursuant to Sections 13(a), (b), (c), or (d) above or otherwise by mutual agreement of the parties; provided, however, that any such termination by mutual agreement shall in all cases be deemed to provide that Section 9, Section 11, Section 12, Section 18 and Section 19 shall remain in full force and effect. Upon termination of this Agreement, the Company shall not have any liability to MLV for any discount, commission or other compensation with respect to any Placement Shares not otherwise sold by MLV under this Agreement.

(f) Any termination of this Agreement shall be effective on the date specified in such notice of termination; provided, however, that such termination shall not be effective until the close of business on the date of receipt of such notice by MLV or the Company, as the case may be. If such termination shall occur prior to the Settlement Date for any sale of Placement Shares, such Placement Shares shall settle in accordance with the provisions of this Agreement.

14. Notices. All notices or other communications required or permitted to be given by any party to any other party pursuant to the terms of this Agreement shall be in writing, unless otherwise specified, and if sent to MLV, shall be delivered to:

MLV & Co. LLC  
1251 Avenue of the Americas, 41st Floor  
New York, NY 10020  
Attention: General Counsel  
Telephone: (212) 542-5870  
Facsimile: (212) 317-1515

with a copy to:

LeClairRyan, A Professional Corporation  
One Riverfront Plaza  
1037 Raymond Boulevard, 16th Floor  
Newark, NJ 07102  
Attention: James T. Seery  
Telephone: (973) 491-3315  
Facsimile: (973) 491-3415

and if to the Company, shall be delivered to:

MannKind Corporation  
28903 North Avenue Paine  
Valencia, CA 91355  
Attention: General Counsel  
Telephone (661) 775-5350  
Facsimile: (661) 775-2086

with a copy to:

Cooley LLP  
4401 Eastgate Mall  
San Diego, CA 92121  
Attention: L. Kay Chandler  
              Sean M. Clayton  
Telephone: (858) 550-6000  
Facsimile: (858) 550-6420

Each party to this Agreement may change such address for notices by sending to the parties to this Agreement written notice of a new address for such purpose. Each such notice or other communication shall be deemed given (i) when delivered personally or by verifiable facsimile transmission (with an original to follow) on or before 4:30 p.m., New York City time, on a Business Day or, if such day is not a Business Day, on the next succeeding Business Day, (ii) on the next Business Day after timely delivery to a nationally-recognized overnight courier and (iii) on the Business Day actually received if deposited in the U.S. mail (certified or registered mail, return receipt requested, postage prepaid). For purposes of this Agreement, "Business Day" shall mean any day on which the Exchange and commercial banks in the City of New York are open for business.

An electronic communication ("Electronic Notice") shall be deemed written notice for purposes of this Section 14 if sent to the electronic mail address specified by the receiving party under separate cover. Electronic Notice shall be deemed received at the time the party sending Electronic Notice receives confirmation of receipt by the receiving party. Any party receiving Electronic Notice may request and shall be entitled to receive the notice on paper, in a nonelectronic form ("Nonelectronic Notice") which shall be sent to the requesting party within ten (10) days of receipt of the written request for Nonelectronic Notice.

15. Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the Company and MLV and their respective successors and the affiliates, controlling persons, officers and directors referred to in Section 11 hereof. References to any of the parties contained in this Agreement shall be deemed to include the successors and permitted assigns of such party. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assigns any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement. Neither party may assign its rights or obligations under this Agreement without the prior written consent of the other party.

16. Adjustments for Stock Splits. The parties acknowledge and agree that all share-related numbers contained in this Agreement shall be adjusted to take into account any share consolidation, stock split, stock dividend, corporate domestication or similar event effected with respect to the Placement Shares.

17. Entire Agreement; Amendment; Severability. This Agreement (including all schedules and exhibits attached hereto and Placement Notices issued pursuant hereto) constitutes the entire agreement of the parties with respect to the subject matter hereof and supersedes all

other prior and contemporaneous agreements and undertakings, both written and oral, among the parties hereto with regard to the subject matter hereof. Neither this Agreement nor any term hereof may be amended except pursuant to a written instrument executed by the Company and MLV. In the event that any one or more of the provisions contained herein, or the application thereof in any circumstance, is held invalid, illegal or unenforceable as written by a court of competent jurisdiction, then such provision shall be given full force and effect to the fullest possible extent that it is valid, legal and enforceable, and the remainder of the terms and provisions herein shall be construed as if such invalid, illegal or unenforceable term or provision was not contained herein, but only to the extent that giving effect to such provision and the remainder of the terms and provisions hereof shall be in accordance with the intent of the parties as reflected in this Agreement.

**18. GOVERNING LAW AND TIME; WAIVER OF JURY TRIAL. THIS AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK WITHOUT REGARD TO THE PRINCIPLES OF CONFLICTS OF LAWS. SPECIFIED TIMES OF DAY REFER TO NEW YORK CITY TIME. THE COMPANY HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.**

**19. CONSENT TO JURISDICTION. EACH PARTY HEREBY IRREVOCABLY SUBMITS TO THE NON-EXCLUSIVE JURISDICTION OF THE STATE AND FEDERAL COURTS SITTING IN THE CITY OF NEW YORK, BOROUGH OF MANHATTAN, FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION WITH ANY TRANSACTION CONTEMPLATED HEREBY, AND HEREBY IRREVOCABLY WAIVES, AND AGREES NOT TO ASSERT IN ANY SUIT, ACTION OR PROCEEDING, ANY CLAIM THAT IT IS NOT PERSONALLY SUBJECT TO THE JURISDICTION OF ANY SUCH COURT, THAT SUCH SUIT, ACTION OR PROCEEDING IS BROUGHT IN AN INCONVENIENT FORUM OR THAT THE VENUE OF SUCH SUIT, ACTION OR PROCEEDING IS IMPROPER. EACH PARTY HEREBY IRREVOCABLY WAIVES PERSONAL SERVICE OF PROCESS AND CONSENTS TO PROCESS BEING SERVED IN ANY SUCH SUIT, ACTION OR PROCEEDING BY MAILING A COPY THEREOF (CERTIFIED OR REGISTERED MAIL, RETURN RECEIPT REQUESTED) TO SUCH PARTY AT THE ADDRESS IN EFFECT FOR NOTICES TO IT UNDER THIS AGREEMENT AND AGREES THAT SUCH SERVICE SHALL CONSTITUTE GOOD AND SUFFICIENT SERVICE OF PROCESS AND NOTICE THEREOF. NOTHING CONTAINED HEREIN SHALL BE DEEMED TO LIMIT IN ANY WAY ANY RIGHT TO SERVE PROCESS IN ANY MANNER PERMITTED BY LAW.**

**20. Use of Information. MLV may not use any information gained in connection with this Agreement and the transactions contemplated by this Agreement, including due diligence, to advise any party with respect to transactions not expressly approved by the Company.**

21. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Delivery of an executed Agreement by one party to the other may be made by facsimile transmission.

22. Effect of Headings. The section and Exhibit headings herein are for convenience only and shall not affect the construction hereof.

23. Permitted Free Writing Prospectuses. The Company represents, warrants and agrees that, unless it obtains the prior consent of MLV (such consent not to be unreasonably withheld, conditioned or delayed), and MLV represents, warrants and agrees that, unless it obtains the prior consent of the Company (such consent not to be unreasonably withheld, conditioned or delayed), it has not made and will not make any offer relating to the Placement Shares that would constitute an Issuer Free Writing Prospectus, or that would otherwise constitute a "free writing prospectus," as defined in Rule 405, required to be filed with the Commission. Any such free writing prospectus consented to by MLV or by the Company, as the case may be, is hereinafter referred to as a "Permitted Free Writing Prospectus." The Company represents and warrants that it has treated and agrees that it will treat each Permitted Free Writing Prospectus as an "issuer free writing prospectus," as defined in Rule 433, and has complied and will comply with the requirements of Rule 433 applicable to any Permitted Free Writing Prospectus, including timely filing with the Commission where required, legending and record keeping. For the purposes of clarity, the parties hereto agree that all free writing prospectuses, if any, listed in Exhibit 23 hereto are Permitted Free Writing Prospectuses.

24. Absence of Fiduciary Relationship. The Company acknowledges and agrees that:

(a) MLV is acting solely as agent in connection with the public offering of the Placement Shares and in connection with each transaction contemplated by this Agreement and the process leading to such transactions, and no fiduciary or advisory relationship between the Company or any of its respective affiliates, stockholders (or other equity holders), creditors or employees or any other party, on the one hand, and MLV, on the other hand, has been or will be created in respect of any of the transactions contemplated by this Agreement, irrespective of whether or not MLV has advised or is advising the Company on other matters, and MLV has no obligation to the Company with respect to the transactions contemplated by this Agreement except the obligations expressly set forth in this Agreement;

(b) it is capable of evaluating and understanding, and understands and accepts, the terms, risks and conditions of the transactions contemplated by this Agreement;

(c) MLV has not provided any legal, accounting, regulatory or tax advice with respect to the transactions contemplated by this Agreement and it has consulted its own legal, accounting, regulatory and tax advisors to the extent it has deemed appropriate;

(d) it is aware that MLV and its affiliates are engaged in a broad range of transactions which may involve interests that differ from those of the Company and MLV has no obligation to disclose such interests and transactions to the Company by virtue of any fiduciary, advisory or agency relationship or otherwise; and

(e) it waives, to the fullest extent permitted by law, any claims it may have against MLV for breach of fiduciary duty or alleged breach of fiduciary duty in connection with the sale of Placement Shares under this Agreement and agrees that MLV shall not have any liability (whether direct or indirect, in contract, tort or otherwise) to it in respect of such a fiduciary duty claim or to any person asserting a fiduciary duty claim on its behalf or in right of it or the Company, employees or creditors of Company, other than in respect of MLV's obligations under this Agreement and to keep information provided by the Company to MLV and MLV's counsel confidential to the extent not otherwise publicly-available.

**25. Definitions.** As used in this Agreement, the following terms have the respective meanings set forth below:

**"Applicable Time"** means (i) each Representation Date and (ii) the time of each sale of any Placement Shares pursuant to this Agreement.

**"Issuer Free Writing Prospectus"** means any "issuer free writing prospectus," as defined in Rule 433, relating to the Placement Shares that (1) is required to be filed with the Commission by the Company, (2) is a "road show" that is a "written communication" within the meaning of Rule 433(d)(8)(i) whether or not required to be filed with the Commission, or (3) is exempt from filing pursuant to Rule 433(d)(5)(i) because it contains a description of the Placement Shares or of the offering that does not reflect the final terms, in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company's records pursuant to Rule 433(g) under the Securities Act Regulations.

**"Rule 164," "Rule 172," "Rule 405," "Rule 415," "Rule 424," "Rule 424(b)," "Rule 430B," and "Rule 433"** refer to such rules under the Securities Act Regulations.

All references in this Agreement to financial statements and schedules and other information that is "contained," "included" or "stated" in the Registration Statement or the Prospectus (and all other references of like import) shall be deemed to mean and include all such financial statements and schedules and other information that is incorporated by reference in the Registration Statement or the Prospectus, as the case may be.

All references in this Agreement to the Registration Statement, the Prospectus or any amendment or supplement to any of the foregoing shall be deemed to include the copy filed with the Commission pursuant to EDGAR; all references in this Agreement to any Issuer Free Writing Prospectus (other than any Issuer Free Writing Prospectuses that, pursuant to Rule 433, are not required to be filed with the Commission) shall be deemed to include the copy thereof filed with the Commission pursuant to EDGAR; and all references in this Agreement to "supplements" to the Prospectus shall include, without limitation, any supplements, "wrappers" or similar materials prepared in connection with any offering, sale or private placement of any Placement Shares by MLV outside of the United States.

If the foregoing correctly sets forth the understanding between the Company and MLV, please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding agreement between the Company and MLV.

Very truly yours,

**MANNKIND CORPORATION**

By: /s/ Matthew J. Pfeffer

\_\_\_\_\_  
Name: Matthew J. Pfeffer

Title: Chief Financial Officer

**ACCEPTED as of the date first-above written:**

**MLV & CO. LLC**

By: /s/ Patrice McNicoll

\_\_\_\_\_  
Name: Patrice McNicoll

Title: Chief Executive Officer

[Signature Page to At-The-Market Issuance Sales Agreement]

SCHEDULE 1

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FORM OF PLACEMENT NOTICE

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From: MannKind Corporation

To: MLV & Co. LLC

Attention: Patrice McNicoll

Subject: At-The-Market Issuance—Placement Notice

Gentlemen:

Pursuant to the terms and subject to the conditions contained in the At-The-Market Issuance Sales Agreement between MannKind Corporation, a Delaware corporation (the "Company"), and MLV & Co. LLC ("MLV"), dated March 18, 2013, the Company hereby requests that MLV sell up to \_\_\_\_\_ of the Company's Common Stock, par value \$0.01 per share, at a minimum market price of \$ \_\_\_\_\_ per share, during the time period beginning [month, day, time] and ending [month, day, time]. [The Company may include such other sales parameters as it deems appropriate.]

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## SCHEDULE 2

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### Compensation

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The Company shall pay to MLV in cash, upon each sale of Placement Shares pursuant to this Agreement, an amount up to 3.0% of the gross proceeds from each sale of Placement Shares.

**SCHEDULE 3**

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**Notice Parties**

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The Company  
Matthew Pfeffer  
David Thomson  
Hakan Edstrom

MLV  
Randy Billhardt  
Dean Colucci  
Ryan Loforte  
Patrice McNicoll

With a copy to [mlvatmdesk@mlvco.com](mailto:mlvatmdesk@mlvco.com)

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**SCHEDULE 4**

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**Subsidiaries**

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None.

## EXHIBIT 7(I)

### Form of Representation Date Certificate

This Officers Certificate (this "Certificate") is executed and delivered in connection with Section 7(l) of the At-The-Market Issuance Sales Agreement (the "Agreement"), dated March 18, 2013, and entered into between MannKind Corporation (the "Company") and MLV & Co. LLC. All capitalized terms used but not defined herein shall have the meanings given to such terms in the Agreement.

The undersigned, a duly appointed and authorized officer of the Company, having made reasonable inquiries to establish the accuracy of the statements below and having been authorized by the Company to execute this certificate on behalf of the Company, hereby certifies, on behalf of the Company and not in the undersigned's individual capacity, as follows:

1. As of the date of this Certificate, (i) the Registration Statement does not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein not misleading and (ii) neither the Registration Statement nor the Prospectus contains any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading and (iii) no event has occurred as a result of which it is necessary to amend or supplement the Prospectus in order to make the statements therein not untrue or misleading for (i) and (ii) to be true.

2. Each of the representations and warranties of the Company contained in the Agreement was true and correct in all material respects, when originally made, and, except for those representations and warranties that speak solely as of a specific date, is true and correct as of the date of this Certificate.

3. Except as waived by MLV in writing, each of the covenants required to be performed by the Company in the Agreement on or prior to the date of the Agreement, this Representation Date, and each such other date prior to the date hereof as set forth in the Agreement, has been duly, timely and fully performed in all material respects and each condition required to be complied with by the Company on or prior to the date of the Agreement, this Representation Date, and each such other date prior to the date hereof as set forth in the Agreement has been duly, timely and fully complied with in all material respects.

4. No stop order suspending the effectiveness of the Registration Statement or of any part thereof has been issued, and, to the Company's knowledge, no proceedings for that purpose have been instituted or are pending or threatened by any securities or other governmental authority (including, without limitation, the Commission).

5. No order suspending the effectiveness of the Registration Statement or the qualification or registration of the Placement Shares under the securities or Blue Sky laws of any jurisdiction are in effect and no proceeding for such purpose is pending before, or threatened, to the Company's knowledge or in writing by, any securities or other governmental authority (including, without limitation, the Commission).

The undersigned has executed this Officer's Certificate on behalf of the Company as of the date first written above.

MANKIND CORPORATION

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

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**Exhibit 23**

**Permitted Free Writing Prospectus**

None.

## MANKIND CORPORATION

Common Stock  
(par value \$0.01 per share)

## At-The-Market Issuance Sales Agreement

March 18, 2013

Brinson Patrick Securities Corporation  
1515 Broadway  
11<sup>th</sup> Floor  
New York, NY 10036

Ladies and Gentlemen:

MannKind Corporation, a Delaware corporation (the "Company"), confirms its agreement (this "Agreement") with Brinson Patrick Securities Corporation ("BPSC"), as follows:

1. Issuance and Sale of Shares. The Company agrees that, from time to time during the term of this Agreement, on the terms and subject to the conditions set forth herein, it may issue and sell through BPSC, shares (the "Placement Shares") of the Company's common stock, par value \$0.01 per share (the "Common Stock"), up to an aggregate offering price of \$50,000,000 less the aggregate offering price of any Common Stock sold pursuant to the Concurrent Facility Agreement (as defined below), *provided however*, that in no event shall the Company issue or sell through BPSC such number of Placement Shares that (a) would cause the Company to not satisfy the eligibility requirements for use of Form S-3 (including Instruction I.B.6. thereof), (b) exceeds the number of shares of Common Stock registered on the effective Registration Statement (as defined below) pursuant to which the offering is being made or (c) exceeds the number of authorized but unissued shares of the Company's Common Stock (the lesser of (a), (b) and (c), the "Maximum Amount"). Notwithstanding anything to the contrary contained herein, the parties hereto agree that compliance with the limitations set forth in this Section 1 on the amount of Placement Shares issued and sold under this Agreement shall be the sole responsibility of the Company and that BPSC shall have no obligation in connection with such compliance. The issuance and sale of Placement Shares through BPSC will be effected pursuant to the Registration Statement filed by the Company and declared effective by the Securities and Exchange Commission (the "Commission"), although nothing in this Agreement shall be construed as requiring the Company to use the Registration Statement to issue any Placement Shares.

The Company has filed, in accordance with the provisions of the Securities Act of 1933, as amended (the "Securities Act"), and the rules and regulations thereunder (the "Securities Act Regulations"), with the Commission a registration statement on Form S-3 (File No. 333-183679), including a base prospectus, relating to certain securities, including the Placement

Shares to be issued from time to time by the Company, and which incorporates by reference documents that the Company has filed or will file in accordance with the provisions of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the rules and regulations thereunder. The Company has prepared a prospectus supplement specifically relating to the Placement Shares (the "Prospectus Supplement") to the base prospectus included as part of such registration statement. The Company will furnish to BPSC, for use by BPSC, copies of the prospectus included as part of such registration statement, as supplemented by the Prospectus Supplement, relating to the Placement Shares. Except where the context otherwise requires, such registration statement, including all documents filed as part thereof or incorporated by reference therein, and including any information contained in a Prospectus (as defined below) subsequently filed with the Commission pursuant to Rule 424(b) under the Securities Act Regulations or deemed to be a part of such registration statement pursuant to Rule 430B of the Securities Act Regulations, is herein called the "Registration Statement." The base prospectus, including all documents incorporated therein by reference, included in the Registration Statement, as it may be supplemented by the Prospectus Supplement, in the form in which such prospectus and/or Prospectus Supplement have most recently been filed by the Company with the Commission pursuant to Rule 424(b) under the Securities Act Regulations, is herein called the "Prospectus." Any reference herein to the Registration Statement, the Prospectus or any amendment or supplement thereto shall be deemed to refer to and include the documents incorporated by reference therein, and any reference herein to the terms "amend," "amendment" or "supplement" with respect to the Registration Statement or the Prospectus shall be deemed to refer to and include the filing after the execution hereof of any document with the Commission deemed to be incorporated by reference therein (the "Incorporated Documents").

For purposes of this Agreement, all references to the Registration Statement, the Prospectus or to any amendment or supplement thereto shall be deemed to include the most recent copy filed with the Commission pursuant to its Electronic Data Gathering Analysis and Retrieval System, or if applicable, the Interactive Data Electronic Application system when used by the Commission (collectively, "EDGAR").

2. Placements. Each time that the Company wishes to issue and sell Placement Shares hereunder (each, a "Placement"), it will notify BPSC by email notice (or other method mutually agreed to in writing by the parties) of the proposed terms of such Placement, which shall include at a minimum the number of Placement Shares to be issued, the time period during which sales are requested to be made, any limitation on the number of Placement Shares that may be sold in any one day and any minimum price below which sales may not be made (a "Placement Notice"), the form of which is attached hereto as Schedule 1. The Placement Notice shall originate from any of the individuals from the Company set forth on Schedule 3 (with a copy to each of the other individuals from the Company listed on such schedule), and shall be addressed to each of the individuals from BPSC set forth on Schedule 3, as such Schedule 3 may be amended from time to time. The Placement Notice shall be effective unless and until (i) BPSC declines to accept the terms contained therein for any reason, in its sole discretion by email notice to the Company within one Business Day (as defined below) from the time the Placement Notice is received, (ii) the entire amount of the Placement Shares thereunder have been sold, (iii) the Company suspends or terminates the Placement Notice or (iv) this Agreement has been terminated under the provisions of Section 13. The amount of any discount,

commission or other compensation to be paid by the Company to BPSC in connection with the sale of the Placement Shares shall be calculated in accordance with the terms set forth in Schedule 2. It is expressly acknowledged and agreed that neither the Company nor BPSC will have any obligation whatsoever with respect to a Placement or any Placement Shares unless and until the Company delivers a Placement Notice to BPSC and BPSC does not decline such Placement Notice pursuant to the terms set forth above, and then only upon the terms specified therein and herein. In the event of a conflict between the terms of this Agreement and the terms of a Placement Notice, the terms of the Placement Notice will control.

### 3. Sale of Placement Shares by BPSC.

(a) Subject to the terms and conditions of this Agreement, for the period specified in the Placement Notice, BPSC will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of the NASDAQ Global Market (the "Exchange"), to sell the Placement Shares up to the amount specified, and otherwise in accordance with the terms of such Placement Notice. BPSC will provide written confirmation to the Company no later than the opening of the Trading Day (as defined below) immediately following the Trading Day on which it has made sales of Placement Shares hereunder setting forth the number of Placement Shares sold on such day, the compensation payable by the Company to BPSC pursuant to Section 2 with respect to such sales, and the Net Proceeds (as defined below) payable to the Company, with an itemization of the deductions made by BPSC (as set forth in Section 5(b)) from the gross proceeds that it receives from such sales. Subject to the terms of the Placement Notice, BPSC shall sell Placement Shares only by methods deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act Regulations, including without limitation sales made directly on the Exchange, on any other existing trading market for the Common Stock or to or through a market maker. Subject to the terms of the Placement Notice and only with the Company's prior written consent, BPSC may also sell Placement Shares by any other method permitted by law, including but not limited to in negotiated transactions. "Trading Day" means any day on which shares of Common Stock are purchased and sold on the Exchange.

(b) During the term of this Agreement, neither BPSC nor any of its affiliates or subsidiaries shall engage in (i) any short sale of any security of the Company, (ii) any sale of any security of the Company that BPSC does not own or any sale which is consummated by the delivery of a security of the Company borrowed by, or for the account of, BPSC or (iii) any market making bidding, stabilization or other trading activity with respect to the Common Stock or related derivative securities if such activity would be prohibited under Regulation M or other anti-manipulation rules under the Securities Act. Neither BPSC nor any of its affiliates or subsidiaries shall engage in any proprietary trading or trading for BPSC's (or its affiliates' or subsidiaries') own account.

4. Suspension of Sales. The Company or BPSC may, upon notice to the other party in writing (including by email correspondence to each of the individuals of the other party set forth on Schedule 3, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply) or by telephone (confirmed immediately by verifiable facsimile transmission or email correspondence to each of the

individuals of the other party set forth on Schedule 3), suspend any sale of Placement Shares; provided, however, that such suspension shall not affect or impair any party's obligations with respect to any Placement Shares sold hereunder prior to the receipt of such notice. Each of the parties agrees that no such notice under this Section 4 shall be effective against any other party unless it is made to one of the individuals named on Schedule 3 hereto, as such Schedule may be amended from time to time.

#### 5. Sale and Delivery to BPSC; Settlement.

(a) Sale of Placement Shares. On the basis of the representations and warranties herein contained and subject to the terms and conditions herein set forth, unless BPSC declines to accept the terms of a Placement Notice, and unless the sale of the Placement Shares described therein has been declined, suspended, or otherwise terminated in accordance with the terms of this Agreement, BPSC, for the period specified in the Placement Notice, will use its commercially reasonable efforts consistent with its normal trading and sales practices to sell such Placement Shares up to the amount specified in, and otherwise in accordance with, the terms of such Placement Notice. The Company acknowledges and agrees that (i) there can be no assurance that BPSC will be successful in selling Placement Shares, (ii) BPSC will incur no liability or obligation to the Company or any other person or entity if it does not sell Placement Shares for any reason other than a failure by BPSC to use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable law and regulations to sell such Placement Shares as required under this Agreement and (iii) BPSC shall be under no obligation to purchase Placement Shares on a principal basis pursuant to this Agreement, except as otherwise agreed by BPSC and the Company.

(b) Settlement of Placement Shares. Unless otherwise specified in the applicable Placement Notice, settlement for sales of Placement Shares will occur on the third (3rd) Trading Day (or such earlier day as is industry practice for regular-way trading) following the date on which such sales are made (each, a "Settlement Date"). The amount of proceeds to be delivered to the Company on a Settlement Date against receipt of the Placement Shares sold (the "Net Proceeds") will be equal to the aggregate sales price received by BPSC, after deduction for (i) BPSC's commission, discount or other compensation for such sales payable by the Company pursuant to Section 2 hereof, and (ii) any transaction fees imposed by any governmental or self-regulatory organization in respect of such sales.

(c) Delivery of Placement Shares. On or before each Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Placement Shares being sold by crediting BPSC's or its designee's account (provided BPSC shall have given the Company written notice of such designee a reasonable period of time prior to the Settlement Date) at The Depository Trust Company through its Deposit and Withdrawal at Custodian System or by such other means of delivery as may be mutually agreed upon by the parties hereto which in all cases shall be freely tradable, transferable, registered shares in good deliverable form. On each Settlement Date, BPSC will deliver the related Net Proceeds in same day funds to an account designated by the Company on, or prior to, the Settlement Date. If the Company, or its transfer agent (if applicable), defaults in its obligation to deliver Placement Shares on a Settlement Date through no fault of BPSC, the Company agrees that in addition to and in no way

limiting the rights and obligations set forth in Section 11(a) hereto, it will (i) hold BPSC harmless against any loss, claim, damage, or expense (including reasonable legal fees and expenses), as incurred, arising out of or in connection with such default by the Company or its transfer agent (if applicable) and (ii) pay to BPSC (without duplication) any commission, discount, or other compensation to which it would otherwise have been entitled absent such default.

(d) Limitations on Offering Size. Under no circumstances shall the Company cause or request the offer or sale of any Placement Shares if, after giving effect to the sale of such Placement Shares, the aggregate gross sales proceeds of Placement Shares sold pursuant to this Agreement would exceed the lesser of (A) together with all sales of Placement Shares under this Agreement, the Maximum Amount and (B) the amount authorized from time to time to be issued and sold under this Agreement by the Company's board of directors, a duly authorized committee thereof or a duly authorized executive committee, and notified to BPSC in writing. Under no circumstances shall the Company cause or request the offer or sale of any Placement Shares pursuant to this Agreement at a price lower than any minimum price authorized from time to time by the Company's board of directors, a duly authorized committee thereof or a duly authorized executive committee, and notified to BPSC in writing.

6. Representations and Warranties of the Company. Except as disclosed in the Registration Statement or the Prospectus (including Incorporated Documents), the Company represents and warrants to, and agrees with BPSC that as of the date of this Agreement and as of each Applicable Time (as defined below), unless such representation, warranty or agreement specifies a different time:

(a) Registration Statement and Prospectus. The Company and, assuming no act or omission on the part of BPSC that would make such statement untrue, the transactions contemplated by this Agreement meet the requirements for and comply with the conditions for the use of Form S-3 under the Securities Act. The Registration Statement has been filed with the Commission and has been declared effective under the Securities Act. The Prospectus Supplement will name BPSC as an agent in the section entitled "Plan of Distribution." The Company has not received, and has no notice of, any order of the Commission preventing or suspending the use of the Registration Statement, or threatening or instituting proceedings for that purpose. The Registration Statement and the offer and sale of Placement Shares as contemplated hereby meet the requirements of Rule 415 under the Securities Act and comply in all material respects with said Rule. Any statutes, regulations, contracts or other documents that are required to be described in the Registration Statement or the Prospectus or to be filed as exhibits to the Registration Statement have been so described or filed. Copies of the Registration Statement, the Prospectus, and any such amendments or supplements and all documents incorporated by reference therein that were filed with the Commission on or prior to the date of this Agreement have been delivered, or are available through EDGAR, to BPSC and its counsel. The Company has not distributed and, prior to the later to occur of each Settlement Date and completion of the distribution of the Placement Shares, will not distribute any offering material in connection with the offering or sale of the Placement Shares other than the Registration Statement and the Prospectus and any Issuer Free Writing Prospectus (as defined below) to which BPSC has consented, such consent not to be unreasonably withheld, conditioned

or delayed. The Common Stock is currently quoted on the Exchange under the trading symbol "MNKD". The Company has not, in the 12 months preceding the date hereof, received notice from the Exchange to the effect that the Company is not in compliance with the listing or maintenance requirements and the Company has no reason to believe that it will not in the foreseeable future continue to be in compliance with all such listing and maintenance requirements.

(b) No Misstatement or Omission. The Registration Statement, when it became effective, and the Prospectus, and any amendment or supplement thereto, on the date of such Prospectus or amendment or supplement, conformed and will conform in all material respects with the requirements of the Securities Act. At each Settlement Date, the Registration Statement and the Prospectus, as of such date, will conform in all material respects with the requirements of the Securities Act. The Registration Statement, when it became effective, did not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. The Prospectus and any amendment and supplement thereto, on the date thereof and at each Applicable Time (defined below), did not or will not include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in light of the circumstances under which they were made, not misleading. The documents incorporated by reference in the Prospectus or any Prospectus Supplement did not, and any further documents filed and incorporated by reference therein will not, when filed with the Commission, contain an untrue statement of a material fact or omit to state a material fact required to be stated in such document or necessary to make the statements in such document, in light of the circumstances under which they were made, not misleading. The foregoing shall not apply to statements in, or omissions from, any such document made in reliance upon, and in conformity with, information furnished to the Company by BPSC specifically for use in the preparation thereof.

(c) Conformity with Securities Act and Exchange Act. The Registration Statement, the Prospectus, or any amendment or supplement thereto, and the documents incorporated by reference in the Registration Statement, the Prospectus or any amendment or supplement thereto, when such documents were or are filed with the Commission under the Securities Act or the Exchange Act or became or become effective under the Securities Act, as the case may be, conformed or will conform in all material respects with the requirements of the Securities Act and the Exchange Act, as applicable.

(d) Financial Information. The consolidated financial statements of the Company included or incorporated by reference in the Registration Statement and the Prospectus, together with the related notes and schedules, present fairly, in all material respects, the consolidated financial position of the Company and the Subsidiaries (as defined below) as of the dates indicated and the consolidated results of operations, cash flows and changes in stockholders' equity of the Company for the periods specified (subject, in the case of unaudited statements, to normal year-end audit adjustments) and have been prepared in compliance with the requirements of the Securities Act and Exchange Act, as applicable, and in conformity with GAAP (as defined below) applied on a consistent basis (except for such adjustments to accounting standards and practices as are noted therein and except in the case of unaudited financial statements to the extent they may exclude footnotes or may be condensed or summary

statements) during the periods involved; the other financial and statistical data with respect to the Company and the Subsidiaries contained or incorporated by reference in the Registration Statement and the Prospectus are accurately and fairly presented and prepared on a basis consistent with the financial statements and books and records of the Company; there are no financial statements (historical or pro forma) that are required to be included or incorporated by reference in the Registration Statement or the Prospectus that are not included or incorporated by reference as required; the Company and the Subsidiaries do not have any material liabilities or obligations, direct or contingent (including any off-balance sheet obligations), not described in the Registration Statement (including the exhibits thereto and Incorporated Documents) and the Prospectus which are required to be described in the Registration Statement or the Prospectus (including exhibits thereto and Incorporated Documents); and all disclosures contained or incorporated by reference in the Registration Statement and the Prospectus regarding "non-GAAP financial measures" (as such term is defined by the rules and regulations of the Commission) comply in all material respects with Regulation G of the Exchange Act and Item 10 of Regulation S-K under the Securities Act, to the extent applicable;

(e) Conformity with EDGAR Filing. The Prospectus delivered to BPSC for use in connection with the sale of the Placement Shares pursuant to this Agreement will be identical to the versions of the Prospectus created to be transmitted to the Commission for filing via EDGAR, except to the extent permitted by Regulation S-T.

(f) Organization. The Company and each of its Subsidiaries are, and will be, duly organized, validly existing as a corporation and in good standing under the laws of their respective jurisdictions of organization. The Company and each of its Subsidiaries are, and will be, duly licensed or qualified as a foreign corporation for transaction of business and in good standing under the laws of each other jurisdiction in which their respective ownership or lease of property or the conduct of their respective businesses requires such license or qualification, and have all corporate power and authority necessary to own or hold their respective properties and to conduct their respective businesses as described in the Registration Statement and the Prospectus, except where the failure to be so qualified or in good standing or have such power or authority would not, individually or in the aggregate, have a material adverse effect or would reasonably be expected to have a material adverse effect on the assets, business, operations, earnings, properties, condition (financial or otherwise), prospects, stockholders' equity (as set forth on the Company's most recent balance sheet included in the Incorporated Documents) or results of operations of the Company and the Subsidiaries (as defined below) taken as a whole (a "Material Adverse Effect").

(g) Subsidiaries. Schedule 4 hereto sets forth each of the Company's significant subsidiaries (as such term is defined in Rule 1-02 of Regulation S-X promulgated by the Commission), if any (each such significant subsidiary, a "Subsidiary" and collectively, the "Subsidiaries"). Except as set forth in the Registration Statement and in the Prospectus, the Company owns, directly or indirectly, all of the equity interests of the Subsidiaries free and clear of any lien, charge, security interest, encumbrance, right of first refusal or other restriction, and all the equity interests of the Subsidiaries are validly issued and are fully paid, nonassessable and free of preemptive and similar rights.

(h) No Violation or Default. Neither the Company nor any of its Subsidiaries is (i) in violation of its charter or by-laws or similar organizational documents; (ii) in default, and no event has occurred that, with notice or lapse of time or both, would constitute such a default, in the due performance or observance of any term, covenant or condition contained in any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company or any of its Subsidiaries is a party or by which the Company or any of its Subsidiaries is bound or to which any of the property or assets of the Company or any of its Subsidiaries are subject; or (iii) in violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority, except, in the case of each of clauses (ii) and (iii) above, for any such violation or default that would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. To the Company's knowledge, no other party under any material contract or other agreement to which it or any of its Subsidiaries is a party is in default in any respect thereunder where such default would have a Material Adverse Effect.

(i) No Material Adverse Change. Subsequent to December 31, 2012, and other than the Company's execution of this Agreement and the sale of any Placement Shares hereunder and the Company's execution of an At-The-Market Issuance Sales Agreement substantially similar to this Agreement with MLV & Co. LLC (the "Concurrent Facility Agreement") and the sale of any shares of the Company's common stock thereunder, there has not been (i) any Material Adverse Effect, (ii) any transaction which is material to the Company and the Subsidiaries taken as a whole, (iii) any obligation or liability, direct or contingent (including any off-balance sheet obligations), incurred by the Company or any Subsidiary, which is material to the Company and the Subsidiaries taken as a whole, (iv) any material change in the capital stock or outstanding long-term indebtedness of the Company or any of its Subsidiaries or (v) any dividend or distribution of any kind declared, paid or made on the capital stock of the Company or any Subsidiary, other than in each case above (A) in the ordinary course of business, (B) as otherwise disclosed in the Registration Statement or Prospectus (including any document deemed incorporated by reference therein) or (C) where such matter, item, change or development would not make the statements in the Registration Statement or the Prospectus contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading.

(j) Capitalization. The issued and outstanding shares of capital stock of the Company have been validly issued, are fully paid and non-assessable and, other than as disclosed in or contemplated by the Registration Statement or the Prospectus, and are not subject to any preemptive rights, rights of first refusal or similar rights. The Company has an authorized, issued and outstanding capitalization as set forth in the Registration Statement and the Prospectus as of the dates referred to therein (other than the grant of additional options or other equity awards under the Company's existing stock option plans, or changes in the number of outstanding shares of Common Stock of the Company due to the issuance of shares upon the exercise or conversion of securities exercisable for, or convertible into, shares of Common Stock outstanding on the date hereof or described in the Registration Statement and the Prospectus (including any document deemed incorporated by reference therein) or as a result of the issuance of Placement Shares or shares of the Company's common stock under the Concurrent Facility Agreement) and such authorized capital stock conforms in all material respects to the description

thereof set forth in the Registration Statement and the Prospectus. The description of the Common Stock in the Registration Statement and the Prospectus (including any document deemed incorporated by reference therein) is complete and accurate in all material respects. Other than as set forth or described in the Registration Statement and the Prospectus, as of the dates referred to therein, the Company did not have outstanding any options to purchase, or any rights or warrants to subscribe for, or any securities or obligations convertible into, or exchangeable for, or any contracts or commitments to issue or sell, any shares of capital stock or other securities.

(k) Authorization; Enforceability. The Company has full legal right, power and authority to enter into this Agreement and perform the transactions contemplated hereby. This Agreement has been duly authorized, executed and delivered by the Company and is a legal, valid and binding agreement of the Company enforceable against the Company in accordance with its terms, except to the extent that (i) enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally and by general equitable principles and (ii) the indemnification and contribution provisions of Section 11 hereof may be limited by federal or state securities laws and public policy considerations in respect thereof.

(l) Authorization of Placement Shares. The Placement Shares, when issued and delivered pursuant to the terms approved by the board of directors of the Company or a duly authorized committee thereof, or a duly authorized executive committee, against payment therefor as provided herein, will be duly and validly authorized and issued and fully paid and nonassessable, free and clear of any pledge, lien, encumbrance, security interest or other claim (other than any pledge, lien, encumbrance, security interest or other claim arising from an act or omission of BPSC or a purchaser), including any statutory or contractual preemptive rights, resale rights, rights of first refusal or other similar rights, and will be registered pursuant to Section 12 of the Exchange Act. The Placement Shares, when issued, will conform in all material respects to the description thereof set forth in or incorporated into the Prospectus.

(m) No Consents Required. No consent, approval, authorization, order, registration or qualification of or with any court or arbitrator or any governmental or regulatory authority is required for the execution, delivery and performance by the Company of this Agreement, and the issuance and sale by the Company of the Placement Shares as contemplated hereby, except for the registration of the Placement Shares under the Securities Act and such consents, approvals, authorizations, orders and registrations or qualifications as may be required under applicable state securities laws or by the by-laws and rules of the Financial Industry Regulatory Authority ("FINRA") or the Exchange in connection with the sale of the Placement Shares by BPSC.

(n) No Preferential Rights. Except as set forth in the Registration Statement and the Prospectus, (i) no person, as such term is defined in Rule 1-02 of Regulation S-X promulgated under the Securities Act (each, a "Person"), has the right, contractual or otherwise, to cause the Company to issue or sell to such Person any shares of Common Stock or shares of any other capital stock or other securities of the Company (other than upon the exercise of options or warrants to purchase Common Stock or upon the exercise of options or stock awards

that may be granted from time to time under the Company's stock option plans), (ii) no Person has any preemptive rights, rights of first refusal, or any other rights (whether pursuant to a "poison pill" provision or otherwise) to purchase any shares of Common Stock or shares of any other capital stock or other securities of the Company from the Company which have not been duly waived with respect to the offering contemplated hereby, (iii) except as may be disclosed to BPSC in writing, no Person has the right to act as an underwriter or as a financial advisor to the Company in connection with the offer and sale of the Common Stock, and (iv) no Person has the right, contractual or otherwise, to require the Company to register under the Securities Act any shares of Common Stock or shares of any other capital stock or other securities of the Company, or to include any such shares or other securities in the Registration Statement or the offering contemplated thereby, whether as a result of the filing or effectiveness of the Registration Statement or the sale of the Placement Shares as contemplated thereby or otherwise.

(o) Independent Public Accountants. Deloitte & Touche LLP, whose report on the consolidated financial statements of the Company is filed with the Commission as part of the Company's most recent Annual Report on Form 10-K filed with the Commission and incorporated into the Registration Statement, is and, during the periods covered by its reports, was an independent public accounting firm within the meaning of the Securities Act and the Public Company Accounting Oversight Board (United States). To the Company's knowledge, Deloitte & Touche LLP is not in violation of the auditor independence requirements of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act") with respect to the Company.

(p) Enforceability of Agreements. To the Company's knowledge, all agreements between the Company and third parties expressly referenced in the Prospectus, other than such agreements that have expired by their terms or whose termination is disclosed in documents filed by the Company on EDGAR, are legal, valid and binding obligations of the Company enforceable in accordance with their respective terms, except to the extent that (i) enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally and by general equitable principles and (ii) the indemnification provisions of certain agreements may be limited by federal or state securities laws or public policy considerations in respect thereof, except for any unenforceability that, individually or in the aggregate, would not reasonably be expected to have a Material Adverse Effect.

(q) No Litigation. There are no legal, governmental or regulatory actions, suits or proceedings pending, nor, to the Company's knowledge, any legal, governmental or regulatory investigations, to which the Company or a Subsidiary is a party or to which any property of the Company or any of its Subsidiaries is the subject that, individually or in the aggregate, if determined adversely to the Company or any of its Subsidiaries, would reasonably be expected to have a Material Adverse Effect or materially and adversely affect the ability of the Company to perform its obligations under this Agreement; to the Company's knowledge, no such actions, suits or proceedings are threatened or contemplated by any governmental or regulatory authority or threatened by others that, individually or in the aggregate, if determined adversely to the Company or any of its Subsidiaries, would reasonably be expected to have a Material Adverse Effect; and (i) there are no current or pending legal, governmental or regulatory actions, suits or proceedings or, to the Company's knowledge, investigations that are

required under the Securities Act to be described in the Prospectus that are not described in the Prospectus including any Incorporated Document; and (ii) there are no contracts or other documents that are required under the Securities Act to be filed as exhibits to the Registration Statement that are not so filed.

(r) Licenses and Permits. The Company and each of its Subsidiaries possess or have obtained, all licenses, certificates, consents, orders, approvals, permits and other authorizations issued by, and have made all declarations and filings with, the appropriate federal, state, local or foreign governmental or regulatory authorities that are necessary for the ownership or lease of their respective properties or the conduct of their respective businesses as described in the Registration Statement and the Prospectus (the "Permits"), except where the failure to possess, obtain or make the same would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. Neither the Company nor any of its Subsidiaries have received written notice of any proceeding relating to revocation or modification of any such Permit or has any reason to believe that such Permit will not be renewed in the ordinary course, except where the failure to obtain any such renewal would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(s) Market Capitalization. As of the close of trading on the Exchange on the Trading Day immediately prior to the date of this Agreement, the aggregate market value of the outstanding voting and non-voting common equity (as defined in Securities Act Rule 405) of the Company held by persons other than affiliates (as defined in Securities Act Rule 405) was \$75 million or more (calculated in accordance with Instruction 1.B.1 of Form S-3). The Company is not a shell company (as defined in Rule 405 under the Securities Act) and has not been a shell company for at least 12 calendar months previously and if it has been a shell company at any time previously, has filed current Form 10 information (as defined in Instruction 1.B.6 of Form S-3) with the Commission at least 12 calendar months previously reflecting its status as an entity that is not a shell company. To enable BPSC to rely on Rule 5110(b)(7)(C)(i) of FINRA, the Company represents that, as of the date of this Agreement, the Company (i) has a non-affiliate, public common equity float of at least \$150 million or a non-affiliate, public common equity float of at least \$100 million and annual trading volume of at least three million shares and (ii) has been subject to the Exchange Act reporting requirements for a period of at least 36 months.

(t) No Material Defaults. Neither the Company nor any of the Subsidiaries has defaulted on any installment on indebtedness for borrowed money or on any rental on one or more long-term leases, which defaults, individually or in the aggregate, would reasonably be expected to have a Material Adverse Effect. The Company has not filed a report pursuant to Section 13(a) or 15(d) of the Exchange Act since the filing of its last Annual Report on Form 10-K, indicating that it (i) has failed to pay any dividend or sinking fund installment on preferred stock or (ii) has defaulted on any installment on indebtedness for borrowed money or on any rental on one or more long-term leases, which defaults, individually or in the aggregate, would reasonably be expected to have a Material Adverse Effect.

(u) Certain Market Activities. Neither the Company, nor any of the Subsidiaries, nor, to the Company's knowledge, any of their respective directors, officers or controlling persons has taken, directly or indirectly, any action designed, or that has constituted

or might reasonably be expected to cause or result in, under the Exchange Act or otherwise, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Placement Shares.

(v) Broker/Dealer Relationships. Neither the Company nor any of the Subsidiaries or any related entities (i) is required to register as a “broker” or “dealer” in accordance with the provisions of the Exchange Act or (ii) directly or indirectly through one or more intermediaries, controls or is a “person associated with a member” or “associated person of a member” (within the meaning set forth in the FINRA Manual).

(w) No Reliance. The Company has not relied upon BPSC or legal counsel for BPSC for any legal, tax or accounting advice in connection with the offering and sale of the Placement Shares.

(x) Taxes. The Company and each of its Subsidiaries have filed all federal, state, local and foreign tax returns which have been required to be filed and paid all taxes shown thereon through the date hereof, to the extent that such taxes have become due and are not being contested in good faith, except where the failure to do so would not reasonably be expected to have a Material Adverse Effect. Except as otherwise disclosed in or contemplated by the Registration Statement or the Prospectus, no tax deficiency has been determined adversely to the Company or any of its Subsidiaries which has had, or would reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect. The Company has no knowledge of any federal, state or other governmental tax deficiency, penalty or assessment which has been asserted or threatened against it which would have a Material Adverse Effect.

(y) Title to Real and Personal Property. The Company and its Subsidiaries have good and marketable title in fee simple to all items of real property and good and valid title to all personal property (excluding Intellectual Property) described in the Registration Statement or Prospectus as being owned by them that are material to the businesses of the Company or such Subsidiary, in each case free and clear of all liens, encumbrances and claims, except those that (i) do not materially interfere with the use made of such property by the Company and any of its Subsidiaries or (ii) would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. Any real property described in the Registration Statement or Prospectus as being leased by the Company and any of its Subsidiaries is held by them under valid, existing and enforceable leases, except those that (A) do not materially interfere with the use made or proposed to be made of such property by the Company or any of its Subsidiaries or (B) would not be reasonably expected, individually or in the aggregate, to have a Material Adverse Effect.

(z) Intellectual Property. To its knowledge, the Company and its Subsidiaries own or possess adequate rights to use all patents, patent applications, trademarks (both registered and unregistered), service marks, trade names, trademark registrations, service mark registrations, copyrights, licenses and know-how (including trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures) (collectively, the “Intellectual Property”), necessary for the conduct of their respective businesses as conducted as of the date hereof, except to the extent that the failure to own or possess adequate rights to use

such Intellectual Property would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect; except as disclosed in writing to BPSC, the Company and any of its Subsidiaries have not received any written notice of any claim of infringement or conflict which asserted Intellectual Property rights of others, which infringement or conflict, if the subject of an unfavorable decision, would result in a Material Adverse Effect; there are no pending, or to the Company's knowledge, threatened judicial proceedings or interference proceedings against the Company or its Subsidiaries challenging the Company's or its Subsidiaries' rights in or to or the validity of the scope of any of the Company's or its Subsidiaries' owned material patents, patent applications or proprietary information; no other entity or individual has any right or claim in any of the Company's or its Subsidiaries' owned material patents, patent applications or any patent to be issued therefrom by virtue of any contract, license or other agreement entered into between such entity or individual and the Company or a Subsidiary or by any non-contractual obligation of the Company or a Subsidiary, other than by written licenses granted by the Company or a Subsidiary and other than such rights or claims that would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect; the Company and its Subsidiaries have not received any written notice of any claim challenging the rights of the Company or a Subsidiary in or to any Intellectual Property owned, licensed or optioned by the Company or such Subsidiary which claim, if the subject of an unfavorable decision, would result in a Material Adverse Effect.

(aa) Environmental Laws. The Company and its Subsidiaries (i) are in compliance with any and all applicable federal, state, local and foreign laws, rules, regulations, decisions and orders relating to the protection of human health and safety, the environment or hazardous or toxic substances or wastes, pollutants or contaminants (collectively, "Environmental Laws"); (ii) have received and are in compliance with all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses as described in the Registration Statement and the Prospectus; and (iii) have not received notice of any actual or potential liability for the investigation or remediation of any disposal or release of hazardous or toxic substances or wastes, pollutants or contaminants, except, in the case of any of clauses (i), (ii) or (iii) above, for any such failure to comply or failure to receive required permits, licenses, other approvals or liability as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(bb) Disclosure Controls. The Company and each of its Subsidiaries maintain systems of internal accounting controls designed to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company is not aware of any material weaknesses in its internal control over financial reporting (other than as set forth in the Prospectus). Since the date of the latest audited financial statements of the Company included in the Prospectus, there has been no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting (other than as

set forth in the Prospectus). The Company has established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15 and 15d-15) for the Company and designed such disclosure controls and procedures to ensure that material information relating to the Company and each of its Subsidiaries is made known to the certifying officers by others within those entities, particularly during the period in which the Company's Annual Report on Form 10-K or Quarterly Report on Form 10-Q, as the case may be, is being prepared. The Company's certifying officers have evaluated the effectiveness of the Company's controls and procedures as of a date within 90 days prior to the filing date of the Form 10-K for the fiscal year most recently ended (such date, the "Evaluation Date"). The Company presented in its Form 10-K for the fiscal year most recently ended the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there have been no significant changes in the Company's internal controls (as such term is defined in Item 307(b) of Regulation S-K under the Securities Act) or, to the Company's knowledge, in other factors that could significantly adversely affect the Company's internal controls. To the knowledge of the Company, the Company's "internal controls over financial reporting" and "disclosure controls and procedures" are effective.

(cc) Sarbanes-Oxley. There is and has been no failure on the part of the Company or, to the knowledge of the Company, any of the Company's directors or officers, in their capacities as such, to comply with any applicable provisions of the Sarbanes-Oxley Act and the rules and regulations promulgated thereunder. Each of the principal executive officer and the principal financial officer of the Company (or each former principal executive officer of the Company and each former principal financial officer of the Company as applicable) has made all certifications required by Sections 302 and 906 of the Sarbanes-Oxley Act with respect to all reports, schedules, forms, statements and other documents required to be filed by it or furnished by it to the Commission. For purposes of the preceding sentence, "principal executive officer" and "principal financial officer" shall have the meanings given to such terms in the Sarbanes-Oxley Act.

(dd) Finder's Fees. Neither the Company nor any of the Subsidiaries has incurred any liability for any finder's fees, brokerage commissions or similar payments in connection with the transactions herein contemplated, except as may otherwise exist with respect to BPSC pursuant to this Agreement.

(ee) Labor Disputes. No labor disturbance by or dispute with employees of the Company or any of its Subsidiaries exists or, to the knowledge of the Company, is threatened which would reasonably be expected to result in a Material Adverse Effect

(ff) Investment Company Act. Neither the Company nor any of the Subsidiaries is or, after giving effect to the offering and sale of the Placement Shares, will be an "investment company" or an entity "controlled" by an "investment company," as such terms are defined in the Investment Company Act of 1940, as amended (the "Investment Company Act").

(gg) Operations. The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial record keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as

amended, the money laundering statutes of all jurisdictions to which the Company or its Subsidiaries are subject, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency having jurisdiction over the Company or its Subsidiaries (collectively, the "Money Laundering Laws"), except as would not reasonably be expected to result in a Material Adverse Effect; and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its Subsidiaries with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(hh) Off-Balance Sheet Arrangements. There are no transactions, arrangements and other relationships between and/or among the Company, and/or, to the knowledge of the Company, any of its affiliates and any unconsolidated entity, including, but not limited to, any structured finance, special purpose or limited purpose entity (each, an "Off Balance Sheet Transaction") that would reasonably be expected to affect materially the Company's liquidity or the availability of or requirements for its capital resources, including those Off Balance Sheet Transactions described in the Commission's Statement about Management's Discussion and Analysis of Financial Conditions and Results of Operations (Release Nos. 33-8056; 34-45321; FR-61), in each case that are required to be described in the Prospectus which have not been described as required.

(ii) Underwriter Agreements. The Company anticipates being a party to the Concurrent Facility Agreement simultaneous with this Agreement, but will not have an open sales order in force with more than one agent or underwriter under such agreements at any given time, provided, however, that nothing in this Agreement shall prohibit the Company from entering into the Concurrent Facility Agreement, a committed equity financing facility or similar transaction.

(jj) ERISA. To the knowledge of the Company, (i) each material employee benefit plan, within the meaning of Section 3(3) of the Employee Retirement Income Security Act of 1974, as amended ("ERISA"), that is maintained, administered or contributed to by the Company or any of its affiliates for employees or former employees of the Company and any of its Subsidiaries has been maintained in material compliance with its terms and the requirements of any applicable statutes, orders, rules and regulations, including but not limited to ERISA and the Internal Revenue Code of 1986, as amended (the "Code"); (ii) no prohibited transaction, within the meaning of Section 406 of ERISA or Section 4975 of the Code, has occurred with respect to any such plan excluding transactions effected pursuant to a statutory or administrative exemption; and (iii) for each such plan that is subject to the funding rules of Section 412 of the Code or Section 302 of ERISA, no "accumulated funding deficiency" as defined in Section 412 of the Code has been incurred, whether or not waived, and the fair market value of the assets of each such plan (excluding for these purposes accrued but unpaid contributions) equals or exceeds the present value of all benefits accrued under such plan determined using reasonable actuarial assumptions, other than, in the case of (i), (ii) and (iii) above, as would not reasonably be expected to have a Material Adverse Effect.

(kk) Forward Looking Statements. No forward-looking statement (within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act) (a "Forward

Looking Statement”) contained in the Registration Statement and the Prospectus has been made or reaffirmed without a reasonable basis or has been disclosed other than in good faith. The Forward Looking Statements incorporated by reference in the Registration Statement and the Prospectus from the Company’s Annual Report on Form 10-K for the fiscal year most recently ended (i) except for any Forward Looking Statement included in any financial statements and notes thereto, are within the coverage of the safe harbor for forward looking statements set forth in Section 27A of the Securities Act, Rule 175(b) under the Securities Act or Rule 3b-6 under the Exchange Act, as applicable, (ii) were made by the Company with a reasonable basis and in good faith and reflect the Company’s good faith commercially reasonable best estimate of the matters described therein, and (iii) have been prepared in accordance with Item 10 of Regulation S-K under the Securities Act.

(ll) Margin Rules. Neither the issuance, sale and delivery of the Placement Shares nor the application of the proceeds thereof by the Company as described in the Registration Statement and the Prospectus will violate Regulation T, U or X of the Board of Governors of the Federal Reserve System or any other regulation of such Board of Governors.

(mm) Insurance. The Company and each of its Subsidiaries carry, or are covered by, insurance in such amounts and covering such risks as the Company and each of its Subsidiaries reasonably believe are adequate for the use of their properties and as is customary for companies of similar size engaged in similar businesses in similar industries.

(nn) No Improper Practices. (i) Neither the Company nor, to the Company’s knowledge, the Subsidiaries, nor to the Company’s knowledge, any of their respective executive officers has, in the past five years, made any unlawful contributions to any candidate for any political office (or failed fully to disclose any contribution in violation of law) or made any contribution or other payment to any official of, or candidate for, any federal, state, municipal, or foreign office or other person charged with similar public or quasi-public duty in violation of any law or of the character required to be disclosed in the Prospectus; (ii) no relationship, direct or indirect, exists between or among the Company or, to the Company’s knowledge, any Subsidiary or any affiliate of any of them, on the one hand, and the directors, officers and stockholders of the Company or, to the Company’s knowledge, any Subsidiary, on the other hand, that is required by the Securities Act to be described in the Registration Statement and the Prospectus that is not so described; (iii) no relationship, direct or indirect, exists between or among the Company or any Subsidiary or any affiliate of them, on the one hand, and the directors, officers, stockholders or directors of the Company or, to the Company’s knowledge, any Subsidiary, on the other hand, that is required by the rules of FINRA to be described in the Registration Statement and the Prospectus that is not so described; (iv) except as described in the Prospectus, there are no material outstanding loans or advances or material guarantees of indebtedness by the Company or, to the Company’s knowledge, any Subsidiary to or for the benefit of any of their respective officers or directors or any of the members of the families of any of them; (v) the Company has not offered, or caused any placement agent to offer, Common Stock to any person with the intent to influence unlawfully (A) a customer or supplier of the Company or any Subsidiary to alter the customer’s or supplier’s level or type of business with the Company or any Subsidiary or (B) a trade journalist or publication to write or publish favorable information about the Company or any Subsidiary or any of their respective products or services; and (vi)

neither the Company nor any Subsidiary nor, to the Company's knowledge, any employee or agent of the Company or any Subsidiary has made any payment of funds of the Company or any Subsidiary or received or retained any funds in violation of any law, rule or regulation (including, without limitation, the Foreign Corrupt Practices Act of 1977), which payment, receipt or retention of funds is of a character required to be disclosed in the Registration Statement or the Prospectus.

(oo) Status Under the Securities Act. The Company was not and is not an ineligible issuer as defined in Rule 405 under the Securities Act at the times specified in Rules 164 and 433 under the Securities Act in connection with the offering of the Placement Shares.

(pp) No Misstatement or Omission in an Issuer Free Writing Prospectus. Each Issuer Free Writing Prospectus, as of its issue date and as of each Applicable Time (as defined in Section 24 below), did not, does not and will not include any information that conflicted, conflicts or will conflict with the information contained in the Registration Statement or the Prospectus, including any incorporated document deemed to be a part thereof that has not been superseded or modified. The foregoing sentence does not apply to statements in or omissions from any Issuer Free Writing Prospectus based upon and in conformity with written information furnished to the Company by BPSC specifically for use therein.

(qq) No Conflicts. Neither the execution of this Agreement by the Company, nor the issuance, offering or sale of the Placement Shares, nor the consummation by the Company of any of the transactions contemplated herein and therein, nor the compliance by the Company with the terms and provisions hereof and thereof will conflict with, or will result in a breach of, any of the terms and provisions of, or has constituted or will constitute a default under, or has resulted in or will result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company pursuant to the terms of any contract or other agreement to which the Company may be bound or to which any of the property or assets of the Company is subject, except (i) such conflicts, breaches or defaults as may have been waived and (ii) such conflicts, breaches, defaults, liens, charges or encumbrances that would not reasonably be expected to have a Material Adverse Effect; nor will such action result (x) in any violation of the provisions of the certificate of incorporation or bylaws of the Company, or

(y) in any material violation of the provisions of any statute or any order, rule or regulation applicable to the Company or of any court or of any federal, state or other regulatory authority or other government body having jurisdiction over the Company, except where such violation would not reasonably be expected to have a Material Adverse Effect.

(rr) Clinical Studies. The clinical, pre-clinical and other studies and tests conducted by or, to the knowledge of the Company, on behalf of the Company were, and, if still pending, are being, conducted in accordance in all material respects with all applicable statutes, laws, rules and regulations (including, without limitation, those administered by the United States Food and Drug Administration (the "FDA") or by any foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA), except where the failure do so would not have a Material Adverse Effect. The Company has not received any written notices or other written correspondence from the FDA or any other foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA requiring the Company to terminate or suspend any ongoing clinical or pre-clinical studies or tests.

(ss)Compliance Program. The Company has established and administers a compliance program applicable to the Company, to assist the Company and the directors, officers and employees of the Company in complying with applicable regulatory guidelines (including, without limitation, those administered by the FDA and any other foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA); except where such noncompliance would not reasonably be expected to have a Material Adverse Effect.

(tt)OFAC. (i) Neither the Company nor any of its Subsidiaries (collectively, the "Entity") or, to the Company's knowledge, any director, officer, employee, agent, affiliate or representative of the Entity, is a government, individual, or entity (in this paragraph (tt), "Person") that is, or is owned or controlled by a Person that is:

(A) the subject of any sanctions administered or enforced by the U.S. Department of Treasury's Office of Foreign Assets Control ("OFAC"), the United Nations Security Council ("UNSC"), the European Union ("EU"), Her Majesty's Treasury ("HMT"), or other relevant sanctions authority (collectively, "Sanctions"), nor

(B) located, organized or resident in a country or territory that is the subject of Sanctions (including, without limitation, Burma/Myanmar, Cuba, Iran, North Korea, Sudan and Syria).

(ii) The Company represents and covenants that the Entity will not, directly or indirectly, knowingly use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other Person:

(A) to fund or facilitate any activities or business of or with any Person or in any country or territory that, at the time of such funding or facilitation, is the subject of Sanctions; or

(B) in any other manner that will result in a violation of Sanctions by any Person (including any Person participating in the offering, whether as underwriter, advisor, investor or otherwise).

(iii) The Company represents and covenants that, except as detailed in the Prospectus, for the past five years, the Entity has not knowingly engaged in, is not now knowingly engaged in, and will not knowingly engage in, any dealings or transactions with any Person, or in any country or territory, that at the time of the dealing or transaction is or was the subject of Sanctions.

(uu)Stock Transfer Taxes. On each Settlement Date, all stock transfer or other taxes (other than income taxes) which are required to be paid in connection with the sale and

transfer of the Placement Shares to be sold hereunder will be, or will have been, fully paid or provided for by the Company and all laws imposing such taxes will be or will have been fully complied with in all material respects.

Any certificate signed by an officer of the Company and delivered to BPSC or to counsel for BPSC pursuant to or in connection with this Agreement shall be deemed to be a representation and warranty by the Company, as applicable, to BPSC as to the matters set forth therein.

**7. Covenants of the Company.** The Company covenants and agrees with BPSC that:

(a) **Registration Statement Amendments.** After the date of this Agreement and during any period in which a Prospectus relating to any Placement Shares is required to be delivered by BPSC under the Securities Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act) (the "Prospectus Delivery Period"), (i) the Company will notify BPSC promptly of the time when any subsequent amendment to the Registration Statement, other than documents incorporated by reference, has been filed with the Commission and/or has become effective or any subsequent supplement to the Prospectus (other than documents incorporated by reference therein) has been filed and of any request by the Commission for any amendment or supplement to the Registration Statement or Prospectus or for additional information, (ii) the Company will not file any amendment or supplement to the Registration Statement or Prospectus (except for documents incorporated by reference therein) unless a copy thereof has been submitted to BPSC at least two Business Days before the filing and BPSC has not reasonably and in good faith objected thereto within two Business Days of receiving such copy (provided, however, that (A) the failure of BPSC to make such objection shall not relieve the Company of any obligation or liability hereunder, or affect BPSC's right to rely on the representations and warranties made by the Company in this Agreement, (B) the Company has no obligation to provide BPSC any advance copy of such filing or to provide BPSC an opportunity to object to such filing if such filing does not name BPSC or does not relate to the transactions contemplated by this Agreement, and (C) the only remedy BPSC shall have with respect to the failure by the Company to provide BPSC with such copy or the filing of such amendment or supplement despite BPSC's objection shall be to cease making sales under this Agreement) and the Company will furnish to BPSC at the time of filing thereof a copy of any document that upon filing is deemed to be incorporated by reference into the Registration Statement or Prospectus, except for those documents available via EDGAR; and (iii) the Company will cause each amendment or supplement to the Prospectus to be filed with the Commission as required pursuant to the applicable paragraph of Rule 424(b) of the Securities Act or, in the case of any document to be incorporated therein by reference, to be filed with the Commission as required pursuant to the Exchange Act, within the time period prescribed (the determination to file or not file any amendment or supplement with the Commission under this Section 7(a), based on the Company's reasonable opinion or reasonable objections, shall be made exclusively by the Company).

(b) **Notice of Commission Stop Orders.** The Company will advise BPSC, promptly after it receives notice or obtains knowledge thereof, of the issuance or threatened issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement, of the suspension of the qualification of the Placement Shares for offering or sale in

any jurisdiction, or of the initiation or threatening of any proceeding for any such purpose; and it will promptly use its commercially reasonable efforts to prevent the issuance of any stop order or to obtain its withdrawal if such a stop order should be issued. The Company will advise BPSC promptly after it receives any request by the Commission for any amendments to the Registration Statement or any amendment or supplements to the Prospectus or any Issuer Free Writing Prospectus or for additional information related to the offering of the Placement Shares or for additional information related to the Registration Statement, the Prospectus or any Issuer Free Writing Prospectus.

(c) Delivery of Prospectus; Subsequent Changes. During the Prospectus Delivery Period, the Company will use commercially reasonable efforts to comply in all material respects with all requirements imposed upon it by the Securities Act, as from time to time in force, and to file on or before their respective due dates all reports and any definitive proxy or information statements required to be filed by the Company with the Commission pursuant to Sections 13(a), 13(c), 14, 15(d) or any other provision of or under the Exchange Act. If the Company has omitted any information from the Registration Statement pursuant to Rule 430A under the Securities Act, it will use its best efforts to comply with the provisions of and make all requisite filings with the Commission pursuant to said Rule 430A and to notify BPSC promptly of all such filings. If during the Prospectus Delivery Period any event occurs as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances then existing, not misleading, or if during such period it is necessary to amend or supplement the Registration Statement or Prospectus to comply with the Securities Act, the Company will promptly notify BPSC to suspend the offering of Placement Shares during such period and the Company will promptly amend or supplement the Registration Statement or Prospectus (at the expense of the Company) so as to correct such statement or omission or effect such compliance; provided, however, that the Company may delay any such amendment or supplement if, in the judgment of the Company, it is in the best interests of the Company to do so.

(d) Listing of Placement Shares. During the Prospectus Delivery Period, the Company will use its commercially reasonable efforts to cause the Placement Shares to be listed on the Exchange and to qualify the Placement Shares for sale under the securities laws of such jurisdictions as BPSC reasonably designates and to continue such qualifications in effect so long as required for the distribution of the Placement Shares; provided, however, that the Company shall not be required in connection therewith to qualify as a foreign corporation or dealer in securities or file a general consent to service of process in any jurisdiction.

(e) Delivery of Registration Statement and Prospectus. The Company will furnish to BPSC and its counsel (at the expense of the Company) copies of the Registration Statement, the Prospectus (including all documents incorporated by reference therein) and all amendments and supplements to the Registration Statement or Prospectus that are filed with the Commission during the Prospectus Delivery Period (including all documents filed with the Commission during such period that are deemed to be incorporated by reference therein), in each case as soon as reasonably practicable and in such quantities as BPSC may from time to time reasonably request and, at BPSC's request, will also furnish copies of the Prospectus to each

exchange or market on which sales of the Placement Shares may be made; provided, however, that the Company shall not be required to furnish any document (other than the Prospectus) to BPSC to the extent such document is available on EDGAR.

(f) Earnings Statement. The Company will make generally available to its security holders as soon as practicable, but in any event not later than 15 months after the end of the Company's current fiscal quarter, an earnings statement covering a 12-month period that satisfies the provisions of Section 11(a) and Rule 158 of the Securities Act.

(g) Use of Proceeds. The Company will use the Net Proceeds as described in the Prospectus in the section entitled "Use of Proceeds."

(h) Notice of Other Sales. Without the prior written consent of BPSC, the Company will not, directly or indirectly, offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any Common Stock (other than the Placement Shares offered pursuant to this Agreement) or securities convertible into or exchangeable for Common Stock, warrants or any rights to purchase or acquire, Common Stock during the period beginning on the second (2nd) Trading Day immediately prior to the date on which any Placement Notice is delivered to BPSC hereunder and ending on the second (2nd) Trading Day immediately following the final Settlement Date with respect to Placement Shares sold pursuant to such Placement Notice (or, if the Placement Notice has been terminated or suspended prior to the sale of all Placement Shares covered by a Placement Notice, the date of such suspension or termination); and, at any time during which a Placement Notice is pending and for two (2) Trading Days after the last sale of Placement Shares under such Placement Notice, will not directly or indirectly in any other "at the market" or continuous equity transaction offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any shares of Common Stock (other than the Placement Shares offered pursuant to this Agreement) or securities convertible into or exchangeable for Common Stock, warrants or any rights to purchase or acquire, Common Stock prior to the termination of this Agreement with respect to Placement Shares sold pursuant to such Placement Notice; provided, however, that such restrictions will not be required in connection with the Company's issuance or sale of (i) Common Stock, options to purchase Common Stock or stock awards or Common Stock issuable upon the exercise of options or vesting of stock awards, pursuant to any employee or director stock option or benefits plan, stock ownership plan or dividend reinvestment plan (but not Common Stock subject to a waiver to exceed plan limits in its dividend reinvestment plan) of the Company whether now in effect or hereafter implemented; (ii) Common Stock issuable upon conversion of securities or the exercise of warrants, options or other rights in effect or outstanding, and disclosed in filings by the Company available on EDGAR or otherwise in writing to BPSC and (iii) Common Stock, or securities convertible into or exercisable for Common Stock, offered and sold in a privately negotiated transaction to vendors, customers, investors, strategic partners or potential strategic partners and conducted in a manner so as not to be integrated with the offering of Common Stock hereby.

(i) Change of Circumstances. The Company will, at any time during the pendency of a Placement Notice advise BPSC promptly after it shall have received notice or obtained knowledge thereof, of any information or fact that would alter or affect in any material respect any opinion, certificate, letter or other document required to be provided to BPSC pursuant to this Agreement.

(j) Due Diligence Cooperation. The Company will cooperate with any reasonable due diligence review conducted by BPSC or its representatives in connection with the transactions contemplated hereby, including, without limitation, providing information and making available documents and senior corporate officers, during regular business hours and at the Company's principal offices or such other location mutually agreeable by the parties, as BPSC may reasonably request.

(k) Required Filings Relating to Placement of Placement Shares. The Company agrees that on such dates as the Securities Act shall require, the Company will (i) file a prospectus supplement with the Commission under the applicable paragraph of Rule 424(b) under the Securities Act (the date of each and every such filing under Rule 424(b), a "Filing Date"), which prospectus supplement will set forth, within the relevant period, the amount of Placement Shares sold through BPSC, the Net Proceeds to the Company and the compensation payable by the Company to BPSC with respect to such Placement Shares, and (ii) deliver such number of copies of each such prospectus supplement to each exchange or market on which such sales were effected as may be required by the rules or regulations of such exchange or market.

(l) Representation Dates; Certificate. On the date of this Agreement and each time during the term of this Agreement the Company:

(i) files the Prospectus relating to the Placement Shares or amends or supplements (other than a prospectus supplement relating solely to an offering of securities other than the Placement Shares) the Registration Statement or the Prospectus relating to the Placement Shares by means of a post-effective amendment, sticker, or supplement but not by means of incorporation of documents by reference into the Registration Statement or the Prospectus relating to the Placement Shares;

(ii) files an annual report on Form 10-K under the Exchange Act (including any Form 10-K/A containing restated financial statements or a material amendment to the previously filed Form 10-K);

(iii) files its quarterly reports on Form 10-Q under the Exchange Act; or

(iv) files a current report on Form 8-K containing amended audited financial information (other than information "furnished" pursuant to Items 2.02 or 7.01 of Form 8-K or to provide disclosure pursuant to Item 8.01 of Form 8-K relating to the reclassification of certain properties as discontinued operations in accordance with Statement of Financial Accounting Standards No. 144) under the Exchange Act;

(Each date of filing of one or more of the documents referred to in clauses (i) through (iv) shall be a "Representation Date")

the Company shall furnish BPSC (but in the case of clause (iv) above only if BPSC reasonably

determines that the information contained in such Form 8-K is material) with a certificate, in the form attached hereto as Exhibit 7(l). The requirement to provide a certificate under this Section 7(l) shall be automatically waived for any Representation Date occurring at a time at which no Placement Notice is pending, which waiver shall continue until the date the Company delivers a Placement Notice hereunder (which for such calendar quarter shall be considered a Representation Date); provided, however, that such waiver shall not apply for any Representation Date on which the Company files its annual report on Form 10-K. Notwithstanding the foregoing, if the Company subsequently decides to sell Placement Shares following a Representation Date when the Company relied on such waiver and did not provide BPSC with a certificate under this Section 7(l), then before the Company delivers the Placement Notice or BPSC sells any Placement Shares, the Company shall provide BPSC with a certificate, in the form attached hereto as Exhibit 7(l), dated the date of the Placement Notice.

(m) Legal Opinion. On or prior to the date of the first Placement Notice given hereunder, the Company shall cause to be furnished to BPSC a written opinion and letter of Cooley LLP ("Company Counsel"), or such other counsel reasonably satisfactory to BPSC, covering opinions and statements substantially in the forms attached hereto as Exhibits 7(m)(1) and 7(m)(2). Thereafter within five (5) Trading Days of each Representation Date with respect to which the Company is obligated to deliver a certificate in the form attached hereto as Exhibit 7(l) for which no waiver is applicable, the Company shall cause to be furnished to BPSC a letter of Company Counsel, or other counsel reasonably satisfactory to BPSC, covering statements substantially in the form attached hereto as Exhibits 7(m)(2), modified, as necessary, to relate to the Registration Statement and the Prospectus as then amended or supplemented; provided, however, the Company shall be required to furnish to BPSC no more than one letter hereunder per calendar quarter and the Company shall not be required to furnish letter if the Company does not intend to deliver a Placement Notice in such calendar quarter until such time as the Company delivers its next Placement Notice; provided, further, that in lieu of such letters for subsequent periodic filings under the Exchange Act, counsel may furnish BPSC with a letter (a "Reliance Letter") to the effect that BPSC may rely on a prior letter delivered under this Section 7(m) to the same extent as if it were dated the date of such letter (except that statements in such prior letter shall be deemed to relate to the Registration Statement and the Prospectus as amended or supplemented as of the date of the Reliance Letter).

(n) Comfort Letter. On or prior to the date the first Placement Notice is given hereunder and thereafter within five (5) Trading Days after each Representation Date referred to in Section 7(l)(ii), the Company shall cause its independent accountants to furnish BPSC letters (the "Comfort Letters"), dated the date the Comfort Letter is delivered, which shall meet the requirements set forth in this Section 7(n); provided, that if requested by BPSC, the Company shall cause a Comfort Letter to be furnished to BPSC prior to the tenth (10th) Trading Day after the date of occurrence of any material transaction or event (including the restatement of the Company's financial statements) requiring the filing of a current report on Form 8-K containing material financial information and the date the first Placement Notice is given hereunder following such a material transaction or event, whichever is later. The Comfort Letter from the Company's independent accountants shall be in a form and substance reasonably satisfactory to BPSC, (i) confirming that they are an independent public accounting firm within the meaning of the Securities Act and the PCAOB, (ii) stating, as of such date, the conclusions and findings of

such firm with respect to the financial information and other matters ordinarily covered by accountants' "comfort letters" to underwriters in connection with registered public offerings (the first such letter, the "Initial Comfort Letter") and (iii) updating the Initial Comfort Letter with any information that would have been included in the Initial Comfort Letter had it been given on such date and modified as necessary to relate to the Registration Statement and the Prospectus, as amended and supplemented to the date of such letter.

(o) Market Activities. The Company will not, directly or indirectly, (i) take any action designed to cause or result in, or that constitutes or might reasonably be expected to constitute, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of Common Stock or (ii) sell, bid for, or purchase Common Stock in violation of Regulation M, or pay anyone any compensation for soliciting purchases of the Placement Shares other than BPSC.

(p) Investment Company Act. The Company will conduct its affairs in such a manner so as to reasonably ensure that neither it nor any of its Subsidiaries will be or become, at any time prior to the termination of this Agreement, an "investment company," as such term is defined in the Investment Company Act.

(q) Sarbanes-Oxley Act. The Company and the Subsidiaries will maintain and keep accurate books and records reflecting their assets and maintain internal accounting controls in a manner designed 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 and including those policies and procedures that (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company, (ii) provide reasonable assurance that transactions are recorded as necessary to permit the preparation of the Company's consolidated financial statements in accordance with generally accepted accounting principles, (iii) that receipts and expenditures of the Company are being made only in accordance with management's and the Company's directors' authorization, and (iv) 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 its financial statements. The Company and the Subsidiaries will maintain such controls and other procedures, including, without limitation, those required by Sections 302 and 906 of the Sarbanes-Oxley Act, and the applicable regulations thereunder that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms, including, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure and to ensure that material information relating to the Company or the Subsidiaries is made known to them by others within those entities, particularly during the period in which such periodic reports are being prepared.

8. Representations and Covenants of BPSC. BPSC represents and warrants that it is duly registered as a broker-dealer under FINRA, the Exchange Act and the applicable statutes and regulations of each state in which the Placement Shares will be offered and sold, except such states in which BPSC is exempt from registration or such registration is not otherwise required. BPSC shall continue, for the term of this Agreement, to be duly registered as a broker-dealer under FINRA, the Exchange Act and the applicable statutes and regulations of each state in which the Placement Shares will be offered and sold, except such states in which BPSC is exempt from registration or such registration is not otherwise required, during the term of this Agreement. BPSC will comply with all applicable laws and regulations (including, without limitation, Regulation M) in connection with performing its obligations under this Agreement.

9. Payment of Expenses.

(a) The Company will pay all expenses incident to the performance of its obligations under this Agreement, including (i) the preparation, filing, including any fees required by the Commission, and printing of the Registration Statement (including financial statements and exhibits) as originally filed and of each amendment and supplement thereto and each Issuer Free Writing Prospectus, in such number as BPSC shall reasonably deem necessary, (ii) the printing and delivery to BPSC of this Agreement and such other documents as may be required in connection with the offering, purchase, sale, issuance or delivery of the Placement Shares, (iii) the preparation, issuance and delivery of the certificates, if any, for the Placement Shares to BPSC, including any stock or other transfer taxes and any capital duties, stamp duties or other duties or taxes payable upon the sale, issuance or delivery of the Placement Shares to BPSC, (iv) the fees and disbursements of the counsel, accountants and other advisors to the Company, (v) the reasonable fees and disbursements of counsel to BPSC, up to a maximum amount of \$25,000, (vi) the fees and expenses of the transfer agent and registrar for the Common Stock, (vii) the filing fees incident to any review by FINRA of the terms of the sale of the Placement Shares, and (viii) the fees and expenses incurred in connection with the listing of the Placement Shares on the Exchange.

(b) If this Agreement is terminated by BPSC in accordance with the provisions of Section 13(a) hereof as a result of a material breach by the Company of its obligations hereunder, the Company shall reimburse BPSC for all of its reasonable out-of-pocket expenses, including reasonable fees and disbursements of counsel for BPSC (less any amounts paid under clause (a)(v) above) up to a maximum of \$25,000.

10. Conditions to BPSC's Obligations. The obligations of BPSC hereunder with respect to a Placement will be subject to the continuing accuracy and completeness of the representations and warranties made by the Company herein, to the due performance by the Company of its obligations hereunder, to the completion by BPSC of a due diligence review satisfactory to it in its reasonable judgment, and to the continuing satisfaction (or waiver by BPSC in its sole discretion) of the following additional conditions:

(a) Registration Statement Effective. The Registration Statement shall have become effective and shall be available for the sale of all Placement Shares contemplated to be issued by any Placement Notice.

(b) No Material Notices. None of the following events shall have occurred and be continuing: (i) receipt by the Company of any request for additional information from the Commission or any other federal or state governmental authority during the period of effectiveness of the Registration Statement, the response to which would require any post-effective amendments or supplements to the Registration Statement or the Prospectus; (ii) the issuance by the Commission or any other federal or state governmental authority of any stop order suspending the effectiveness of the Registration Statement or the initiation of any proceedings for that purpose; (iii) receipt by the Company of any notification with respect to the suspension of the qualification or exemption from qualification of any of the Placement Shares for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose; or (iv) any event that makes any material statement made in the Registration Statement or the Prospectus or any material document incorporated or deemed to be incorporated therein by reference untrue in any material respect or that requires the making of any changes in the Registration Statement, the Prospectus or documents so that, in the case of the Registration Statement, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading and, that in the case of the Prospectus, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(c) No Misstatement or Material Omission. BPSC shall not have advised the Company that the Registration Statement or Prospectus, or any amendment or supplement thereto, contains an untrue statement of fact that in BPSC's reasonable opinion is material, or omits to state a fact that in BPSC's opinion is material and is required to be stated therein or is necessary to make the statements therein not misleading.

(d) Material Changes. Except as contemplated in the Prospectus, or disclosed in the Company's reports filed with the Commission, there shall not have been any material adverse change, on a consolidated basis, in the authorized capital stock of the Company or any Material Adverse Effect, or any development in the business or affairs of the Company that could reasonably be expected to cause a Material Adverse Effect.

(e) Legal Opinion. BPSC shall have received the opinions of Company Counsel required to be delivered pursuant Section 7(m) on or before the date on which such delivery of such opinions are required pursuant to Section 7(m).

(f) Comfort Letter. BPSC shall have received the Comfort Letter required to be delivered pursuant Section 7(n) on or before the date on which such delivery of such letter is required pursuant to Section 7(n).

(g) Representation Certificate. BPSC shall have received the certificate required to be delivered pursuant to Section 7(l) on or before the date on which delivery of such certificate is required pursuant to Section 7(l).

(h) No Suspension. Trading in the Common Stock shall not have been suspended on the Exchange and the Common Stock shall not have been delisted from the Exchange.

(i) Other Materials. On each date on which the Company is required to deliver a certificate pursuant to Section 7(l), the Company shall have furnished to BPSC such appropriate further information, certificates and documents as BPSC may have reasonably requested in writing prior to such date and which are usually and customarily furnished by an issuer of securities in connection with the underwritten public offering thereof. All such opinions, certificates, letters and other documents will be in compliance with the provisions hereof. The Company will furnish BPSC with such conformed copies of such opinions, certificates, letters and other documents as BPSC shall reasonably request.

(j) Securities Act Filings Made. All filings with the Commission required by Rule 424 under the Securities Act to have been filed prior to the issuance of any Placement Notice hereunder shall have been made within the applicable time period prescribed for such filing by Rule 424.

(k) Approval for Listing. The Placement Shares shall either have been approved for listing on the Exchange, subject only to notice of issuance, or the Company shall have filed an application for listing of the Placement Shares on the Exchange at, or prior to, the issuance of any Placement Notice.

(l) No Termination Event. There shall not have occurred any event that would permit BPSC to terminate this Agreement pursuant to Section 13(a).

#### 11. Indemnification and Contribution.

(a) Company Indemnification. The Company agrees to indemnify and hold harmless BPSC, its partners, members, directors, officers, employees and agents and each person, if any, who controls BPSC within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act as follows:

(i) against any and all loss, liability, claim, damage and expense whatsoever, as incurred, joint or several, arising out of or based upon any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement (or any amendment thereto), or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading, or arising out of any untrue statement or alleged untrue statement of a material fact included in the any related Issuer Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto), or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading;

(ii) against any and all loss, liability, claim, damage and expense whatsoever, as incurred, joint or several, to the extent of the aggregate amount paid in settlement of any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or of any claim whatsoever based upon any such untrue statement or omission, or any such alleged untrue statement or omission; provided that (subject to Section 11(d) below) any such settlement is effected with the written consent of the Company, which consent shall not unreasonably be delayed or withheld; and

(iii) against any and all expense whatsoever, as incurred (including the reasonable fees and disbursements of counsel), reasonably incurred in investigating, preparing or defending against any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever based upon any such untrue statement or omission, or any such alleged untrue statement or omission, to the extent that any such expense is not paid under (i) or (ii) above, provided, however, that this indemnity agreement shall not apply to any loss, liability, claim, damage or expense to the extent arising out of any untrue statement or omission or alleged untrue statement or omission made solely in reliance upon and in conformity with written information furnished to the Company by BPSC expressly for use in the Registration Statement (or any amendment thereto) or in any related Issuer Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto).

(b) BPSC Indemnification. BPSC agrees to indemnify and hold harmless the Company and its directors and each officer of the Company who signed the Registration Statement, and each person, if any, who (i) controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act or (ii) is controlled by or is under common control with the Company against any and all loss, liability, claim, damage and expense described in the indemnity contained in Section 11(a), as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions, made in the Registration Statement (or any amendments thereto) or any Issuer Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto) in reliance upon and in conformity with information furnished to the Company in writing by BPSC expressly for use therein.

(c) Procedure. Any party that proposes to assert the right to be indemnified under this Section 11 will, promptly after receipt of notice of commencement of any action against such party in respect of which a claim is to be made against an indemnifying party or parties under this Section 11, notify each such indemnifying party of the commencement of such action, enclosing a copy of all papers served, but the omission so to notify such indemnifying party will not relieve the indemnifying party from (i) any liability that it might have to any indemnified party otherwise than under this Section 11 and (ii) any liability that it may have to any indemnified party under the foregoing provision of this Section 11 unless, and only to the extent that, such omission results in the forfeiture or material impairment of substantive rights or defenses by the indemnifying party. If any such action is brought against any indemnified party and it notifies the indemnifying party of its commencement, the indemnifying party will be entitled to participate in and, to the extent that it elects by delivering written notice to the indemnified party promptly after receiving notice of the commencement of the action from the indemnified party, jointly with any other indemnifying party similarly notified, to assume the defense of the action, with counsel reasonably satisfactory to the indemnified party, and after

notice from the indemnifying party to the indemnified party of its election to assume the defense, the indemnifying party will not be liable to the indemnified party for any legal or other expenses except as provided below and except for the reasonable costs of investigation subsequently incurred by the indemnified party in connection with the defense. The indemnified party will have the right to employ its own counsel in any such action, but the fees, expenses and other charges of such counsel will be at the expense of such indemnified party unless (1) the employment of counsel by the indemnified party has been authorized in writing by the indemnifying party, (2) the indemnified party has reasonably concluded (based on advice of counsel) that there may be legal defenses available to it or other indemnified parties that are different from or in addition to those available to the indemnifying party, (3) a conflict or potential conflict exists (based on advice of counsel to the indemnified party) between the indemnified party and the indemnifying party (in which case the indemnifying party will not have the right to direct the defense of such action on behalf of the indemnified party) or (4) the indemnifying party has not in fact employed counsel to assume the defense of such action within a reasonable time after receiving notice of the commencement of the action, in each of which cases the reasonable fees, disbursements and other charges of counsel will be at the expense of the indemnifying party or parties. It is understood that the indemnifying party or parties shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable fees, disbursements and other charges of more than one separate firm admitted to practice in such jurisdiction at any one time for all such indemnified party or parties. All such fees, disbursements and other charges will be reimbursed by the indemnifying party promptly after the indemnifying party receives a written invoice relating to fees, disbursements and other charges in reasonable detail. An indemnifying party will not, in any event, be liable for any settlement of any action or claim effected without its written consent. No indemnifying party shall, without the prior written consent of each indemnified party, settle or compromise or consent to the entry of any judgment in any pending or threatened claim, action or proceeding relating to the matters contemplated by this Section 11 (whether or not any indemnified party is a party thereto), unless such settlement, compromise or consent (1) includes an unconditional release of each indemnified party from all liability arising out of such litigation, investigation, proceeding or claim and (2) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party.

(d) Contribution. In order to provide for just and equitable contribution in circumstances in which the indemnification provided for in the foregoing paragraphs of this Section 11 is applicable in accordance with its terms but for any reason is held to be unavailable from the Company or BPSC, the Company and BPSC will contribute to the total losses, claims, liabilities, expenses and damages (including any investigative, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claim asserted, but after deducting any contribution received by the Company from persons other than BPSC, such as persons who control the Company within the meaning of the Securities Act, officers of the Company who signed the Registration Statement and directors of the Company, who also may be liable for contribution) to which the Company and BPSC may be subject in such proportion as shall be appropriate to reflect the relative benefits received by the Company on the one hand and BPSC on the other hand. The relative benefits received by the Company on the one hand and BPSC on the other hand shall be deemed to be in the same proportion as the total net proceeds from the sale of the Placement Shares (before deducting

expenses) received by the Company bear to the total compensation received by BPSC (before deducting expenses) from the sale of Placement Shares on behalf of the Company. If, but only if, the allocation provided by the foregoing sentence is not permitted by applicable law, the allocation of contribution shall be made in such proportion as is appropriate to reflect not only the relative benefits referred to in the foregoing sentence but also the relative fault of the Company, on the one hand, and BPSC, on the other hand, with respect to the statements or omission that resulted in such loss, claim, liability, expense or damage, or action in respect thereof, as well as any other relevant equitable considerations with respect to such offering. Such relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or BPSC, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and BPSC agree that it would not be just and equitable if contributions pursuant to this Section 11(d) were to be determined by pro rata allocation or by any other method of allocation that does not take into account the equitable considerations referred to herein. The amount paid or payable by an indemnified party as a result of the loss, claim, liability, expense, or damage, or action in respect thereof, referred to above in this Section 11(d) shall be deemed to include, for the purpose of this Section 11(d), any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim to the extent consistent with Section 11(c) hereof. Notwithstanding the foregoing provisions of this Section 11(d), BPSC shall not be required to contribute any amount in excess of the commissions received by it under this Agreement and no person found guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 11(d), any person who controls a party to this Agreement within the meaning of the Securities Act, and any officers, directors, partners, employees or agents of BPSC, will have the same rights to contribution as that party, and each officer and director of the Company who signed the Registration Statement will have the same rights to contribution as the Company, subject in each case to the provisions hereof. Any party entitled to contribution, promptly after receipt of notice of commencement of any action against such party in respect of which a claim for contribution may be made under this Section 11(d), will notify any such party or parties from whom contribution may be sought, but the omission to so notify will not relieve that party or parties from whom contribution may be sought from any other obligation it or they may have under this Section 11(d) except to the extent that the failure to so notify such other party materially prejudiced the substantive rights or defenses of the party from whom contribution is sought. Except for a settlement entered into pursuant to the last sentence of Section 11(c) hereof, no party will be liable for contribution with respect to any action or claim settled without its written consent if such consent is required pursuant to Section 11(c) hereof.

12. Representations and Agreements to Survive Delivery. The indemnity and contribution agreements contained in Section 11 of this Agreement and all representations and warranties of the Company and BPSC herein or in certificates delivered pursuant hereto shall survive, as of their respective dates, regardless of (i) any investigation made by or on behalf of BPSC, any controlling persons, or the Company (or any of their respective officers, directors or controlling persons), (ii) delivery and acceptance of the Placement Shares and payment therefor or (iii) any termination of this Agreement.

### 13. Termination.

(a) BPSC may terminate this Agreement, by notice to the Company, as hereinafter specified at any time (1) if there has been, since the time of execution of this Agreement or since the date as of which information is given in the Prospectus, any Material Adverse Effect, or any development that has occurred that is reasonably likely to have a Material Adverse Effect has occurred or in the sole judgment of BPSC makes it impractical or inadvisable to market the Placement Shares or to enforce contracts for the sale of the Placement Shares, (2) if there has occurred any material adverse change in the financial markets in the United States or the international financial markets, any outbreak of hostilities or escalation thereof or other calamity or crisis or any change or development involving a prospective change in national or international political, financial or economic conditions, in each case the effect of which is such as to make it, in the sole judgment of BPSC, impracticable or inadvisable to market the Placement Shares or to enforce contracts for the sale of the Placement Shares, (3) if trading in the Common Stock has been suspended or limited by the Commission or the Exchange, or if trading generally on the Exchange has been suspended or limited, or minimum prices for trading have been fixed on the Exchange, (4) if any suspension of trading of any securities of the Company on any exchange or in the over-the-counter market shall have occurred and be continuing for at least ten (10) Trading Days, (5) if a major disruption of securities settlements or clearance services in the United States shall have occurred and be continuing, or (6) if a banking moratorium has been declared by either U.S. Federal or New York authorities. Any such termination shall be without liability of any party to any other party except that the provisions of Section 9 (Payment of Expenses), Section 11 (Indemnification and Contribution), Section 12 (Representations and Agreements to Survive Delivery), Section 18 (Governing Law and Time; Waiver of Jury Trial) and Section 19 (Consent to Jurisdiction) hereof shall remain in full force and effect notwithstanding such termination. If BPSC elects to terminate this Agreement as provided in this Section 13(a), BPSC shall provide the required notice as specified in Section 14 (Notices).

(b) The Company shall have the right, by giving ten (10) days notice as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 9, Section 11, Section 12, Section 18 and Section 19 hereof shall remain in full force and effect notwithstanding such termination.

(c) BPSC shall have the right, by giving ten (10) days notice as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 9, Section 11, Section 12, Section 18 and Section 19 hereof shall remain in full force and effect notwithstanding such termination.

(d) Unless earlier terminated pursuant to this Section 13, this Agreement shall automatically terminate upon the earlier to occur of (i) the third (3<sup>rd</sup>) year anniversary of the date hereof and (ii) the issuance and sale of all of the Placement Shares through BPSC on the terms and subject to the conditions set forth herein except that the provisions of Section 9, Section 11, Section 11, Section 12, Section 18 and Section 19 hereof shall remain in full force and effect notwithstanding such termination.

(e) This Agreement shall remain in full force and effect unless terminated pursuant to Sections 13(a), (b), (c), or (d) above or otherwise by mutual agreement of the parties; provided, however, that any such termination by mutual agreement shall in all cases be deemed to provide that Section 9, Section 11, Section 12, Section 18 and Section 19 shall remain in full force and effect. Upon termination of this Agreement, the Company shall not have any liability to BPSC for any discount, commission or other compensation with respect to any Placement Shares not otherwise sold by BPSC under this Agreement.

(f) Any termination of this Agreement shall be effective on the date specified in such notice of termination; provided, however, that such termination shall not be effective until the close of business on the date of receipt of such notice by BPSC or the Company, as the case may be. If such termination shall occur prior to the Settlement Date for any sale of Placement Shares, such Placement Shares shall settle in accordance with the provisions of this Agreement.

14. Notices. All notices or other communications required or permitted to be given by any party to any other party pursuant to the terms of this Agreement shall be in writing, unless otherwise specified, and if sent to BPSC, shall be delivered to:

Brinson Patrick Securities Corporation  
1515 Broadway, 11<sup>th</sup> Floor  
New York, NY 10036  
Attention: Corporate Finance  
Telephone: (212) 453-5000  
Facsimile: (212) 453-5555

with a copy to:

LeClairRyan, A Professional Corporation  
One Riverfront Plaza  
1037 Raymond Boulevard, 16th Floor  
Newark, NJ 07102  
Attention: James T. Seery  
Telephone: (973) 491-3315  
Facsimile: (973) 491-3415

and if to the Company, shall be delivered to:

MannKind Corporation  
28903 North Avenue Paine  
Valencia, CA 91355  
Attention: General Counsel  
Telephone (661) 775-5350  
Facsimile: (661) 775-2086

with a copy to:

Cooley LLP  
4401 Eastgate Mall  
San Diego, CA 92121  
Attention: L. Kay Chandler  
              Sean M. Clayton  
Telephone: (858) 550-6000  
Facsimile: (858) 550-6420

Each party to this Agreement may change such address for notices by sending to the parties to this Agreement written notice of a new address for such purpose. Each such notice or other communication shall be deemed given (i) when delivered personally or by verifiable facsimile transmission (with an original to follow) on or before 4:30 p.m., New York City time, on a Business Day or, if such day is not a Business Day, on the next succeeding Business Day, (ii) on the next Business Day after timely delivery to a nationally-recognized overnight courier and (iii) on the Business Day actually received if deposited in the U.S. mail (certified or registered mail, return receipt requested, postage prepaid). For purposes of this Agreement, "Business Day" shall mean any day on which the Exchange and commercial banks in the City of New York are open for business.

An electronic communication ("Electronic Notice") shall be deemed written notice for purposes of this Section 14 if sent to the electronic mail address specified by the receiving party under separate cover. Electronic Notice shall be deemed received at the time the party sending Electronic Notice receives confirmation of receipt by the receiving party. Any party receiving Electronic Notice may request and shall be entitled to receive the notice on paper, in a nonelectronic form ("Nonelectronic Notice") which shall be sent to the requesting party within ten (10) days of receipt of the written request for Nonelectronic Notice.

15. Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the Company and BPSC and their respective successors and the affiliates, controlling persons, officers and directors referred to in Section 11 hereof. References to any of the parties contained in this Agreement shall be deemed to include the successors and permitted assigns of such party. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assigns any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement. Neither party may assign its rights or obligations under this Agreement without the prior written consent of the other party.

16. Adjustments for Stock Splits. The parties acknowledge and agree that all share-related numbers contained in this Agreement shall be adjusted to take into account any share consolidation, stock split, stock dividend, corporate domestication or similar event effected with respect to the Placement Shares.

17. Entire Agreement; Amendment; Severability. This Agreement (including all schedules and exhibits attached hereto and Placement Notices issued pursuant hereto) constitutes

the entire agreement of the parties with respect to the subject matter hereof and supersedes all other prior and contemporaneous agreements and undertakings, both written and oral, among the parties hereto with regard to the subject matter hereof. Neither this Agreement nor any term hereof may be amended except pursuant to a written instrument executed by the Company and BPSC. In the event that any one or more of the provisions contained herein, or the application thereof in any circumstance, is held invalid, illegal or unenforceable as written by a court of competent jurisdiction, then such provision shall be given full force and effect to the fullest possible extent that it is valid, legal and enforceable, and the remainder of the terms and provisions herein shall be construed as if such invalid, illegal or unenforceable term or provision was not contained herein, but only to the extent that giving effect to such provision and the remainder of the terms and provisions hereof shall be in accordance with the intent of the parties as reflected in this Agreement.

**18. GOVERNING LAW AND TIME; WAIVER OF JURY TRIAL. THIS AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK WITHOUT REGARD TO THE PRINCIPLES OF CONFLICTS OF LAWS. SPECIFIED TIMES OF DAY REFER TO NEW YORK CITY TIME. THE COMPANY HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.**

**19. CONSENT TO JURISDICTION. EACH PARTY HEREBY IRREVOCABLY SUBMITS TO THE NON-EXCLUSIVE JURISDICTION OF THE STATE AND FEDERAL COURTS SITTING IN THE CITY OF NEW YORK, BOROUGH OF MANHATTAN, FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION WITH ANY TRANSACTION CONTEMPLATED HEREBY, AND HEREBY IRREVOCABLY WAIVES, AND AGREES NOT TO ASSERT IN ANY SUIT, ACTION OR PROCEEDING, ANY CLAIM THAT IT IS NOT PERSONALLY SUBJECT TO THE JURISDICTION OF ANY SUCH COURT, THAT SUCH SUIT, ACTION OR PROCEEDING IS BROUGHT IN AN INCONVENIENT FORUM OR THAT THE VENUE OF SUCH SUIT, ACTION OR PROCEEDING IS IMPROPER. EACH PARTY HEREBY IRREVOCABLY WAIVES PERSONAL SERVICE OF PROCESS AND CONSENTS TO PROCESS BEING SERVED IN ANY SUCH SUIT, ACTION OR PROCEEDING BY MAILING A COPY THEREOF (CERTIFIED OR REGISTERED MAIL, RETURN RECEIPT REQUESTED) TO SUCH PARTY AT THE ADDRESS IN EFFECT FOR NOTICES TO IT UNDER THIS AGREEMENT AND AGREES THAT SUCH SERVICE SHALL CONSTITUTE GOOD AND SUFFICIENT SERVICE OF PROCESS AND NOTICE THEREOF. NOTHING CONTAINED HEREIN SHALL BE DEEMED TO LIMIT IN ANY WAY ANY RIGHT TO SERVE PROCESS IN ANY MANNER PERMITTED BY LAW.**

20. Use of Information. BPSC may not use any information gained in connection with this Agreement and the transactions contemplated by this Agreement, including due diligence, to advise any party with respect to transactions not expressly approved by the Company.

21. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Delivery of an executed Agreement by one party to the other may be made by facsimile transmission.

22. Effect of Headings. The section and Exhibit headings herein are for convenience only and shall not affect the construction hereof.

23. Permitted Free Writing Prospectuses. The Company represents, warrants and agrees that, unless it obtains the prior consent of BPSC (such consent not to be unreasonably withheld, conditioned or delayed), and BPSC represents, warrants and agrees that, unless it obtains the prior consent of the Company (such consent not to be unreasonably withheld, conditioned or delayed), it has not made and will not make any offer relating to the Placement Shares that would constitute an Issuer Free Writing Prospectus, or that would otherwise constitute a "free writing prospectus," as defined in Rule 405, required to be filed with the Commission. Any such free writing prospectus consented to by BPSC or by the Company, as the case may be, is hereinafter referred to as a "Permitted Free Writing Prospectus." The Company represents and warrants that it has treated and agrees that it will treat each Permitted Free Writing Prospectus as an "issuer free writing prospectus," as defined in Rule 433, and has complied and will comply with the requirements of Rule 433 applicable to any Permitted Free Writing Prospectus, including timely filing with the Commission where required, legending and record keeping. For the purposes of clarity, the parties hereto agree that all free writing prospectuses, if any, listed in Exhibit 23 hereto are Permitted Free Writing Prospectuses.

24. Absence of Fiduciary Relationship. The Company acknowledges and agrees that:

(a) BPSC is acting solely as agent in connection with the public offering of the Placement Shares and in connection with each transaction contemplated by this Agreement and the process leading to such transactions, and no fiduciary or advisory relationship between the Company or any of its respective affiliates, stockholders (or other equity holders), creditors or employees or any other party, on the one hand, and BPSC, on the other hand, has been or will be created in respect of any of the transactions contemplated by this Agreement, irrespective of whether or not BPSC has advised or is advising the Company on other matters, and BPSC has no obligation to the Company with respect to the transactions contemplated by this Agreement except the obligations expressly set forth in this Agreement;

(b) it is capable of evaluating and understanding, and understands and accepts, the terms, risks and conditions of the transactions contemplated by this Agreement;

(c) BPSC has not provided any legal, accounting, regulatory or tax advice with respect to the transactions contemplated by this Agreement and it has consulted its own legal, accounting, regulatory and tax advisors to the extent it has deemed appropriate;

(d) it is aware that BPSC and its affiliates are engaged in a broad range of transactions which may involve interests that differ from those of the Company and BPSC has no obligation to disclose such interests and transactions to the Company by virtue of any fiduciary, advisory or agency relationship or otherwise; and

(e) it waives, to the fullest extent permitted by law, any claims it may have against BPSC for breach of fiduciary duty or alleged breach of fiduciary duty in connection with the sale of Placement Shares under this Agreement and agrees that BPSC shall not have any liability (whether direct or indirect, in contract, tort or otherwise) to it in respect of such a fiduciary duty claim or to any person asserting a fiduciary duty claim on its behalf or in right of it or the Company, employees or creditors of Company, other than in respect of BPSC's obligations under this Agreement and to keep information provided by the Company to BPSC and BPSC's counsel confidential to the extent not otherwise publicly-available.

25. Definitions. As used in this Agreement, the following terms have the respective meanings set forth below:

"Applicable Time" means (i) each Representation Date and (ii) the time of each sale of any Placement Shares pursuant to this Agreement.

"Issuer Free Writing Prospectus" means any "issuer free writing prospectus," as defined in Rule 433, relating to the Placement Shares that (1) is required to be filed with the Commission by the Company, (2) is a "road show" that is a "written communication" within the meaning of Rule 433(d)(8)(i) whether or not required to be filed with the Commission, or (3) is exempt from filing pursuant to Rule 433(d)(5)(i) because it contains a description of the Placement Shares or of the offering that does not reflect the final terms, in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company's records pursuant to Rule 433(g) under the Securities Act Regulations.

"Rule 164," "Rule 172," "Rule 405," "Rule 415," "Rule 424," "Rule 424(b)," "Rule 430B," and "Rule 433" refer to such rules under the Securities Act Regulations.

All references in this Agreement to financial statements and schedules and other information that is "contained," "included" or "stated" in the Registration Statement or the Prospectus (and all other references of like import) shall be deemed to mean and include all such financial statements and schedules and other information that is incorporated by reference in the Registration Statement or the Prospectus, as the case may be.

All references in this Agreement to the Registration Statement, the Prospectus or any amendment or supplement to any of the foregoing shall be deemed to include the copy filed with the Commission pursuant to EDGAR; all references in this Agreement to any Issuer Free Writing Prospectus (other than any Issuer Free Writing Prospectuses that, pursuant to Rule 433, are not required to be filed with the Commission) shall be deemed to include the copy thereof filed with the Commission pursuant to EDGAR; and all references in this Agreement to "supplements" to the Prospectus shall include, without limitation, any supplements, "wrappers" or similar materials prepared in connection with any offering, sale or private placement of any Placement Shares by BPSC outside of the United States.

If the foregoing correctly sets forth the understanding between the Company and BPSC, please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding agreement between the Company and BPSC.

Very truly yours,

**MANKIND CORPORATION**

By: /s/ Matthew J. Pfeffer

Name: Matthew J. Pfeffer

Title: Chief Financial Officer

**ACCEPTED as of the date first-above written:**

**BRINSON PATRICK SECURITIES CORPORATION**

By: /s/ Todd Wyche

Name: Todd Wyche

Title: Chief Executive Officer

[Signature Page to At-The-Market Issuance Sales Agreement]

SCHEDULE 1

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FORM OF PLACEMENT NOTICE

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From: MannKind Corporation

To: Brinson Patrick Securities Corporation

Attention: Todd Wyche

Subject: At-The-Market Issuance—Placement Notice

Gentlemen:

Pursuant to the terms and subject to the conditions contained in the At-The-Market Issuance Sales Agreement between MannKind Corporation, a Delaware corporation (the "Company"), and Brinson Patrick Securities Corporation ("BPSC"), dated March 18, 2013, the Company hereby requests that BPSC sell up to of the Company's Common Stock, par value \$0.01 per share, at a minimum market price of \$ per share, during the time period beginning [month, day, time] and ending [month, day, time]. [The Company may include such other sales parameters as it deems appropriate.]

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## SCHEDULE 2

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### Compensation

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The Company shall pay to BPSC in cash, upon each sale of Placement Shares pursuant to this Agreement, an amount up to 3.0% of the gross proceeds from each sale of Placement Shares.

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## SCHEDULE 3

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### Notice Parties

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The Company  
Matthew Pfeffer  
David Thomson  
Hakan Edstrom

#### BPSC

Nino Jimenz  
Tim Studley  
Todd Wyche

The above-mentioned individuals from BPSC can be reached at [trading@brinsonpatrick.com](mailto:trading@brinsonpatrick.com) and at 212-453-3000

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**SCHEDULE 4**

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**Subsidiaries**

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None.

## EXHIBIT 7(I)

### Form of Representation Date Certificate

This Officers Certificate (this "Certificate") is executed and delivered in connection with Section 7(l) of the At-The-Market Issuance Sales Agreement (the "Agreement"), dated March 18, 2013, and entered into between MannKind Corporation (the "Company") and Brinson Patrick Securities Corporation. All capitalized terms used but not defined herein shall have the meanings given to such terms in the Agreement.

The undersigned, a duly appointed and authorized officer of the Company, having made reasonable inquiries to establish the accuracy of the statements below and having been authorized by the Company to execute this certificate on behalf of the Company, hereby certifies, on behalf of the Company and not in the undersigned's individual capacity, as follows:

1. As of the date of this Certificate, (i) the Registration Statement does not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein not misleading and (ii) neither the Registration Statement nor the Prospectus contains any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading and (iii) no event has occurred as a result of which it is necessary to amend or supplement the Prospectus in order to make the statements therein not untrue or misleading for (i) and (ii) to be true.

2. Each of the representations and warranties of the Company contained in the Agreement was true and correct in all material respects, when originally made, and, except for those representations and warranties that speak solely as of a specific date, is true and correct as of the date of this Certificate.

3. Except as waived by BPSC in writing, each of the covenants required to be performed by the Company in the Agreement on or prior to the date of the Agreement, this Representation Date, and each such other date prior to the date hereof as set forth in the Agreement, has been duly, timely and fully performed in all material respects and each condition required to be complied with by the Company on or prior to the date of the Agreement, this Representation Date, and each such other date prior to the date hereof as set forth in the Agreement has been duly, timely and fully complied with in all material respects.

4. No stop order suspending the effectiveness of the Registration Statement or of any part thereof has been issued, and, to the Company's knowledge, no proceedings for that purpose have been instituted or are pending or threatened by any securities or other governmental authority (including, without limitation, the Commission).

5. No order suspending the effectiveness of the Registration Statement or the qualification or registration of the Placement Shares under the securities or Blue Sky laws of any jurisdiction are in effect and no proceeding for such purpose is pending before, or threatened, to the Company's knowledge or in writing by, any securities or other governmental authority (including, without limitation, the Commission).

The undersigned has executed this Officer's Certificate on behalf of the Company as of the date first written above.

MANKIND CORPORATION

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

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**Exhibit 23**

**Permitted Free Writing Prospectus**

None.

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in Registration Statement No. 333-166404 and 333-183679 on Form S-3 and Registration Statement Nos. 333-117811, 333-127876, 333-137332, 333-149049, 333-160225, 333-176409 and 333-182457 on Form S-8 of our reports dated March 18, 2013, relating to the consolidated financial statements of MannKind Corporation and subsidiaries (a development stage company) ("MannKind Corporation") (which report expresses an unqualified opinion and includes an explanatory paragraph relating to the Company's ability to continue as a going concern), and the effectiveness of MannKind Corporation's internal control over financial reporting, appearing in the Annual Report on Form 10-K of MannKind Corporation for the year ended December 31, 2012.

/s/ Deloitte & Touche LLP

Los Angeles, California  
March 18, 2013

**RULE 13a-14(a)/15d-14(a) CERTIFICATION**

I, Alfred E. Mann, certify that:

1. I have reviewed this Annual Report on Form 10-K of MannKind Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Alfred E. Mann

Alfred E. Mann

Chief Executive Officer and

Chairman of the Board of Directors

Date: March 18, 2013

**RULE 13a-14(a)/15d-14(a) CERTIFICATION**

I, Matthew J. Pfeffer, certify that:

1. I have reviewed this Annual Report on Form 10-K of MannKind Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Matthew J. Pfeffer

Matthew J. Pfeffer  
Corporate Vice President and  
Chief Financial Officer

Date: March 18, 2013

**CERTIFICATION:**

Pursuant to the requirement set forth in Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Alfred E. Mann, Chief Executive Officer of MannKind Corporation (the "Company"), and Matthew J. Pfeffer, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2012, to which this Certification is attached as Exhibit 32 (the "Annual Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and
2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company. **In Witness Whereof**, the undersigned have set their hands hereto as of the 18<sup>th</sup> day of March 2013.

/s/ Alfred E. Mann

Alfred E. Mann

Chief Executive Officer

/s/ Matthew J. Pfeffer

Matthew J. Pfeffer

Corporate Vice President and Chief Financial Officer

<sup>1</sup> This certification accompanies the Annual Report on Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of MannKind Corporation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Annual Report on Form 10-K to which this certification relates), irrespective of any general incorporation language contained in such filing.