MANNKIND CORP
Form 10-K
March 15, 2016
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2015

or

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

Commission file number: 000-50865

MannKind Corporation

(Exact name of registrant as specified in its charter)

Delaware	**13-3607736**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
25134 Rye Canyon Loop Suite 300	
Valencia, California	**91355**
(Address of principal executive offices)	*(Zip Code)*

Registrant s telephone number, including area code

(661) 775-5300

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

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

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

None

(Title of Class)

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

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

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

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

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

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

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

As of June 30, 2015, 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 $1,461,620,053.

As of February 22, 2016, there were 428,850,858 shares of the registrant s Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive Proxy Statement (the Proxy Statement) for the 2016 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form 10-K, are incorporated by reference in Part III of this Annual Report on Form 10-K.

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MANNKIND CORPORATION

Annual Report on Form 10-K

For the Fiscal Year Ended December 31, 2015

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Forward-Looking Statements

Statements in this report that are not strictly historical in nature are forward-looking statements within the meaning of the federal securities laws made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward-looking statements by terms such as anticipate, believe, could, estimate, expect, goal, intend, may, plan, potential, p should, will, would, and similar expressions intended to identify forward-looking statements, though not all forward-looking statements contain these identifying words. These statements may include, but are not limited to, statements regarding: our ability to successfully market, commercialize and achieve market acceptance for AFREZZA or any other product candidates or therapies that we may develop; our ability to manufacture sufficient quantities of AFREZZA and obtain insulin supply as needed; our ability to successfully commercialize our Technosphere drug delivery platform; our estimates for future performance; our estimates regarding anticipated operating losses, future revenues, capital requirements and our needs for additional financing; the timing and amount of our future recognition of deferred product sales from collaboration, product costs from collaboration and income from collaboration; the progress or success of our research, development and clinical programs, including the application for and receipt of regulatory clearances and approvals; our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; and scientific studies and the conclusions we draw from them. 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.

MannKind Corporation is a biopharmaceutical company focused on the discovery and development of therapeutic products for diseases such as diabetes. Our only approved product, AFREZZA, is a rapid-acting inhaled insulin that was approved by the U.S. Food and Drug Administration (the FDA) on June 27, 2014 to improve glycemic control in adult patients with diabetes. AFREZZA became available by prescription in United States retail pharmacies in February 2015. According to the Centers for Disease Control and Prevention, in the United States in 2012, approximately 29.1 million people had diabetes. Globally, the International Diabetes Federation has estimated that approximately 415.0 million people had diabetes in 2015 and approximately 642.0 million people will have diabetes by 2040.

AFREZZA is a rapid-acting, inhaled insulin used to control high blood sugar in adults with type 1 and type 2 diabetes. The product consists of a dry formulation of human insulin delivered from a small and portable inhaler. Administered at the beginning of a meal, AFREZZA dissolves rapidly upon inhalation to the lung and delivers insulin quickly to the bloodstream. Peak insulin levels are achieved within 12 15 minutes of administration.

On August 11, 2014, we entered into a license and collaboration agreement (the Sanofi License Agreement) with Sanofi-Aventis Deutschland GmbH (which subsequently assigned its rights and obligations under the agreement to Sanofi-Aventis U.S. LLC (Sanofi)), pursuant to which Sanofi became responsible for global commercial, regulatory and development activities for AFREZZA. For the year ended December 31, 2015, Sanofi reported a total of 7.0 million in annual sales of AFREZZA.

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On January 4, 2016, we received written notice from Sanofi of its election to terminate in its entirety the Sanofi License Agreement. Sanofi s notice indicated that the termination was pursuant to Sanofi s right to terminate the agreement upon Sanofi s good faith determination that the commercialization of AFREZZA is no longer economically viable in the United States, in which case the effective date of termination (the Termination Date) would be April 4, 2016. In the alternative, Sanofi indicated that the termination was also pursuant to its right to terminate the agreement for any reason, in which case the Termination Date would be July 4, 2016. We believe that Sanofi lacks a good faith basis for determining that commercialization of AFREZZA is no longer economically viable in the United States. Nonetheless, in the interest of an expedient transition, we are currently working with Sanofi to transfer and wind down the agreement activities by April 4, 2016, or as soon as practicable thereafter. As required by the Sanofi License Agreement, we and Sanofi are currently using diligent efforts to facilitate the smooth and orderly transition of development and commercialization activities related to AFREZZA, and are negotiating in good faith a written transition agreement for this purpose. As a result of the foregoing termination, effective on the Termination Date and thereafter during any period which Sanofi is required to perform any wind-down activities pursuant to the terms of the Sanofi License Agreement, the rights granted to Sanofi under the Sanofi License Agreement to develop and commercialize AFREZZA will become non-exclusive and we will have the right to engage one or more other distributors and/or licensees of AFREZZA. Sanofi will continue to distribute AFREZZA during the wind-down period as required by the agreement until such time that we or our designee takes over responsibility for distribution. All profits and losses from AFREZZA product sales by Sanofi or its affiliates after the Termination Date, if any, will continue to be shared 65% by Sanofi and 35% by us pursuant to the terms of the Sanofi License Agreement. We and Sanofi are also parties to a supply agreement, dated August 11, 2014 (the Sanofi Supply Agreement), pursuant to which we are required to supply Sanofi or its affiliates or its sublicensees such quantities of AFREZZA as requested by Sanofi to cover its commercial requirements. As a result of the termination of the Sanofi License Agreement, the Sanofi Supply Agreement will terminate by its terms on the Termination Date. In addition to the foregoing agreements, we and Aventisub LLC, an affiliate of Sanofi, are parties to a Senior Secured Revolving Promissory Note, dated September 23, 2014 (the Sanofi Loan Facility) and a Guaranty and Security Agreement (the Security Agreement). Both the Sanofi Loan Facility and the Security Agreement remain in effect. Pursuant to the Sanofi Loan Facility, we may borrow up to an aggregate of $175.0 million to fund our share of net losses from AFREZZA product sales by Sanofi or its affiliates. The original maturity date of September 23, 2024 for repayment of the outstanding principal amount of the loans under the Sanofi Loan Facility is not affected by the termination of the Sanofi License Agreement.

As part of the approval of AFREZZA, the FDA required us to conduct the following post-marketing studies:

- A dose-ranging pharmacokinetic (PK)-pharmacodynamic (PD) glucose-clamp trial to characterize the dose-response of AFREZZA relative to subcutaneous insulin in patients with type 1 diabetes, which Sanofi completed in 2015;

- A PK-PD glucose-clamp trial to characterize within-subject variability, which Sanofi completed in 2015;

- An open-label PK and multiple-dose safety and tolerability dose-titration trial of AFREZZA in pediatric patients ages 4 to 17 years with type 1 diabetes, for which Sanofi is in the process of enrolling subjects, followed by a prospective, open-label, randomized, controlled trial comparing the efficacy and safety of prandial AFREZZA to prandial subcutaneous insulin as part used in combination with subcutaneous basal insulin in pediatric patients 4 to 17 years old with type 1 or type 2 diabetes; and

- A five-year, randomized, controlled trial in 8,000-10,000 patients with type 2 diabetes to assess the potential serious risk of pulmonary malignancy with AFREZZA use.

Pursuant to the Sanofi License Agreement, we transferred the approved new drug application (NDA) for AFREZZA to Sanofi following the closing of the transaction. Sanofi has completed the two PK-PD studies and is in the process of enrolling subjects in the first part of the pediatric study. The obligation to complete the pediatric study and to conduct the five-year pulmonary safety study will revert to us when the NDA for AFREZZA is transferred back to us in connection with the termination of the Sanofi License Agreement. At that time, we will become responsible for the NDA and its maintenance.

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Manufacturing and Supply

We manufacture AFREZZA in our Danbury, Connecticut facility, where we formulate the AFREZZA inhalation powder, fill it into plastic cartridges and then blister package the cartridges and seal the blister cards inside a foil overwrap. These overwraps are then packaged into cartons along with inhalers and printed material by a third-party packager. The cartridges and inhalers are manufactured for us by a third-party plastic-molding company; the cartridges are delivered to our Connecticut facility whereas the inhalers are shipped directly to the packaging contractor.

The quality management systems of our Connecticut facility were certified to be in conformance with the ISO 13485 and ISO 9001 standards. Our facility has been inspected twice by the FDA, once for a pre-approval inspection in the fall of 2009 and once for a regular inspection in May 2013. The FDA is expected to conduct additional inspections of our facility.

We believe that our Connecticut facility has enough capacity to satisfy the current commercial demand for AFREZZA. We currently have three operational filling lines with the capacity to process 300-360 million cartridges per year. In addition, the facility includes expansion space to accommodate additional filling lines and other equipment, allowing production capacity to be increased based on the demand for AFREZZA over the next several years.

Currently, the only approved source of insulin for AFREZZA is manufactured by Amphastar France Pharmaceuticals S.A.S. (Amphastar). In April 2014, Amphastar acquired a manufacturing facility from N.V. Organon, a subsidiary of Merck & Co., Inc., where we had previously obtained the insulin that we use to make AFREZZA. On July 31, 2014, we entered into a supply agreement with Amphastar (the Insulin Supply Agreement), pursuant to which we agreed to purchase certain annual minimum quantities of insulin for calendar years 2015 through 2019 for an aggregate total purchase price of approximately 120.1 million, of which 98.5 million is remaining at December 31, 2015. We have contracted for the purchase of 28.8 million in 2016 and the remaining annual minimum quantities will be 23.3 million for the years ending December 31, 2017 through 2019. We also may purchase additional quantities of insulin over such annual minimum quantities at our option. Unless earlier terminated, the term of the Insulin Supply Agreement expires on December 31, 2019 and can be renewed for additional, successive two year terms upon 12 months written notice given prior to the end of the initial term or any additional two year term. We and Amphastar each have normal and customary termination rights, including termination for material breach that is not cured within a specific time frame or in the event of liquidation, bankruptcy or insolvency of the other party. In addition, we may terminate the Insulin Supply Agreement upon two years prior written notice to Amphastar without cause or upon 30 days prior written notice to Amphastar if a controlling regulatory authority withdraws approval for AFREZZA, provided, however, in the event of a termination pursuant to either of the latter two scenarios, the provisions of the Insulin Supply Agreement require us to pay the full amount of all unpaid purchase commitments due over the initial term within 60 calendar days of the effective date of such termination.

We also own a quantity of bulk insulin that we acquired in June 2009 from Pfizer Manufacturing Frankfurt GmbH, a subsidiary of Pfizer Inc., as well as an option to purchase from Pfizer additional insulin inventory, in whole or in part, at a specified price, to the extent it remains available. The purchase price for this insulin was fully expensed at the time of the purchase. To date, none of this insulin has been qualified as a source of insulin for AFREZZA.

Currently, we purchase the raw material from which we produce Technosphere particles (fumaryl diketopiperazine (FDKP)) 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.

We have a three-year supply agreement with the contract manufacturer that produces our inhaler and the corresponding cartridges. We expect to be able to qualify an additional vendor of plastic-molding contract manufacturing services, if warranted by demand.

We also have a three-year agreement with the contractor that performs the final packaging of AFREZZA overwraps, inhalers and printed material into patient kits. We expect to be able to qualify an additional vendor of packaging services, if warranted by demand.

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Our third-party suppliers are subject to extensive governmental regulation. We rely on our suppliers to comply with relevant regulatory requirements, including compliance with Quality System Regulations (QSRs).

Technosphere Formulation Technology

AFREZZA utilizes our proprietary Technosphere formulation technology; however, the application of this technology is not limited to insulin delivery. We believe it represents a versatile drug delivery platform that may allow the oral inhalation of a wide range of therapeutics. We have successfully prepared Technosphere formulations of anionic and cationic drugs, hydrophobic and hydrophilic drugs, proteins, peptides, and small molecules. Technosphere powders are based on our proprietary excipient, FDKP, which is a pH-sensitive organic molecule that self-assembles into small particles under acidic conditions. Certain drugs, such as insulin, can be loaded onto these particles by combining a solution of the drug with a suspension of Technosphere material, which is then dried to powder form. The resulting powder has a consistent and narrow range of particle sizes with good aerodynamic properties that enable them to fly efficiently deep into the lungs. Technosphere powders dissolve extremely fast after inhalation when the particles contact the moist lung surface with its neutral pH, releasing the drug molecules to diffuse across a thin layer of cells into the arterial circulation, bypassing the liver to provide excellent systemic exposure.

We have also created an innovative line of breath-powered, dry powder inhalers. Our inhalers are easy to use, cost-effective and can be produced in both a reusable (chronic treatment) and a single-use (acute treatment) format. Both the reusable and single use inhaler formats use the same internal air-flow design. Being breath-powered, our inhalers require only the patient s inhalation effort to deliver the powder. Patients are not required to activate the inhaler prior to use and no activation step with inhalation is required. To administer the inhalation powder, a patient loads a cartridge into our inhaler and inhales through the mouthpiece. Upon inhalation, the dry powder is lifted out of the cartridge and broken (or de-agglomerated) into small particles. The inhalers are engineered to produce an aggressive airstream to de-agglomerate the powder while keeping the powder moving slowly. This slow-moving powder effectively navigates the patient s airways for delivery into the lung with minimal deposition at the back of the throat. Our inhalers show very little change in performance over a wide range of inhalation efforts and produce high bioavailability. In a handling study, pediatric subjects as young as four years old were readily able to use the inhaler.

To aid in the development of our oral inhalation products, we have created a number of innovative development tools and techniques. For example, our BluHale technology is a novel inhalation profiling tool that uses miniature acoustic sensors to assess the drug delivery process at the level of an individual inhaler. This tool provides real-time insight into patient usage, device system performance and pharmacokinetic effects. We can combine this tool with other development tools, such as patient inhalation simulators and anatomically correct airway models, in order to integrate inhaler performance with formulation development right from the beginning of the development program. The result is a powder/inhaler combination product customized to the target patient population from the first clinical study.

In January 2016, we entered into a collaboration and license agreement with a newly formed entity, Receptor Life Sciences, Inc., pursuant to which Receptor is evaluating the feasibility of developing multiple inhaled therapeutic products using our technology to explore their potential to treat conditions such as chronic pain, neurologic diseases and inflammatory disorders.

Our Strategy

The following are the key elements of our strategy:

Commercialization and development of AFREZZA. As soon as practicable following the Termination Date of the Sanofi License Agreement, our intention is to assume the responsibility for commercializing and developing AFREZZA in the United States. In order to commercially market AFREZZA, we will need to develop an internal sales team and expand our marketing infrastructure, collaborate with third parties who have greater sales and marketing capabilities, purchase services from a contract commercial organization, or utilize some combination of one or more of the above. We also intend to seek regional partnerships for the development and commercialization of AFREZZA in foreign jurisdictions where there are appropriate commercial opportunities.

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Capitalize on our proprietary Technosphere and inhaler technology for the delivery of active pharmaceutical ingredients. 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. In addition to our collaboration with Receptor, we are actively exploring other opportunities to out-license our proprietary Technosphere formulation and device technologies. We are also evaluating several product opportunities that we would consider developing as internally funded efforts.

Sales and Marketing

To date, we have relied on Sanofi to conduct all sales and marketing activities related to AFREZZA. As soon as practicable following the Termination Date of the Sanofi License Agreement, our intention is to assume the responsibility for these activities.

In order to commercially market AFREZZA, we will need to develop an internal sales team and expand our marketing infrastructure, collaborate with third parties who have greater sales and marketing capabilities, purchase services from a contract commercial organization, or utilize some combination of these approaches.

Intellectual Property

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 the commercial version of our inhaler and cartridges. 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 330 issued patents in the United States and selected jurisdictions around the world and we also have over 350 applications pending that may provide additional protection if and when they are allowed. These include composition and inhaler and cartridge patents providing protection for AFREZZA with various expiration dates, the longer-lived of which will not expire until 2032. In addition, we have certain method of treatment claims that have terms extending into 2026 and 2029.

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

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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 AFREZZA and our oral inhalation technologies, we have identified certain third-party patents having claims that may trigger an allegation of infringement by virtue of the commercial manufacture and sale of AFREZZA. We believe that AFREZZA does not infringe any valid claims of any patent owned by a third party. However, if a court were to determine that the manufacture or sale of AFREZZA were infringing any of these patent rights, we would have to establish with the court that these patents were invalid in order to avoid legal liability for infringement of these patents. Proving patent invalidity can be difficult because issued patents are presumed valid. Therefore, in the event that we are unable to prevail in an infringement or invalidity action we will either have to acquire the third-party patents outright or seek a royalty-bearing license. Royalty-bearing licenses effectively increase costs and therefore may materially affect product profitability. Furthermore, if the patent holder refuses to either assign or license us the infringed patents, it may be necessary to cease manufacturing the product entirely and/or design around the patents. In either event, our business would be harmed and our profitability could be materially adversely impacted. If third parties file patent applications, or are issued patents claiming technology also claimed by us in pending applications, we may be required to participate in interference proceedings in the United States Patent and Trademark Office (USPTO) to determine priority of invention. We may also be required to participate in interference proceedings involving our issued patents. We also rely on trade secrets and know-how, which are not protected by patents, to maintain our competitive position. We require our officers, employees, consultants and advisors to execute proprietary information and invention and assignment agreements upon commencement of their relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of our relationship must be kept confidential, except in specified circumstances. These agreements also provide that all inventions developed by the individual on behalf of us must be assigned to us and that the individual will cooperate with us in connection with securing patent protection on the invention if we wish to pursue such protection. There can be no assurance, however, that these agreements will provide meaningful protection for our inventions, trade secrets or other proprietary information in the event of unauthorized use or disclosure of such information.

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

Competition

The pharmaceutical and biotechnology industries are highly competitive and characterized by rapidly evolving technology and intense research and development efforts. We compete with companies, including major global 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 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

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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 15 minutes after administration. There are several formulations of rapid-acting insulin analogs that reach peak insulin levels within 45 to 90 minutes after injection. The principal products in this category are insulin lispro, which is marketed by Eli Lilly & Company, or Lilly; insulin aspart, which is marketed by Novo Nordisk A/S, or Novo Nordisk; and insulin glulisine, which is marketed 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 injected rapid-acting insulin analogs. For example, Novo Nordisk is developing NN1218, an insulin analog that is intended to provide faster onset of action than aspart. NN1218 is currently undergoing regulatory review in the United States and Europe. In addition, Biodel, Inc. has conducted a Phase 2 clinical trial of BIOD-123, a formulation of human insulin with certain excipients that increase the rate of absorption following injection.

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.

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.

Dance Biopharm, Inc. has completed Phase 2 clinical studies of an inhaled insulin product that utilizes a liquid formulation of human insulin, dispensed through a handheld electronic aerosol device, and is preparing to commence pivotal studies.

Non-insulin Medications

AFREZZA also competes with currently available non-insulin medication products for type 2 diabetes. These products include the following:

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

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

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

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

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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, such as dapagliflozin and canagliflozin, are a class of medications that lower blood glucose by increasing glucose excretion in urine.

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 (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 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 (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 and places a clinical hold, the IND becomes effective 30 days following receipt by the FDA.

Approval of clinical protocols by independent institutional review boards (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. The IRB also approves the consent form signed by the trial participants. The IRB of FDA may place a trial on hold at any time if it believes the risks to subjects outweigh the potential benefits.

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

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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 and can provide important safety information to augment the FDA s voluntary adverse event 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 (cGMPs), 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 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 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.

In its review of an NDA, the FDA may also convene an advisory committee of external experts to provide input on certain review issues relating to risk, benefit and interpretation of clinical trial data. The FDA may delay approval of an NDA if applicable regulatory criteria are not satisfied and/or the FDA requires additional testing or information. Before approving an NDA, the FDA may inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facility complies with cGMPs and will also inspect clinical trial sites for integrity of data supporting safety and efficacy. The FDA will issue either an approval of the NDA or a Complete Response Letter, detailing the deficiencies and information required in order for reconsideration of the NDA.

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.

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 post marketing study

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commitments or requirements, risk evaluation and mitigation strategies, 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.

Numerous device regulatory requirements apply to the device part of a drug-device combination. These include:

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

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

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

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

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

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 or marketing 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.

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.

Healthcare Regulatory and Pharmaceutical Pricing

Government coverage and reimbursement policies both directly and indirectly affect our ability to successfully commercialize our approved products, 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. Recently, in the United States there has been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products. For example, there have been several recent U.S. Congressional inquiries regarding certain drug manufacturers pricing practices and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. 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 Reconciliation Act (collectively, PPACA), enacted in March 2010. The Physician Payments Sunshine Act within PPACA, and its implementing regulations, require certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children s Health Insurance Program (with certain

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exceptions) to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members.

Further, if a drug product is reimbursed by Medicare, Medicaid or other federal or state healthcare programs, we must comply with, among others, the federal civil and criminal false claims laws, including the civil 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 changed the way healthcare is financed by both governmental and private insurers. Among other cost containment measures, PPACA established: 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 increased the rebates a manufacturer must pay under the Medicaid Drug Rebate Program. There have been judicial and Congressional challenges to certain aspects of PPACA, and we expect there will be additional challenges and amendments to PPACA. Other legislative changes have been proposed and adopted in the United States since PPACA. For example, through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, following passage of the Bipartisan Budget Act of 2015, will remain in effect through 2025 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers. 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. The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology and Clinical Health Act (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.

Also, many states have similar healthcare statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, that apply regardless of the payer. Additional state laws require pharmaceutical companies to implement a comprehensive compliance program and/or limit expenditure for, or payments to, individual medical or health professionals.

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, disgorgement, 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.

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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 $29.7 million, $100.2 million, and $109.7 million for the years ended December 31, 2015, 2014, and 2013, respectively.

Our long-lived assets are located in the United States and totaled $48.7 million, $192.1 million, and $176.6 million as of December 31, 2015, 2014, and 2013, respectively.

Employees

As of December 31, 2015, we had 192 full-time employees. Six of these employees were engaged in basic research and development, 105 in manufacturing, 41 in clinical research and development, regulatory affairs and quality assurance and 40 in administration, finance, management, information systems, marketing, corporate development and human resources. Twenty 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 or business development.

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

Corporate Information

We were incorporated in the State of Delaware on February 14, 1991. Our principal executive offices are located at 25134 Rye Canyon Loop Suite 300, Valencia, California 91355, and our telephone number at that address is (661) 775-5300. MannKind Corporation and the MannKind Corporation logo are our service marks. Our website address is http://www.mannkindcorp.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, are available free of charge on our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The contents of these websites are not incorporated into this Annual Report. Further, our references to the URLs for these websites are intended to be inactive textual reference only.

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.

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Executive Officers of the Registrant

The following table sets forth our current executive officers and their ages:

Name	Age	Position(s)
Matthew J. Pfeffer	58	Chief Executive Officer, Chief Financial Officer, and Director
Raymond W. Urbanski, M.D, Ph.D.	56	Corporate Vice President, Chief Medical Officer
Michael E. Castagna, Pharm.D	39	Chief Commercial Officer
David B. Thomson, Ph.D., J.D	49	Corporate Vice President, General Counsel and Secretary
Joseph Kocinsky	52	Corporate Vice President, Chief Technology Officer
Linda Adreveno	60	Senior Vice President, Human Resources

Matthew J. Pfeffer has served as our Chief Executive Officer and one of our directors since January 2016 and as our Chief Financial Officer since April 2008. Mr. Pfeffer also served as our Corporate Vice President from April 2008 until January 2016. Previously, Mr. Pfeffer served as Chief Financial Officer and Senior Vice President of Finance and Administration of VaxGen, Inc. from March 2006 until April 2008, with responsibility for finance, tax, treasury, human resources, IT, purchasing and facilities functions. Prior to VaxGen, Mr. Pfeffer served as CFO of Cell Genesys, Inc. During his nine year tenure at Cell Genesys, Mr. Pfeffer served as Director of Finance before being named CFO in 1998. Prior to that, Mr. Pfeffer served in a variety of financial management positions at other companies, including roles as Corporate Controller, Manager of Internal Audit and Manager of Financial Reporting. Mr. Pfeffer began his career at Price Waterhouse. Mr. Pfeffer graduated from the University of California, Berkeley and is a Certified Public Accountant.

Raymond W. Urbanski, M.D., Ph.D. has been our Chief Medical Officer since August 2015. Prior to joining us, he served as Chief Medical Officer at Mylan, Inc. from September 2012 to September 2014 and Chief Medical Officer at Metabolex, Inc. from October 2011 to June 2012. From June 2004 to October 2011, Dr. Urbanski held several positions with Pfizer Inc. most recently as Vice President and Medical Head of the Established Products Business Unit. He also served as Vice President of Research and Development and Chief Medical Officer at Suntory Pharmaceutical, Inc. Dr. Urbanski earned both his M.D. and Ph.D. in pharmacology and toxicology at the University of Medicine and Dentistry of New Jersey. He completed his residency and fellowship training at Thomas Jefferson University Hospital in Philadelphia.

Michael E. Castagna, Pharm.D. has been our Chief Commercial Officer since March 2016. From November 2012 until he joined MannKind, Dr. Castagna was at Amgen, Inc., where he initially served as Vice President, Global Lifecycle Management and was most recently Vice President, Global Commercial Lead for Amgen s Biosimilar Business Unit. From 2010 to 2012, he was Executive Director, Immunology, at Bristol-Myers Squibb. Before BMS, Dr. Castagna served as Vice President & Head, Biopharmaceuticals, North America, at Sandoz. He has also held positions with commercial responsibilities at EMD (Merck) Serono, Pharmasset and DuPont Pharmaceuticals. He received his pharmacy degree from University of the Sciences-Philadelphia College of Pharmacy, a Doctor of Pharmacy from Massachusetts College of Pharmacy & Sciences and an MBA from The Wharton School of Business at the University of Pennsylvania.

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. from Queens University and obtained his J.D. from the University of Toronto.

Joseph Kocinsky has been our Corporate Vice President, Chief Technology Officer since October 2015. Mr. Kocinsky has over 28 years of experience in the pharmaceutical industry in technical operations and product development. Prior to joining us in 2003, he held a variety of technical and management positions with increased responsibility at Schering-Plough Corp. Mr. Kocinsky holds a bachelor s degree in chemical engineering and a master s degree in Biomedical Engineering from New Jersey Institute of Technology and a master s degree in business administration from Seton Hall University.

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Linda Adreveno has been our Senior Vice President of Human Resources since March 2015. Prior to joining us, she was President of reOptimize, Inc., a boutique Human Resources consulting firm working with small to medium sized companies, from April 2006 to March 201, and Senior Director of Human Resources at Nektar Therapeutics from August 2001 to January 2006. Previously, she held senior management positions at Scient, a consulting company, and Sybase. She is a member of the Society of Human Resources Management (SHRM) and is also a certified Senior Professional in Human Resources (SPHR). She holds a bachelor s degree in liberal arts from Regents College (now Excelsior College) in New York, and a master s degree in management from John F. Kennedy University in California.

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 commercialization of our only approved product, AFREZZA.

We have expended significant time, money and effort in the development of our only approved product, AFREZZA. We anticipate that in the near term, our ability to generate revenues will depend on the successful commercialization of AFREZZA and our ability to enter into licensing arrangements for our Technosphere platform technology that involve license, milestone, royalty or other payments to us.

On February 3, 2015, AFREZZA became available by prescription in United States retail pharmacies. We must receive the necessary approvals from foreign regulatory agencies before AFREZZA can be marketed outside of the United States. Even with such 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. As of December 31, 2015, Sanofi reported 7.0 million in annual sales of AFREZZA.

As a result of the termination of the Sanofi License Agreement, we intend to pursue development and commercialization of AFREZZA in the United States on our own and seek regional partnerships for the development and commercialization of AFREZZA in foreign jurisdictions where there are appropriate commercial opportunities. If we fail to commercialize AFREZZA successfully, our business, financial condition and results of operations will be materially and adversely affected.

We may not be able to successfully develop and commercialize AFREZZA on our own in the United States or find regional partnerships for the development and commercialization of AFREZZA in foreign jurisdictions. The commercialization and development of AFREZZA will require substantially increased capital that we may not be able to fund.

Sanofi has been responsible for global commercial, regulatory and post-approval development activities for AFREZZA pursuant to the Sanofi License Agreement, and we have been responsible for manufacturing AFREZZA to supply Sanofi s demand for the product. On January 4, 2016, we received written notice from Sanofi of Sanofi s election to terminate in its entirety the Sanofi License Agreement.

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Our ability to continue the development and commercialization of AFREZZA is dependent upon the successful transition of AFREZZA from Sanofi. Pursuant to the terms of the Sanofi License Agreement, we and Sanofi are required to use diligent efforts to facilitate the smooth and orderly transition of relevant obligations and rights to us with respect to development and commercialization activities related to AFREZZA, and are also required to negotiate in good faith a written transition agreement for this purpose. During the transition period, we will be dependent on Sanofi to perform certain activities related to AFREZZA, which subjects us to a number of risks, including:

- Sanofi may not perform as expected and we are not be able to control the amount and timing of resources that Sanofi devotes to the transition;
- there may be disputes between us and Sanofi that may result in the delay of the achievement of regulatory and commercial objectives, or costly litigation or arbitration that diverts our management s attention and resources;
- the manner in which Sanofi effects the transition could adversely impact the development of or sales of AFREZZA and failure to comply with applicable regulatory guidelines could result in administrative or judicially imposed sanctions, including warning letters, civil and criminal penalties, injunctions, product seizures or detention, product recalls, total or partial suspension of production and refusal to approve any new drug applications;
- business combinations or significant changes in Sanofi s business strategy or failure to apply financial and other resources to the transition may also adversely affect Sanofi s ability to perform its obligations; and
- Sanofi may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation.

There are also risks relating to whether we will have the available financial and other resources to implement the transition smoothly.

As a result of the termination of the Sanofi License Agreement, we will also assume the responsibility for commercializing and developing AFREZZA in the United States. We have no experience with commercializing AFREZZA and may not have the resources to undertake such activities on our own. In order to commercialize AFREZZA in the United States, we will need to build our commercialization capabilities, including sales and marketing capabilities, which we will do through hiring our own personnel or subcontracting to a commercial sales organization, or a combination of these. The market for skilled commercial personnel is highly competitive, and we may not be able to find and hire all of the personnel we need on a timely basis. We may engage in sales and marketing activities by subcontracting with a skilled commercial sales organization, though there are risks regarding whether a subcontractor will provide the level of effort and attention to AFREZZA necessary for successful commercialization. We will also become responsible for negotiating and securing coverage and reimbursement for AFREZZA. If we are unable to obtain coverage of, and adequate payment levels for AFREZZA, physicians may limit how much or under what circumstances they will prescribe or administer AFREZZA and patients may decline to purchase AFREZZA, which would have an adverse effect on our ability to generate revenues. Building the internal infrastructure to further develop and commercialize AFREZZA will be costly and time-consuming, and may be distracting to management, and we may not be successful in our efforts or successful in obtaining financing to support those efforts.

We will also become responsible for the NDA for AFREZZA and its maintenance. We have no experience with the maintenance of an NDA and may fail to comply with maintenance requirements, including timely submitting required reports, particularly if Sanofi is not fully cooperative in transferring required data to us. Furthermore, we will become responsible for the conduct of ongoing or still required post-approval trials of AFREZZA once transferred from Sanofi. The transfer of these trials and our financial and resources constraints may result in delays or adversely impact their reliability and completion.

We also intend to seek regional partnerships for the development and commercialization of AFREZZA in foreign jurisdictions where there are appropriate commercial opportunities. It may be difficult to find a new

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collaboration partner that is willing to devote the time and resources necessary to successfully commercialize AFREZZA. Collaborations with third parties may require us to relinquish material rights, including revenue from commercialization, on terms that are less attractive than our collaboration with Sanofi or to assume material ongoing development obligations that we would have to fund. These collaboration arrangements are complex and time-consuming to negotiate, and if we are unable to reach agreements with third-party collaborators, we may fail to meet our business objectives and our financial condition may be adversely affected. We may also face significant competition in seeking collaboration partners, especially in the current market, and may not be able to find a suitable collaboration partner in a timely manner on acceptable terms, or at all. Any of these factors could cause delay or prevent the successful commercialization of AFREZZA and could have a material and adverse impact on our business, financial condition and results of operations and the market price of our common stock and other securities could decline.

We may not be successful in our efforts to develop and commercialize our other product candidates.

We have sought to develop our other 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. Further research and development on these programs will require significant financial resources. Given our limited financial resources and our focus on development and commercialization of AFREZZA, we will not be able to advance these programs unless we are able to enter into collaborations with third parties to fund of these programs or to obtain funding to enable us to continue these programs.

A significant portion of the research that we have conducted involves new technologies, including our Technosphere platform technology. Even if our research programs identify product 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 develop and commercialize our other product candidates, or if we are significantly delayed in doing so, our business, financial condition and results of operations will be harmed and the market price of our common stock and other securities could decline.

We have a history of operating losses, we expect to incur losses in the future and we may not generate positive cash flow from operations in the future.

We have never been profitable or generated positive cash flow from cumulative operations to date. Historically, we have reported negative cash flow from operations other than for the nine months ended September 30, 2014, for the year ended December 31, 2014, and for the three months ended March 31, 2015 as a result of our receipt of an upfront payment and milestone payments from Sanofi. As of December 31, 2015, we had an accumulated deficit of $2.9 billion. The accumulated deficit has resulted principally from costs incurred in our research and development programs, the write-off of goodwill and general operating expenses. We expect to make substantial expenditures and to incur increasing operating losses in the future in order to continue the commercialization of AFREZZA, after the termination of the Sanofi License Agreement is effective. In connection with our quarterly assessment of impairment indicators and inventory valuation, we identified an impairment of our long-lived assets which resulted in charges of $140.4 million in the fourth quarter of 2015. In addition, we have agreed to purchase annual minimum quantities of insulin for calendar years 2015 through 2019 under the Insulin Supply Agreement with Amphastar in the aggregate of approximately 120.1 million, of which 104.0 million is remaining at December 31, 2015. We are obligated to purchase 34.1 million in 2016 and the remaining annual minimum quantities will be 23.3 million for the years ending December 31, 2017 through 2019. We may not have the necessary capital resources on hand in order to service this contractual commitment. We recognized a loss on purchase commitments of $66.2 million in the fourth quarter of 2015. Additional impairment charges may be identified and recognized in the future. Our cumulative net loss may therefore increase significantly.

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Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders equity. As of December 31, 2015, we had stockholders deficit of $350.3 million. Our ability to achieve and sustain positive cash flow from operations and profitability depends heavily upon successfully commercializing AFREZZA, and we cannot be sure when we will generate positive cash flow from operations or become profitable, if at all.

We will need 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.

We will need to raise additional capital, whether through the sale of equity or debt securities, additional strategic business collaborations, the establishment of other funding facilities, licensing arrangements, asset sales or other means, in order to support our ongoing activities including the commercialization of AFREZZA and the development of other product candidates and to avoid defaulting under the covenant in our facility agreement with Deerfield Private Design Fund II, L.P. (Deerfield Private Design Fund) and Deerfield Private Design International II, L.P. (collectively, Deerfield) dated July 1, 2013 (as amended, the Facility Agreement) that requires us to maintain at least $25.0 million in cash and cash equivalents or available borrowings under the loan arrangement, dated as of October 2, 2007, between us and The Mann Group LLC (as amended, restated, or otherwise modified as of the date hereof, The Mann Group Loan Arrangement), as of the last day of each fiscal quarter. It may be difficult for us to raise additional funds on favorable terms, or at all. As of December 31, 2015, we had stockholders deficit of $350.3 million, which may raise concerns about our solvency and affect our ability to raise additional capital. The extent of our additional funding requirements will depend on a number of factors, including:

- the degree to which AFREZZA is commercially successful;
- the degree to which we are able to generate revenue from our Technosphere drug delivery platform;
- the costs of developing and commercializing AFREZZA on our own in the United States, including the costs of building our commercialization capabilities;
- the costs of finding regional collaboration partners for the development and commercialization of AFREZZA in foreign jurisdictions;
- the demand by any or all of the holders of the 5.75% Convertible Senior Subordinated Exchange Notes due 2018 (the 2018 notes), the 9.75% Senior Convertible Notes due 2019 issued to Deerfield (the 2019 notes), and the 8.75% Senior Convertible Notes due 2019 issued to Deerfield (the Tranche B notes) to require us to repay or repurchase such debt securities if and when required;
- our ability to repay or refinance existing indebtedness, and the extent to which the 2018 notes or any other convertible debt securities we may issue are converted into or exchanged for shares of our common stock;
- the rate of progress and costs of our clinical studies and research and development activities;
- the costs of procuring raw materials and operating our manufacturing facilities;
- our obligation to make milestone payments pursuant to the milestone rights issued to Deerfield Private Design Fund and Horizon Santé FLML SÁRL (collectively, the Milestone Purchasers) and pursuant to the Milestone Rights Purchase Agreement dated July 1, 2013 (the Milestone Agreement);

our obligation to bear our share of net losses, if any, if Sanofi makes any product sales under the Sanofi License Agreement after the Termination Date;

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;

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

the emergence of competing technologies and products and other market developments;

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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 and litigation expenses; 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 through the sale of equity and debt securities and 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 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 will dilute their ownership percentage. Moreover, the establishment of other funding facilities may impose restrictions on our operations. These restrictions could include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. We also will need 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 may be required to reduce expenses through the delay, reduction or curtailment of our projects, 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, holders of our common stock or other securities may lose the entire value of their investment.

We cannot provide assurances that changed or unexpected circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate, in which case we will be required to raise additional capital. There can be no assurances that we will be able to raise additional capital on favorable terms, or at all. If we are unable to raise adequate additional capital we will be required to reduce expenses through the delay, reduction or curtailment of our projects, 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.

We have a substantial amount of debt pursuant to the 2018 notes, 2019 notes, Tranche B notes, The Mann Group Loan Arrangement and the Sanofi Loan Facility, and we may incur additional indebtedness under The Mann Group Loan Arrangement and we may be unable to make required payments of interest and principal as they become due.

As of February 22, 2016, we had $219.6 million principal amount of outstanding debt, consisting of:

$27.7 million principal amount of 2018 notes bearing interest at 5.75% per annum and maturing on August 15, 2018;

$60.0 million principal amount of 2019 notes bearing interest at 9.75% per annum, $5.0 million of which is due and payable in July 2016, $15.0 million of which is due and payable in July 2017, $15.0 million of which is due and payable in July 2018 and $25.0 million of which is due and payable in July and December 2019;

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$20.0 million principal amount of Tranche B notes bearing interest at 8.75% per annum, $5.0 million of which is due and payable in each of May 2017, 2018 and 2019, the balance of which is due and payable in December 2019;

$49.5 million principal amount of indebtedness under The Mann Group Loan Arrangement, bearing interest at 5.84% and maturing and due on January 5, 2020; and

$62.4 million principal amount borrowed under the Sanofi Loan Facility to fund our share of net losses under the Sanofi License Agreement, bearing interest at a rate of 8.5% per annum, with accrued interest payable in-kind and compounded quarterly, and maturing and due on September 23, 2024.

We may borrow an additional $30.1 million under The Mann Group Loan Arrangement. We anticipate using a portion of these available borrowings to capitalize accrued interest into principal, upon mutual agreement of the parties, as it becomes due and payable under The Mann Group Loan Arrangement. As of December 31, 2015 the accrued and unpaid interest under The Mann Group Loan Arrangement was $6.4 million.

All profits and losses from AFREZZA product sales by Sanofi or its affiliates after the Termination Date, if any, will continue to be shared 65% by Sanofi and 35% by us pursuant to the terms of the Sanofi License Agreement, and we may borrow up to an aggregate of $175.0 million pursuant to the Sanofi Loan Facility to fund our share of net losses from AFREZZA product sales by Sanofi or its affiliates. Our total share of the net losses are $62.4 million as of December 31, 2015, classified as Sanofi loan facility and loss share obligation, and such amount has been borrowed under the Sanofi Loan Facility as of February 22, 2016.

There can be no assurance that we will have sufficient resources to make any required repayments of principal under the terms of our indebtedness when required. Further, if we undergo a fundamental change, as that term is defined in the indentures governing the terms of the 2018 notes, or certain Major Transactions as defined in the Facility Agreement in respect of the 2019 notes and the Tranche B notes, the holders of the respective debt securities will have the option to require us to repurchase all or any portion of such debt securities at a repurchase price of 100% of the principal amount of such debt securities to be repurchased plus accrued and unpaid interest, if any. The 2018 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. The 2019 notes bear interest at the rate of 9.75% per year on the outstanding principal amount and the Tranche B notes bear interest at the rate of 8.75% on the outstanding principal amount, with accrued interest on each payable in cash quarterly in arrears on the last business day of March, June, September and December of each year. Loans under the Sanofi Loan Facility bear interest at a rate of 8.5% per annum, paid-in-kind on a quarterly basis (2.06% per quarter compounded). Loans under The Mann Group Loan Arrangement accrue interest at a rate of 5.84% per annum, 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. 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 2018 notes, 2019 notes, Tranche B notes, or on the loans under the Sanofi Loan Facility, or if we fail to repay or repurchase the 2018 notes, 2019 notes, Tranche B notes, or the loans under the Sanofi Loan Facility when required, we will be in default under the indenture governing the terms of the 2018 notes, the Facility Agreement or other applicable instrument for such debt securities or loans, 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 note holders initiating bankruptcy proceedings or causing us to cease operations altogether.

The agreements governing our indebtedness contain covenants that we may not be able to meet and place restrictions on our operating and financial flexibility.

Our obligations under the Facility Agreement, including any indebtedness under the 2019 notes and the Tranche B notes, and the Milestone Agreement are secured by substantially all of our assets, including our intellectual property, accounts receivables, equipment, general intangibles, inventory (excluding the insulin inventory) and investment property, and all of the proceeds and products of the foregoing. Our obligations under the Facility Agreement and the Milestone Agreement are also secured by a certain mortgage on our facility in

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Danbury, Connecticut. Our obligations under the Sanofi Loan Facility are secured by a first priority mortgage on our facility in Valencia, California, a first priority security interest in certain insulin inventory located in the United States and any contractual rights and obligations pursuant to which we purchase or have purchased such insulin, and a second priority security interest in our assets that secure our obligations under the Facility Agreement.

The Facility Agreement includes customary representations, warranties and covenants by us, including restrictions on our ability to incur additional indebtedness, grant certain liens, engage in certain mergers and acquisitions, make certain distributions and make certain voluntary prepayments. Events of default under the Facility Agreement include: our failure to timely make payments due under the 2019 notes or the Tranche B notes; inaccuracies in our representations and warranties to Deerfield; our failure to comply with any of our covenants under any of the Facility Agreement, Milestone Agreement or certain other related security agreements and documents entered into in connection with the Facility Agreement, subject to a cure period with respect to most covenants; our insolvency or the occurrence of certain bankruptcy-related events; certain judgments against us; the suspension, cancellation or revocation of governmental authorizations that are reasonably expected to have a material adverse effect on our business; the acceleration of a specified amount of our indebtedness; our cash and cash equivalents, including amounts available to us under The Mann Group Loan Arrangement, falling below $25.0 million as of the last day of any fiscal quarter. If one or more events of default under the Facility Agreement occurs and continues beyond any applicable cure period, the holders of the 2019 notes and Tranche B notes may declare all or any portion of the 2019 notes and Tranche B notes to be immediately due and payable. The Milestone Agreement includes customary representations and warranties and covenants by us, including restrictions on transfers of intellectual property related to AFREZZA. The milestones are subject to acceleration in the event we transfer our intellectual property related to AFREZZA in violation of the terms of the Milestone Agreement.

Similarly, the Sanofi Loan Facility includes customary representations, warranties and covenants by us, including restrictions on our ability to incur additional indebtedness, grant certain liens and make certain changes to our organizational documents. Events of default under the Sanofi Loan Facility include: our failure to make timely payments due under the Sanofi Loan Facility; inaccuracies in our representations and warranties to the lender; our failure to comply with any of our covenants under any of the Sanofi Loan Facility or certain other related security agreements and documents entered into in connection with the Sanofi Loan Facility, subject to a cure period with respect to most covenants; our insolvency or the occurrence of certain bankruptcy-related events; termination by Sanofi of the Sanofi License Agreement as a result of our breach of the Sanofi License Agreement; and the failure of any material provision under any of the Sanofi Loan Facility or certain other related security agreements and documents entered into in connection with the Sanofi Loan Facility to remain in full force and effect. If one or more events of default occurs and is continuing, the lender may terminate its obligation to make advances under the Sanofi Loan Facility, and, if certain specified events of default (including our failure to timely make payments due under the Sanofi Loan Facility; our failure to comply with the negative covenants under the Sanofi Loan Facility limiting our ability to incur additional indebtedness or grant certain liens; our insolvency or the occurrence of certain bankruptcy-related events; termination by Sanofi of the Sanofi License Agreement as a result of our breach of the non-compete provisions of the Sanofi License Agreement; or the failure of any material provision under any of the Sanofi Loan Facility or certain other related security agreements and documents entered into in connection with the Sanofi Loan Facility to remain in full force and effect) occur and are continuing, the lender may accelerate all of our repayment obligations under the Sanofi Loan Facility and otherwise exercise any of its remedies as a secured creditor.

There can be no assurance that we will be able to comply with the covenants under any of the foregoing agreements, and we cannot predict whether the holders of the 2019 notes or Tranche B notes or the lender under the Sanofi Loan Facility would demand repayment of the outstanding balance of the 2019 notes, the Tranche B notes or the loans under the Sanofi Loan Facility as applicable or exercise any other remedies available to such holders if we were unable to comply with these covenants. The covenants and restrictions contained in the foregoing agreements could significantly limit our ability to respond to changes in our business or competitive activities or take advantage of business opportunities that may create value for our stockholders and the holders

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of our other securities. In addition, our inability to meet or otherwise comply with the covenants under these agreements could have an adverse impact on our financial position and results of operations and could result in an event of default under the terms of our other indebtedness, including our indebtedness under the 2018 notes. In the event of certain future defaults under the foregoing agreements for which we are not able to obtain waivers, the holders of the 2018 notes, 2019 notes and Tranche B notes and the lender under the Sanofi Loan Facility may accelerate all of our repayment obligations, and, with respect to the 2019 notes and Tranche B notes and the loans under the Sanofi Loan Facility, take control of our pledged assets, potentially requiring us to renegotiate the terms of our indebtedness on terms less favorable to us, or to immediately cease operations.

If we enter into additional debt arrangements, the terms of such additional arrangements could further restrict our operating and financial flexibility. In the event we must cease operations and liquidate our assets, the rights of any holders of our outstanding secured debt would be senior to the rights of the holders of our unsecured debt and our common stock to receive any proceeds from the liquidation.

If we do not achieve our projected development goals in the timeframes we expect, our business, financial condition and results of operations will be harmed and the market price of our common stock and other securities 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 studies 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 studies and preclinical research and development activities;
- our ability to identify and enroll patients who meet clinical study eligibility criteria;
- our ability to access sufficient, reliable and affordable supplies of components used in the manufacture of our product candidates;
- the costs of expanding and maintaining manufacturing operations, as necessary;
- the extent to which our clinical studies compete for clinical sites and eligible subjects with clinical studies sponsored by other companies; and
- actions by regulators.

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

AFREZZA or 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 unmet medical needs.

The rapid rate of scientific discoveries and technological changes could result in AFREZZA or one or more of our product candidates becoming obsolete or noncompetitive. Our competitors may develop or introduce new products that render our technology or AFREZZA less competitive, uneconomical or obsolete. Our future

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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 competition from universities and other non-profit research organizations. These institutions carry out a significant amount of research and development in various areas of unmet medical need. 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.

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

Forecasts about the effects of the use of drugs, including AFREZZA, over terms longer than the clinical studies or in much larger populations may not be consistent with the earlier clinical results. For example, with the approval of AFREZZA, the FDA has required a five-year, randomized, controlled trial in 8,000 10,000 patients with type 2 diabetes, the primary objective of which is to compare the incidence of pulmonary malignancy observed with AFREZZA to that observed in a standard of care control group. If long-term use of a drug results in adverse health effects or reduced efficacy or both, the FDA or other regulatory agencies may terminate our or any of our current or future marketing partner s ability to market and sell the drug, may narrow the approved indications for use or otherwise require restrictive product labeling or marketing, or may require further clinical studies, which may be time-consuming and expensive and may not produce favorable results.

Our research and development programs are designed to test the safety and efficacy of our 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 impact commercialization of any of our product candidates, including the following:

- safety and efficacy results obtained in our nonclinical and early clinical testing may be inconclusive or may not be predictive of results that we may obtain in our future clinical studies or following long-term use, and we may as a result be forced to stop developing a product candidate or alter the marketing of an approved product;

- the analysis of data collected from clinical studies of our product candidates may not reach the statistical significance necessary, or otherwise be sufficient to support FDA or other regulatory approval for the claimed indications;

- after reviewing clinical data, we or any 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 once approved.

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

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

For the commercial manufacture of AFREZZA, we need access to sufficient, reliable and affordable supplies of insulin, our AFREZZA inhaler, the related cartridges and other materials. Currently, the only approved source of insulin for AFREZZA is manufactured by Amphastar and the only source of our proprietary inert excipient, FDKP (fumaryl diketopiperazine), which is the primary component of our Technosphere technology platform, is manufactured by Lonza. We must rely on our suppliers, including Amphastar, to comply with relevant regulatory

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and other legal requirements, including the production of insulin and FDKP in accordance with the FDA s cGMPs for drug products, and the production of the AFREZZA inhaler and related cartridges in accordance with QSRs. The supply of any of these materials may be limited or any of the manufacturers may not meet relevant regulatory requirements, and if we are unable to obtain any of these materials in sufficient amounts, in a timely manner and at reasonable prices, or if we encounter delays or difficulties in our relationships with manufacturers or suppliers, the production of AFREZZA may be delayed. Likewise, if Amphastar or Lonza ceases to manufacture or is otherwise unable to deliver insulin for AFREZZA, we will need to locate an alternative source of supply and the production of AFREZZA may be delayed. If any of our suppliers is unwilling or unable to meet its supply obligations and we are unable to secure an alternative supply source in a timely manner and on favorable terms, our business, financial condition, and results of operations may be harmed and the market price of our common stock and other securities may decline.

If we fail as an effective manufacturing organization or fail to engage third-party manufacturers with this capability, we may be unable to support commercialization of this product.

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 utilize a contract packager to assemble the final kits of foil-pouched blisters containing cartridges along with inhalers and the package insert. 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 production, could entail higher costs and may result in our being unable to effectively support commercialization of AFREZZA. Furthermore, if we or a third-party manufacturer fail to deliver the required commercial quantities of the product or any raw material 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 AFREZZA and we would lose potential revenues.

If AFREZZA or any other 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 other products that we may develop in the future may not gain market acceptance among physicians, patients, third-party payors and the healthcare community. For example, as of December 31, 2015, Sanofi reported 7.0 million in annual sales of AFREZZA. 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 other products that we may develop in the future depends on many factors, including the:

- approved labeling claims;
- effectiveness of efforts by us or any of our current or future marketing partner(s) 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;

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perception of patients and the healthcare community, including third-party payors, regarding the safety, efficacy and benefits compared to competing products or therapies;

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, AFREZZA and any other product that we get approved may not gain market acceptance, which would materially harm our business, financial condition and results of operations.

If third-party payors do not cover AFREZZA or any of our product candidates for which we receive regulatory approval, AFREZZA or such product candidates might not be prescribed, 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 and reimbursement reform proposals or legislation. Such reforms may limit our ability to generate revenues from sales of AFREZZA or other products that we may develop in the future and achieve profitability. Further, to the extent that such reforms have a material adverse effect on the business, financial condition and profitability of any of our current or future marketing partners for AFREZZA, and companies that are prospective collaborators for our product candidates, our ability to commercialize AFREZZA and 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 coverage and adequate 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 AFREZZA and 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 may 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 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 European Union 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 AFREZZA or any of our

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other product candidates that receives marketing approval 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.

If we or any of our current or future marketing partners are unable to obtain coverage of, and adequate payment levels for, AFREZZA or any of our other product candidates that receive marketing approval 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 and any of our current or future marketing partner s ability to successfully commercialize AFREZZA and our ability to successfully commercialize any of our other product candidates that receives regulatory approval and impact our profitability, results of operations, financial condition, and prospects.

Healthcare legislation may make it more difficult to receive revenues.

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. For example, in March 2010, 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 us 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;

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 certain drug-device combination products;

an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively;

a licensure framework for follow-on biological products;

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 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 annually to the Centers for Medicare & Medicaid Services (CMS) 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;

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a new requirement to annually report drug samples that certain manufacturers and authorized 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.

The medical device excise tax has been suspended by the Consolidated Appropriations Act of 2016 (the CAA) through December 31, 2017. Absent further Congressional action, the excise tax will be reinstated for medical device sales beginning January 1, 2018. The CAA also temporarily delays implementation of other taxes intended to help fund PPACA programs. Further, there have been judicial and Congressional challenges to other aspects of PPACA, and we expect there will be additional challenges and amendments to PPACA in the future.

In addition, other legislative changes have been proposed and adopted since PPACA was enacted. For example, 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, and, following passage of the Bipartisan Budget Act of 2015, will stay in effect through 2025 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 (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. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. These new laws and initiatives 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 third-party 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 or any of our current or future marketing partners 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, including those pertaining to fraud and abuse and patients rights are and will be applicable to our business. For example, 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, among others:

the federal Anti-Kickback Statute (as amended by PPACA, which modified the intent requirement of the federal Anti-Kickback Statute so that a person or entity no longer needs to have actual knowledge of the Statute or specific intent to violate it to have committed a violation), which constrains our business activities, including our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities by prohibiting, among other things, knowingly and willfully offering 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;

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federal civil and criminal false claims laws, including without limitation the civil False Claims Act, 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 federal healthcare programs that are false or fraudulent and under PPACA, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal false claims laws;

HIPAA, which created new federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

HIPAA, as amended by HITECH and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

the federal physician sunshine requirements under PPACA, which requires certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the CMS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members; 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; state laws that require pharmaceutical companies to comply with the industry s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government that otherwise restricts certain payments that may be made to healthcare providers and entities; and state laws that require drug manufacturers to report information related to payments and other transfer of value to physicians and other healthcare providers and entities.

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 AFREZZA or any of our product candidates that receives marketing approval is ultimately sold in a foreign country, we may be subject to similar 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, individual imprisonment, disgorgement, 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 studies volunteers and loss of revenues. We currently carry worldwide product liability insurance in the amount of $10.0 million. However, our insurance coverage may not 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

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incur substantial liabilities. If we are required to pay a product liability claim our business, financial condition and results of operations would be harmed and the market price of our common stock and other securities 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 AFREZZA successfully, we may be required to expand our work force, particularly in the areas of manufacturing and sales and marketing. These activities will require the addition of new personnel, including management, and the development of additional expertise by existing personnel, 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 products successfully.

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

We have identified a material weakness in our internal control over financial reporting. If our internal controls over financial reporting are not considered effective, our business, financial condition and market price of our common stock and other securities 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.

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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. In connection with the audit of our financial statements for the year ended December 31, 2015, we concluded that there was a material weakness in our internal control over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness we identified related to impairment testing that we performed in accordance with ASC 360-10, *Impairment and Disposal of Long-Lived Assets* and ASC 330-10, *Inventories*, as of December 31, 2015. Specifically, our review controls did not operate at a sufficient level of precision to identify certain errors. As a result of this material weakness, we and our independent registered public accounting firm evaluated our internal control over financial reporting as ineffective.

We are taking steps to remediate the material weakness in our internal control over financial reporting, including designing additional training programs for relevant personnel and developing specific review procedures regarding the review of the impairment of assets. However, we cannot assure you that these efforts will remediate our material weakness in a timely manner, or at all. If we are unable to successfully remediate our material weakness, or identify any future material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports and we may experience a loss of public confidence, which could have an adverse effect on our business, financial condition and the market price of our common stock and other securities.

We may undertake internal restructuring activities in the future that could result in disruptions to our business or otherwise materially harm our results of operations or financial condition.

From time to time we may undertake internal restructuring activities as we continue to evaluate and attempt to optimize our cost and operating structure in light of developments in our business strategy and long-term operating plans. These activities may result in write-offs or other restructuring charges. There can be no assurance that any restructuring activities that we undertake will achieve the cost savings, operating efficiencies or other benefits that we may initially expect. Restructuring activities may also result in a loss of continuity, accumulated knowledge and inefficiency during transitional periods and thereafter. In addition, internal restructurings can require a significant amount of time and focus from management and other employees, which may divert attention from commercial operations. If we undertake any internal restructuring activities and fail to achieve some or all of the expected benefits therefrom, our business, results of operations and financial condition could be materially and adversely affected.

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

Several complaints were filed in the U.S. District Court for the Central District of California against us and certain of our officers and directors on behalf of certain purchasers of our common stock. The complaints include claims asserted under Sections 10(b) and 20(a) of the Exchange Act and have been pled as putative shareholder class actions. In general, the complaints allege that we and certain of our officers and directors violated federal securities laws by making materially false and misleading statements regarding the prospects for AFREZZA, thereby artificially inflating the price of our common stock. We and certain of our directors and executive officers have also been named in similar lawsuits filed in Israel. We intend to vigorously defend against these claims. If we are not successful in our defense, we could be forced to make significant payments to or other settlements with our stockholders and their lawyers, and such payments or settlement arrangements could have a material adverse effect on our business, operating results or financial condition. Even if such claims are not successful, the litigation could result in substantial costs and significant adverse impact on our reputation and divert management s attention and resources, which could have a material adverse effect on our business, operating results and financial condition.

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

We expect that at least for the foreseeable future, our manufacturing facility in Danbury, Connecticut will be the sole location for the manufacturing of AFREZZA. This facility and the manufacturing equipment we use

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would be costly to replace and could require substantial lead time to repair or replace. We depend on our facilities and on collaborators, contractors and vendors for the continued operation of our business, some of whom are located in other countries. Natural disasters or other catastrophic events, including interruptions in the supply of natural resources, political and governmental changes, severe weather conditions, wildfires and other fires, explosions, actions of animal rights activists, terrorist attacks, volcanic eruptions, earthquakes and wars could disrupt our operations or those of our collaborators, contractors and vendors. We might suffer losses as a result of business interruptions that exceed the coverage available under our and our contractors insurance policies or for which we or our contractors do not have coverage. For example, we are not insured against a terrorist attack. Any natural disaster or catastrophic event could have a significant negative impact on our operations and financial results. Moreover, any such event could delay our research and development programs or cause interruptions in our commercialization of AFREZZA.

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 and commercialization of AFREZZA 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 $20.0 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, a soil and groundwater investigation and remediation was being conducted by a former site operator (the responsible party) under the oversight of the Connecticut Department of Environmental Protection. During the construction of our expanded manufacturing facility, we excavated contaminated soil under the footprint of our building expansion location. The responsible party reimbursed us for our increased excavation and disposal costs of contaminated soil in the amount of $1.6 million. It has conducted at its expense all work and will make all filings necessary to achieve closure for the environmental remediation conducted at the site, and has agreed to indemnify us for any future costs and expenses we may incur that are directly related to the final closure. If we are unable to collect these future costs and expenses, if any, from the responsible party, our business, financial condition and results of operations may be harmed.

RISKS RELATED TO GOVERNMENT REGULATION

Our product candidates must undergo costly and time-consuming rigorous nonclinical and clinical testing and we must obtain regulatory approval prior to the sale and marketing of any product in each jurisdiction. The results of this testing or issues that develop in the review and approval by a regulatory agency may 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 AFREZZA and our product candidates, 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:

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product design, development, manufacture and testing;

product labeling;

product storage and shipping;

pre-market clearance or approval;

advertising and promotion; and

product sales and distribution.

The requirements governing the conduct of clinical studies and manufacturing and marketing of AFREZZA and our product candidates 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 study 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.

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 regulatory agencies 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 studies of our product candidates may not be completed on schedule, 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 studies may not be sufficient to support regulatory approval of our product candidates. Even if we believe the data collected from our clinical studies are sufficient, regulatory agencies have 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.

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 regulatory agencies 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.

If we do not comply with regulatory requirements at any stage, whether before or after marketing approval is obtained, we may be fined or forced to remove a product from the market, subject to criminal prosecution, 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 studies. For example, the FDA required the following post-marketing studies for AFREZZA that remain to be completed:

a clinical trial to evaluate pharmacokinetics, safety and efficacy in pediatric patients; and

a clinical trial to evaluate the potential risk of pulmonary malignancy with AFREZZA (as well as cardiovascular risk and the long-term effect of AFREZZA on pulmonary function).

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 studies, 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, financial condition and results of operations will be harmed and the market price of our common stock and other securities may decline.

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We are subject to stringent, ongoing government regulation.

The manufacture, marketing and sale of AFREZZA are 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. For example, stability failure of AFREZZA could lead to product recall or other sanctions.

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. In complying with cGMP and foreign regulatory requirements, we and any of our potential third-party manufacturers or suppliers will be obligated to expend time, money and effort in production, record-keeping and quality control to ensure that our products meet applicable specifications and other requirements. QSR requirements also impose extensive testing, control and documentation requirements. State regulatory agencies and the regulatory agencies of other countries have similar requirements. In addition, we will be required to comply with regulatory requirements of the FDA, state regulatory agencies and the regulatory agencies of other countries concerning the reporting of adverse events and device malfunctions, corrections and removals (e.g., recalls), promotion and advertising and general prohibitions against the manufacture and distribution of adulterated and misbranded devices. Failure to comply with these regulatory requirements could result in civil fines, product seizures, injunctions and/or criminal prosecution of responsible individuals and us. Any such actions would have a material adverse effect on our business, financial condition and results of operations.

FDA and comparable foreign regulatory authorities subject AFFREZZA and any approved drug product to extensive and ongoing regulatory requirements concerning the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCP requirements for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA s and other regulatory authorities policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Our suppliers are subject to FDA inspection.

We depend on suppliers for insulin and other materials that comprise AFREZZA, including our AFREZZA inhaler and cartridges. Each supplier must comply with relevant regulatory requirements and is subject to

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inspection by the FDA. Although we conduct our own inspections and investigations of each supplier, there can be no assurance that the FDA, upon inspection, 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.

If 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 commercialization of AFREZZA.

Reports of side effects or safety concerns in related technology fields or in other companies clinical studies could delay or prevent us from obtaining regulatory approval for our product candidates or negatively impact public perception of AFREZZA or any other products we may develop.

At present, there are a number of clinical studies being conducted by other pharmaceutical companies involving insulin delivery systems. If other pharmaceutical companies announce that they observed frequent adverse events in their studies involving insulin therapies, we may be subject to class warnings in the label for AFREZZA. In addition, the public perception of AFREZZA might be adversely affected, which could harm our business, financial condition and results of operations and cause the market price of our common stock and other securities to decline, even if the concern relates to another company s products or product candidates.

There are also a number of clinical studies 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 studies could delay or prevent us from obtaining regulatory approval or negatively impact public perception of our product candidates, which could harm our business, financial condition and results of operations and cause the market price of our common stock and other securities 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 AFREZZA inhalation powder have terms extending into 2020, 2029, 2030 and 2031. In addition, patents providing protection for our inhaler and cartridges have terms extending into 2023, 2031 and 2032, 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 or other review in the United States. In some instances we may seek re-examination or

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reissuance of our own patents. 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 (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 all of the substantive changes to patent law associated with the Leahy-Smith Act have become effective, their true impact will only emerge with time. Moreover there will be a transitional period of many years during which some applications may be eligible for prosecution under the previous rules. There are many ambiguities in this new law and how the courts will interpret it cannot be predicted with confidence. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. 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, financial condition and results of operations.

Moreover, patent law continues to evolve. Several further changes to patent law are before Congress. The United States Supreme Court has exhibited an increased interest in patent law and several of its recent decisions have tended to narrow the scope of patentable subject matter related to medical products and methods. For example, in March 2014 the USPTO, in response to Supreme Court decisions, issued new examination guidelines which call into question the patentability of biological inventions that had previously been considered patentable. While none of this has an immediately apparent impact on our core technology and patents, the full and ultimate effect of these developments is not yet known. 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. These agreements 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. We also execute confidentiality agreements with outside collaborators. There can be no assurance, however, that our inventions and assignment agreements and our confidentiality 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 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. In particular Inter Partes Review (IPR) has resulted in a higher rate of claim invalidation as compared to re-examination, due in part to the much reduced opportunity to repair claims by amendment. Moreover, the filing of IPR petitions has been used by short-sellers as a tool to help drive down stock prices. Litigation, post-grant

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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 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 and other securities 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 and financial condition.

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) (a 337 action) with the International Trade Commission (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 that may trigger an allegation of infringement in connection with 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

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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, financial condition and results of operations would be harmed and our profitability could be materially and adversely impacted.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, the market price of our common stock and other securities 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, financial condition and results of operations and cause the market price of our common stock and other securities 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 such potential trade names for our product candidates, nor can we assure that we will be granted registration of any potential trade names for which we do file. No assurance can be given that any of our trademarks will be registered in the United States or elsewhere, or once registered that, prior to our being able to enter a particular market, they will not be cancelled for non-use. Nor can we give assurances, that the use of any of our trademarks will confer a competitive advantage in the marketplace.

Furthermore, even if we are successful in our trademark registrations, the FDA has its own process for drug nomenclature and its own views concerning appropriate proprietary names. It also has the power, even after granting market approval, to request a company to reconsider the name for a product because of evidence of confusion in the marketplace. We cannot assure you that the FDA or any other regulatory authority will approve of any of our trademarks or will not request reconsideration of one of our trademarks at some time in the future.

RISKS RELATED TO OUR COMMON STOCK

We may not be able to generate sufficient cash to service all of our indebtedness. We may be forced to take other actions to satisfy our obligations under our indebtedness or we may experience a financial failure.

Our ability to make scheduled payments on or to refinance our debt obligations will depend on our financial and operating performance, which is subject to prevailing economic and competitive conditions and to certain financial, business and other factors beyond our control. We cannot assure you that we will maintain a level of cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness. We cannot assure you that we would be able to take any of these actions, that these actions would be successful and permit us to meet our scheduled debt service obligations or that these actions would be permitted under the terms of our future debt agreements. In the absence of sufficient operating results and resources, we could face substantial liquidity problems and might be required to dispose of material assets or operations to meet our debt service and other obligations. We may not be able to consummate

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those dispositions or obtain sufficient proceeds from those dispositions to meet our debt service and other obligations when due.

Future sales of shares of our common stock in the public market, or the perception that such sales may occur, may depress our stock price and adversely impact the market price of our common stock and other securities.

If our existing stockholders or their distributees sell substantial amounts of our common stock in the public market, the market price of our common stock could decrease significantly. The perception in the public market that our existing stockholders might sell shares of common stock could also depress the market price of our common stock and the market price of our other securities. Any such sales of our common stock in the public market may affect the price of our common stock or the market price of our other securities.

In the future, we may sell additional shares of our common stock to raise capital. In addition, a substantial number of shares of our common stock is reserved for: issuance upon the exercise of stock options and, in the future, may be reserved for the vesting of restricted stock unit awards; the purchase of shares of common stock under our employee stock purchase program; and the issuance of shares upon exchange or conversion of the 2018 notes or any other convertible debt we may issue. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price for our common stock. The issuance or sale of substantial amounts of common stock, or the perception that such issuances or sales may occur, could adversely affect the market price of our common stock and other securities.

Our stock price is volatile and may affect the market price of our common stock and other securities.

Since January 1, 2013, our closing stock price as reported on The NASDAQ Global Market has ranged from $0.66 to $10.96, through February 22, 2016. The trading price of our common stock is likely to continue to be 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:

- our ability to develop and commercialize AFREZZA on our own in the United States;
- our ability to find collaboration partners for the development and commercialization of AFREZZA in foreign jurisdictions;
- the progress of the commercial launch of AFREZZA and other events or circumstances that we or others estimate will impact the future commercialization of AFREZZA;
- our future estimates of AFREZZA sales, prescriptions or other operating metrics;
- our ability to successful commercialize our Technosphere drug delivery platform;
- the progress of preclinical and clinical studies of our product candidates and the post-approval studies of AFREZZA required by the FDA;
- the results of preclinical and clinical studies of our product candidates;
- general economic, political or stock market conditions;
- legislative developments;

announcements by us, our collaborators, or our competitors concerning clinical study 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;

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developments or disputes concerning our relationship with any of our current or future collaborators or third party manufacturers;

developments or disputes concerning our patents or proprietary rights;

the expense and time associated with, and the extent of our ultimate success in, securing regulatory approvals;

announcements by us concerning our financial condition or operating performance;

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

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

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

the status of any legal proceedings or regulatory matters against or involving us or any of our executive officers and directors; 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 value of our common stock and other securities to decline.

If we fail to continue to meet all applicable listing requirements, our common stock may be delisted from The NASDAQ Global Market, which could have an adverse impact on the liquidity and market price of our common stock.

Our common stock is currently listed on The NASDAQ Global Market, which has qualitative and quantitative listing criteria. If we are unable to meet any of the NASDAQ listing requirements in the future, including, for example, if the closing bid price for our common stock falls below $1.00 per share for 30 consecutive trading days, NASDAQ could determine to delist our common stock, which could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease. As of February 22, 2016, the closing price of our common stock on The NASDAQ Global Market was $1.00. A delisting of our common stock could also adversely affect our ability to obtain financing for the continuation of our operations and could result in the loss of confidence in our company.

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

Public companies in general, including companies listed on The NASDAQ Global Market, have experienced 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 and other securities 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.

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As a result of the death of Alfred Mann, the stock that he previously controlled is currently controlled by various trusts, and we cannot assure you of the manner in which the trustees will manage the holdings.

At December 31, 2015, Alfred E. Mann beneficially owned approximately 35.7% of our outstanding shares of capital stock, including shares held in the Alfred E. Mann Living Trust, Mann Group LLC, Mannco LLC, Biomed Partners, LLC and Biomed Partners II, LLC.

Mr. Mann passed away on February 25, 2016. All of the shares beneficially owned by Mr. Mann in the Alfred E. Mann Living Trust, The Mann Group LLC and Mannco LLC are controlled by an administrative trust during the period of administration of Mr. Mann s estate. The trustees of the administrative trust are Mr. Mann s wife and two other trustees. The trustees have the power to sell the shares or deal with them as an owner. Relatives and other individuals may receive bequests of shares under Mr. Mann s trust. The residuary beneficiary of the trust is the Alfred E. Mann Family Foundation, a charitable organization under section 501(c)(3) of the Internal Revenue Code that is a private foundation under section 509 of the Code. The same three trustees control the Alfred E. Mann Family Foundation. The Alfred E. Mann Family Foundation will have the power to sell the shares or deal with them as an owner. If not sold by the trust, the shares owned by the trust may be distributed to one or more of the individual or charitable beneficiaries of the trust.

The managing members of Biomed Partners, LLC and Biomed Partners II, LLC are now controlled by trusts for which the same individuals described above are the trustees. Biomed Partners, LLC and Biomed Partners II, LLC will have the power to sell the shares or deal with them as an owner.

Although we understand that the trustees now in control of Mr. Mann s holdings have been advised of Mr. Mann s objectives, we cannot assure you as to how those shares will be distributed or how they will be voted.

The future sale of our common stock, the exchange or conversion of our 2018 notes into common stock or the exercise of our warrants for common stock could negatively affect the market price of our common stock and other securities.

As of February 22, 2016, we had 428,850,858 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 and other securities may decline. Likewise the issuance of additional shares of our common stock upon the exchange or conversion of some or all of our 2018 notes or upon the exercise of outstanding warrants, could adversely affect the market price of our common stock and other securities. In addition, the existence of these notes and warrants may encourage short selling of our common stock by market participants, which could adversely affect the market price of our common stock and other securities.

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 and other securities may decline.

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 or the holders of our other securities. 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

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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 any investment in our common stock.

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. Pursuant to the Facility Agreement, we are subject to contractual restrictions on the payment of dividends. There is no guarantee that our common stock will appreciate or maintain its current price. You could lose the entire value of any investment in our common stock.

We have a limited number of unreserved shares available for future issuance, which may impair our ability to conduct future financing and other transactions.

Our amended and restated certificate of incorporation currently authorizes us to issue up to 550,000,000 shares of common stock and 10,000,000 shares of preferred stock. As of February 22, 2016, we had a total of 121,149,142 shares of common stock that were authorized but unissued, and we have currently reserved a significant number of these shares for future issuance pursuant to outstanding equity awards, our equity plans and our 2018 notes. As a result, our ability to issue shares of common stock other than pursuant to existing arrangements will be limited until such time, if ever, that we are able to amend our amended and restated certificate of incorporation to further increase our authorized shares of common stock or shares currently reserved for issuance otherwise become available (for example, due to the termination of the underlying agreement to issue the shares).

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

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 for AFREZZA. We believe the Danbury facility will have sufficient space to satisfy commercial demand for AFREZZA.

We own approximately 142,000 square feet of laboratory, office and warehouse space in Valencia, California. This facility is currently listed for sale.

Our obligations under the Facility Agreement, the Milestone Agreement, and Sanofi Loan Facility are secured by certain mortgages on our facilities in Danbury, Connecticut and Valencia, California.

We also lease approximately 12,500 square feet of office space in Valencia, California pursuant to a lease that expires in April 2017. The facility contains our principal executive offices.

Item 3. ***Legal Proceedings***

Following the receipt by us of the notice of termination from Sanofi regarding the Sanofi License Agreement and the subsequent decline of the price of our common stock, several complaints were filed in the U.S. District Court for the Central District of California against us and certain of our officers and directors on behalf of certain purchasers of our common stock. The complaints include claims asserted under Sections 10(b) and 20(a) of the Exchange Act and have been pled as putative shareholder class actions. In general, the complaints allege that we and certain of our officers and directors violated federal securities laws by making materially false and misleading statements regarding the prospects for AFREZZA, thereby artificially inflating the price of our common stock. The plaintiffs are seeking monetary damages and other relief. We expect the complaints to be transferred to a single court and consolidated for all purposes, following which the court would be expected to appoint a lead plaintiff and lead counsel and to order the lead plaintiff to file a consolidated complaint. We will vigorously defend against the claims advanced.

Following the receipt by us of the notice of termination from Sanofi regarding the Sanofi License Agreement and the subsequent decline of the price of our common stock, two motions were submitted to the District Court at Tel Aviv (Economic Department) for the certification of a class action against us and certain of our officers and directors. In general, the complaints allege that we and certain of our officers and directors violated Israeli and US securities laws by making materially false and misleading statements regarding the prospects for AFREZZA, thereby artificially inflating the price of our common stock. The plaintiffs are seeking monetary damages. We will vigorously defend against these claims.

We are also 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.

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

Not applicable.

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PART II

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

Common Stock Market Price

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

	High	Low
Year ended December 31, 2015		
First quarter	$ 7.88	$ 5.03
Second quarter	$ 7.32	$ 3.46
Third quarter	$ 5.80	$ 3.00
Fourth quarter	$ 4.07	$ 1.38
Year ended December 31, 2014		
First quarter	$ 7.21	$ 3.80
Second quarter	$ 11.48	$ 4.02
Third quarter	$ 10.81	$ 5.91
Fourth quarter	$ 6.65	$ 4.45

The closing sales price of our common stock on The NASDAQ Global Market was $1.00 on February 22, 2016 and there were 183 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, or the Exchange Act, except to the extent we specifically incorporate this section by reference.

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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 graph assumes a $100 investment, on December 31, 2010, in (i) our common stock, (ii) the securities comprising The NASDAQ Composite Index and (iii) the securities comprising 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.

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. In addition, under the terms of the Facility Agreement, we are restricted from distributing any of our assets or declaring and distributing a dividend to our stockholders.

Recent Sales of Unregistered Securities

Pursuant to the terms of our engagement letter with Sunrise Securities Corp., our placement agent for the registered direct offering that we completed in November 2015, on November 16, 2015 we issued three affiliates of Sunrise Securities Corp. warrants to purchase an aggregate of 159,303 shares of our common stock at an exercise price of $2.61 per share. The warrants are exercisable for cash, and in some cases on a cashless basis, for a period of five years following the issuance date. On December 15, 2015, we registered for resale the shares of common stock issuable upon exercise of the warrants.

We issued the warrants in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended. The recipients acquired the warrants for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the warrants.

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

The information set forth below should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and the audited consolidated financial statements, and the notes thereto, and other financial information included herein this Annual Report on Form 10-K.

	Year Ended December 31,				
Statement of Operations Data:	**2015**	**2014**	**2013**	**2012**	**2011**
	(In thousands, except per share amounts)				
Revenue	$	$	$	$ 35	$ 50
Operating expenses:					
Research and development	29,674	100,244	109,719	101,522	99,959
General and administrative	40,960	79,383	59,682	45,473	40,630
Product Manufacturing	67,442				
Property and equipment impairment	140,412				
Loss on purchase commitments	66,167				
Total operating expenses	344,655	179,627	169,401	146,995	140,589
Loss from operations	(344,655)	(179,627)	(169,401)	(146,960)	(140,539)
Other income (expense)	1,366	1,679	(635)	(1,191)	1,541
Loss on extinguishment of debt	(1,049)				
Interest expense on note payable to principal stockholder	(2,894)	(2,894)	(6,309)	(10,491)	(10,883)
Interest expense	(21,231)	(17,549)	(15,153)	(11,139)	(10,941)
Interest income	18	9	8	7	18
Loss before provision for income taxes	(368,445)	(198,382)	(191,490)	(169,774)	(160,804)
Income taxes				408	
Net loss	$ (368,445)	$ (198,382)	$ (191,490)	$ (169,366)	$ (160,804)
Basic and diluted net loss per share	$ (0.91)	$ (0.51)	$ (0.64)	$ (0.94)	$ (1.32)
Shares used to compute basic and diluted net loss per share	406,165	385,229	299,591	180,855	121,817

	December 31,				
Balance Sheet Data:	**2015**	**2014**	**2013**	**2012**	**2011**
	(In thousands)				
Cash and cash equivalents	$ 59,074	$ 120,841	$ 70,790	$ 61,840	$ 2,681
Total assets	126,412	394,439	258,646	251,314	199,553
Senior convertible notes	27,613	99,355	98,439	212,026	210,642
Note payable to our principal stockholder	49,521	49,521	49,521	119,635	277,203
Facility financing obligation	74,582	72,995	102,300		
Sanofi loan facility and loss share obligation	62,371	3,034			
Accumulated deficit	(2,863,229)	(2,494,784)	(2,296,402)	(2,104,912)	(1,935,546)
Total stockholders deficit	(350,329)	(73,770)	(30,713)	(110,679)	(313,652)

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

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

Overview

We are a biopharmaceutical company focused on the discovery and development of therapeutic products for diseases such as diabetes. Our only approved product, AFREZZA, is a rapid-acting inhaled insulin that was approved by the FDA on June 27, 2014 to improve glycemic control in adult patients with diabetes. AFREZZA became available by prescription in United States retail pharmacies in February 2015.

For the year ended December 31, 2015, Sanofi reported a total of 7.0 million in annual sales of AFREZZA. As of December 31, 2015, we had an accumulated deficit of $2.9 billion and a stockholders deficit of $350.3 million. We incurred net losses of approximately $368.4 million, $198.4 million, and $191.5 million in the years ended December 31, 2015, 2014, and 2013, respectively. We have funded our operations primarily through the sale of equity securities and convertible debt securities, borrowings under the Facility Agreement, borrowings under The Mann Group Loan Arrangement, receipt of upfront and milestone payments under the Sanofi License Agreement and borrowings under the Sanofi Loan Facility to fund our portion of the loss share. As discussed below in Liquidity and Capital Resources , if we are unable to obtain additional funding, there will be substantial doubt about our ability to continue as a going concern.

To date, all sales and marketing activities related to AFREZZA have been conducted by Sanofi pursuant to the Sanofi License Agreement, and we have been responsible for manufacturing AFREZZA to supply Sanofi s demand for the product pursuant to the Sanofi Supply Agreement. On January 4, 2016, we received written notice from Sanofi of its election to terminate in its entirety the Sanofi License Agreement. Sanofi s notice indicated that the termination was pursuant to Sanofi s right to terminate the agreement upon Sanofi s good faith determination that the commercialization of AFREZZA is no longer economically viable in the United States, in which case the effective date of termination (the Termination Date) would be April 4, 2016. In the alternative, Sanofi indicated that the termination was also pursuant to its right to terminate the Sanofi License Agreement for any reason, in which case the Termination Date would be July 4, 2016. We believe that Sanofi lacks a good faith basis for determining that commercialization of AFREZZA is no longer economically viable in the United States. Nonetheless, in the interest of an expedient transition, we are currently working with Sanofi to transfer and wind down the agreement activities by April 4, 2016, or as soon as practicable thereafter. We intend to assume responsibility for commercializing and developing AFREZZA in the United States as soon as practicable following the Termination Date. As a result of the termination of the Sanofi License Agreement, the Sanofi Supply Agreement will terminate by its terms on the Termination Date. We also intend to seek regional partnerships for the development and commercialization of AFREZZA in foreign jurisdictions where there are appropriate commercial opportunities.

Our business is subject to significant risks, including but not limited to our ability to successfully commercialize and manufacture sufficient quantities of AREZZA and the risks inherent in our ongoing clinical trials and the regulatory approval process for our product candidates. Additional significant risks also include 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

Historically our research and development expenses have consisted mainly of costs associated with research and development of our product candidates, including associated clinical trials, and manufacturing process development. This includes the salaries, benefits and stock-based compensation of research and development personnel, raw materials, 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.

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

General and Administrative Expenses

Our general and administrative expenses are driven by 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.

Product Manufacturing Expenses

Product manufacturing expenses represent under-absorbed labor and overhead and inventory write-offs, which are expensed in the period in which they are incurred rather than as a portion of the inventory cost.

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.

License and collaboration agreements

Pursuant to the Sanofi License Agreement, we granted to Sanofi exclusive, worldwide licenses to certain of our patents, trademarks and know-how for the development and commercialization of AFREZZA. The terms of the Sanofi License Agreement provide for consideration to us in the form of a non-refundable up-front payment, product sales, manufacturing, regulatory and sales milestone payments and profit and loss sharing. On January 4, 2016, we received written notice from Sanofi of its election to terminate in its entirety the Sanofi License Agreement, effective either on April 4, 2016 or July 4, 2016 depending on the permitted basis for termination.

We analyze consideration received under the provisions of ASC 605, Revenue Recognition, to determine whether the consideration, or a portion thereof, could be recognized as revenue. ASC 605 provides that revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collection is reasonably assured.

In arrangements involving the delivery of more than one element, each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting. This determination is generally based on whether the deliverable has stand-alone value to the customer. The arrangement s consideration that is fixed and determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The estimated selling price of each deliverable is determined using the following hierarchy of values: (i) vendor-specific objective evidence of fair value, (ii) third-party evidence of selling price and (iii) best estimate of selling price (BESP). The BESP reflects our best estimate of what the selling price would be if the deliverable was regularly sold by us on a stand-alone basis. In general, the consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables.

The assessment of multiple element arrangements requires judgment in order to determine the appropriate units of accounting and the points in time that, or periods over which, revenue should be recognized. As of

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December 31, 2015, we did not have the ability to estimate the amount of costs that would potentially be incurred under the loss sharing provision of the Sanofi License Agreement, and accordingly we believe the fixed and determinable fee requirement for revenue recognition was not met. Given the fact that Sanofi has terminated the Sanofi License Agreement, we expect to have the ability in the future to estimate the amount of costs that would potentially be incurred under the loss sharing provision of the Sanofi License Agreement, and accordingly we believe the fixed and determinable fee requirement for revenue recognition will be met in 2016.

Inventories

Inventories are stated at the lower of cost or market value. We determine the cost of inventory using the first-in, first-out (FIFO) method. We capitalize inventory costs associated with AFREZZA based on management s judgment and the future economic benefit expected to be realized; otherwise, such costs are expensed as research and development or as product manufacturing expense for under-absorbed labor and overhead. We periodically analyze our inventory levels to identify inventory that may expire or has a cost basis in excess of its estimated realizable value, and write down such inventories as appropriate. In addition, AFREZZA is subject to strict quality control and monitoring, which we perform throughout the manufacturing process. If certain batches of AFREZZA inhalation powder, the inhaler or cartridges, no longer meet quality specifications or become obsolete due to expiration, we will record a charge to write down such unmarketable inventory to its estimated realizable value. Inventory that is not expected to be used within one year is classified as a long term asset on the accompanying condensed consolidated balance sheet.

We analyzed our inventory levels to identify inventory that may expire or has a cost basis in excess of its estimated realizable value. We performed an assessment of projected sales to evaluate the lower of cost or market and the potential excess inventory on hand at December 31, 2015. As a result of this assessment, we recorded a charge of $39.3 million to record the inventory raw materials on hand at the lower of cost or market, inventory expiry, and write-off other inventory related assets.

In connection with the projected sales assessment, we also evaluated our inventory purchase commitments totalling $116.2 million for potential impairment. As a result of this assessment, we recorded a $66.2 million charge related to a loss on future purchase commitments both from a lower of cost or market and excess inventory perspective. The purchase commitment obligation has been reduced to reflect our expectation that a portion will be recoverable from a third party.

Deferred product costs from collaboration

Cost of product manufacturing includes costs in connection with producing commercial and clinical product for Sanofi. Deferred costs represent the costs of product manufactured and shipped to Sanofi, not to exceed the amount of deferred product sales related to the collaboration, for which recognition of revenue has been deferred. Given that the costs of inventory delivered to Sanofi, but for which revenue may not yet be recognized, meet both the definition and characteristics of an asset and management believes that it is probable that the amount of future revenue will exceed the amount of deferred costs (i.e., the asset would be realizable through the recognition of probable future income), we have elected to account for the deferred costs related to the product sold to Sanofi as an asset and carry forward to future periods until the related revenue is recognized.

Milestone Rights

In connection with the execution of the Facility Agreement on July 1, 2013, we issued Milestone Rights to the Milestone Purchasers. The Milestone Rights provide the Milestone Purchasers certain rights to receive payments up to $90.0 million upon the occurrence of specified strategic and sales milestones, including the first commercial sale of an AFREZZA product, and the achievement of specified net sales figures. We analyzed the Milestone Rights under the provisions of Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC), 815 *Derivatives and Hedging*, referred to as ASC 815, and determined that the instruments do not meet the definition of a freestanding derivative. Since we have not elected to apply the fair value option to the Milestone Rights, we have recorded the Milestone Rights at their estimated fair value and accounted for the Milestone Rights as a liability by applying the indexed debt guidance contained in paragraphs ASC 470-10-25-3 and 35-4.

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The initial fair value estimate of the Milestone Rights was calculated using the income approach in which the cash flows associated with the specified contractual payments were adjusted for both the expected timing and the probability of achieving the milestones and discounted to present value using a selected market discount rate. The expected timing and probability of achieving the milestones was developed with consideration given to both internal data, such as progress made to date and assessment of criteria required for achievement, and external data, such as market research studies. The discount rate was selected based on an estimation of required rate of returns for similar investment opportunities using available market data.

The Milestone Rights liability will be remeasured as the specified milestone events are achieved. Specifically, as each milestone event is achieved, the portion of the initially recorded Milestone Rights liability that pertains to such milestone event being achieved, will be remeasured to the amount of the specified related milestone payment. The resulting change in the balance of the Milestone Rights liability due to remeasurement will be recorded in our Statement of Operations as interest expense. Furthermore, the Milestone Rights liability will be reduced upon each milestone payment being paid. As a result, each milestone payment would be effectively allocated between a reduction of the recorded Milestone Rights liability and an expense representing a return on a portion of the Milestone Rights liability paid to the investor for the achievement of the related milestone event.

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.

In connection with our quarterly assessment of impairment indicators, we evaluated the continued lower than expected sales of AFREZZA as reported by Sanofi throughout the fourth quarter of 2015, revised forecasts for sales of AFREZZA provided by Sanofi in the fourth quarter of 2015 and level of commercial production in the fourth quarter of 2015, as well as the uncertainty associated with Sanofi s announcement during the fourth quarter of their intent to reorganize their diabetes business. These factors indicated potentially significant changes in the timing and extent of cash flows, and we therefore determined that an impairment indicator existed in the fourth quarter of 2015.

On January 4, 2016, we received written notice from Sanofi of its election to terminate in its entirety the Sanofi License Agreement. Sanofi s notice indicated that the termination was pursuant to Sanofi s right to terminate the agreement upon Sanofi s good faith determination that the commercialization of AFREZZA is no longer economically viable in the United States, in which case the effective date of termination (the Termination Date) would be April 4, 2016. In the alternative, Sanofi indicated that the termination was also pursuant to its right to terminate the License Agreement for any reason, in which case the Termination Date would be July 4, 2016. We believe that Sanofi lacks a good faith basis for determining that commercialization of AFREZZA is no longer economically viable in the United

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States. Nonetheless, in the interest of an expedient transition, we are currently working with Sanofi to transfer and wind down the agreement activities by April 4, 2016, or as soon as practicable thereafter.

We identified two primary asset groups to be evaluated for impairment: the Danbury manufacturing facility, which currently performs all the manufacturing of AFREZZA, and the Valencia facility, which was previously our corporate headquarters. The Danbury manufacturing facility is the primary asset group that has been impacted by the impairment indicators noted above but we also evaluated the Valencia facility for potential impairment given the circumstances, and identified an impairment charge of $1.8 million based on a valuation utilizing a combination of market, income and cost approaches. Within the Danbury manufacturing facility, we identified the machinery and equipment as the primary assets within the asset group as they are associated with the production of AFREZZA. As such, we performed the fixed asset impairment test and performed the first step to test for recoverability of the Danbury manufacturing facility by utilizing two undiscounted cash flow projections and applying a probability weighted average to those cash flow projections. The first undiscounted cash flow projection was developed under a scenario assuming Sanofi would continue to sell and market AFREZZA as the termination of the arrangement by Sanofi was not known as of the balance sheet date. The second undiscounted cash flow projection assumed Sanofi would terminate the Sanofi License Agreement and that we would manufacture, sell and market AFREZZA independently.

Based on the evaluation performed, the probabilities assigned to the two undiscounted cash flows were not significant to the evaluation due to the projected negative cash flows over the estimation period, and it was determined that the probability weighted undiscounted cash flows were not sufficient to recover the carrying value of the Danbury manufacturing facility. As such, we were required to determine the fair value of the Danbury manufacturing facility to recognize an impairment loss if the carrying amount exceeds its fair value. We determined the fair value of the Danbury manufacturing facility by applying the highest and best use valuation concept and utilizing the market approach valuation technique to value the machinery and equipment and a combination of the market approach and cost approach in valuing the land, buildings, and building improvements. As a result of this assessment, we recorded an impairment charge of $138.6 million for the Danbury manufacturing facility.

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 require additional write downs of 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.

Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in our reporting amounts that are too high or too low for any particular period.

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Stock-Based Compensation

We account for stock-based compensation in accordance with 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. Option valuation models require the input of assumptions, including the expected life of the stock-based awards, the estimated stock price volatility, the risk-free interest rate, and the expected dividend yield. Beginning in the third quarter of 2014, we began to assess both historical and implied volatility in order to determine the estimated volatility rate for our stock. Implied volatility was considered due to the change in our business, which occurred with the approval for the sale of AFREEZA. The expected volatility assumption is based on an assessment of the historical volatility and the implied volatility of our common stock, derived from an analysis of historical traded and quoted options on our common stock. Restricted stock units are valued based on the market price on the grant date. We evaluate stock awards with performance conditions as to the probability that the performance conditions will be met and estimate the date at which the performance conditions will be met in order to properly recognize stock-based compensation expense over the requisite service period.

Accounting for Income Taxes

Our management must make 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, 2015, we had established a valuation allowance of $962.6 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, 2015 and 2014

Revenues

During the years ended December 31, 2015 and 2014, we did not recognize any revenue. Due to the termination of the Sanofi License Agreement and based on our current operating plan, we expect to recognize, likely within 2016, $17.5 million as product sales from collaboration, $13.5 million as product costs from collaboration and income from collaboration related to upfront and milestone payments in excess of $100 million, which amounts are deferred as of December 31, 2015 due to the revenue recognition criteria not being met as of such date.

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Research and Development Expenses

The following table provides a comparison of the research and development expense categories for the years ended December 31, 2015 and 2014 (dollars in thousands):

	Year Ended December 31,			
	2015	2014	$ Change	% Change
Clinical	$ 11,941	$ 27,962	$ (16,021)	(57%)
Manufacturing	8,939	44,901	(35,962)	(80%)
Research	6,554	5,841	713	12%
Research and development tax credit	(789)	(817)	28	(3%)
Stock-based compensation expense	3,029	22,357	(19,328)	(86%)
Research and development expenses	$ 29,674	$ 100,244	$ (70,570)	(70%)

The decrease in research and development expenses of $70.6 million for the year ended December 31, 2015 compared to the year ended December 31, 2014 was primarily due to a decrease of $36.0 million in manufacturing process development expenses resulting from the shift to commercial production of AFREZZA of $30.8 million and decreased expenses of $0.7 million following the completion of restructuring activities in early 2015. The decrease is also attributable to a $19.3 million decrease in stock-based compensation expense compared to 2014 as a result of a non-recurring modification of the settlement terms (the Modification) of certain performance-based restricted stock units and the achievement of performance-based grants in 2014 and the first quarter of 2015. The Modification resulted in the reclassification of these performance grants from equity awards to liability awards, which required re-measurement on the modification date and resulted in incremental stock-based compensation expense. Further, the reductions in research and development expenses was also driven by a decrease in clinical trial related expenses of $16.0 million primarily resulting from the completion of the affinity trials of $11.1 million and decreased personnel costs related to restructuring of $9.0 million.

We anticipate that our overall research and development expenses will decrease in 2016 compared to 2015 due to the focus on the transition of the AFREZZA rights in 2016 and minimal incremental cost associated with our development pipeline.

General and Administrative Expenses

The following table provides a comparison of the general and administrative expense categories for the years ended December 31, 2015 and 2014 (dollars in thousands):

	Year Ended December 31,			
	2015	2014	$ Change	% Change
Salaries, employee related and other general expenses	$ 35,264	$ 53,118	$ (17,854)	(34%)
Stock-based compensation expense	5,696	26,265	(20,569)	(78%)
General and administrative expenses	$ 40,960	$ 79,383	$ (38,423)	(48%)

The decrease in general and administrative expenses of $38.4 million for the year ended December 31, 2015 compared to the year ended December 31, 2014 was primarily due to decreased stock-based compensation expense of $20.6 million, resulting from the modification and achievement of performance-based grants in 2014 and the first quarter of 2015, as described above. Additionally, the decrease is also attributable to professional fees of $13.8 million related to the Sanofi License Agreement incurred in the third quarter of 2014 and decreased expenses of $3.2 million following the completion of restructuring activities and decreased personnel costs in early 2015.

We expect general and administrative expenses to remain relatively flat in 2016 as compared to 2015 due to restructuring measures in 2015 offset by an increase in professional fees related to the Sanofi termination.

We expect to have sales and marketing expenses in 2016 due to termination of the Sanofi License Agreement and the transition of sales and marketing efforts to us in 2016.

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Product Manufacturing Expenses

Product manufacturing expenses were $67.4 million for the year ended December 31, 2015, resulting from product manufacturing costs associated with AFREZZA product sales, which cannot be capitalized due to excess capacity. We had no product manufacturing expense for the year ended December 31, 2014, as pre-commercial manufacturing costs associated with AFREZZA were accounted for as research and development expenses. Product manufacturing expenses represent under-absorbed labor and overhead of $21.4 million and inventory write-offs of 36.1 million, which are expensed in the period in which they are incurred.

Although the Sanofi License Agreement will terminate in the second quarter of 2016, we expect our 2016 production of AFREZZA to be relatively consistent with production levels in 2015, primarily as a result of existing customer demand. With the exception of the inventory write-off, we expect product manufacturing expense to remain relatively flat in 2016 compared to 2015.

Property and equipment impairment

Property and equipment impairment increased $140.4 million for the year ended December 31, 2015 compared to the year ended December 31, 2014. The property and equipment impairment was to reduce the carrying amount of our real property and machinery and equipment to fair value based on our impairment assessment in the fourth quarter of 2015.

Loss on purchase commitments

Loss on purchase commitments increased $66.2 million for the year ended December 31, 2015 compared to the year end 2014. The loss on purchase commitments was related to the loss on future purchase commitments resulting from our assessment of excess inventory as a result of lower than expected sales of AFREZZA as well as a lower of cost or market adjustment due to estimated conversion costs in excess of our estimated selling price of AFREZZA.

Other Income (Expense)

Other income for the year ended December 31, 2015 was $1.4 million resulting from the relief of an accrual for potential expenses associated with the sale of intellectual property related to oncology in 2014, which was subsequently resolved without payment in the first quarter of 2015. For the year ended December 31, 2014, other income was $1.7 million resulting from the sale of intellectual property related to oncology in the third quarter of 2014 in the amount of $7.9 million, partially offset by a $6.4 million non-cash charge recognized upon the conversion of 2019 notes into equity.

Loss on Extinguishment of Debt

Loss on extinguishment of debt increased $1.0 million for the year ended December 31, 2015 compared to the year ended December 31, 2014. The loss on extinguishment is due to the settlement of the 2015 notes through payment of cash and issuance of new debt.

Interest Income and Expense

Interest expense increased $3.7 million from $20.4 million for the year ended December 31, 2014 to $24.1 million for the year ended December 31, 2015. The increase was primarily due to $5.8 million interest expense associated with the milestone payment resulting from the achievement and re-measurement of the second milestone under the Milestone Agreement in the first quarter of 2015 compared to the $1.9 million interest expense from the payment of the first milestone in 2014. The increase was also due to an increase of $1.7 million related to the Sanofi Loan Facility and $0.8 million in interest for 2018 notes, which was offset by a decrease in interest expense of $2.7 million resulting from the maturity of 2015 notes.

Years ended December 31, 2014 and 2013

Revenues

During the years ended December 31, 2014 and 2013, we did not recognize any revenue.

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Research and Development Expenses

The following table provides a comparison of the research and development expense categories for the years ended December 31, 2014 and 2013 (dollars in thousands):

	Year Ended December 31,			
	2014	2013	$ Change	% Change
Clinical	$ 27,962	$ 42,711	$ (14,749)	(35)%
Manufacturing	44,901	40,530	4,371	11%
Research	5,841	6,351	(510)	(8)%
Research and development tax credit	(817)	(282)	(535)	190%
Stock-based compensation expense	22,357	20,409	1,948	10%
Research and development expenses	$ 100,244	$ 109,719	$ (9,475)	(9)%

The decrease in research and development expenses for the year ended December 31, 2014 compared to the year ended December 31, 2013 was driven by a decrease in clinical trial related expenses of $14.8 million with the completion of two Phase 3 clinical studies of AFREZZA in 2013. This decrease was offset by a $4.4 million increase in manufacturing spending due to supply purchases, increased headcount for commercial readiness and a $1.9 million increase in stock-based compensation resulting from the net effect of $10.4 million in increased stock-based compensation expense due to the Modifications. The foregoing increase in stock-based compensation in 2014 was partially offset by an overall decrease in stock-based compensation of $7.1 million due to the decreased recognition period in 2014 as a result of the achievement of milestones under company-wide performance-based grants in the second and third quarters of 2014, in addition to a reduction of other option and award compensation of $1.4 million due to a reduction in force.

We began commercial manufacturing in the latter part of the fourth quarter of 2014. As such, commercial manufacturing costs incurred in the fourth quarter and included in manufacturing expenses above are immaterial for the year ended December 31, 2014.

General and Administrative Expenses

The following table provides a comparison of the general and administrative expense categories for the years ended December 31, 2014 and 2013 (dollars in thousands):

	Year Ended December 31,			
	2014	2013	$ Change	% Change
Salaries, employee related and other general expenses	$ 53,118	$ 34,905	$ 18,213	52%
Stock-based compensation expense	26,265	24,777	1,488	6%
General and administrative expenses	$ 79,383	$ 59,682	$ 19,701	33%

General and administrative expenses for the year ended December 31, 2014 increased compared to the prior year, driven by an increase in professional fees of $15.4 million associated with the closing of the Sanofi License Agreement, the amendment of the Facility Agreement and assessment of new product opportunities. Salaries and employee-related expenses increased by $2.8 million in 2014 primarily due to increased compensation related to the achievement of significant corporate milestones and severance expense related to a reduction in force in the fourth quarter of 2014. Stock-based compensation expense increased by $1.5 million as a result of the net effect of $12.6 million in increased stock-based compensation expense due to the Modifications and settlement of value during 2014 for certain performance awards, partially offset by an overall decrease in stock-based compensation of $9.5 million due to the decreased recognition period in 2014 as a result of the achievement of milestones under company-wide performance based grants in the second and third quarters of 2014, in addition to a reduction of other option and award compensation of $1.9 million due to a reduction in force.

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Other Income (Expense)

Other income for the year ended December 31, 2014 was $1.7 million resulting from the sale of intellectual property related to oncology in the third quarter of 2014 in the amount of $7.9 million, partially offset by a $6.4 million non-cash charge recognized upon the conversion of 2019 notes into equity. For the year ended December 31, 2013, other expense was $0.6 million related to the loss on conversion of debt to equity at the end of 2013 upon the conversion of 2019 notes into common stock in accordance with the Facility Agreement.

Interest Income and Expense

Interest expense decreased $1.1 million from $21.5 million for the year ended December 31, 2013 to $20.4 million for the year ended December 31, 2014 due to lower principal balances resulting from the repayment of senior convertible notes and the conversion of 2019 notes into equity in 2014.

Liquidity and Capital Resources

To date, we have funded our operations through the sale of equity securities and convertible debt securities, borrowings under The Mann Group Loan Arrangement, borrowings under the Facility Agreement with Deerfield, receipt of upfront, milestone payments under the Sanofi License Agreement, and borrowings under the Sanofi Loan Facility.

As of December 31, 2015, we had $201.7 million principal amount of outstanding debt, consisting of:

- $27.7 million principal amount of 2018 notes bearing interest at 5.75% per annum and maturing on August 15, 2018;
- $60.0 million principal amount of 2019 notes bearing interest at 9.75% per annum, $5.0 million of which is due and payable in July 2016, $15.0 million of which is due and payable in July 2017, $15.0 million of which is due and payable in July 2018 and $25.0 million of which is due and payable in July and December 2019;
- $20.0 million principal amount of Tranche B notes bearing interest at 8.75% per annum, $5.0 million of which is due and payable in each of May 2017, 2018 and 2019, and $5.0 million of which is due and payable in December 2019;
- $49.5 million principal amount of indebtedness under The Mann Group Loan Arrangement bearing interest at 5.84% and maturing and due on January 5, 2020; and
- $44.5 million principal amount borrowed under the Sanofi Loan Facility to fund our share of net losses under the Sanofi License Agreement, bearing interest at a rate of 8.5% per annum, with accrued interest payable in-kind and compounded quarterly, and maturing and due on September 23, 2024.

As of December 31, 2015, the amount available for future borrowings under The Mann Group Loan Arrangement was $30.1 million. A portion of these available borrowings may be used to capitalize accrued interest into principal, upon mutual agreement of the parties, as it becomes due and payable under The Mann Group Loan Arrangement. As of December 31, 2015 the accrued and unpaid interest under The Mann Group Loan Arrangement was $6.4 million.

All profits and losses from AFREZZA product sales by Sanofi or its affiliates after the Termination Date, if any, will continue to be shared 65% by Sanofi and 35% by us pursuant to the terms of the Sanofi License Agreement. Our total share of the net losses are $62.4 million, classified as Sanofi loan facility and loss share obligation, of which $44.5 million has been borrowed under the Sanofi Loan Facility as of December 31, 2015. Subsequent to December 31, 2015, we borrowed an additional $17.9 million under the Sanofi Loan Facility to finance our share of the net losses for the fourth quarter of 2015, which was reclassified from current deferred payments from collaboration to Sanofi loan facility and loss share obligation, for a total of $62.4 million, which includes $1.7 million in paid-in-kind interest. We will be required to make mandatory prepayments on any outstanding loans under the Sanofi Loan Facility from our share of any profits under the Sanofi License

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Agreement. Additionally, if we sell our Valencia facility, which we no longer use as our corporate headquarters, we will be required to prepay the loans under the Sanofi Loan Facility from the net cash proceeds of the sale within five business days of receipt.

There can be no assurance that we will have sufficient resources to make any required repayments of principal under the 2018 notes, 2019 notes, Tranche B notes, The Mann Group Loan Arrangement or Sanofi Loan Facility when required. Further, if we undergo a fundamental change, as that term is defined in the indentures governing the terms of the 2018 notes, or certain Major Transactions as defined in the Facility Agreement in respect of the 2019 notes and the Tranche B notes, the holders of the respective debt securities will have the option to require us to repurchase all or any portion of such debt securities at a repurchase price of 100% of the principal amount of such debt securities to be repurchased plus accrued and unpaid interest, if any. The 2018 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. The 2019 notes bear interest at the rate of 9.75% per year on the outstanding principal amount and the Tranche B notes bear interest at the rate of 8.75% on the outstanding principal amount, with accrued interest on each payable in cash quarterly in arrears on the last business day of March, June, September and December of each year. Loans under the Sanofi Loan Facility bear interest at a rate of 8.5% per annum, paid-in kind on a quarterly basis (2.06% per quarter compounded). Loans under the Loan Arrangement accrue interest at a rate of 5.84% per annum, 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 LLC mutually agree. 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 2018 notes, 2019 notes, Tranche B notes, or on the loans under the Sanofi Loan Facility, or if we fail to repay or repurchase the 2018 notes, 2019 notes, Tranche B notes, or borrowings under The Mann Group Loan Arrangement or the Sanofi Loan Facility when required, we will be in default under the applicable instrument for such indebtedness, 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 note holders initiating bankruptcy proceedings or causing us to cease operations altogether.

In connection with the execution of the Facility Agreement, on July 1, 2013, we issued Milestone Rights to the Milestone Purchasers. The Milestone Rights provide the Milestone Purchasers certain rights to receive payments of up to $90.0 million upon the occurrence of specified strategic and sales milestones, including the first commercial sale of an AFREZZA product and the achievement of specified net sales figures. In the first quarter of 2015, the second milestone triggering event was achieved following our product launch on February 3, 2015. In connection with the milestone triggering event, we paid a $10.0 million payment to Milestone Purchasers pursuant to the terms of the Milestone Agreement in the first quarter of 2015 and we do not expect to pay any milestone payments in the next 12 months.

The Facility Agreement includes customary representations, warranties and covenants, including, a restriction on the incurrence of additional indebtedness, and a financial covenant which requires our cash and cash equivalents, which includes available borrowings under The Mann Group Loan Arrangement, on the last day of each fiscal quarter to not be less than $25.0 million. In the event of default under the Facility Agreement, the holders of the 2019 notes and Tranche B notes may declare all or any portion of the 2019 notes and Tranche B notes to be immediately due and payable. In addition, our inability to meet or otherwise comply with the covenants under these agreements could have an adverse impact on our financial position and results of operations and could result in an event of default under the terms of our other indebtedness, including our indebtedness under the 2018 notes. In the event of certain future defaults under the foregoing agreements for which we are not able to obtain waivers, the holders of the 2018 notes, 2019 notes and Tranche B notes and the lender under the Sanofi Loan Facility may accelerate all of our repayment obligations, and, with respect to the 2019 notes and Tranche B notes and the loans under the Sanofi Loan Facility, take control of our pledged assets, potentially requiring us to renegotiate the terms of our indebtedness on terms less favorable to us, or to immediately cease operations.

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In August 2015, we issued $27.7 million aggregate principal amount of new 5.75% Convertible Senior Subordinated Exchange Notes due 2018 (the 2018 notes). The 2018 notes are general, unsecured, senior obligations, except that the 2018 notes are subordinated in right of payment to the outstanding notes issued pursuant to the Facility Agreement and our borrowings under the Sanofi Loan Facility. The 2018 notes rank equally in right of payment with our other unsecured senior debt. The 2018 notes bear interest at the rate of 5.75% per year on the principal amount, payable semiannually in arrears in cash on February 15 and August 15 of each year, beginning February 15, 2016, with interest accruing from August 15, 2015. The 2018 notes mature on August 15, 2018.

On July 31, 2014, we entered into the Insulin Supply Agreement, pursuant to which we agreed to purchase certain annual minimum quantities of insulin for calendar years 2015 through 2019, for an aggregate total purchase price of approximately 120.1 million, of which 98.5 million is remaining at December 31, 2015. We have contracted for the purchase of 28.8 million in 2016 and the remaining annual minimum quantities will be 23.3 million for the years ended December 31, 2017 through 2019. Unless earlier terminated, the term of the Insulin Supply Agreement expires on December 31, 2019 and can be renewed for additional, successive two year terms upon 12 months written notice, given prior to the end of the initial term or any additional two year term. We and Amphastar each have normal and customary termination rights, including termination for material breach that is not cured within a specific time frame or in the event of liquidation, bankruptcy or insolvency of the other party. In addition, we may terminate the Insulin Supply Agreement upon two years prior written notice to Amphastar without cause or upon 30 days prior written notice to Amphastar if a controlling regulatory authority withdraws approval for AFREZZA, provided, however, in the event of a termination pursuant to either of the latter two scenarios, the provisions of the Insulin Supply Agreement require us to pay the full amount of all unpaid purchase commitments due over the initial term within 60 calendar days of the effective date of such termination.

During the year ended December 31, 2015, we raised gross proceeds of $28.4 million from the sale of 8.9 million shares of common stock under our at-the-market issuance sales agreements, resulting in net proceeds of $27.8 million after issuance costs.

Pursuant to the Sanofi License Agreement, we received milestone payments of $50.0 million in the first quarter of 2015 upon satisfaction of certain manufacturing milestones specified in the Sanofi License Agreement. As a result of the termination of the Sanofi License Agreement, we will not receive any additional milestone payments from Sanofi under the agreement.

During the year ended December 31, 2015, we used $57.2 million of cash for operating activities as a result of our net loss of $368.4 million, adjusted by non-cash charges of $231.5 million and a net decrease in assets and liabilities of $41.0 million. The non-cash charges included $206.6 million of impairment charges, $22.0 million of depreciation and accretion and stock-based compensation, $1.7 million interest accrued through borrowings under Sanofi Loan Facility, $ 1.0 million for the loss on extinguishment of debt, with the remainder due to an adjustment for foreign currency transaction losses. The change in net assets and liabilities was predominately due to the net decreases in receivables from collaboration from the $50.0 million received in milestone payments and $13.5 million due to the decrease in prepaids and other current assets at December 31, 2015 compared to December 31, 2014 primarily due to prepayment on insulin in 2014, which did not occur in 2015. This was offset by net decreases in inventory as we purchased significant inventory in 2014 related to Amphastar, which did not occur in 2015.

During the year ended December 31, 2014, cash provided by operations was $4.1 million as a result of our net loss of $198.4 million, adjusted by non-cash charges of $67.2 million and a net increase in assets and liabilities of $133.8 million. The non-cash charges were predominately related to depreciation and accretion and stock-based compensation. The change in net assets and liabilities was predominately due to the net increases in receivables and deferred payments from collaboration of $150.0 million deferred up-front payment recorded from the up-front fee associated with the Sanofi License Agreement being partially offset by the $15.0 million deposit to Amphastar as prepayment for 2015 quantities of insulin as part of the Insulin Supply Agreement.

We used $10.2 million of cash for investing activities during the year ended December 31, 2015, compared to $24.1 million for the year ended December 31, 2014. The $13.9 million decrease was due a decrease in purchases of machinery and equipment. For the year ended December 31, 2014, cash used for investing activities increased

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by $16.1 million over the amount used during the year ended December 31, 2013, due to purchases of machinery and equipment for the preparation for commercialization of AFREZZA in 2014.

Our financing activities provided $5.7 million of cash for the year ended December 31, 2015, compared to $70.1 million for the year ended December 31, 2014. For the year ended December 31, 2015, cash used in financing activities was comprised of a $64.3 million payment on the outstanding 2015 notes obligation and a $4.2 million payment associated with the achievement of the second milestone to Deerfield for product launched on February 3, 2015. These outflows were offset by $34.7 million received in net proceeds from the sale of stock on the Tel Aviv Stock Exchange in November 2015, $27.8 million net of issuance costs in proceeds from at-the-market sales of stock, and $14.3 million received in proceeds from exercise of stock options and warrants. Cash inflows were offset by the payment of employment taxes related to vested restricted stock units.

Our financing activities provided $70.1 million of cash for the year ended December 31, 2014, compared to $145.7 million for the year ended December 31, 2013. For the year ended December 31, 2014, cash provided by financing activities was comprised of $40.0 million in proceeds received from the issuance of the fourth tranche of 2019 notes to Deerfield, $20.0 million from the sale of Tranche B notes to Deerfield, $27.8 million from warrant exercises, and $12.3 million from the exercise of stock options, which were partially offset by $26.9 million paid for employment taxes related to vested restricted stock units and a $3.2 million milestone principal payment. For the year ended December 31, 2013 cash provided by financing activities was comprised of $119.5 million in net proceeds received from issuance of the 2019 notes and the Milestone Rights and $94.2 million in net proceeds from warrant exercises. Additionally, we received $48.9 million in net proceeds from at-the market issuance sales in 2013, and on December 15, 2013 we paid $115.0 million in settlement of our 3.75% Senior Convertible Notes due 2013 upon maturity.

As of December 31, 2015, we had $59.1 million in cash and cash equivalents. We expect to expend our capital resources for the manufacturing, sales and marketing of AFREZZA subsequent to the termination with Sanofi and to develop our other product candidates. We also intend to use our capital resources for general corporate purposes.

If we enter into strategic business collaborations with respect to our other product candidates, 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.

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, if needed, through equity or debt financing or entering business collaborations, we may be required to reduce expenses through the delay, reduction or curtailment of our projects, 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, 2015, we did not have any off-balance sheet arrangements.

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Contractual Obligations

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 (excluding payments in respect of the Milestone Rights) below are estimated based on current information. Future payments relate to operating lease obligations, the 2018 notes, the facility financing obligation, open purchase order and supply commitments, contractual minimum purchase commitments under the Insulin Supply Agreement with Amphastar and Sanofi Loan Facility consisted of the following at December 31, 2015 (in thousands):

	Payments Due in				
Contractual Obligations	**Less Than One Year**	**1-3 Years**	**4-5 Years**	**More Than 5 Years**	**Total**
Open purchase order and supply commitments(1)	$ 13,411	$ 904	$ 360	$ 348	$ 15,023
Senior convertible notes long term(2)	1,619	30,445			32,064
Note payable to principal stockholder(3)			67,523		67,523
Facility financing obligation(4)	12,376	87,715			100,091
Insulin supply agreement(5)	31,358	76,069			107,427
Sanofi Loan Facility(6)				44,507	44,507
Operating lease obligations	315	101			416
Total contractual obligations	$ 59,079	$ 195,234	$ 67,883	$ 44,855	$ 367,051

(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 commercial production.

(2) The amounts include future interest payments at fixed rates of 5.75% and payment of the 2018 notes in full upon maturity in 2018.

(3) The obligation for the note payable to the principal stockholder includes future principal and interest payments related to the $49.5 million of borrowings as of December 31, 2015. Interest is accrued based on a fixed rate of 5.84% and the outstanding principal amount and all accrued interest thereon will be due on January 5, 2020.

(4) The facility financing obligation includes future principal and interest payments on $60.0 million aggregate principal amount of 2019 notes issued in the first and fourth tranches under the Facility Agreement, and on $20.0 million aggregate principal amount of Tranche B notes, payable in accordance with the provisions of the Facility Agreement, as amended. Interest accrues on the 2019 notes at a fixed rate of 9.75% per annum and on the Tranche B notes at a fixed rate of 8.75% per annum.

(5) On July 31, 2014, we entered into the Insulin Supply Agreement, pursuant to which we agreed to purchase certain annual minimum quantities of insulin for calendar years 2015 through 2019 for an aggregate total purchase price of approximately 120.1 million, of which 98.5 million is remaining at December 31, 2015. We have contracted for the purchase of 28.8 million in 2016 and the remaining annual minimum quantities will be 23.3 million. Future payments due were converted to U.S. dollars using the December 31, 2015 euro-to-dollar exchange.

(6)

On September 23, 2014, we entered into the Sanofi Loan Facility, consisting of a senior secured revolving promissory note and a guaranty with an affiliate of Sanofi which provides us with a secured loan facility of up to $175.0 million to fund our share of net losses under the Sanofi License Agreement. Advances under the Sanofi Loan Facility bear interest at a rate of 8.5% per annum and are payable in-kind and compounded quarterly and added to the outstanding principal balance under the Sanofi Loan Facility. Subsequent to

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December 31, 2015, we borrowed $17.9 million under the Sanofi Loan Facility to finance the portion of our loss for the quarter ended December 31, 2015.

Related Party Transactions

For a description of our related party transactions see Note 7 Related-Party Arrangements in the notes to our financial statements.

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09 related to revenue recognition, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The guidance requires a company to recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration it expects to be entitled to receive in exchange for those goods or services. In July 2015, the FASB issued ASU 2015-14, which delayed the effective date of the new revenue standard by one year. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. The standard is effective beginning the first quarter of our 2018 fiscal year and is required to be adopted using either a full retrospective or a modified retrospective approach. We are assessing the potential impact of the new standard on our consolidated financial statements and have not yet selected a transition method.

In August 2014, the FASB issued ASU 2014-15, which provides guidance on determining when and how reporting entities must disclose going-concern uncertainties in their financial statements. The new standard requires management to perform interim and annual assessments of an entity s ability to continue as a going concern within one year of the date of issuance of the entity s financial statements (or within one year after the date on which the financial statements are available to be issued, when applicable). Further, an entity must provide certain disclosures if there is substantial doubt about the entity s ability to continue as a going concern . The ASU is effective for annual periods ending after December 15, 2016, and interim periods thereafter; early adoption is permitted. We are evaluating the impact the adoption of ASU 2014-15 will have on our consolidated financial statements.

In April 2015, the FASB issued ASU 2015-03, Simplifying the Presentation of Debt Issuance Costs. The guidance requires debt issuance costs to be presented in the balance sheet as a direct deduction from the carrying value of the associated debt, consistent with the presentation of a debt discount. The guidance is effective for annual reporting periods beginning after December 15, 2015 and interim periods thereafter. As permitted by the standard, we adopted the new presentation and the adoption did not have an impact on our consolidated financial statements and disclosures.

In July 2015, the FASB issued ASU 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory. Topic 330, Inventory, currently requires an entity to measure inventory at the lower of cost or market. Market could be replacement cost, net realizable value, or net realizable value less an approximately normal profit margin. The amendments do not apply to inventory that is measured using last-in, first-out (LIFO) or the retail inventory method. The amendments apply to all other inventory, which includes inventory that is measured using first-in, first-out (FIFO) or average cost. The amendments are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. The amendments should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. We are evaluating the impact the adoption of ASU 2015-11 will have on our consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes. The new standard requires that deferred tax assets and liabilities be classified as noncurrent in a classified statement of financial position. For public business entities, the amendments in this Update are effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. As permitted by the standard, we adopted the new presentation and the adoption did not have an impact on our consolidated financial statements and disclosures.

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In January 2016, the FASB issued ASU 2016-01, Financial Instruments Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities. The update is intended to improve the recognition and measurement of financial instruments. The ASU affects public and private companies, not-for-profit organizations, and employee benefit plans that hold financial assets or owe financial liabilities. The update is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. We are evaluating the impact the adoption of ASU 2016-01 will have on our consolidated financial statements.

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

Interest Rate Risk

Due to the fixed interest rates of our debt, we currently do not have an exposure to changes in our interest expense as a result of changes in interest rates. The interest rate on amounts borrowed under The Mann Group Loan Arrangement is fixed at 5.84%. As of December 31, 2015, the total principal amount outstanding under The Mann Group Loan Arrangement was $49.5 million. As of December 31, 2015, we also had debt related to the 2018 notes at a fixed interest rate of 5.75%, debt related to the 2019 notes at a fixed interest rate of 9.75%, debt related to the Tranche B notes at a fixed interest rate of 8.75%, and debt related to the Sanofi Loan Facility at a fixed rate of 8.5%.

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 are entered into for trading purposes. Our cash is deposited in and invested through highly rated financial institutions in North America.

If a change in interest rates equal to 10% of the interest rates on December 31, 2015 were to have occurred, this change would not have had a material effect on the value of our short-term investment portfolio.

Foreign Currency Exchange Risk

We incur and will continue to incur significant expenditures for insulin supply obligations under our supply agreement with Amphastar. Such obligations are denominated in euros. At the end of each reporting period, these liabilities, if any, are converted to U.S. dollars at the then-applicable foreign exchange rate. As a result, our business is affected by fluctuations in exchange rates between the U.S. dollar and foreign currencies. We have not entered into foreign currency hedging transactions to mitigate our exposure to foreign currency exchange risks, but may enter into foreign currency hedging transactions in the future. Exchange rate fluctuations may adversely affect our expenses, results of operations, financial position and cash flows. During the year ended December 31, 2015, we were required to purchase the minimum quarterly supply purchases of insulin contemplated under our supply agreement with Amphastar, and if a change in the U.S. dollar to euro exchange rate equal to 10% of the U.S. dollar to euro exchange rate on December 31, 2015 were to have occurred on December 31, 2015, this change would not have had a material effect on our results of operations or financial condition.

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

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

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

None.

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Item 9A. ***Controls And Procedures***

Evaluation of Disclosure Controls and Procedures

Our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and chief financial officer, or persons performing similar functions, as appropriate to allow 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 necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our system contains control-monitoring mechanisms, and actions are taken to correct deficiencies as they are identified.

As of the end of the period covered by this Annual Report on Form 10-K, we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and our chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)). Based upon that evaluation, our chief executive officer and our principal accounting officer concluded that our disclosure controls and procedures were not effective as of December 31, 2015 because of the material weakness in our internal control over financial reporting as described below.

Management s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Exchange Act Rules 13a-15(f) and 15d-15(f). With the participation of our chief executive officer and chief financial officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework and criteria established in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management identified a material weakness in our internal control over financial reporting, as described below.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company s annual or interim financial statements will not be prevented or detected on a timely basis.

We did not maintain sufficient internal control over financial reporting due to the lack of operating effectiveness of our controls over the impairment testing that we performed in accordance with ASC 360-10, *Impairment and Disposal of Long-Lived Assets* and ASC 330-10, *Inventories*, as of December 31, 2015. Specifically, our review controls did not operate at a sufficient level of precision to identify certain errors, which management has determined constituted a material weakness.

Deloitte & Touche LLP, the registered public accounting firm that audited our consolidated financial statements, has issued an attestation report on our internal control over financial reporting included below.

Plan for Remediation of Material Weakness

The Company has identified remediation measures to address the above-described material weakness and enhance our internal control over financial reporting. To date, we are in the process of taking the following actions to improve the design and operating effectiveness of our internal control in order to remediate this material weakness:

Review the processes and controls related to impairment assessments.

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Design and document review controls with enhanced precision related to the review of impairment assessments.

Design and document additional training programs for relevant personnel and developing specific review procedures regarding the review of impairment assessments.

As of the date of filing this Annual Report on Form 10-K, we are starting the remediation measures set forth above. We expect the enhanced review controls to begin operating in connection with our impairment testing performed in accordance with ASC 360-10 and ASC 330-10 during 2016. We believes the remediation measures will strengthen our internal control over financial reporting and, once completed, will remediate the material weakness identified. We will continue to monitor the effectiveness of these remediation measures and will make any changes and take such other actions that we deem appropriate given the circumstances.

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 changes in our internal control over financial reporting that occurred during our last fiscal quarter and 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 that occurred during our latest fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting except as follows.

In connection with year-end procedures, we have designed and implemented new processes and internal controls to address fixed asset impairment valuation procedures to ensure that information required to be disclosed by us is recorded, processed, summarized and reported. The addition of these processes and internal controls is considered a material change in our internal control over financial reporting.

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of MannKind Corporation

Valencia, California

We have audited the internal control over financial reporting of MannKind Corporation and subsidiaries (the Company) as of December 31, 2015, based on criteria established in *Internal Control Integrated Framework (2013)* 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.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company s annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management s assessment:

The Company did not maintain sufficient internal control over financial reporting due to the lack of operating effectiveness of its controls over its impairment testing that it performed in accordance with ASC 360-10, Impairment and Disposal of Long-Lived Assets and ASC 330-10, Inventories, as of December 31, 2015. Specifically, the Company s review controls did not operate at a sufficient level of precision to identify certain errors, which was determined to constitute a material weakness.

This material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the consolidated financial statements as of and for the year ended December 31, 2015, of the Company and this report does not affect our report on such financial statements.

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In our opinion, because of the effect of the material weakness identified above on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of December 31, 2015, based on the criteria established in *Internal Control Integrated Framework (2013)* 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, 2015 of the Company and our report dated March 15, 2016 expressed an unqualified opinion on those financial statements and includes an explanatory paragraph relating to the Company s ability to continue as a going concern.

/s/ DELOITTE & TOUCHE LLP

Los Angeles, California

March 15, 2016

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

On March 11, 2016, we entered into a separation agreement with Mr. Martens (the Separation Agreement) providing for the terms of Mr. Martens separation from MannKind. Pursuant to the terms of the Separation Agreement, Mr. Martens last day of employment with us will be no later than March 18, 2016 (the Separation Date). The Separation Agreement supersedes all prior agreements regarding Mr. Martens entitlement to receive compensation or other benefits from us after the Separation Date. Mr. Martens has agreed to provide us with a general release of claims in exchange for the following severance compensation and other benefits: (i) continuation of Mr. Martens annual base salary for a period of 12 months following the Separation Date (the Severance Period); (ii) continuation of Mr. Martens health insurance coverage until the earliest of (A) the end of the Severance Period, (B) the expiration of Mr. Martens eligibility for continuation coverage under the Consolidated Omnibus Reconciliation Act of 1985, and (C) the date on which Mr. Martens becomes eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment; and (iii) acceleration of all time-based restricted stock units and stock options held by Mr. Martens that would otherwise have vested through the Severance Period.

The foregoing description of the Separation Agreement is not complete and is qualified in its entirety by reference to the full text of the Separation Agreement, a copy of which is filed herewith as Exhibit 10.8 to this Annual Report on Form 10-K.

On March 9, 2016, we entered into an offer letter agreement (the Offer Letter Agreement) with Michael Castagna, Pharm.D., our new Chief Commercial Officer, pursuant to which we agreed to provide Dr. Castagna with the following compensation: (i) annual base salary of $400,000; (ii) a signing bonus of $50,000; (iii) eligibility to receive annual discretionary bonuses, with a target bonus equal to 50% of annual earnings; (iv) an annual car allowance of $14,400; and (v) subject to the approval by our board of directors, the grant of the following equity awards under our 2013 Equity Incentive Plan (the Plan): (A) a stock option to purchase 329,200 shares of our common stock, (B) a performance-based stock option to purchase 1,000,000 shares of our common stock, and (C) a restricted stock unit for 80,000 shares of our common stock. Twenty-five percent of the shares subject to the stock option in subsection (A) and the restricted stock unit in subsection (C) will vest one year following Dr. Castagna s first day of employment with us, and the balance of the shares will vest in equal monthly installments over the following three years, subject in each case to Dr. Castagna s continued service with us. In addition, the shares subject to the performance-based stock option in subsection (B) will vest according to terms to be mutually agreed upon in advance of the grant date. The foregoing options will be evidenced by a Stock Option Grant Notice and Option Agreement and the foregoing restricted stock unit will be evidenced by a Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement, which, together with the Plan, will set forth the terms and conditions of the foregoing options and restricted stock unit.

Dr. Castagna will also be entitled to enter into our standard form of indemnity agreement, a copy of which is attached as Exhibit 10.1 to our Registration Statement on Form S-1 (File No. 333-115020), filed with the Securities and Exchange Commission on April 30, 2004.

The foregoing description of the Offer Letter Agreement is not complete and is qualified in its entirety by reference to the full text of the Offer Letter Agreement, a copy of which is filed herewith as Exhibit 10.38 to this Annual Report on Form 10-K.

Dr. Castagna s biographical information is set forth under the heading Executive Officers of the Registrant under Part I, Item 1 of this Annual Report on Form 10-K.

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 ended December 31, 2015 pursuant to Regulations 14A for our 2016 Annual Meeting of Stockholders, and the information included in the Proxy Statement is incorporated herein by reference.

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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 of the Registrant in Part I, Item 1 of this Annual Report on Form 10-K.

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

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

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

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

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

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

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

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

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PART IV

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

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

(1)(2) Financial Statements and Financial Statement Schedules. The following Financial Statements of MannKind Corporation, Financial Statement Schedules and Report of Independent Registered Public Accounting Firm are included in a separate section of this report beginning on page 67:

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:

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to MannKind s Registration Statement on Form S-1 (File No. 333-115020), originally filed with the SEC on April 30, 2004, as amended).
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation (incorporated by reference to MannKind s Quarterly Report on Form 10-Q (File No. 000-50865), originally filed with the SEC on August 9, 2007).
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation (incorporated by reference to MannKind s Quarterly report on Form 10-Q (File No. 000-50865), originally filed with the SEC on August 2, 2010).
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to MannKind s Current Report on Form 8-K (File No. 000-50865), filed with the SEC on May 22, 2012).
3.5	Certificate of Amendment of Amended and Restated Certificate of Incorporation (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), originally filed with the SEC on July 1, 2013).
3.6	Amended and Restated Bylaws (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), originally filed with the SEC on November 19, 2007).
4.1	Form of common stock certificate (incorporated by reference to MannKind s Annual Report on Form 10-K (File No. 000-50865), originally filed with the SEC on March 18, 2013).

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Exhibit Number	Description of Document
4.2	Form of 9.75% Senior Secured Convertible Promissory Note due 2019 (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), originally filed with the SEC on July 1, 2013).
4.3	Form of Amended and Restated 9.75% Senior Secured Convertible Promissory Note due 2019 (incorporated by reference to Exhibit 4.7 to MannKind s Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 3, 2014).
4.4	Milestone Rights Purchase Agreement, dated as of July 1, 2013, by and among MannKind, Deerfield Private Design Fund II, L.P. and Horizon Santé FLML SÁRL (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), originally filed with the SEC on July 1, 2013).
4.5	Guaranty and Security Agreement, dated as of July 1, 2013, by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P. and Horizon Santé FLML SÁRL (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), originally filed with the SEC on July 1, 2013).
4.6	Registration Rights Agreement, dated as of July 1, 2013, by and among MannKind, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), originally filed with the SEC on July 1, 2013).
4.7	Facility Agreement, dated as of July 1, 2013, by and among MannKind, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), originally filed with the SEC on July 1, 2013).
4.8	First Amendment to Facility Agreement and Registration Rights Agreement, dated as of February 28, 2014, by and among MannKind, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (see Exhibit 10.27).
4.9	Form of Tranche B Senior Secured Note due 2019 (incorporated by reference to Exhibit 4.8 to MannKind s Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on May 12, 2014).
4.10	Second Amendment to Facility Agreement and Registration Rights Agreement, dated as of August 11, 2014, by and among MannKind, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 4.14 to MannKind s Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on November 10, 2014).
4.11	Senior Secured Revolving Promissory Note, dated as of September 23, 2014, by and between MannKind and Aventisub LLC (incorporated by reference to Exhibit 99.1 to MannKind s Current Report on Form 8-K (File No. 000-50865), filed with the SEC on September 29, 2014).
4.12	Guaranty and Security Agreement, dated as of September 23, 2014, by and among MannKind, MannKind LLC and Aventisub LLC (incorporated by reference to Exhibit 99.2 to MannKind s Current Report on Form 8-K (File No. 000-50865), filed with the SEC on September 29, 2014).
4.13	Indenture, by and between MannKind and Wells Fargo Bank, N.A., dated August 10, 2015 (incorporated by reference to Exhibit 4.18 to MannKind s Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on August 10, 2015).
4.14	Form of 5.75% Convertible Senior Subordinated Exchange Note due 2018 (included in Exhibit 4.18 as Exhibit A thereto) (incorporated by reference to Exhibit 4.19 to MannKind s Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on August 10, 2015).

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Exhibit Number	Description of Document
4.15	Indenture, by and between MannKind and Wells Fargo Bank, N.A., dated August 14, 2015 (incorporated by reference to Exhibit 4.1 to MannKind s Current Report on Form 8-K (File No. 000-50865), filed with the SEC on August 18, 2015).
4.16	Form of 5.75% Convertible Senior Subordinated Exchange Note due 2015 (incorporated by reference to Exhibit 4.2 to MannKind s Current Report on Form 8-K (File No. 000-50865), filed with the SEC on August 18, 2015).
4.17	Form of Warrant to Purchase Common Stock issued November 16, 2015.
10.1	Amended and Restated Promissory Note made by MannKind in favor of The Mann Group LLC, dated October 18, 2012 (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), filed with the SEC on October 19, 2012).
10.2	Agreement, dated September 13, 2006, between MannKind and Torcon, Inc. (incorporated by reference to MannKind s Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on August 9, 2007).
10.3	Securities Purchase Agreement, dated August 2, 2005 by and among MannKind and the purchasers listed on Exhibit A thereto (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), filed with the SEC on August 5, 2005).
10.4**	Supply Agreement, dated December 31, 2004, between MannKind and Vaupell, Inc. (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), filed with the SEC on February 23, 2005).
10.5*	Form of Indemnity Agreement entered into between MannKind and each of its directors and officers (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).
10.6*	Description of Officers Incentive Program (incorporated by reference to MannKind s Annual Report on Form 10-K (File No. 000-50865), originally filed with the SEC on March 16, 2006).
10.7*	Executive Severance Agreement, dated October 10, 2007, between MannKind and David Thomson (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).
10.8*	Separation Agreement, dated March 11, 2016, by and between MannKind and Juergen Martens.
10.9*	Executive Severance Agreement, dated April 21, 2008, between MannKind and Matthew J. Pfeffer (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).
10.10*	Change of Control Agreement, dated October 10, 2007, between MannKind and David Thomson (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).
10.11*	Change of Control Agreement, dated April 21, 2008, between MannKind and Matthew J. Pfeffer (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).
10.12*	2004 Equity Incentive Plan, as amended (incorporated by reference to MannKind s proxy statement on Schedule 14A (File No. 000-50865), originally filed with the SEC on April 6, 2012).
10.13*	Form of Stock Option Agreement under the 2004 Equity Incentive Plan (incorporated by reference to MannKind s Registration Statement on Form S-1 (File No. 333-115020), originally filed with the SEC on April 30, 2004, as amended).

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Exhibit Number	Description of Document
10.14*	Form of Phantom Stock Award Agreement under the 2004 Equity Incentive Plan (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), filed with the SEC on December 14, 2005).
10.15*	2004 Non-Employee Directors Stock Option Plan and form of stock option agreement there under (incorporated by reference to MannKind s Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 16, 2006).
10.16*	2004 Employee Stock Purchase Plan and form of offering document there under (incorporated by reference to MannKind s Registration Statement on Form S-1 (File No. 333-115020), originally filed with the SEC on April 30, 2004, as amended).
10.17**	Letter Agreement, dated June 4, 2011, between MannKind and N.V. Organon (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).
10.18**	Insulin Maintenance and Call-Option Agreement, dated June 19, 2009, by and among Pfizer Manufacturing Frankfurt GmbH, Pfizer Inc. and MannKind (incorporated by reference to MannKind s Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on May 4, 2009).
10.19	At-The-Market Issuance Sales Agreement, dated March 3, 2014, by and between MannKind and MLV & Co. LLC (incorporated by reference to Exhibit 10.31 to MannKind s Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 3, 2014).
10.20	At-The-Market Issuance Sales Agreement, dated March 3, 2014, by and between MannKind and Meyers Associates, L.P. (doing business as Brinson Patrick, a division of Meyers Associates, L.P.) (incorporated by reference to Exhibit 10.32 to MannKind s Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 3, 2014).
10.21*	Acknowledgment and Agreement, dated as of October 31, 2013, by and between MannKind and The Mann Group LLC (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), filed with the SEC on November 4, 2013).
10.22*	Non-Employee Director Compensation Program (incorporated by reference to MannKind s Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on August 9, 2013).
10.23*	MannKind Corporation 2013 Equity Incentive Plan (incorporated by reference to MannKind s registration statement on Form S-8 (File No. 000-188790), filed with the SEC on May 23, 2013).
10.24*	Form of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the MannKind 2013 Equity Incentive Plan (incorporated by reference to MannKind s registration statement on Form S-8 (File No. 000-188790), filed with the SEC on May 23, 2013).
10.25*	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the MannKind 2013 Equity Incentive Plan (incorporated by reference to MannKind s registration statement on Form S-8 (File No. 000-188790), filed with the SEC on May 23, 2013).
10.26	Facility Agreement, dated as of July 1, 2013, by and among MannKind, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).
10.27	First Amendment to Facility Agreement and Registration Rights Agreement, dated as of February 28, 2014, by and among MannKind, Deerfield Private Design Fund II, L.P., and Deerfield Private (incorporated by reference to Exhibit 10.39 to MannKind s Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 3, 2014).

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Exhibit Number	Description of Document
10.28**	License and Collaboration Agreement, dated as of August 11, 2014, by and among MannKind, Technosphere International C.V., MannKind Netherlands B.V. and Sanofi-Aventis Deutschland GmbH (incorporated by reference to Exhibit 10.1 to MannKind s Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on November 10, 2014).
10.29**	Supply Agreement, dated as of August 11, 2014, by and between MannKind and Sanofi-Aventis Deutschland GmbH (incorporated by reference to Exhibit 10.2 to MannKind s Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on November 10, 2014).
10.30**	Supply Agreement, dated as of July 31, 2014, by and between MannKind and Amphastar France Pharmaceuticals S.A.S. (incorporated by reference to Exhibit 10.3 to MannKind s Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on November 10, 2014).
10.31*	Transition and Separation Agreement, dated March 20, 2015, by and between MannKind and Diane Palumbo (incorporated by reference to Exhibit 10.1 to MannKind s Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on May 11, 2015).
10.32	Amendment No. 1 to At-The-Market Issuance Sales Agreement, by and between MannKind and Meyers Associates, L.P. (doing business as BP Capital, a division of Meyers Associates, L.P.), dated September 4, 2015 (incorporated by reference to Exhibit 99.1 to MannKind s Current Report on Form 8-K (File No. 000-50865), filed with the SEC on September 4, 2015).
10.33	Amendment No. 1 to At-The-Market Issuance Sales Agreement, by and between MannKind and MLV & Co. LLC, dated September 4, 2015 (incorporated by reference to Exhibit 99.2 to MannKind s Current Report on Form 8-K (File No. 000-50865), filed with the SEC on September 4, 2015).
10.34	Form of Stock Purchase Agreement (incorporated by reference to Exhibit 99.1 to MannKind s Current Report on Form 8-K (File No. 000-50865), filed with the SEC on November 9, 2015).
10.35	Form of Escrow Agreement (incorporated by reference to Exhibit 99.2 to MannKind s Current Report on Form 8-K (File No. 000-50865), filed with the SEC on November 9, 2015).
10.36*	Separation Agreement, dated December 1, 2015, by and between MannKind and Hakan S. Edstrom.
10.37	Sublease Agreement, dated May 1, 2015, by and between MannKind and the Alfred Mann Foundation for Scientific Research.
10.38*	Offer Letter, dated March 9, 2016, by and between MannKind and Michael Castagna.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (see signature page hereto).
31	Certification of the Chief Executive Officer and Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32	Certifications of the Chief Executive Officer and Chief Financial Officer pursuant to Rules 13a-14(b) and 15d-14(b) of the Securities Exchange Act of 1934, as amended and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).
101	Interactive Data Files pursuant to Rule 405 of Regulation S-T.

* Indicates management contract or compensatory plan.

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

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SIGNATURES

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

MANNKIND CORPORATION

By: /s/ Matthew J. Pfeffer
Matthew J. Pfeffer
Chief Executive Officer, Chief Financial Officer, and Director

Dated: March 15, 2016

POWER OF ATTORNEY

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Matthew J. Pfeffer	Chief Executive Officer, Chief Financial	March 15, 2016
Matthew J. Pfeffer	Officer and Director	
	(Principal Executive Officer and Principal Financial Officer)	
/s/ Rosabel R. Alinaya	Senior Vice President, Finance	March 15, 2016
Rosabel R. Alinaya	*(Principal Accounting Officer)*	
/s/ Kent Kresa	Chairman of the Board of Directors	March 15, 2016
Kent Kresa		
/s/ Ronald J. Consiglio	Director	March 15, 2016
Ronald J. Consiglio		
/s/ Michael Friedman	Director	March 15, 2016
Michael Friedman, M.D.		

/s/ David H. MacCallum	Director	March 15, 2016
David H. MacCallum		
/s/ Henry L. Nordhoff	Director	March 15, 2016
Henry L. Nordhoff		
/s/ James S. Shannon	Director	March 15, 2016
James S. Shannon		

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MANNKIND CORPORATION AND SUBSIDIARIES

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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 (the Company) as of December 31, 2015 and 2014 and the related consolidated statements of operations, comprehensive loss, stockholders deficit, and cash flows for each of the three years in the period ended December 31, 2015. 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, 2015 and 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated 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 consolidated financial statements. The consolidated 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, 2015, based on the criteria established in *Internal Control Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 15, 2016 expressed an adverse opinion on the Company s internal control over financial reporting because of a material weakness.

/s/ DELOITTE & TOUCHE LLP

Los Angeles, California

March 15, 2016

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MANNKIND CORPORATION AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

	December 31, 2015	2014
	(In thousands, except share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 59,074	$ 120,841
Receivables from collaboration	23	50,436
Inventory-current		9,670
Deferred product costs from collaboration	13,539	
Prepaid expenses and other current assets	4,018	20,206
Total current assets	76,654	201,153
Property and equipment net	48,749	192,127
State research and development credit exchange receivable net of current portion		311
Other assets	1,009	848
Total	$ 126,412	$ 394,439
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 15,599	$ 7,394
Accrued expenses and other current liabilities	7,929	26,206
Facility financing obligation	74,582	72,995
Senior convertible notes current		99,355
Deferred product sales from collaboration	17,503	436
Purchase commitment liabilities current	12,475	
Deferred payments from collaboration	140,231	196,967
Total current liabilities	268,319	403,353
Note payable to principal stockholder	49,521	49,521
Sanofi loan facility and loss share obligation	62,371	3,034
Senior convertible notes long term	27,613	
Purchase commitments long term	53,692	
Other liabilities	15,225	12,301
Total liabilities	476,741	468,209
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, 2015 and 2014		
Common stock, $0.01 par value 550,000,000 shares authorized at December 31, 2015 and 2014, respectively; 428,670,943 and 406,059,089 shares issued and outstanding at December 31, 2015 and 2014, respectively	4,287	4,061
Additional paid-in capital	2,508,633	2,416,967
Accumulated other comprehensive loss	(20)	(14)
Accumulated deficit	(2,863,229)	(2,494,784)
Total stockholders deficit	(350,329)	(73,770)

Total	$ 126,412	$ 394,439

See notes to consolidated financial statements.

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MANNKIND CORPORATION AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2015	2014	2013
	(In thousands, except per share data)		
Revenue	$	$	$
Operating expenses:			
Research and development	29,674	100,244	109,719
General and administrative	40,960	79,383	59,682
Product manufacturing	67,442		
Property and equipment impairment	140,412		
Loss on purchase commitments	66,167		
Total operating expenses	344,655	179,627	169,401
Loss from operations	(344,655)	(179,627)	(169,401)
Other income (expense)	1,366	1,679	(635)
Loss on extinguishment of debt	(1,049)		
Interest expense on note payable to principal stockholder	(2,894)	(2,894)	(6,309)
Interest expense on notes	(21,231)	(17,549)	(15,153)
Interest income	18	9	8
Loss before benefit for income taxes	(368,445)	(198,382)	(191,490)
Income tax benefit			
Net loss	$ (368,445)	$ (198,382)	(191,490)
Net loss per share basic and diluted	$ (0.91)	$ (0.51)	$ (0.64)
Shares used to compute basic and diluted net loss per share	406,165	385,229	299,591

See notes to consolidated financial statements.

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MANNKIND CORPORATION AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Year ended December 31,		
	2015	2014	2013
		(In thousands)	
Net Loss	$ (368,445)	$ (198,382)	$ (191,490)
Other comprehensive loss:			
Cumulative translation (loss) gain	(6)	(10)	2
Other comprehensive (loss) gain	(6)	(10)	2
Comprehensive loss	$ (368,451)	$ (198,392)	$ (191,488)

See notes to consolidated financial statements.

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MANNKIND CORPORATION AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS DEFICIT

(In thousands)	Common Stock		Additional Paid-In Capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total
	Shares	Amount				
BALANCE, JANUARY 1, 2013	286,035	2,860	1,991,379	(6)	(2,104,912)	(110,679)
Exercise of stock options	880	9	2,261			2,270
Issuance of common shares from the release of restricted stock units	1,870	20	(4,821)			(4,801)
Issuance of common shares pursuant to warrant exercises	66,353	664	171,485			172,149
Issuance of common shares pursuant to debt conversions by Deerfield	1,095	12	5,489			5,501
Issuance of common stock pursuant to at-the-market issuances	9,824	99	48,789			48,888
Issuance of common shares pursuant to litigation settlement	2,778	28	(28)			
Issuance of common shares under Employee Stock Purchase Plan	557	5	1,258			1,263
Stock-based compensation			45,186			45,186
Cumulative translation (loss) gain				2		2
Commitment to deliver common shares pursuant to Deerfield conversion to additional paid-in capital			998			998
Net loss					(191,490)	(191,490)
BALANCE, DECEMBER 31, 2013	369,392	3,697	2,261,996	(4)	(2,296,402)	(30,713)
Exercise of stock options	3,251	35	10,943			10,978
Issuance of common shares from the release of restricted stock units	3,996	38	(26,946)			(26,908)
Issuance of common shares pursuant to warrant exercises	11,575	115	27,664			27,779
Issuance of common shares pursuant to debt conversions by Deerfield	17,521	174	93,327			93,501
Issuance of common shares under Employee Stock Purchase Plan	324	2	1,361			1,363
Remeasurement of performance based grants pursuant to the modification of terms			22,962			22,962
Stock-based compensation			25,660			25,660
Cumulative translation (loss) gain				(10)		(10)
Net loss					(198,382)	(198,382)
BALANCE, DECEMBER 31, 2014	406,059	$ 4,061	$ 2,416,967	$ (14)	$ (2,494,784)	$ (73,770)
Exercise of stock options	1,701	17	3,241			3,258
Issuance of common shares from the release of restricted stock units	720	7	(7)			
Restricted stock units taxes paid in cash			(1,856)			(1,856)
Issuance of common shares pursuant to warrant exercises	4,216	42	10,081			10,123
Capital contribution			40			40
Issuance of common shares pursuant to conversions of certain 2015 notes	1,874	19	7,907			7,926
Issuance of common stock for lender financing fees	39		160			160
Discount on notes-for-stock exchange			169			169
Issuance of common stock pursuant to TASE stock sale	13,853	139	34,571			34,710
Return of loaned common stock	(9,000)	(90)	90			
Issuance of common stock pursuant to at-the-market issuances	8,940	89	27,754			27,844
Issuance of common shares under Employee Stock Purchase Plan	269	3	884			887
Issuance of warrant liability			(202)			(202)
Reclassification of warrant liability to equity			108			108
Stock-based compensation			8,725			8,725
Cumulative translation (loss) gain				(6)		(6)
Net loss					(368,445)	(368,445)
BALANCE, DECEMBER 31, 2015	428,671	$ 4,287	$ 2,508,633	$ (20)	$ (2,863,229)	$ (350,329)

See notes to consolidated financial statements.

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MANNKIND CORPORATION AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2015	2014	2013
		(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (368,445)	$ (198,382)	$ (191,490)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and accretion	13,276	18,575	14,057
Stock-based compensation expense	8,725	48,622	45,186
Loss on extinguishment of debt	1,049		
Loss on purchase commitments	66,167		
Write-off of Inventory	36,104		
Loss on sale, abandonment/disposal or impairment of property and equipment	140,582	97	817
Interest incurred through borrowings under Sanofi Loan Facility	1,652		
Write-off of derivative liability		(363)	
Write-off Tranche B Commitment Asset		1,753	
Foreign exchange loss	2,697	(10)	2
Changes in assets and liabilities:			
Inventory	(26,434)	(9,670)	
Receivables from collaboration	50,413	(50,436)	
Prepaid expenses and other current assets	13,485	(14,734)	(499)
Deferred product costs from collaboration	(13,539)		
Other assets	150	(615)	
Accounts payable	8,413	3,622	(1,071)
Accrued expenses and other current liabilities	(12,467)	2,276	3,675
Deferred product sales from collaboration	17,067		
Deferred payments from collaboration	950	200,436	
Other liabilities	2,927	2,915	591
Net cash (used in) provided by operating activities	(57,232)	4,086	(128,732)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(10,285)	(24,097)	(7,987)
Proceeds from sale of property and equipment	82		
Net cash used in investing activities	(10,203)	(24,097)	(7,987)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock	4,146	12,341	3,534
Proceeds from issuance of common stock under Tel Aviv Stock Exchange	36,142		
Issuance costs associated with the Tel Aviv Stock Exchange	(1,432)		
Exercise of warrants for common stock	10,123	27,779	94,147
Payment of 2015 notes	(64,287)		
Payment of debt issuance costs on 2018 notes	(831)		
Payment of 3.75% Senior Convertible Notes due 2013			(115,000)
Proceeds from issuance of facility financing obligation & milestone rights		40,000	119,500
Proceeds from issuance of Tranche B of the facility financing obligation		20,000	
Facility financing obligation & milestone rights issuance costs			(598)
Milestone payment	(4,219)	(3,150)	
Proceeds from issuance of common stock pursuant to at-the-market issuance	28,392		49,990
Issuance costs of at-the-market transactions	(548)		(1,103)
Other	40		
Payment of employment taxes related to vested restricted stock units	(1,858)	(26,908)	(4,801)
Net cash provided by financing activities	5,668	70,062	145,669

NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	$ (61,767)	$ 50,051	$ 8,950
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	120,841	70,790	61,840
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 59,074	$ 120,841	$ 70,790
SUPPLEMENTAL CASH FLOWS DISCLOSURES:			
Interest paid in cash, net of amounts capitalized to Construction in progress	$ 13,355	$ 11,218	$ 13,452
Payment of 2015 notes and interest through issuance of common stock	8,253		
Issuance of common stock pursuant to debt conversion by Deerfield		93,500	6,500
Non-cash construction in progress and property and equipment		1,768	856
Capitalization of interest on note payable to principal stockholder			7,886
Reduction of principal on note payable to principal stockholder upon issuance of common stock and exercise of warrants			78,000
Reclassification of deferred payments from collaboration to Sanofi loan facility and loss share obligation	59,337	3,034	

See notes to consolidated financial statements.

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MANNKIND CORPORATION AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Description of business and basis of presentation

Business MannKind Corporation and subsidiaries (the Company) is a biopharmaceutical company focused on the discovery and development of therapeutic products for diseases such as diabetes. The Company s only approved product, AFREZZA, (insulin human [rDNA origin]) inhalation powder, is a rapid-acting inhaled insulin that was approved by the U.S. Food and Drug Administration (the FDA) on June 27, 2014 to improve glycemic control in adult patients with diabetes.

Basis of Presentation The Company s primary activities since incorporation have been establishing its facilities, recruiting personnel, conducting research and development, business development, business and financial planning, raising capital, and commercial manufacturing. It is costly to develop therapeutic products and conduct clinical studies for these products. As of and for the year ended December 31, 2015, the Company has reported an accumulated deficit of $2.9 billion and has reported negative cash flow from operations for each year since inception, except for 2014, when the Company received the $150.0 million upfront payment from Sanofi.

At December 31, 2015, the Company s capital resources consisted of cash and cash equivalents of $59.1 million. The Company expects to continue to incur significant expenditures to support commercial manufacturing and sales and marketing of AFREZZA and the development of other product candidates. The facility agreement (the Facility Agreement) with Deerfield Private Design Fund II, L.P. (Deerfield Private Design Fund) and Deerfield Private Design International II, L.P. (collectively, Deerfield) and the First Amendment to Facility Agreement and Registration Rights Agreement (the First Amendment) that resulted in additional sales of an additional tranche of notes (the Tranche B notes) (see Note 17 Facility Agreement) requires the Company to maintain at least $25.0 million in cash and cash equivalents or available borrowings under the loan arrangement, dated as of October 2, 2007, between The Company and The Mann Group LLC (as amended, restated, or otherwise modified as of the date hereof, the Mann Group Loan Arrangement), as of the last day of each fiscal quarter. The Company will need to continue to incur expenses for the commercialization of AFREZZA and will need to raise additional capital to finance such activities. The Company cannot be certain that it will be able to raise additional capital on favorable terms, or at all, which raises substantial doubt about the Company s ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

On August 11, 2014, we executed a license and collaboration agreement (the Sanofi License Agreement) with Sanofi-Aventis Deutschland GmbH (which subsequently assigned its rights and obligations under the agreement to Sanofi-Aventis U.S. LLC (Sanofi)), pursuant to which Sanofi is responsible for global commercial, regulatory and development activities for AFREZZA. The Sanofi License Agreement became effective on September 23, 2014. The Company manufactured AFREZZA at its manufacturing facility in Danbury, Connecticut to supply Sanofi s demand for the product pursuant to a supply agreement dated August 11, 2014 (the Sanofi Supply Agreement).

On January 4, 2016 the Company received notification from Sanofi of its election to terminate in its entirety the Sanofi License Agreement. Sanofi s notice indicated that the termination was pursuant to Sanofi s right to terminate the Sanofi License Agreement upon Sanofi s good faith determination that the commercialization of AFREZZA is no longer economically viable in the United States, in which case the effective date of termination (the Termination Date) will be April 4, 2016. In the alternative, Sanofi indicated that the termination was also pursuant to its right to terminate the Sanofi License Agreement for any reason, in which case the Termination Date will be July 4, 2016. In the interest of an expedient transition, the Company is working with Sanofi to transfer and wind down the agreement activities by April 4, 2016, or as soon as practicable thereafter.

Under the Sanofi License Agreement, worldwide profits and losses, which are determined based on the difference between the net sales of AFREZZA and the costs and expenses incurred by the Company and Sanofi that are specifically attributable or related to the development, regulatory filings, manufacturing, or

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MANNKIND CORPORATION AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

commercialization of AFREZZA, are shared 65% by Sanofi and 35% by the us. As a result of the loss share provision, and because the Company does not have the ability to estimate the amount of costs that would potentially be incurred related to the Sanofi License Agreement, the amount of up-front cash payment or milestone payments that could be recognized as revenue is not fixed or determinable. In connection with the Sanofi License Agreement, an affiliate of Sanofi provided the Company with a secured loan facility (the Sanofi Loan Facility) of up to $175.0 million to fund the Company s share of net losses under the Sanofi License Agreement.

Additional funding sources that are, or in certain circumstances may be available to the Company, include approximately $30.1 million principal amount of available borrowings under The Mann Group Loan Arrangement. A portion of these available borrowings may be used to capitalize accrued interest into principal, upon mutual agreement of the parties, as it becomes due and payable under The Mann Group Loan Arrangement. (see note 7 Related-party arrangements). 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 a 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 on acceptable terms or at all.

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 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. Management considers many factors in selecting appropriate financial accounting policies, and in developing the estimates and assumptions that are used in the preparation of the financial statements. Management must apply significant judgment in this process. The more significant estimates reflected in these accompanying financial statements involve assessing long-lived assets for impairment, accrued expenses, including clinical study expenses, inventory recoverability, valuation of the facility financing obligation, commitment asset, milestone rights, 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.

License and Collaboration and Supply Agreements Pursuant to the Sanofi License Agreement and the Sanofi Supply Agreement, the Company granted to Sanofi exclusive, worldwide licenses to certain of the Company s patents, trademarks and know-how for the development and commercialization of AFREZZA and retained the right to be the exclusive manufacturer and supplier of AFREZZA until specified conditions are met upon which a portion of the manufacturing activities may be assumed by Sanofi. The terms of the Sanofi License Agreement provide for consideration to the Company in the form of a non-refundable up-front payment, product sales, manufacturing, regulatory and sales milestone payments and profit and loss sharing.

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MANNKIND CORPORATION AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company analyzes consideration received under the provisions of ASC 605, Revenue Recognition, to determine whether the consideration, or a portion thereof, could be recognized as revenue. ASC 605 provides that revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collection is reasonably assured.

In arrangements involving the delivery of more than one element, each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting. This determination is generally based on whether the deliverable has stand-alone value to the customer. The arrangement s consideration that is fixed and determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The estimated selling price of each deliverable is determined using the following hierarchy of values: (i) vendor-specific objective evidence of fair value, (ii) third-party evidence of selling price and (iii) best estimate of selling price (BESP). The BESP reflects the Company s best estimate of what the selling price would be if the deliverable was regularly sold by the Company on a stand-alone basis. In general, the consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables.

The assessment of multiple element arrangements requires judgment in order to determine the appropriate units of accounting and the points in time that, or periods over which, revenue should be recognized. Given that, as of December 31, 2015, the Company did not have the ability to estimate the amount of costs that would potentially be incurred under the loss share provision related to the Sanofi License Agreement and the Sanofi Supply Agreement, the Company believe the fixed and determinable fee requirement for revenue recognition was not met.

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. As of December 31, 2015 and 2014, cash equivalents were comprised of cash and money market accounts with maturities less than 90 days from the date of purchase.

Concentration of Credit Risk Financial instruments which potentially subject the Company to concentration of credit risk consist of cash and cash equivalents. Cash and cash equivalents consist of interest-bearing accounts, which 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 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.

Prepaid expenses and other current assets Prepaid expenses and other current assets primarily consist of prepaid expenses for goods and services to be received. As of December 31, 2015, prepaid and other current assets had a balance of $4.0 million, mainly comprised of prepaid insurance. As of December 31, 2014 prepaid and other current assets had a balance of $20.2 million, mainly comprised of a $15.0 million prepayment for 2015 quantities of insulin, and prepaid insurance.

Sale of intellectual property On July 18, 2014, the Company entered into an assignment agreement with a third party whereby the third party acquired all proprietary rights, technology and know-how that related to a small molecule inhibitor compound and all pre-clinical data and results related thereto. Under the terms of the assignment agreement, the Company received total consideration of $9.3 million and accrued $1.4 million in expense for a net amount of $7.9 million recorded as other income. In 2015, the Company recorded other income of $1.4 million related to the relief of the $1.4 million accrual for expenses associated with the sale of intellectual property related to oncology in 2014, which was subsequently resolved without payment.

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MANNKIND CORPORATION AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Milestone Rights On July 1, 2013, in conjunction with the execution of the Facility Agreement, the Company issued Milestone Rights to Deerfield whereby the Company agreed to provide Deerfield with pre-specified Milestone Payments upon the achievement of 13 specific Milestone Events related to the commercial release and future cumulative net sales of AFREZZA. The Company analyzed the Milestone Rights under the provisions of ASC 815 and determined that the agreement does not meet the definition of a freestanding derivative. Since the Company has not elected to apply the fair value option to the Milestone Rights Purchase Agreement, the Company recorded the Milestone Rights at their estimated fair value and accounted for the Milestone Rights as a liability by applying the indexed debt guidance contained in paragraphs ASC 470-10-25-3 and 35-4.

The initial fair value estimate of the Milestone Rights was calculated using the income approach in which the cash flows associated with the specified contractual payments were adjusted for both the expected timing and the probability of achieving the milestones and discounted to present value using a selected market discount rate. The expected timing and probability of achieving the milestones was developed with consideration given to both internal data, such as progress made to date and assessment of criteria required for achievement, and external data, such as market research studies. The discount rate was selected based on an estimation of required rate of returns for similar investment opportunities using available market data. The Milestone Rights liability will be remeasured as the specified milestone events are achieved. Specifically, as each milestone event is achieved, the portion of the initially recorded Milestone Rights liability that pertains to the milestone event being achieved, will be remeasured to the amount of the specified related milestone payment. The resulting change in the balance of the Milestone Rights liability due to remeasurement will be recorded in the Company s Statement of Operations as interest expense. Furthermore, the Milestone Rights liability will be reduced upon the settlement of each milestone payment. As a result, each milestone payment would be effectively allocated between a reduction of the recorded Milestone Rights liability and an expense representing a return on a portion of the Milestone Rights liability paid to the investor for the achievement of the related milestone event (see Note 17 Facility Agreement). As of December 31, 2015, the remaining liability balance of $8.9 million was classified as long-term liability in other liabilities.

Deferred product costs from collaboration Deferred product costs represent the costs of product manufactured and sold to Sanofi, as long as they are not greater than the amount of deferred product sales related to the collaboration, for which recognition of revenue has been deferred. Given that the costs of inventory delivered to a customer, but for which revenue may not yet be recognized, meet both the definition and characteristics of an asset and the Company believes that it is probable that the amount of future revenue will exceed the amount of deferred costs (i.e., the asset would be realizable through the recognition of probable future income), the Company has elected to account for the deferred costs related to the product sold to Sanofi as an asset and carry forward to future periods until the related revenue is recognized.

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.

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MANNKIND CORPORATION AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The carrying amounts reflected in the consolidated balance sheets for cash equivalents, other current assets, accounts payable, and accrued expenses and other current liabilities, approximate fair value due to their relatively short maturities.

Inventories Inventories are stated at the lower of cost or market. The Company determines the cost of inventory using the first-in, first-out, or FIFO, method. The Company capitalizes inventory costs associated with the Company s products based on management s judgment that future economic benefit is expected to be realized; otherwise, such costs are expensed as product manufacturing. The Company periodically analyzes its inventory levels to identify inventory that may expire or has a cost basis in excess of its estimated realizable value, and writes-down such inventories as appropriate. In addition, the Company s products are subject to strict quality control and monitoring which the Company performs throughout the manufacturing process. If certain batches or units of product no longer meet quality specifications or become obsolete due to expiration, the Company will record a charge to write down such unmarketable inventory to its estimated realizable value. Inventory that is not expected to be used within one year is classified as a long term asset on the accompanying condensed consolidated balance sheet.

We analyzed our inventory levels to identify inventory that may expire or has a cost basis in excess of its estimated realizable value. We performed an assessment of projected sales and to evaluate the lower of cost or market and the potential excess inventory on hand at December 31, 2015. As a result of this assessment, we recorded a charge of $39.3 million to record the inventory raw materials on hand at the lower of cost or market, inventory expiry, and write-off other inventory related assets.

In connection with the projected sales assessment, we also evaluated our inventory purchase commitments totalling $116.2 million for potential impairment. As a result of this assessment, we recorded a $66.2 million charge related to a loss on future purchase commitments both from a lower of cost or market excess inventory perspective. The purchase commitment obligation has been reduced to reflect our expectation that a portion will be recoverable from a third party.

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. Maintenance and repairs are expensed as incurred. 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 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 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.

The Company recorded an asset impairment of $140.4 million for the year ended December 31, 2015 (see Note 5 Property and Equipment). No asset impairment was recognized during the years ended December 31, 2014, and 2013, respectively.

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MANNKIND CORPORATION AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Income Taxes The 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 measured using enacted tax rates expected to apply to taxable income in the year in which the temporary differences are expected to be recovered or settled. A valuation allowance is recorded to reduce net deferred income tax assets to amounts that are more likely than not to be realized.

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, deferred tax liabilities, and any valuation allowance recorded against 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 total 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. These accruals represent management s best estimate of probable loss. Disclosure also is provided when it is reasonably possible that a loss will be incurred or when it is reasonably possible that the amount of a loss will exceed the recorded provision. On a quarterly basis, the Company reviews the status of each significant matter and assesses its potential financial exposure. Significant judgment is required in both the determination of probability and the determination as to whether an exposure is reasonably estimable. Because of uncertainties related to these matters, accruals are based only on the best information available at the time. As additional information becomes available, the Company reassesses the potential liability related to pending claims and litigation and may revise its estimates. These revisions in the estimates of the potential liabilities could have a material impact on the Company s consolidated results of operations and financial position.

Stock-Based Compensation As of December 31, 2015, the Company had three active stock-based compensation plans, which are described more fully in Note 13. 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. 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 statement of operations based upon the fair value of the awards at the grant date. The Company uses the Black-Scholes option valuation model to estimate the grant date fair value of employee stock options and the compensatory elements of employee stock purchase plans. Option valuation models require the input of assumptions, including the expected life of the stock-based awards, the estimated stock price volatility, the risk-free interest rate, and the expected dividend yield. Beginning in the third quarter of 2014, the Company began to assess both historical and implied volatility in order to determine its estimated volatility rate. Implied volatility

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MANNKIND CORPORATION AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

was considered due to the change in the Company s business, which occurred with the approval for the sale of AFREZZA. The expected volatility assumption is based on an assessment of the historical volatility and the implied volatility of the Company s common stock, derived from an analysis of historical traded and quoted options on the Company s common stock. 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, Contracts in an Entity s Own Stock, previously EITF Issue No. 00-19: *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock.*

Comprehensive Loss Other comprehensive loss is recorded in accordance with ASC 220-10-45 *Comprehensive Income,* which requires that all components of comprehensive loss be reported in the financial statements in the period in which they are recognized. Other comprehensive loss includes certain changes in stockholders equity that are excluded from net income. Specifically, the Company includes unrealized gains and foreign exchange translation losses, if any, and cumulative translation gains and losses in other comprehensive loss.

Research and Development Expenses Research and development expenses consist of costs associated with the clinical trials of the Company s product candidates, manufacturing supplies and other development materials, 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.* The Company began commercial manufacturing in the latter part of the fourth quarter of 2014. As such, commercial manufacturing costs incurred in the fourth quarter of 2014 and included in research and development as expenses were immaterial for the year ended December 31, 2014.

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.

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, 2015, 2014 and 2013 was $24.1 million, $20.4 million, and $21.5 million, respectively. Interest costs capitalized for the years ended December 31, 2015, 2014, and 2013 were $0.1 million, $0.8 million, and $0.4 million, respectively.

Net Loss Per Share of Common Stock Basic net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is computed by dividing the net loss by the sum of the weighted-average number of common shares outstanding during the period plus the potential dilutive effect of stock options, restricted stock units, warrants,

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

and shares that could be issued upon conversion of the senior convertible notes outstanding during the period calculated in accordance with the treasury stock method, but are excluded if their effect is anti-dilutive. Because the impact of these items is anti-dilutive during periods of net loss, there was no difference between basic and diluted loss per common share for the years ended December 31, 2015, 2014, and 2013.

Recently Issued Accounting Standards From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB) or other standard setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on the Company s financial position or results of operations upon adoption.

In May 2014, the FASB issued ASU 2014-09 related to revenue recognition, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The guidance requires a company to recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration it expects to be entitled to receive in exchange for those goods or services. In July 2015, the FASB issued ASU 2015-14, which delayed the effective date of the new revenue standard by one year. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. The standard is effective beginning the first quarter of the Company s 2018 fiscal year and is required to be adopted using either a full retrospective or a modified retrospective approach. The Company is assessing the potential impact of the new standard on its consolidated financial statements and has not yet selected a transition method.

In August 2014, the FASB issued ASU 2014-15, which provides guidance on determining when and how reporting entities must disclose going-concern uncertainties in their financial statements. The new standard requires management to perform interim and annual assessments of an entity s ability to continue as a going concern within one year of the date of issuance of the entity s financial statements (or within one year after the date on which the financial statements are available to be issued, when applicable). Further, an entity must provide certain disclosures if there is substantial doubt about the entity s ability to continue as a going concern . The ASU is effective for annual periods ending after December 15, 2016, and interim periods thereafter; early adoption is permitted. The Company is evaluating the impact the adoption of ASU 2014-15 will have on its consolidated financial statements.

In April 2015, the FASB issued ASU 2015-03, Simplifying the Presentation of Debt Issuance Costs. The guidance requires debt issuance costs to be presented in the balance sheet as a direct deduction from the carrying value of the associated debt, consistent with the presentation of a debt discount. The guidance is effective for annual reporting periods beginning after December 15, 2015 and interim periods thereafter. As permitted by the standard, the Company adopted the new presentation prospectively and the adoption did not have an impact on its consolidated financial statements and disclosures.

In July 2015, the FASB issued ASU 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory. Topic 330, Inventory, currently requires an entity to measure inventory at the lower of cost or market. Market could be replacement cost, net realizable value, or net realizable value less an approximately normal profit margin. The amendments do not apply to inventory that is measured using last-in, first-out (LIFO) or the retail inventory method. The amendments apply to all other inventory, which includes inventory that is measured using first-in, first-out (FIFO) or average cost. The amendments are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. The amendments should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The Company is evaluating the impact the adoption of ASU 2015-11 will have on its consolidated financial statements.

In November 2015, the FASB issued ASU No. 2015-17, Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes. The new standard requires that deferred tax assets and liabilities be classified as noncurrent in a classified statement of financial position. For public business entities, the amendments in this

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Update are effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. As permitted by the standard, the Company adopted the new presentation and the adoption did not have an impact on its consolidated financial statements and disclosures.

In January 2016, the FASB issued ASU 2016-01, Financial Instruments Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities. The update is intended to improve the recognition and measurement of financial instruments. The update are effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The Company is evaluating the impact the adoption of ASU 2016-01 will have on its consolidated financial statements.

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, 2015, 2014 and 2013, research and development expenses were offset by $743,000, $816,000, and $282,000, respectively.

4. Inventories

Inventories consist of the following (in thousands):

	December 31,	
	2015	2014
Raw materials	$	$ 4,856
Work-in-process		4,719
Finished goods		95
Inventory current		9,670
Total Inventory	$	$ 9,670

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5. Property and equipment

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

	Estimated Useful Life (Years)	December 31, 2015	2014
Land		$ 5,273	$ 5,273
Buildings	39-40	54,948	54,948
Building improvements	5-40	131,383	114,131
Machinery and equipment	3-15	95,182	80,919
Furniture, fixtures and office equipment	5-10	4,137	5,015
Computer equipment and software	3	9,707	10,465
Leasehold improvements	4		17
Construction in progress		8,044	39,580
		308,674	310,348
Less impairment		(140,412)	
Less accumulated depreciation and amortization		(119,513)	(118,221)
Total property and equipment, net		$ 48,749	$ 192,127

Leasehold improvements are amortized over four years which is the shorter of the term or the service lives of the improvements. Depreciation and amortization expense related to property and equipment for the years ended December 31, 2015, 2014, and 2013, was $11.0 million, $9.8 million, and $11.5 million, respectively.

In connection with the Company s quarterly assessment of impairment indicators, the Company evaluated the continued lower than expected sales of AFREZZA as reported by Sanofi throughout the fourth quarter of 2015, revised forecasts for sales of AFREZZA provided by Sanofi in the fourth quarter of 2015 and level of commercial production in the fourth quarter of 2015, as well as the uncertainty associated with Sanofi s announcement during the fourth quarter of their intent to reorganize their diabetes business. These factors indicated potentially significant changes in the timing and extent of cash flows, and the Company therefore determined that an impairment indicator existed in the fourth quarter of 2015.

On January 4, 2016, the Company received written notice from Sanofi of its election to terminate in its entirety the Sanofi License Agreement. Sanofi s notice indicated that the termination was pursuant to Sanofi s right to terminate the agreement upon Sanofi s good faith determination that the commercialization of AFREZZA is no longer economically viable in the United States, in which case the effective date of termination would be April 4, 2016. In the alternative, Sanofi indicated that the termination was also pursuant to its right to terminate the License Agreement for any reason, in which case the Termination Date would be July 4, 2016. In the interest of an expedient transition, the Company is currently working with Sanofi to transfer and wind down the agreement activities by April 4, 2016, or as soon as practicable thereafter.

The Company identified two primary asset groups to be evaluated for impairment: the Danbury manufacturing facility, which currently performs all the manufacturing of AFREZZA, and the Valencia facility, which was previously the Company s corporate headquarters. The Danbury manufacturing facility is the primary asset group that has been impacted by the impairment indicators noted above but the Company also evaluated the Valencia facility for potential impairment given the circumstances and identified an impairment charge of $1.8 million

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based on a valuation utilizing a combination of market, income and cost approaches. Within the Danbury manufacturing facility, the Company identified the machinery and equipment as the primary assets within the asset group as they are associated with the production of AFREZZA. As such, the Company performed the fixed asset impairment test and performed the first step to test for recoverability of the Danbury manufacturing facility by utilizing two undiscounted cash flow projections and applying a probability weighted average to those cash flow projections. The first undiscounted cash flow projection was developed under a scenario assuming Sanofi would continue to sell and market AFREZZA as the termination of the arrangement by Sanofi was not known as of the balance sheet date. The second undiscounted cash flow projection assumed Sanofi would terminate the Sanofi License Agreement and that the Company would manufacture, sell and market AFREZZA independently.

Based on the evaluation performed, the probabilities assigned to the two undiscounted cash flows were not significant to the evaluation due to the projected negative cash flows over the estimation period, and it was determined that the probability weighted undiscounted cash flows were not sufficient to recover the carrying value of the Danbury manufacturing facility. As such, the Company was required to determine the fair value of the Danbury manufacturing facility to recognize an impairment loss if the carrying amount exceeds its fair value. The Company determined the fair value of the Danbury manufacturing facility by applying the highest and best use valuation concept and utilizing the market approach valuation technique to value the machinery and equipment and a combination of the market approach and cost approach in valuing the land, buildings, and building improvements. As a result of this assessment, the Company recorded an impairment charge of $138.6 million for the Danbury manufacturing facility.

6. Accrued expenses and other current liabilities

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

	December 31,	
	2015	2014
Salary and related expenses	$ 5,662	$ 14,928
Accrued interest	615	2,396
Construction in progress	238	1,343
Other	1,414	7,539
Accrued expenses and other current liabilities	$ 7,929	$ 26,206

7. Related-party arrangements

In October 2007, the Company entered into a $350.0 million loan arrangement with its principal stockholder. The Loan Arrangement has been amended from time to time. On October 31, 2013, the promissory note underlying The Mann Group Loan Arrangement was amended to, among other things, extend the maturity date of the loan to January 5, 2020, extend the date through which the Company can borrow under The Mann Group Loan Arrangement to December 31, 2019, increase the aggregate borrowing amount under The Mann Group Loan Arrangement from $350.0 million to $370.0 million and provide that repayments or cancellations of principal under The Mann Group Loan Arrangement will not be available for reborrowing.

As of December 31, 2015, the total principal amount outstanding under The Mann Group Loan Arrangement was $49.5 million, and the amount available for future borrowings was $30.1 million. Interest, at a fixed rate of 5.84%, is due and payable quarterly in arrears on the first day of each calendar quarter for the preceding quarter,

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 as additional borrowings at any time upon mutual agreement of the parties, and has been classified as non-current. 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 (less approximately $105.0 million aggregate principal amount that has been cancelled in connection with two common stock purchase agreements). 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. However, pursuant to a letter agreement entered into in August 2010, The Mann Group has agreed 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 addition, The Mann Group entered into a subordination agreement with Deerfield pursuant to which The Mann Group agreed with Deerfield not to demand or accept any payment under The Mann Group Loan Arrangement until the Company s payment obligations to Deerfield under the Facility Agreement have been satisfied in full. Subject to the foregoing, in the event of a default under The Mann Group Loan Arrangement, 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 Mann Group Loan Arrangement are unsecured. The Mann Group Loan Arrangement contains no financial covenants.

As of December 31, 2015 and 2014, the Company had accrued and unpaid interest of $6.4 million and $3.5 million, in long term other liabilities respectively, which related to the amount outstanding and had $30.1 million of available borrowings. Interest expense on the Company s note payable to the Company s principal stockholder for the years ended December 31, 2015, 2014, and 2013 was $2.9 million, $2.9 million, and $6.3 million, respectively.

In May 2015, the Company entered into sublease agreement with the Alfred Mann Foundation for Scientific Research (the Mann Foundation), a California Not-For-Profit Corporation. The lease is for approximately 12,500 square feet of office space in Valencia, California and expires in April 2017. The office space contains the Company s principal executive offices. Lease payments to the Mann Foundation for the year ended December 31, 2015 were $175,000. There were no lease payments to the Mann Foundation for the years ended December 31, 2014 and 2013.

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 principal stockholder approximately $18,000, $79,000, and $82,000, respectively, for the years ended December 31, 2015, 2014, and 2013 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 14 Commitments and contingencies).

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8. Senior convertible notes

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

	December 31, 2015	2014
2015 notes		
Principal amount	$	$ 100,000
Unaccreted debt issuance cost		(645)
Net carrying amount	$	$ 99,355
2018 notes		
Principal amount	$ 27,690	$
Unamortized premium	660	
Unaccreted debt issuance costs	(737)	
Net carrying amount	$ 27,613	$

Issuance of new 5.75% Convertible Senior Subordinated Exchange Notes due 2018 in exchange for 2015 notes

On July 28, 2015, the Company entered into privately-negotiated exchange agreements (the Note Exchange Agreements) with a select holder of the Company s 5.75% Senior Convertible Notes due 2015 (the 2015 notes), pursuant to which the Company agreed to issue $27.7 million aggregate principal amount of new 5.75% Convertible Senior Subordinated Exchange Notes due 2018 (the 2018 notes) to such holders in exchange for the delivery to the Company of the same principal amount of 2015 notes. The 2018 notes were issued at the closing of the exchange on August 10, 2015. The Company analyzed this exchange under the provisions of ASC 470-50 and concluded that the exchange represents an extinguishment of the 2015 notes and a new issuance of 2018 notes and recorded such notes at fair value which resulted in a premium of $0.7 million.

The 2018 notes are the Company s general, unsecured, senior obligations, except that the 2018 notes are subordinated in right of payment to the outstanding notes issued pursuant to the Facility Agreement and the Company s borrowings under the Sanofi Loan Facility with an affiliate of Sanofi-Aventis U.S. LLC. The 2018 notes rank equally in right of payment with the Company s other unsecured senior debt. The 2018 notes bear interest at the rate of 5.75% per year on the principal amount, payable semiannually in arrears in cash on February 15 and August 15 of each year, beginning February 15, 2016, with interest accruing from August 15, 2015. The 2018 notes mature on August 15, 2018.

The 2018 notes are convertible, at the option of the holder, at any time on or prior to the close of business on the business day immediately preceding the stated maturity date, into shares of the Company s common stock at an initial conversion rate of 147.0859 shares per $1,000 principal amount of 2018 notes, which is equal to a conversion price of approximately $6.80 per share, the same conversion price as that of the 2015 notes on the date of exchange. The conversion rate is subject to adjustment under certain circumstances described in an indenture governing the 2018 notes dated August 10, 2015 with Wells Fargo, National Association, including in connection with a make-whole fundamental change.

If certain fundamental changes occur, the Company will be obligated to pay a fundamental change make-whole premium on any 2018 notes converted in connection with such fundamental change by increasing the conversion rate on such 2018 notes. In such instances, the amount of the fundamental change make-whole premium will be based on the Company s common stock price and the effective date of the applicable fundamental change.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

If the Company undergoes certain fundamental changes, except in certain circumstances, each holder of 2018 notes will have the option to require the Company to repurchase all or any portion of that holder s 2018 notes. The fundamental change repurchase price will be 100% of the principal amount of the 2018 notes to be repurchased plus accrued and unpaid interest, if any.

On or after the date that is one year following the original issue date of the 2018 notes, the Company will have the right to redeem for cash all or part of the 2018 notes if the last reported sale price of its common stock exceeds 130% of the conversion price then in effect for 20 or more trading days during the 30 consecutive trading day period ending on the trading day immediately prior to the date of the redemption notice. The redemption price will equal the sum of 100% of the principal amount of the 2018 notes to be redeemed, plus accrued and unpaid interest. Under the terms of the 2018 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 indenture, 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 term of the 2018 notes under existing commitments. Applying the Company s sequencing policy, the Company performed an analysis at the time of the offering of the 2018 notes and each reporting date since and has 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 term of the 2018 notes under existing commitments.

The 2018 notes provide that upon an acceleration of certain indebtedness, including the 9.75% Senior Convertible Notes due 2019 (the 2019 notes) and the 8.75% Senior Convertible Notes due 2019 (the Tranche B notes) issued to Deerfield pursuant to the Facility Agreement (see Note 17 Facility Agreement), the holders may elect to accelerate the Company s repayment obligations under the notes if such acceleration is not cured, waived, rescinded or annulled. There can be no assurance that the holders would not choose to exercise these rights in the event such events were to occur.

The Company incurred approximately $0.8 million in issuance costs which are recorded as an offset to the 2018 notes in the accompanying condensed consolidated balance sheet. These costs are being accreted to interest expense using the effective interest method over the term of the 2018 notes.

Accretion of debt issuance expense in connection with the 2018 notes during the year ended December 31, 2015 was $93,000. Amortization of 2018 notes premium during the year ended December 31, 2015 was $86,000.

Issuance of common stock in exchange for 2015 notes

On July 28, 2015, the Company entered into separate, privately-negotiated exchange agreements (the Stock-for-Note Exchange Agreements) with certain holders of the 2015 notes pursuant to which the Company agreed to issue shares of its common stock to such holders in exchange for the delivery to the Company of up to $56.9 million aggregate principal amount of 2015 notes.

Pursuant to the Stock-for-Note Exchange Agreements, the parties agreed to price the exchange transactions over a 10 trading day period spanning from July 29, 2015 to and including August 11, 2015. Between July 28, 2015 and August 10, 2015, the Company issued an aggregate of 1.9 million shares of common stock to such holders in exchange for such holders delivery to the Company of $8.0 million aggregate principal amount of 2015 notes, resulting in a weighted-average exchange price of $4.40 per share.

Issuance of new 5.75% Convertible Senior Subordinated Exchange Notes due 2015 in exchange for 2015 notes

On August 14, 2015, the Company exchanged $32.1 million aggregate principal amount of newly issued, 5.75% Convertible Senior Subordinated Exchange Notes due 2015 (the Exchange Notes) for the same principal amount of the Company s previously outstanding 2015 notes. The Exchange Notes, payable at maturity on

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September 30, 2015, were convertible, at the option of each holder thereof, at any time on or prior to the close of business on the business day immediately preceding the stated maturity date. The holders of the Exchange Notes did not elect to convert any of the outstanding principal amount of the Exchange Notes into shares of the Company s common stock. As a result, on September 30, 2015, the Company paid $32.1 million to settle the Exchange Notes.

Settlement of 2015 notes and Exchange Notes

On August 17, 2015, the Company paid $32.2 million to settle the remaining 2015 notes. As of September 30, 2015, all 2015 notes, including the Exchange Notes, have been settled resulting in a total loss on extinguishment equal to $1.0 million. The loss on extinguishment resulted from write-off of debt discount and debt issuance costs associated with the 2015 notes and Exchange Notes and the difference between the principal amounts being exchanged for shares of the Company s common stock, pursuant to the various Stock-for-Note Exchange Agreements, and the fair market value of the Company s common stock issued in exchange for such reduction in principal.

Accretion of debt issuance expense in connection with the 2015 notes during the years ended December 31, 2015, 2014, and 2013 was $0.6 million, $0.9 million, and $0.9 million, respectively.

9. Collaboration arrangement

Sanofi License Agreement and Sanofi Supply Agreement

On August 11, 2014, the Company and Sanofi entered into the Sanofi License Agreement, which became effective on September 23, 2014. Under the terms of the Sanofi License Agreement, the Company granted to Sanofi exclusive, worldwide licenses to certain of the Company s patents, trademarks and know-how for the development and commercialization of AFREZZA. Under the terms of the Sanofi License Agreement, Sanofi has the exclusive right and responsibility to develop AFREZZA worldwide, subject to certain development activities that will be performed by the Company. Sanofi will also be obligated to use commercially reasonable efforts to file for, obtain and maintain marketing approvals for AFREZZA in certain major markets and countries. In addition, Sanofi will have exclusive, worldwide rights to commercialize AFREZZA and will be obligated to use commercially reasonable efforts to market, promote and commercialize AFREZZA in all countries in the world where regulatory approval for AFREZZA has been received. Pursuant to the terms of the Sanofi Supply Agreement, the Company is responsible for the manufacture and supply to Sanofi of its requirements of AFREZZA.

Under the Sanofi License Agreement, Sanofi paid the Company an up-front cash payment of $150.0 million in the third quarter of 2014. If certain manufacturing, regulatory and sales milestones are achieved, the Company will also be eligible to receive up to $775.0 million in milestone payments, of which $75.0 million relates to certain development and manufacturing milestone events, $50.0 million relates to the filing and completion of regulatory approvals and $650.0 million relates to the achievement of certain product sales milestones. As of December 31, 2014, the Company earned and recorded a total of $50.0 million in milestone payments in connection with the satisfaction of manufacturing milestones specified in the Sanofi agreement, which were received subsequent to December 31, 2014. In addition, worldwide profits and losses, which are determined based on the difference between the net sales of AFREZZA and the costs and expenses incurred by the Company and Sanofi that are specifically attributable or related to the development, improvement, regulatory filings, manufacturing, and commercialization of AFREZZA will be shared 65% by Sanofi and 35% by the Company. In accordance with the terms of the Sanofi License Agreement, profit and loss sharing commenced in the fourth quarter of 2014.

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Pursuant to the terms of the Sanofi Supply Agreement, the Company will be the exclusive manufacturer and supplier of AFREZZA until the specified conditions are met, upon which a portion of the manufacturing activities may be assumed by Sanofi.

The Company analyzed the agreements entered into with Sanofi under the provisions of ASC 605, Revenue Recognition, to determine whether the consideration, or a portion thereof, could be recognized as revenue. ASC 605 provides that revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collection is reasonably assured. In addition, revenue arrangements with multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the customer. When deliverables are separable, consideration received is allocated to the separate units of accounting based on the relative selling price of each deliverable and the appropriate revenue recognition principles are applied to each unit.

The assessment of multiple element arrangements requires judgment in order to determine the appropriate units of accounting and the points in time that, or periods over which, revenue should be recognized. Under the terms of the Sanofi License Agreement, Sanofi Supply Agreement and the Sanofi Loan Facility the Company determined that the arrangement contained significant deliverables including (i) licenses to develop and commercialize AFREZZA and to use the Company s trademarks, (ii) development activities, and (iii) manufacture and supply services for AFREZZA. Due to the proprietary nature of the manufacturing services being provided by the Company, the Company determined that all of the significant deliverables should be combined into a single unit of accounting. The Company believes that the manufacturing services are proprietary due to the fact that since the late 1990 s, the Company has developed proprietary knowledge and patented equipment and tools that are used in the manufacturing process of AFREZZA. Due to the complexities of particle formulation and the specialized knowledge and equipment needed to handle the AFREZZA powder, neither Sanofi nor any third-party contract manufacturing organization currently possesses the capability of manufacturing AFREZZA.

In order for revenue to be recognized, the seller s price to the buyer must be fixed and determinable. Given that as of December 31, 2015, the Company did not have the ability to estimate the amount of costs that would potentially be incurred under the loss share provision related to the Sanofi License Agreement and the Sanofi Supply Agreement, the Company believes this requirement for revenue recognition has not been met.

As such, the Company did not recognize any revenue pursuant to the Sanofi License Agreement or the Sanofi Supply Agreement for the years ended December 31, 2015 and 2014. The Company has recorded the $150.0 million up-front payment and $50.0 million from milestone payments as deferred payments from collaboration. In addition, as of December 31, 2015 the Company has recorded $17.5 million in AFREZZA product shipments to Sanofi as deferred product sales from collaboration and recorded $13.5 million as deferred product costs from collaboration. Deferred product costs represent the costs of product manufactured and shipped to Sanofi, not to exceed the amount of deferred product sales, for which recognition of revenue has been deferred. During the year ended December 31, 2015, the Company s portion of the loss sharing was $57.7 million, which resulted in the reclassification from current deferred payments from collaboration to Sanofi loan facility and loss share obligation to reflect amounts owed to Sanofi.

Sanofi Loan Facility

On September 23, 2014, the Company entered into the Sanofi Loan Facility, consisting of a senior secured revolving promissory note and a guaranty and security agreement (the Security Agreement) with an affiliate of Sanofi which provides the Company with a secured loan facility of up to $175.0 million to fund the Company s share of net losses under the Sanofi License Agreement. In the event of certain future defaults under the Sanofi Loan facility agreement for which the Company is not able to obtain waivers, the lender under the Sanofi Loan Facility may accelerate all of the Company s repayment obligations, and take control of the Company s pledged

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

assets, potentially requiring the Company to renegotiate the terms of its indebtedness on terms less favorable to the Company, or to immediately cease operations.

The obligations of the Company under the Sanofi Loan Facility are guaranteed by the Company s wholly-owned subsidiary, MannKind LLC, and are secured by a first priority security interest in certain insulin inventory located in the United States and any contractual rights and obligations pursuant to which the Company purchases or has purchased such insulin, and a second priority security interest in the Company s assets that secure the Company s obligations under the Facility Agreement, as amended. In addition, the Company granted to Sanofi, as additional security for the obligations under the Sanofi Loan Facility, a first priority mortgage on the Company s facility in Valencia, California, which has a carrying value of $17.9 million as of December 31, 2015.

Advances under the Sanofi Loan Facility bear interest at a rate of 8.5% per annum and are payable in-kind and compounded quarterly and added to the outstanding principal balance under the Sanofi Loan Facility. The Company is required to make mandatory prepayments on the outstanding loans under the Sanofi Loan Facility from its share of any Profits (as defined in the Sanofi License Agreement) under the Sanofi License Agreement within 30 days of receipt of its share of any such Profits. No advances may be made under the Sanofi Loan Agreement if Deerfield has commenced enforcement proceedings in connection with an event of default under the Facility Agreement.

The outstanding principal of all loans under the Sanofi Loan Facility, if not prepaid, will become due and payable on September 23, 2024 unless accelerated pursuant to the terms of the Sanofi Loan Facility. Additionally, if the Company sells its Valencia facility, the Company is required to prepay the loans under the Sanofi Loan Facility from the net cash proceeds of the sale within five business days of receipt.

The Company s total portion of the loss sharing was $57.7 million for the year ended December 31, 2015, of which $44.5 million was borrowed under the Sanofi Loan Facility as of December 31, 2015. Subsequent to December 31, 2015, the Company borrowed $17.9 million under the Sanofi Loan Facility to finance the portion of the Company s loss for the quarter ended December 31, 2015. The total amount owed to Sanofi is $62.4 million, which includes $1.7 million in paid-in-kind interest.

The Sanofi Loan Facility includes customary representations, warranties and covenants by the Company, including restrictions on its ability to incur additional indebtedness, grant certain liens and make certain changes to its organizational documents. Events of default under the Sanofi Loan Facility include: the Company s failure to timely make payments due under the Sanofi Loan Facility; inaccuracies in the Company s representations and warranties to the noteholder; the Company s failure to comply with any of its covenants under any of the Sanofi Loan Facility or certain other related security agreements and documents entered into in connection with the Sanofi Loan Facility, subject to a cure period with respect to most covenants; the Company s insolvency or the occurrence of certain bankruptcy-related events; termination by Sanofi of the Sanofi License Agreement as a result of the Company s breach of the Sanofi License Agreement; and the failure of any material provision under any of the Sanofi Loan Facility or certain other related security agreements and documents entered into in connection with the Sanofi Loan Facility to remain in full force and effect. If one or more events of default occurs and is continuing, Sanofi may terminate its obligation to make advances under the Sanofi Loan Facility, and, if certain specified events of default (including the Company s failure to timely make payments due under the Sanofi Loan Facility; the Company s failure to comply with the negative covenants under the Sanofi Loan Facility limiting the Company s ability to incur additional indebtedness or grant certain liens; the Company s insolvency or the occurrence of certain bankruptcy-related events; termination by Sanofi of the Sanofi License Agreement as a result of the Company s breach of the non-compete provisions of the Sanofi License Agreement; or the failure of any material provision under any of the Sanofi Loan Facility or certain other related security agreements and documents entered into in connection with the Sanofi Loan Facility to remain in full force and effect) occur and are continuing, the noteholder may accelerate all of the Company s repayment obligations under the Sanofi Loan Facility and otherwise exercise any of its remedies as a secured creditor. There can be no assurance that the noteholder would not choose to exercise these rights in the event such events were to occur.

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MANNKIND CORPORATION AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Subsequent to December 31, 2015, the Company received written notice on January 4, 2016 from Sanofi of its election to terminate in its entirety the Sanofi License Agreement. Pursuant to its terms, the Sanofi Supply Agreement will terminate concurrently with the Sanofi License Agreement. Sanofi s notice indicated that the termination was pursuant to Sanofi s right to terminate the Sanofi License Agreement upon Sanofi s good faith determination that the commercialization of AFREZZA is no longer economically viable in the United States, in which case the effective date of termination will be April 4, 2016. In the alternative, Sanofi indicated that the termination was also pursuant to its right to terminate the Sanofi License Agreement for any reason, in which case the effective date of termination will be July 4, 2016. In the interest of an expedient transition, the Company is currently working with Sanofi to transfer and wind down the agreement activities by April 4, 2016, or as soon as practicable thereafter.

Pursuant to the terms of the Sanofi License Agreement, the Company and Sanofi are required to use diligent efforts to facilitate the smooth and orderly transition of relevant obligations and rights to the Company with respect to development and commercialization activities related to AFREZZA, and are also required to negotiate in good faith a written transition agreement for this purpose. As a result of the foregoing termination, effective on the Termination Date and thereafter during any period which Sanofi is required to perform any wind-down activities pursuant to the terms of the Sanofi License Agreement, the rights granted to Sanofi under the Sanofi License Agreement to develop and commercialize AFREZZA will become non-exclusive and the Company will have the right to engage one or more other distributors and/or licensees of AFREZZA. Sanofi will continue to distribute AFREZZA during the wind-down period as required by the agreement until such time that the Company or its designee takes over responsibility for distribution. All profits and losses from AFREZZA product sales by Sanofi or its affiliates after the Termination Date, if any, will continue to be shared 65% by Sanofi and 35% by the Company pursuant to the terms of the License Agreement.

In addition to the Sanofi License Agreement and Sanofi Supply Agreement, as discussed above, the Company and Aventisub LLC, an affiliate of Sanofi, are parties to a Senior Secured Revolving Promissory Note, dated September 23, 2014 and a Guaranty and Security Agreement. Both the Sanofi Loan Facility and the Security Agreement remain in effect. The original maturity date of September 23, 2024 for repayment of the outstanding principal amount of the loans under the Sanofi Loan Facility will not be affected by the termination of the Sanofi License Agreement.

10. 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 the Company s principal stockholder cannot be reasonably estimated as the Company would not be able to obtain a similar credit arrangement in the current economic environment.

As of December 31, 2015 and 2014, the Company held $59.1 million and $120.8 million, respectively of cash and cash equivalents, consisting of money market funds of $55.8 million and $118.5 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).

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2018 notes, facility financing obligation and Sanofi Loan Facility

The following is a summary of the carrying values and estimated fair values of the 2018 notes, the facility financing obligation (i.e., the 2019 notes and Tranche B notes), and the Sanofi Loan Facility (in millions):

	December 31, 2015		December 31, 2014	
	Carrying value	Estimated fair value	Carrying value	Estimated fair value
2015 notes	$	$	$ 99.4	$ 102.9
2018 notes	$ 27.6	$ 21.3	$	$
Facility financing obligation	$ 74.6	$ 78.4	$ 73.0	$ 75.1
Sanofi Loan Facility	$ 44.5	$ 36.5	$ 3.0	$ 3.0

2015 notes

The estimated fair value of the 2015 notes 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 longer-term historical volatility (55%) (Level 3 in the fair value hierarchy). As there was no current active and observable market for the 2015 notes, 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. As of December 31, 2015, all 2015 notes, including the Exchange Notes, have been extinguished through exchange for stock, exchange for 2018 notes or settlement in cash. (See Note 8 Senior convertible notes).

2018 notes

The estimated fair value of the 2018 notes was calculated based on model-derived valuations whose inputs were observable, such as the Company s stock price and yields on U.S. Treasury notes and actively traded bonds, and non-observable, such as the Company s longer-term historical volatility, and estimated yields implied from any available market trades of the Company s issued debt instruments. As there is no current active and observable market for the 2018 notes, 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 flows based on terms of the notes with market-based assumptions regarding risk-free rate, risk-adjusted yields (20%), stock price volatility (90%) and recent price quotes and trading information regarding Company issued debt instruments and shares of common stock into which the notes are convertible (Level 3 in the fair value hierarchy).

Facility financing agreement

As discussed in Note 17 Facility Agreement, in connection with the Facility Agreement, the Company issued 2019 notes and subsequently issued Tranche B notes (the Facility Financing Obligation). As there is no current observable market for the 2019 notes or Tranche B notes, the Company determined the estimated fair value using a bond valuation model based on a discounted cash flow methodology. The bond valuation model combined expected cash flows associated with principal repayment and interest based on the contractual terms of the debt agreement discounted to present value using a selected market discount rate. On December 31, 2015 the market discount rate was recalculated at 12.0% for the 2019 notes and the Tranche B notes (Level 3 in the fair value hierarchy).

In addition to the 2019 notes and Tranche B notes, the Company also issued certain rights to receive payments of up to $90.0 million upon occurrence of specified strategic and sales milestones (the Milestone Rights). These rights are not reflected in the facility financing obligation. The estimated fair value of the Milestone Rights

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MANNKIND CORPORATION AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

was calculated using the income approach in which the cash flows associated with the specified contractual payments were adjusted for both the expected timing and the probability of achieving the milestones discounted to present value using a selected market discount rate (Level 3 in the fair value hierarchy). The expected timing and probability of achieving the milestones, starting in 2014, was developed with consideration given to both internal data, such as progress made to date and assessment of criteria required for achievement, and external data, such as market research studies. The discount rate (15.0%) was selected based on an estimation of required rate of returns for similar investment opportunities using available market data. As of December 31, 2015, the carrying value of the Milestone Rights is $8.9 million, classified as a long-term liability in other liabilities and the fair value is estimated at $14.4 million.

Sanofi Loan Facility

As discussed in Note 9 the Sanofi Loan Facility, consists of a senior secured revolving promissory note and a guaranty and security agreement with an affiliate of Sanofi which provides the Company with a secured loan facility of up to $175.0 million to fund the Company s share of net losses under the Sanofi License Agreement. The estimated fair value was determined using a discounted cash flow model in which time outstanding and discount rate were primary variables. This method considered the key elements of the contractual terms of the Sanofi Loan Facility, market-based estimated cost of capital, and time value of money, namely the amount of time to settlement and the estimated discount rate (11%) appropriate for the liability (Level 3 in the fair value hierarchy). As of December 31, 2015 the carrying value of the Sanofi Loan Facility is $44.5 million and the fair value is estimated at $36.5 million.

There were no material re-measurements to fair value during the year ended December 31, 2015 of financial assets and liabilities that are not measured at fair value on a recurring basis. There were no transfers of assets or liabilities between the fair value measurement levels during the twelve months ended December 31, 2015, 2014, and 2013.

Assets and Liabilities Measured at Fair Value on a Non-recurring Basis

In accordance with ASC 360, *Property, Plant, and Equipment* (ASC 360), land, buildings, and machinery and equipment, with a carrying amount of $189.2 million, were written down to a fair value of $48.8 million, resulting in an impairment charge of $140.4 million, which is included in our Statements of Operations and Comprehensive Loss for the year ended December 31, 2015.

Our assessment of the real property includes Level 3 inputs, and was based on a combination of the income, market and cost approaches and the market approach was used for machinery and equipment which required Level 3 inputs.

Embedded Derivatives

The Company identified and evaluated a number of embedded features in the notes issued under the Facility Agreement to determine if they represented embedded derivatives that are required to be separated from the notes and accounted for as freestanding instruments pursuant to ASC 815. In 2014, the Company analyzed the Tranche B notes and identified embedded derivatives which required separate accounting under ASC 815; however all of the embedded derivatives were determined to have a *de minimis* value.

At December 31, 2015, all of the embedded derivatives identified in the Tranche B notes were deemed to have a *de minimis* value.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. Common and preferred stock

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, 2015 and 2014, 428,670,943 and 406,059,089 shares of common stock, respectively, were issued and outstanding and no shares of preferred stock were outstanding.

On November 9, 2015, the Company entered into a series of stock purchase agreements to sell up to an aggregate of 50,000,000 shares its common stock in a registered direct offering to selected investment funds in Israel that hold securities included within certain stock indexes of the Tel Aviv Stock Exchange (the TASE). Pursuant to the agreements, the shares of common stock were sold at a price per share equal to 97% of the closing price of the Company s common stock on the TASE on November 12, 2015. During November 2015, the Company sold 13,852,435 shares of common stock for an aggregate price of approximately $34,710,000, or $2.61 per share, which is net of $1,433,000 of issuance costs.

The Company engaged Sunrise Securities Corporation as its exclusive placement agent in connection with the offering of 50,000,000 shares. In connection with the services provided the Company issued to Sunrise Securities Corporation, or its designee, restricted warrants to purchase a number of shares of the Company s common stock in an aggregate equal to 1.15% of the aggregate shares sold in the offering, which totaled 159,303 shares on November 16, 2015. The warrants are exercisable for a five year period at an exercise price of $2.61, the price paid per share in connection with the offering. The Company had an obligation to register the common stock that may be issued pursuant to the exercise of the warrants, which resulted in their initial classification as liability and were deemed immaterial. On December 15, 2015 the warrants were reclassified to equity as the Company registered the common stock pursuant to registration statement. As of December 31, 2015 the warrants were classified within equity.

Included in the common stock outstanding as of December 31, 2014 is 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. Bank of America was obligated to return the borrowed shares (or, in certain circumstances, the cash value thereof) to the Company on or about the 45th business day following the date as of which the entire principal amount of the 2015 notes ceases to be outstanding, subject to extension or acceleration in certain circumstances or early termination at Bank of America s option. On October 23, 2015, the 9,000,000 shares of common stock loaned to Bank of America were returned, as the Company settled all payments and deliveries in respect of such convertible notes on August 17, 2015. The Company did not receive any proceeds from the sale of the borrowed shares by Bank of America, but the Company did receive a nominal lending fee of $0.01 per share from Bank of America for the use of borrowed shares.

On 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.

For the years ended December 31, 2015, 2014, and 2013, the Company received $10.1 million, $27.8 million, and $94.2 million in proceeds, respectively, from the exercise of the February 2012 public offering warrants. Any unexercised February 2012 public offering warrants expired on February 8, 2016.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. Net loss per common share

Basic net loss per share excludes dilution for potentially dilutive securities and is computed by dividing net loss by the weighted average number of common shares outstanding during the period excluding the 9,000,000 shares loaned to Bank of America under a share lending arrangement (see Note 11 Common and preferred stock). In the third quarter of 2015, the 9,000,000 million shares loaned to Bank of America were returned. Prior to the return of those shares, the borrowed shares were not considered outstanding for the purpose of computing and reporting basic or diluted earnings (loss) per share because the share borrower had to return all borrowed shares to the Company (or, in certain circumstances, the cash value thereof). 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 condensed consolidated 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 and excluded the 9,000,000 shares of the Company s common stock loaned under the share lending arrangement as of December 31, 2014, and 2013.

Potentially dilutive securities outstanding are summarized as follows (in shares):

	December 31,		
	2015	2014	2013
Exercise of common stock options	19,779,229	21,541,664	24,237,940
Conversion of senior convertible notes into common stock	4,072,809	17,323,080	25,415,366
Exercise of common stock warrants	4,074,596	9,987,876	19,706,240
Vesting of restricted stock units	1,804,620	2,610,720	9,115,821
	29,731,254	51,463,340	78,475,367

13. Stock award plans

On May 23, 2013, the Company adopted the 2013 Equity Incentive Plan (the 2013 Plan) as the successor to and continuation of the 2004 Equity Incentive Plan (the 2004 Plan). The 2013 Plan consists of 21.5 million newly requested shares and the number of unallocated shares remaining available for grant for new awards under the 2004 Plan. The 2013 Plan provides for the granting of stock awards including stock options and restricted stock units, to employees, directors and consultants. The Plan also provides for the automatic, non-discretionary grant of options to the Company s non-employee directors. No additional awards will be granted under the 2004 Plan or under the 2004 Non-Employee Directors Stock Option Plan (the NED Plan) as all future awards will be made out of the 2013 Plan.

As of December 31, 2015, the Company has two active stock-based compensation plans the 2013 Plan and the 2004 Employee Stock Purchase Plan (the ESPP). The following table summarizes information about the Company s stock-based award plans as of December 31, 2015:

	Outstanding Options	Outstanding Restricted Stock Units	Shares Available for Future Issuance
2004 Equity Incentive Plan	11,309,136	276,784	
2013 Equity Incentive Plan	8,026,762	1,527,836	15,540,652
2004 Non-Employee Directors Stock Option Plan	443,331		

Total	19,779,229	1,804,620	15,540,652

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 2004 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, 2013 and 2014 the ESPP share reserve was increased by 700,000 and 700,000 shares, respectively. There was no ESPP share reserve increase during 2015. As of December 31, 2015, 2,752,703 shares were available for issuance under the ESPP. For the years ended December 31, 2015, 2014 and 2013 the Company sold 321,228, 305,076, and 463,290 shares, respectively, of its common stock to employees participating in the ESPP. The ESPP purchase for the period ending December 31, 2015 was initiated prior to year-end but did not settle until January 5, 2016. As a result, the shares sold are reflected in the ESPP share reserves but is excluded from common stock outstanding as of December 31, 2015.

The Company s board of directors determines eligibility, vesting schedules and exercise prices for stock awards granted under the 2013 Plan. Options and other stock awards under the 2013 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. There are no outstanding performance-based awards as all milestones have been achieved as of December 31, 2015. The 2013 Plan provides for full acceleration of vesting if an employee is terminated within three months of a change in control, as defined in the 2013 Plan.

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, 2015, there were options to purchase 523,487 shares of common stock outstanding to consultants.

During the years ended December 31, 2015, 2014 and 2013 the Company recorded stock-based compensation expense related to its stock award plans and the ESPP of $8.7 million, $48.6 million, and $45.2 million, respectively.

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

	Year Ended December 31,		
	2015	2014	2013
Employee-related	$ 8,407	$ 48,622	$ 45,181
Consultant-related	318		5
Total	$ 8,725	$ 48,622	$ 45,186

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	Year Ended December 31,		
	2015	2014	2013
Research and development	$ 3,029	$ 22,357	$ 20,409
General and administrative	5,696	26,265	24,777
Total	$ 8,725	$ 48,622	$ 45,186

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.

Beginning in the third quarter of 2014, the Company began to assess both historical and implied volatility in order to determine its estimated volatility rate. Implied volatility was considered due to the change in the Company s business, which occurred with the approval for the sale of AFREEZA. 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, 2015, 2014 and 2013 using the following assumptions:

	Year Ended December 31,		
	2015	2014	2013
Risk-free interest rate	1.61% 1.86%	1.64% 2.11%	0.94% 1.82%
Expected lives	5.79 5.86 years	5.77 6.09 years	2.64 5.77 years
Volatility	69.76% 71.84%	73.98% 84.85%	75.83% 86.26%
Dividends			

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, 2015	21,541,664	4.53	$ 33,495
Granted	1,541,100	4.11	
Exercised	(1,700,964)	1.91	
Forfeited	(706,387)	5.78	
Expired	(896,184)	7.70	
Outstanding at December 31, 2015	19,779,229	4.54	$

Vested and expected to vest at December 31, 2015	19,597,097	4.53	$
Exercisable at December 31, 2015	17,217,332	4.47	$

The weighted average grant date fair value of the stock options granted during the years ended December 31, 2015, 2014 and 2013 was $2.56, $4.76 and $3.26 per option, respectively. The total intrinsic value of options exercised during the years ended December 31, 2015, 2014 and 2013 was $6.2 million, $14.9 million and $3.1

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

million, respectively. Intrinsic value is measured using the fair market value at the date of exercise (for options exercised) or at December 31 (for outstanding options), less the applicable exercise price.

Cash received from the exercise of options during the years ended December 31, 2015, 2014 and 2013 was approximately $3.3 million, $11.0 million and $2.3 million, respectively. The weighted-average remaining contractual terms for options outstanding, vested and expected to vest, and exercisable at December 31, 2015 was 6.34 years, 6.31 years and 5.97 years, respectively.

A summary of restricted stock unit activity for the year ended December 31, 2015 is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value per Share
Outstanding at January 1, 2015	2,610,720	$ 5.20
Granted	1,133,404	$ 4.14
Vested	(1,111,134)	$ 4.93
Forfeited	(828,370)	$ 4.88
Outstanding at December 31, 2015	1,804,620	$ 4.85

The total restricted stock units expected to vest as of December 31, 2015 was 1,651,859 with a weighted average grant date fair value of $4.86. The total intrinsic value of restricted stock units expected to vest as of December 31, 2015 was $2.4 million. Intrinsic value of restricted stock units expected to vest is measured using the closing share price at December 31, 2015.

Total intrinsic value of restricted stock units vested during the years ended December 31, 2015, 2014 and 2013 was $5.2 million, $62.7 million and $13.9 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 grant date fair value of restricted stock units vested during the years ended December 31, 2015, 2014 and 2013 was $5.5million, $36.4 million and $14.9 million, respectively.

As of December 31, 2015, there was $4.9 million and $6.7 million of unrecognized compensation expense related to options and restricted stock units, respectively, which is expected to be recognized over the weighted average vesting period of 2.7 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, 2015, all milestones have been achieved.

During the year ended December 31, 2015, there was $1.6 million of stock compensation expense related to certain Executives who entered into severance agreements which resulted in a modification to the terms of their awards. The severance agreements generally allowed for the separated Executives to continue to vest under their original award terms for a stated period of time without providing substantive services.

14. Commitments and contingencies

Operating Leases The Company leases certain facilities and equipment under various operating leases, which expire at various dates through 2016 and beyond. Future payments are deemed insignificant.

Rent expense under all operating leases, including office space and equipment, for the years ended December 31, 2015, 2014, and 2013 was approximately $426,000, $737,000, and $645,000 respectively.

Leases The Company s capital leases were not material for the years ended December 31, 2015, 2014 and 2013.

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MANNKIND CORPORATION AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 condensed 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 and the amount can be reasonably estimated. No such losses have been recorded to date.

Litigation The Company is subject to legal proceedings and claims which arise in the ordinary course of its business. As of December 31, 2015, 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 and no accrual has been recorded. 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.

In addition, several complaints were filed in the U.S. District Court for the Central District of California against the Company and certain of its officers and directors on behalf of certain purchasers of its common stock. The complaints include claims asserted under Sections 10(b) and 20(a) of the Exchange Act and have been pled as putative shareholder class actions. In general, the complaints allege that the Company and certain of its officers and directors violated federal securities laws by making materially false and misleading statements regarding the prospects for AFREZZA, thereby artificially inflating the price of its common stock. The plaintiffs are seeking monetary damages and other relief. The Company expects the complaints to be transferred to a single court and consolidated for all purposes, following which the court would be expected to appoint a lead plaintiff and lead counsel and to order the lead plaintiff to file a consolidated complaint. The Company will vigorously defend against the claims advanced.

Following the receipt by the Company of the notice of termination from Sanofi regarding the Sanofi License Agreement and the subsequent decline of the price of its common stock, two motions were submitted to the District Court at Tel Aviv (Economic Department) for the certification of a class action against the Company and certain of its officers and directors. In general, the complaints allege that the Company and certain of its officers and directors violated Israeli and US securities laws by making materially false and misleading statements regarding the prospects for AFREZZA, thereby artificially inflating the price of its common stock. The plaintiffs are seeking monetary damages. The Company will vigorously defend against these claims.

Contingencies In connection with the Facility Agreement, on July 1, 2013 the Company also entered into a Milestone Rights Purchase Agreement (the Milestone Agreement) with Deerfield Private Design Fund and Horizon Santé FLML SÁRL (collectively, the Milestone Purchasers), pursuant to which the Company sold the Milestone Purchasers the Milestone Rights to receive payments up to $90.0 million upon the occurrence of specified strategic and sales milestones, including the first commercial sale of an AFREZZA product in the United States and the achievement of specified net sales figures (see Note 17 Facility Agreement).

Commitment On July 31, 2014, the Company entered into a supply agreement (the Insulin Supply Agreement) with Amphastar France Pharmaceuticals S.A.S., a French corporation (Amphastar), pursuant to

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which Amphastar will manufacture for and supply to the Company certain quantities of recombinant human insulin for use in AFREZZA. Under the terms of the Insulin Supply Agreement, Amphastar will be responsible for manufacturing the insulin in accordance with the Company s specifications and agreed-upon quality standards. The Company has agreed to purchase annual minimum quantities of insulin for calendar years 2015 through 2019 under the Insulin Supply Agreement of an aggregate total of approximately 120.1 million, of which 98.5 million is remaining at December 31, 2015. The Company has contracted for the purchase of 28.8 million in 2016 and the remaining annual minimum quantities will be 23.3 million for the years ending December 31, 2017 through 2019. The Company may request to purchase additional quantities of insulin over such annual minimum quantities and will incur a cancellation fee of approximately $5.2 million if not purchased (see Note 2 Summary of Significant accounting policies).

Unless earlier terminated, the term of the Insulin Supply Agreement expires on December 31, 2019 and can be renewed for additional, successive two year terms upon 12 months written notice given prior to the end of the initial term or any additional two year term. The Company and Amphastar each have normal and customary termination rights, including termination for material breach that is not cured within a specific time frame or in the event of liquidation, bankruptcy or insolvency of the other party. In addition, the Company may terminate the Insulin Supply Agreement upon two years prior written notice to Amphastar without cause or upon 30 days prior written notice to Amphastar if a controlling regulatory authority withdraws approval for AFREZZA, provided, however, in the event of a termination pursuant to either of the latter two scenarios, the provisions of the Insulin Supply Agreement require the Company to pay the full amount of all unpaid purchase commitments due over the initial term within 60 calendar days of the effective date of such termination.

15. Employee benefit plans

The Company administers a 401(k) Savings Retirement Plan (the MannKind Retirement Plan) for its employees. For the years ended December 31, 2015, 2014, and 2013, the Company contributed $593,000, $623,000, and $533,000 respectively, to the MannKind Retirement Plan.

16. Income taxes

There is no provision for income taxes because the Company has incurred operating losses since inception. At December 31, 2015, the Company has concluded that it is more likely than not that the Company may not realize the benefit of its deferred tax assets due to its history of losses. Accordingly, the net deferred tax assets have been fully reserved. The provision for income taxes consists of the following (in thousands):

	Year Ended December 31,		
	2015	2014	2013
Current			
U.S. federal	$	$	$
U.S. state			
Non-U.S.			
Total current			
Deferred			
U.S. federal	109,512	57,873	59,379
U.S. state	(29,394)	7,631	7,470
Non-U.S.			
Valuation Allowance	(80,118)	(65,504)	(66,849)
Total deferred			

Total	$	$	$

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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, 2015 and 2014 are approximately as follows (in thousands):

	December 31,	
	2015	2014
Deferred tax assets:		
Net operating loss carryforwards	$ 721,588	$ 699,997
Research and development credits	73,646	73,227
Capitalized research	5,872	28,516
Payments from collaboration	52,484	19,217
Milestone Rights	3,242	5,321
Accrued expenses	251	768
Loss on purchase commitment	24,084	
Non-qualified stock option expense	16,941	43,691
Capitalized patent costs	8,574	8,624
Other	7,186	131
Depreciation	48,755	3,010
Total net deferred tax assets	962,623	882,502
Valuation allowance	(962,623)	(882,502)
Net deferred tax assets	$	$

As a result of certain realization requirements of ASC 718, the table of deferred tax assets and liabilities does not include certain deferred tax assets as of December 31, 2015 that arose directly from tax deductions related to equity compensation which are greater than the compensation recognized for financial reporting. Equity would be increased by $10.0 million if and when such deferred tax assets are ultimately realized. The Company considered the requirements under ASC 740 *Income Taxes* (ASC 740) when determining when excess tax benefits have been realized.

The Company s effective income tax rate differs from the statutory federal income tax rate as follows for the years ended December 31, 2015, 2014 and 2013:

	December 31,		
	2015	2014	2013
Federal tax benefit rate	35.0%	35.0%	35.0%
State tax benefit, net of federal benefit			
Permanent items		0.9	
Intercompany transfer of intellectual property	(1.0)	(4.1)	(4.3)
Valuation allowance	(34)	(31.8)	(30.7)
Effective income tax rate	0.0%	0.0%	0.0%

As required by 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. 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, 2015, 2014 and 2013, the change in the valuation allowance was $80.1 million, $65.5 million and $66.8 million, respectively, for income taxes.

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At December 31, 2015, the Company had federal and state net operating loss carryforwards of approximately $1.9 billion and $1.3 billion available, respectively, to reduce future taxable income. The federal net operating loss carryforwards will expire at various dates beginning in 2018 and the state net operating loss carryforwards have started expiring, starting current year through various future dates. As a result of the Company s initial public offering, an ownership change within the meaning of Internal Revenue Code Section 382 occurred in August 2004. As a result, federal net operating loss and credit carry forwards of approximately $216.0 million are subject to an annual use limitation of approximately $13.0 million. The annual limitation is cumulative and therefore, if not fully utilized in a year can be utilized in future years in addition to the Section 382 limitation for those years. The federal net operating losses generated subsequent to the Company s initial public offering in August 2004 are currently not subject to any such limitation as there have been no ownership changes since August 2004 within the meaning of Internal Revenue Code Section 382. At December 31, 2015, the Company had research and development credits of $49.1 million and $37.7 million for federal and state purposes, respectively. The federal credits begin to expire in 2024, and the state credits may be carried forward indefinitely.

The Company has evaluated the impact of ASC 740, previously FIN 48 *Accounting for Uncertainty in Income Taxes*, on its financial statements, which was effective beginning January 1, 2007. The evaluation of a tax position in accordance with this guidance is a two-step process. The first step is recognition: the enterprise determines whether it is more-likely-than-not that a tax position will be sustained upon examination, including resolution of any related appeals or litigation processes, based on the technical merits of the position. In evaluating whether a tax position has met the more-likely-than-not recognition threshold, the enterprise should presume that the position will be examined by the appropriate taxing authority that would have full knowledge of all relevant information. The second step is measurement: a tax position that meets the more-likely-than-not recognition threshold is measured to determine the amount of benefit to recognize in the financial statements. The tax position is measured at the largest amount of benefit that is greater than 50 percent likely of being realized upon ultimate settlement. Tax positions that previously failed to meet the more-likely-than-not recognition threshold should be recognized in the first subsequent financial reporting period in which that threshold is met. Previously recognized tax positions that no longer meet the more-likely-than-not recognition threshold should be derecognized in the first subsequent financial reporting period in which that threshold is no longer met. The Company believes that its income tax filing positions and deductions will be sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position. Therefore, no liabilities for uncertain income tax positions have been recorded. Tax years since 2011 remain subject to examination by the major tax jurisdictions in which the Company is subject to tax.

17. Facility Agreement

As of December 31, 2015 and 2014, there were $60.0 million principal amount of 2019 notes and $20.0 million principal amount of Tranche B notes outstanding. The 2019 notes accrue interest at annual rate of 9.75% and the Tranche B notes accrue interest at an annual rate of 8.75% and is paid quarterly in arrears on the last day of each March, June, September, and December. The Facility Agreement principal repayment schedule is comprised of annual payments beginning on July 1, 2016 and ending December 9, 2019. Future principal payments for the years ended December 31, 2016, 2017, 2018, and 2019 are $5.0 million, $20.0 million, $20.0 million, and $35.0 million, respectively.

In conjunction with the Facility Agreement, the Company entered into a Milestone Rights Agreement with Deerfield which requires the Company to make contingent payments to Deerfield, totaling up to $90.0 million, upon the Company achieving specified commercialization milestones. The Milestone Rights were initially recorded as a short-term liability equal to $3.2 million included in accrued expenses and other current liabilities in the accompanying condensed consolidated balance sheet and a long-term liability equal to $13.1 million included in other liabilities. During the first quarter of 2015, a milestone triggering event was achieved following the Company s product launch on February 3, 2015, which resulted in a $5.8 million incremental charge to

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interest expense due to the increase in carrying value of the liability to the required $10.0 million payment made in February of 2015. During the year ended December 31, 2014, the first milestone triggering event was achieved following the Company s entry into the Sanofi License Agreement, which resulted in a $1.9 million incremental charge to interest expense due to the increase in carrying value of the liability to the required $5.0 million payment, which was paid to Deerfield pursuant to the terms of the Milestone Agreement. As of December 31, 2015, the remaining liability balance of $8.9 million is classified as long-term liability in other liabilities.

As of December 31, 2015, the uncreated debt discount and debt issuance costs were $5.3 million and $0.1 million, respectively.

Accretion of debt issuance cost and debt discount in connection with the Deerfield financing during the year ended December 31, 2015 and 2014 are as follows (in thousands):

	December 31,	
	2015	2014
Accretion expense- debt issuance cost	$ 35	$ 326
Accretion expense- debt discount	$ 1,553	$ 7,550

The Facility Agreement includes customary representations, warranties and covenants, including, a restriction on the incurrence of additional indebtedness, and a financial covenant which requires the Company s cash and cash equivalents, which includes available borrowings on the principal stockholder note, on the last day of each fiscal quarter to not be less than $25.0 million. As discussed in Note 1 Basis of Presentation, the Company will need to raise additional capital to support its current operating plans. Due to the uncertainties related to maintaining sufficient resources to comply with the aforementioned covenant, the 2019 notes have been classified as current liabilities in the accompanying balance sheet as of December 31, 2015. In the event of non-compliance, Deerfield may declare all or any portion of the 2019 notes and/or Tranche B notes to be immediately due and payable.

Milestone Rights

The Milestone Agreement includes customary representations and warranties and covenants by the Company, including restrictions on transfers of intellectual property related to AFREZZA. The Milestone Rights are subject to acceleration in the event the Company transfers its intellectual property related to AFREZZA in violation of the terms of the Milestone Agreement.

The Company analyzed the Milestone Rights under the provisions of ASC 815 *Derivatives and Hedging,* and determined that the instruments do not meet the definition of a freestanding derivative. Since the Company has not elected to apply the fair value option to the Milestone Rights, the Company has initially recorded the Milestone Rights at their estimated fair value and accounted for the Milestone Rights as a liability by applying the indexed debt guidance contained in paragraphs ASC 470-10-25-3 and 35-4.

The initial fair value estimate of the Milestone Rights was calculated using the income approach in which the cash flows associated with the specified contractual payments were adjusted for both the expected timing and the probability of achieving the milestones discounted to present value using a selected market discount rate. In determining the fair value of the Milestone Rights, the 13 individual milestone payments were adjusted for both (i) the expected timing and (ii) the probability of achieving the milestones, and then discounted to present value using a discount rate of 17.5%. Once the initial valuation of each specified milestone payment was determined, the individual milestone payments were then aggregated to arrive at a total fair value of $16.3 million. The discount rate was based on the estimated cost of equity which was derived using the capital asset pricing model. In addition, a 5% risk premium was added to the computation of the cost of equity to adjust for non-systemic risk factors, such as the Company s lack of product diversification and history of financial losses, which were not captured in other model inputs.

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Security Agreement

In connection with the Facility Agreement, the Company and its subsidiary, MannKind LLC, entered into a Guaranty and Security Agreement (the Security Agreement) with Deerfield and HS (collectively, the Purchasers), pursuant to which the Company and MannKind LLC each granted the Purchasers a security interest in substantially all of their respective assets, including respective intellectual property, accounts, receivables, equipment, general intangibles, inventory and investment property, and all of the proceeds and products of the foregoing. The Security Agreement includes customary covenants by the Company and MannKind LLC, remedies of the Purchasers and representations and warranties by the Company and MannKind LLC. The security interests granted by the Company and MannKind LLC will terminate upon repayment of the 2019 notes and tranche B notes, if applicable, in full. The Company s obligations under the Facility Agreement and the Milestone Agreement are also secured by the mortgage on the Company s facilities in Danbury, Connecticut, which has a carrying value of $23.0 million.

Embedded Derivatives

The Company identified and evaluated a number of embedded features in the notes issued under the Facility Agreement to determine if they represented embedded derivatives that are required to be separated from the notes and accounted for as freestanding instruments pursuant to ASC 815. In 2014, the Company analyzed the Tranche B notes and identified embedded derivatives which required separate accounting under ASC 815; however all of the embedded derivatives were determined to have a *de minimis* value.

At December 31, 2015, all of the embedded derivatives identified in the Tranche B notes were deemed to have a *de minimis* value.

18. Restructuring Charges

On September 2015, the Company initiated a restructuring of the organization as a result of its shift to commercial production of AFREZZA. In connection with the restructuring, the Company reduced its total workforce by approximately 26% to 198 employees. The Company recorded restructuring charges of $5.9 million, $1.9 million, and $0.4 million for the years ended December 31, 2015, 2014, and 2013, respectively. As of December 31, 2015, the Company paid $2.8 million and the remaining balance is expected to be paid in the first quarter of 2016.

The $5.9 million of costs associated with the restructuring are included in Research and development and General and administrative operating expenses in the condensed consolidated statements of operations as $3.0 million and $2.9 million, respectively, for the year ended December 31, 2015.

As of December 31, 2015 and 2014, the Company had a restructuring accrual of $3.0 million and $0.3 million, respectively. The Company did not have a restructuring accrual as of December 31, 2013.

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19. Selected quarterly financial data (unaudited)

Summarized quarterly financial data for the years ended December 31, 2015 and 2014 are set forth in the following tables:

	March 31	June 30	September 30	December 31
	(In thousands, except per share data)			
2015				
Net loss	$ (30,658)	$ (28,910)	$ (31,857)	$ (277,020)
Net loss per share basic and diluted	$ (0.08)	$ (0.07)	$ (0.08)	$ (0.66)
Weighted average common shares used to compute basic and diluted net loss per share	398,916	401,018	405,199	419,314

	March 31	June 30	September 30	December 31
	(In thousands, except per share data)			
2014				
Net loss	$ (52,056)	$ (73,365)	$ (36,520)	$ (36,439)
Net loss per share basic and diluted	$ (0.14)	$ (0.19)	$ (0.09)	$ (0.09)
Weighted average common shares used to compute basic and diluted net loss per share	368,784	380,770	394,163	396,793

Impairment charges were recorded in 2015 for $242.7 million related to long-lived assets, inventory and loss on purchase commitments.

20. Subsequent Events

Sanofi Termination

On January 4, 2016, the Company received written notice from Sanofi of its election to terminate in its entirety the Sanofi License Agreement. Sanofi s notice indicated that the termination was pursuant to Sanofi s right to terminate the agreement upon Sanofi s good faith determination that the commercialization of AFREZZA is no longer economically viable in the United States, in which case the effective date of termination would be April 4, 2016. In the alternative, Sanofi indicated that the termination was also pursuant to its right to terminate the Sanofi License Agreement for any reason, in which case the Termination Date would be July 4, 2016. In the interest of an expedient transition, the Company is currently working with Sanofi to transfer and wind down the agreement activities by April 4, 2016, or as soon as practicable thereafter.

Pursuant to the terms of the Sanofi License Agreement, the Company and Sanofi are required to use diligent efforts to facilitate the smooth and orderly transition of relevant obligations and rights to the Company with respect to development and commercialization activities related to AFREZZA, and are also required to negotiate in good faith a written transition agreement for this purpose. As a result of the foregoing termination, effective on the Termination Date and thereafter during any period which Sanofi is required to perform any wind-down activities pursuant to the terms of the Sanofi License Agreement, the rights granted to Sanofi under the Sanofi License Agreement to develop and commercialize AFREZZA will become non-exclusive and the Company will have the right to engage one or more other distributors and/or licensees of AFREZZA. Sanofi will continue to distribute AFREZZA during the wind-down period as required by the agreement until such time

that the Company or its designee takes over responsibility for distribution. All profits and losses from AFREZZA product sales by Sanofi or its affiliates after the Termination Date, if any, will continue to be shared 65% by Sanofi and 35% by the Company pursuant to the terms of the Sanofi License Agreement.

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The Company and Sanofi are also parties to the Sanofi Supply Agreement, pursuant to which the Company is required to supply Sanofi or its affiliates or its sublicensees such quantities of AFREZZA as requested by Sanofi to cover its commercial requirements. As a result of the termination of the Sanofi License Agreement, the Sanofi Supply Agreement will terminate by its terms on the Termination Date.

Borrowings under Sanofi Loan Facility

On February 10, 2016, the Company borrowed $17.9 million under the Sanofi Loan Facility to finance the portion of its losses for the quarter ended December 31, 2015 (see Note 9 Collaboration arrangement).