MANNKIND CORP
Form 10-K
March 02, 2015
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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, 2014

or

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

Commission file number: 000-50865

MannKind Corporation

(Exact name of registrant as specified in its charter)

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

Registrant s telephone number, including area code

(661) 775-5300

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

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

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

None

(Title of Class)

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No 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, 2014, 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 $2,616,079,653.

As of February 23, 2015, there were 408,837,603 shares of the registrant s Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive Proxy Statement, or the Proxy Statement, for the 2015 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, 2014

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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 and our marketing partner s 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 estimates for future performance; our estimates regarding anticipated operating losses, future revenues, capital requirements and our needs for additional financing; our and our marketing partner s plans to expand manufacturing capacity to meet global demand for AFREZZA, including with respect to the construction and qualification of an additional manufacturing facility; 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. 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 387.0 million people had diabetes in 2014 and approximately 592.0 million people will have diabetes by 2035.

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 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. We manufacture AFREZZA at our manufacturing facility in Danbury,

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Connecticut to supply Sanofi s demand for the product. In addition, we and Sanofi are planning to collaborate to expand manufacturing capacity to meet global demand as necessary.

Under the Sanofi License Agreement, Sanofi paid us an up-front cash payment of $150.0 million in the third quarter of 2014. As of December 31, 2014, we have earned an additional $50.0 million in milestone payments in connection with the satisfaction of specified manufacturing milestones. We are also eligible to receive up to $725.0 million in additional milestone payments under the Sanofi License Agreement if certain development, regulatory and sales milestones are achieved. 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 us and Sanofi that are specifically attributable or related to the development, regulatory filings, manufacturing, or commercialization of AFREZZA, will be shared 65% by Sanofi and 35% by us. In connection with the Sanofi License Agreement, an affiliate of Sanofi provided us with a secured loan facility (the Sanofi Loan Facility) of up to $175.0 million to fund our share of net losses under the Sanofi License Agreement. As a result of the loss share provision, and because we do 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 that could be recognized, as revenue is not fixed or determinable.

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;
- A PK-PD glucose-clamp trial to characterize within-subject variability;
- 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, followed by a prospective, open-label, randomized, controlled trial comparing the efficacy and safety of prandial AFREZZA to prandial subcutaneous insulin aspart 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. The obligation for conducting these required post-marketing studies now rests with Sanofi, as does the responsibility to conduct other clinical studies as may be required to obtain regulatory approval in other countries or for marketing purposes.

On February 3, 2015, we and Sanofi announced that AFREZZA had become available by prescription in United States retail pharmacies.

Manufacturing and Supply

Our primary role in our collaboration with Sanofi is to manufacture AFREZZA to meet Sanofi s commercial demand as well as its requirements for ongoing clinical studies of AFREZZA. 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 initial commercial demand for AFREZZA. We are currently operating a single filling line with the capacity to process 100-120 million

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cartridges per year, and have installed and preliminarily qualified two additional filling lines that will bring our annual fill/packing capacity to 300-360 million later this year. In addition, the facility includes expansion space to accommodate as many as 12 filling lines and other equipment, allowing production capacity to be increased based on the demand for AFREZZA over the next several years. Before the Connecticut facility reaches its maximum capacity, we and Sanofi expect to coordinate the construction and qualification of an additional manufacturing facility, which may be owned and operated by Sanofi.

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 an aggregate total purchase price of approximately 120.1 million for calendar years 2015 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.

In addition to our supply relationship with Amphastar, we are working with Sanofi to qualify insulin manufactured by Sanofi as an additional source of insulin for AFREZZA.

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, where we recently completed pilot-scale development batches of FDKP produced using a more streamlined and less costly process compared to earlier campaigns. We intend to transfer this more efficient process to a contract manufacturer for production of registration and validation batches of FDKP.

We have a three-year supply agreement with the contract manufacturer that produces our inhaler and the corresponding cartridges. As demand increases, we intend to qualify an additional vendor of plastic-molding contract manufacturing services.

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. As demand increases, we intend to qualify an additional vendor of packaging services.

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

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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.

Our Strategy

The following are the key elements of our strategy:

Support the commercialization of AFREZZA. Our primary role in our collaboration with Sanofi for the commercialization of AFREZZA is to manufacture and supply AFREZZA as necessary based on the demand for the product in the United States and any other jurisdictions where Sanofi obtains regulatory approval. Through our participation in a joint committee and various working groups created as part of the alliance, we support Sanofi s development and marketing activities, gain alignment on patent strategy and coordinate other activities with Sanofi.

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. We are actively exploring 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

We rely on Sanofi to conduct all sales and marketing activities related to AFREZZA.

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We depend on the success of Sanofi in performing under the Sanofi License Agreement, and we cannot be certain Sanofi will, devote sufficient resources to the commercialization of AFREZZA, or perform its obligations under the agreement. Any failure of Sanofi to perform its obligations or allocate sufficient resources to the commercialization of AFREZZA in a timely manner could materially harm our business, financial condition and results of operations.

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 292 issued patents, and we also have over 230 pending applications in the United States and selected jurisdictions around the world 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 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

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

Diabetes Treatments

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

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

Rapid-acting (Injected) Insulin

Currently, there is no approved insulin product that is absorbed into the bloodstream as rapidly as AFREZZA, i.e., reaching peak levels within 12 to 15 minutes after administration. There are several formulations of

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

Novo Nordisk is conducting Phase 3 clinical studies of NN1218, an insulin analog that is intended to provide faster onset of action than aspart.

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.

In August 2013, Dance Biopharm, Inc. announced that it had conducted a Phase 1/2 clinical study of an inhaled insulin product that utilizes a liquid formulation of human insulin, dispensed through a handheld electronic aerosol device.

Non-insulin Medications

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

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

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

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

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

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

SGLT-2 inhibitors, such as dapagliflozin and canagliflozin, are a class of medications that lower blood glucose by increasing glucose excretion in urine.

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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, 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.

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

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

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

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

Submission to the FDA of an NDA 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 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.

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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.

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

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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. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

The United States and some foreign jurisdictions have enacted or are considering a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives, including, most recently, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, the ACA, enacted in March 2010. The Physician Payments Sunshine Act within the ACA, 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 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 the False Claims Act, as amended, the federal Anti-Kickback Statute, as amended, and similar state laws. If a drug product is reimbursed by Medicare or Medicaid, pricing and rebate programs must comply with, as applicable, the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Medicare Prescription Drug Improvement and Modernization Act of 2003. Additionally, the ACA substantially changed the way healthcare is financed by both governmental and private insurers. Among other cost containment measures, the ACA 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. 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

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products, or the amounts of reimbursement available for our products. If drug products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

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

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, exclusion of products from reimbursement under government programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Research and Development Expenses; Long-Lived Assets

A significant portion of our operating expenses relates to research and development. Our research and development expenses totaled $100.2 million, $109.7 million, and $101.5 million for the years ended December 31, 2014, 2013, and 2012, respectively. 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 research and development as manufacturing expenses are immaterial for the year ended December 31, 2014.

Our long-lived assets are located in the United States and totaled $192.1 million, $176.6 million, and $184.0 million as of December 31, 2014, 2013, and 2012, respectively.

Employees

As of December 31, 2014, we had 287 full-time employees. Six of these employees were engaged in basic research and development, 151 in manufacturing, 70 in clinical research and development, regulatory affairs and quality assurance and 60 in administration, finance, management, information systems, marketing, corporate development and human resources. Twenty-six 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 28903 North Avenue Paine, Valencia, California 91355, and our telephone number at that address is

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(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.

Executive Officers of the Registrant

The following table sets forth our current executive officers and their ages as of December 31, 2014:

Name	Age	Position(s)
Hakan S. Edstrom	64	President, Chief Executive Officer and Director
Matthew J. Pfeffer	57	Corporate Vice President and Chief Financial Officer
Juergen A. Martens, Ph.D.	59	Corporate Vice President, Chief Operating Officer
Diane M. Palumbo	61	Corporate Vice President, Human Resources
David B. Thomson, Ph.D., J.D	48	Corporate Vice President, General Counsel and Secretary

Hakan S. Edstrom has served as our president and one of our directors since 2001 and as our chief executive officer since January 2015. From 2001 until January 2015, he also served as our Chief Operating Officer. Mr. Edstrom was with Bausch & Lomb, Inc., a health care product company, from January 1998 to April 2001, advancing to the position of Senior Corporate Vice President and President of Bausch & Lomb, Inc. Americas Region. From 1981 to 1997, Mr. Edstrom was with Pharmacia Corporation, where he held various executive positions, including President and Chief Executive Officer of Pharmacia Ophthalmics Inc. Mr. Edstrom was educated in Sweden and holds a master s degree in Business Administration from the Stockholm School of Economics.

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

Prior to that, Mr. Pfeffer served in a variety of financial management positions at other companies, including roles as Corporate Controller, Manager of Internal Audit and Manager of Financial Reporting. Mr. Pfeffer began his career at Price Waterhouse. Mr. Pfeffer graduated from the University of California, Berkeley and is a Certified Public Accountant.

Juergen A. Martens, Ph.D. has been our Chief Operating Officer since January 2015 and, before that, was our Corporate Vice President of Operations and Chief Technology Officer since September 2005. From 2000 to August 2005, he was employed by Nektar Therapeutics most recently as Vice President of Pharmaceutical

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Technology Development. Previously, he held technical management positions at Aerojet Fine Chemicals from 1998 to 2000 and at FMC Corporation from 1996 to 1998. From 1987 to 1996, Dr. Martens held a variety of management positions with increased responsibility in R&D, plant management, and business process development at Lonza, in Switzerland and in the United States. Dr. Martens holds a bachelor s degree in chemical engineering from the Technical College Mannheim/Germany, a bachelor s and master s degree in Chemistry and a doctorate in Physical Chemistry from the University of Marburg/Germany.

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

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

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

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

You should consider carefully the following information about the risks described below, together with the other information contained in this Annual Report before you decide to buy or maintain an investment in our common stock or other securities. 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 and other securities could decline, and you may lose all or part of the money you paid to buy our common stock or other securities.

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. On August 11, 2014, we executed the Sanofi License Agreement, which became effective on September 23, 2014. Pursuant to the Sanofi License Agreement, Sanofi is responsible for global commercial, regulatory and development activities for AFREZZA and we are responsible for manufacturing AFREZZA at our facility in Danbury, Connecticut to supply Sanofi s demand for the product. On February 3, 2015, we and Sanofi announced that AFREZZA had become available by prescription in United States retail pharmacies. We and Sanofi 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 and Sanofi, ultimately may be unable to gain market acceptance of AFREZZA for a variety of reasons, including the treatment and dosage regimen, potential adverse effects, the availability of alternative treatments and lack of coverage or adequate reimbursement. If we fail to commercialize AFREZZA successfully, our business, financial condition and results of operations will be materially and adversely affected.

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,

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clinical and other testing prior to seeking regulatory approval to market them. Accordingly, these product candidates will not be commercially available for a number of years, if at all.

A significant portion of the research that we have conducted involves new 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 are dependent on our collaboration with Sanofi to further develop and to commercialize AFREZZA worldwide. This collaboration places the development and commercialization largely outside our control, and poor performance under or failure to maintain the collaboration agreement between us and Sanofi 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 entered into the Sanofi License Agreement to provide for the future development and commercialization of AFREZZA. We cannot be certain that our collaboration with Sanofi will continue for as long as there is a potential market for AFREZZA. Both we and Sanofi have certain rights to terminate the collaboration agreement, in certain circumstances, including a right by Sanofi to terminate the agreement upon specified prior written notice. If the agreement is terminated prior to the end of the commercial life of AFREZZA, we may not be able to find another collaborator for the development and commercialization of AFREZZA, and even if we elected to pursue further development and commercialization of AFREZZA on our own, we might not be able to do so successfully and would experience substantially increased capital requirements that we might not be able to fund. Our dependence on Sanofi and the Sanofi License Agreement subjects us to a number of risks, including:

Sanofi may not perform as expected and we may not be able to control the amount and timing of resources that Sanofi may devote to the development or commercialization of AFREZZA; moreover, Sanofi may elect to prioritize its other insulin products over AFREZZA;

we and Sanofi could disagree as to commercialization and development plans and Sanofi may delay clinical trials or stop a clinical trial;

there may be disputes between us and Sanofi, including disagreements regarding the Sanofi License Agreement, that may result in (a) the delay of (or prevent entirely) the achievement of regulatory and commercial objectives that would result in milestone payments, (b) the delay or termination of the development or commercialization of AFREZZA, and/or (c) costly litigation or arbitration that diverts our management s attention and resources;

Sanofi may not comply with applicable regulatory guidelines with respect to the development or commercialization of AFREZZA, which could adversely impact the development of or sales of AFREZZA and 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;

Sanofi may not provide us with timely and accurate information regarding sales activities and supply forecasts, which could adversely impact our ability to comply with our manufacturing and supply obligations under our supply agreement with Sanofi and our and Sanofi s ability to commercialize AFREZZA;

Sanofi may experience financial difficulties;

business combinations or significant changes in Sanofi s business strategy may also adversely affect Sanofi s ability to perform its obligations under the Sanofi License Agreement;

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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; and

notwithstanding the non-competition requirements in the Sanofi License Agreement, Sanofi could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors.

Any failure of Sanofi to adequately perform its obligations under the Sanofi License Agreement or the termination of such agreement 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 have a history of operating losses, we expect to continue to incur losses and we may never generate positive cash flow from operations.

We have never been profitable or generated positive cash flow from cumulative operations to date and, as of December 31, 2014, we had an accumulated deficit of $2.5 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 support the commercialization of AFREZZA, including costs and expenses to manufacture AFREZZA on a commercial scale. In addition, we have agreed to purchase annual minimum quantities of insulin under the Insulin Supply Agreement with Amphastar in the aggregate of approximately 120.1 million in calendar years 2015 through 2019. We may not have the necessary capital resources on hand in order to service this contractual commitment, and we may become obligated to make additional payments under the Insulin Supply Agreement in the event of its termination under certain scenarios. Our cumulative net loss may therefore increase significantly.

To date, we have received cash payments from Sanofi but have deferred revenue recognition of such payments. We will continue to defer revenue recognition of future milestone payments as and to the extent appropriate under applicable revenue recognition rules. Accordingly, even if we continue to earn and receive milestone payments, revenue recognition may continue to be deferred and our cumulative net loss may therefore be higher than it would be if we recognized the full amount of the milestone payments upon receipt.

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, 2014, we had stockholders deficit of $73.8 million. Our ability to achieve and sustain positive cash flow from operations and profitability depends upon successfully commercializing AFREZZA in collaboration with Sanofi. We may not generate positive cash flow from operations or be profitable even if we succeed in commercializing any of our product candidates. As a result, we cannot be sure when we will generate positive cash flow from operations or become profitable, if at all.

In the future we may need to raise additional capital to fund our operations.

In the future, we may 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 related to the commercialization of AFREZZA and the development of other product candidates. It may be difficult for us to raise additional funds on favorable terms, or at all. As of December 31, 2014, we had stockholders deficit of $73.8 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 election of any or all of the holders of our 5.75% Senior Convertible Notes due 2015 (the 2015 notes), the 9.75% Senior Convertible Notes due 2019 issued to Deerfield Private Design Fund II, L.P. (Deerfield Private Design Fund) and Deerfield Private Design International II, L.P. (collectively, 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;

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our ability to repay or refinance existing indebtedness, including indebtedness under the 2015 notes which mature in August 2015; and the extent to which the 2015 notes or any other convertible debt securities we may issue are converted into 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 and pursuant to the Milestone Rights Purchase Agreement dated July 1, 2013 (the Milestone Agreement);

our obligation to bear our share of net losses under the Sanofi License Agreement;

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

the degree of success in commercializing AFREZZA;

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;

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, including sales of our common stock through our at-the-market sales agreements, 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 may dilute their ownership percentage. Moreover, the establishment of other funding facilities may impose restrictions on our operations. These restrictions could include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. We also may seek to raise additional capital by pursuing opportunities for the licensing or sale of certain intellectual property and other assets. We cannot offer assurances, however, that any strategic collaborations, sales of securities or sales or licenses of assets will be available to us on a timely basis or on acceptable terms, if at all. We may be required to enter into relationships with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop independently, and any such relationships may not be on terms as commercially favorable to us as might otherwise be the case.

In the event that sufficient additional funds are not obtained through strategic collaboration opportunities, sales of securities, funding facilities, licensing arrangements and/or asset sales on a timely basis, we may be required to reduce expenses through the delay, reduction or curtailment of our projects, or further reduction of costs for facilities and administration. 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, including, among other things, delays in manufacturing AFREZZA on a commercial scale, will not result in the depletion of our capital

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resources more rapidly than we currently anticipate, in which case we may be required to raise additional capital. There can be no assurances that we will be able to raise additional capital, if needed, on favorable terms, or at all. If we need but cannot raise adequate additional capital in the future 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 could be substantial doubt about our ability to continue as a going concern.

We have a substantial amount of debt pursuant to the 2015 notes, 2019 notes, Tranche B notes, and our loan arrangement with The Mann Group LLC, may incur additional indebtedness under such loan arrangement as well as the Sanofi Loan Facility and may be unable to make required payments of interest and principal as they become due.

As of December 31, 2014, we had $229.5 million principal amount of outstanding debt, consisting of:

- $100.0 million principal amount of 2015 notes bearing interest at 5.75% per annum and maturing on August 15, 2015;
- $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, the balance of which is due and payable in December 2019; and
- $49.5 million principal amount of indebtedness 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 Loan Arrangement) bearing interest at 5.84% and maturing and due on January 5, 2020.

In addition, we may borrow up to an aggregate $175.0 million pursuant to the Sanofi Loan Facility to fund our share of net losses under the Sanofi License Agreement, $3.0 million, and an additional $30.1 million under the Loan Arrangement. There can be no assurance that we will have sufficient resources to make any required repayments of principal under the 2015 notes, 2019 notes or Tranche B notes when required. Further, if we undergo a fundamental change, as that term is defined in the indentures governing the terms of the 2015 notes, or certain Major Transactions as defined in our facility agreement with Deerfield dated July 1, 2013 (as amended, 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 2015 notes bear interest at the rate of 5.75% per year on the outstanding principal amount, payable in cash semiannually in arrears on February 15 and August 15 of each year, and the 2019 notes bear interest at the rate of 9.75% per year on the outstanding principal amount, payable in cash quarterly in arrears on the last business day of March, June, September and December of each year. The Tranche B notes bear interest at the rate of 8.75% on the outstanding principal amount, 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 2015 notes, 2019 notes, Tranche B notes, or on the loans under the Sanofi Loan Facility, or if we fail to repay or repurchase the 2015 notes, 2019 notes, Tranche B notes, or the loans under the Sanofi Loan Facility when required, we will be in default under the indenture 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.

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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 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 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

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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 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 2015 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 2015 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 announce and 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 announce and 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.

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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 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 our 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

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of insulin for AFREZZA is manufactured by Amphastar. We must rely on our suppliers, including Amphastar, to comply with relevant regulatory and other legal requirements, including the production of insulin in accordance with the FDA s current Good Manufacturing Practices (cGMPs) for drug products, and the production of the AFREZZA inhaler and related cartridges in accordance with Quality System Regulations (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 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. Pursuant to our supply agreement with Sanofi, we are required to identify alternative suppliers for all critical raw materials for the manufacture of AFREZZA within two years after the date of the agreement. However, there can be no assurance that we will be able to identify and qualify such suppliers within the time period required under the agreement. 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.

We have little experience manufacturing AFREZZA in commercial quantities, and 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, and could result in the termination of the Sanofi License Agreement by Sanofi at its election if specified circumstances exist and certain conditions are met.

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 our other product candidates may not gain market acceptance among physicians, patients, third-party payors and the healthcare community. Failure to achieve market acceptance would limit our ability to generate revenue and would adversely affect our results of operations.

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

approved labeling claims;

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effectiveness of efforts by us or our 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;

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 reform proposals or legislation. Such reforms may limit our ability to generate revenues from sales of AFREZZA or our other product candidates and achieve profitability. Further, to the extent that such reforms have a material adverse effect on the business, financial condition and profitability of our marketing partner 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 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 would be required to provide scientific and clinical support for the use of any product to each third-party payor separately with no assurance that approval would be obtained. This process could delay the market acceptance of any product and could have a negative effect on our future revenues and operating results. Even if we succeed in bringing 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

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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 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 our marketing partner 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 our 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. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, PPACA), became law in the United States. PPACA substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the healthcare industry. Among the provisions of PPACA of importance to 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;

- 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,

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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;

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.

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 will stay in effect through 2024 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. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

We expect that PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private 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 our marketing partner 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, 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, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

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

the federal Health Insurance Portability and Accountability Act of 1996 (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 the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

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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. In addition, we carry local clinical trial insurance policies per study in each country in which we conduct clinical studies that require us to carry coverage based on local statutory requirements. 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 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

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the areas of manufacturing. 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.

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. We cannot assure you that we or our independent registered public accounting firm will not identify a material weakness in our internal controls in the future. A material weakness in our internal controls over financial reporting would require management and our independent registered public accounting firm to evaluate our internal controls as ineffective. If our internal controls over financial reporting are not considered effective, we may experience a loss of public confidence, which could have an adverse effect on our business, 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

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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.

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

We expect that at least for the foreseeable future, our manufacturing facility in Danbury, Connecticut will be the sole location for the manufacturing of AFREZZA. This facility and the manufacturing equipment we use would be costly to replace and could require substantial lead time to repair or replace. In addition, we are headquartered in Valencia, California. This facility contains our principal executive offices and is used to provide support for the development of our Technosphere technology programs. We depend on our facilities and on collaborators, contractors and vendors for the continued operation of our business, some of whom are located in 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 and adversely affect, which may include stopping, our readiness for commercial production.

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

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

When we purchased the facilities located in Danbury, Connecticut in 2001, 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

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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:

- 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.

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

Even if we comply with regulatory requirements, we may not be able to obtain the labeling claims necessary or desirable for product promotion. We may also be required to undertake post-marketing studies. For example, the FDA is requiring the following post-marketing studies for AFREZZA:

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

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); and

two pharmacokinetic-pharmacodynamic studies, one to characterize dose-response and one to characterize within-subject variability.

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.

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.

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.

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 inspection by the FDA. There can be no assurance, in the conduct of an inspection of any of our suppliers that the agency would find that the supplier substantially complies with the QSR or cGMP requirements, where applicable. If we or any potential third-party manufacturer or supplier fails to comply with these requirements or comparable requirements in foreign countries, regulatory authorities may subject us to regulatory action, including criminal prosecutions, fines and suspension of the manufacture of our products.

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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 our other product candidates.

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, 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 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 United States Patent and Trademark Office (USPTO) is continuing to develop

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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, many changes have only recently become effective. 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. 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. Litigation, post-grant review, or interference proceedings may fail and, even if successful, may result in substantial costs and be a distraction to our management. We may not be able, alone or with our collaborators and licensors, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. We may not prevail in any litigation, post-grant review, or interference proceeding in which we are involved. Even if we do prevail, these proceedings can be very expensive and distract our management.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public

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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 upon the commercial manufacture and sale of AFREZZA. If a court were to determine that AFREZZA was infringing any of these patent rights, we would have to establish with the court that these patents were invalid or unenforceable in order to avoid legal liability for infringement of these patents. However, proving patent invalidity or unenforceability can be difficult because issued patents are presumed valid. Therefore, in the event that we are unable to prevail in a non-infringement or invalidity action we will have to either acquire the third-party patents outright or seek a royalty-bearing license. Royalty-bearing licenses effectively increase production costs and therefore may materially affect product profitability. Furthermore, should the patent holder refuse to either assign or license us the infringed patents, it may be necessary to cease manufacturing the product entirely and/or design around the patents, if possible. In either event, our business, 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

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

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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 upon conversion of any shares under the 2015 notes. 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.

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

- the progress of the commercial launch of AFREZZA and other events or circumstances that we or others estimate will impact the future commercialization of AFREZZA;
- our or Sanofi s future estimates of AFREZZA sales, prescriptions or other operating metrics;
- the progress and results of our preclinical and clinical studies of our product candidates and the post-approval studies of AFREZZA required by the FDA;
- 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;
- developments or disputes concerning our collaboration with Sanofi or our relationships with 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;

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

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

discussion of AFREZZA, our other product candidates, competitors products, or our stock price by the financial and scientific press, the healthcare community and online investor communities such as chat

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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 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 and companies included on The NASDAQ Global Market in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. There has been particular volatility in the market prices of securities of biotechnology and other life sciences companies, and the market prices of these companies have often fluctuated because of problems or successes in a given market segment or because investor interest has shifted to other segments. These broad market and industry factors may cause the market price of our common stock 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.

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

At December 31, 2014, Alfred E. Mann our Executive Chairman and principal stockholder beneficially owned approximately 37.7% of our outstanding shares of capital stock. By virtue of his holdings, Mr. Mann may be able to heavily influence elections of directors, our management and our affairs and prevent corporate transactions such as mergers, consolidations or the sale of all or substantially all of our assets that may be favorable from our standpoint or that of our other stockholders or cause a transaction that we or our other stockholders may view as unfavorable.

Subject to compliance with United States federal and state securities laws, Mr. Mann is free to sell the shares of our stock he holds at any time. Upon his death, we have been advised by Mr. Mann that his shares of our capital stock will be left to the Alfred E. Mann Medical Research Organization (AEMMRO), and AEM Foundation for Biomedical Engineering (AEMFBE), not-for-profit medical research foundations that serve as funding organizations for Mr. Mann s various charities, including the Alfred Mann Foundation (AMF), and the Alfred Mann Institutes at the University of Southern California, the Technion-Israel Institute of Technology, and Purdue University, and that may serve as funding organizations for any other charities that he may establish. The AEMMRO is a membership foundation consisting of nine members, including Mr. Mann, his wife, three of his children and Dr. Joseph Schulman, the chief scientist of the AEMFBE. The AEMFBE is a membership foundation consisting of five members, including Mr. Mann, his wife, and the same three of his children. Although we understand that the members of AEMMRO and AEMFBE have been advised of Mr. Mann s objectives for these foundations, once Mr. Mann s shares of our capital stock become the property of the foundations, we cannot assure you as to how those shares will be distributed or how they will be voted.

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The future sale of our common stock, the conversion of our 2015 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 23, 2015, we had 408,837,603 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 conversion of some or all of our 2015 notes, or upon the exercise of some or all of the warrants we issued in February 2012, 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 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 December 31, 2014, we had a total of 76,326,082 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 2015 notes. As a result, our ability to issue shares of common stock other than pursuant to existing

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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.

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, filling and packaging. We believe the Danbury facility will have sufficient space to satisfy potential commercial demand for the launch of AFREZZA and, with the expansion completed, the first few years thereafter for AFREZZA and other AFREZZA-related products.

We own and occupy approximately 142,000 square feet of laboratory, office and warehouse space in Valencia, California. The facility contains our principal executive offices.

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 lease approximately 23,000 square feet of office space in Paramus, New Jersey pursuant to a lease that expires in May 2015. The facility houses our medical, regulatory affairs, clinical operations and administrative staff.

Item 3. ***Legal Proceedings***

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

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, 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
Year ended December 31, 2013		
First quarter	$ 3.67	$ 2.32
Second quarter	$ 8.06	$ 3.39
Third quarter	$ 8.70	$ 5.37
Fourth quarter	$ 5.84	$ 4.21

The closing sales price of our common stock on The NASDAQ Global Market was $6.72 on February 23, 2015 and there were 197 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.

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, 2009, in (i) our common stock, (ii) the securities comprising The NASDAQ Composite Index and (iii) the securities comprising The NASDAQ Biotechnology Index.

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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.

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

The following selected consolidated financial data should be read in conjunction with our consolidated financial statements and notes thereto and with Management s Discussion and Analysis of Financial Condition and Results of Operations, which are included elsewhere in this Annual Report on Form 10-K. The selected financial data included in this section are not intended to replace our audited financial statements and the related notes included elsewhere in this Annual Report.

	Year Ended December 31,				
Statement of Operations Data:	**2014**	**2013**	**2012**	**2011**	**2010**
	(In thousands, except per share amounts)				
Revenue	$	$	$ 35	$ 50	$ 93
Operating expenses:					
Research and development	100,244	109,719	101,522	99,959	112,279
General and administrative	79,383	59,682	45,473	40,630	40,312
Total operating expenses	179,627	169,401	146,995	140,589	152,591
Loss from operations	(179,627)	(169,401)	(146,960)	(140,539)	(152,498)
Other income (expense)	1,679	(635)	(1,191)	1,541	(725)
Interest expense on note payable to principal stockholder	(2,894)	(6,309)	(10,491)	(10,883)	(10,249)
Interest expense on senior convertible notes	(17,549)	(15,153)	(11,139)	(10,941)	(7,128)
Interest income	9	8	7	18	40
Loss before provision for income taxes	(198,382)	(191,490)	(169,774)	(160,804)	(170,560)
Income taxes			408		
Net loss	$ (198,382)	$ (191,490)	$ (169,366)	$ (160,804)	$ (170,560)
Basic and diluted net loss per share	$ (0.51)	$ (0.64)	$ (.94)	$ (1.32)	$ (1.50)
Shares used to compute basic and diluted net loss per share	385,229	299,591	180,855	121,817	113,672

	December 31,				
Balance Sheet Data:	**2014**	**2013**	**2012**	**2011**	**2010**
	(In thousands)				
Cash and cash equivalents	$ 120,841	$ 70,790	$ 61,840	$ 2,681	$ 66,061
Total assets	394,439	258,646	251,314	199,553	277,256
Senior convertible notes	99,355	98,439	212,026	210,642	209,335
Facility financing obligation	72,995	102,300			
Note payable to our principal stockholder	49,521	49,521	119,635	277,203	235,319
Accumulated deficit	(2,494,784)	(2,296,402)	(2,104,912)	(1,935,546)	(1,774,742)
Total stockholders deficit	(73,770)	(30,713)	(110,679)	(313,652)	(185,532)

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 candidate, AFREZZA, is a rapid-acting inhaled insulin t that was approved by the FDA on June 27, 2014 to improve glycemic control in adult patients with diabetes.

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As of December 31, 2014, we had an accumulated deficit of $2.5 billion and a stockholders deficit of $73.8 million. We incurred net losses of approximately $198.4 million, $191.5 million, and $169.4 million in the years ended December 31, 2014, 2013, and 2012, respectively. Through December 31, 2014, we have not generated any product revenues and have funded our operations through the sale of equity securities and convertible debt securities, borrowings under the Facility Agreement, and borrowings under the Loan Arrangement. As discussed below in Liquidity and Capital Resources, if we are unable to obtain additional funding in the future, there could be substantial doubt about our ability to continue as a going concern.

Our business is subject to significant risks, including but not limited to our ability to support the commercialization of AFREZZA through our marketing partner, Sanofi, by manufacturing sufficient quantities of AFREZZA to meet Sanofi s demands in a timely and cost-efficient manner, Sanofi s ability to successful market and sell AFREZZA, Sanofi s ability to obtain regulatory approval for AFREZZA outside of the United States, and the risks inherent in our ongoing clinical trials and the regulatory approval process. 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 manufacturing startup costs and the clinical trials of our product candidates that have not yet received regulatory approval for marketing and for which no alternative future use has been identified. This includes the salaries, benefits and stock-based compensation of research and development personnel, raw materials, such as insulin purchases, laboratory supplies and materials, facility costs, costs for consultants and related contract research, licensing fees, and depreciation of equipment. We track research and development costs by the type of cost incurred. We partially offset research and development expenses with the recognition of estimated amounts receivable from the State of Connecticut pursuant to a program under which we can exchange qualified research and development income tax credits for cash.

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

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.

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.

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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.

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. Given that, as of December 31, 2014, 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, we believe the fixed and determinable fee requirement for revenue recognition was not met.

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. We periodically analyzes 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.

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.

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

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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.

Commitment Asset

In connection with the issuance of the first tranche of the 2019 notes and the Milestone Rights, we recorded a commitment asset (the Commitment Asset) on July 1, 2013. The Commitment Asset represents the right to receive additional funding under future tranches of 2019 notes pursuant to the Facility Agreement. The initial value of the Commitment Asset was calculated using the income approach by estimating the fair value of the future tranches using a market debt rate commensurate with the risk of the future tranches and the fair value of the cash expected to be received by us and by assessing the probability of the commitments being funded in the future based on the operational hurdles required for funding being met. The Commitment Asset attributable to each future tranche of 2019 notes under the Facility Agreement is derecognized and recorded as a debt discount on the 2019 notes when issued. The debt discount is amortized using the effective interest rate method over the life of the 2019 notes. Prior to derecognition occurring, we monitor the Commitment Asset on an ongoing basis to determine whether an impairment indicator is present that would result in a full or partial write down of the Commitment Asset as a result of events that may lead to the subsequent tranches of 2019 notes not being issued. On December 30, 2014, we elected not to draw on the $70.0 million of funding remaining under the Facility Agreement, as amended, from the sale of the Tranche B notes. Consequently, the remaining carrying value of the Tranche B Commitment Asset of $1.8 million was written off.

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.

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

Clinical Trial Expenses

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

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.

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 our estimated volatility rate. Implied volatility is now considered due to the change in our 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 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.

Forward Contracts

In February and October 2012, we entered into agreements with The Mann Group whereby we agreed to sell and The Mann Group agreed to purchase common stock and/or warrants. These agreements have been accounted for as forward contracts, having met the definition of derivative instruments in accordance with the provisions of ASC 815. We determine the fair value of the forward contract upon its issuance, record fair value adjustments of the forward contract to Other income (expense) during the reporting period and through the settlement of the

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forward contract, and reclassify the forward contract to equity upon settlement of the forward contract. The fair value of the forward purchase contract is highly sensitive to the discount applied for lack of marketability and the stock price, and changes in this discount and/or the stock price could cause the value of the forward purchase contract to change significantly. In the years ended December 31, 2014 and 2013, there were no forward purchase contracts.

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, 2014, we had established a valuation allowance of $882.5 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, 2014 and 2013

Revenues

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

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 is offset by $4.4 million increased 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 modification and settlement of value during 2014 for certain performance awards. 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.

We anticipate that our overall research and development expenses will decrease in 2015 compared to 2014 due to manufacturing efforts related to the Sanofi License Agreement and pursuing new product opportunities.

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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 increased 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 $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 $1.5 million resulting from the net effect of $12.6 million in increased stock-based compensation expense due to the modification 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.

We expect general and administrative expenses to decrease in 2015 as compared to 2014 due to a decrease in professional fees and stock-based compensation expense.

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.

Years ended December 31, 2013 and 2012

Revenues

During the years ended December 31, 2013 we recognized no revenue and during the year ended December 31, 2012, we recognized $35,000 in revenue under a license agreement.

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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, 2013 and 2012 (dollars in thousands):

	Year Ended December 31,			
	2013	2012	$ Change	% Change
Clinical	$ 42,711	$ 47,936	$ (5,225)	(11)%
Manufacturing	40,530	40,094	436	1%
Research	6,351	7,614	(1,263)	(17)%
Research and development tax credit	(282)	(289)	7	(2)%
Stock-based compensation expense	20,409	6,167	14,242	231%
Research and development expenses	$ 109,719	$ 101,522	$ 8,197	8%

The increase in research and development expenses for the year ended December 31, 2013 compared to the year ended December 31, 2012 was driven by an increase in stock-based compensation expense of $14.2 million in connection with company-wide performance-based grants in the first and second quarters of 2013, as well as a full year of expense from grants in early 2012, and the achievement of certain milestones in the fourth quarter of 2013. This increase is offset by a decrease of $5.2 million in clinical study related expenses from the completion of two Phase 3 studies in the second quarter of 2013, and $1.3 million in reduced research expenses resulting from the positive effect of our cost cutting measures in addition to decreasing efforts in other non-AFREZZA related research as we focused on our primary objective of gaining approval of AFREZZA.

General and Administrative Expenses

The following table provides a comparison of the general and administrative expense categories for the years ended December 31, 2013 and 2012 (dollars in thousands):

	Year Ended December 31,			
	2013	2012	$ Change	% Change
Salaries, employee related and other general expenses	$ 34,905	$ 38,348	$ (3,443)	(9)%
Stock-based compensation expense	24,777	7,125	17,652	248%
General and administrative expenses	$ 59,682	$ 45,473	$ 14,209	31%

General and administrative expenses for the year ended December 31, 2013 increased as compared to the prior year driven by an increase in stock-based compensation expense of $17.7 million in connection with company-wide performance-based grants to all employees, in the first and second quarters of 2013, as well as a full year of expense from grants in early 2012, and the achievement of certain milestones in the fourth quarter of 2013. This increase was partially offset by a $4.2 million decrease in legal and professional fees.

Other Income (Expense)

Other expense for the year ended December 31, 2013 was $0.6 million as compared to other expense of $1.2 million for the year ended December 31, 2012. In 2013, other expense reflects the loss on conversion of debt to equity at the end of 2013 related to the conversion of 2019 notes in accordance with the Facility Agreement. In 2012, other expense reflects the adjustment in fair value of forward purchase contracts with our principal stockholder.

Interest Income and Expense

Interest expense for the year ended December 31, 2013 was relatively consistent compared to the year ended December 31, 2012, due to lower interest expense on our note payable to our principal stockholder in 2013 as a result of a lower carrying value being offset by higher interest

expense associated with the 2019 notes issued in 2013.

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Liquidity and Capital Resources

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

As of December 31, 2014, we had $229.5 million principal amount of outstanding debt, consisting of:

- $100.0 million principal amount of 2015 notes bearing interest at 5.75% per annum and maturing on August 15, 2015;
- $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, the balance of which is due and payable in December 2019; and
- $49.5 million principal amount of indebtedness 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 Loan Arrangement) bearing interest at 5.84% and maturing and due on January 5, 2020.

As of December 31, 2014, the amount available for future borrowings under the Loan Arrangement was $30.1 million. 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 Loan Arrangement.

In addition, we may borrow up to an aggregate $175.0 million pursuant to the Sanofi Loan Facility to fund our share of net losses under the Sanofi License Agreement. Subsequent to December 31, 2014, we borrowed $3.0 million under the Sanofi Loan Facility to settle the corresponding portion of the loss, which was reclassified from current deferred payments from collaboration to other long term liabilities. 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 Agreement.

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 third quarter of 2014, the first milestone triggering event was achieved following our entry into the Sanofi License Agreement. In connection with the milestone triggering event, we paid a $5.0 million payment to Deerfield pursuant to the terms of the Milestone Agreement in the fourth quarter of 2014.

In March 2014, we entered into an At-The-Market Issuance Sales Agreement with MLV & Co. LLC (MLV) and an At-The-Market Issuance Sales Agreement with Meyers Associates, L.P. (doing business as Brinson Patrick, a division of Meyers Associates, L.P.) (Brinson Patrick). We refer to the foregoing agreements as the ATM Agreements. Under each ATM Agreement, we may issue or sell shares of our common stock having an aggregate offering price of up to $50.0 million from time to time through MLV or Brinson Patrick, as our sales agents, provided in no event may we sell more than $50.0 million of common stock under both agreements in the aggregate, and provided no sales may be made except pursuant to an effective registration statement. We expect that all or substantially all sales of our common stock made under the ATM Agreements will be made in at the market offerings as defined in Rule 415 of the Securities Act of 1933, as amended. We have not yet sold or issued any shares of our common stock under the ATM Agreements. There can be no assurance that we will be able to access capital through the ATM Agreements on a timely basis, or at all.

On August 11, 2014, we and Sanofi executed the Sanofi License Agreement, which subsequently became effective on September 23, 2014. Pursuant to the Sanofi License Agreement, we received a $150.0 million

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upfront payment and a subsequent $50.0 million in milestone payments upon satisfaction of certain manufacturing milestones specified in the Sanofi License Agreement. We are eligible to earn up to $725.0 million in further development, regulatory and sales milestones, and are also eligible to receive a share of profits on sales of AFREZZA. Worldwide profits and losses will be shared 65% by Sanofi and 35% by us. Pursuant to a separate supply agreement, we will manufacture AFREZZA at our manufacturing facility in Danbury, Connecticut to supply Sanofi s demand for AFREZZA. Pursuant to the Insulin Supply Agreement with Amphastar, we have agreed to purchase annual minimum quantities of insulin under the Insulin Supply Agreement of an aggregate total of approximately 120.1 million in calendar years 2015 through 2019.

During the year ended December 31, 2014, our operations provided $4.1 million of cash and we had a net loss of $198.4 million, which included $67.2 million of non-cash charges consisting of depreciation and accretion, and stock-based compensation. By comparison, during the year ended December 31, 2013, we used $128.7 million of cash for our operations and had a net loss of $191.5 million, which included $59.2 million of non-cash charges consisting of depreciation and accretion, and stock-based compensation. The operating cash outflow decreased by $132.8 million primarily due to the $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 Supply Agreement. For the year ended December 31, 2013, operating cash flow decreased by $10.6 million due to decreases in the following: accrued expenses associated with the clinical trials, accrued interest associated with our loan arrangement with The Mann Group due to the capitalization of the outstanding balance in October 2013, and accrued expenses related to equipment in 2013. As a result, cash used for operations for the years ended December 31, 2013 increased by $8.9 million compared to 2012. Going forward, we expect our operating cash flow to be negative at least until we achieve profitability with AFREZZA.

We used $24.1 million of cash for investing activities during the year ended December 31, 2014, compared to $8.0 million for the year ended December 31, 2013. The $16.1 million increase was due to in purchases of machinery and equipment for the preparation for commercialization of AFREZZA. For the year ended December 31, 2013, the cash used for investing activities increased by $7.4 million of which $8.0 was due to the purchase of machinery and equipment to expand our manufacturing operations and our quality systems that supported clinical trials for AFREZZA in 2013, as compared to $0.6 million of machinery and equipment purchased in 2012.

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 from $119.5 million in proceeds received from issuance of the 2019 notes and the Milestone Rights and $94.2 million net proceeds from warrants exercised. Additionally, there were $48.9 million in the net proceeds from use of our prior at-the market issuance sales agreements and on December 15, 2013, we paid $115.0 million to repay the 2013 notes upon maturity.

As of December 31, 2014, we had $120.8 million in cash and cash equivalents. We expect to continue to incur significant expenditures to support commercial manufacturing of AFREZZA and the development of other product candidates. In addition, the 2015 notes in the aggregate principal amount of $100.0 million have a maturity date of August 15, 2015, and payment on the outstanding amount is due in full, if not converted into common shares, on that date. Based upon our current operating plan, including our expectation that we will be able to convert or refinance the 2015 notes, we believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital requirements for at least the next 12 months. We may 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.

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However, we cannot provide assurances that such additional capital, if needed, will be available through these or other means.

We intend to use our capital resources to support the commercialization of AFREZZA. We are expending a portion of our capital resources to scale up our manufacturing capabilities in our Danbury facilities 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, including potentially sales of our common stock through the ATM Agreements, 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 could be substantial doubt about our ability to continue as a going concern.

Off-Balance Sheet Arrangements

As of December 31, 2014, we did not have any off-balance sheet arrangements.

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 2015 notes, the facility financing obligation, open purchase order and supply commitments, and contractual minimum purchase commitments under the Insulin Supply Agreement with Amphastar, and consisted of the following at December 31, 2014 (in thousands):

	Payments Due in				
Contractual Obligations	**Less Than One Year**	**1-3 Years**	**3-5 Years**	**More Than 5 Years**	**Total**
Open purchase order and supply commitments(1)	$ 39,135	$ 325	$ 650	$ 250	$ 40,360
2015 notes(2)	103,610				103,610
Note payable to principal stockholder(3)			64,243		64,243
Facility financing obligation(4)	7,600	62,753	37,338		107,691
Insulin supply agreement (5)	28,166	84,782	28,260		141,208
Operating lease obligations	348	25			373
Total contractual obligations	$ 178,859	$ 147,885	$ 130,491	$ 250	$ 457,485

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

(2) The amounts include future interest payments at fixed rates of 5.75% and payment of the 2015 notes in full upon maturity in 2015.

(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, 2014. 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 an aggregate total purchase price of approximately 120.1 million for calendar years 2015 through 2019. Future payments due were converted to U.S. dollars using the December 31, 2014 euro-to-dollar exchange.

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, a new standard was issued 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 new standard will replace most of the existing revenue recognition standards in U.S. GAAP when it becomes effective on January 1, 2017. Early adoption is not permitted. The new standard allows for either full retrospective adoption, whereby the new standard is applied to each prior reporting period presented or modified retrospective adoption, whereby the new standard is only applied to the most current period presented with the cumulative effect of the change recognized at the date of the initial application. We are assessing the potential impact of the new standard on its consolidated statements of financial position and results of operations and comprehensive income (loss) and has not yet selected a transition method.

In June 2014, the FASB issued ASU No. 2014-10, Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation. The amendments in this ASU remove all incremental financial reporting requirements from GAAP for development stage entities, including the removal of Topic 915, Development Stage Entities, from the FASB Accounting Standards Codification. In addition, the ASU: (a) adds an example disclosure in Topic 275, Risks and Uncertainties, to illustrate one way that an entity that has not begun planned principal operations could provide information about the risks and uncertainties related to the company s current activities; and (b) removes an exception provided to development stage entities in Topic 810, Consolidation, for determining whether an entity is a variable interest entity. The presentation and disclosure requirements in Topic 915 will no longer be required for the first annual period beginning after December 15, 2014. The revised consolidation standards are effective one year later, in annual periods beginning after December 15, 2015. Early adoption is permitted. We early adopted ASU 2014-10 resulting in the elimination of certain presentation and disclosure requirements previously required by topic 915.

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On August 27, 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.

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

We are exposed to market risk related to changes in interest rates impacting our short-term investment portfolio as well as the interest rate on the promissory note underlying our Loan Arrangement with The Mann Group, Senior Convertible Notes due 2015, Tranche 1 and Tranche 4 notes, and Tranche B notes.

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 our Loan Arrangement with The Mann Group for the year ended December 31, 2014 was a fixed rate equal to 5.84%. As of December 31, 2014, the total principal amount outstanding under the Loan Arrangement was $49.5 million. We also have debt related to our Senior Convertible Notes due 2015 at a fixed interest rate of 5.75%, debt related to the Tranche 1 and Tranche 4 notes at a fixed interest rate of 9.75%, and debt related to the Tranche B notes at a fixed interest rate of 8.75%.

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, 2014 were to have occurred, this change would not have had a material effect on the value of our short-term investment portfolio or on our interest expense obligations with respect to outstanding borrowed amounts.

Foreign Currency Exchange Risk

We will incur significant expenditures for insulin supply obligation under our supply agreement with Amphastar. Such obligations are denominated in the euros. At the end of each reporting period, these liabilities 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. If in 2014 we had been 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, 2014 were to have occurred on December 31, 2014, 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.

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

None.

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

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of December 31, 2014. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2014, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable assurance level.

Management s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act as a process designed by, or under the supervision of, a company s principal executive and principal financial officers and effected by a 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 U.S. GAAP. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework set forth in *Internal Control Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework set forth in *Internal Control Integrated Framework (2013)*, our management concluded that our internal control over financial reporting was effective as of December 31, 2014. Deloitte & Touche LLP, the independent registered public accounting firm that audited the financial statements included in this 2014 Form 10-K, has issued an attestation report on our internal control over financial reporting as of December 31, 2014, which is included herein.

Changes in Internal Control Over Financial Reporting

In June 2014, we obtained approval from the U.S. Food and Drug Administration to sell our first product, AFREZZA. Effective September 23, 2014 we also entered in to the Sanofi License Agreement, Sanofi Supply Agreement, Sanofi Loan Facility and we commenced commercial manufacturing in the fourth quarter of 2014. We have designed and implemented new processes and internal controls to address collaboration arrangements and inventory to ensure that information required to be disclosed by us is recorded, processed, summarized and reported. The addition of these new control processes is considered a material change in our system of internal controls 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, 2014, 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.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, 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, 2014 of the Company and our report dated March 2, 2015 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 2, 2015

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

None

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K, because we will file our Proxy Statement within 120 days after the end of our fiscal year ended December 31, 2014 pursuant to Regulations 14A for our 2015 Annual Meeting of Stockholders, and the information included in the Proxy Statement is incorporated herein by reference.

Item 10. ***Directors, Executive Officers and Corporate Governance.***

(a) *Executive Officers* For information regarding the identification and business experience of our executive officers, see Executive Officers 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 this reference.

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

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

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

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

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

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PART IV

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

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

(1)(2) Financial Statements and Financial Statement Schedules. The following Financial Statements of MannKind Corporation, Financial Statement Schedules and Report of Independent Registered Public Accounting Firm are included in a separate section of this report beginning on page 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 MannKind s Current Report on Form 8-K (File No. 000-50865), originally filed with the SEC on July 1, 2013).
3.5	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).
4.2	Indenture, by and between MannKind and Wells Fargo Bank, N.A., dated August 24, 2010 (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), originally filed with the SEC on August 24, 2010).

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Exhibit Number	Description of Document
4.3	Form of 5.75% Senior Convertible Note due 2015 (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), originally filed with the SEC on August 24, 2010).
4.4	Form of Warrant to Purchase Common Stock issued February 8, 2012 (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), originally filed with the SEC on February 6, 2012).
4.5	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).
4.6	Form of Amended and Restated 9.75% Senior Secured Convertible Promissory Note due 2019 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).
4.9	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).
4.10	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).
4.11	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).
4.12	Facility Agreement, dated as of July 1, 2013, by and among MannKind Corporation, 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).
4.13	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 10.39).
4.14	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).
4.15	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).
4.15	Senior Secured Revolving Promissory Note, dated as of September 23, 2014, by and between MannKind Corporation 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).
4.17	Guaranty and Security Agreement, dated as of September 23, 2014, by and among MannKind Corporation, 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).

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Exhibit Number	Description of Document
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 Hakan Edstrom (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*	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).
10.9*	Executive Severance Agreement, dated October 10, 2007, between MannKind and Juergen Martens (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*	Executive Severance Agreement, dated October 10, 2007, between MannKind and Diane Palumbo (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*	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).
10.12*	Change of Control Agreement, dated October 10, 2007, between MannKind and Hakan Edstrom (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).
10.13*	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).
10.14*	Change of Control Agreement, dated October 10, 2007, between MannKind and Juergen Martens (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).
10.15*	Change of Control Agreement, dated October 10, 2007, between MannKind and Diane Palumbo (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).

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Exhibit Number	Description of Document
10.16*	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).
10.17*	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).
10.18*	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).
10.19*	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).
10.20*	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).
10.21*	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).
10.22**	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).
10.23**	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).
10.24	Share Lending Agreement, dated August 18, 2010, by and between MannKind and Bank of America, N.A. (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), filed with the SEC on August 24, 2010).
10.25	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).
10.26	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).
10.27*	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).
10.28*	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).
10.29*	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).
10.30*	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).

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Exhibit Number	Description of Document
10.31*	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).
10.32	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).
10.33	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).
10.34**	License and Collaboration Agreement, dated as of August 11, 2014, by and among MannKind Corporation, 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).
10.35**	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).
10.36**	Supply Agreement, dated as of July 31, 2014, by and between MannKind Corporation 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).
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (see signature page hereto).
31.1	Certification of the Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of the Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32	Certifications of the Chief Executive Officer and Chief Financial Officer pursuant to Rules 13a-14(b) and 15d-14(b) of the Securities Exchange Act of 1934, as amended and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).
101	Interactive Data Files pursuant to Rule 405 of Regulation S-T.

* Indicates management contract or compensatory plan.

** 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/ Hakan S. Edstrom
Hakan S. Edstrom
President, Chief Executive Officer and Director

Dated: March 2, 2015

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Hakan S. Edstrom, 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/ Hakan S. Edstrom Hakan S. Edstrom	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 2, 2015
/s/ Matthew J. Pfeffer Matthew J. Pfeffer	Corporate Vice President and Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 2, 2015
/s/ Alfred E. Mann Alfred E. Mann	Executive Chairman of the Board of Directors	March 2, 2015
/s/ Ronald J. Consiglio Ronald J. Consiglio	Director	March 2, 2015
/s/ Michael Friedman Michael Friedman, M.D.	Director	March 2, 2015
/s/ Kent Kresa	Director	March 2, 2015

Kent Kresa		
/s/ David H. MacCallum David H. MacCallum	Director	March 2, 2015
/s/ Henry L. Nordhoff Henry L. Nordhoff	Director	March 2, 2015

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MANNKIND CORPORATION AND SUBSIDIARIES

INDEX TO FINANCIAL STATEMENTS

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of MannKind Corporation

Valencia, California

We have audited the accompanying consolidated balance sheets of MannKind Corporation and subsidiaries (the Company) as of December 31, 2014 and 2013 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, 2014. 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, 2014 and 2013, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2014, 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, 2014, 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 2, 2015 expressed an unqualified opinion on the Company s internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Los Angeles, California

March 2, 2015

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MANNKIND CORPORATION AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2014	2013
	(In thousands, except share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 120,841	$ 70,790
Receivables from collaboration	50,436	
Inventory	9,670	
Prepaid expenses and other current assets	20,206	5,485
Total current assets	201,153	76,275
Property and equipment net	192,127	176,557
State research and development credit exchange receivable net of current portion	311	298
Other assets	848	5,516
Total	$ 394,439	$ 258,646
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 7,394	$ 3,860
Accrued expenses and other current liabilities	26,206	21,634
Facility financing obligation	72,995	102,300
Senior convertible notes	99,355	
Deferred payments from collaboration	197,403	
Total current liabilities	403,353	127,794
Senior convertible notes		98,439
Note payable to principal stockholder	49,521	49,521
Other liabilities	15,335	13,605
Total liabilities	468,209	289,359
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, 2014 and 2013		
Common stock, $0.01 par value 550,000,000 shares authorized at December 31, 2014 and 2013, respectively; 406,059,089 and 369,391,972 shares issued and outstanding at December 31, 2014 and 2013, respectively	4,061	3,697
Additional paid-in capital	2,416,967	2,261,996
Accumulated other comprehensive income (loss)	(14)	(4)
Accumulated deficit	(2,494,784)	(2,296,402)
Total stockholders deficit	(73,770)	(30,713)
Total	$ 394,439	