MANNKIND CORP
Form 10-K
March 16, 2017
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2016

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

Registrant s telephone number, including area code

(661) 775-5300

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

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

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

None

(Title of Class)

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

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

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

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

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

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

Large accelerated filer Accelerated filer
Non-accelerated filer (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

As of June 30, 2016, 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 $372,097,776.

As of March 10, 2017, there were 95,776,246 shares of the registrant s Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive Proxy Statement (the Proxy Statement) for the 2017 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than May 1, 2017 are incorporated by reference in Part III of this Annual Report on Form 10-K.

Table of Contents

MANNKIND CORPORATION

Annual Report on Form 10-K

For the Fiscal Year Ended December 31, 2016

TABLE OF CONTENTS

PART I

Item 1.	Business	1
Item 1A.	Risk Factors	16
Item 1B.	Unresolved Staff Comments	46
Item 2.	Properties	46
Item 3.	Legal Proceedings	46
Item 4.	Mine Safety Disclosures	47

PART II

Item 5.	Market for the Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	48
Item 6.	Selected Financial Data	50
Item 7.	Management s Discussion and Analysis of Financial Condition and Results of Operations	51
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	67
Item 8.	Financial Statements and Supplementary Data	67
	REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM	80
	CONSOLIDATED BALANCE SHEETS	81
	CONSOLIDATED STATEMENTS OF OPERATIONS	82
	CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)	83
	CONSOLIDATED STATEMENTS OF STOCKHOLDERS DEFICIT	84
	CONSOLIDATED STATEMENTS OF CASH FLOWS	85
	NOTES TO CONSOLIDATED FINANCIAL STATEMENTS	87
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	67
Item 9A.	Controls and Procedures	68
Item 9B.	Other Information	72

PART III

Item 10.	Directors, Executive Officers and Corporate Governance	72
Item 11.	Executive Compensation	72
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	72
Item 13.	Certain Relationships and Related Transactions, and Director Independence	72
Item 14.	Principal Accounting Fees and Services	72

PART IV

Item 15.	Exhibits, Financial Statement Schedules	73
Signatures		78

Table of Contents

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, predict, project, should, will, would, and intended to identify forward-looking statements, though not all forward-looking statements contain these identifying words. These statements may include, but are not limited to, statements regarding: our ability to successfully market, commercialize and achieve market acceptance for Afrezza or any other product candidates or therapies that we may develop; our ability to manufacture sufficient quantities of Afrezza and obtain insulin supply as needed; our ability to successfully commercialize our Technosphere drug delivery platform; our estimates for future performance; our estimates regarding anticipated operating losses, future revenues, capital requirements and our needs for additional financing; the timing and amount of our future recognition of deferred product sales from collaboration, costs of revenue from collaboration and income from collaboration; the progress or success of our research, development and clinical programs, including the application for and receipt of regulatory clearances and approvals; our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; and scientific studies and the conclusions we draw from them. These statements are only predictions or conclusions based on current information and expectations and involve a number of risks and uncertainties. The underlying information and expectations are likely to change over time. Actual events or results may differ materially from those projected in the forward-looking statements due to various factors, including, but not limited to, those set forth under the caption Risk Factors and elsewhere in this report. Except as required by law, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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

PART I

Item 1. *Business*

Unless the context requires otherwise, the words MannKind, we, Company, us and our refer to MannKind Corporation and its subsidiaries.

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

Afrezza is a rapid-acting, inhaled insulin used to control high blood sugar in adults with type 1 and type 2 diabetes. The product consists of a dry powder 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 to 15 minutes of administration.

On August 11, 2014, we entered into a license and collaboration agreement (the Sanofi License Agreement) with Sanofi-Aventis Deutschland GmbH (which subsequently assigned its rights and obligations

Table of Contents

under the agreement to Sanofi-Aventis U.S. LLC (Sanofi)), pursuant to which Sanofi was responsible for global commercial, regulatory and development activities for Afrezza.

On January 4, 2016, we received written notification from Sanofi of its election to terminate in its entirety the Sanofi License Agreement. The effective date of termination was April 4, 2016, which was when we assumed responsibility for worldwide development and commercialization of Afrezza. Under the terms of a transition agreement, Sanofi continued to fulfill orders for Afrezza in the United States until we began distributing MannKind-branded Afrezza product to major wholesalers in late July 2016. We began recognizing commercial product sales revenue when MannKind-branded Afrezza was dispensed from pharmacies to patients in August 2016.

On November 9, 2016, we entered into a settlement agreement with Sanofi (the Settlement Agreement). Under the terms of the Settlement Agreement, the promissory note (the Sanofi Loan Facility) between us and Aventisub LLC (Aventisub), a Sanofi affiliate, was terminated, with Aventisub agreeing to forgive the full outstanding loan balance of $72.0 million, which includes $0.5 million in the previously uncharged costs. Sanofi also agreed to purchase $10.2 million of insulin from us in December 2016 under an existing insulin put option as well as make a cash payment of $30.6 million to us in early January 2017 as acceleration and in replacement of all other payments that Sanofi would otherwise have been required to make in the future pursuant to the insulin put option, without us being required to deliver any insulin for such payment. We were also relieved of our obligation to pay Sanofi $0.5 million in previously uncharged costs pursuant to the Sanofi License Agreement. We and Sanofi also agreed to a general release of potential claims against each other. As of the date of this filing, we have received $30.6 million and $10.2 million related to this agreement.

During our initial transition of the commercial responsibilities from Sanofi, we utilized a contract sales organization to promote Afrezza while we focused our internal resources on establishing a channel strategy, entering into distribution agreements and developing co-pay assistance programs, a voucher program, data agreements and payor relationships. In early 2017, we recruited our own sales force, which included some of the sales representatives that previously were employed by the contract sales organization. We intend to continue the commercialization of Afrezza in the United States through our internal commercial organization. Our current strategy for the future commercialization of Afrezza outside of the United States, subject to receipt of the necessary foreign regulatory approvals, is to seek and establish regional partnerships in foreign jurisdictions where there are appropriate commercial opportunities.

As part of the approval of Afrezza, the FDA required us to conduct certain post-marketing studies, including:

- 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 as part used in combination with subcutaneous basal insulin in pediatric patients 4 to 17 years old with type 1 or type 2 diabetes; and

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

The obligation to complete the pediatric study and to conduct the five-year pulmonary safety study reverted to us when the NDA for Afrezza was transferred back to us in connection with the termination of the Sanofi License Agreement. In addition, we plan to conduct other clinical studies of Afrezza, including dose optimization studies in type 1 and type 2 patients and a study of the time that Afrezza patients remain within a desirable glycemic range as

determined by continuous glucose monitoring.

Manufacturing and Supply

We manufacture Afrezza in our Danbury, Connecticut facility, where we formulate the Afrezza inhalation powder, fill it into plastic cartridges and then blister package the cartridges and seal the blister cards inside a foil

Table of Contents

overwrap. These overwraps are then packaged into cartons along with inhalers and printed material by a third-party packager. The cartridges and inhalers are manufactured for us by a third-party plastic-molding company; the cartridges are delivered to our Connecticut facility whereas the inhalers are shipped directly to the packaging contractor.

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

We believe that our Connecticut facility has enough capacity to satisfy the current commercial demand for Afrezza. In addition, the facility includes expansion space to accommodate additional filling lines and other equipment, allowing production capacity to be increased based on the demand for Afrezza over the next several years.

Currently, the only approved source of insulin for Afrezza is manufactured by Amphastar France Pharmaceuticals S.A.S. (Amphastar). In April 2014, Amphastar acquired a manufacturing facility from N.V. Organon, a subsidiary of Merck & Co., Inc., where we had previously obtained the insulin that we use to make Afrezza. On July 31, 2014, we entered into a supply agreement with Amphastar (the Insulin Supply Agreement), pursuant to which we agreed to purchase certain annual minimum quantities of insulin for calendar years 2015 through 2019 for an aggregate total purchase price of approximately 120.1 million, of which 93.0 million remained unpurchased as of December 31, 2016. On November 9, 2016, we amended the contract with Amphastar to extend the term over which we are required to purchase insulin, by four additional years, without reducing the total amount of insulin we will purchase. Unless earlier terminated, the term of the Insulin Supply Agreement now expires on December 31, 2023 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.

Currently, we purchase the raw material for our proprietary excipient, FDKP (fumaryl diketopiperazine), which is the primary component of our Technosphere technology platform, from a major chemical manufacturer with facilities in Europe and North America. However, we also have the capability to manufacture FDKP in our Connecticut facility.

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

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

Our third-party suppliers are subject to extensive governmental regulation. We rely on our suppliers to comply with relevant regulatory requirements, including compliance with Current Good Manufacturing Practices (CGMP s).

Table of Contents

Technosphere Formulation Technology

Afrezza utilizes our proprietary Technosphere formulation technology; however, the application of this technology is not limited to insulin delivery. We believe it represents a versatile drug delivery platform that may allow the oral inhalation of a wide range of therapeutics. We have successfully prepared Technosphere formulations of anionic and cationic drugs, hydrophobic and hydrophilic drugs, proteins, peptides and small molecules. Technosphere powders are based on our proprietary excipient, FDKP, which is a pH-sensitive organic molecule that self-assembles into small particles under acidic conditions. Certain drugs, such as insulin, can be loaded onto these particles by combining a solution of the drug with a suspension of Technosphere material, which is then dried to powder form. The resulting powder has a consistent and narrow range of particle sizes with good aerodynamic properties that enable efficient delivery 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. 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 effectively 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 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.

As one example of an additional application of our formulation and delivery technologies, we entered into a collaboration and license agreement with Receptor Life Sciences (Receptor) in January 2016, pursuant to which we performed initial formulation studies on compounds identified by Receptor that treat conditions such as chronic pain, neurologic diseases and inflammatory disorders. Following the successful completion of these formulation studies, Receptor exercised its option to acquire an exclusive license to develop, manufacture and commercialize inhaled formulations of these compounds utilizing our technology.

Our Strategy

The following are the key elements of our strategy:

Commercialization and development of Afrezza. Our primary focus is the commercial success of Afrezza. Over the course of the last year, we have transformed from a manufacturing-based company into an integrated company with new capabilities in marketing, sales, managed care and market access. During the second half of 2016, we undertook a

number of initiatives, such as launching a new marketing campaign, expanding the patient assistance program, creating a robust speakers program, introducing new product packages that enhance dosing

Table of Contents

flexibility and securing improved insurance coverage, all of which are expected to increase the promotional responsiveness of Afrezza. Our current priority is the commercial opportunity for Afrezza in the United States; however, in the future we also intend to seek regional partnerships for the development and commercialization of Afrezza in foreign jurisdictions where there are appropriate commercial opportunities.

Capitalize on our proprietary Technosphere and inhaler technology for the delivery of active pharmaceutical ingredients. We believe that Technosphere formulations of active pharmaceutical ingredients have the potential to demonstrate clinical advantages over existing therapeutic options in a variety of therapeutic areas. In addition to our collaboration with Receptor, we are actively exploring other opportunities to out-license our proprietary Technosphere formulation and device technologies. We are also evaluating several product opportunities that we would consider developing as internally and/or externally funded efforts.

Intellectual Property

Our success will depend in large measure on our ability to continue enforcing 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 dry powder formulations and 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 425 issued patents in the United States and selected jurisdictions around the world and we also have over 250 applications pending that may provide additional protection if and when they are allowed. These include composition and inhaler and cartridge patents providing protection for Afrezza with various expiration dates, the longer-lived of which will not expire until 2032. In addition, we have certain method of treatment claims that have terms extending into 2031.

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

Table of Contents

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

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

Competition

The pharmaceutical and biotechnology industries are highly competitive and characterized by rapidly evolving technology and intense research and development efforts. We compete with companies, including major global pharmaceutical companies, and other institutions that have substantially greater financial, research and development, marketing and sales capabilities and have substantially greater experience in undertaking preclinical and clinical testing of products, obtaining regulatory approvals and marketing and selling biopharmaceutical products. We face competition based on, among other things, product efficacy and safety, the timing and scope of regulatory approvals, product ease of use and price.

Diabetes Treatments

We believe that Afrezza has important competitive advantages in the delivery of insulin when compared with currently known alternatives. However, new drugs or further developments in alternative drug delivery

Table of Contents

methods may provide greater therapeutic benefits, or comparable benefits at lower cost, than Afrezza. There can be no assurance that existing or new competitors will not introduce products or processes competitive with or superior to our product candidates.

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

Rapid-acting (Injected) Insulin

Currently, there is no approved insulin product that is absorbed into the bloodstream as rapidly as Afrezza, i.e., reaching peak levels within 12 to 15 minutes after administration. There are several formulations of rapid-acting insulin analogs that reach peak insulin levels within 45 to 90 minutes after injection. The principal products in this category are insulin lispro, which is marketed by Eli Lilly & Company, or Lilly; insulin aspart, which is marketed by Novo Nordisk A/S, or Novo Nordisk; and insulin glulisine, which is marketed by Sanofi.

In January 2017, Novo Nordisk announced that Fiasp®, a faster formulation of insulin aspart, was approved in Europe and Canada. It is currently undergoing regulatory review in the United States.

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. Pfizer subsequently withdrew the NDA for Exubera from the FDA.

In January 2008, Novo Nordisk announced that it was halting development of its inhaled insulin product, having reached the conclusion that the product did not have adequate commercial potential.

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

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

Non-insulin Medications

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

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

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

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

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

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.

Table of Contents

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

Government Regulation and Product Approval

The FDA and comparable regulatory agencies in state, local and foreign jurisdictions impose substantial requirements upon the clinical development, manufacture and marketing of medical devices and new drug and biologic products. These agencies, through regulations that implement the Federal Food, Drug and Cosmetic Act, as amended (FDCA), and other regulations, regulate research and development activities and the development, testing, manufacture, labeling, storage, shipping, approval, recordkeeping, advertising, promotion, sale and distribution of such products. In addition, if any of our products are marketed abroad, they will also be subject to export requirements and to regulation by foreign governments. The regulatory approval process is generally lengthy, expensive and uncertain. Failure to comply with applicable FDA and other regulatory requirements can result in sanctions being imposed on us or the manufacturers of our products, including hold letters on clinical research, civil or criminal fines or other penalties, product recalls, or seizures, or total or partial suspension of production or injunctions, refusals to permit products to be imported into or exported out of the United States, refusals of the FDA to grant approval of drugs or to allow us to enter into government supply contracts, withdrawals of previously approved marketing applications and criminal prosecutions.

The steps typically required before an unapproved new drug or biologic product for use in humans may be marketed in the United States include:

Preclinical studies that include laboratory evaluation of product chemistry and formulation, as well as animal studies to assess the potential safety and efficacy of the product. Certain preclinical tests must be conducted in compliance with good laboratory practice regulations. Violations of these regulations can, in some cases, lead to invalidation of the studies, or requiring such studies to be repeated. In some cases, long-term preclinical studies are conducted while clinical studies are ongoing.

Submission to the FDA of an investigational new drug application (IND), which must become effective before human clinical trials may commence. The results of the preclinical studies are submitted to the FDA as part of the IND. Unless the FDA objects and places a clinical hold, the IND becomes effective 30 days following receipt by the FDA.

Approval of clinical protocols by independent institutional review boards (IRBs) at each of the participating clinical centers conducting a study. The IRBs consider, among other things, ethical factors, the potential risks to individuals participating in the trials and the potential liability of the institution. The IRB also approves the consent form signed by the trial participants. The IRB of FDA may place a trial on hold at any time if it believes the risks to subjects outweigh the potential benefits.

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

FDA as part of the IND. Human clinical trials are typically conducted in the following four sequential phases that may overlap or be combined:

In Phase 1, the drug is initially introduced into a small number of individuals and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. Phase 1 clinical trials are often conducted in healthy human volunteers and such cases do not provide evidence of efficacy. In the case of severe or life-threatening diseases, the initial human testing is often conducted in patients rather than healthy volunteers. Because these patients already have the target disease, these studies may provide initial 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

Table of Contents

trials. The FDA receives reports on the progress of each phase of clinical testing and it may require the modification, suspension or termination of clinical trials if it concludes that an unwarranted risk is presented to patients or healthy volunteers.

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

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

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

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

Submission to the FDA of an NDA based on the clinical trials. The results of product development, preclinical studies and clinical trials are submitted to the FDA in the form of an NDA for approval of the marketing and commercial shipment of the product. Under the Pediatric Research Equity Act, NDAs are required to include an assessment, generally based on clinical study data, of the safety and efficacy of drugs for all relevant pediatric populations. The statute provides for waivers or deferrals in certain situations.

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

Medical products containing a combination of new drugs, biological products, or medical devices are regulated as combination products in the United States. A combination product generally is defined as a product comprised of components from two or more regulatory categories (e.g., drug/device, device/biologic, drug/biologic). Each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a new drug, biologic, or device.

The testing and approval process requires substantial time, effort and financial resources. Data that we submit are subject to varying interpretations, and the FDA and comparable regulatory authorities in foreign

Table of Contents

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 investigational products will be granted on a timely basis, if at all. For an approved product such as Afrezza, we are subject to continuing regulation by the FDA, including post marketing study commitments or requirements, risk evaluation and mitigation strategies, record-keeping requirements, reporting of adverse experiences with the product, submitting other periodic reports, drug sampling and distribution requirements, notifying the FDA and gaining its approval of certain manufacturing or labeling changes, and complying with certain electronic records and signature requirements. Prior to and following approval, if granted, all manufacturing sites are subject to inspection by the FDA and other national regulatory bodies and must comply with cGMP, QSR and other requirements enforced by the FDA and other national regulatory bodies through their facilities inspection program. Foreign manufacturing establishments must comply with similar regulations. In addition, our drug-manufacturing facilities located in Danbury and the facilities of our insulin supplier, the supplier(s) of FDKP and the supplier(s) of our inhaler and cartridges are subject to federal registration and listing requirements and, if applicable, to state licensing requirements. Failure, including those of our suppliers, to obtain and maintain applicable federal registrations or state licenses, or to meet the inspection criteria of the FDA or the other national regulatory bodies, would disrupt our manufacturing processes and would harm our business. In complying with standards set forth in these regulations, manufacturers must continue to expend time, money and effort in the area of production and quality control to ensure full compliance. Numerous device regulatory requirements apply to the device part of a drug-device combination. These include:

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

Further, the supplier we contract with to manufacture our inhaler and cartridges is subject to QSRs, 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

Table of Contents

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 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. Third-party payors, like government health administration authorities, private health insurers and other organizations that provide healthcare coverage, generally decide which drugs they will pay for and establish reimbursement levels for covered drugs. In particular, in the United States, private 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 other third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales and results of operations. Recently, in the United States there has been heightened governmental scrutiny of the manner in which drug manufacturers set prices for their marketed products. For example, there have been several recent U.S. Congressional inquiries regarding certain drug manufacturers pricing practices and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare and reform government program reimbursement methodologies for drugs. Pricing pressures can arise from rules and practices of managed care organizations, judicial decisions and governmental laws and regulations related to Medicare, Medicaid, 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

Table of Contents

in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives, including, most recently, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, PPACA), enacted in March 2010. The Physician Payments Sunshine Act within PPACA, and its implementing regulations, require certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children s Health Insurance Program (with certain exceptions) to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members.

Further, if a drug product is reimbursed by Medicare, Medicaid or other federal or state healthcare programs, we must comply with, among others, the federal civil and criminal false claims laws, including the civil False Claims Act, as amended, the federal Anti-Kickback Statute, as amended, and similar state laws. If a drug product is reimbursed by Medicare or Medicaid, pricing and rebate programs must comply with, as applicable, the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Medicare Prescription Drug Improvement and Modernization Act of 2003. Additionally, PPACA substantially changed the way healthcare is financed by both governmental and private insurers. Among other cost containment measures, PPACA established: an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents; a new Medicare Part D coverage gap discount program; and a new formula that increased the rebates a manufacturer must pay under the Medicaid Drug Rebate Program. There have been judicial and Congressional challenges to certain aspects of PPACA. As a result there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the PPACA. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Further, in January 2017, Congress adopted a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the PPACA. Following the passage of the Budget Resolution, in March 2017, the U.S. House of Representatives introduced legislation known as the American Health Care Act, which, if enacted, would amend or repeal significant portions of the PPACA. Among other changes, the American Health Care Act would repeal the annual fee on certain brand prescription drugs and biologics imposed on manufacturers and importers, eliminate the 2.3% excise tax on medical devices, eliminate penalties on individuals and employers that fail to maintain or provide minimum essential coverage, and create refundable tax credits to assist individuals in buying health insurance. The American Health Care Act would also make significant changes to Medicaid by, among other things, making Medicaid expansion optional for states, repealing the requirement that state Medicaid plans provide the same essential health benefits that are required by plans available on the exchanges, modifying federal funding, including implementing a per capita cap on federal payments to states, and changing certain eligibility requirements. Other legislative changes have been proposed and adopted in the United States since PPACA. For example, through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, following passage of the Bipartisan Budget Act of 2015, will remain in effect through 2025 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers. In the future, there are likely to be additional proposals relating to the reform of the U.S. health care system, some of which could further limit the prices we are able to charge for our products, or the amounts of reimbursement available for our products. If drug products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

Table of Contents

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology and Clinical Health Act (HITECH), and their respective 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, individual imprisonment, disgorgement, exclusion of products from reimbursement under government programs, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws 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

Our research and development expenses totaled $14.9 million, $29.7 million and $100.2 million for the years ended December 31, 2016, 2015 and 2014, respectively.

Long-Lived Assets

Our long-lived assets are located in the United States and totaled $28.9 million, $48.7 million and $192.1 million as of December 31, 2016, 2015 and 2014, respectively. Our long-lived assets as of December 31, 2016 do not include an asset held for sale totaling $16.7 million.

Employees

As of December 31, 2016, we had 153 full-time employees, of which 66 were engaged in manufacturing, 34 in research and development, 30 in general and administrative and 23 in selling and marketing. Fifteen 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 is subject to a collective bargaining agreement. We believe relations with our employees are good.

Corporate Information

We were incorporated in the State of Delaware on February 14, 1991. Our principal executive offices are located at 25134 Rye Canyon Loop Suite 300, Valencia, California 91355, and our telephone number at that

Table of Contents

address is (661) 775-5300. MannKind Corporation and the MannKind Corporation logo are our service marks. Our website address is http://www.mannkindcorp.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, are available free of charge on our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The contents of these websites are not incorporated into this Annual Report. Further, our references to the URLs for these websites are intended to be inactive textual reference only.

On March 1, 2017, we filed with the Secretary of State of the State of Delaware a Certificate of Amendment to our Amended and Restated Certificate of Incorporation (the Charter Amendment) to (i) implement a one-for-five reverse stock split of our outstanding common stock (the Reverse Stock Split), without any change in par value per share, and (ii) reduce the authorized number of shares of our common stock from 700,000,000 to 140,000,000 shares, as previously authorized and approved at a special meeting of stockholders on March 1, 2017. The Charter Amendment became effective at 5:01 p.m. Eastern Time on March 2, 2017 (the Effective Time). No fractional shares were issued in connection with the Reverse Stock Split. Instead, we issued one full share of the post-Reverse Stock Split common stock to any stockholder of record who was entitled to receive a fractional share as a result of the process.

As a result of the Reverse Stock Split, proportionate adjustments were made to the per share exercise price and the number of shares issuable upon the exercise or vesting of all stock options, restricted stock units and warrants issued by us and outstanding immediately prior to the Effective Time, which resulted in a proportionate decrease in the number of shares of our common stock reserved for issuance upon exercise or vesting of such stock options, restricted stock units and warrants, and, in the case of stock options and warrants, a proportionate increase in the exercise price of all such stock options and warrants. In addition, the number of shares authorized for future grant under our equity incentive/compensation plans immediately prior to the Effective Time were reduced proportionately.

On March 3, 2017, our common stock began trading on The NASDAQ Global Market on a split-adjusted basis. All references to shares of common stock, all per share data, and all warrant, stock option and restricted stock unit activity for all periods presented in this Annual Report have been adjusted to reflect the Reverse Stock Split on a retroactive basis.

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.

Table of Contents

Executive Officers of the Registrant

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

Name	Age	Position(s)
Matthew J. Pfeffer	59	Chief Executive Officer, Chief Financial Officer and Director
Michael E. Castagna, Pharm.D.	40	Corporate Vice President, Chief Commercial Officer
Joseph Kocinsky	53	Corporate Vice President, Chief Technology Officer
David B. Thomson, Ph.D., J.D.	50	Corporate Vice President, General Counsel and Secretary
Stuart A. Tross, Ph.D.	50	Corporate Vice President, Chief People Officer
Raymond W. Urbanski, M.D., Ph.D.	57	Corporate Vice President, Chief Medical Officer
Rosabel R. Alinaya	56	Senior Vice President, Principal Accounting Officer

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

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

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

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

Stuart A. Tross, Ph.D. has been our Corporate Vice President, Chief People Officer since December 2016, with responsibilities for human resources, information technology and west coast facilities. From 2006 to 2016 he served in various roles of increasing responsibility at Amgen, Inc., most recently as Senior Vice President and Chief Human Resources Officer responsible for human resources and security on a global basis. From 1998 to 2006 he served in a series of leadership roles at Bristol-Myers Squibb Co, most recently as Vice President and

Table of Contents

Global Head of Human Resources for Mead Johnson Company. Stuart received a B.S. degree from Cornell University and M.S. and Ph.D. degrees in Industrial-Organizational Psychology from the Georgia Institute of Technology.

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

Rosabel R. Alinaya has been our Senior Vice President, Principal Accounting Officer since January 2016 with responsibility for finance, accounting, tax, treasury, investor relations and risk management. Previously, she was our Vice President, Finance since March 2011 after serving as our Corporate Controller since June 2003. Ms. Alinaya began her career at Deloitte & Touche LLP, graduating from California State University, Northridge and is a Certified Public Accountant. She is also a member of the American Institute of Certified Public Accountants and a member of the California Society of Certified Public Accountants.

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

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

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

RISKS RELATED TO OUR BUSINESS

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

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

December 31, 2016, we had cash and cash equivalents of $22.9 million and a stockholders deficit of $183.6 million, which raises concerns about our

Table of Contents

solvency and ability to continue as a going concern. The extent of our additional funding requirements will depend on a number of factors, including:

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

- the emergence of competing technologies and products and other market developments;
- the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights or defending against claims of infringement by others;
- the level of our legal and litigation expenses; and
- the costs of discontinuing projects and technologies, and/or decommissioning existing facilities, if we undertake any such activities.

We have raised capital in the past through the sale of equity and debt securities and we may in the future pursue the sale of additional equity and/or debt securities, or the establishment of other funding facilities including asset-based borrowings. There can be no assurances, however, that we will be able to raise additional capital on acceptable terms, or at all. Issuances of additional debt or equity securities or the conversion of any of our currently outstanding convertible debt securities into shares of our common stock or the exercise of our currently outstanding warrants for shares of our common stock could impact the rights of the holders of our common stock and will dilute their ownership percentage. Moreover, the establishment of other funding facilities may impose restrictions on our operations. These restrictions could include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. We also will need to raise additional capital by pursuing opportunities for the licensing or sale of certain intellectual property and other assets. We cannot offer assurances, however, that any strategic collaborations, sales of securities or sales or licenses of assets will be available to us on a timely basis or on acceptable terms, if at all. We may be required to enter into relationships

Table of Contents

with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop independently, and any such relationships may not be on terms as commercially favorable to us as might otherwise be the case.

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

We cannot provide assurances that changed or unexpected circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate, in which case we will be required to raise additional capital. There can be no assurances that we will be able to raise additional capital on favorable terms, or at all. If we are unable to raise adequate additional capital we will be required to reduce expenses through the delay, reduction or curtailment of our projects, or further reduction of costs for facilities and administration, and there will continue to be substantial doubt about our ability to continue as a going concern.

Our prospects are heavily dependent on the successful commercialization of our only approved product, Afrezza. The continued commercialization and development of Afrezza will require substantial capital that we may not be able to obtain.

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 prospects and ability to generate significant revenues will heavily depend on our ability to successfully commercialize Afrezza in the United States. We anticipate that our near term revenues will also, to a much lesser extent, depend on our ability to enter into licensing arrangements for our Technosphere platform technology that involve license, milestone, royalty or other payments to us.

We assumed responsibility for worldwide commercialization of Afrezza in April 2016, prior to which time Sanofi was responsible for global commercial activities for Afrezza. We began distributing Afrezza in the United States in late July 2016, and intend to continue the commercialization of Afrezza in the United States through our own commercial organization. Successful commercialization of Afrezza is subject to many risks and there are many factors that could cause the commercialization of Afrezza to be unsuccessful, including a number of factors that are outside our control. We ultimately may be unable to gain market acceptance of Afrezza for a variety of reasons, including the treatment and dosage regimen, potential adverse effects, relative pricing compared with alternative products, the availability of alternative treatments and lack of coverage or adequate reimbursement.

We have never, as an organization, launched or commercialized a product other than Afrezza, and there is no guarantee that we will be able to successfully do so with Afrezza. There are numerous examples of unsuccessful product launches, second launches that underperform original expectations and other failures to fully exploit the market potential of drug products, including by pharmaceutical companies with more experience and resources than us. During our initial transition of the commercial responsibilities from Sanofi, we utilized a contract sales organization to promote Afrezza while we focused our internal resources on establishing a channel strategy, entering into distribution agreements and developing co-pay assistance programs, a voucher program, data agreements and payor relationships. In early 2017, we recruited our own sales force, which included some of the sales representatives

that previously were employed by the contract sales organization. We intend to continue the commercialization of Afrezza in the United States through our internal commercial organization. We will need to maintain and continue to build our commercialization capabilities in order to successfully commercialize Afrezza in the United States, and we may not have sufficient resources to do so. The market for skilled

Table of Contents

commercial personnel is highly competitive, and we may not be able to retain and find and hire all of the personnel we need on a timely basis or retain them for a sufficient period. In addition, Afrezza is a novel insulin therapy with a distinct profile and non-injectable administration, and we are therefore required to expend significant time and resources to train our sales force to be credible, persuasive and compliant with applicable laws in marketing Afrezza for the treatment diabetes to physicians and to ensure that a consistent and appropriate message about Afrezza is being delivered to our potential customers. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits of Afrezza and its proper administration, our efforts to successfully commercialize Afrezza could be put in jeopardy, which would negatively impact our ability to generate product revenues.

If we are unable to maintain coverage of, and adequate payment levels for Afrezza, physicians may limit how much or under what circumstances they will prescribe or administer Afrezza. As a result, patients may decline to purchase Afrezza, which would have an adverse effect on our ability to generate revenues.

We are responsible for the NDA for Afrezza and its maintenance. Prior to the termination of the Sanofi License Agreement in April 2016, we had no experience with the maintenance of an NDA and may fail to comply with maintenance requirements, including timely submitting required reports. Furthermore, we are responsible for the conduct of the remaining required post-approval trials of Afrezza. Our financial and other resource constraints may result in delays or adversely impact the reliability and completion of these trials.

Maintaining and further building the internal infrastructure to further develop and commercialize Afrezza is costly and time-consuming, and we may not be successful in our efforts or successful in obtaining financing to support those efforts.

If we fail to successfully commercialize Afrezza in the United States, our business, financial condition and results of operations will be materially and adversely affected.

We expect that our results of operations will fluctuate for the foreseeable future, which may make it difficult to predict our future performance from period to period.

Our operating results have fluctuated in the past and are likely to do so in future periods. Some of the factors that could cause our operating results to fluctuate from period to period include the factors that will affect our funding requirements described above under Risk Factors We will need to raise additional capital to fund our operations, and our inability to do so could raise substantial doubt about our ability to continue as a going concern.

We believe that comparisons from period to period of our financial results are not necessarily meaningful and should not be relied upon as indications of our future performance.

If we do not obtain regulatory approval of Afrezza in foreign jurisdictions, we will not be able to market Afrezza in any jurisdiction outside of the United States, which could limit our commercial revenues. We may not be successful in establishing regional partnerships or other arrangements with third parties for the commercialization of Afrezza outside of the United States.

While Afrezza has been approved in the United States by the FDA for glycemic control in adult patients with diabetes, we have not yet sought approval in any other jurisdiction. In order to market Afrezza outside of the United States, we must obtain regulatory approval in each applicable foreign jurisdiction, and we may never be able to obtain such approvals. The research, testing, manufacturing, labeling, approval, sale, import, export, marketing, and distribution of pharmaceutical products outside the United States are subject to extensive

19

Table of Contents

regulation by foreign regulatory authorities, whose regulations differ from country to country. We will be required to comply with different regulations and policies of the jurisdictions where we seek approval for Afrezza, and we have not yet identified all of the requirements that we will need to satisfy to submit Afrezza for approval for other jurisdictions. This will require additional time, expertise and expense, including the potential need to conduct additional studies or development work for other jurisdictions beyond the work that we have conducted to support the NDA for Afrezza.

Our current strategy for the future commercialization of Afrezza outside of the United States, subject to receipt of the necessary regulatory approvals, is to seek and establish regional partnerships in foreign jurisdictions where there are appropriate commercial opportunities. It may be difficult to find collaboration partners that are able and willing to devote the time and resources necessary to successfully commercialize Afrezza. Collaborations with third parties may require us to relinquish material rights, including revenue from commercialization, agree to unfavorable terms or assume material ongoing development obligations that we would have to fund. These collaboration arrangements are complex and time-consuming to negotiate, and if we are unable to reach agreements with third-party collaborators, we may fail to meet our business objectives and our financial condition may be adversely affected. We may also face significant competition in seeking collaboration partners, especially in the current market, and may not be able to find a suitable collaboration partner in a timely manner on acceptable terms, or at all. Any of these factors could cause delay or prevent the successful commercialization of Afrezza in foreign jurisdictions and could have a material and adverse impact on our business, financial condition and results of operations and the market price of our common stock and other securities could decline.

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

We have sought to develop our product candidates through our internal research programs. All of our product candidates will require additional research and development and, in some cases, significant preclinical, clinical and other testing prior to seeking regulatory approval to market them. Accordingly, these product candidates will not be commercially available for a number of years, if at all. Further research and development on these programs will require significant financial resources. Given our limited financial resources and our focus on development and commercialization of Afrezza, we will not be able to advance these programs unless we are able to enter into collaborations with third parties to fund of these programs or to obtain funding to enable us to continue these programs.

A significant portion of the research that we have conducted involves new technologies, including our Technosphere platform technology. Even if our research programs identify product candidates that initially show promise, these candidates may fail to progress to clinical development for any number of reasons, including discovery upon further research that these candidates have adverse effects or other characteristics that indicate they are unlikely to be effective. In addition, the clinical results we obtain at one stage are not necessarily indicative of future testing results. If we fail to develop and commercialize our product candidates, or if we are significantly delayed in doing so, our ability to generate product revenues will be limited to the revenues we can generate from Afrezza.

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

We have never been profitable or generated positive cash flow from cumulative operations to date. Historically, we have reported negative cash flow from operations other than for the nine months ended September 30, 2014, for the year ended December 31, 2014, and for the three months ended March 31, 2015 as a result of our receipt of an upfront payment and milestone payments from Sanofi. As of December 31, 2016, we had an accumulated deficit of $2.7 billion. The accumulated deficit has resulted principally from costs incurred in our research and development

programs, the write-off of goodwill and general operating expenses. We expect to make substantial expenditures and to incur increasing operating losses in the future in order to continue the

Table of Contents

commercialization of Afrezza. In connection with our quarterly assessment of impairment indicators and inventory valuation for the quarter ended December 31, 2015, we identified an impairment of our long-lived assets and inventory, which resulted in charges of $140.4 million and $36.1 million, respectively, in such quarter. In addition, under the amended Insulin Supply Agreement with Amphastar, we agreed to purchase certain annual minimum quantities of insulin for calendar years 2017 through 2023 for an aggregate total remaining purchase price of 93.0 million at December 31, 2016. We may not have the necessary capital resources on hand in order to service this contractual commitment.

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, 2016, we had stockholders deficit of $183.6 million. Our ability to achieve and sustain positive cash flow from operations and profitability depends heavily upon successfully commercializing Afrezza, and we cannot be sure when, if ever, we will generate positive cash flow from operations or become profitable.

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

As of December 31, 2016, we had $152.1 million principal amount of outstanding debt, consisting of:

- $27.6 million principal amount of 2018 notes bearing interest at 5.75% per annum and maturing on August 15, 2018;
- $55.0 million principal amount of 2019 notes bearing interest at 9.75% per annum, $15.0 million of which is due and payable in July 2017, $15.0 million of which is due and payable in July 2018 and $25.0 million of which is due and payable in July and December 2019;
- $20.0 million principal amount of Tranche B notes bearing interest at 8.75% per annum, $5.0 million of which is due and payable in each of May 2017, 2018 and 2019, and $5.0 million of which is due and payable in December 2019; and
- $49.5 million principal amount of indebtedness under The Mann Group Loan Arrangement bearing interest at 5.84% and maturing and due on January 5, 2020.

We may borrow an additional $30.1 million under The Mann Group Loan Arrangement. The available borrowings may be used to capitalize accrued interest into principal upon mutual agreement of the parties, as accrued interest becomes due and payable under The Mann Group Loan Arrangement. As of December 31, 2016 the accrued and unpaid interest under The Mann Group Loan Arrangement was $9.3 million.

There can be no assurance that we will have sufficient resources to make any required repayments of principal under the terms of our indebtedness when required. Further, if we undergo a fundamental change, as that term is defined in the indentures governing the terms of the 2018 notes, or certain Major Transactions as defined in the Facility Agreement in respect of the 2019 notes and the Tranche B notes, the holders of the respective debt securities will have the option to require us to repurchase all or any portion of such debt securities at a repurchase price of 100% of the

principal amount of such debt securities to be repurchased plus accrued and unpaid interest, if any. The 2018 notes bear interest at the rate of 5.75% per year on the outstanding principal amount, payable in cash semiannually in arrears on February 15 and August 15 of each year. The 2019 notes bear interest at the rate of 9.75% per year on the outstanding principal amount and the Tranche B notes bear interest at the rate of 8.75% on the outstanding principal amount, with accrued interest on each payable in cash quarterly in arrears on the last business day of March, June, September and December of each year. Loans under The Mann Group Loan Arrangement accrue interest at a rate of 5.84% per annum, due and payable quarterly in arrears on the first day of each calendar quarter for the preceding quarter, or at such other time as we and The Mann Group mutually agree. While we have been able to timely make our required interest payments to date, we cannot guarantee that we will be able to do so in the future. If we fail to pay interest on the 2018 notes, 2019 notes, or

Table of Contents

Tranche B notes, or if we fail to repay or repurchase the 2018 notes, 2019 notes, Tranche B notes, or the loans under The Mann Group Loan Arrangement when required, we will be in default under the instrument for such debt securities or loans, and may also suffer an event of default under the terms of other borrowing arrangements that we may enter into from time to time. Any of these events could have a material adverse effect on our business, results of operations and financial condition, up to and including the note holders initiating bankruptcy proceedings or causing us to cease operations altogether.

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

Our obligations under the Facility Agreement, including any indebtedness under the 2019 notes and the Tranche B notes, and the Milestone Agreement are secured by substantially all of our assets, including our intellectual property, accounts receivables, equipment, general intangibles, inventory (excluding the insulin inventory) and investment property, and all of the proceeds and products of the foregoing. Our obligations under the Facility Agreement and the Milestone Agreement are also secured by a certain mortgage on our facility in Danbury, Connecticut. The Facility Agreement includes customary representations, warranties and covenants by us, including restrictions on our ability to incur additional indebtedness, grant certain liens, engage in certain mergers and acquisitions, make certain distributions and make certain voluntary prepayments. Events of default under the Facility Agreement include: our failure to timely make payments due under the 2019 notes or the Tranche B notes; inaccuracies in our representations and warranties to Deerfield; our failure to comply with any of our covenants under any of the Facility Agreement, Milestone Agreement or certain other related security agreements and documents entered into in connection with the Facility Agreement, subject to a cure period with respect to most covenants; our insolvency or the occurrence of certain bankruptcy-related events; certain judgments against us; the suspension, cancellation or revocation of governmental authorizations that are reasonably expected to have a material adverse effect on our business; the acceleration of a specified amount of our indebtedness; our cash and cash equivalents, including amounts available to us under The Mann Group Loan Arrangement, falling below $25.0 million as of the last day of any fiscal quarter. If we fail to timely pay accrued interest under The Mann Group Loan Arrangement when required, we will be in default under The Mann Group Loan Arrangement. During any such time as an event of default is continuing under The Mann Group Loan Arrangement, The Mann Group will not be obligated to make additional borrowings available to us. If an event of default is continuing under The Mann Group Loan Arrangement as of the last day of a fiscal quarter, we may be in breach of the financial covenant under the Facility Agreement that requires us to maintain cash and cash equivalents (including available borrowings under The Mann Group Loan Arrangement) of at least $25.0 million if our other cash and cash equivalents on hand do not equal or exceed $25.0 million. 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.

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 would demand repayment of the outstanding balance of the 2019 notes or the Tranche B notes 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 2018 notes. In the event of certain

future defaults under the foregoing agreements for which we are not able to obtain waivers, the holders of the 2018 notes, 2019 notes and Tranche B notes may

Table of Contents

accelerate all of our repayment obligations, and, with respect to the 2019 notes and Tranche B notes, take control of our pledged assets, potentially requiring us to renegotiate the terms of our indebtedness on terms less favorable to us, or to immediately cease operations. If we enter into additional debt arrangements, the terms of such additional arrangements could further restrict our operating and financial flexibility. In the event we must cease operations and liquidate our assets, the rights of any holders of our outstanding secured debt would be senior to the rights of the holders of our unsecured debt and our common stock to receive any proceeds from the liquidation.

If we do not achieve our projected development goals in the timeframes we expect, our business, financial condition and results of operations will be harmed and the market price of our common stock and other securities could decline.

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

- the rate of progress, costs and results of our clinical studies and preclinical research and development activities;
- our ability to identify and enroll patients who meet clinical study eligibility criteria;
- our ability to access sufficient, reliable and affordable supplies of components used in the manufacture of our product candidates;
- the costs of expanding and maintaining manufacturing operations, as necessary;
- the extent to which our clinical studies compete for clinical sites and eligible subjects with clinical studies sponsored by other companies; and
- actions by regulators.

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

Afrezza or our product candidates may be rendered obsolete by rapid technological change.

A number of established pharmaceutical companies have or are developing technologies for the treatment of unmet medical needs.

The rapid rate of scientific discoveries and technological changes could result in Afrezza or one or more of our product candidates becoming obsolete or noncompetitive. Our competitors may develop or introduce new products that render our technology or Afrezza less competitive, uneconomical or obsolete. For example, in January 2017, Novo Nordisk announced that Fiasp®, a faster formulation of insulin aspart, was approved in Europe and Canada. It is currently undergoing regulatory review in the United States. 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.

Table of Contents

We also expect to face competition from universities and other non-profit research organizations. These institutions carry out a significant amount of research and development in various areas of unmet medical need. These institutions are becoming increasingly aware of the commercial value of their findings and are more active in seeking patent and other proprietary rights as well as licensing revenues.

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

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

Our research and development programs are designed to test the safety and efficacy of our product candidates through extensive nonclinical and clinical testing. We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or impact commercialization of any of our product candidates, including the following:

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

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

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

For the commercial manufacture of Afrezza, we need access to sufficient, reliable and affordable supplies of insulin, our Afrezza inhaler, the related cartridges and other materials. Currently, the only approved source of insulin for Afrezza is manufactured by Amphastar. We must rely on our suppliers, including Amphastar, to comply with relevant regulatory and other legal requirements, including the production of insulin and FDKP in accordance with the FDA s cGMP for drug products, and the production of the Afrezza inhaler and related cartridges in accordance with QSRs. The supply of any of these materials may be limited or any of the

Table of Contents

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. If any of our suppliers is unwilling or unable to meet its supply obligations and we are unable to secure an alternative supply source in a timely manner and on favorable terms, our business, financial condition, and results of operations may be harmed and the market price of our common stock and other securities may decline.

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

We use our Danbury, Connecticut facility to formulate Afrezza inhalation powder, fill plastic cartridges with the powder, package the cartridges in blister packs, and place the blister packs into foil pouches. We utilize a contract packager to assemble the final kits of foil-pouched blisters containing cartridges along with inhalers and the package insert. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, especially in scaling up initial production. These problems include difficulties with production costs and yields, quality control and assurance and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. If we engage a third-party manufacturer, we would need to transfer our technology to that third-party manufacturer and gain FDA approval, potentially causing delays in product delivery. In addition, our third-party manufacturer may not perform as agreed or may terminate its agreement with us.

Any of these factors could cause us to delay or suspend production, could entail higher costs and may result in our being unable to obtain sufficient quantities for the commercialization of Afrezza at the costs that we currently anticipate. 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, sustainable compliance and acceptable quality, and we were unable to promptly find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volume and quality on a timely basis, we would likely be unable to meet demand for Afrezza and we would lose potential revenues.

If Afrezza or any other product that we develop does not become widely accepted by physicians, patients, third-party payors and the healthcare community, we may be unable to generate significant revenue, if any.

Afrezza and other products that we may develop in the future may not gain market acceptance among physicians, patients, third-party payors and the healthcare community. Failure to achieve market acceptance would limit our ability to generate revenue and would adversely affect our results of operations.

The degree of market acceptance of Afrezza and other products that we may develop in the future depends on many factors, including the:

- approved labeling claims;

effectiveness of efforts by us or any future marketing partner 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;

Table of Contents

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 develop may not gain market acceptance, which would materially harm our business, financial condition and results of operations.

If third-party payors do not cover 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 government and other third-party payors to contain or reduce the costs of healthcare through various means. For example, in certain foreign markets the pricing of prescription pharmaceuticals is subject to governmental control. In the United States, there has been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental controls. We cannot be certain what legislative proposals will be adopted or what actions federal, state or private payors for healthcare goods and services may take in response to any drug pricing and reimbursement reform proposals or legislation. Such reforms may limit our ability to generate revenues from sales of Afrezza or other products that we may develop in the future and achieve profitability. Further, to the extent that such reforms have a material adverse effect on the business, financial condition and profitability of any future 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 coverage and adequate reimbursement to the consumer from third-party payors, such as governmental and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. The market for Afrezza and our product candidates for which we may receive regulatory approval will depend significantly on access to third-party payors drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. In addition, because each third-party payor individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time-consuming and costly process. We may be required to provide scientific and clinical support for the use of any product to each third-party payor separately with no assurance that approval would be obtained. This process could delay the market acceptance of any product and could have a negative effect on our future revenues and operating results. Even if we succeed in bringing more products to market, we cannot be certain that any such products would be considered cost-effective or that coverage and adequate reimbursement to the consumer would be available. Patients will be unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the

Table of Contents

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 any future marketing partner is unable to obtain coverage of, and adequate payment levels for, Afrezza or any of our other product candidates that receive marketing approval from third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them and patients may decline to purchase them. This in turn could affect our and any future marketing partner s ability to successfully commercialize Afrezza and our ability to successfully commercialize any of our other product candidates that receives regulatory approval and impact our profitability, results of operations, financial condition, and prospects.

Healthcare legislation may make it more difficult to receive revenues.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals in recent years to change the healthcare system in ways that could impact our ability to sell our products profitably. For example, in March 2010, PPACA became law in the United States. PPACA substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the healthcare industry. Among the provisions of PPACA of importance to us are the following:

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

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

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

- a licensure framework for follow-on biological products;

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

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

Part D;

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

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

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

new requirements to report annually to the Centers for Medicare & Medicaid Services (CMS) certain financial arrangements with physicians and teaching hospitals, as defined in PPACA and its implementing regulations, including reporting any payments or transfers of value made or distributed to prescribers, teaching hospitals and other healthcare providers and reporting any ownership and

Table of Contents

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.

The medical device excise tax has been suspended by the Consolidated Appropriations Act of 2016 (the CAA) through December 31, 2017. Absent further Congressional action, the excise tax will be reinstated for medical device sales beginning January 1, 2018. The CAA also temporarily delays implementation of other taxes intended to help fund PPACA programs.

Further, there have been judicial and Congressional challenges to other aspects of PPACA. As a result there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the PPACA. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Further, in January 2017, Congress adopted a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the PPACA. Following the passage of the Budget Resolution, in March 2017, the U.S. House of Representatives introduced legislation known as the American Health Care Act, which, if enacted, would amend or repeal significant portions of the PPACA. Among other changes, the American Health Care Act would repeal the annual fee on certain brand prescription drugs and biologics imposed on manufacturers and importers, eliminate the 2.3% excise tax on medical devices, eliminate penalties on individuals and employers that fail to maintain or provide minimum essential coverage, and create refundable tax credits to assist individuals in buying health insurance. The American Health Care Act would also make significant changes to Medicaid by, among other things, making Medicaid expansion optional for states, repealing the requirement that state Medicaid plans provide the same essential health benefits that are required by plans available on the exchanges, modifying federal funding, including implementing a per capita cap on federal payments to states, and changing certain eligibility requirements. While it is uncertain when or if the provisions in the American Health Care Act will become law, or the extent to which any changes may impact our business, it is clear that concrete steps are being taken to repeal and replace certain aspects of the PPACA.

In addition, other legislative changes have been proposed and adopted since PPACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013, and, following passage of the Bipartisan Budget Act of 2015, will stay in effect through 2025 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 (the ATRA), which, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Specifically, there have been several recent U.S. Congressional

inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. These new laws and initiatives may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

Table of Contents

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

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

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

the federal Anti-Kickback Statute (as amended by PPACA, which modified the intent requirement of the federal Anti-Kickback Statute so that a person or entity no longer needs to have actual knowledge of the Statute or specific intent to violate it to have committed a violation), which constrains our business activities, including our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities by prohibiting, among other things, knowingly and willfully 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, including without limitation the civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other federal healthcare programs that are false or fraudulent, and knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government, and under PPACA, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal false claims laws;

HIPAA, which created new federal criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program or falsifying, concealing, or covering up a material fact in connection with the delivery of or payment for health care benefits;

HIPAA, as amended by HITECH, and their respective implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information on entities subject to the law, such as healthcare providers, health plans, and healthcare clearinghouses and

their respective business associates that perform services for them that involve the creation, use, maintenance or disclosure of, individually identifiable health information;

the federal physician sunshine requirements under PPACA, which requires certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the CMS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members; and

state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state and foreign laws governing the privacy and security of health

Table of Contents

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, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, 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 we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the United States, we could be subject to additional reimbursement requirements, fines, sanctions and exposure under other laws which could have a material adverse effect on our business, results of operations and financial condition.

We participate in the Medicaid Drug Rebate Program, as administered by CMS, and other federal and state government pricing programs in the United States, and we may participate in additional government pricing programs in the future. These programs generally require us to pay rebates or otherwise provide discounts to government payors in connection with drugs that are dispensed to beneficiaries/recipients of these programs. In some cases, such as with the Medicaid Drug Rebate Program, the rebates are based on pricing that we report on a monthly and quarterly basis to the government agencies that administer the programs. Pricing requirements and rebate/discount calculations are complex, vary among products and programs, and are often subject to interpretation by governmental or regulatory agencies and the courts. The requirements of these programs, including, by way of example, their respective terms and scope, change frequently. Responding to current and future changes may increase our costs, and the complexity of compliance will be time consuming. Invoicing for rebates is provided in arrears, and there is frequently a time lag of up to several months between the sales to which rebate notices relate and our receipt of those notices, which further complicates our ability to accurately estimate and accrue for rebates related to the Medicaid program as implemented by individual states. Thus, there can be no assurance that we will be able to identify all factors that may cause our discount and rebate payment obligations to vary from period to period, and our actual results may differ significantly from our estimated allowances for discounts and rebates. Changes in estimates and assumptions may have a material adverse effect on our business, results of operations and financial condition.

In addition, the Office of Inspector General of the Department of Health and Human Services and other Congressional, enforcement and administrative bodies have recently increased their focus on pricing requirements for products, including, but not limited to the methodologies used by manufacturers to calculate average manufacturer price (AMP) and best price (BP) for compliance with reporting requirements under the

30

Table of Contents

Medicaid Drug Rebate Program. We are liable for errors associated with our submission of pricing data and for any overcharging of government payors. For example, failure to submit monthly/quarterly AMP and BP data on a timely basis could result in a civil monetary penalty of $10,000 per day for each day the submission is late beyond the due date. Failure to make necessary disclosures and/or to identify overpayments could result in allegations against us under the False Claims Act and other laws and regulations. Any required refunds to the U.S. government or responding to a government investigation or enforcement action would be expensive and time consuming and could have a material adverse effect on our business, results of operations and financial condition. In addition, in the event that the CMS were to terminate our rebate agreement, no federal payments would be available under Medicaid or Medicare for our covered outpatient drugs.

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 any clinical testing of our 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. 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 seek to obtain, or be able to obtain if desired, sufficient additional coverage. If losses from such claims exceed our liability insurance coverage, we may incur substantial liabilities that we may not have the resources to pay. If we are required to pay a product liability claim our business, financial condition and results of operations would be harmed and the market price of our common stock and other securities may decline.

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

We face intense competition for qualified employees among companies in the biotechnology and biopharmaceutical industries. Our success depends upon our ability to attract, retain and motivate highly skilled employees. We may be unable to attract and retain these individuals on acceptable terms, if at all. In addition, in order to commercialize Afrezza successfully, we may be required to expand our work force, particularly in the areas of manufacturing and sales and marketing. These activities will require the addition of new personnel, including management, and the development of additional expertise by existing personnel, and we cannot assure you that we will be able to attract or retain any such new personnel on acceptable terms, if at all.

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

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

companies to assist those companies in developing technologies that may compete with Afrezza or our product candidates.

Table of Contents

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. A material weakness in our internal controls has been identified in the past, and 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

Table of Contents

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

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

Following the public announcement of Sanofi s election to terminate the Sanofi License Agreement and the subsequent decline in our stock price, several complaints were filed in the U.S. District Court for the Central District of California (the District Court) against MannKind and certain of our officers and directors on behalf of certain purchasers of our common stock, which were consolidated into a single action. The amended complaint alleged that MannKind and certain of our officers and directors violated federal securities laws by making materially false and misleading statements regarding the prospects for Afrezza, thereby artificially inflating the price of MannKind s common stock. We and the other defendants brought a motion to dismiss the class action that was pending against MannKind and two of our executives, which the District Court granted without leave to amend the complaint. The lead plaintiff appealed that decision to the Ninth Circuit Court of Appeals. On March 2, 2017, the lead plaintiff filed a voluntary motion to dismiss his appeal, which the Court of Appeals granted on March 9, 2017.

We and certain of our directors and executive officers have also been named in similar lawsuits filed in Israel. In November 2016, the court in Israel dismissed one of the actions without prejudice. In the remaining action, a hearing is scheduled for May 2017 to determine whether Israeli or U.S. law is applicable before the case can be certified as a class action. We intend to vigorously defend against these claims. If we are not successful in our defense, we could be forced to make significant payments to or other settlements with our stockholders and their lawyers, and such payments or settlement arrangements could have a material adverse effect on our business, operating results or financial condition. Even if such claims are not successful, the litigation could result in substantial costs and significant adverse impact on our reputation and divert management s attention and resources, which could have a material adverse effect on our business, operating results and financial condition.

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

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

33

Table of Contents

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

Our research and development and commercialization of Afrezza work involves the controlled storage and use of hazardous materials, including chemical and biological materials. In addition, our manufacturing operations involve the use of a chemical that may form an explosive mixture under certain conditions. Our operations also produce hazardous waste products. We are subject to federal, state and local laws and regulations (i) governing how we use, manufacture, store, handle and dispose of these materials (ii) imposing liability for costs of cleaning up, and damages to natural resources from past spills, waste disposals on and off-site, or other releases of hazardous materials or regulated substances, and (iii) regulating workplace safety. Moreover, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated, and in the event of an accident, we could be held liable for any damages that may result, and any liability could fall outside the coverage or exceed the limits of our insurance. Currently, our general liability policy provides coverage up to $1.0 million per occurrence and $2.0 million in the aggregate and is supplemented by an umbrella policy that provides a further $20.0 million of coverage; however, our insurance policy excludes pollution liability coverage and we do not carry a separate hazardous materials policy. In addition, we could be required to incur significant costs to comply with environmental laws and regulations in the future. Finally, current or future environmental laws and regulations may impair our research, development or production efforts or have an adverse impact on our business, results of operations and financial condition. When we purchased the facilities located in Danbury, Connecticut in 2001, a soil and groundwater investigation and remediation was being conducted by a former site operator (the responsible party) under the oversight of the Connecticut Department of Environmental Protection. During the construction of our expanded manufacturing facility, we excavated contaminated soil under the footprint of our building expansion location. The responsible party reimbursed us for our increased excavation and disposal costs of contaminated soil in the amount of $1.6 million. It has conducted at its expense all work and will make all filings necessary to achieve closure for the environmental remediation conducted at the site, and has agreed to indemnify us for any future costs and expenses we may incur that are directly related to the final closure. If we are unable to collect these future costs and expenses, if any, from the responsible party, our business, financial condition and results of operations may be harmed.

We are increasingly dependent on information technology systems, infrastructure and data security.

We are increasingly dependent upon information technology systems, infrastructure and data security. Our business requires manipulating, analyzing and storing large amounts of data. In addition, we rely on an enterprise software system to operate and manage our business. Our business therefore depends on the continuous, effective, reliable and secure operation of our computer hardware, software, networks, Internet servers and related infrastructure. The multitude and complexity of our computer systems and the potential value of our data make them inherently vulnerable to service interruption or destruction, malicious intrusion and random attack. Likewise, data privacy or security breaches by employees or others may pose a risk that sensitive data including intellectual property, trade secrets or personal information belonging to us or our customers or other business partners may be exposed to unauthorized persons or to the public. Our systems are also potentially subject to cyber-attacks, which can be highly sophisticated and may be difficult to detect. Such attacks are often carried out by motivated, well-resourced, skilled and persistent actors including nation states, organized crime groups and hacktivists. Cyber-attacks could include the deployment of harmful malware and key loggers, a denial-of-service attack, a malicious website, the use of social engineering and other means to affect the confidentiality, integrity and availability of our information technology systems, infrastructure and data. Our key business partners face similar risks and any security breach of their systems could adversely affect our security status. While we continue to invest in the protection of our critical or sensitive data and information technology, there can be no assurance that our efforts will prevent or detect service interruptions or breaches in our systems that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us.

34

Table of Contents

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.

The FDA and other regulatory authorities impose significant restrictions on approved products through regulations on advertising, promotional and distribution activities. This oversight encompasses, but is not limited to, direct-to-consumer advertising, healthcare provider-directed advertising and promotion, sales representative communications to healthcare professionals, promotional programming and promotional activities involving the

Table of Contents

Internet. Regulatory authorities may also review industry-sponsored scientific and educational activities that make representations regarding product safety or efficacy in a promotional context. The FDA and other regulatory authorities may take enforcement action against a company for promoting unapproved uses of a product or for other violations of its advertising and labeling laws and regulations. Enforcement action may include product seizures, injunctions, civil or criminal penalties or regulatory letters, which may require corrective advertising or other corrective communications to healthcare professionals. Failure to comply with such regulations also can result in adverse publicity or increased scrutiny of company activities by the U.S. Congress or other legislators. Certain states have also adopted regulations and reporting requirements surrounding the promotion of pharmaceuticals. Failure to comply with state requirements may affect our ability to promote or sell our products in certain states.

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

Even if we comply with regulatory requirements, we may not be able to obtain the labeling claims necessary or desirable for product promotion. We may also be required to undertake post-marketing studies. For example, as part of the approval of Afrezza, the FDA required that we complete a clinical trial to evaluate the potential risk of pulmonary malignancy with Afrezza. To date, we have not enrolled any subjects in this trial.

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. For example, stability failure of Afrezza could lead to product recall or other sanctions.

We also are required to register our establishments and list our products with the FDA and certain state agencies. We and any third-party manufacturers or suppliers must continually adhere to federal regulations setting forth requirements, known as cGMP (for drugs) and QSR (for medical devices), and their foreign equivalents, which are enforced by the FDA and other national regulatory bodies through their facilities inspection programs. In complying with cGMP and foreign regulatory requirements, we and any of our potential third-party manufacturers or suppliers will be obligated to expend time, money and effort in production, record-keeping and quality control to ensure that our products meet applicable specifications and other requirements. QSR requirements also impose extensive testing, control and documentation requirements. State regulatory agencies and the regulatory agencies of other countries have similar requirements. In addition, we will be required to comply with regulatory requirements of the FDA, state regulatory agencies and the regulatory agencies of other countries concerning the reporting of adverse events and device malfunctions, corrections and removals (e.g., recalls), promotion and advertising and general prohibitions against the manufacture and distribution of adulterated and misbranded devices. Failure to comply with these regulatory requirements could result in civil fines, product seizures, injunctions and/or criminal prosecution of

responsible individuals and us. Any such actions would have a material adverse effect on our business, financial condition and results of operations.

Table of Contents

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

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

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

Our suppliers are subject to FDA inspection.

We depend on suppliers for insulin and other materials that comprise Afrezza, including our Afrezza inhaler and cartridges. Each supplier must comply with relevant regulatory requirements and is subject to inspection by the FDA. Although we conduct our own inspections and review and/or approve investigations of each supplier, there can be no assurance that the FDA, upon inspection, would find that the supplier substantially complies with the QSR or cGMP requirements, where applicable. If we or any potential third-party manufacturer or supplier fails to comply with these requirements or comparable requirements in foreign countries, regulatory authorities may subject us to regulatory action, including criminal prosecutions, fines and suspension of the manufacture of our products.

If we are required to find a new or additional supplier of insulin, we will be required to evaluate the new supplier s ability to provide insulin that meets regulatory requirements, including cGMP requirements as well as our specifications and quality requirements, which would require significant time and expense and could delay the manufacturing and commercialization of Afrezza.

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

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.

Table of Contents

There are also a number of clinical studies being conducted by other pharmaceutical companies involving compounds similar to, or potentially competitive with, our 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, 2026, 2028, 2029, and 2030. 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, 2029, 2030 and 2031. 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.

An issued patent is presumed valid unless it is declared otherwise by a court of competent jurisdiction. However, 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 post grant proceedings, including, oppositions, 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.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. We therefore cannot be certain that we or our licensors were the first to make the invention claimed in our owned and licensed patents or pending applications, or that we or our licensor were the first to file for patent protection of such inventions. Assuming the other requirements for patentability are met, in the United States prior to March 15, 2013, the first to make the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. After March 15, 2013, under the Leahy-Smith America Invents Act (AIA), or the Leahy-Smith Act, enacted on September 16, 2011, the United States moved to a first inventor to file system. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and may also affect patent litigation. The full effects of these changes are currently unclear. In general, the Leahy-Smith Act and its

implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Table of Contents

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. These and recent decisions of lower courts and guidelines issued by the USPTO call into question the patentability of biological inventions that had previously been considered patentable. While none of this has had 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 pre-AIA patent applications or those of our collaborators or licensors. Additionally, the Leahy-Smith Act has greatly expanded the options for post-grant review of patents that can be brought by third parties. In particular Inter Partes Review (IPR), available against any issued United States patent (pre - and post-AIA), has resulted in a higher rate of claim invalidation, due in part to the much reduced opportunity to repair claims by amendment as compared to re-examination, as well as the lower standard of proof used at the USPTO as compared to the federal courts. With the passage of time an increasing number of patents related to successful pharmaceutical products are being subjected to IPR. Moreover, the filing of IPR petitions has been used by short-sellers as a tool to help drive down stock prices. We may not prevail in any litigation, post-grant review, or interference proceedings in which we are involved and, even if we are successful, these proceedings may result in substantial costs and be a distraction to our management. Further, 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.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, the market price of our common stock and other securities may decline.

39

Table of Contents

If our technologies conflict with the proprietary rights of others, we may incur substantial costs as a result of litigation or other proceedings and we could face substantial monetary damages and be precluded from commercializing our products, which would materially harm our business and financial condition.

Biotechnology patents are numerous and may, at times, conflict with one another. As a result, it is not always clear to industry participants, including us, which patents cover the multitude of biotechnology product types. Ultimately, the courts must determine the scope of coverage afforded by a patent and the courts do not always arrive at uniform conclusions.

A patent owner may claim that we are making, using, selling or offering for sale an invention covered by the owner s patents and may go to court to stop us from engaging in such activities. Such litigation is not uncommon in our industry.

Patent lawsuits can be expensive and would consume time and other resources. There is a risk that a court would decide that we are infringing a third party s patents and would order us to stop the activities covered by the patents, including the commercialization of our products. In addition, there is a risk that we would have to pay the other party damages for having violated the other party s patents (which damages may be increased, as well as attorneys fees ordered paid, if infringement is found to be willful), or that we will be required to obtain a license from the other party in order to continue to commercialize the affected products, or to design our products in a manner that does not infringe a valid patent. We may not prevail in any legal action, and a required license under the patent may not be available on acceptable terms or at all, requiring cessation of activities that were found to infringe a valid patent. We also may not be able to develop a non-infringing product design on commercially reasonable terms, or at all.

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

Although we own a number of domestic and foreign patents and patent applications relating to Afrezza, we have identified certain third-party patents having claims that may trigger an allegation of infringement in connection with the commercial manufacture and sale of Afrezza. If a court were to determine that Afrezza was infringing any of these patent rights, we would have to establish with the court that these patents are 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 type of litigation. In addition, during the course of this kind of litigation, there could be public

Table of Contents

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 in our pipeline; 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 the commercial success of Afrezza, the extent to which we are able to successfully develop and commercialize our Technosphere drug delivery platform and any other product candidates that we develop, 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 when due.

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

If our existing stockholders or their distributees sell substantial amounts of our common stock in the public market, the market price of our common stock could decrease significantly. The perception in the public market

Table of Contents

that our existing stockholders might sell shares of common stock could also depress the market price of our common stock and the market price of our other securities. Any such sales of our common stock in the public market may affect the price of our common stock or the market price of our other securities.

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

As a result of the death of Alfred E. Mann, our founder and former largest stockholder, the stock that he previously controlled is currently controlled by a trust, and we cannot assure you of the manner in which the trustees will manage the holdings.

At February 1, 2017, the estate of Alfred E. Mann beneficially owned approximately 23.7% of our outstanding shares of capital stock, including shares held in the Alfred E. Mann Living Trust and The Mann Group LLC (collectively, the Mann Affiliated Entities).

Mr. Mann passed away on February 25, 2016. All of the shares beneficially owned by Mr. Mann in his individual capacity, the Alfred E. Mann Living Trust and The Mann Group LLC are controlled by the Alfred E. Mann Living Trust. The trustees of the Alfred E. Mann Living Trust are Mr. Mann s wife and two other trustees. The trustees have the power to sell the shares or deal with them as an owner. Relatives, other individuals and charities may receive bequests of shares under the trust. The residuary beneficiary of the trust is the Alfred E. Mann Family Foundation, a charitable organization under section 501(c)(3) of the Internal Revenue Code that is a private foundation under section 509 of the Code. The same three trustees control the Alfred E. Mann Family Foundation. The Alfred E. Mann Family Foundation will have the power to sell the shares or deal with them as an owner.

We have been informed by the trustees for the Mann Affiliated Entities that the trustees may seek to dispose of some or all of the shares beneficially owned by the Mann Affiliated Entities, pursuant to distributions to trust beneficiaries, one or more trading plans under Rule 10b5-1 of the Exchange Act or otherwise. Any sales or other disposition of our common stock by the Mann Affiliated Entities, or the perception that such sales may occur, including the entry into any such trading plans, could have a material adverse effect on the trading price of our common stock and could make it more difficult for us to raise capital through the sale of our common stock or securities convertible into or exercisable for our common stock, which could have a material adverse effect on our business and financial condition.

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

Since January 1, 2014, our closing stock price as reported on The NASDAQ Global Market has ranged from $1.89 to $54.80 (giving retroactive effect to our recently completed 1-for-5 reverse stock split). The trading price of our common stock is likely to continue to be volatile. The stock market, particularly in recent years, has experienced significant volatility particularly with respect to pharmaceutical and biotechnology stocks, and this trend may continue.

The volatility of pharmaceutical and biotechnology stocks often does not relate to the operating performance of the companies represented by the stock. Our business and the market price of our common stock may be influenced by a large variety of factors, including:

the progress of our recent commercial launch of Afrezza in the United States and other events or circumstances that we or others estimate will impact the future commercial success of Afrezza;

Table of Contents

our ability to obtain marketing approval for Afrezza outside of the United States and to find collaboration partners for the commercialization of Afrezza in foreign jurisdictions;

our future estimates of Afrezza sales, prescriptions or other operating metrics;

our ability to successful commercialize our Technosphere drug delivery platform;

the progress of preclinical and clinical studies of our product candidates and of post-approval studies of Afrezza required by the FDA;

the results of preclinical and clinical studies of our product candidates;

general economic, political or stock market conditions;

legislative developments;

announcements by us, our collaborators, or our competitors concerning clinical study results, acquisitions, strategic alliances, technological innovations, newly approved commercial products, product discontinuations, or other developments;

the availability of critical materials used in developing and manufacturing Afrezza or other product candidates;

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

developments or disputes concerning our patents or proprietary rights;

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

announcements by us concerning our financial condition or operating performance;

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

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

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

our ability, or the perception of investors of our ability, to continue to meet all applicable requirements for continued listing of our common stock on The NASDAQ Stock Market, and the possible delisting of our common stock if we are unable to do so;

the status of any legal proceedings or regulatory matters against or involving us or any of our executive officers and directors; and

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

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

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

Our common stock is currently listed on The NASDAQ Global Market, which has qualitative and quantitative listing criteria. If we are unable to meet any of the NASDAQ listing requirements in the future, such

Table of Contents

as the corporate governance requirements, the minimum closing bid price requirement, or the minimum market value of listed securities requirement, NASDAQ could determine to delist our common stock. A delisting of our common stock could adversely affect the market liquidity of our common stock, decrease the market price of our common stock, adversely affect our ability to obtain financing for the continuation of our operations and result in the loss of confidence in our company. On September 14, 2016, we received notice from the Listing Qualifications Department of the NASDAQ Stock Market indicating that, for the previous 30 consecutive business days, the bid price for our common stock closed below the minimum $1.00 per share required for continued inclusion on The NASDAQ Global Market. The notification letter stated that we would be afforded 180 calendar days, or until March 13, 2017, to regain compliance with the minimum bid price requirement. In order to regain compliance, shares of our common stock must maintain a minimum bid closing price of at least $1.00 per share for a minimum of 10 consecutive business days. On March 1, 2017, our board of directors and stockholders approved the Charter Amendment to effect the Reverse Stock Split. On March 3, 2017, our common stock began trading on The NASDAQ Global Market on a split-adjusted basis at a ratio of 1 share for 5. As of the date of this filing, the shares of our common stock have maintained a minimum bid closing price of at least $1.00 per share for 10 consecutive business days. Accordingly, we expect to receive a notice from the Listing Qualifications Department of the NASDAQ Stock Market indicating that we have regained compliance with the minimum closing bid price requirement. Despite effecting the Reverse Stock Split, there can be no assurance that the market price per share of our common stock will remain in excess of the $1.00 minimum closing bid price requirement in the future. The continuing effect of the Reverse Stock Split on the market price of our common stock cannot be predicted with any certainty, and the history of similar stock split combinations for companies in like circumstances is varied.

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

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

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

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

As of March 10, 2017, we had 95,776,246 shares of common stock outstanding. Substantially all of these shares are available for public sale, subject in some cases to volume and other limitations or delivery of a prospectus. If our common stockholders sell substantial amounts of common stock in the public market, or the market perceives that such sales may occur, the market price of our common stock and other securities may decline. Likewise the issuance of additional shares of our common stock upon the exchange or conversion of some or all of our 2018 notes or upon the exercise of outstanding warrants, could adversely affect the market price of our common stock and other

securities. In addition, the existence of these notes and warrants may encourage short selling of our common stock by market participants, which could adversely affect the market price of our common stock and other securities.

Table of Contents

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, as amended on March 1, 2017 to effect the Reverse Stock Split, currently authorizes us to issue up to 140,000,000 shares of common stock and 10,000,000 shares of preferred stock. As of March 10, 2017, we had a total of 44,223,754 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, outstanding warrants, our equity plans and our 2018 notes. As a result, our ability to issue shares of common stock other than pursuant to existing arrangements will be limited until such time, if ever, that we are able to amend our amended and restated certificate of incorporation to further increase our authorized shares of common stock or shares currently reserved for issuance otherwise become available (for example, due to the termination of the underlying agreement to issue the shares).

If we are unable to enter into new arrangements to issue shares of our common stock or securities convertible or exercisable into shares of our common stock, our ability to complete equity-based financings or other transactions that involve the potential issuance of our common stock or securities convertible or exercisable into our common stock,

will be limited. In lieu of issuing common stock or securities convertible into our common stock in any future equity financing transactions, we may need to issue some or all of our authorized but unissued shares of preferred stock, which would likely have superior rights, preferences and privileges to those of our common stock, or we may need to issue debt that is not convertible into shares of our common stock, which

Table of Contents

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. We believe the Connecticut facility will have sufficient space to satisfy commercial demand for Afrezza.

As of December 31, 2016, we owned approximately 142,000 square feet of laboratory, office and warehouse space in Valencia, California. On February 17, 2017, we sold certain parcels of real estate in Valencia, California and certain related improvements, personal property, equipment, supplies and fixtures, including the aforementioned space, to Rexford Industrial Realty, L.P. for $17.3 million.

Our obligations under the Facility Agreement and the Milestone Agreement are secured by certain mortgages on our facility in Danbury, Connecticut.

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

Item 3. ***Legal Proceedings***

Following the public announcement of Sanofi s election to terminate the Sanofi License Agreement and the subsequent decline in our stock price, several complaints were filed in the U.S. District Court for the Central District of California (the District Court) against MannKind and certain of our officers and directors on behalf of certain purchasers of our common stock, which were consolidated into a single action. The amended complaint alleged that MannKind and certain of our officers and directors violated federal securities laws by making materially false and misleading statements regarding the prospects for Afrezza, thereby artificially inflating the price of MannKind s common stock. We and the named defendants brought a motion to dismiss the class action, which the District Court granted in August 2016 without leave to amend the complaint. The lead plaintiff appealed that decision to the Ninth Circuit Court of Appeals. On March 2, 2017, the lead plaintiff filed a voluntary motion to dismiss his appeal, which the Court of Appeals granted on March 9, 2017.

Following the public announcement of Sanofi s election to terminate the Sanofi License Agreement and the subsequent decline in our stock price, two motions were submitted to the district court at Tel Aviv, Economic Department for the

certification of a class action against MannKind and certain of our officers and directors. In general, the complaints allege that MannKind and certain of our officers and directors violated Israeli and U.S. securities laws by making materially false and misleading statements regarding the prospects for Afrezza,

Table of Contents

thereby artificially inflating the price of its common stock. The plaintiffs are seeking monetary damages. In November 2016, the district court dismissed one of the actions without prejudice. In the remaining action, a hearing is scheduled for May 2017 to determine whether Israeli or U.S. law is applicable before the case can be certified as a class action. We will vigorously defend against the claims advanced.

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

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

Not applicable.

Table of Contents

PART II

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

Common Stock Market Price

Our common stock has been traded on The NASDAQ Global Market under the symbol MNKD since July 28, 2004. The following table sets forth for the quarterly periods indicated, the high and low sales prices for our common stock as reported by The NASDAQ Global Market (adjusted for the Reverse Stock Split effective March 3, 2017).

	High	Low
Year ended December 31, 2016		
First quarter	$ 11.20	$ 3.20
Second quarter	$ 10.15	$ 4.25
Third quarter	$ 6.05	$ 2.75
Fourth quarter	$ 4.35	$ 2.05
Year ended December 31, 2015		
First quarter	$ 39.40	$ 25.15
Second quarter	$ 36.60	$ 17.30
Third quarter	$ 29.00	$ 15.00
Fourth quarter	$ 18.95	$ 6.90

The closing sales price of our common stock on The NASDAQ Global Market was $1.95 on March 10, 2017 and there were 171 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, 2010, in (i) our common stock, (ii) the securities comprising The NASDAQ Composite Index and (iii) the securities comprising The NASDAQ Biotechnology Index.

Table of Contents

The comparisons in the graph are required by the SEC and are not intended to forecast or be indicative of possible future performance of our common stock.

Dividend Policy

We have never declared or paid any cash dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business. Accordingly, we do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors. In addition, under the terms of the Facility Agreement, we are restricted from distributing any of our assets or declaring and distributing a dividend to our stockholders.

Recent Sales of Unregistered Securities

None.

Table of Contents

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

The following data has been derived from our audited financial statements, including the consolidated balance sheets at December 31, 2016 and 2015 and the related consolidated statements of operations for each of the three years ended December 31, 2016 and related notes appearing elsewhere in this report. The consolidated statement of operations data for the years ended December 31, 2013 and 2012 and the consolidated balance sheet data as of December 31, 2014, 2013 and 2012 are derived from our audited consolidated financial statements that are not included in this report. The selected financial data set forth below should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and the audited consolidated financial statements, and the notes thereto, and other financial information included herein this Annual Report on Form 10-K.

	Year Ended December 31,				
	2016	2015	2014	2013	2012
	(In thousands, except per share amounts)				
Statement of Operations Data:					
Revenue:					
Net revenue collaboration	$ 171,965(1)	$	$	$	$ 35
Net revenue commercial product sales	1,895				
Revenue bulk insulin sales	898				
Total net revenue	174,758				35
Expense:					
Costs of revenue collaboration	32,971(1)				
Cost of goods sold	17,121	64,745			
Research and development	14,917	29,674	100,244	109,719	101,522
Selling, general and administrative	46,928	40,960	79,383	59,682	45,473
Property and equipment impairment	1,259(2)	140,412(2)			
(Gain) loss on foreign currency translation	(3,433)	$ 2,697			
(Gain) loss on purchase commitments	(2,265)(3)	66,167(3)			
Total expense	107,498	344,655	179,627	169,401	146,995
Income (loss) from operations	67,260	(344,655)	(179,627)	(169,401)	(146,960)
Other income (expense):					
Change in fair value of warrant liability	5,369(4)				
Interest income	85	18	9	8	7
Interest expense on notes	(15,576)	(21,231)	(17,549)	(15,153)	(11,139)
Interest expense on note payable to principal stockholder	(2,901)	(2,894)	(2,894)	(6,309)	(10,491)
	72,024(5)	(1,049)(5)			

Gain (loss) on extinguishment of debt					
Other (expense) income	(597)	1,366	1,679	(635)	(1,191)
Total other income (expense)	58,404	(23,790)	(18,755)	(22,089)	(22,814)
Income (loss) before benefit from income taxes	125,664	(368,445)	(198,382)	(191,490)	(169,774)
Income tax benefit					408
Net income (loss)	$ 125,664	$ (368,445)	$ (198,382)	$ (191,490)	$ (169,366)
Basic net income (loss) per share	$ 1.37	$ (4.54)	$ (2.57)	$ (3.20)	$ (4.68)
diluted net income (loss) per share	$ 1.36	$ (4.54)	$ (2.57)	$ (3.20)	$ (4.68)
Shares used to compute basic net income (loss) per share	92,053	81,233	77,045	59,918	36,171
Shares used to compute diluted net income (loss) per share	92,085	81,233	77,045	59,918	36,171

Table of Contents

	2016	2015	December 31, 2014	2013	2012
			(In thousands)		
Balance Sheet Data:					
Cash and cash equivalents	$ 22,895	$ 59,074	$ 120,841	$ 70,790	$ 61,840
Total assets	107,063	126,412	394,439	258,646	251,314
Facility financing obligation	71,339	74,582	72,995	102,300	
Note payable to principal stockholder	49,521	49,521	49,521	49,521	119,635
Accrued interest note payable to principal stockholder	9,281	6,380	3,486	592	2,170
Senior convertible notes	27,635	27,613	99,355	98,439	212,026
Sanofi loan facility and loss share obligation		62,371(5)	3,034		
Accumulated deficit	(2,737,565)	(2,863,229)	(2,494,784)	(2,296,402)	(2,104,912)
Total stockholders deficit	(183,593)	(350,329)	(73,770)	(30,713)	(110,679)

(1) The amount of revenue recognized in 2016 totaled $172.0 million, which consisted of an upfront payment of $150.0 million and two milestone payments of $25.0 million each, net of $64.9 million of net loss share with Sanofi, as well as $17.5 million in sales of Afrezza and $19.4 million related to a sale of bulk insulin, both to Sanofi. These payments and sales were made pursuant to the contractual terms of the agreements with Sanofi. Costs of revenue collaboration represents the costs of product manufactured and sold to Sanofi, as well as certain direct costs associated with a firm purchase commitment entered into in connection with the collaboration with Sanofi.

(2) In 2016, property and equipment impairment was a result of impairment charges of $695 thousand and $564 thousand for property, plant and equipment and asset held for sale, respectively. In 2015, in connection with our quarterly assessment of impairment indicators and inventory valuation, we identified an impairment of our long-lived assets which resulted in charges of $140.4 million in the fourth quarter of 2015.

(3) In 2016, the $2.3 million gain on purchase commitments was related to a renegotiation of certain of our purchase commitments. In 2015, the $66.2 million recognized loss on purchase commitments resulted from our assessment of excess inventory as a result of lower than expected sales of Afrezza as well as a lower of cost or net realizable value adjustment due to estimated conversion costs in excess of our estimated selling price of Afrezza.

(4) In 2016, we recognized a change in fair value of warrant liability of $5.4 million to reflect the fair value adjustments of the warrant liability from May 12, 2016, the date certain warrants were issued in connection with a registered public offering.

(5) The $72.0 million gain from extinguishment of debt in 2016 was a result of the termination of the Sanofi License Agreement on November 9, 2016 and forgiveness of the full outstanding loan balance on the Sanofi Loan Facility. The $1.0 million loss in 2015 was from extinguishment of debt driven by the settlement of the 5.75% Senior Convertible Notes due 2015 through the payment of cash and issuance of new debt.

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

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

Overview

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

As of December 31, 2016, we had an accumulated deficit of $2.7 billion and a stockholders deficit of $183.6 million. We had net income (losses) of approximately $125.7 million, ($368.4) million and ($198.4)

Table of Contents

million in the years ended December 31, 2016, 2015 and 2014, respectively. We have funded our operations primarily through the sale of equity securities and convertible debt securities, borrowings under the Facility Agreement with Deerfield, borrowings under The Mann Group Loan Arrangement, receipt of upfront and milestone payments under the Sanofi License Agreement and borrowings under the Sanofi Loan Facility to fund our portion of the loss share. As discussed below in Liquidity and Capital Resources , if we are unable to obtain additional funding, there will be substantial doubt about our ability to continue as a going concern.

Our business is subject to significant risks, including but not limited to our need to raise additional capital to fund our operations, our ability to successfully commercialize Afrezza and manufacture sufficient quantities of Afrezza and the risks inherent in our ongoing clinical trials and the regulatory approval process for our product candidates. Additional significant risks also include the results of our research and development efforts, competition from other products and technologies and uncertainties associated with obtaining and enforcing patent rights.

Critical Accounting Policies

The preparation of our consolidated financial statements is in accordance with accounting principles generally accepted in the United States. The preparation of our consolidated financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, and expenses and related disclosure of contingent assets and liabilities. We consider an accounting estimate to be critical to the consolidated financial statements if (i) the estimate is complex in nature or requires a high degree of judgment and (ii) different estimates and assumptions were used, the results could have a material impact on the consolidated financial statements. On an ongoing basis, we evaluate our estimates and the application of our policies. We base our estimates on historical experience, current conditions and on various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The policies that we believe are critical to the preparation of the consolidated financial statements are presented below.

The following critical accounting policies are more fully described in Note 2 Summary of Significant Accounting Policies of the Notes to Consolidated Financial Statements included in Part II, Item 8 Financial Statements and Supplementary Data.

Revenue Revenue is recognized when the four basic criteria of revenue recognition are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. When the accounting requirements for revenue recognition are not met, we defer the recognition of revenue by recording deferred revenue on the balance sheet until such time that all criteria are met.

We have entered into a Commercial Outsourcing Services Agreement with Integrated Commercialization Solutions, Inc. (ICS), a third party logistics provider, under which ICS distributes our product to wholesalers on our behalf. To enable us to distribute product in all necessary jurisdictions, on July 1, 2016, we entered into a first amendment to our contract with ICS for an interim period. Under this amendment, ICS, through Integrated Commercialization Solutions Direct (ICS Direct), purchased product from us and title and risk of loss transferred to ICS Direct. However, we did not recognize revenue upon transfer of product to ICS Direct because (1) we were required to indemnify and hold harmless ICS for all accounts receivable arising out of product sales under the first amendment that were not collected from the customers according to payment terms, and (2) ICS Direct could return product to us under the right of return.

On September 26, 2016, we provided notice to ICS of our election to terminate the interim period agreement effective December 15, 2016. After that date, ICS no longer took title to inventory. However, the Commercial Outsourcing Services Agreement continues to be in effect and ICS continues to distribute our product to wholesalers on our behalf.

Table of Contents

We invoice our customers upon shipment of Afrezza to them and record an accounts receivable, with a corresponding liability for deferred revenue equal to the gross invoice price net of estimated gross-to-net adjustments. Given our limited sales history for Afrezza, we cannot reliably estimate expected returns of the product at the time of shipment. Accordingly, we defer recognition of revenue on Afrezza product shipments until the right of return no longer exists, which occurs at the earlier of the time Afrezza is dispensed through patient prescriptions or expiration of the right of return. We recognize revenue based on Afrezza patient prescriptions dispensed as estimated by syndicated data provided by a third party. We also analyze additional data points to ensure that such third-party data is reasonable, including data related to inventory movements within the channel and ongoing prescription demand. In addition, the costs of Afrezza associated with the deferred revenue are recorded as deferred costs until such time as the related deferred revenue is recognized.

Estimated gross-to-net adjustments for Afrezza include wholesaler distribution fees, prompt pay discounts, rebates and patient discount and co-pay assistance programs, and are based on estimated amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with our customers and the levels of inventory within the distribution and retail channels that may result in future rebates or discounts taken. In certain cases, such as patient support programs, we recognize the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, we may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment. We record product sales deductions in the statement of operations at the time product revenue is recognized.

Product Returns We do not provide a reserve for product refunds for sales of Afrezza due to our revenue recognition policy of deferring recognition of revenue on product shipments of Afrezza until the right of return no longer exists.

Deferred Costs Deferred costs from collaboration represents the cost of product manufactured and sold to Sanofi as well as certain direct costs associated with a firm purchase commitment entered into in connection with the Sanofi License Agreement. At December 31, 2016, deferred costs from commercial product sales represented the cost of product shipped to ICS and wholesale distributors, but not sold through by pharmacies to patients. Cost of goods sold related to commercial product sales for the twelve months ended December 31, 2016 included $0.3 million of cost related to product sold through from pharmacies to patients.

As of December 31, 2015, deferred costs from collaboration of $13.5 million represented the costs of product manufactured and sold to Sanofi. During the third quarter of 2016, the costs related to the Sanofi product sales were recognized as costs of revenue collaboration in the consolidated statements of operations, as the related revenue was recognized at that time.

License and Collaboration Agreements We analyzed consideration received under the Sanofi License Agreement to determine whether the consideration, or a portion thereof, could be recognized as revenue. 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. Due to the proprietary nature of the manufacturing services to be provided by us, we determined that all of the significant

Table of Contents

deliverables should be combined into a single unit of accounting. During the term of the Sanofi License Agreement, worldwide profits and losses were determined based on the difference between the net sales of Afrezza and the costs and expenses incurred by us and Sanofi that were specifically attributable or related to the development, regulatory filings, manufacturing, or commercialization of Afrezza. These profits and losses were shared 65% by Sanofi and 35% by us. Prior to December 31, 2015, we did not have the ability to estimate the amount of costs that would potentially be incurred under the loss sharing provision of the Sanofi License Agreement, and accordingly we believed the fixed and determinable fee requirement for revenue recognition was not met.

In the first and second quarters of 2016, after we received notice of termination from Sanofi, we evaluated whether the criteria had been met. We determined that the requirement had not been met because Sanofi had not finalized necessary adjustments to the profit and loss share provision statements and Sanofi had not yet transferred all of the information to enable us to commercialize Afrezza on our own. Therefore, we were still unable to estimate the costs to be incurred under the agreement with Sanofi. During the third quarter of 2016, Sanofi provided us with enough information to enable us to reasonably estimate the remaining costs under the Sanofi License Agreement and the Sanofi Supply Agreement. Accordingly, the fixed or determinable fee requirement for revenue recognition was met and there were no future obligations to Sanofi. Therefore, we recognized $172.0 million of net revenue collaboration for the year ended December 31, 2016. The revenue recognized includes the upfront payment of $150.0 million and the two milestone payments of $25.0 million each, net of $64.9 million of net loss share with Sanofi, as well as $17.5 million in sales of Afrezza and $19.4 million from sales of bulk insulin, both to Sanofi. These payments and sales were made pursuant to the contractual terms of the agreements with Sanofi.

On November 9, 2016, we entered into the Settlement Agreement with Sanofi. The accounting for this agreement is described in Note 8 Collaboration Arrangements of the Notes to Consolidated Financial Statements included in Part II, Item 8 Financial Statements and Supplementary Data.

On January 20, 2016, we entered into the CLA with Receptor pursuant to which we performed initial formulation studies on compounds identified by Receptor. Following successful completion of the studies, Receptor exercised its option to acquire an exclusive license to develop, manufacture and commercialize inhalation formulations of these compounds utilizing our technology. See Note 8 Collaboration Arrangements of the Notes to Consolidated Financial Statements included in Part II, Item 8 Financial Statements and Supplementary Data for additional information related to the accounting for the CLA.

Inventories Inventories are stated at the lower of cost or net realizable 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 in the period incurred. 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.

We analyzed our inventory levels to identify inventory that may expire or has a cost basis in excess of its estimated realizable value. We performed an assessment of projected sales to evaluate the lower of cost or net realizable value and the potential excess inventory on hand at December 31, 2016 and 2015. As a result of these assessments, we recorded a $0.2 million charge at December 31, 2016 to write-off inventory that will expire prior to sale. At December 31, 2015, we recorded a charge of $36.1 million to record the raw materials inventory on hand at the lower of cost or net realizable value and inventory expiry, and $3.2 million related to the write-off of prepaid deposits related to the purchase of inventory.

Recognized Loss on Purchase Commitments At December 31, 2016 and 2015, in connection with the projected sales assessment, we also evaluated our inventory purchase commitments totaling $101.0 million and

Table of Contents

$116.2 million, respectively, for potential impairment. As a result of these assessments, we recorded $101.0 million and $66.2 million, respectively, to the liability for recognized loss on purchase commitments both from a lower of cost or net realizable value and excess inventory perspective. Prior to December 31, 2016, the recognized loss on purchase commitments was reduced to reflect our expectation that a portion was recoverable from Sanofi. At December 31, 2016 the recognized loss on purchase commitments no longer reflects recoverability from Sanofi because it was recognized as a receivable from Sanofi due to the Settlement Agreement.

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.

If we believe an asset to be impaired, the impairment we recognize is the amount by which the carrying value of the asset exceeds the fair value of the asset. Fair value is determined using market, income or cost approaches, as appropriate for the asset. Any write-downs would be treated as permanent reductions in the carrying amount of the asset and an operating loss would be recognized. In addition, we base the useful lives and related amortization or depreciation expense on our estimate of the useful lives of the assets. If a change were to occur in any of the above-mentioned factors or estimates, our reported results could materially change.

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

As disclosed more fully in Note 4 Property and Equipment of the Notes to Consolidated Financial Statements included in Part II, Item 8 Financial Statements and Supplementary Data , based on the above impairment factors in 2015, we identified an impairment charge of $1.8 million related to our Valencia property, which was previously our corporate headquarters, as well as a $138.6 million impairment charge to our Danbury manufacturing facility, which currently performs all manufacturing of Afrezza. As disclosed in Note 20 Subsequent Events of the Notes to Consolidated Financial Statements included in Part II, Item 8 Financial Statements and Supplementary Data , in 2016 we also recorded an additional $1.2 million impairment charge related to facilities of which $0.5 million is associated with the Valencia property, when it became probable that the property would be sold within one year.

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

Milestone Rights Liability In addition to the Facility Financing Obligation, we also issued certain rights to receive payments of up to $90.0 million upon occurrence of specified strategic and sales milestones (the Milestone Rights). These rights are not reflected in the Facility Financing Obligation. The estimated fair value of the Milestone Rights was calculated using the income approach in which the cash flows associated with the specified contractual payments were adjusted for both the expected timing and the probability of achieving the milestones discounted to present value using a selected market discount rate (Level 3 in the fair value hierarchy). The expected timing and probability of achieving the milestones, starting in 2014, was developed with consideration given to both internal data, such as our forecast, progress made to date towards meeting the milestones, and assessment of criteria required for achievement, and external data, such as market research studies. The discount rate (14.5%) was selected based on an estimation of

required rate of returns for similar

Table of Contents

investment opportunities using available market data. As of December 31, 2016, the carrying value of the Milestone Rights is $8.9 million, classified as a long-term liability and the fair value is estimated at $18.4 million. The fair value measurement of the liability is sensitive to the discount rate and the timing and probability of making milestone payments. If the achievement of each of the milestones which require payments were to be 12 months earlier or later than in our current forecast, the fair value of the liability would increase by 15 percent or decrease by 14, respectively. If the probability of achieving each milestones was increased or decreased by 5 percent, the fair value of the liability would increase or decrease by 17 percent, respectively. If the discount rate were to increase or decrease by 1 percent, the fair value of the liability would increase or decrease by 2 percent, respectively. Over the long term, these inputs are interrelated because if our performance improves, the timing of meeting the milestones would likely be earlier, the probability of making payments on the milestones would likely be higher, and the discount rate would likely decrease, all of which would increase the fair value of the liability. The inverse is also true.

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 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, are recognized in the consolidated income statements 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 inputs, including the stock price, the exercise price, the expected life of the stock-based awards, the estimated stock price volatility, the risk-free interest rate, and the expected dividend yield. The expected volatility assumption is based on an assessment of the historical volatility, with consideration of implied volatility, derived from an analysis of historical trade activity. 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.

Warrants We account for our warrants as either equity or liabilities based upon the characteristics and provisions of each instrument and evaluation of sufficient authorized shares available to satisfy the obligations. Warrants classified

as derivative liabilities are recorded on our consolidated balance sheets at their fair value on the date of issuance and are revalued at each subsequent balance sheet date, with fair value changes recognized as increases or decreases in other income (expense) in the consolidated statements of operations. The Company estimates the fair value of its derivative liabilities using a third party valuation analysis that utilizes a Monte

Table of Contents

Carlo pricing valuation model and assumptions that are based on the individual characteristics of the warrants or instruments on the valuation date, such as probability of a dilutive issuance, as well as expected volatility, expected life, yield and a risk-free interest rate. The expected volatility assumption is primarily based on an assessment of the historical volatility, with consideration of implied volatility, derived from an analysis of historical trade activity. Warrants classified as equity are recorded within additional paid in capital at the issuance date and are not remeasured in subsequent periods, unless the underlying assumptions change to trigger liability accounting.

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, 2016 and December 31, 2015, respectively, we had established a valuation allowance of $914.5 million and $962.6 million against all of our net deferred tax asset balances, 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, 2016 and 2015

Revenues

The following table provides a comparison of the revenue categories for the years ended December 31, 2016 and 2015 (dollars in thousands):

	Twelve Months Ended December 31,			
	2016	2015	$ Change	% Change
Revenue:				
Net revenue collaboration	$ 171,965	$	$ 171,965	100%
Net revenue commercial product sales:				
Gross revenue from commercial product sales	2,714		2,714	100%
Gross-to-net adjustments:				
Wholesale distribution fees and prompt pay discounts	(489)		(489)	100%
Patient discount and co-pay assistance programs	(196)		(196)	100%
Rebates	(134)		(134)	100%
Net revenue commercial product sales	1,895		1,895	100%
Revenue bulk insulin sales	898		898	100%
Total net revenue	$ 174,758	$	$ 174,758	100%

In 2016, we derived a significant amount of revenue from our collaboration with Sanofi under which we had to perform certain obligations and we received periodic payments. During the year ended December 31, 2016, we

recognized net revenue from our collaboration with Sanofi of $172.0 million. The recognized collaboration revenue relates to payments for activities from prior periods which were previously deferred as the transactions did not meet the criteria for revenue recognition until 2016. In the third quarter of 2016, due to the termination of the Sanofi License Agreement, we determined the costs related to the collaboration with Sanofi were reasonably estimable, resulting in the recognition of revenue as there were no future obligations to Sanofi. The amount of revenue recognized was the upfront payment of $150.0 million and two milestone payments of $25.0 million each, offset by $64.9 million of net loss share with Sanofi, as well as $17.5 million in sales of Afrezza and $19.4 million in sales of bulk insulin, both to Sanofi. During the year ended December 31, 2015, we did not recognize any revenues from collaboration.

Table of Contents

We began distributing MannKind-branded Afrezza product to wholesalers through ICS Direct during the week of July 25, 2016. We recognize commercial product revenue based on Afrezza prescriptions dispensed to patients. During the year ended December 31, 2016, we recognized net revenue from commercial product sales of $1.9 million. During the year ended December 31, 2015, we did not recognize any revenues from commercial product sales. At December 31, 2016, year to date total gross-to-net adjustments were approximately 30% of gross revenue from product sales.

In the fourth quarter of 2016 we sold $0.9 million of bulk insulin to a third party. During the year ended December 31, 2015, we did not sell any bulk insulin.

Expenses

The following table provides a comparison of the expense categories for the year ended December 31, 2016 and 2015 (dollars in thousands):

	Twelve Months Ended December 31,			
	2016	2015	$ Change	% Change
Expenses:				
Costs of revenue collaboration	$ 32,971	$	$ 32,971	100%
Cost of goods sold	17,121	64,745	(47,624)	(74)%
Research and development	14,917	29,674	(14,757)	(50)%
Selling and marketing	19,854	1,587	18,267	1,151%
General and administrative	27,074	39,373	(12,299)	(31)%
Property and equipment impairment	1,259	140,412	(139,153)	(99)%
(Gain) loss on foreign currency translation	(3,433)	2,697	(6,130)	(227)%
(Gain) loss on purchase commitments	(2,265)	66,167	(68,432)	(103)%
Total expenses	$ 107,498	$ 344,655	$ (237,157)	(69)%

Costs of revenue from collaboration represents the costs of product manufactured and sold to Sanofi, as well as certain direct costs associated with a firm purchase commitment entered into in connection with the collaboration with Sanofi. During the year ended December 31, 2016, we recognized $33.0 million of costs of revenue from collaboration, which consists of $13.5 million in Afrezza manufacturing costs for product sold to Sanofi, and $19.5 million related to the cost of bulk insulin sold to Sanofi. The Afrezza manufacturing costs were previously deferred on the consolidated balance sheet at December 31, 2015. During the year ended December 31, 2015, we did not recognize any costs of revenue from collaboration.

Cost of goods sold includes the costs related to Afrezza product dispensed by pharmacies to patients as well as under-absorbed labor and overhead and inventory write-offs, which are recorded as expenses in the period in which they are incurred, rather than as a portion of the inventory cost. The decrease in cost of goods sold of $47.6 million for the year ended December 31, 2016 compared to the same period in the prior year is primarily due to $36.1 million of inventory impairment write offs and $3.2 million in deposit write offs, which were recorded in other assets, related to impairment in 2015 that did not recur in 2016 and a $8.6 million decrease in under-absorbed labor and overhead due to the reduction in force and decreased depreciation following the fixed asset impairment write-down in 2015. These decreases are offset by $0.3 million cost of goods attributable to commercial product sales, which consists of the manufacturing costs for Afrezza dispensed to patients. This $0.3 million attributable to commercial product sales only

includes conversion cost as we wrote off the cost of our raw materials held in inventory at the end of 2015.

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

Table of Contents

personnel, raw materials, laboratory supplies and materials, facility costs, costs for consultants and related contract research, licensing fees and depreciation of equipment. The decrease in research and development expense of $14.8 million for the year ended December 31, 2016 compared to the same period in the prior year is due to the expense associated with the 2015 reduction in force exceeding the expense associated with the 2016 reduction in force by $6.2 million, as well as decreases in facility spending of $3.3 million due to the reduction in force and lower depreciation expense following the write-off of property, plant and equipment in 2015; in research and development project costs of $3.1 million due to completion of projects in 2015; in clinical trial expenses of $2.1 million due to completion of Afrezza trials in 2015; in stock-based compensation expense of $1.1 million due to fewer employees as a result of the reduction in force and lower stock price; and the receipt of $0.4 million research and development reimbursement payment from Receptor in 2016, which was offset against expense. These decreases were partially offset by an increase in FDA fees for the 2016 filing of a supplemental new drug application for $1.0 million and a $0.9 million reduction in our research and development tax credit as a result of lower qualifying expenses coupled with a transition to commercial sales activity.

Our selling and marketing expenses are driven by salaries, benefits and stock-based compensation for sales and marketing support personnel. The increase in selling and marketing expenses of $18.3 million for the year ended December 31, 2016 compared to the same period in the prior year is due to an increase in costs for the support of sales and marketing of Afrezza as a result of our assuming responsibility for these activities which were previously the responsibility of Sanofi. Included in these costs are salaries of $2.9 million, contracted sales force and diabetic educators of $7.6 million, travel of $0.4 million, and consultants and related expenses for sales and marketing of $7.4 million.

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. The decrease in general and administrative expenses of $12.3 million for the year ended December 31, 2016 compared to the same period in the prior year is primarily due to a decrease in costs associated with the 2015 reduction in force of $6.4 million; stock-based compensation expense of $2.6 million due to lower stock price and fewer employees; professional fees of $1.7 million due to lower internal communications, information technology, legal and outside service expenses due to concerted efforts to conserve cash; and facility spending of $1.7 million due to a lower operating cost as a result of the reduction in force and move to the leased Valencia offices, which helped save on facility costs.

Property and equipment impairment decreased $139.2 million for the year ended December 31, 2016 compared to year ended December 31, 2015. In the fourth quarter of 2015 and the first quarter of 2016, factors indicated the existence of impairment in connection with the lower than expected sales of Afrezza and the Sanofi termination. The property and equipment impairment in 2015 and the first quarter of 2016 reduced the carrying amount of our real property and machinery and equipment to fair value based on our impairment assessments. In the fourth quarter of 2016 we recorded a $0.5 million impairment charge associated with the Valencia property when it became probable that the property would be sold within one year.

Under the Insulin Supply Agreement with Amphastar, which is denominated in Euros, we were required to record the foreign currency translation impact of the U.S. dollar to euro exchange rate associated with the recognized loss on purchase commitments in 2016. We were also required to record the foreign currency translation impact of the U.S. dollar to euro exchange rate associated with the deposit we made with Amphastar on this agreement in 2015. The gain on foreign currency translation for the year ended December 31, 2016 was $3.4 million as compared to a loss in 2015 of $2.7 million, resulting in a $6.1 million net variance.

(Gain) loss on purchase commitments changed by $68.4 million as a result of a gain recorded in 2016 compared to a loss in 2015. The $2.3 million gain on purchase commitments in 2016, related to a renegotiation of certain of our purchase commitments (primarily the reduction in cancellation fees under the Amphastar agreement). The $66.2 million loss on purchase commitments in 2015 resulted from our assessment of excess inventory as a result of lower than expected sales of Afrezza as well as a lower of cost or net realizable value adjustment due to estimated conversion costs in excess of our estimated selling price of Afrezza.

Table of Contents

Other Income (Expense)

The following table provides a comparison of the other income (expense) categories for the years ended December 31, 2016 and 2015 (dollars in thousands):

	Twelve Months Ended December 31,			
	2016	2015	$ Change	% Change
Change in fair value of warrant liability	$ 5,369	$	$ 5,369	100%
Interest income	85	18	67	372%
Interest expense on notes	(15,576)	(21,231)	5,655	(27%)
Interest expense on note payable to principal stockholder	(2,901)	(2,894)	(7)	0%
Gain (loss) on extinguishment of debt	72,024	(1,049)	73,073	(6,966%)
Other (expense) income	(597)	1,366	(1,963)	(144%)
Total other income (expense)	$ 58,404	$ (23,790)	$ 82,194	(346%)

During the year ended December 31, 2016 we recorded a $5.4 million change in the fair value of the warrant liability from May 12, 2016, the date that certain warrants were issued in connection with a registered public offering. There was no warrant liability for the twelve months ended December 31, 2015.

The decrease of $5.7 million in the interest expense on notes for the year ended December 31, 2016 compared to the same period in the prior year was primarily due to interest expense paid in 2015 for the achievement and re-measurement of the second milestone under the Milestone Agreement. There was no such payment in 2016.

The $72.0 million gain from extinguishment of debt in 2016 was a result of the Settlement Agreement with Sanofi and forgiveness of the full outstanding loan balance of the Sanofi Loan Facility. The $1.0 million loss in 2015 was from extinguishment of debt driven by the settlement of the 5.75% Senior Convertible Notes due 2015 through payment of cash and issuance of new debt.

The change in other (expense) income of $2.0 million for the year ended December 31, 2016 compared to the same period in the prior year was primarily due to a one-time adjustment in 2015 for patents we sold to a third party.

Years ended December 31, 2015 and 2014

Revenues

During the years ended December 31, 2015 and 2014, we did not recognize any revenue.

Expenses

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

	Year Ended December 31,			
	2015	2014	$ Change	% Change
Expenses:				
Cost of goods sold	$ 64,745	$	$ 64,745	100%
Research and development	29,674	100,244	(70,570)	(70%)
Selling and marketing	1,587	3,556	(1,969)	(55%)
General and administrative	39,373	75,827	(36,454)	(48%)
Property and equipment impairment	140,412		140,412	100%
Loss on foreign currency translation	2,697		2,697	100%
Loss on purchase commitments	66,167		66,167	100%
Total expenses	$ 344,655	$ 179,627	$ 165,028	92%

Table of Contents

Cost of goods sold was $64.7 million for the year ended December 31, 2015, resulting from product manufacturing costs associated with Afrezza product sales, which could not be capitalized due to excess capacity as well as inventory write-offs. We had no cost of goods sold for the year ended December 31, 2014, as pre-commercial manufacturing costs associated with Afrezza were accounted for as research and development expenses. Cost of goods sold represents under-absorbed labor and overhead of $21.4 million which is expensed in the period in which it is incurred and inventory write-offs of $36.1 million and $3.2 million in write-offs of deposits placed with inventory suppliers, which were previously included in other assets in the accompanying consolidated balance sheets.

Historically our research and development expenses have consisted mainly of costs associated with research and development of our product candidates, including associated clinical trials and manufacturing process development. This includes the salaries, benefits and stock-based compensation of research and development personnel, raw materials, laboratory supplies and materials, facility costs, costs for consultants and related contract research, licensing fees and depreciation of equipment. The decrease in research and development expenses of $70.6 million for the year ended December 31, 2015 compared to the year ended December 31, 2014 was primarily due to a decrease of $36.0 million in manufacturing process development expenses resulting from the shift to commercial production of Afrezza, a $19.3 million decrease in stock-based compensation expense as a result of a non-recurring modification of the settlement terms of certain performance-based restricted stock units recorded in 2014 and the achievement of performance-based grants in 2014 and the first quarter of 2015, and a decrease in clinical trial related expenses of $16.0 million, primarily resulting from the completion of the Phase 3 clinical trials.

Our selling, general and administrative expenses are driven by salaries, benefits and stock-based compensation for sales, administrative, finance, business development, human resources, legal and information systems support personnel. In addition, selling, general and administrative expenses include professional service fees and business insurance costs. The decrease in selling, general and administrative expenses of $38.4 million for the year ended December 31, 2015 compared to the year ended December 31, 2014 was primarily due to decreased stock-based compensation expense of $20.6 million, resulting from the modification and achievement of performance-based grants in 2014 and the first quarter of 2015, as described above. Additionally, the decrease is also attributable to professional fees of $13.8 million related to the Sanofi License Agreement incurred in the third quarter of 2014 and decreased expenses of $3.2 million following the completion of restructuring activities and decreased personnel costs in early 2015.

Property and equipment impairment increased $140.4 million for the year ended December 31, 2015 compared to the year ended December 31, 2014. In connection with the lower than expected sales of Afrezza and the termination of the Sanofi License Agreement, factors indicated the existence of impairment in the fourth quarter of 2015. A property and equipment impairment was recorded which reduced the carrying amount of our real property and machinery and equipment to fair value based on our impairment assessment in the fourth quarter of 2015.

Under our Insulin Supply Agreement with Amphastar, which is denominated in Euros, we were required to record the foreign currency translation impact of the U.S. dollar to euro exchange rate associated with the deposit on this agreement. The loss on foreign currency translation for the year ended December 31, 2015 was $2.7 million. There was no gain or loss in the prior year because we did not have amounts on deposit with Amphastar in 2014.

Inventory purchase commitments were analyzed in 2015 for potential impairment. Loss on purchase commitments increased $66.2 million for the year ended December 31, 2015 compared to the year ended December 31, 2014. The loss on purchase commitments was related to the recognized loss on future purchase commitments resulting from our assessment of excess inventory as a result of lower than expected sales of Afrezza as well as a lower of cost or net realizable value adjustment due to estimated conversion costs in excess of our estimated selling price of Afrezza.

61

Table of Contents

Other Income (Expense)

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

	Year Ended December 31,			
	2015	2014	$ Change	% Change
Interest income	$ 18	$ 9	$ 9	100%
Interest expense on notes	(21,231)	(17,549)	(3,682)	21%
Interest expense on note payable to principal stockholder	(2,894)	(2,894)		%
Loss on extinguishment of debt	(1,049)		(1,049)	(100%)
Other income	1,366	1,679	(313)	(19%)
Total other income (expense)	$ (23,790)	$ (18,755)	$ (5,035)	27%

Interest expense on notes increased $3.7 million from $17.5 million for the year ended December 31, 2014 to $21.2 million for the year ended December 31, 2015. The increase was primarily due to $5.8 million interest expense associated with the milestone payment resulting from the achievement and re-measurement of the second milestone under the Milestone Agreement in the first quarter of 2015 compared to the $1.9 million interest expense from the payment of the first milestone in 2014. The increase was also due to an increase of $1.7 million related to the Sanofi Loan Facility and $0.8 million in interest for 2018 notes, which was offset by a decrease in interest expense of $2.7 million resulting from the maturity of the 5.75% Senior Convertible Notes due 2015.

Loss on extinguishment of debt was $1.0 million for the year ended December 31, 2015 compared to no loss on extinguishment of debt for the year ended December 31, 2014. The loss on extinguishment is due to the settlement of the 5.75% Senior Convertible Notes due 2015 through payment of cash and issuance of new debt.

Other income for the year ended December 31, 2015 was $1.4 million resulting from the relief of an accrual for potential expenses associated with the sale of intellectual property related to oncology in 2014, which was subsequently resolved without payment in the first quarter of 2015. For the year ended December 31, 2014, other income was $1.7 million resulting primarily 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.

Liquidity and Capital Resources

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

As of December 31, 2016, we had $152.1 million principal amount of outstanding debt, consisting of:

$27.6 million principal amount of 2018 notes bearing interest at 5.75% per annum and maturing on August 15, 2018;

$55.0 million principal amount of 2019 notes bearing interest at 9.75% per annum, $15.0 million of which is due and payable in July 2017, $15.0 million of which is due and payable in July 2018 and $25.0 million of which is due and payable in July and December 2019;

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

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

Table of Contents

As of December 31, 2016, the amount available for future borrowings under The Mann Group Loan Arrangement was $30.1 million. A portion of these available borrowings may be used to capitalize accrued interests into principal, upon mutual agreement of the parties, as it becomes due and payable. As of December 31, 2016, the accrued and unpaid interest under The Mann Group Loan Arrangement was $9.3 million.

Outstanding debt is more fully described in Note 6 Related-Party Arrangements, Note 7 Borrowings, Note 9 Fair Value of Financial Instruments and Note 13 Commitments and Contingencies.

There can be no assurance that we will have sufficient resources to make any required repayments of principal under the 2018 notes, 2019 notes, Tranche B notes, or The Mann Group Loan Arrangement when required. Further, if we undergo a fundamental change, as that term is defined in the indentures governing the terms of the 2018 notes, or certain Major Transactions as defined in the Facility Agreement in respect of the 2019 notes and the Tranche B notes, the holders of the respective debt securities will have the option to require us to repurchase all or any portion of such debt securities at a repurchase price of 100% of the principal amount of such debt securities to be repurchased plus accrued and unpaid interest, if any. The 2018 notes bear interest at the rate of 5.75% per year on the outstanding principal amount, payable in cash semiannually in arrears on February 15 and August 15 of each year. The 2019 notes bear interest at the rate of 9.75% per year on the outstanding principal amount and the Tranche B notes bear interest at the rate of 8.75% on the outstanding principal amount, with accrued interest on each payable in cash quarterly in arrears on the last business day of March, June, September and December of each year. Loans under the Mann Group Loan Arrangement accrue interest at a rate of 5.84% per annum due and payable quarterly in arrears on the first day of each calendar quarter for the preceding quarter, or at such other time as we and The Mann Group LLC mutually agree. While we have been able to timely make our required interest payments to date, we cannot guarantee that we will be able to do so in the future. If we fail to pay interest on the 2018 notes, 2019 notes, or Tranche B notes, or if we fail to repay or repurchase the 2018 notes, 2019 notes, Tranche B notes, or borrowings under the Mann Group Loan Arrangement when required, we will be in default under the applicable instrument for such indebtedness, and may also suffer an event of default under the terms of other borrowing arrangements that we may enter into from time to time. Any of these events could have a material adverse effect on our business, results of operations and financial condition, up to and including the note holders initiating bankruptcy proceedings or causing us to cease operations altogether.

In connection with the execution of the Facility Agreement, on July 1, 2013, we issued Milestone Rights to the Milestone Purchasers. The Milestone Rights provide the Milestone Purchasers certain rights to receive payments of up to $90.0 million upon the occurrence of specified strategic and sales milestones, including the first commercial sale of an Afrezza product and the achievement of specified net sales figures. In addition, the Facility Agreement includes customary representations, warranties and covenants, including a restriction on the incurrence of additional indebtedness, and a financial covenant which requires our cash and cash equivalents, which includes available borrowings under The Mann Group Loan Arrangement, on the last day of each fiscal quarter to not be less than $25.0 million. See Note 13 Commitments and Contingencies and Note 7 Borrowings for further information related to the Facility Agreement.

On July 31, 2014, we entered into the Insulin Supply Agreement, pursuant to which we agreed to purchase certain annual minimum quantities of insulin. See Note 13 Commitments and Contingencies for further information related to the Insulin Supply Agreement.

Pursuant to the Sanofi License Agreement, we received an initial upfront payment of $150.0 million and milestone payments totaling $50.0 million in the first quarter of 2015 upon satisfaction of certain manufacturing milestones specified in the Sanofi License Agreement. As a result of the termination of the Sanofi License Agreement, we will not receive any additional milestone payments from Sanofi under the agreement. In addition, on November 9, 2016, in

connection with the Settlement Agreement, we and Aventisub LLC, an affiliate of Sanofi, agreed to terminate the Sanofi Loan Facility and the Security Agreement (the Security Agreement). In

Table of Contents

connection with such termination, Aventisub LLC agreed to forgive the full outstanding loan balance on the Sanofi Loan Facility of $72.0 million owed by us and agreed to release its security interests encumbering our assets. Sanofi also agreed to make a cash payment of $30.6 million to the Company, which was received in early January 2017 as acceleration and in replacement of all other payments that Sanofi would otherwise have been required to make in the future pursuant to the insulin put option, without the Company being required to deliver any insulin for such payment. See Note 8 Collaboration Arrangements for further information related to the Sanofi agreements.

In May 2016, we sold in a registered public offering (the May 2016 Offering) 9,708,737 shares of our common stock, together with certain warrants exercisable for up to an aggregate of 7,281,553 shares of our common stock and certain warrants exercisable for up to an aggregate of 2,427,184 shares of our common stock. Net proceeds from this offering were approximately $47.3 million after deducting placement agent fees and expenses and paying for offering expenses, and excluding any future proceeds from the exercise of the warrants. See Note 16 Warrants for further information related to the May 2016 Offering.

Cash used in operating activities, which consists of net income adjusted for the various non-cash included in income, changes in working capital and changes in certain other balance sheet accounts, totaled $78.1 million in 2016. Operating activities used $57.2 million and provided $4.1 million of cash in 2015 and 2014, respectively.

Cash used in operating activities in 2016 of $78.1 was primarily driven by an excess of cash used in operations of approximately $105.1 million over cash received from operations of approximately $29.4 million. Cash received of approximately $29.4 million represented $19.4 million from sales of insulin to Sanofi, $4.8 million from Afrezza product sales, $2.7 million from sales of insulin to a third party, $1.4 million from our collaboration with Receptor and $1.1 million from other sources. Cash used in operations of approximately $105.1 million represented by $69.5 million in cash used for selling, general and administrative expenses, cost of goods sold, and research and development, a $12.1 million decrease in accounts payable between December 31, 2015 and December 31, 2016, $11.6 million in purchases of inventory from Amphastar, $9.0 million in interest paid and a $2.5 million increase in inventory between December 31, 2015 and December 31, 2016.

During the year ended December 31, 2015, we used $57.2 million of cash for operating activities as a result of our net loss of $368.4 million, adjusted by noncash charges of $273.1 million and a net change in operating assets and liabilities of $38.1 million. The non-cash charges included $206.6 million of impairment charges, $22.0 million of depreciation and accretion and stock-based compensation, $1.7 million interest accrued through borrowings under Sanofi Loan Facility, $1.0 million for the loss on extinguishment of debt, with the remainder due to an adjustment for foreign currency transaction losses. The change in net assets and liabilities was predominately due to the net decreases in receivables from collaboration from the $50.0 million received in milestone payments and $13.5 million due to the decrease in prepaids and other current assets at December 31, 2015 compared to December 31, 2014 primarily due to prepayment on insulin in 2014, which did not occur in 2015. This was offset by net decreases in inventory as we purchased significant inventory in 2014 related to Amphastar, which did not occur in 2015.

During the year ended December 31, 2014, cash provided by operations was $4.l million as a result of our net loss of $198.4 million, adjusted by non-cash charges of $71.6 million and a net change in operating assets and liabilities of $130.9 million. The non-cash charges were predominately related to depreciation and accretion and stock-based compensation. The change in net assets and liabilities was predominately due to the net increases in receivables and deferred payments from collaboration of $150.0 million related to the fee associated with the Sanofi License Agreement, partially offset by the $15.0 million deposit to Amphastar as prepayment for 2015 quantities of insulin as part of the Insulin Supply Agreement.

Cash used in investing activities decreased by $9.1 million for the year ended December 31, 2016 versus December 31, 2015, which is primarily a result of decreasing expenditures on property and equipment to conserve cash. Cash used in investing activities in 2016 was primarily comprised of purchases of property and equipment of $1.1 million. Investing activities used $10.2 million and $24.1 million of cash in 2015 and 2014, respectively, which primarily comprised of purchases of property and equipment.

Table of Contents

Cash provided by financing activities, which mainly accounts for external activities that allow us to raise capital, primarily represents proceeds of $47.3 million (net of related issuance costs) from the May 2016 Offering, offset by $5.0 million from payments of notes payable in 2016. Financing activities provided $5.7 million and $70.1 million of cash in 2015 and 2014, respectively.

As of December 31, 2016, we had $22.9 million in cash and cash equivalents. We expect to expend our capital resources primarily for the manufacturing, sales and marketing of Afrezza and to develop our other product candidates. We also intend to use our capital resources for general corporate purposes.

If we enter into strategic business collaborations with respect to our other product candidates, we would expect, as part of the transaction, to receive additional capital. In addition, we expect to pursue the sale of equity and/or debt securities, or the establishment of other funding facilities. Issuances of debt or additional equity could impact the rights of our existing stockholders, dilute the ownership percentages of our existing stockholders and may impose restrictions on our operations. These restrictions could include limitations on additional borrowing, specific restrictions on the use of our assets as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. We also may seek to raise additional capital by pursuing opportunities for the licensing, sale or divestiture of certain intellectual property and other assets, including our Technosphere technology platform. There can be no assurance, however, that any strategic collaboration, sale of securities or sale or license of assets will be available to us on a timely basis or on acceptable terms, if at all. If we are unable to raise additional capital, we may be required to enter into agreements with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop independently, and any such agreements may not be on terms as commercially favorable to us.

We cannot provide assurances that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. If planned operating results are not achieved or we are not successful in raising additional capital, if needed, through equity or debt financing or entering business collaborations, we may be required to reduce expenses through the delay, reduction or curtailment of our projects, or further reduction of costs for facilities and administration, and there will continue to be substantial doubt about our ability to continue as a going concern.

Off-Balance Sheet Arrangements

As of December 31, 2016, we did not have any off-balance sheet arrangements.

Table of Contents

Contractual Obligations

Our contractual obligations represent future cash commitments and liabilities under agreements with third parties, and exclude contingent liabilities for which we cannot reasonably predict future payments. Accordingly, the table below excludes contractual obligations relating to milestone and royalty payments due to third parties, all of which are contingent upon certain future events. The expected timing of payment of the obligations presented (excluding payments in respect of the Milestone Rights) below are estimated based on current information. Future payments relate to operating lease obligations, the 2018 notes, the facility financing obligation, open purchase order and supply commitments, and contractual minimum purchase commitments under the Insulin Supply Agreement with Amphastar consisted of the following at December 31, 2016 (in thousands):

	Payments Due in				
Contractual Obligations	Less Than One Year	1-3 Years	4-5 Years	More Than 5 Years	Total
Open purchase order and commitments (1)	$ 5,943	$ 1,535	$ 483	$	$ 7,961
Senior convertible notes long term (2)	1,614	29,441			31,055
Note payable to principal stockholder (3)		67,523			67,523
Facility financing obligation (4)	26,138	61,576			87,714
Insulin supply agreement (5)	4,227	38,895	36,673	20,374	100,169
Other (6)	866				866
Operating lease obligations	120	6			126
Total contractual obligations	$ 38,908	$ 198,976	$ 37,156	$ 20,374	$ 295,414

(1) The amounts included in open purchase order and supply commitments are subject to performance under the purchase order or contract by the supplier of the goods or services and do not become our obligation until such performance is rendered. The amount shown is principally for the purchase of materials for commercial operations or sales and marketing efforts.

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

(3) The obligation for the note payable to the principal stockholder includes future principal and interest payments related to the $49.5 million of borrowings as of December 31, 2016. 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 $55.0 million aggregate principal amount of 2019 notes issued in the first and fourth tranches under the Facility Agreement, and on $15.0 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 originally agreed to purchase certain annual minimum quantities of insulin for calendar years 2015 through 2019 for an aggregate total purchase price of approximately 120.1 million The Insulin Supply Agreement specifies that Amphastar will be deemed to have satisfied its obligations with respect to quantity, if the actual quantity supplied is within plus or minus ten percent (+/- 10%) of the quantity set forth in the applicable purchase order. On November 9, 2016,

we amended the Insulin Supply Agreement to lower the annual minimum quantities purchased of insulin for calendar year 2017 through 2023 to an aggregate total remaining purchase price of 93.0 million at December 31, 2016. Future payments due were converted to U.S. dollars using the December 31, 2016 euro-to-dollar exchange. In addition, the aggregate cancellation fees that we would incur in the event that certain insulin quantities are not purchased was lowered from $5.3 million to $3.4 million.

(6) The amount relates to purchase orders for inhalers in 2017.

Table of Contents

Related Party Transactions

For a description of our related party transactions see Note 6 Related-Party Arrangements of the Notes to Consolidated Financial Statements included in Part II, Item 8 Financial Statements and Supplementary Data .

Recent Accounting Pronouncements

See Note 2 Summary of Significant Accounting Policies of the Notes to Consolidated Financial Statements included in Part II, Item 8 Financial Statements and Supplementary Data , for information regarding accounting standards we adopted in 2016 and other new accounting standards that have been issued by the FASB but are not effective until after December 31, 2016.

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

Interest Rate Risk

Due to the fixed interest rates of our debt, we currently do not have an exposure to changes in our interest expense as a result of changes in interest rates. The interest rate on amounts borrowed under The Mann Group Loan Arrangement is fixed at 5.84%. As of December 31, 2016, the total principal amount outstanding under The Mann Group Loan Arrangement was $49.5 million. As of December 31, 2016, we also had debt related to the 2018 notes at a fixed interest rate of 5.75%, debt related to the 2019 notes at a fixed interest rate of 9.75% 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, 2016 were to have occurred, this change would not have had a material effect on the value of our short-term investment portfolio.

Foreign Currency Exchange Risk

We incur and will continue to incur significant expenditures for insulin supply obligations under our supply agreement with Amphastar. Such obligations are denominated in euros. At the end of each reporting period, these liabilities, if any, are converted to U.S. dollars at the then-applicable foreign exchange rate. As a result, our business is affected by fluctuations in exchange rates between the U.S. dollar and foreign currencies. We have not entered into foreign currency hedging transactions to mitigate our exposure to foreign currency exchange risks, but may enter into foreign currency hedging transactions in the future. Exchange rate fluctuations may adversely affect our expenses, results of operations, financial position and cash flows. During the year ended December 31, 2016, associated with our requirement to purchase insulin contemplated under our supply agreement with Amphastar, 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, 2016 were to occur, this change would have resulted in a foreign currency impact to our pre-tax income (losses) of approximately $9.8 million.

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

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

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

None.

Table of Contents

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

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15 under the Securities Exchange Act of 1934, as amended (the Exchange Act), the Company carried out an evaluation under the supervision and with the participation of the Company s management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness of the Company s disclosure controls and procedures. In designing and evaluating the Company s disclosure controls and procedures, the Company and its management recognize that there are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their desired control objectives. Additionally, in evaluating and implementing possible controls and procedures, the Company s management was required to apply its reasonable judgment.

Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2016.

Management s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for the Company, as such term is defined in Rule 13a-15(f) under the Exchange Act. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may not operate effectively because of changes in conditions such as replacing consulting resources with permanent personnel or that the degree of compliance with the policies or procedures may deteriorate. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2016. In making this assessment, the Company s management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in the Internal Control-Integrated Framework (2013 Framework).

Based on this assessment, our management concluded that, as of December 31, 2016, our internal control over financial reporting is effective based on those criteria.

Remediation Steps Taken to Address Prior Material Weaknesses

As of December 31, 2015 our management concluded that our internal control over financial reporting was not effective based on the COSO criteria. In making this assessment, the Company s management used the criteria set forth by the 2013 COSO Framework. A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

The following is a description of the material weakness previously identified in our internal control over financial reporting: In connection with the preparation of our annual report on Form 10-K for the year ended December 31, 2015 we did not maintain sufficient internal control over financial reporting due to the lack of operating effectiveness of our controls over the impairment testing that we performed in accordance with ASC 360-10*, Impairment and Disposal of Long-Lived Assets* and ASC 330-10, *Inventories*, as of December 31, 2015. Specifically, our review controls did not operate at a sufficient level of precision to identify certain errors, which management has determined constituted a material weakness.

As soon as we learned of the material weakness as of December 31, 2015, we began taking steps intended to remediate this material weakness and improve our control processes and procedures with respect to operating

Table of Contents

effectiveness regarding our controls over impairment and disposal of long lived assets and inventories. The following activities have been implemented as part of our efforts to become compliant with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002:

- Improved the design of and increased the level of precision in which documentation of review controls related to the review of the asset impairment assessment and impairment and disposal of long-lived assets and inventories so these controls would operate effectively to identify errors;

- Held training sessions with relevant personnel and developed specific review procedures regarding the review of impairment assessments; and

- Developed checklists to ensure that all appropriate accounting principles were being applied during the accounting for these transactions and to facilitate the review of the accounting of these transactions by knowledgeable accounting personnel.

In addition to the material weakness noted above, as of June 30, 2016 our management concluded that our internal control over financial reporting was not effective based on the COSO criteria. In making this assessment, the Company s management used the criteria set forth by the 2013 Framework.

The following is a description of the material weakness previously identified in our internal control over financial reporting: In connection with the preparation of our quarterly report on Form 10-Q for the quarter ended June 30, 2016 we identified a material weakness in our internal control over significant non-routine transactions. Specifically, this deficiency in operation of internal controls resulted in an inadequate evaluation of the underlying accounting guidance for transactions entered into during the quarter and insufficient review of underlying analyses.

As soon as we learned of the material weakness as of June 30, 2016, we began taking steps intended to remediate this material weakness and improve our control processes and procedures with respect to operating effectiveness regarding our controls over significant and non-routine transactions. The following activities have been implemented as part of our efforts to become compliant with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002:

- Enhanced the design of the existing controls related to significant non-routine transactions;

- Conduct weekly meetings with relevant personnel so that significant non-routine transactions are identified and addressed in a timely manner; and

- Hired consultants with accounting expertise to review the accounting for significant non-routine transactions to ensure that the accounting for these transactions are proper.

In particular, our remediation steps, noted above, were designed and implemented to ensure that the recording of the impairment of long-lived assets and inventories is appropriate and that adequate evaluations of the underlying accounting guidance for significant non-routine transactions are appropriate, sufficiently reviewed and addressed in a timely manner. The newly implemented controls have also been tested by management and concluded to be operating

effectively. Management believes that as of December 31, 2016, the remediation steps implemented during 2016 successfully remediated the material weaknesses in 2015 and the quarter ended June 30, 2016.

Changes in Internal Control over Financial Reporting

Except as described above related to the remediation of the material weaknesses, there were no changes in internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) that occurred during the fourth quarter of 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of MannKind Corporation

Valencia, California

We have audited the internal control over financial reporting of MannKind Corporation and subsidiaries (the Company) as of December 31, 2016, 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, 2016, 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, 2016 of the Company and our report dated March 16, 2017 expressed an unqualified opinion on those financial statements and includes explanatory

paragraphs relating to the Company s ability to continue as a going concern and the effects of a reverse stock split.

/s/ DELOITTE & TOUCHE LLP

Stamford, Connecticut

March 16, 2017

Table of Contents

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

None.

PART III

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 will be contained in the section entitled Proposal 1 Election of Directors and Corporate Governance Principles and Board and Committee Matters in our definitive proxy statement for our 2017 Annual Meeting of Stockholders (the Proxy Statement), to be filed with the SEC on or before May 1, 2017, and is incorporated herein by reference.

Additional information required by this Item will be set forth in the Proxy Statement under the section entitled Section 16(a) Beneficial Ownership Reporting Compliance, and is incorporated herein by reference.

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 required by this Item will be set forth under the caption Executive Compensation, Compensation of Directors, Compensation Committee Interlocks and Insider Participation and Compensation Committee Report in the Proxy Statement, and is incorporated herein by reference.

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

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

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

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

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

The information required by this Item will be set forth under the caption Principal Accounting Fees and Services and Pre-Approval Policies and Procedures in the Proxy Statement and 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.

Table of Contents

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 81:

Report of Independent Registered Public Accounting Firm	81
Consolidated Balance Sheets	82
Consolidated Statements of Operations	83
Consolidated Statements of Comprehensive Income (Loss)	84
Consolidated Statements of Stockholders Deficit	85
Consolidated Statements of Cash Flows	86
Notes to Consolidated Financial Statements	88

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 Exhibit 3.1 to MannKind s Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on August 9, 2016).
3.2	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), filed with the SEC on March 2, 2017).
3.3	Amended and Restated Bylaws (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), filed with the SEC on November 19, 2007).
4.1	Reference is made to Exhibits 3.1, 3.2 and 3.3.
4.2	Form of common stock certificate.

4.3	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), filed with the SEC on July 1, 2013).
4.4	Form of Amended and Restated 9.75% Senior Secured Convertible Promissory Note due 2019 (incorporated by reference to Exhibit 4.7 to MannKind s Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 3, 2014).
4.5	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).

Table of Contents

Exhibit Number	Description of Document
4.6	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), filed with the SEC on July 1, 2013).
4.7	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), filed with the SEC on July 1, 2013).
4.8	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).
4.9	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. (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).
4.10	Second Amendment to Facility Agreement and Registration Rights Agreement, dated as of August 11, 2014, by and among MannKind, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 4.14 to MannKind s Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on November 10, 2014).
4.11	Indenture, by and between MannKind and U.S. Bank (as successor trustee to Wells Fargo Bank, N.A.), dated August 10, 2015 (incorporated by reference to Exhibit 4.18 to MannKind s Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on August 10, 2015).
4.12	Form of 5.75% Convertible Senior Subordinated Exchange Note due 2018 (included in Exhibit 4.11 as Exhibit A thereto) (incorporated by reference to Exhibit 4.19 to MannKind s Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on August 10, 2015).
4.13	Form of Warrant to Purchase Common Stock issued November 16, 2015 (incorporated by reference to Exhibit 4.17 to MannKind s Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 15, 2016).
4.14	Form of Series A Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to MannKind s Current Report on Form 8-K (File No. 000-50865), filed with the SEC on May 10, 2016).
4.15	Form of Series B Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 to MannKind s Current Report on Form 8-K (File No. 000-50865), filed with the SEC on May 10, 2016).
4.16	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 99.1 to MannKind s Current Report on Form 8-K (File No. 000-50865), filed with the SEC on May 10, 2016).
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).

Table of Contents

Exhibit Number	Description of Document
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), filed with the SEC on March 16, 2006).
10.7*	Executive Severance Agreement, dated October 10, 2007, between MannKind and David Thomson (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), as amended, filed with the SEC on October 17, 2007).
10.8*	Separation Agreement, dated March 11, 2016, by and between MannKind and Juergen Martens (incorporated by reference to Exhibit 10.8 to MannKind s Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 15, 2016).
10.9*	Executive Severance Agreement, dated April 21, 2008, between MannKind and Matthew J. Pfeffer (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), as amended, filed with the SEC on October 17, 2007).
10.10*	Change of Control Agreement, dated October 10, 2007, between MannKind and David Thomson (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), as amended, filed with the SEC on October 17, 2007).
10.11*	Change of Control Agreement, dated April 21, 2008, between MannKind and Matthew J. Pfeffer (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), as amended, filed with the SEC on October 17, 2007).
10.12*	2004 Equity Incentive Plan, as amended (incorporated by reference to MannKind s proxy statement on Schedule 14A (File No. 000-50865), filed with the SEC on April 6, 2012).
10.13*	Form of Stock Option Agreement under the 2004 Equity Incentive Plan (incorporated by reference to MannKind s Registration Statement on Form S-1 (File No. 333-115020), originally filed with the SEC on April 30, 2004, as amended).
10.14*	Form of Phantom Stock Award Agreement under the 2004 Equity Incentive Plan (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), filed with the SEC on December 14, 2005).
10.15*	2004 Non-Employee Directors Stock Option Plan and form of stock option agreement there under (incorporated by reference to MannKind s Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 16, 2006).
10.16*	2004 Employee Stock Purchase Plan and form of offering document there under (incorporated by reference to MannKind s Registration Statement on Form S-1 (File No. 333-115020), originally filed with the SEC on April 30, 2004, as amended).
10.17**	

	Letter Agreement, dated June 4, 2011, between MannKind and N.V. Organon (incorporated by reference to MannKind s Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).
10.18**	Insulin Maintenance and Call-Option Agreement, dated June 19, 2009, by and among Pfizer Manufacturing Frankfurt GmbH, Pfizer Inc. and MannKind (incorporated by reference to MannKind s Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on May 4, 2009).

Table of Contents

Exhibit Number	Description of Document
10.19*	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).
10.20*	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).
10.21*	MannKind Corporation 2013 Equity Incentive Plan, as amended (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 August 9, 2016).
10.22*	Form of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the MannKind 2013 Equity Incentive Plan (incorporated by reference to MannKind s registration statement on Form S-8 (File No. 000-188790), filed with the SEC on May 23, 2013).
10.23*	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).
10.24	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).
10.25	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. (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).
10.26**	Supply Agreement, dated as of July 31, 2014, by and between MannKind and Amphastar France Pharmaceuticals S.A.S. (incorporated by reference to Exhibit 10.3 to MannKind s Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on November 10, 2014).
10.27	Sublease Agreement, dated May 1, 2015, by and between MannKind and the Alfred Mann Foundation for Scientific Research (incorporated by reference to Exhibit 10.37 to MannKind s Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 15, 2016).
10.28*	Offer Letter, dated March 9, 2016, by and between MannKind and Michael Castagna (incorporated by reference to Exhibit 10.38 to MannKind s Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 15, 2016).
10.29	At Market Issuance Sales Agreement, by and between MannKind and FBR Capital Markets & Co., dated April 26, 2016 (incorporated by reference to MannKind s Current Report on Form 8-K filed with the SEC on April 26, 2016).
10.30	Engagement Letter, dated May 8, 2016, by and between MannKind and H.C. Wainwright & Co. 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 May 10, 2016).
10.31	Settlement Agreement, dated November 9, 2016, by and among MannKind, Technosphere International C.V., MannKind Netherlands B.V. and Sanofi-Aventis U.S. LLC.

10.32	First Amendment to Supply Agreement, dated October 31, 2014, by and between MannKind and Amphastar France Pharmaceuticals, S.A.S. and Amphastar Pharmaceuticals, Inc.
10.33**	Second Amendment to Supply Agreement, dated November 9, 2016, by and between MannKind and Amphastar Pharmaceuticals, Inc.

Table of Contents

Exhibit Number	Description of Document
10.34	Agreement of Purchase and Sale and Joint Escrow Instructions, dated January 6, 2017, by and between MannKind and Rexford Industrial Realty, L.P. (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 January 12, 2017).
10.35	First, Second and Third Amendments to Agreement of Purchase and Sale and Joint Escrow Instructions, dated February 7, 2017, February 10, 2017 and February 15, 2017, respectively, by and between MannKind and Rexford Industrial Realty, L.P.
10.36*	Offer Letter dated December 22, 2016, by and between MannKind and Stuart Tross.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (see signature page hereto).
31	Certification of the Chief Executive Officer and Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32	Certifications of the Chief Executive Officer and Chief Financial Officer pursuant to Rules 13a-14(b) and 15d-14(b) of the Securities Exchange Act of 1934, as amended and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).
101	Interactive Data Files pursuant to Rule 405 of Regulation S-T.

* Indicates management contract or compensatory plan.
** Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

Table of Contents

SIGNATURES

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

MANNKIND CORPORATION

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

Dated: March 16, 2017

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ Matthew J. Pfeffer	Chief Executive Officer, Chief Financial	March 16, 2017
Matthew J. Pfeffer	Officer and Director	
	(Principal Executive Officer and Principal	
	Financial Officer)	
/s/ Rosabel R. Alinaya	Senior Vice President, Finance	March 16, 2017
Rosabel R. Alinaya	*(Principal Accounting Officer)*	
/s/ Kent Kresa	Chairman of the Board of Directors	March 16, 2017

Kent Kresa		
/s/ Ronald J. Consiglio	Director	March 16, 2017
Ronald J. Consiglio		
/s/ Michael Friedman	Director	March 16, 2017
Michael Friedman, M.D.		
/s/ David H. MacCallum	Director	March 16, 2017
David H. MacCallum		

Table of Contents

Signature	Title	Date
/s/ Henry L. Nordhoff	Director	March 16, 2017
Henry L. Nordhoff		
/s/ James S. Shannon	Director	March 16, 2017
James S. Shannon		

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm	81
Consolidated Balance Sheets	82
Consolidated Statements of Operations	83
Consolidated Statements of Comprehensive Income (Loss)	84
Consolidated Statements of Stockholders' Deficit	85
Consolidated Statements of Cash Flows	86
Notes to Consolidated Financial Statements	88

Table of Contents

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of MannKind Corporation

Valencia, California

We have audited the accompanying consolidated balance sheets of MannKind Corporation and subsidiaries (the Company) as of December 31, 2016 and 2015 and the related consolidated statements of operations, comprehensive income (loss), stockholders deficit, and cash flows for each of the three years in the period ended December 31, 2016. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these 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, 2016 and 2015, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2016, 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 available cash resources and continuing cash needs 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.

As discussed in Note 1 to the consolidated financial statements, on March 1, 2017, the Company approved a reverse stock split with a ratio of 1-for-5. As a result, common stock share amounts included in these consolidated financial statements have been retrospectively adjusted.

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, 2016, 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 16, 2017 expressed an unqualified opinion on the Company s internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Stamford, Connecticut

March 16, 2017

80

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

	December 31, 2016	2015
	(In thousands, except share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,895	$ 59,074
Accounts receivable	302	
Receivable from Sanofi	30,557	23
Inventory	2,331	
Asset held for sale	16,730	
Deferred costs from commercial product sales	309	
Deferred costs from collaboration		13,539
Prepaid expenses and other current assets	4,364	4,018
Total current assets	77,488	76,654
Property and equipment net	28,927	48,749
Other assets	648	1,009
Total assets	$ 107,063	$ 126,412
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current liabilities:		
Accounts payable	$ 3,263	$ 15,599
Accrued expenses and other current liabilities	7,937	7,929
Facility financing obligation	71,339	74,582
Deferred revenue net	3,419	
Deferred payments from collaboration	1,000	140,231
Deferred sales from collaboration		17,503
Recognized loss on purchase commitments current	5,093	12,475
Total current liabilities	92,051	268,319
Note payable to principal stockholder	49,521	49,521
Accrued interest note payable to principal stockholder	9,281	6,380
Senior convertible notes	27,635	27,613
Sanofi loan facility and loss share obligation		62,371
Recognized loss on purchase commitments long term	95,942	53,692
Warrant liability	7,381	
Milestone rights liability and other liabilities	8,845	8,845

Total liabilities	290,656	476,741
Commitments and contingencies (Note 13)		
Stockholders deficit:		
Undesignated preferred stock, $0.01 par value 10,000,000 shares authorized; no shares issued or or outstanding at December 31, 2016 and 2015		
Common stock, $0.05 par value 140,000,000 and 110,000,000 shares authorized at December 31, 2016 and 2015, respectively; 95,680,831 and 85,734,188 shares issued and outstanding at December 31, 2016 and 2015, respectively	4,784	4,287
Additional paid-in capital	2,549,212	2,508,633
Accumulated other comprehensive loss	(24)	(20)
Accumulated deficit	(2,737,565)	(2,863,229)
Total stockholders deficit	(183,593)	(350,329)
Total liabilities and stockholders deficit	$ 107,063	$ 126,412

See notes to consolidated financial statements.

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2016	2015	2014
	(In thousands, except per share data)		
Revenue:			
Net revenue collaboration	$ 171,965	$	$
Net revenue commercial product sales	1,895		
Revenue bulk insulin sales	898		
Total net revenue	174,758		
Expenses:			
Costs of revenue collaboration	32,971		
Cost of goods sold	17,121	64,745	
Research and development	14,917	29,674	100,244
Selling, general and administrative	46,928	40,960	79,383
Property and equipment impairment	1,259	140,412	
(Gain) loss on foreign currency translation	(3,433)	2,697	
(Gain) loss on purchase commitments	(2,265)	66,167	
Total expenses	107,498	344,655	179,627
Income (loss) from operations	67,260	(344,655)	(179,627)
Other income (expense):			
Change in fair value of warrant liability	5,369		
Interest income	85	18	9
Interest expense on notes	(15,576)	(21,231)	(17,549)
Interest expense on note payable to principal stockholder	(2,901)	(2,894)	(2,894)
Gain (loss) on extinguishment of debt	72,024	(1,049)	
Other (expense) income	(597)	1,366	1,679
Total other income (expense)	58,404	(23,790)	(18,755)
Income (loss) before benefit for income taxes	125,664	(368,445)	(198,382)
Income tax benefit			
Net income (loss)	$ 125,664	$ (368,445)	$ (198,382)
Net income (loss) per share basic	$ 1.37	$ (4.54)	$ (2.57)

Net income (loss) per share diluted	$ 1.36	$ (4.54)	$ (2.57)
Shares used to compute basic net income (loss) per share	92,053	81,233	77,045
Shares used to compute diluted net income (loss) per share	92,085	81,233	77,045

See notes to consolidated financial statements.

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

	Year Ended December 31,		
	2016	2015	2014
	(In thousands)		
Net income (loss)	$ 125,664	$ (368,445)	$ (198,382)
Other comprehensive loss:			
Cumulative translation loss	(4)	(6)	(10)
Comprehensive income (loss)	$ 125,660	$ (368,451)	$ (198,392)

See notes to consolidated financial statements.

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS DEFICIT

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
			(In thousands)			
BALANCE, JANUARY 1, 2014	73,878	$ 3,697	$ 2,261,996	$ (4)	$ (2,296,402)	$ (30,713)
Exercise of stock options	650	35	10,943			10,978
Issuance of common shares from the release of restricted stock units	799	38	(26,946)			(26,908)
Issuance of common shares pursuant to warrant exercises	2,315	115	27,664			27,779
Issuance of common shares under Employee Stock Purchase Plan	65	2	1,361			1,363
Stock-based compensation expense			25,660			25,660
Issuance of common shares pursuant to debt conversions by Deerfield	3,505	174	93,327			93,501
Remeasurement of performance based grants pursuant to the modification of terms			22,962			22,962
Cumulative translation loss				(10)		(10)
Net loss					(198,382)	(198,382)
BALANCE, DECEMBER 31, 2014	81,212	4,061	2,416,967	(14)	(2,494,784)	(73,770)
Exercise of stock options	340	17	3,241			3,258
Issuance of common shares from the release of restricted stock units	144	7	(7)			
Issuance of common shares pursuant to warrant exercises	843	42	10,081			10,123
Issuance of common shares under Employee Stock Purchase Plan	54	3	884			887
Stock-based compensation expense			8,725			8,725
Restricted stock units taxes paid in cash			(1,856)			(1,856)
Capital contribution			40			40
Issuance of common shares pursuant to conversions of certain 2015 notes	375	19	7,907			7,926
Issuance of common stock for lender financing fees	8		160			160
Discount on notes-for-stock exchange			169			169
Issuance of common stock pursuant to TASE stock sale	2,771	139	34,571			34,710

Return of loaned common stock	(1,800)	(90)	90			
Issuance of common stock pursuant to at-the-market issuances	1,788	89	27,754			27,843
Issuance of warrant liability			(202)			(202)
Reclassification of warrant liability to equity			109			109
Cumulative translation loss				(6)		(6)
Net loss					(368,445)	(368,445)
BALANCE, DECEMBER 31, 2015	85,735	4,287	2,508,633	(20)	(2,863,229)	(350,329)
Exercise of stock options	55	3	464			467
Issuance of common shares from the release of restricted stock units	131	7	(7)			
Issuance of common shares under Employee Stock Purchase Plan	51	2	424			426
Stock-based compensation expense			5,135			5,135
Restricted stock units taxes paid in cash			(165)			(165)
Issuance of direct placement common stock and warrants	9,709	485	49,515			50,000
Issuance costs associated with direct placement			(2,037)			(2,037)
Proceeds allocated to warrant liabilities			(12,750)			(12,750)
Cumulative translation loss				(4)		(4)
Net income					125,664	125,664
BALANCE, DECEMBER 31, 2016	95,681	$ 4,784	$ 2,549,212	$ (24)	$ (2,737,565)	$ (183,593)

See notes to consolidated financial statements.

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2016	2015	2014
		(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income (loss)	$ 125,664	$ (368,445)	$ (198,382)
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:			
Depreciation, amortization and accretion	4,158	13,276	18,575
Stock-based compensation expense	5,135	8,725	48,622
Change in fair value of warrant liability	(5,369)		
(Gain) loss on foreign currency translation	(3,433)	2,697	(10)
(Gain) loss on extinguishment of debt	(72,024)	1,049	
Interest incurred through borrowings under Sanofi Loan Facility	4,478	1,652	
Interest on note payable to principal stockholder	2,901	2,894	2,894
Series A Warrant issuance costs	653		
Other, net	19		
Loss on sale, abandonment/disposal or impairment of property and equipment	1,259	140,582	97
(Gain) loss on purchase commitments	(2,265)	66,167	
Write-off of inventory		36,104	
Write-off of Tranche B commitment asset			1,753
Write-off of derivative liability			(363)
Changes in operating assets and liabilities:			
Accounts receivable	(302)		
Receivable from Sanofi	(30,534)		
Inventory	(2,331)	(26,434)	(9,670)
Receivables from collaboration		50,413	(50,436)
Deferred costs from commercial product sales	(309)		
Deferred costs from collaboration	13,539	(13,539)	
Prepaid expenses and other current assets	(346)	13,481	(14,734)
Other assets	361	150	(615)
Accounts payable	(12,118)	8,413	3,622
Accrued expenses and other current liabilities	348	(12,467)	2,276
Deferred revenue	3,419		
Deferred payments from collaboration	(134,056)	950	200,436
Deferred sales from collaboration	(17,503)	17,067	
Recognized loss on purchase commitments	40,566		
Milestone rights liability and other liabilities		33	21
Net cash (used in) provided by operating activities	(78,090)	(57,232)	4,086
CASH FLOWS FROM INVESTING ACTIVITIES:			

Purchase of property and equipment	(1,144)	(10,285)	(24,097)
Proceeds from sale of property and equipment	17	82	
Net cash used in investing activities	(1,127)	(10,203)	(24,097)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from direct placement of common stock and warrants	50,000		
Issuance costs associated with direct placement	(2,690)		
Payment of notes payable to Deerfield	(5,000)		
Payment of employment taxes related to vested restricted stock units	(165)	(1,858)	(26,908)
Proceeds from issuance of common stock	893	4,146	12,341
Proceeds from issuance of common stock under Tel Aviv Stock Exchange		36,142	
Issuance costs associated with the Tel Aviv Stock Exchange		(1,432)	
Exercise of warrants for common stock		10,123	27,779
Payment of 2015 notes		(64,287)	
Payment of debt issuance costs on 2018 notes		(831)	
Proceeds from issuance of facility financing obligation and milestone rights			40,000
Proceeds from issuance of Tranche B of the facility financing obligation			20,000
Milestone payment		(4,219)	(3,150)
Proceeds from issuance of common stock pursuant to at-the-market issuance		28,392	
Issuance costs of at-the-market transactions		(548)	
Other		40	
Net cash provided by financing activities	43,038	5,668	70,062

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)

	Year Ended December 31,		
	2016	2015	2014
	(In thousands)		
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	$ (36,179)	$ (61,767)	$ 50,051
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	59,074	120,841	70,790
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 22,895	$ 59,074	$ 120,841
SUPPLEMENTAL CASH FLOWS DISCLOSURES:			
Interest paid in cash, net of amounts capitalized to construction in progress	$ 8,991	$ 13,355	$ 11,218
NON-CASH INVESTING AND FINANCING ACTIVITIES:			
Payment of 2015 notes and interest through issuance of common stock	$	$ 8,253	$
Issuance of common stock pursuant to debt conversion by Deerfield	$	$	$ 93,500
Non-cash construction in progress and property and equipment	$ 588	$	$ 1,768
Reclassification of deferred payments from collaboration to Sanofi loan facility and loss share obligation	$ 5,174	$ 59,337	$ 3,034
Reclassification of property and equipment to asset held for sale	$ 17,294	$	$

See notes to consolidated financial statements.

Table of Contents

MANNKIND CORPORATION AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Description of Business

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

Basis of Presentation On August 11, 2014, the Company entered into a license and collaboration agreement (the Sanofi License Agreement) with Sanofi-Aventis Deutschland GmbH (which subsequently assigned its rights and obligations under the agreement to Sanofi-Aventis U.S. LLC (Sanofi)), pursuant to which Sanofi was responsible for Afrezza global commercial, regulatory and development activities for Afrezza.

On January 4, 2016, the Company received written notification from Sanofi of its election to terminate in its entirety the Sanofi License Agreement. The effective date of termination (the Termination Date) was April 4, 2016, which was when the Company assumed responsibility for worldwide development and commercialization of Afrezza. Under terms of a transition agreement, Sanofi continued to fulfill orders for Afrezza in the United States until the Company began distributing MannKind-branded Afrezza product to major wholesalers in late July 2016. The Company began recognizing commercial product sales revenue when MannKind-branded Afrezza was dispensed from pharmacies to patients in August 2016.

On November 9, 2016, the Company entered into a settlement agreement with Sanofi (the Settlement Agreement). Under the terms of the Settlement Agreement, the promissory note (the Sanofi Loan Facility) between the Company and Aventisub LLC (Aventisub), a Sanofi affiliate, was terminated, with Aventisub agreeing to forgive the full outstanding loan balance of $72.0 million, which includes $0.5 million of previously uncharged costs pursuant to the Sanofi License Agreement. Sanofi also agreed to purchase $10.2 million of insulin from the Company in December 2016 under an existing insulin put option as well as make a cash payment of $30.6 million to the Company in early January 2017 as acceleration and in replacement of all other payments that Sanofi would otherwise have been required to make in the future pursuant to the insulin put option, without the Company being required to deliver any insulin for such payment. The Company and Sanofi also agreed to a general release of potential claims against each other.

During their initial transition of the commercial responsibilities from Sanofi, the Company utilized a contract sales organization to promote Afrezza while the Company focused its internal resources on establishing a channel strategy, entering into distribution agreements and developing co-pay assistance programs, a voucher program, data agreements and payor relationships. In early 2017, the Company recruited their own sales force, which included some of the sales reps that previously were employed by the contract sales organization. The Company intend to continue the commercialization of Afrezza in the United States through their own commercial organization. The Company s current strategy for the future commercialization of Afrezza outside of the United States, subject to receipt of the necessary foreign regulatory approvals, is to seek and establish regional partnerships in foreign jurisdictions where there are appropriate commercial opportunities.

It has been costly to develop our therapeutic product, conduct clinical studies, and market and sell Afrezza. As of and for the year ended December 31, 2016, the Company has reported an accumulated deficit of $2.7 billion and has reported negative cash flow from operations for each year since inception, except for 2014, when the Company

received the $150.0 million upfront payment from Sanofi.

At December 31, 2016, the Company s capital resources consisted of cash and cash equivalents of $22.9 million. The Company expects to continue to incur significant expenditures to support commercial

Table of Contents

manufacturing and sales and marketing of Afrezza and the development of other product candidates. The facility agreement (the Facility Agreement) with Deerfield Private Design Fund II, L.P. (Deerfield Private Design Fund) and Deerfield Private Design International II, L.P. (collectively, Deerfield) and the First Amendment to Facility Agreement and Registration Rights Agreement (the First Amendment) that resulted in additional sales of an additional tranche of notes (the Tranche B notes) (see Note 7 Borrowings) requires the Company to maintain at least $25.0 million, which can be comprised of cash and cash equivalents and available borrowings under the loan arrangement, dated as of October 2, 2007, between the Company and The Mann Group LLC (as amended, restated, or otherwise modified as of the date hereof, the Mann Group Loan Arrangement), as of the last day of each fiscal quarter.

Additional funding sources that are, or in certain circumstances may be available to the Company, include approximately $30.1 million principal amount of available borrowings under The Mann Group Loan Arrangement. A portion of these available borrowings may be used to capitalize accrued interest into principal, upon mutual agreement of the parties, as it becomes due and payable under The Mann Group Loan Arrangement (see Note 6 Related-party Arrangements). The Company cannot provide assurances that its plans will not change or that changed circumstances will not result in the depletion of its capital resources more rapidly than it currently anticipates. The Company will need to raise additional capital, whether through a sale of equity or debt securities, a strategic business collaboration with a pharmaceutical company, the establishment of other funding facilities, licensing arrangements, asset sales or other means, in order to continue the commercialization of Afrezza and development of other product candidates and to support its other ongoing activities. The Company cannot provide assurances that such additional capital will be available on acceptable terms or at all. These factors raise substantial doubt about the Company s ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

On September 14, 2016, the Company received notice from the Listing Qualifications Department of the NASDAQ Stock Market indicating that, for the previous 30 consecutive business days, the bid price for the common stock closed below the minimum $1.00 per share required for continued inclusion on The NASDAQ Global Market. The notification letter stated that the Company would be afforded 180 calendar days, or until March 13, 2017, to regain compliance with the minimum bid price requirement. In order to regain compliance, shares of the Company s common stock must maintain a minimum bid closing price of at least $1.00 per share for a minimum of 10 consecutive business days.

Reverse Stock Split On March 1, 2017, following stockholder approval, the Company s board of directors approved a reverse stock split ratio of 1-for-5. On March 1, 2017, the Company filed with the Secretary of State of the State of Delaware a Certificate of Amendment of the Company s Amended and Restated Certificate of Incorporation to effect the 1-for-5 reverse stock split of the Company s outstanding common stock and to reduce the authorized number of shares of the Company s common stock from 700,000,000 to 140,000,000 shares. The Company s common stock began trading on The NASDAQ Global Market on a split-adjusted basis when the market opened on March 3, 2017. See Note 20 Subsequent Events for further information. As a result, all common stock share amounts included in these consolidated financial statements have been retroactively reduced by a factor of five, and all common stock per share amounts have been increased by a factor of five, with the exception of the Company s common stock par value.

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

Segment Information Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. To date, the Company has viewed its operations and manages its business as one segment operating in the United States of America.

88

Table of Contents

2. Summary of Significant Accounting Policies

Financial Statement Estimates The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (GAAP) requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies, and in developing the estimates and assumptions that are used in the preparation of the financial statements. Management must apply significant judgment in this process. The more significant estimates reflected in these accompanying consolidated financial statements include revenue recognition, assessing long-lived assets for impairment, accrued expenses, including clinical study expenses, inventory recoverability, valuation of the facility financing obligation, loss on purchase commitment, warrant liability, milestone rights, stock-based compensation and the determination of the provision for income taxes and corresponding deferred tax assets and liabilities and any valuation allowance recorded against net deferred tax assets.

Reclassifications Certain amounts from previous periods have been reclassified to conform to the 2016 presentation. Specifically, accrued interest note payable to principal stockholder has been reclassified from the previously reported classification of other liabilities in the accompanying consolidated balance sheets. Additionally, the remaining balance from the previously reported classification of other liabilities is now identified as milestone rights liability, and is disclosed as a separate line item on the consolidated statements of cash flows. Additionally, on the consolidated statement of operations, product manufacturing has been renamed to cost of goods sold. The Company also reclassified (gain) loss on foreign currency translation from the previously reported classification of product manufacturing in the accompanying consolidated statements of operations. Additionally, certain balances from prepaid expenses and other current assets were reclassed to (gain) loss on foreign currency translation in the consolidated statements of cash flows.

Revenue Recognition Revenue is recognized when the four basic criteria of revenue recognition are met: (1) persuasive evidence that an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. When the accounting requirements for revenue recognition are not met, the Company defers the recognition of revenue by recording deferred revenue on the consolidated balance sheets until such time that all criteria are met. To date, the Company has had revenue from collaborations, commercial sales of Afrezza, and from sales of bulk insulin, which are described more fully below.

Revenue Recognition Net Revenue Collaborations The Company enters into collaborations under which we must perform certain obligations and we receive periodic payments. We evaluate the collaborations under the multiple element revenue recognition accounting guidance. Revenue arrangements with multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered elements have stand-alone value to the customer. When deliverables are separable, consideration received is allocated to the separate units of accounting based on the relative selling price of each deliverable and the appropriate revenue recognition principles are applied to each unit.

The assessment of multiple element arrangements requires judgment in order to determine the appropriate units of accounting and the points in time that, or periods over which, revenue should be recognized. The terms of and the accounting for the Company s collaborations are described more fully in Note 8 Collaboration Arrangements.

Revenue Recognition Net Revenue Commercial Product Sales Between July 1, 2016 and December 15, 2016, the Company sold Afrezza to Integrated Commercialization Solutions Direct (ICS) and title and risk of loss transferred to ICS upon shipment. After December 15, 2016, ICS became a third party logistics provider and stopped taking title and risk of loss upon shipment of Afrezza to ICS. The Company sells Afrezza in the United States to wholesale

pharmaceutical distributors through ICS, and ultimately to retail pharmacies, which are collectively referred to as customers .

Table of Contents

The Company provides the right of return to ICS (through December 15, 2016) and its wholesale distributors and, through them, to its retail pharmacy customers for unopened product for a period beginning six months prior to and ending twelve months after its expiration date. Once the product has been prescribed and dispensed to the patient, any right of return ceases to exist.

Given the Company s limited sales history for Afrezza, the Company cannot reliably estimate expected returns of the product at the time of shipment into the distribution channel. Accordingly, the Company defers recognition of revenue on Afrezza product shipments until the right of return no longer exists, which occurs at the earlier of the time Afrezza is dispensed from pharmacies to patients or expiration of the right of return. The Company recognizes revenue based on Afrezza patient prescriptions dispensed as estimated by syndicated data provided by a third party. The Company also analyzes additional data points to ensure that such third-party data is reasonable including data related to inventory movements within the channel and ongoing prescription demand.

For the year ended December 31, 2016, net revenue from commercial product sales consisted of $1.9 million of net sales of Afrezza dispensed to patients. As of December 31, 2016, the Company recorded $3.4 million in deferred revenue on its consolidated balance sheet, of which $1.6 million (net of estimated gross-to-net adjustments) represents product shipped to the Company s third-party logistics provider and wholesale distributors, but not yet dispensed to patients. The difference represents deferred revenue from bulk insulin sales, which is described more fully under the heading *Revenue Recognition Revenue Bulk Insulin Sales* below.

Gross-to-net Adjustments Estimated gross-to-net adjustments for Afrezza include wholesaler distribution fees, prompt pay discounts, estimated rebates and patient discount and co-pay assistance programs, and are based on estimated amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of the Company s agreements with its customers and the levels of inventory within the distribution and retail channels that may result in future rebates or discounts taken. In certain cases, such as patient support programs, the Company recognizes the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, the Company may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment. The Company records product sales deductions in the consolidated statements of operations at the time product revenue is recognized. At December 31, 2016, year to date total gross-to-net adjustments were approximately $0.8 million, which represents 30% of gross revenue from product sales.

Wholesaler Distribution Fees The Company pays distribution fees to certain wholesale distributors based on contractually determined rates. The Company accrues the distribution fees on shipment to the respective wholesale distributors and recognizes the distribution fees as a reduction of revenue in the same period the related revenue is recognized.

Prompt Pay Discounts The Company offers cash discounts to its customers, generally 2% of the sales price, as an incentive for prompt payment. The Company accounts for cash discounts by reducing accounts receivable by the prompt pay discount amount and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

Rebates The Company participates in federal and state government-managed Medicare and Medicaid rebate programs and intends to pursue participation in certain other qualifying federal and state government programs whereby discounts and rebates are provided to participating federal and state government entities. Rebates provided through these other qualifying programs are included in the Medicaid and Medicare rebate accrual. The Company accounts for these rebates by establishing an accrual equal to the estimate of rebate claims attributable to a sale and determines its estimate of the rebates accrual based on historical payor data provided by a third-party vendor along with additional data including a forecasted participation rate for Medicare and Medicaid. From that data, as well as input received

from MannKind s commercial team, an estimated participation rate for Medicare and Medicaid is determined and applied at the mandated rate for those sales. Any new information regarding changes in the programs regulations and guidelines or any changes in the Company s

Table of Contents

government price reporting calculations that would impact the amount of the rebates will also be taken into account in determining or modifying the appropriate reserve. The time period between the date the product is sold into the channel and the date such rebates are paid ranges from approximately six to nine months. As such, continuous monitoring of these estimates are performed on a periodic basis and if necessary, adjusted to reflect new facts and circumstances. Rebates are recognized as a reduction of revenue in the period the related revenue is recognized.

Patient Discount and Co-Pay Assistance Programs The Company offers discount card programs to patients for Afrezza in which patients receive discounts on their prescriptions or a reduction in their co-pay amounts that are reimbursed by the Company. The Company estimates the total amount that will be redeemed based on levels of inventory in the distribution and retail channels and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

Product Returns The Company does not provide a reserve for product returns of sales of Afrezza due to its revenue recognition policy of deferring recognition of revenue on product shipments of Afrezza until the right of return no longer exists.

Revenue Recognition Revenue Bulk Insulin Sales In 2016, revenue from bulk insulin sales was recognized after delivery and customer acceptance of the bulk insulin. When the accounting requirements for revenue recognition of bulk insulin sales are not met, the Company defers recognition of revenue by recording deferred revenue on the balance sheet until such time that all criteria are met.

Deferred revenue includes $1.8 million received from a sale of surplus bulk insulin to a third party that was delivered prior to, but accepted after, December 31, 2016. No deferred cost was recognized related to this sale because the inventory was written off on December 31, 2015.

Deferred Costs from Collaboration Deferred costs from collaboration represents the costs of product manufactured and sold to Sanofi, as well as certain direct costs associated with a firm purchase commitment entered into in connection with the collaboration with Sanofi. During the third quarter of 2016, the costs related to the Sanofi product sales were recognized as costs of revenue collaboration in the consolidated statements of operations, as related revenue was recognized at that time.

Deferred Costs from Commercial Product Sales Deferred costs from commercial product sales represents the cost of product (including labor, overhead and costs to ship to third party logistics) shipped to ICS and wholesale distributors, but not yet dispensed by pharmacies to patients.

Cost of Goods Sold Cost of goods sold includes the costs related to Afrezza product dispensed by pharmacies to patients as well as under-absorbed labor and overhead and inventory write-offs, which are recorded as expenses in the period in which they are incurred, rather than as a portion of the inventory cost.

Cash and Cash Equivalents The Company considers all highly liquid investments with original or remaining maturities of 90 days or less at the time of purchase, that are readily convertible into cash to be cash equivalents. As of December 31, 2016 and 2015, cash equivalents were comprised of money market accounts with maturities less than 90 days from the date of purchase.

Concentration of Credit Risk Financial instruments which potentially subject the Company to concentration of credit risk consist of cash and cash equivalents. Cash and cash equivalents are held in high credit quality institutions. Cash equivalents consist of interest-bearing money market accounts, which are regularly monitored by management.

Accounts Receivable and Allowance for Doubtful Accounts Accounts receivable are recorded at the invoiced amount and are not interest bearing. The Company maintains an allowance for doubtful accounts for

Table of Contents

estimated losses resulting from the inability of its customers to make required payments. The Company makes ongoing assumptions relating to the collectability of its accounts receivable in its calculation of the allowance for doubtful accounts. As of December 31, 2016 and 2015, there was no allowance for doubtful accounts.

Inventories Inventories are stated at the lower of cost or net realizable value. The Company determines the cost of inventory using the first-in, first-out, or FIFO, method. The Company capitalizes inventory costs associated with the Company s products based on management s judgment that future economic benefits are expected to be realized; otherwise, such costs are expensed as cost of goods sold. The Company periodically analyzes its inventory levels to identify inventory that may expire or has a cost basis in excess of its estimated realizable value, and writes down such inventories as appropriate. In addition, the Company s products are subject to strict quality control and monitoring which the Company performs throughout the manufacturing process. If certain batches or units of product no longer meet quality specifications or become obsolete due to expiration, the Company will record a charge to write down such unmarketable inventory to its estimated net realizable value.

The Company analyzed its inventory levels to identify inventory that may expire or has a cost basis in excess of its estimated realizable value. The Company performed an assessment of projected sales and evaluated the lower of cost or net realizable value and the potential excess inventory on hand at December 31, 2016 and 2015. As a result of these assessments, the Company recorded a $0.2 million charge at December 31, 2016 to write-off inventory that will expire prior to sale. At December 31, 2015, the Company recorded a charge of $39.3 million to record the inventory raw materials on hand at the lower of cost or net realizable value, inventory expiry and write-off other inventory related assets.

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

Prepaid Expenses and Other Current Assets As of December 31, 2016 and 2015, prepaid expenses and other current assets primarily consist of prepaid expenses for goods and services to be received and includes a certificate of deposit for $350,000 as collateral as required by an agreement with the bank.

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

Assets Held for Sale The Company classifies long-lived assets anticipated to be sold within one year as held for sale at the lower of their carrying value or fair value less estimated selling costs.

Property and Equipment Property and equipment are depreciated using the straight-line method over the estimated useful lives of the related assets. Leasehold improvements are amortized over the term of the lease or the service lives of the improvements, whichever is shorter. Maintenance and repairs are expensed as incurred. Assets under

construction are not depreciated until placed into service.

Impairment of Long-Lived Assets The Company evaluates long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Assets are considered to be impaired if the carrying value may not be recoverable.

Table of Contents

If the Company believes an asset to be impaired, the impairment recognized is the amount by which the carrying value of the asset exceeds the fair value of the asset. Fair value is determined using the market, income or cost approaches as appropriate for the asset. Any write-downs are treated as permanent reductions in the carrying amount of the asset and an operating loss would be recognized.

The Company recorded an asset impairment of $1.3 million and $140.4 million for the years ended December 31, 2016 and 2015, respectively. No asset impairment was recognized during the year ended December 31, 2014 (see Note 4 Property and Equipment and Note 20 Subsequent Events).

Recognized Loss on Purchase Commitments The Company assesses whether losses on long term purchase commitments should be accrued. Losses that are expected to arise from firm, non-cancellable, commitments for the future purchases of inventory items are recognized unless recoverable. The recognized loss on purchase commitments is reduced as inventory items are purchased. Changes in estimates are recorded in the relevant period in (gain) loss on purchase commitments.

During the year ended December 31, 2015, the Company recorded a loss on purchase commitments amounting to $116.2 million offset by $50 million expected to be recovered from Sanofi, primarily due to a long term purchase commitment for insulin raw materials. During the year ended December 31, 2016, the balance was adjusted for the recovery received from Sanofi, current purchases on the contracts and a reduction in the recognized loss related to amendments to purchase contracts. No new contracts were identified in 2016 requiring a new loss on purchase commitment accrual.

Milestone Rights Liability On July 1, 2013, in conjunction with the execution of the Facility Agreement, the Company issued Milestone Rights to Deerfield whereby the Company agreed to provide Deerfield with pre-specified Milestone Payments upon the achievement of 13 specific Milestone Events related to the commercial release and future cumulative net sales of Afrezza. The Company analyzed the Milestone Rights and determined that the agreement does not meet the definition of a freestanding derivative. Since the Company has not elected to apply the fair value option to the Milestone Rights Purchase Agreement, the Company recorded the Milestone Rights at their estimated initial fair value and accounted for the Milestone Rights as a liability.

The initial fair value estimate of the Milestone Rights was calculated using the income approach in which the cash flows associated with the specified contractual payments were adjusted for both the expected timing and the probability of achieving the milestones and discounted to present value using a selected market discount rate. The expected timing and probability of achieving the milestones was developed with consideration given to both internal data, such as progress made to date and assessment of criteria required for achievement, and external data, such as market research studies. The discount rate was selected based on an estimation of required rate of returns for similar investment opportunities using available market data. The Milestone Rights liability will be remeasured as the specified milestone events are achieved. Specifically, as each milestone event is achieved, the portion of the initially recorded Milestone Rights liability that pertains to the milestone event being achieved, will be remeasured to the amount of the specified related milestone payment. The resulting change in the balance of the Milestone Rights liability due to remeasurement will be recorded in the Company s consolidated statements of operations as interest expense. Furthermore, the Milestone Rights liability will be reduced upon the settlement of each milestone payment. As a result, each milestone payment would be effectively allocated between a reduction of the recorded Milestone Rights liability and an expense representing a return on a portion of the Milestone Rights liability paid to the investor for the achievement of the related milestone event (see Note 7 Borrowings). As of December 31, 2016, the remaining liability balance is $8.9 million.

Fair Value of Financial Instruments The Company utilizes fair value measurement guidance to value its financial instruments. The guidance includes a definition of fair value, prescribes methods for measuring fair value, establishes a fair value hierarchy based on the inputs used to measure fair value and expands disclosures about the use of fair value measurements. The valuation techniques utilized are based upon observable and

Table of Contents

unobservable inputs. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect internal market assumptions. These two types of inputs create the following fair value hierarchy:

Level 1 Quoted prices for identical instruments in active markets.

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

Level 3 Significant inputs to the valuation model are unobservable.

Income Taxes The provisions for federal, foreign, state and local income taxes are calculated on pre-tax income based on current tax law and include the cumulative effect of any changes in tax rates from those used previously in determining deferred tax assets and liabilities. Deferred income tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which the temporary differences are expected to be recovered or settled. A valuation allowance is recorded to reduce net deferred income tax assets to amounts that are more likely than not to be realized.

Income tax positions are considered for uncertainty. The Company believes that its income tax filing positions and deductions will be sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position. Therefore, no liabilities for uncertain income tax positions have been recorded. If a tax position does not meet the minimum statutory threshold to avoid payment of penalties, the Company recognizes an expense for the amount of the penalty in the period the tax position is claimed in the tax return of the Company. The Company recognizes interest accrued related to unrecognized tax benefits in income tax expense, if any. Penalties, if probable and reasonably estimable, are recognized as a component of income tax expense.

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

Contingencies The Company records a loss contingency for a liability when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. These accruals represent management s best estimate of probable loss. Disclosure also is provided when it is reasonably possible that a loss will be incurred or when it is reasonably possible that the amount of a loss will exceed the recorded provision. On a quarterly basis, the Company reviews the status of each significant matter and assesses its potential financial exposure. Significant judgment is required in both the determination of probability and the determination as to whether an exposure is reasonably estimable. Because of uncertainties related to these matters, accruals are based only on the best information available at the time. As additional information becomes available, the Company reassesses the potential liability related to pending claims and litigation and may revise its estimates.

Stock-Based Compensation As of December 31, 2016, the Company had three active stock-based compensation plans, which are described more fully in Note 12 Stock Award Plans. The Company accounts for all share-based payments to employees, including grants of stock awards and the compensatory elements of the employee stock purchase plan. 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, are recognized in the consolidated statements of operations based upon the fair value of the awards at the

Table of Contents

grant date. The Company uses the Black-Scholes option valuation model to estimate the grant date fair value of employee stock options and the compensatory elements of employee stock purchase plans. Option valuation models require the input of assumptions, including the expected life of the stock-based awards, the estimated stock price volatility, the risk-free interest rate and the expected dividend yield. The expected volatility assumption is based on an assessment of the historical volatility, with consideration of implied volatility, derived from an analysis of historical trade activity. Restricted stock units are valued based on the market price on the grant date. The Company evaluates stock awards with performance conditions as to the probability that the performance conditions will be met and estimates the date at which the performance conditions will be met in order to properly recognize stock-based compensation expense over the requisite service period.

Warrants The Company has issued warrants to purchase shares of its common stock. The Company accounts for its warrants as either equity or liabilities based upon the characteristics and provisions of each instrument and evaluation of sufficient authorized shares available to satisfy the obligations. Warrants classified as derivative liabilities are recorded on the Company s consolidated balance sheets at their fair value on the date of issuance and are revalued at each subsequent balance sheet date, with fair value changes recognized in the consolidated statements of operations. The Company estimates the fair value of its derivative liabilities using a third party valuation analysis that utilizes a Monte Carlo pricing valuation model and assumptions that are based on the individual characteristics of the warrants or instruments on the valuation date, as well as expected volatility, expected life, yield and a risk-free interest rate. The expected volatility assumption is primarily based on an assessment of the historical volatility, with consideration of implied volatility, derived from an analysis of historical trade activity. Warrants classified as equity are recorded within additional paid in capital at the issuance date and are not re-measured in subsequent periods, unless the underlying assumptions change to trigger liability accounting.

Comprehensive Income (Loss) Other comprehensive income (loss) requires that all components of comprehensive income (loss) to be reported in the financial statements in the period in which they are recognized. Other comprehensive income (loss) includes certain changes in stockholders equity that are excluded from net income (loss). Specifically, the Company includes unrealized gains and losses on foreign exchange translation in accumulated other comprehensive loss on the consolidated balance sheets.

Research and Development Expenses Research and development expenses consist of costs associated with the clinical trials of the Company s product candidates, manufacturing supplies and other development materials, compensation and other expenses for research and development personnel, costs for consultants and related contract research, facility costs, and depreciation. Research and development costs, which are net of any tax credit exchange recognized for the Connecticut state research and development credit exchange program, are expensed as incurred. The Company began commercial manufacturing in the latter part of the fourth quarter of 2014. Commercial manufacturing costs incurred in the fourth quarter of 2014 were included in research and development expense and were immaterial for the year ended December 31, 2014.

State Research and Development Credit Exchange Receivable The State of Connecticut provides certain companies with the opportunity to exchange certain research and development income tax credit carryforwards for cash in exchange for forgoing the carryforward of the research and development income tax credits. The program provides for an exchange of research and development income tax credits for cash equal to 65% of the value of corporation tax credit available for exchange. Estimated amounts receivable under the program are recorded as a reduction of research and development expenses. During the years ended December 31, 2016, 2015 and 2014, research and development expenses were offset by research and development tax credits of $246,000, $743,000 and $816,000, respectively.

Clinical Trial Expenses Clinical trial expenses, which are reflected in research and development expenses in the accompanying consolidated statements of operations, result from obligations under contracts with vendors,

consultants and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to the Company under

Table of Contents

such contracts. The appropriate level of trial expenses are reflected in the Company s consolidated financial statements by matching period expenses with period services and efforts expended. These expenses are recorded according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. Clinical trial accrual estimates are determined through discussions with internal clinical personnel and outside service providers as to the progress or state of completion of trials, or the services completed. Service provider status is then compared to the contractually obligated fee to be paid for such services. During the course of a clinical trial, the Company may adjust the rate of clinical expense recognized if actual results differ from management s estimates.

Interest Expense Interest costs are expensed as incurred, except to the extent such interest is related to construction in progress, in which case interest is capitalized. Interest cost capitalized for the years ended December 31, 2015 and 2014 was $0.1 million and $0.8 million, respectively. There were no capitalized interest costs for the year ended December 31, 2016.

Net Income (Loss) Per Share of Common Stock Basic net income (loss) per share excludes dilution for potentially dilutive securities and is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share reflects the potential dilution under the treasury method that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. For periods where the Company has presented a net loss, potentially dilutive securities are excluded from the computation of diluted net loss per share as they would be antidilutive.

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

In May 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which requires an entity to recognize the amount of revenue when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. This new guidance supersedes previous revenue recognition requirements, along with most existing industry-specific guidance. In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which delayed the effective date of the new standard from January 1, 2017 to January 1, 2018. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. In 2016 the FASB has issued additional ASUs which clarify certain aspects of the new guidance.

The Company will adopt the new guidance for the year beginning January 1, 2018. The Company has the option to either apply the new guidance retrospectively for all prior reporting periods presented (full retrospective) or retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (modified retrospective). The Company currently anticipates it will apply the new guidance using the modified retrospective approach with the cumulative effect of initial application recognized as of January 1, 2018. The Company plans to continue analyzing the potential impacts of the application throughout 2017 and, depending on factors that may impact the results, could elect to apply the new guidance on a full retrospective basis.

Currently, for commercial sales of Afrezza, the Company has limited sales and returns history, and as such, is unable to reliably estimate expected returns of the product at the time of shipment into the distribution channel. Accordingly, the Company defers recognition of revenue on Afrezza product shipments until the right of return no longer exists, which occurs at the earlier of the time Afrezza is dispensed from pharmacies to patients or expiration of the right of return. The Company recognizes revenue based on Afrezza patient prescriptions dispensed, a sell-through model, as

estimated by syndicated data provided by a third party. The Company also analyzes additional data points to ensure that such third-party data is reasonable, including data related to inventory movements within the channel and ongoing prescription demand.

Table of Contents

Upon adoption of the new guidance, the Company expects that it will move from its current sell-through model to a sell-to model for revenue related to commercial sales of Afrezza and will record revenue at the time title and risk of loss passes to its distributors (generally at shipment or delivery to the distributors) along with an estimate of potential returns as variable consideration. The Company also anticipates that its ability to estimate potential returns will improve with an additional 12 months of sales history that it will have obtained by January 1, 2018.

In addition, the Company has historically entered into collaborative agreements with third-parties under which periodic payments have been received. Revenue recognition for certain payments received has been deferred until the price is fixed and determinable. Further, revenue for certain payments to be received in the future has been prohibited from recognition until received. The Company expects that some of these amounts will be considered variable consideration and may be able to be recognized earlier under the new guidance.

The Company has begun its evaluation of the impact of adoption and plans to continue its evaluation throughout 2017. The financial impact upon adoption will be dependent upon a number of factors including; the amount of revenue that has been deferred under the sell-through model for Afrezza, the amount of the revenue deferred under collaborative arrangements and the Company s estimates of variable consideration at the date of adoption. At this time, the Company has not completed its evaluation of the inputs, assumptions and methodologies that will be used to recognize revenue related to variable consideration under the new guidance.

In July 2015, the FASB issued ASU No. 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory.* Topic 330 currently requires an entity to measure inventory at the lower of cost or market. Market could be replacement cost, net realizable value, or net realizable value less an approximately normal profit margin. The amendments indicate that after adoption an entity should measure inventory within the scope of this ASU at the lower of cost or net realizable value. The amendments are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. The amendments should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The adoption of ASU No. 2015-11 will have no impact on the Company s annual consolidated financial statements because the Company currently measures inventory at the lower of cost or net realizable value.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements Going Concern*, which requires management of an entity to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity s ability to continue as a going concern within one year after the date that the financial statements are issued or available to be issued. This update was effective for annual periods ending after December 15, 2016. The adoption of this standard did not have a material impact on its consolidated financial statements.

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities.* The update is intended to improve the recognition and measurement of financial instruments. The update is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The Company is evaluating the impact the adoption of ASU 2016-01 will have on its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842).* The new standard requires that a lessee recognize the assets and liabilities that arise from operating leases. A lessee should recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period

presented using a modified retrospective approach. The new standard will be effective on January 1, 2019. The Company is evaluating the impact the adoption of ASU No. 2016-02 will have on its consolidated financial statements.

Table of Contents

In March 2016, the FASB issued ASU No. 2016-09, *Compensation Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. The new standard involves several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. For public business entities, the amendments in this standard are effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. The Company has evaluated the effect that this guidance will have on its consolidated financial statements and related disclosures and has determined it will not result in a material impact.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*. The new standard seeks to reduce diversity in practice related to the classification of certain transactions in the statement of cash flows. For public business entities, the amendments in this standard are effective for annual periods beginning after December 15, 2017, and interim periods within those annual periods. The amendments should be applied using a retrospective transition method to each period presented. If it is impracticable to apply the amendments retrospectively for some of the issues, the amendments for those issues would be applied prospectively as of the earliest date practicable. The Company is evaluating the impact the adoption of ASU No. 2016-15 will have on its consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash.* This ASU requires that the reconciliation of the beginning-of-period and end-of-period amounts shown in the statement of cash flows include cash and restricted cash equivalents. ASU 2016-08 is effective for fiscal years beginning after December 15, 2018, including interim periods within those periods, using a retrospective transition method to each period presented. The Company has evaluated the effect that this guidance will have on its consolidated financial statements and related disclosures and has determined it will not result in a material impact.

3. Inventories

Inventories consist of the following (in thousands):

	December 31,	
	2016	2015
Raw materials	$	$
Work-in-process	2,120	
Finished goods	211	
Total Inventory	$ 2,331	$

As of December 31, 2015, the Company recorded a write-off of all of its inventory. There were no raw materials as of December 31, 2016 because purchases of raw materials in 2016 were recorded at zero value because they had been accrued at December 31, 2015 through the loss on purchase commitment. Work-in-process and finished goods as of December 31, 2016 include conversion costs but not materials cost because the materials used in its production were previously written off.

Table of Contents

4. Property and Equipment

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

	Estimated Useful Life (Years)	December 31, 2016	2015
Land		$ 875	$ 3,435
Buildings	39-40	17,389	21,590
Building improvements	5-40	34,957	60,584
Machinery and equipment	3-15	62,992	68,434
Furniture, fixtures and office equipment	5-10	3,556	4,114
Computer equipment and software	3	8,531	9,519
Construction in progress		202	586
		128,502	168,262
Less accumulated depreciation		(99,575)	(119,513)
Total property and equipment, net		$ 28,927	$ 48,749

Depreciation and amortization expense related to property and equipment for the years ended December 31, 2016, 2015 and 2014, was $2.4 million, $11.0 million and $9.8 million, respectively.

The December 31, 2016 amounts do not include the Valencia property because it is classified as held for sale as of that date.

In connection with the Company s quarterly assessment of impairment indicators, the Company evaluated the continued lower than expected sales of Afrezza as reported by Sanofi throughout the fourth quarter of 2015, revised forecasts for sales of Afrezza provided by Sanofi in the fourth quarter of 2015 and level of commercial production in the fourth quarter of 2015, as well as the uncertainty associated with Sanofi s announcement during the fourth quarter of their intent to reorganize their diabetes business. These factors indicated potentially significant changes in the timing and extent of cash flows, and the Company therefore determined that an impairment indicator existed in the fourth quarter of 2015 and recorded an impairment for the year ended December 31, 2015. No such indications were identified in the current year ended December 31, 2016.

The Company identified two primary asset groups to be evaluated for impairment: the Danbury manufacturing facility, which currently performs all the manufacturing of Afrezza, and the Valencia facility, which was previously the Company s corporate headquarters. The Danbury manufacturing facility was the primary asset group that was impacted by the impairment indicators noted above but the Company also evaluated the Valencia facility for potential impairment given the circumstances and identified an impairment charge of $1.8 million based on a valuation utilizing a combination of market, income and cost approaches. Within the Danbury manufacturing facility, the Company identified the machinery and equipment as the primary assets within the asset group as they are associated with the production of Afrezza. As such, the Company performed the fixed asset impairment test and performed the first step to test for recoverability of the Danbury manufacturing facility by utilizing two undiscounted cash flow projections and applying a probability weighted average to those cash flow projections. The first undiscounted cash flow projection was developed under a scenario assuming Sanofi would continue to sell and market Afrezza as the

termination of the arrangement by Sanofi was not known as of the balance sheet date. The second undiscounted cash flow projection assumed Sanofi would terminate the Sanofi License Agreement and that the Company would manufacture, sell and market Afrezza independently.

Based on the evaluation performed, the probabilities assigned to the two undiscounted cash flows were not significant to the evaluation due to the projected negative cash flows over the estimation period, and it was determined that the probability weighted undiscounted cash flows were not sufficient to recover the carrying

Table of Contents

value of the Danbury manufacturing facility. As such, the Company was required to determine the fair value of the Danbury manufacturing facility to recognize an impairment loss if the carrying amount exceeds its fair value. The Company determined the fair value of the Danbury manufacturing facility by applying the highest and best use valuation concept and utilizing the market approach valuation technique to value the machinery and equipment and a combination of the market approach and cost approach in valuing the land, buildings and building improvements. As a result of this assessment, the Company recorded, as of December 31, 2015, an impairment charge of $138.6 million for the Danbury manufacturing facility.

The December 31, 2015 balances have been reclassified to the current year presentation by allocating an impairment of $140.4 million, which was previously disclosed in total, to the individual asset groups. An additional impairment of $0.7 million was charged to the individual asset groups for the year ended December 31, 2016, which is included in property and equipment impairment in the accompany consolidated statements of operations, additionally with a $0.6 million impairment charge related to assets held for sale.

5. Accrued Expenses and Other Current Liabilities

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

	December 31,	
	2016	2015
Salary and related expenses	$ 3,814	$ 2,634
Restructuring	1,376	3,028
Sales and marketing services	144	
Professional fees	875	931
Discounts and allowances for commercial product sales	754	
Accrued interest	619	615
Other	355	483
Construction in progress		238
Accrued expenses and other current liabilities	$ 7,937	$ 7,929

6. Related-Party Arrangements

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

As of December 31, 2016, the total principal amount outstanding under The Mann Group Loan Arrangement was $49.5 million, and the amount available for future borrowings is $30.1 million. Interest, at a fixed rate of 5.84%, is due and payable quarterly in arrears on the first day of each calendar quarter for the preceding quarter, or at such other time as the Company and The Mann Group mutually agree. All or any portion of accrued and unpaid interest that becomes due and payable may be paid-in-kind and capitalized as additional borrowings at any time upon mutual

agreement of the parties, and has been classified as non-current. The Mann Group can require the Company to prepay up to $200.0 million in advances that have been outstanding for at least 12 months, less approximately $105.0 million aggregate principal amount that has been cancelled in connection with two common stock purchase agreements. If The Mann Group exercises this right, the Company will have 90 days after The Mann Group provides written notice, or the number of days to maturity of the note if less than 90 days, to prepay such advances. However, pursuant to a letter agreement entered into in August 2010, The Mann Group has agreed to not require the Company to prepay amounts outstanding under the amended and

Table of Contents

restated promissory note if the prepayment would require the Company to use its working capital resources. In addition, The Mann Group entered into a subordination agreement with Deerfield pursuant to which The Mann Group agreed with Deerfield not to demand or accept any payment under The Mann Group Loan Arrangement until the Company s payment obligations to Deerfield under the Facility Agreement have been satisfied in full. Subject to the foregoing, in the event of a default under The Mann Group Loan Arrangement, all unpaid principal and interest either becomes immediately due and payable or may be accelerated at The Mann Group LLC s option, and the interest rate will increase to the one-year LIBOR rate calculated on the date of the initial advance or in effect on the date of default, whichever is greater, plus 5% per annum. All borrowings under The Mann Group Loan Arrangement are unsecured. The Mann Group Loan Arrangement contains no financial covenants.

As of December 31, 2016 and 2015, the Company had accrued and unpaid interest related to the above note of $9.3 million and $6.4 million, respectively, and had $30.1 million of available borrowings. Interest expense on the Company s note payable to the Company s principal stockholder for each of the years ended December 31, 2016, 2015 and 2014 was $2.9 million.

In May 2015, the Company entered into a sublease agreement with the Alfred Mann Foundation for Scientific Research (the Mann Foundation), a California Not-For-Profit Corporation. The lease is for approximately 12,500 square feet of office space in Valencia, California and expires in April 2017. The office space contains the Company s principal executive offices. Lease payments to the Mann Foundation for the year ended December 31, 2016 and 2015 were $268,000 and $175,000, respectively. There were no lease payments to the Mann Foundation for the year ended December 31, 2014.

In connection with certain meetings of the Company s board of directors and on other occasions when the Company s business necessitated air travel for the Company s principal stockholder and other Company employees, the Company utilized the principal stockholder s private aircraft, and the Company paid the charter company that manages the aircraft on behalf of the Company s principal stockholder approximately $18,000 and $79,000 for the years ended December 31, 2015 and 2014, respectively, on the basis of the corresponding cost of commercial airfare. There were no payments to the principal stockholder related to the usage of the aircraft during the year ended December 31, 2016.

The Company has entered into indemnification agreements with each of its directors and executive officers, in addition to the indemnification provided for in its amended and restated certificate of incorporation and amended and restated bylaws (see Note 13 Commitments and Contingencies).

7. Borrowings

Borrowings consist of the following (in thousands):

	December 31,	
	2016	2015
Facility Financing Obligation (2019 Notes)		
Principal amount	$ 75,000	$ 80,000
Unamortized debt discount	(3,661)	(5,418)
Net carrying amount	$ 71,339	$ 74,582
Senior Convertible Notes (2018 Notes)		

Principal amount		$ 27,690	$ 27,690
Unamortized premium		426	660
Unaccreted debt issuance costs		(481)	(737)
Net carrying amount		$ 27,635	$ 27,613
Note payable to principal stockholder	**net carrying amount**	$ 49,521	$ 49,521

Table of Contents

Facility Financing Obligation (2019 Notes) As of December 31, 2016, there were $55.0 million principal amount of 2019 notes and $20.0 million principal amount of Tranche B notes outstanding. As of December 31, 2015, there were $60.0 million principal amount of 2019 notes and $20.0 million principal amount of Tranche B notes outstanding. The 2019 notes accrue interest at annual rate of 9.75% and the Tranche B notes accrue interest at an annual rate of 8.75%. Interest is paid quarterly in arrears on the last day of each March, June, September and December. The Facility Financing Obligation principal repayment schedule is comprised of annual payments beginning on July 1, 2016 and ending December 9, 2019. Future principal payments for the years ended December 31, 2017, 2018 and 2019 are $20.0 million, $20.0 million and $35.0 million, respectively.

In conjunction with the Facility Agreement, the Company entered into a Milestone Rights Agreement with Deerfield which requires the Company to make contingent payments to Deerfield, totaling up to $90.0 million, upon the Company achieving specified commercialization milestones. The Milestone Rights were initially recorded as a short-term liability equal to $3.2 million included in accrued expenses and other current liabilities in the accompanying consolidated balance sheets and a long-term liability equal to $13.1 million included in other liabilities. During the first quarter of 2015, a milestone triggering event was achieved following the Company s product launch on February 3, 2015, which resulted in a $5.8 million incremental charge to interest expense due to the increase in carrying value of the liability to the required $10.0 million payment made in February of 2015. During the year ended December 31, 2014, the first milestone triggering event was achieved following the Company s entry into the Sanofi License Agreement, which resulted in a $1.9 million incremental charge to interest expense due to the increase in carrying value of the liability to the required $5.0 million payment, which was paid to Deerfield pursuant to the terms of the Milestone Agreement. As of December 31, 2016 and 2015, the remaining liability balance of $8.9 million is classified as a long-term liability.

As of December 31, 2016, the unamortized debt discount and debt issuance costs were $3.7 million and $0.1 million, respectively.

Accretion of debt issuance cost and debt discount in connection with the Deerfield financing during the years ended December 31, 2016, 2015 and 2014 are as follows (in thousands):

		December 31,		
		2016	2015	2014
Accretion expense	debt issuance cost	$ 35	$ 35	$ 326
Accretion expense	debt discount	$ 1,722	$ 1,553	$ 7,550

The Facility Agreement includes customary representations, warranties and covenants, including, a restriction on the incurrence of additional indebtedness, and a financial covenant which requires the Company s cash and cash equivalents, which includes available borrowings on the note payable to principal stockholder, on the last day of each fiscal quarter to not be less than $25.0 million. As discussed in Note 1 Description of Business, the Company will need to raise additional capital to support its current operating plans. Due to the uncertainties related to maintaining sufficient resources to comply with the aforementioned covenant, the 2019 notes and the Tranche B notes have been classified as current liabilities in the accompanying consolidated balance sheets as of December 31, 2016 and 2015. In the event of non-compliance, Deerfield may declare all or any portion of the 2019 notes and/or Tranche B notes to be immediately due and payable.

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

terms of the Milestone Agreement. The Company has initially recorded the Milestone Rights at their estimated fair value See Note 2 Summary of Significant Accounting Policies under Milestone Rights Liability.

In determining the fair value of the Milestone Rights, the 13 individual milestone payments were adjusted for both (i) the expected timing and (ii) the probability of achieving the milestones, and then discounted to

Table of Contents

present value using a discount rate of 14.5%. Once the initial valuation of each specified milestone payment was determined, the individual milestone payments were then aggregated to arrive at a total fair value of $18.4 million. The discount rate was based on the estimated cost of equity which was derived using the capital asset pricing model. In addition, a 5% risk premium was added to the computation of the cost of equity to adjust for non-systemic risk factors, such as the Company s lack of product diversification and history of financial losses, which were not captured in other model inputs.

Security Agreement In connection with the Facility Agreement, the Company and its subsidiary, MannKind LLC, entered into a Guaranty and Security Agreement (the Security Agreement) with Deerfield and Horizon Sante FLML SA RL (collectively, the Purchasers), pursuant to which the Company and MannKind LLC each granted the Purchasers a security interest in substantially all of their respective assets, including respective intellectual property, accounts, receivables, equipment, general intangibles, inventory and investment property, and all of the proceeds and products of the foregoing. The Security Agreement includes customary covenants by the Company and MannKind LLC, remedies of the Purchasers and representations and warranties by the Company and MannKind LLC. The security interests granted by the Company and MannKind LLC will terminate upon repayment of the 2019 notes and Tranche B notes, if applicable, in full. The Company s obligations under the Facility Agreement and the Milestone Agreement are also secured by the mortgage on the Company s facilities in Danbury, Connecticut, which has a carrying value of $28.7 million.

Embedded Derivatives The Company identified and evaluated a number of embedded features in the notes issued under the Facility Agreement to determine if they represented embedded derivatives that are required to be separated from the notes and accounted for as freestanding instruments. In 2014, the Company analyzed the Tranche B notes and identified embedded derivatives which required separate accounting. However, all of the embedded derivatives were determined to have a *de minimis* value at December 31, 2016 and 2015.

Conversion Option During 2014, Deerfield elected to convert a total of $93.5 million of principal, which consisted of $20.0 million, $33.5 million, and $40.0 million of Tranche 1 notes, Tranche 2 notes, and Tranche 3 notes, respectively, into an aggregate 3,464,616 shares of common stock. In conjunction with the conversion by Deerfield, we recorded an aggregate expense of $6.4 million for the difference between the principal amount of the notes converted and their carrying amount (which included unamortized discount and debt issuance costs) which consisted of $1.2 million, $3.0 million, and $2.2 million related to the Tranche 1 notes, Tranche 2 notes, and Tranche 3 notes, respectively. Further, upon Deerfield converting $40.0 million of Tranche 3 notes and $20.0 million of Tranche 1 notes, Deerfield has reached the conversion limits (i.e., Applicable Limits) with respect to the Facility Agreement and therefore, no additional amount of the 2019 notes is convertible.

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

The 2018 notes are the Company s general, unsecured, senior obligations, except that the 2018 notes were subordinated to the Sanofi Loan facility prior to the extinguishment of the facility on November 9, 2016. The 2018 notes rank equally in right of payment with the Company s other unsecured senior debt. The 2018 notes bear interest at

the rate of 5.75% per year on the principal amount, payable semiannually in arrears in cash on February 15 and August 15 of each year, beginning February 15, 2016, with interest accruing from August 15, 2015. The 2018 notes mature on August 15, 2018. Accrued interest related to these notes is recorded in accrued expenses and other current liabilities on the accompanying consolidated balance sheets.

Table of Contents

The 2018 notes are convertible, at the option of the holder, at any time on or prior to the close of business on the business day immediately preceding the stated maturity date, into shares of the Company s common stock at an initial conversion rate of 29 shares per $1,000 principal amount of the 2018 notes, which is equal to a conversion price of approximately $34.00 per share, the same conversion price as that of the 2015 notes on the date of exchange. The conversion rate is subject to adjustment under certain circumstances described in an indenture governing the 2018 notes dated August 10, 2015 with Wells Fargo, National Association, including in connection with a make-whole fundamental change.

If certain fundamental changes occur, the Company will be obligated to pay a fundamental change make-whole premium on any 2018 notes converted in connection with such fundamental change by increasing the conversion rate on such 2018 notes. In such instances, the amount of the fundamental change make-whole premium will be based on the Company s common stock price and the effective date of the applicable fundamental change. If the Company undergoes certain fundamental changes, except in certain circumstances, each holder of 2018 notes will have the option to require the Company to repurchase all or any portion of that holder s 2018 notes. The fundamental change repurchase price will be 100% of the principal amount of the 2018 notes to be repurchased plus accrued and unpaid interest, if any.

On or after the date that is one year following the original issue date of the 2018 notes, the Company will have the right to redeem for cash all or part of the 2018 notes if the last reported sale price of its common stock exceeds 130% of the conversion price then in effect for 20 or more trading days during the 30 consecutive trading day period ending on the trading day immediately prior to the date of the redemption notice. The redemption price will equal the sum of 100% of the principal amount of the 2018 notes to be redeemed, plus accrued and unpaid interest. Under the terms of the 2018 Note Indenture, the conversion option can be net-share settled and the maximum number of shares that could be required to be delivered under the indenture, including the make-whole shares, is fixed and less than the number of authorized and unissued shares less the maximum number of shares that could be required to be delivered during the term of the 2018 notes under existing commitments. Applying the Company s sequencing policy, the Company performed an analysis at the time of the offering of the 2018 notes and each reporting date since and has concluded that the number of available authorized shares at the time of the offering and each subsequent reporting date was sufficient to deliver the number of shares that could be required to be delivered during the term of the 2018 notes under existing commitments.

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

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

Accretion of debt issuance expense in connection with the 2018 notes during the years ended December 31, 2016 and 2015 was $257,000 and $93,000, respectively. Amortization of the 2018 notes premium during the years ended December 31, 2016 and 2015 was $234,000 and $86,000, respectively.

Issuance of Common Stock in Exchange for the 2015 Notes On July 28, 2015, the Company entered into separate, privately-negotiated exchange agreements (the Stock-for-Note Exchange Agreements) with certain holders of the 2015 notes pursuant to which the Company agreed to issue shares of its common stock to such holders in exchange for

the delivery to the Company of up to $56.9 million aggregate principal amount of the 2015 notes.

Table of Contents

Pursuant to the Stock-for-Note Exchange Agreements, the parties agreed to price the exchange transactions over a 10 trading day period spanning from July 29, 2015 to and including August 11, 2015. Between July 28, 2015 and August 10, 2015, the Company issued an aggregate of 380,000 shares of common stock to such holders in exchange for such holders delivery to the Company of $8.0 million aggregate principal amount of the 2015 notes, resulting in a weighted-average exchange price of $110.00 per share.

Issuance of New 5.75% Convertible Senior Subordinated Exchange Notes Due 2015 in Exchange for the 2015 Notes On August 14, 2015, the Company exchanged $32.1 million aggregate principal amount of newly issued, 5.75% Convertible Senior Subordinated Exchange Notes due 2015 (the Exchange Notes) for the same principal amount of the Company s previously outstanding 2015 notes. The Exchange Notes, payable at maturity on September 30, 2015, were convertible, at the option of each holder thereof, at any time on or prior to the close of business on the business day immediately preceding the stated maturity date. The holders of the Exchange Notes did not elect to convert any of the outstanding principal amount of the Exchange Notes into shares of the Company s common stock. As a result, on September 30, 2015, the Company paid $32.1 million to settle the Exchange Notes.

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

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

Refer to Note 6 Related-Party Arrangements for information regarding the Note payable to principal stockholder.

8. Collaboration Arrangements

Receptor Collaboration and License Agreement On January 20, 2016, the Company entered into a Collaboration and License Agreement (the CLA) with Receptor Life Sciences, Inc. (Receptor) pursuant to which the Company performed initial formulation studies on compounds identified by Receptor. Following successful completion of the studies, Receptor obtained the option to acquire an exclusive license to develop, manufacture and commercialize certain products that use MannKind s technology to deliver the compounds via oral inhalation.

The Company received $0.4 million in nonrefundable payments in 2016 prior to Receptor exercising the option. On December 30, 2016, Receptor exercised the option and paid the Company a $1.0 million nonrefundable option exercise and license fee. Under the CLA, the Company may receive the following additional payments:

Nonrefundable milestone payments upon the completion of certain technology transfer activities and the achievement of specified sales targets.

Royalties upon Receptor s and its sublicensee s sale of the product.

Milestones upon total worldwide sales reaching certain agreed upon levels.

The Company evaluated the accounting for the payments received in 2016 under the multiple element accounting guidance and determined that the $0.4 million in payments received prior to Receptor exercising its

option are separable from the other elements of the agreement and represented payments to offset costs incurred. Therefore, those payments reduced the Company s research and development expense in 2016. The $1.0 million license fee received in 2016 does not have standalone value from the follow-on transfer of technology. Therefore, the license fee was recorded in deferred payments from collaboration at December 31, 2016 and will be recognized in net revenue collaboration over four years. See Note 2 Summary of Significant Accounting Policies for additional information on the Company s accounting for multiple element arrangements.

Sanofi License Agreement and Sanofi Supply Agreement and Loan Facility On August 11, 2014, the Company 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 was responsible for global commercial, regulatory and development activities for Afrezza. The Company manufactured Afrezza at its manufacturing facility in Danbury, Connecticut to supply Sanofi s demand for the product pursuant to a supply agreement dated August 11, 2014 (the Sanofi Supply Agreement).

During the term of the Sanofi License Agreement, worldwide profits and losses were determined based on the difference between the net sales of Afrezza and the costs and expenses incurred by the Company and Sanofi that were specifically attributable or related to the development, regulatory filings, manufacturing, or commercialization of Afrezza. These profits and losses were shared 65% by Sanofi and 35% by the Company. On January 4, 2016 the Company received a 90-day notification from Sanofi of its election to terminate in its entirety the Sanofi License Agreement. The effective date of termination (the Termination Date) was April 4, 2016. On April 5, 2016 the Company assumed responsibility for the worldwide development and commercialization of Afrezza from Sanofi. Under the terms of the transition agreement, Sanofi continued to fulfill orders for Afrezza in the United States until the Company began distributing MannKind-branded Afrezza product to major wholesalers during the week of July 25, 2016.

The Company analyzed the agreements entered into with Sanofi at their inception to determine whether the consideration, paid or payable to the Company, or a portion thereof, could be recognized as revenue. Under the terms of the Sanofi License Agreement, the Sanofi Supply Agreement and the Sanofi Loan Facility, the Company determined that the arrangement contained significant deliverables including (i) licenses to develop and commercialize Afrezza and to use the Company s trademarks, (ii) development activities, and (iii) manufacture and supply services for Afrezza. Due to the proprietary nature of the manufacturing services to be provided by the Company, the Company determined that all of the significant deliverables should be combined into a single unit of accounting. The Company believed that the manufacturing services are proprietary due to the fact that since the late 1990 s, the Company has developed proprietary knowledge and patented equipment and tools that are used in the manufacturing process of Afrezza. Due to the complexities of particle formulation and the specialized knowledge and equipment needed to handle the Afrezza powder, neither Sanofi nor, to the Company s knowledge, any third-party contract manufacturing organization currently possesses the capability of manufacturing Afrezza.

In order for revenue to be recognized, the seller s price to the buyer must be fixed or determinable. Prior to December 31, 2015, because the Company did not have the ability to estimate the amount of costs that would potentially be incurred under the loss share provision related to the Sanofi License Agreement and the Sanofi Supply Agreement, the Company believed this requirement for revenue recognition had not been met. Therefore, the Company had recorded the $150.0 million up-front payment and the two milestone payments of $25.0 million each as deferred payments from collaboration. In addition, as of December 31, 2015 the Company had recorded $17.5 million in Afrezza product shipments to Sanofi as deferred sales from collaboration and recorded $13.5 million as deferred costs from collaboration. Deferred costs from collaboration represented the costs of product manufactured and shipped to Sanofi, as well as certain direct costs associated with a firm purchase commitment entered into in connection with the collaboration with Sanofi.

In the first and second quarters of 2016, after the Company received notice of termination from Sanofi, the Company evaluated whether the revenue recognition criteria had been met. The Company determined that the

Table of Contents

requirement had not been met because Sanofi had not finalized necessary adjustments to the profit and loss share provision statements and Sanofi had not yet transferred all of the information to enable the Company to commercialize Afrezza on its own. Therefore, the Company was still unable to estimate the costs to be incurred under the agreement with Sanofi. During the three months ended September 30, 2016, Sanofi provided enough information to the Company to enable it to reasonably estimate the remaining costs under the Sanofi License Agreement and the Sanofi Supply Agreement. Accordingly, the fixed or determinable fee requirement for revenue recognition was met and there were no future obligations to Sanofi. Therefore, the Company recognized $172.0 million of net revenue collaboration for the year ended December 31, 2016. The revenue recognized includes the upfront payment of $150.0 million and the two milestone payments of $25.0 million each, net of $64.9 million of net loss share with Sanofi, as well as $17.5 million in sales of Afrezza and $19.4 million from sales of bulk insulin, both to Sanofi. These payments and sales were made pursuant to the contractual terms of the agreements with Sanofi.

Sanofi Loan Facility On September 23, 2014, the Company entered into the Sanofi Loan Facility, consisting of a senior secured revolving promissory note and a guaranty and security agreement (the Security Agreement) with an affiliate of Sanofi, which provided the Company with a secured loan facility of up to $175.0 million to fund the Company s share of net losses under the Sanofi License Agreement.

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

Advances under the Sanofi Loan Facility bore interest at a rate of 8.5% per annum and were payable in-kind and compounded quarterly and added to the outstanding principal balance under the Sanofi Loan Facility. The Company was required to make mandatory prepayments on the outstanding loans under the Sanofi Loan Facility from its share of any profits (as defined in the Sanofi License Agreement) under the Sanofi License Agreement within 30 days of receipt of its share of any such profits.

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

On November 9, 2016, the Company entered into a settlement agreement with Sanofi (the Settlement Agreement). Under the terms of the Settlement Agreement, the promissory note between the Company and Aventisub LLC (Aventisub), a Sanofi affiliate, was terminated, with Aventisub agreeing to forgive the full outstanding loan balance of $72.0 million. Sanofi also agreed to purchase $10.2 million of insulin from the Company in December 2016 under an existing insulin put option as well as make a cash payment of $30.6 million to the Company in early January 2017 as acceleration and in replacement of all other payments that Sanofi would otherwise have been required to make in the future pursuant to the insulin put option, without the Company being required to deliver any insulin for such payment. The Company was also relieved of its obligation to pay Sanofi $0.5 million in previously uncharged costs pursuant to the Sanofi License Agreement. The Company and Sanofi also agreed to a general release of potential claims against each other.

The forgiveness of the full outstanding loan balance on the Sanofi Loan Facility and the previously uncharged costs related to the collaboration were accounted for in (gain) loss on extinguishment of debt in the

Table of Contents

accompanying consolidated statements of operations. The $10.2 million sale of insulin was accounted for as net revenue collaboration, consistent with the Company sales of insulin to Sanofi in the third quarter of 2016 (see Note 2 Summary of Significant Accounting Policies *Revenue Recognition Net Revenue Collaboration*). The $30.6 million accelerated put option payment was recognized as a receivable from Sanofi at December 31, 2016 and an increase in the recognized loss on purchase commitments as the purchase commitment obligation had previously been reduced to reflect the Company s expectation that amounts associated with purchases of insulin were recoverable (see Note 2 Summary of Significant Accounting Policies *Inventories*).

9. Fair Value of Financial Instruments

The carrying amounts reported in the accompanying consolidated financial statements for cash, accounts receivable, accounts payable and accrued expenses and other current liabilities approximate their fair value due to their relatively short maturities. The fair value of the cash equivalents, note payable to principal stockholder, senior convertible notes, the Facility Financing Obligation (as defined below), the Milestone Rights (as defined below) and warrant liability are discussed below.

Cash Equivalents As of December 31, 2016 and 2015, the Company held $20.5 million and $55.8 million, respectively, of cash equivalents, consisting of money market funds. The fair value of these money market funds was determined by using quoted prices for identical investments in an active market (Level 1 in the fair value hierarchy).

Note Payable to Principal Stockholder The fair value of the note payable to the Company s principal stockholder cannot be reasonably estimated as the Company would not be able to obtain a similar credit arrangement in the current economic environment. Therefore, the fair value is based upon carrying value.

Financial Liabilities The following tables set forth the fair value of the Company s financial instruments (in millions):

	As of December 31, 2016				
	Carrying Value	Level 1	Level 2	Level 3	Total
Financial liabilities:					
Senior convertible notes	$ 27.6	$	$	$ 22.9	$ 22.9
Facility Financing Obligation	71.3			74.5	74.5
Milestone Rights	8.9			18.4	18.4
Warrant liability (at recurring fair values)	7.4			7.4	7.4
Total financial liabilities	$ 115.2	$	$	$ 123.2	$ 123.2

	As of December 31, 2015				
	Carrying Value	Level 1	Level 2	Level 3	Total
Financial liabilities:					
Senior convertible notes	$ 27.6	$	$	$ 21.3	$ 21.3
Facility Financing Obligation	74.6			78.4	78.4
Milestone Rights	8.9			14.4	14.4
Sanofi Loan Facility	44.5			36.5	36.5

Total financial liabilities	$ 155.6	$	$	$ 150.6	$ 150.6

Table of Contents

The following table provides a roll forward of the fair values of financial assets and liabilities that are carried at fair value (in millions):

	Warrants	Assets Held for Sale
Fair value, January 1, 2015	$	$
Additions		
Changes in fair value		
Payments		
Fair value, December 31, 2015	$	$
Additions	12.8	17.3
Changes in fair value	(5.4)	(0.6)
Payments		
Fair value, December 31, 2016	$ 7.4	$ 16.7

Senior Convertible Notes The estimated fair value of the 2018 notes was calculated based on model-derived valuations where inputs were observable, such as the Company s stock price and yields on U.S. Treasury notes and actively traded bonds, and non-observable, such as the Company s longer-term historical volatility, and estimated yields implied from any available market trades of the Company s issued debt instruments. As there is no current active and observable market for the 2018 notes, the Company determined the estimated fair value using a convertible bond valuation model within a lattice framework. The convertible bond valuation model combined expected cash flows based on terms of the notes with market-based assumptions regarding risk-free rate, risk-adjusted yields (20%), stock price volatility (111%) and recent price quotes and trading information regarding Company issued debt instruments and shares of common stock into which the notes are convertible.

Facility Financing Obligation As discussed in Note 7 Borrowings, in connection with the Facility Agreement, the Company issued 2019 notes and subsequently issued Tranche B notes (the Facility Financing Obligation). As there is no current observable market for the Facility Financing Obligation, the Company determined the estimated fair value using a bond valuation model based on a discounted cash flow methodology. The bond valuation model combined expected cash flows associated with principal repayment and interest based on the contractual terms of the debt agreement discounted to present value using a selected market discount rate. On December 31, 2016 the market discount rate was recalculated at 12.0% for the Facility Financing Obligation. Under the terms of the Facility Agreement, the Company is restricted from distributing any of its assets or declaring and distributing a dividend to its stockholders.

Milestone Rights Liability In addition to the Facility Financing Obligation, the Company also issued certain rights to receive payments of up to $90.0 million upon occurrence of specified strategic and sales milestones (the Milestone Rights). These rights are not reflected in the Facility Financing Obligation. The estimated fair value of the Milestone Rights was calculated using the income approach in which the cash flows associated with the specified contractual payments were adjusted for both the expected timing and the probability of achieving the milestones discounted to present value using a selected market discount rate (Level 3 in the fair value hierarchy). The expected timing and probability of achieving the milestones, starting in 2014, was developed with consideration given to both internal data, such as the Company s forecast, progress made to date towards meeting the milestones, and assessment of criteria

required for achievement, and external data, such as market research studies. The discount rate (14.5%) was selected based on an estimation of required rate of returns for similar investment opportunities using available market data. As of December 31, 2016, the carrying value of the Milestone Rights is $8.9 million, classified as a long-term liability and the fair value is estimated at $18.4 million.

Warrant Liability Warrant liabilities are measured at fair value using a Monte Carlo pricing valuation model and various assumptions. The significant unobservable input used in measuring the fair value of the common stock warrant liabilities is the expected volatility. Significant increases in volatility would result in a higher fair value measurement (Level 3 in the fair value hierarchy). See Note 16 Warrants for further discussion of the valuation technique and inputs used in the fair value measurement.

Table of Contents

Sanofi Loan Facility As discussed in Note 8 Collaboration Arrangements, the Sanofi Loan Facility consisted of a senior secured revolving promissory note and a guaranty and security agreement with an affiliate of Sanofi which provided the Company with a secured loan facility of up to $175.0 million to fund the Company s share of net losses under the Sanofi License Agreement. The estimated fair value was determined using a discounted cash flow model where time outstanding and discount rate were primary variables. This method considered the key elements of the contractual terms of the Sanofi Loan Facility, market-based estimated cost of capital, and time value of money, namely the amount of time to settlement and the estimated discount rate (11%) appropriate for the liability (Level 3 in the fair value hierarchy). The Sanofi Loan Facility was forgiven on November 9, 2016.

There were no transfers of assets or liabilities between the fair value measurement levels during the twelve months ended December 31, 2016, 2015 and 2014.

Assets and Liabilities Measured at Fair Value on a Non-recurring Basis Land, buildings, and machinery and equipment, with a carrying amount of $189.2 million, were written down to a fair value of $48.8 million, resulting in an impairment charge of $140.4 million, which is included in our consolidated statements of operations for the year ended December 31, 2015. See Note 4- Property and Equipment for further discussion of the valuation technique and inputs used in the fair value measurement.

An additional impairment of $0.7 million was charged for the year ended December 31, 2016. At that time, an analysis of the lower of carrying value to fair value, which was deemed to be the sales price of the property, less selling costs determined a loss of $0.6 million, which is included in property and equipment impairment on the consolidated statement of operations for 2016.

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

Embedded Derivatives The Company identified and evaluated a number of embedded features in the notes issued under the Facility Agreement to determine if they represented embedded derivatives that are required to be separated from the notes and accounted for as freestanding instruments. The Company analyzed the Tranche B notes and identified embedded derivatives, which required separate accounting. However, all of the embedded derivatives were determined to have a *de minimis* value at December 31, 2016 and 2015.

10. Common and Preferred Stock

On March 1, 2017, the Company effected a 1-for-5 reverse stock split of the Company s outstanding common stock. As a result, all common stock share amounts included in these consolidated financial statements have been retroactively reduced by a factor of five, and all common stock per share amounts have been increased by a factor of five, with the exception of the Company s common stock par value. See Note 1 Description of Business.

The Company is authorized to issue 140,000,000 shares of common stock, par value $0.05 per share, and 10,000,000 shares of undesignated preferred stock, par value $0.01 per share, issuable in one or more series as designated by the Company s board of directors. No other class of capital stock is authorized. As of December 31, 2016 and 2015, 95,680,831 and 85,734,188 shares of common stock, respectively, were issued and outstanding and no shares of preferred stock were outstanding.

As more fully described in Note 16 Warrants, in May 2016, the Company sold in a registered offering an aggregate of 9,708,737 shares of common stock together with certain warrants exercisable for up to an aggregate of 7,281,553 shares of common stock (A Warrants) and certain warrants exercisable for up to an aggregate of 2,427,184 shares of

common stock (B Warrants) in a direct offering for proceeds of $50.0 million.

On November 9, 2015, the Company entered into a series of stock purchase agreements to sell up to an aggregate of 10,000,000 shares of its common stock in a registered direct offering to selected investment funds in Israel that hold securities included within certain stock indexes of the Tel Aviv Stock Exchange (the TASE). Pursuant to the agreements, the shares of common stock were sold at a price per share equal to 97% of the

Table of Contents

closing price of the Company s common stock on the TASE on November 12, 2015. During November 2015, the Company sold 2,770,487 shares of common stock for an aggregate price of approximately $34,710,000, or $13.05 per share, which is net of $1,432,000 of issuance costs.

The Company engaged Sunrise Securities Corporation as its exclusive placement agent in connection with the offering of the 10,000,000 shares. In connection with the services provided, the Company issued to Sunrise Securities Corporation, or its designee, restricted warrants to purchase a number of shares of the Company s common stock in an aggregate equal to 1.15% of the aggregate shares sold in the offering, which totaled 31,860 shares on November 16, 2015. The warrants are exercisable for a five year period at an exercise price of $13.05, the price paid per share in connection with the offering. The Company had an obligation to register the common stock that may be issued pursuant to the exercise of the warrants, which resulted in their initial classification as liability and were deemed immaterial. On December 15, 2015 the warrants were reclassified to equity as the Company registered the common stock pursuant to a registration statement and continue to be classified in equity as of December 31, 2016.

Included in the common stock outstanding as of December 31, 2014 is 1,800,000 shares of common stock loaned to Bank of America under a share lending agreement in connection with the offering of the $100.0 million aggregate principal amount of the 2015 notes. Bank of America was obligated to return the borrowed shares (or, in certain circumstances, the cash value thereof) to the Company on or about the 45th business day following the date as of which the entire principal amount of the 2015 notes ceases to be outstanding, subject to extension or acceleration in certain circumstances or early termination at Bank of America s option. On October 23, 2015, the 1,800,000 shares of common stock loaned to Bank of America were returned, as the Company settled all payments and deliveries in respect of such convertible notes on August 17, 2015. The Company did not receive any proceeds from the sale of the borrowed shares by Bank of America, but the Company did receive a nominal lending fee of $0.05 per share from Bank of America for the use of borrowed shares.

On February 8, 2012, the Company sold 7,187,500 units in an underwritten public offering, including 937,500 units sold pursuant to the full exercise of an over-allotment option granted to the underwriters, with each unit consisting of one share of common stock and a warrant to purchase 0.1 of a share of common stock. All of the securities were offered by the Company at a combined price to the public of $12.00 per unit and the underwriters purchased the units at a price of $11.28 per unit. Net proceeds from this offering were approximately $80.6 million, excluding any warrant exercises. The 4,312,500 shares of common stock underlying the warrants are exercisable at $12.00 per share and expire four years from the date of the issuance.

For the years ended December 31, 2015 and 2014, the Company received $10.1 million and $27.8 million in proceeds, respectively, from the exercise of the February 2012 public offering warrants. There were no warrant exercises during the year ended December 31, 2016 and any unexercised February 2012 public offering warrants expired on February 8, 2016.

11. Net Income (Loss) per Common Share

On March 1, 2017, the Company effected a 1-for-5 reverse stock split of the Company s outstanding common stock. As a result, all common stock share amounts included in these consolidated financial statements have been retroactively reduced by a factor of five, and all common stock per share amounts have been increased by a factor of five, with the exception of the Company s common stock par value. See Note 1 Description of Business.

Basic net income (loss) per share excludes dilution for potentially dilutive securities and is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share reflects the potential dilution under the treasury method that could occur if securities or other contracts

to issue common stock were exercised or converted into common stock. For periods where the Company has presented a net loss, potentially dilutive securities are excluded from the computation of diluted net loss per share as they would be antidilutive. During 2015, 1,800,000 shares of the Company s

Table of Contents

common stock, which were loaned to Bank of America pursuant to the terms of a share lending agreement, were issued and outstanding, with the holder of the borrowed shares having all the rights of a holder of the Company s common stock. As the share borrower was required to return all borrowed shares to the Company, the borrowed shares were not considered outstanding for the purpose of computing and reporting basic or diluted loss per share during the period presented for 2015. These shares were returned to the Company in the third quarter of 2015.

The following tables summarize the components of the basic and diluted net income (loss) per common share computations:

	Year Ended December 31,		
	2016	2015	2014
	(In thousands, except per share data)		
Basic EPS:			
Net income (loss) (numerator)	$ 125,664	$ (368,445)	$ (198,382)
Weighted average common shares (denominator)	92,053	81,233	77,045
Net income (loss) per share	$ 1.37	$ (4.54)	$ (2.57)
Diluted EPS:			
Net income (loss) (numerator)	$ 125,664	$ (368,445)	$ (198,382)
Weighted average common shares	92,053	81,233	77,045
Effect of dilutive securities common shares issuable	32		
Adjusted weighted average common shares (denominator)	92,085	81,233	77,045
Net income (loss) per share	$ 1.36	$ (4.54)	$ (2.57)

Common shares issuable represents incremental shares of common stock which consist of stock options, restricted stock units, warrants, and shares that could be issued upon conversion of the senior convertible notes.

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

	December 31,		
	2016	2015	2014
Exercise of common stock options	5,530,256	3,955,845	4,308,332
Conversion of senior convertible notes into common stock	814,561	814,561	3,464,616
Exercise of common stock warrants	9,740,597	814,919	1,997,575
Vesting of restricted stock units	702,867	360,924	522,144
	16,788,281	5,946,249	10,292,667

12. Stock Award Plans

On March 1, 2017, the Company effected a 1-for-5 reverse stock split of the Company s outstanding common stock. As a result, all common stock share amounts included in these consolidated financial statements have been retroactively reduced by a factor of five, and all common stock per share amounts have been increased by a factor of five, with the exception of the Company s common stock par value. See Note 1 Description of Business.

On May 23, 2013, the Company adopted the 2013 Equity Incentive Plan (the 2013 Plan) as the successor to and continuation of the 2004 Equity Incentive Plan (the 2004 Plan). The 2013 Plan consists of 4.3 million additional shares and the number of unallocated shares remaining available for grant for new awards under the

Table of Contents

2004 Plan. The 2013 Plan provides for the granting of stock awards including stock options and restricted stock units, to employees, directors and consultants. The 2013 Plan also provides for the automatic, non-discretionary grant of options to the Company s non-employee directors. No additional awards will be granted under the 2004 Plan or under the 2004 Non-Employee Directors Stock Option Plan (the NED Plan) as all future awards will be made out of the 2013 Plan.

The following table summarizes information about the Company s stock-based award plans as of December 31, 2016:

	Outstanding Options	Outstanding Restricted Stock Units	Shares Available for Future Issuance
2004 Equity Incentive Plan	2,052,345	14,203	97,574
2013 Equity Incentive Plan	3,399,245	723,763	3,743,013
2004 Non-Employee Directors Stock Option Plan	78,666		
Total	5,530,256	737,966	3,840,587

In March 2004, as part of the 2004 Plan, the Company s board of directors approved the Employee Stock Purchase Plan (ESPP), which became effective upon the closing of the Company s initial public offering. Initially, the aggregate number of shares that could be sold under the 2004 Plan was 400,000 shares of common stock. On January 1 of each year, for a period of ten years beginning January 1, 2005, the share reserve automatically increased by the lesser of: 140,000 shares, 1% of the total number of shares of common stock outstanding on that date, or an amount as may be determined by the board of directors. However, under no event can the annual increase cause the total number of shares reserved under the ESPP to exceed 10% of the total number of shares of capital stock outstanding on December 31 of the prior year. On January 1, 2013 and 2014 the ESPP share reserve was increased each year by 140,000 shares. There was no ESPP share reserve increases during 2015 or 2016. As of December 31, 2016, 445,782 shares were available for issuance under the ESPP. For the years ended December 31, 2016, 2015 and 2014, the Company sold 104,758, 64,245 and 61,015 shares, respectively, of its common stock to employees participating in the ESPP. The ESPP purchase of 43,672 shares for the period ending December 31, 2016 was initiated prior to year-end but did not settle until January 5, 2017. As a result, the shares sold are reflected in the ESPP share reserves but are excluded from common stock outstanding as of December 31, 2016.

The Company s board of directors determines eligibility, vesting schedules and criteria and exercise prices for stock awards granted under the 2013 Plan. Options and restricted stock unit awards under the 2013 Plan expire not more than ten years from the date of the grant and are exercisable upon vesting. Stock options that vest over time generally vest over four years. Current time-based vesting stock option grants vest and become exercisable at the rate of 25% after one year and ratably on a monthly basis over a period of 36 months thereafter. Restricted stock units with time-based vesting generally vest at a rate of 25% per year over four years with consideration satisfied by service to the Company. The Company also issues stock awards with performance conditions. The 2013 Plan provides for full acceleration of vesting if an employee is terminated within three months of a change in control, as defined in the 2013 Plan.

Share-based payment transactions are recognized as compensation cost based on the fair value of the instrument on the date of grant. The Company accounts for non-employee stock-based compensation expense based on the estimated fair value of the options, which is determined using the Black-Scholes option valuation model and amortizes such

expense on a straight-line basis over the service period for time-based awards and over the expected dates of achievement for performance-based awards. These awards are subject to re-measurement until service is complete. As of December 31, 2016, there were options to purchase 100,697 shares of common stock outstanding to consultants.

During the years ended December 31, 2016, 2015 and 2014 the Company recorded stock-based compensation expense of $5.1 million, $8.7 million and $48.6 million, respectively.

Table of Contents

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

	Year Ended December 31,		
	2016	2015	2014
Employee-related	$ 5,135	$ 8,407	$ 48,622
Consultant-related		318	
Total	$ 5,135	$ 8,725	$ 48,622

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

	Year Ended December 31,		
	2016	2015	2014
Cost of goods sold	$ 695	$	$
Research and development	1,309	3,029	22,357
Selling, general and administrative	3,131	5,696	26,265
Total	$ 5,135	$ 8,725	$ 48,622

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

The expected volatility assumption is based on an assessment of the historical volatility, with consideration of implied volatility, derived from an analysis of historical trade activity. The Company has selected risk-free interest rates based on U.S. Treasury securities with an equivalent expected term in effect on the date the options were granted. Additionally, the Company uses historical data and management judgment to estimate stock option exercise behavior and employee turnover rates to estimate the number of stock option awards that will eventually vest. The Company calculated the fair value of employee stock options granted during the years ended December 31, 2016, 2015 and 2014 using the following assumptions:

	Year Ended December 31,					
	2016		2015		2014	
Risk-free interest rate	1.18%	1.80%	1.61%	1.86%	1.64%	2.11%
Expected lives	5.13	5.82 years	5.79	5.86 years	5.77	6.09 years
Volatility	77.57%	82.75%	69.76%	71.84%	73.98%	84.85%
Dividends						

The following table summarizes information about stock options outstanding:

	Number of Shares	Weighted Average Exercise Price per Share	Aggregate Intrinsic Value ($000)
Outstanding at January 1, 2016	3,955,845	$ 22.70	$
Granted	2,236,693	4.50	
Exercised	(55,231)	8.45	
Forfeited	(407,161)	13.60	
Expired	(199,890)	23.65	
Outstanding at December 31, 2016	5,530,256	$ 16.10	$ 2
Vested and expected to vest at December 31, 2016	5,399,777	$ 16.35	$ 2
Exercisable at December 31, 2016	3,414,586	$ 22.50	$

Table of Contents

The weighted average grant date fair value of the stock options granted during the years ended December 31, 2016, 2015 and 2014 was $3.05, $12.80 and $23.80 per option, respectively. The total intrinsic value of options exercised during the years ended December 31, 2016, 2015 and 2014 was $0.1 million, $6.2 million and $14.9 million, respectively. Intrinsic value is measured using the fair market value at the date of exercise for options exercised or at December 31 for outstanding options, less the applicable exercise price.

Cash received from the exercise of options during the years ended December 31, 2016, 2015 and 2014 was approximately $0.5 million, $3.3 million and $11.0 million, respectively. The weighted-average remaining contractual terms for options outstanding, vested and expected to vest and exercisable at December 31, 2016 was 5.31 years, 5.22 years and 2.93 years, respectively.

A summary of restricted stock unit activity for the year ended December 31, 2016 is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value per Share
Outstanding at January 1, 2016	360,924	$ 24.25
Granted	800,530	4.50
Vested	(131,000)	21.70
Forfeited	(292,488)	11.60
Outstanding at December 31, 2016	737,966	$ 8.40

The total restricted stock units expected to vest as of December 31, 2016 was 629,424 with a weighted average grant date fair value of $8.60 per share. The total intrinsic value of restricted stock units expected to vest as of December 31, 2016 was $2.0 million. Intrinsic value of restricted stock units expected to vest is measured using the closing share price at December 31, 2016.

Total intrinsic value of restricted stock units vested during the years ended December 31, 2016, 2015 and 2014 was $0.6 million, $5.2 million and $62.7 million, respectively. Intrinsic value of restricted stock units vested is measured using the closing share price on the day prior to the vest date. The total grant date fair value of restricted stock units vested during the years ended December 31, 2016, 2015 and 2014 was $2.6 million, $5.5 million and $36.4 million, respectively.

As of December 31, 2016, there was $4.0 million and $4.8 million of unrecognized compensation expense related to options and restricted stock units with performance conditions, respectively, which is expected to be recognized over the weighted average vesting period of 2.9 years. The Company evaluates stock awards with performance conditions as to the probability that the performance conditions will be met and uses that information to estimate the date at which those performance conditions will be met in order to properly recognize stock-based compensation expense over the requisite service period.

As of December 31, 2016, the Company reviewed the probability of achieving the performance conditions for each of the four vesting tranches of the performance-based stock options and determined that it was probable that the

Company would achieve the first vesting tranche in December 2017. Therefore, the Company recorded a non-material cumulative catchup of the expense from the grant date through December 31, 2016 and will record the unrecognized compensation cost related to the first tranche in the amount of $0.3 million through December 31, 2017. The Company further determined that no compensation costs would be recognized for the second, third and fourth vesting tranches as it had not been determined that it was probable that the performance conditions related to these tranches would be achieved.

During the year ended December 31, 2015, there was $1.6 million of stock compensation expense related to certain executives who entered into severance agreements which resulted in a modification to the terms of their

Table of Contents

awards. The severance agreements generally allowed for the separated executives to continue to vest under their original award terms for a stated period of time without providing substantive services. There were no modifications in 2016.

13. Commitments and Contingencies

Operating Leases The Company leases its executive offices in Valencia, California and certain equipment under various operating leases, which expire at various dates through 2017 and beyond. Future payments are insignificant.

Rent expense under all operating leases, including office space and equipment, for the years ended December 31, 2016, 2015 and 2014 was approximately $373,000, $426,000 and $737,000, respectively.

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

Litigation The Company is subject to legal proceedings and claims which arise in the ordinary course of its business. As of December 31, 2016, the Company believes that the final disposition of such matters will not have a material adverse effect on the consolidated financial position, results of operations or cash flows of the Company and no accrual has been recorded. The Company maintains liability insurance coverage to protect the Company s assets from losses arising out of or involving activities associated with ongoing and normal business operations. The Company records a provision for a liability when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. The Company s policy is to accrue for legal expenses in connection with legal proceeding and claims as they are incurred.

Following the public announcement of Sanofi s election to terminate the Sanofi License Agreement and the subsequent decline of the price of its common stock, several complaints were filed in the U.S. District Court for the Central District of California against the Company and certain of its officers and directors on behalf of certain purchasers of its common stock, which were consolidated into a single action. The amended complaint alleged that the Company and certain of its officers and directors violated federal securities laws by making materially false and misleading statements regarding the prospects for Afrezza, thereby artificially inflating the price of its common stock. The Company and the named defendants brought a motion to dismiss the class action that was pending against them, which the District Court granted in August 2016 without leave to amend the complaint. The lead plaintiff appealed that decision to the Ninth Circuit Court of Appeals. On March 2, 2017, the lead plaintiff filed a voluntary motion to dismiss his appeal, which the Court of Appeals granted on March 9, 2017.

Following the public announcement of Sanofi s election to terminate the Sanofi License Agreement and the subsequent decline of the price of its common stock, two motions were submitted to the District Court at Tel Aviv, Economic Department for the certification of a class action against the Company and certain of its officers and directors. In general, the complaints allege that the Company and certain of its officers and directors violated Israeli and U.S.

securities laws by making materially false and misleading statements regarding the prospects for Afrezza, thereby artificially inflating the price of its common stock. The plaintiffs are seeking monetary

Table of Contents

damages. In November 2016, the district court dismissed one of the actions without prejudice. In the remaining action, a hearing is scheduled for May 2017 to determine whether Israeli or U.S. law is applicable before the case can be certified as a class action. The Company will vigorously defend against these claims.

Subsequent to the filing of the federal securities class action against the Company, two shareholder derivative complaints were filed in the Superior Court for the State of California, County of Los Angeles against certain of the Company s directors and officers. The complaints allege breaches of fiduciary duties by the defendants and other violations of law. Among other allegations, the complaints allege that the defendants caused the Company to make false and misleading statements or omissions of material fact regarding the Company s business and the prospects for sales of Afrezza, thereby artificially inflating the price of the Company s common stock. Following the dismissal of the federal securities class action, each derivative complaint was voluntarily dismissed by its plaintiff.

Contingencies In connection with the Facility Agreement, on July 1, 2013 the Company also entered into a Milestone Rights Purchase Agreement (the Milestone Agreement) with Deerfield Private Design Fund and Horizon Santé FLML SÁRL (collectively, the Milestone Purchasers), pursuant to which the Company sold the Milestone Purchasers the Milestone Rights to receive payments up to $90.0 million upon the occurrence of specified strategic and sales milestones, including the first commercial sale of an Afrezza product in the United States and the achievement of specified net sales figures (see Note 7 Borrowings).

Commitment On July 31, 2014, the Company entered into a supply agreement (the Insulin Supply Agreement) with Amphastar France Pharmaceuticals S.A.S., a French corporation (Amphastar), pursuant to which Amphastar will manufacture for and supply to the Company certain quantities of recombinant human insulin for use in Afrezza. Under the terms of the Insulin Supply Agreement, Amphastar will be responsible for manufacturing the insulin in accordance with the Company s specifications and agreed-upon quality standards. The Company had agreed to purchase annual minimum quantities of insulin for calendar years 2015 through 2019 under the Insulin Supply Agreement of an aggregate total of approximately 120.1 million. The Company could have requested to purchase additional quantities of insulin over such annual minimum quantities with a cancellation fee.

On November 9, 2016, the supply agreement with Amphastar was amended to extend the term over which the Company is required to purchase insulin, without reducing the total amount of insulin to be purchased. Under the amendment, annual minimum quantities of insulin to be purchased for calendar years 2017 through 2023 total an aggregate purchase price of 93.0 million at December 31, 2016. The Insulin Supply Agreement specifies that Amphastar will be deemed to have satisfied its obligations with respect to quantity, if the actual quantity supplied is within plus or minus ten percent (+/- 10%) of the quantity set forth in the applicable purchase order. In addition, the aggregate cancellation fees that the Company would incur in the event that the above insulin quantities are not purchased was lowered from $5.3 million for the period October 1, 2016 through 2018 to $3.4 million over the same period. The annual purchase requirements under the contract are as follows:

2017	2.7 million
2018	8.9 million
2019	11.6 million
2020	15.5 million
2021	15.5 million
2022	19.4 million
2023	19.4 million

Unless earlier terminated, the term of the Insulin Supply Agreement expires on December 31, 2023 and can be renewed for additional, successive two year terms upon 12 months written notice given prior to the end of the

Table of Contents

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

The Company also has another firm commitment with another supplier for an aggregate of $0.9 million.

14. Employee Benefit Plans

The Company administers a 401(k) savings retirement plan (the MannKind Retirement Plan) for its employees. For the years ended December 31, 2016, 2015 and 2014, the Company contributed $418,000, $593,000 and $623,000, respectively, to the MannKind Retirement Plan.

15. Income Taxes

At December 31, 2016, the Company has concluded that it is more likely than not that the Company may not realize the benefit of its deferred tax assets due to its history of losses. There is no provision for income taxes in 2015 or 2014 because the Company had incurred operating losses since inception. Accordingly, the net deferred tax assets have been fully reserved. The provision for income taxes consists of the following (in thousands):

	Year Ended December 31,		
	2016	2015	2014
Current			
U.S. federal	$	$	$
U.S. state			
Non-U.S.			
Total current			
Deferred			
U.S. federal	(43,814)	109,512	57,873
U.S. state	(4,311)	(29,394)	7,631
Non-U.S.			
Total deferred	(48,125)	80,118	65,504
Valuation allowance	48,125	(80,118)	(65,504)
Total	$	$	$

118

Table of Contents

Deferred income taxes reflect the tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting and income tax purposes. A valuation allowance is established when uncertainty exists as to whether all or a portion of the net deferred tax assets will be realized. Components of the net deferred tax assets as of December 31, 2016 and 2015, are as follows (in thousands):

	December 31,	
	2016	2015
Deferred tax assets:		
Net operating loss carryforwards	$ 712,124	$ 721,588
Research and development credits	77,998	73,646
Capitalized research	5,117	5,872
Payments from collaboration		52,484
Milestone Rights	3,242	3,242
Accrued expenses	440	251
Loss on purchase commitment	36,775	24,084
Non-qualified stock option expense	17,331	16,941
Capitalized patent costs	8,781	8,574
Other	7,380	7,186
Depreciation	45,310	48,755
Total net deferred tax assets	914,498	962,623
Valuation allowance	(914,498)	(962,623)
Net deferred tax assets	$	$

The table of deferred tax assets and liabilities does not include certain deferred tax assets as of December 31, 2016, that arose directly from tax deductions related to equity compensation which are greater than the compensation recognized for financial reporting. Equity would be increased by $11.6 million if and when such deferred tax assets are ultimately realized. The Company considers certain realization requirements when excess tax benefits have been realized.

The Company s effective income tax rate differs from the statutory federal income tax rate as follows for the years ended December 31, 2016, 2015 and 2014:

	December 31,		
	2016	2015	2014
Federal tax benefit rate	35.0%	35.0%	35.0%
Permanent items	(1.9)		0.9
Intercompany transfer of intellectual property	0.9	(1.0)	(4.1)
Valuation allowance	(34.0)	(34.0)	(31.8)
Effective income tax rate	%	%	%

Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Management has concluded, in accordance with the applicable accounting standards, that it is more likely than not that the Company may not realize the benefit of its deferred tax assets. Accordingly, the net deferred tax assets have been fully reserved. Management reevaluates the positive and negative evidence on an annual basis. During the years ended December 31, 2016, 2015 and 2014, the change in the valuation allowance was $(48.1) million, $80.1 million and $65.5 million, respectively, for income taxes.

At December 31, 2016, the Company had federal and state net operating loss carryforwards of approximately $1.9 billion and $1.3 billion available, respectively, to reduce future taxable income. The federal

Table of Contents

net operating loss carryforwards will expire at various dates beginning in 2018 and the state net operating loss carryforwards have started expiring, starting in the current year through various future dates. As a result of the Company s initial public offering, an ownership change within the meaning of Internal Revenue Code Section 382 occurred in August 2004. As a result, federal net operating loss and credit carry forwards of approximately $216.0 million are subject to an annual use limitation of approximately $13.0 million. The annual limitation is cumulative and therefore, if not fully utilized in a year can be utilized in future years in addition to the Section 382 limitation for those years. The federal net operating losses generated subsequent to the Company s initial public offering in August 2004 are currently not subject to any such limitation as there have been no ownership changes since August 2004 within the meaning of Internal Revenue Code Section 382. At December 31, 2016, the Company had research and development credits of $53.0 million and $38.5 million for federal and state purposes, respectively. The federal credits begin to expire in 2024, and the state credits may be carried forward indefinitely.

The Company has evaluated the impact of uncertainty related to income taxes on its consolidated financial statements. The evaluation of an uncertain tax position is a two-step process. The first step is recognition: the enterprise determines whether it is more-likely-than-not that a tax position will be sustained upon examination, including resolution of any related appeals or litigation processes, based on the technical merits of the position. In evaluating whether a tax position has met the more-likely-than-not recognition threshold, the enterprise should presume that the position will be examined by the appropriate taxing authority that would have full knowledge of all relevant information. The second step is measurement: a tax position that meets the more-likely-than-not recognition threshold is measured to determine the amount of benefit to recognize in the financial statements. The tax position is measured at the largest amount of benefit that is greater than 50 percent likely of being realized upon ultimate settlement. Tax positions that previously failed to meet the more-likely-than-not recognition threshold should be recognized in the first subsequent financial reporting period in which that threshold is met. Previously recognized tax positions that no longer meet the more-likely-than-not recognition threshold should be derecognized in the first subsequent financial reporting period in which that threshold is no longer met. The Company believes that its income tax filing positions and deductions will be sustained on audit and does not anticipate any adjustments that will result in a material change to its consolidated financial position. Therefore, no liabilities for uncertain income tax positions have been recorded. Tax years since 2012 remain subject to examination by the major tax jurisdictions in which the Company is subject to tax.

16. Warrants

In May 2016, the Company sold in a registered offering an aggregate of 9,708,737 shares of common stock together with A Warrants exercisable for up to an aggregate of 7,281,553 shares of common stock and B Warrants exercisable for up to an aggregate of 2,427,184 shares of common stock with a total fair value of $44.7 million. Each of the warrants has an exercise price of $7.50 per share. The A Warrants became exercisable upon issuance and will expire two years thereafter. The B Warrants will become exercisable beginning in May 2017 and will expire 30 months after the date of issuance. The shares of common stock and the warrants are immediately separable and issued separately. There have been no warrants exercised as of December 31, 2016.

The Company determined that the A Warrants require liability classification primarily due to a price-protection clause that applies in the event of certain dilutive financings. The fair value of the A Warrants was recorded as warrant liability in the consolidated balance sheet at issuance and is adjusted to fair value at each reporting period until exercise or expiration. The Company determined that the B Warrants met the criteria for equity classification and has accounted for such warrants in additional paid in capital.

As of December 31, 2016 and May 12, 2016, the fair value of the A Warrants liability was $7.4 million and $12.8 million, respectively. As of May 12, 2016, the fair value of the B Warrants at issuance was $5.0 million. The

fair value of the A Warrants liability as of December 31, 2016 was estimated using a Monte Carlo valuation pricing model with the following underlying assumptions: (a) a risk-free interest rate of 1.1%; (b) an assumed dividend yield of zero percent; (c) an expected term of 1.4 years; and (d) an expected volatility of 118%. The fair

Table of Contents

value of the A Warrants liability as of May 12, 2016, was estimated using a Monte Carlo valuation pricing model with the following underlying assumptions: (a) a risk-free interest rate of 0.76%; (b) an assumed dividend yield of zero percent; (c) an expected term of 2.0 years; and (d) an expected volatility of 95%. The Company assumed a probability of a dilutive financing event or an equity event, as defined in the agreement, of 10% for the each of the measurement periods.

For the year ended December 31, 2016, the Company recognized a change in fair value of warrant liability of $5.4 million in the consolidated statements of operations to reflect the fair value adjustments of the A Warrant liability from the date of issuance.

17. Selling, General and Administrative Expenses

Selling, general and administrative expenses consist of the following (in thousands):

	Year Ended December 31,		
	2016	2015	2014
Selling and marketing	$ 19,854	$ 1,587	$ 3,556
General and administrative	27,074	39,373	75,827
Total selling, general and administrative	$ 46,928	$ 40,960	$ 79,383

18. Restructuring Charges

In September 2016, the Company initiated a restructuring of its organization in order to conserve resources for commercial sales and marketing of Afrezza and to align cost of goods sold in support of these commercial efforts (2016 Restructuring). In connection with the 2016 Restructuring, the Company reduced its total workforce by approximately 18% to 155 employees. The Company recorded charges of approximately $1.5 million, primarily for employee severance as well as other related termination benefits. The $1.5 million of costs associated with the 2016 Restructuring are included in cost of goods sold, research and development and selling, general and administrative in the consolidated statements of operations as $0.4 million, $0.7 million and $0.4 million, respectively, for the year ended December 31, 2016. The Company substantially paid out the obligation for the 2016 Restructuring in the fourth quarter of 2016, resulting in a remaining accrual balance for the 2016 Restructuring of $0.2 million at December 31, 2016. The Company expects to substantially pay out the remainder of this obligation by the first quarter of 2017.

In 2015, the Company initiated a restructuring of the organization as a result of its shift to commercial production of Afrezza (2015 Restructuring). In connection with the 2015 Restructuring, the Company reduced its total workforce by approximately 26% to 198 employees. The Company recorded charges of approximately $6.0 million, primarily for employee severance as well as other related termination benefits. The $6.0 million of costs associated with the 2015 Restructuring are included in operating expenses for cost of goods sold, research and development and selling, general and administrative in the consolidated statements of operations as $1.4 million, $1.3 million and $3.3 million, respectively, for the year ended December 31, 2015. As of December 31, 2016 and 2015, the Company had a remaining accrual balance for the 2015 Restructuring of $1.2 million and $3.0 million, respectively. Certain of the severance arrangements for executives in the 2015 Restructuring were long-term, which the Company expects to substantially pay out the remainder of this obligation by the third quarter of 2017.

121

Table of Contents

A reconciliation of beginning and ending liability balances for the 2016 and 2015 Restructuring charges, which is included in accrued expenses and other current liabilities, is as follows (in thousands):

Description	2016 Restructuring	2015 Restructuring	Total
Accrual January 1, 2015	$	$	$
Costs incurred and charged to expense		6,040	6,040
Costs paid or settled		(3,012)	(3,012)
Accrual December 31, 2015		3,028	3,028
Costs incurred and charged to expense	1,475	560	2,035
Costs paid or settled	(1,266)	(2,421)	(3,687)
Accrual December 31, 2016	$ 209	$ 1,167	$ 1,376

19. Selected quarterly financial data (unaudited)

Summarized quarterly financial data for the years ended December 31, 2016 and 2015, are set forth in the following tables:

	March 31	June 30	September 30	December 31
	(In thousands, except per share data)			
2016				
Net revenues	$	$	$ 162,354	$ 12,404
Net income (loss)	$ (24,873)	$ (29,959)	$ 126,520	53,976
Net income (loss) per share basic	$ (0.29)	$ (0.33)	$ 1.32	$ 0.56
Net income (loss) per share diluted	$ (0.29)	$ (0.33)	$ 1.31	$ 0.56
Weighted average common shares used to compute basic net income (loss) per share	85,771	91,061	95,627	95,676
Weighted average common shares used to compute diluted net income (loss) per share	85,771	91,061	96,548	96,510
2015				
Net loss	$ (30,658)	$ (28,910)	$ (31,857)	$ (277,020)
Net loss per share basic and diluted	$ (0.38)	$ (0.36)	$ (0.39)	$ (3.30)
Weighted average common shares used to compute basic and diluted net loss per share	79,783	80,203	81,039	83,862

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

In the third quarter of 2016, the Company recognized net revenue-collaboration of $161.8 million attributable to collaboration with Sanofi (See Note 8 Collaboration Arrangements).

In the fourth quarter of 2016, the Company recognized net revenue-collaboration of $10.2 million attributable to collaboration with Sanofi and $72.0 million gain on extinguishment of debt (See Note 8 Collaboration Arrangements)

20. Subsequent Events

Reverse Stock Split On September 14, 2016, NASDAQ notified the Company that the bid price of the Company s common stock had closed below the required $1.00 per share for 30 consecutive trading days, and,

Table of Contents

accordingly, the Company did not comply with the applicable NASDAQ minimum bid price requirement. The Company was provided 180 calendar days by NASDAQ, or until March 13, 2017, to regain compliance with this requirement.

On March 1, 2017, the Company held a Special Meeting of Stockholders at which the Company s stockholders approved a proposal to amend the Company s Amended and Restated Certificate of Incorporation to effect a reverse stock split of the Company s outstanding common stock at a ratio to be determined in the discretion of the Company s board of directors and with such reverse stock split to be effected at such time and date as determined by the Company s board of directors in its sole discretion, and to reduce the number of authorized shares of the Company s common stock in a corresponding proportion to the reverse stock split, rounded to the nearest whole share.

On March 1, 2017, following stockholder approval of the reverse split proposal, the Company s board of directors approved a reverse stock split ratio of 1-for-5. On March 1, 2017, the Company filed with the Secretary of State of the State of Delaware a Certificate of Amendment of the Company s Amended and Restated Certificate of Incorporation to effect the 1-for-5 reverse stock split of the Company s outstanding common stock and to reduce the authorized number of shares of the Company s common stock from 700,000,000 to 140,000,000 shares. The Company s common stock began trading on The NASDAQ Global Market on a split-adjusted basis when the market opened on March 3, 2017.

As of the date of this filing, the shares of the Company s common stock have maintained a minimum bid closing price of at least $1.00 per share for 10 consecutive business days. Accordingly, the Company expects to receive a notice from the Listing Qualifications Department of the NASDAQ Stock Market indicating that the Company has regained compliance with the minimum closing bid price requirement.

Sale of Valencia Facility On January 6, 2017, the Company and Rexford Industrial Realty, L.P. (Rexford) entered into an Agreement of Purchase and Sale and Joint Escrow Instructions (the Purchase Agreement), pursuant to which the Company agreed to sell and Rexford agreed to purchase certain parcels of real estate owned by the Company in Valencia, California and certain related improvements, personal property, equipment, supplies and fixtures (collectively, the Property) for $17.3 million. The sale and purchase of the aforementioned Property for $17.3 million pursuant to the terms of the Purchase Agreement, as amended, was completed on February 17, 2017. Net proceeds were approximately $16.7 million after deducting broker s commission and other fees of approximately $624,000 paid by the Company. In the fourth quarter of 2016 the property met the requirements for reclassification from property and equipment, net to asset held for sale when it became probable that the property would be sold within one year. At that time, an analysis of the lower of carrying value which was deemed to be the sales price of the property, to fair value less selling costs determined a loss of $564,000, which was recorded as a property and equipment impairment on the consolidated statement of operations for 2016. At December, 31 2016, this property had a carrying value of $16.7 million and was classified as held for sale. The sale of this property will be reflected in the consolidated financial statements for the quarter ended March 31, 2017.