

**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, 2017

or

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

For the transition period from _____ to _____

Commission file number: 000-50865

MannKind Corporation

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)
30930 Russell Ranch Road, Suite 301
Westlake Village, California
(Address of principal executive offices)

13-3607736
(I.R.S. Employer
Identification No.)

91362
(Zip Code)

Registrant's telephone number, including area code
(818) 661-5000

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

Title of Class
Common Stock, par value \$0.01 per share

Name of Each Exchange on Which Registered
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, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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, 2017, 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 \$103,912,399.

As of February 9, 2018, there were 120,467,137 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 2018 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than April 30, 2018 are incorporated by reference in Part III of this Annual Report on Form 10-K.

MANNKIND CORPORATION

Annual Report on Form 10-K
For the Fiscal Year Ended December 31, 2017

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Forward-Looking Statements

Statements in this report that are not strictly historical in nature are “forward-looking statements” within the meaning of the federal securities laws made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward-looking statements by terms such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “goal,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would,” and similar expressions intended to identify forward-looking statements, though not all forward-looking statements contain these identifying words. These statements may include, but are not limited to, statements regarding: our ability to successfully market, commercialize and achieve market acceptance for Afrezza or any other product candidates or therapies that we may develop; our ability to manufacture sufficient quantities of Afrezza and obtain insulin supply as needed; our ability to successfully commercialize our Technosphere drug delivery platform; our estimates for future performance; our estimates regarding anticipated operating losses, future revenues, capital requirements and our needs for additional financing; the 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. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements. 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, Brazil 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.

We are a biopharmaceutical company focused on the development and commercialization of inhaled therapeutic products for patients with diseases such as diabetes and pulmonary arterial hypertension. Our 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 (“FDA”) in June of 2014 to improve glycemic control in adult patients with diabetes. Afrezza became available by prescription in U.S. retail pharmacies in February 2015. According to the Centers for Disease Control and Prevention, 30.3 million people in the United States had diabetes in 2015. Globally, the International Diabetes Federation has estimated that approximately 425.0 million people had diabetes in 2017 and approximately 629.0 million people will have diabetes by 2045.

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 portable inhaler. Administered at the beginning of a meal, Afrezza dissolves rapidly upon inhalation to the lung and delivers insulin quickly to the bloodstream. The first measurable effects of Afrezza occur approximately 12 minutes after administration.

From August 2014 until April 2016 Sanofi-Aventis Deutschland GmbH (which subsequently assigned its rights and obligations under the agreement to Sanofi-Aventis U.S. LLC (“Sanofi”)), was responsible for commercial, regulatory and development activities associated with Afrezza pursuant to a license and collaboration agreement (the “Sanofi License Agreement”). After a transition period during which Sanofi continued to fulfill orders for Afrezza, we assumed responsibility for worldwide development and commercialization of Afrezza and we began distributing MannKind-branded Afrezza to wholesalers in July 2016. During the second half of 2016, 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 specialty sales force to promote Afrezza to endocrinologists and certain high-prescribing primary care physicians. In the future, we may seek to supplement our sales force through a co-promotion arrangement with a third party that has an underutilized primary care sales force, which can be used to promote Afrezza to greater number of primary care physicians.

Our current strategy for 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. Our first such regional partnership was formed in May 2017, when we entered into a supply and distribution agreement with Biommm S.A. to pursue regulatory approval and commercialization of Afrezza in Brazil.

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

- 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.

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 overwrap. These overwraps are then packaged into cartons along with inhalers and printed material by a third-party packager.

The quality management systems of our Connecticut facility have been 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 and potentially other foreign jurisdictions are expected to conduct additional inspections of our facility from time to time.

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 reasonably foreseeable 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, we entered into a supply agreement with Amphastar (the “Insulin Supply Agreement”), which was later amended in November 2016, to purchase certain annual minimum quantities with an initial aggregate purchase commitment of €120.1 million which, after taking into account contract amendments, extends through December 31, 2023 with the ability to renew for an additional two years with certain restrictions. As of December 31, 2017, there was €90.3 million remaining in aggregate purchase commitments under this agreement. See additional information in Note 14 – Commitments and Contingencies to the consolidated financial statements for further information related to the Insulin Supply Agreement.

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 the parts for 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 assemble the inhalers at our Connecticut facility.

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”).

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.

To aid in the development of our oral inhalation products, we have created a number of innovative development tools and techniques such as 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. In addition, In January 2018, we submitted an investigational new drug application (“IND”) for an inhaled formulation of treprostinil to possibly treat pulmonary arterial hypertension.

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 last several years, we have transformed from a manufacturing-based company into an integrated company with capabilities in marketing, sales, managed care and market access. During 2017, we expanded the footprint of our sales force and initiated direct-to-consumer advertising in selected television markets. Our ongoing priority is to enhance the commercial opportunity for Afrezza in the United States; however, we have also begun to pursue and establish 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 530 issued patents in the United States and selected jurisdictions around the world and we also have over 200 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 inventor of the subject matter covered by our pending patent applications or that we were the first to file patent applications on such inventions.

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 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, we believe that Afrezza has a unique pharmacokinetic profile, i.e., with the first measurable effects occurring approximately 12 minutes after administration, reaching peak effects within 35 to 45 minutes after administration of a 4 or 12 unit dose. 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 September 2017, Novo Nordisk announced that Fiasp®, a faster formulation of insulin aspart, was approved by the FDA for improving glycemic control in adult patients with type 1 or type 2 diabetes. Fiasp was previously approved in Europe and Canada.

Inhaled Insulin Delivery Systems

Dance Biopharm, Inc. is developing a liquid formulation of recombinant human insulin for administration with a small handheld electronic inhaler.

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 pioglitazone and biguanides, such as metformin, which lower blood glucose by improving the sensitivity of cells to insulin, or diminishing insulin resistance.
- Alpha-glucosidase inhibitors, which lower the amount of glucose absorbed from the intestines, thereby reducing the rise in blood glucose that occurs after a meal.
- SGLT-2 inhibitors, 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 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 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 a new drug application (“NDA”) based on the clinical trials. The results of product development, preclinical studies and clinical trials are submitted to the FDA in the form of an NDA for approval of the marketing and commercial shipment of the product. Under the Pediatric Research Equity Act, NDAs are required to include an assessment, generally based on clinical study data, of the safety and efficacy of drugs for all relevant pediatric populations. The statute provides for waivers or deferrals in certain situations.

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

Medical products containing a combination of new drugs, biological products, or medical devices are regulated as “combination products” in the United States. A combination product generally is defined as a product comprised of components from two or more regulatory categories (e.g., drug/device, device/biologic, drug/biologic). Each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a new drug, biologic, or device. The testing and approval process requires substantial time, effort and financial resources. Data that we submit are subject to varying interpretations, and the FDA and comparable regulatory authorities in foreign jurisdictions may not agree that our product candidates have been shown to be safe and effective. We cannot be certain that any approval of our 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 Connecticut and the facilities of our insulin supplier, the supplier(s) of FDKP and the supplier(s) of our 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 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 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 well as recent efforts by the Trump administration to repeal or replace certain aspects of the PPACA. President Trump has signed two Executive Orders to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal portions or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. Additionally, on January 22, 2018, President Trump signed a continuing resolutions on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the PPACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole”. 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 BBA, will remain in effect through 2027 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.

Moreover, in the United States, there have been several congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the costs of prescription pharmaceuticals in the United States has also been the subject of considerable discussion, and members of Congress and the Trump administration have stated that they will address such costs through new legislative and administrative measures. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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. State laws also 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. In addition, the European Union, or EU, has established its own data security and privacy legal framework, including but not limited to Directive 95/46/EC, or the Data Protection Directive. The Data Protection Directive will be replaced starting in May 2018 with the recently adopted European General Data Protection Regulation, or GDPR, which contains new provisions specifically directed at the processing of health information, higher sanctions and extra-territoriality measures intended to bring non-EU companies under the regulation. We anticipate that over time we may expand our business operations to include additional operations in the EU, including potentially conducting preclinical and clinical trials. With such expansion, we would be subject to increased governmental regulation in the EU countries in which we might operate, including the GDPR

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 \$14.1 million, \$14.9 million and \$29.7 million for the years ended December 31, 2017, 2016 and 2015, respectively.

Long-Lived Assets

Our long-lived assets are located in the United States and totaled \$26.9 million, \$28.9 million and \$48.7 million as of December 31, 2017, 2016 and 2015, 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, 2017, we had 250 full-time employees, of which 65 were engaged in manufacturing, 32 in research and development, 40 in general and administrative and 113 in selling and marketing. Seventeen 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 30930 Russell Ranch Road, Suite 301, Westlake Village, California 91362, and our telephone number at that address is (818) 661-5000. MannKind Corporation and the MannKind Corporation logo are our service marks and trademarks. 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 retrospective basis.

On December 13, 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 to increase the authorized number of shares of our common stock from 140,000,000 to 280,000,000 shares, as authorized and approved at a special meeting of stockholders on December 13, 2017.

Scientific Advisors

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

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

Executive Officers of the Registrant

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

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>
Michael E. Castagna, Pharm.D.	41	Chief Executive Officer
Steven B. Binder	55	Chief Financial Officer
Joseph Kocinsky	54	Chief Technology Officer
Patrick McCauley	52	Chief Commercial Officer
David B. Thomson, Ph.D., J.D.	51	General Counsel and Secretary
David M. Kendall, M.D.	56	Chief Medical Officer
Stuart A. Tross, Ph.D.	51	Chief People and Workplace Officer
Rosabel R. Alinaya	57	Senior Vice President, Investor Relations and Treasury
Courtney Barton	35	Vice President, Chief Compliance and Privacy Officer

Michael E. Castagna, Pharm.D. has been our Chief Executive Officer since May 2017 and was our Chief Commercial Officer from March 2016 until May 2017. 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 Company ("BMS"), an innovative global biopharmaceutical company. Before BMS, Dr. Castagna served as Vice President & Head, Biopharmaceuticals, North America, at Sandoz, a division of Novartis. He has also held positions with commercial responsibilities at EMD (Merck) Serono, Pharmasset and DuPont Pharmaceuticals. He received his pharmacy degree from the 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.

Steven B. Binder has been our Chief Financial Officer since July 2017. Before joining us, since 2013 Mr. Binder served as Vice President and Chief Financial Officer of the International Group of Striker Corporation, a leading global medical technology company, based in Singapore. Prior to Stryker, Mr. Binder served in a series of senior leadership roles at BMS. His last four positions at BMS were Vice President, Finance roles over different geographic operating units: United States (2012-2013), Europe (2008-2011), AsiaPacific (2005-2007), and Japan (2003-2005). Prior to his international experience, Mr. Binder served in three senior leadership roles for Oncology Therapeutics Network, a U.S. based independent subsidiary of BMS: Vice President, Strategic Development (2001-2003), Vice President, Customer Operations (2000-2001), and Chief Financial Officer (1997-2000). Before Oncology Therapeutics Network, Mr. Binder progressed through three finance and accounting roles for BMS Worldwide Medicines Group after joining the company in 1992. Before BMS, he worked for Deloitte & Touche LLP in a series of auditing roles with increasing responsibility over an eight year period beginning in 1984. Mr. Binder received a B.S. degree in Accounting and Business Administration from Muhlenberg College and is a Certified Public Accountant.

Joseph Kocinsky has been our Chief Technology Officer since October 2015 and has served in various roles of increasing responsibility since joining us in 2003. He was previously 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.

Patrick McCauley has been our Chief Commercial Officer since July 2017. Prior to joining us, he spent twelve years at Astellas Pharma in a series of senior sales and compliance leadership roles of increasing responsibility. Prior to Astellas, Mr. McCauley was a member of the U.S. commercialization team and held a sales leadership role with Yamanouchi Pharma before the merger of Yamanouchi and Fujisawa Pharma to create Astellas in 2005. Before that, Mr. McCauley spent thirteen years with DuPont Pharmaceuticals and one year with BMS which acquired DuPont Pharmaceuticals in 2001. At DuPont and BMS, Mr. McCauley held a series of leadership roles across the sales, contracting and pricing, and clinical areas. Throughout his various career moves, Mr. McCauley has developed deep commercial expertise serving both specialty and primary care healthcare providers. He received an MBA from the Kellogg School of Management at Northwestern University, a JD from the South Texas College of Law, and a BA in Economics from the University of Notre Dame.

David M. Kendall, M.D. has been our Chief Medical Officer since February 2018. His career includes over 30 years of experience in diabetes and metabolism research, clinical management, research, and policy advocacy. Most recently, he served as Research Physician and Vice President of Global Medical Affairs for Lilly Diabetes from 2011 to 2018, and during that time was responsible for all medical affairs activities and guided research and development strategy across multiple geographies. In this role, he worked to re-establish Lilly Diabetes as a world class medical organization and added to his extensive experience with both injected and mealtime insulins, as well as devices and continuous glucose monitors. Prior to joining Eli Lilly, Dr. Kendall served as Chief Scientific and Medical Officer at the American Diabetes Association, where he was responsible for all medical affairs, medical education, research, outcomes, and medical policy activities. Earlier in his career, Dr. Kendall served as Medical Director at the International Diabetes Center (1997-2009), Executive Director of Medical Affairs at Amylin Pharmaceuticals from 2005 to 2008, and as a consultant in endocrinology at the Park Nicollet Clinic (1994-1997). He received his M.D. and completed his Post Graduate Medical Training at the University of Minnesota, and earned a B.A. in Biology from St. Olaf College.

David B. Thomson, Ph.D., J.D. has been our 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 Chief People and Workplace Officer since December 2016, with responsibilities for human resources, information technology, corporate communications 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 BMS, most recently as Vice President and 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.

Rosabel R. Alinaya has been our Senior Vice President, Investor Relations and Treasury since July 2017. From January 2016 to July 2017, she served as our principal accounting officer, with responsibility for finance, accounting, tax, treasury, investor relations and risk management. From May 2017 until July 2017, she also served as Acting Chief Financial Officer. 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.

Courtney Barton has been our Vice President, Chief Compliance Officer since March 2017. From December 2015 until she joined us, she served as Chief Compliance Officer for Anacor Pharmaceuticals, Inc. Prior to that, Ms. Barton served in compliance and privacy roles for Kythera Biopharmaceuticals, Inc. from November 2014 to November 2015, Allergan, Inc. from September 2013 to October 2014, Bausch & Lomb, Inc. from September 2006 to September 2013 and Winn-Dixie Stores, Inc. from August 2003 to August 2006. She has also held positions with Merrill Lynch and Janus, including an international appointment. Ms. Barton holds Bachelor's degrees in Political Science and International Relations from Syracuse University and is a Certified Compliance and Ethics Professional (CCEP) and Certified Information Privacy Professional (CIPP US/E).

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 there is 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 financial covenant in our Facility Agreement with Deerfield Private Design Fund II, L.P. 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, "The Mann Group Loan Arrangement"), as of the last day of each fiscal quarter. On June 29, 2017, we entered into an Exchange and Third Amendment to the Facility Agreement (the "Third Amendment") with Deerfield, which, among other things, amended such financial covenant to provide that, if certain conditions remain satisfied, then the obligation to maintain at least \$25.0 million in cash and cash equivalents as of the end of each quarter will be reduced to \$10.0 million as of the last day of each month through October 31, 2017 and as of December 31, 2017. We met the required conditions as of the last day of each of those periods. It may be difficult for us to raise additional funds on favorable terms, or at all. As of December 31, 2017, we had cash and cash equivalents of \$43.9 million and a stockholders' deficit of \$214.7 million. Our cash position, together with our short-term debt obligations and anticipated operating losses due to increased effort on commercialization and research and development projects, raises substantial doubt about our 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 expanding 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 our debt instruments 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 our notes with conversion options 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 a Milestone Rights Purchase Agreement (the "Milestone Agreement") with Deerfield and Horizon Santé FLML SÀRL (collectively, the "Milestone Purchasers"), which requires us to make contingent payments to the Milestone Purchasers, totaling up to \$90.0 million, upon us achieving specified commercialization milestones (the "Milestone Rights");
- 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 in the future on acceptable terms, or at all. Issuances of additional debt or equity securities or the issuance of common stock upon conversion of outstanding convertible debt securities or upon the exercise of our currently outstanding warrants for shares of our common stock could impact the rights of the holders of our common stock and will dilute their ownership percentage. Moreover, the establishment of other funding facilities may impose restrictions on our operations. These restrictions could include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. We also will need to raise additional capital by pursuing opportunities for the licensing or sale of certain intellectual property and other assets. We cannot offer assurances, however, that any strategic collaborations, sales of securities or sales or licenses of assets will be available to us on a timely basis or on acceptable terms, if at all. We may be required to enter into relationships with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop independently, and any such relationships may not be on terms as commercially favorable to us as might otherwise be the case.

In the event that sufficient additional funds are not obtained through strategic collaboration opportunities, sales of securities, funding facilities, licensing arrangements and/or asset sales on a timely basis, we may be required to reduce expenses through the delay, reduction or curtailment of our projects, or further reduction of costs for facilities and administration. Moreover, if we do not obtain such additional funds, there will continue to be substantial doubt about our ability to continue as a going concern and increased risk of insolvency and up to total loss of investment to our stockholders and other security holders. 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. There can be no assurances that we will be able to raise additional capital in sufficient amounts or on favorable terms, or at all. If we are unable to raise adequate additional capital when required or in sufficient amounts or on terms acceptable to us, we may have to delay, scale back or discontinue one or more product development programs, curtail our commercialization activities, significantly reduce expenses, sell assets (potentially at a loss), enter into relationships with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop or commercialize independently, cease operations altogether, pursue an acquisition of our company at a price that may result in up to a total loss on investment for our stockholders, file for bankruptcy or seek other protection from creditors, or liquidate all of our assets. In addition, if we default under the Facility Agreement, Deerfield could foreclose on substantially all of our assets.

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 specialty sales force, which included some of the sales representatives that previously were employed by the contract sales 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 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 there is 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 other than Brazil. 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 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 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.

The Company is not currently profitable and has rarely generated positive net cash flow from operations. As of December 31, 2017, we had an accumulated deficit of \$2.9 billion. The accumulated deficit has resulted principally from costs incurred in our research and development programs, the write-off of goodwill, inventory and property, plant and equipment and general operating expenses. We expect to make substantial expenditures and to incur increasing operating losses in the future in order to continue the commercialization of Afrezza. In addition, under the amended Insulin Supply Agreement with Amphastar, we agreed to purchase certain annual minimum quantities of insulin for calendar years 2018 through 2023 for an aggregate total remaining purchase price of €90.3 million at December 31, 2017. 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. 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, and we may be unable to make required payments of interest and principal as they become due.

As of December 31, 2017, we had \$157.8 million principal amount of outstanding debt, consisting of:

- \$23.7 million principal amount of senior convertible notes bearing interest at 5.75% per annum (the "2021 notes"), with interest payable in cash semiannually in arrears on February 15 and August 15 of each year, and maturing on October 23, 2021;
- \$39.4 million principal amount of notes issued pursuant to the Facility Agreement, bearing interest at 9.75% per annum (the "2019 notes"), which is payable in cash quarterly in arrears on the last business day of March, June, September and December of each year, and of which total principal amount \$4.4 million was scheduled to become due and payable on January 19, 2018, \$15.0 million will become due and payable in each of July 2018 and July 2019, and \$5.0 million will become due and payable in December 2019;
- \$15.0 million principal amount of notes issued pursuant to the Facility Agreement, bearing interest at 8.75% per annum (the "Tranche B notes" and together with the 2019 notes, the "Facility Financing Obligation"), which is payable in cash quarterly in arrears on the last business day of March, June, September, and December of each year, and of which total principal amount \$5.0 million will become due and payable in each of May 2018, May 2019, and December 2019; and
- \$79.7 million principal amount of indebtedness under The Mann Group Loan Arrangement maturing on January 5, 2010, bearing interest at a fixed rate of 5.84% per annum payable quarterly in arrears on the first day of each calendar quarter for the preceding quarter, except that the lender has agreed to defer interest payments until July 1, 2018 unless otherwise permitted under the subordination agreement with Deerfield, and such interest payments are subject to additional deferral beyond July 1, 2018 until our payment obligations to Deerfield have been satisfied in full.

On January 18, 2018, we entered into an Exchange and Sixth Amendment to Facility Agreement (the "Sixth Deerfield Amendment") with Deerfield, pursuant to which, among other things, we issued to Deerfield an aggregate of 1,267,972 shares of our common stock in exchange for the cancellation of \$3,157,251 of 2019 notes. In addition, the payment date for the remaining \$1,250,000 in remaining principal amount of the 2019 notes that was previously due to be repaid on January 19, 2018 was extended to May 6, 2018.

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 2021 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. 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 2021 notes, 2019 notes, or Tranche B notes, or if we fail to repay or repurchase the 2021 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 Facility Financing Obligation; 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 falling below \$25.0 million as of the last day of any fiscal quarter, or pursuant to the Third Amendment, \$10.0 million as of the last day of each month through October 31, 2017 and as of December 31, 2017 if certain conditions are met. We met the required conditions as of the last day of those periods. 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. If one or more events of default under the Facility Agreement occurs and continues beyond any applicable cure period, the holders of the Facility Financing Obligation may declare all or any portion of the Facility Financing Obligation 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 Facility Financing Obligation would demand repayment of the outstanding balance of the Facility Financing Obligation 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 2021 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 2021 notes and Facility Financing Obligation may accelerate all of our repayment obligations, and, with respect to the Facility Financing Obligation, 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 September 2017, Novo Nordisk announced that Fiasp®, a faster formulation of insulin aspart injection, was approved by the FDA. Our future success will depend not only on our ability to develop our product candidates but to improve them and keep pace with emerging industry developments. We cannot assure you that we will be able to do so.

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

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

Forecasts about the effects of the use of drugs, including Afrezza, over terms longer than the clinical studies or in much larger populations may not be consistent with the earlier clinical results. For example, with the approval of Afrezza, the FDA has required a five-year, randomized, controlled trial in 8,000 — 10,000 patients with type 2 diabetes, the primary objective of which is to compare the incidence of pulmonary malignancy observed with Afrezza to that observed in a standard of care control group. If long-term use of a drug results in adverse health effects or reduced efficacy or both, the FDA or other regulatory agencies may terminate our or 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 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;
- 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 have been several congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the costs of prescription pharmaceuticals in the United States has also been the subject of considerable discussion, and members of Congress and the Trump administration have stated that they will address such costs through new legislative and administrative measures. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that there will continue to be a number of federal and state proposals to implement similar and/or additional 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 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, which has been suspended for calendar years 2016 through 2019;
- 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% (and 70% commencing January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

- new requirements to report annually to the Centers for Medicare & Medicaid Services (“CMS”) certain financial arrangements with physicians and teaching hospitals, as defined in PPACA and its implementing regulations, including reporting any “payments or transfers of value” made or distributed to prescribers, teaching hospitals and other healthcare providers and reporting any ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations during the preceding calendar year;
- 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.

Some of the provisions of the PPACA have yet to be fully implemented, while certain provisions have been subject to judicial and congressional challenges, as well as efforts by the Trump administration to repeal or replace certain aspects of the PPACA. President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the PPACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, and also increases in 2019 the percentage that a drug manufacturer must discount the cost of prescription drugs from 50 percent under current law to 70 percent. We continue to evaluate the potential effect of the possible repeal and replacement of the PPACA may have on our business.

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 BBA, will stay in effect through 2027 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.

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. In addition, the European Union, or EU, has established its own data security and privacy legal framework, including but not limited to Directive 95/46/EC, or the Data Protection Directive. The Data Protection Directive will be replaced starting in May 2018 with the recently adopted European General Data Protection Regulation, or GDPR, which contains new provisions specifically directed at the processing of health information, higher sanctions and extra-territoriality measures intended to bring non-EU companies under the regulation. We anticipate that over time we may expand our business operations to include additional operations in the EU, including potentially conducting preclinical and clinical trials. With such expansion, we would be subject to increased governmental regulation in the EU countries in which we might operate, including the GDPR.
- 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.
- State and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government that otherwise restricts certain payments that may be made to healthcare providers and entities; and state laws that require drug manufacturers to report information related to payments and other transfer of value to physicians and other healthcare providers and entities.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exceptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. To the extent that Afrezza or any of our product candidates that receives marketing approval is ultimately sold in a foreign country, we may be subject to similar foreign laws and regulations. If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, individual imprisonment, disgorgement, exclusion of products from reimbursement under U.S. federal or state healthcare programs, 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 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 \$18,107 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.

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 our 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.

Changes or modifications in financial accounting standards, including those related to revenue recognition, may harm our results of operations.

From time to time, the Financial Accounting Standards Board ("FASB"), either alone or jointly with other organizations, promulgates new accounting principles that could have an adverse impact on our financial position, results of operations or reported cash flows. In May 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The standard requires a company to recognize revenue to depict the transfer of goods or services when transferred to customers in the amount that reflects the consideration it expects to be entitled to receive in exchange for those goods or services. 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 March 2016, the FASB issued additional ASUs which clarified certain aspects of the new guidance. We adopted the new standard for the year beginning January 1, 2018. We had the option to either apply the new standard retrospectively for all prior reporting periods presented (full retrospective) or retrospectively with the cumulative effect of initially applying the new standard recognized at the date of initial application (modified retrospective). We have elected to apply the new standard using the modified retrospective approach with the cumulative effect of initial application recognized as of January 1, 2018. Based on the expected impact of adopting the new standard, we expect such cumulative effect adjustment to be \$1.7 million decrease to the opening balance of accumulated deficit. Any difficulties in implementing this standard, or in adopting or implementing any other new accounting standard, and to update or modify our internal controls as needed on a timely basis, could result in our failure to meet our financial reporting obligations, which could result in regulatory discipline and harm investors' confidence in us. Finally, if we were to change our critical accounting estimates, including those related to the recognition of collaboration revenue and other revenue sources, our operating results could be significantly affected.

Our ability to use net operating losses to offset future taxable income may be subject to limitations.

As of December 31, 2017, we had federal and state net operating loss carryforwards of \$2.0 billion and \$2.2 billion. The federal and state net operating loss carryforwards have begun to expire in the current year. These net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the newly enacted federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain if and to what extent various states will conform to the newly enacted federal tax law. In addition, under Section 382 of the Code and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. As a result of our initial public offering, an ownership change within the meaning of 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 our 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 Section 382 of the Code. We may however experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

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

From time to time we may undertake internal restructuring activities as we continue to evaluate and attempt to optimize our cost and operating structure in light of developments in our business strategy and long-term operating plans. These activities may result in write-offs or

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

We and certain of our executive officers and directors have been named as defendants in ongoing securities 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, 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. The complaints alleged 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, thereby artificially inflating the price of MannKind's common stock. The plaintiffs are seeking monetary damages. In November 2016, the court in Israel dismissed one of the actions without prejudice. In the remaining action, the district court ruled in October 2017 that U.S. law will apply to this case. The plaintiff has appealed this ruling. 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.

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, which is not completed. The responsible party 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.

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 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.

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.

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.

For example, 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.

In addition, in certain countries, including the United States, applications are generally published 18 months after the application's priority date. In any event, because publication of discoveries in scientific or patent literature often trails behind actual discoveries, we cannot be certain that we were the first inventor of the subject matter covered by our pending patent applications or that we were the first to file patent applications on such inventions. 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, the United States moved to a first inventor to file system. 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.

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.

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.

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. We do not believe that Afrezza infringes on any patents. However, 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 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 that our existing stockholders might sell shares of common stock could also depress the market price of our common stock and the market price of our other securities. Any such sales of our common stock in the public market may affect the price of our common stock or the market price of our other securities.

In the future, we may sell additional shares of our common stock to raise capital. In addition, a substantial number of shares of our common stock is reserved for: issuance upon the exercise of stock options and 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 2021 notes or any other convertible debt we may issue. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price for our common stock. The issuance or sale of substantial amounts of common stock, or the perception that such issuances or sales may occur, could adversely affect the market price of our common stock and other securities.

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

Between January 1, 2014 and December 31, 2017, our closing stock price as reported on The NASDAQ Global Market has ranged from \$0.71 to \$54.80, adjusted for the reverse stock split that occurred during this period. The trading price of our common stock is likely to continue to be volatile. The stock market, particularly in recent years, has experienced significant volatility particularly with respect to pharmaceutical and biotechnology stocks, and this trend may continue.

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

- our ability to 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 successfully 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, especially for emerging growth and pharmaceutical market sectors;
- 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;
- 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 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. In the past, we have received a notice of non-compliance from the Listing Qualifications Department of the NASDAQ Stock Market with respect to the \$1.00 minimum closing bid price requirement. Although we regained compliance with the minimum closing bid price requirement after effecting a reserve stock split there can be no assurance that we will be able to meet the minimum closing bid price requirement or other listing requirements in the future.

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 or the exchange or conversion of our 2021 notes into common stock could negatively affect the market price of our common stock and other securities.

As of February 9, 2018, we had 120,467,137 shares of common stock outstanding. Substantially all of these shares are available for public sale, subject in some cases to volume and other limitations. 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 2021 notes, or Facility Financing Obligation, could adversely affect the market price of our common stock and other securities. In addition, the existence of these notes may encourage short selling of our common stock by market participants, which could adversely affect the market price of our common stock and other securities.

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

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

We are incorporated in Delaware. Certain anti-takeover provisions under Delaware law and in our certificate of incorporation and amended and restated bylaws, as currently in effect, may make a change of control of our company more difficult, even if a change in control would be beneficial to our stockholders or the holders of our other securities. Our anti-takeover provisions include provisions such as a prohibition on stockholder actions by written consent, the authority of our board of directors to issue preferred stock without stockholder approval, and supermajority voting requirements for specified actions. In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits stockholders owning 15% or more of our outstanding voting stock from merging or combining with us in certain circumstances. These provisions may delay or prevent an acquisition of us, even if the acquisition may be considered beneficial by

some of our stockholders. In addition, they may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

Because we do not expect to pay dividends in the foreseeable future, you must rely on stock appreciation for any return on any investment in our common stock.

We have paid no cash dividends on any of our capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future, and payment of cash dividends, if any, will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Pursuant to the Facility Agreement, we are subject to contractual restrictions on the payment of dividends. There is no guarantee that our common stock will appreciate or maintain its current price. You could lose the entire value of any investment in our common stock.

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, manufacturing and certain administrative functions for Afrezza. We believe the Connecticut facility will have sufficient space to satisfy commercial demand for Afrezza. Our obligations under the Facility Agreement and the Milestone Agreement are secured by our facility in Danbury, Connecticut and other assets. We lease approximately 13,210 square feet of office space in Westlake Village, California pursuant to a lease that expires in December 2022. In October 2018, our lease will expand to incorporate an additional 11,265 square feet of office space at this location. 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, 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, 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, the district court ruled in October 2017 that U.S. law will apply to this case. The plaintiff has appealed this ruling. 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.

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).

	<u>High</u>	<u>Low</u>
Year ended December 31, 2017		
First quarter	\$ 3.61	\$ 1.44
Second quarter	\$ 1.88	\$ 0.67
Third quarter	\$ 2.35	\$ 1.09
Fourth quarter	\$ 6.96	\$ 2.01
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

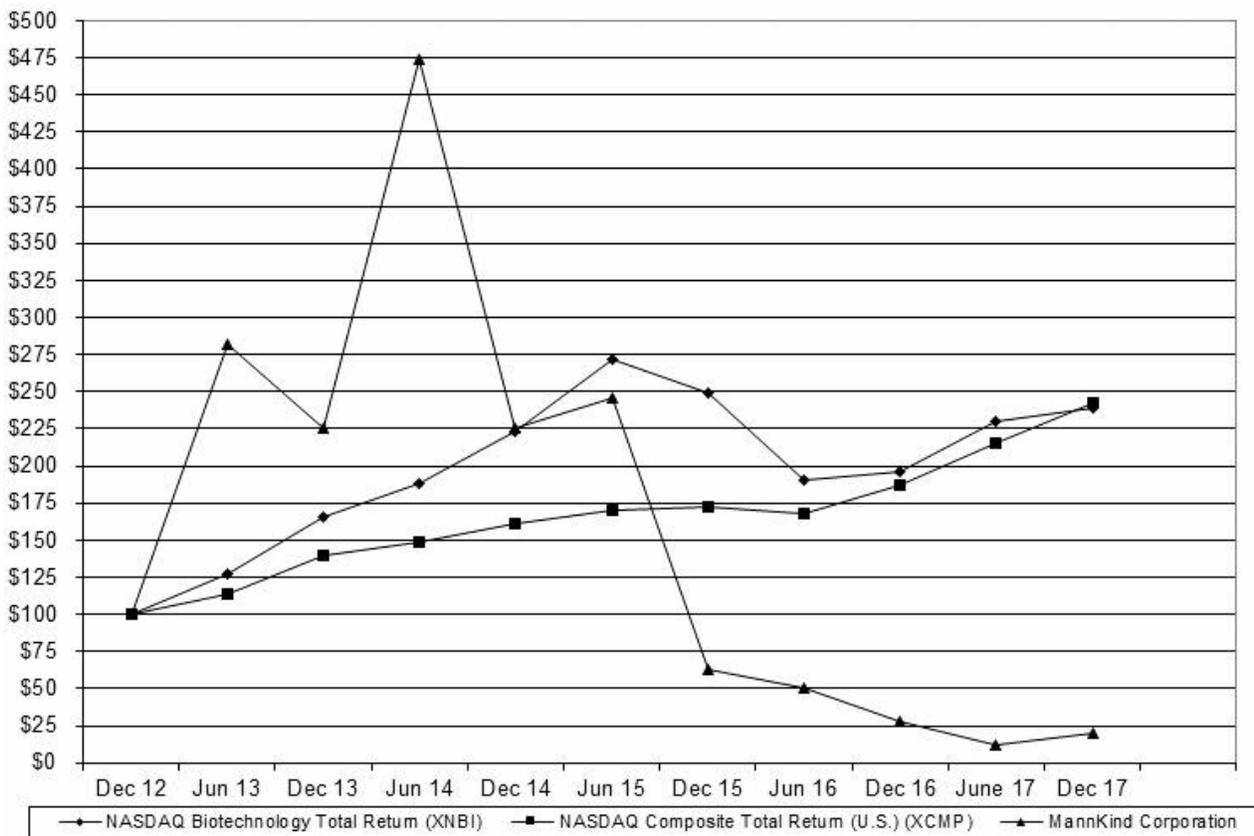
The closing sales price of our common stock on The NASDAQ Global Market was \$2.61 on February 9, 2018 and there were 109 registered holders of record as of that date.

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, 2012, in (i) our common stock, (ii) the securities comprising The NASDAQ Composite Index and (iii) the securities comprising The NASDAQ Biotechnology Index.

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



Dividend Policy

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

Recent Sales of Unregistered Securities

On November 6, 2017, we issued Deerfield 1,720,846 shares of our common stock in exchange for cancellation of \$5,592,750 principal amount of 2019 notes, at a conversion price of \$3.25 per share. The foregoing shares were issued in accordance with the Fourth Amendment to Facility Agreement with Deerfield, dated October 23, 2017. In addition, on January 18, 2018, we entered into an Exchange and Sixth Amendment to Facility Agreement with Deerfield, pursuant to which we issued to Deerfield an aggregate of 1,267,972 shares of our common stock in exchange for cancellation of \$3,157,251 principal amount of 2019 notes, at a conversion price of \$2.49 per share. The foregoing shares were issued in reliance on the exemption from registration provided by Sections 3(a)(9) and 4(a)(2) of the Securities Act of 1933, as amended.

Item 6. Selected Financial Data

The following data has been derived from our audited financial statements, including the consolidated balance sheets at December 31, 2017 and 2016 and the related consolidated statements of operations for each of the three years ended December 31, 2017, 2016 and 2015 and related notes appearing elsewhere in this report. The consolidated statement of operations data for the years ended December 31, 2014 and 2013 and the consolidated balance sheet data as of December 31, 2015, 2014 and 2013 are derived from our audited consolidated financial statements that are not included in this report. Items that significantly impact the comparability among the periods presented include the following:

- Long-lived asset, inventory impairments, and recognition of loss on purchase commitments in 2015,
- Recognition of revenue, related costs and gain on extinguishment of debt related to the collaboration with Sanofi in 2016, and
- Recognition of revenue related to commercial sales of Afrezza in 2016 and 2017.

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, which provide additional information about the items noted above that significantly affect the comparability among the periods presented.

	Year Ended December 31,				
	2017	2016	2015	2014	2013
	(In thousands, except per share amounts)				
Statement of Operations Data:					
Revenue:					
Total net revenue	\$ 11,745	\$ 174,758	\$ -	\$ -	\$ -
(Loss) income from operations	\$ (108,189)	67,260	(344,655)	(179,627)	(169,401)
Net (loss) income	\$ (117,333)	125,664	(368,445)	(198,382)	(191,490)
Net (loss) income per share - basic	\$ (1.13)	1.37	(4.54)	(2.57)	(3.20)
Net (loss) income per share - diluted	\$ (1.13)	1.36	(4.54)	(2.57)	(3.20)
Shares used to compute basic net (loss) income per share	104,245	92,053	81,233	77,045	59,918
Shares used to compute diluted net (loss) income per share	104,245	92,085	81,233	77,045	59,918

	December 31,				
	2017	2016	2015	2014	2013
	(In thousands)				
Balance Sheet Data:					
Cash and cash equivalents	\$ 43,946	\$ 22,895	\$ 59,074	\$ 120,841	\$ 70,790
Total assets	84,575	107,063	126,412	394,439	258,646
Facility financing obligation	52,745	71,339	74,582	72,995	102,300
Note payable to principal stockholder	79,666	49,521	49,521	49,521	49,521
Accrued interest — note payable to principal stockholder	2,347	9,281	6,380	3,486	592
Senior convertible notes	24,411	27,635	27,613	99,355	98,439
Sanofi loan facility and loss share obligation	—	—	62,371	3,034	—
Accumulated deficit	(2,854,898)	(2,737,565)	(2,863,229)	(2,494,784)	(2,296,402)
Total stockholders' deficit	(214,732)	(183,593)	(350,329)	(73,770)	(30,713)

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 development and commercialization of inhaled therapeutic products for patients with diseases such as diabetes and pulmonary arterial hypertension. Our only approved product, Afrezza, is a rapid-acting inhaled insulin that was approved by the FDA in June of 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, 2017, we had an accumulated deficit of \$2.9 billion and a stockholders' deficit of \$214.7 million. We had net income (losses) of approximately \$(117.3) million, \$125.7 million and \$(368.4) million in the years ended December 31, 2017, 2016 and 2015, 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 a senior secured revolving promissory note and a guaranty and security agreement that we entered into with an affiliate of Sanofi in September 2014 in connection with the Sanofi License Agreement (the "Sanofi Loan Facility"), which provided us with a secured loan facility of up to \$175.0 million to fund our share of net losses under the Sanofi License Agreement, which was terminated in 2016. As discussed below in "Liquidity and Capital Resources", if we are unable to obtain additional funding, there is 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.

We consider our critical accounting policies to be those related to revenue recognition and gross-to-net adjustments, inventory costing and recoverability, recognized loss on purchase commitments, impairment of long-lived assets, milestone rights liability, clinical trial expenses, stock-based compensation and accounting for income taxes. These critical accounting policies are also considered significant accounting policies and 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 Recognition and Gross-to-net Adjustments— 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. The current accounting guidance requires the Company to reliably estimate returns in a very narrow range in order to recognize revenue upon shipment. While we can currently estimate returns within a range, it is not sufficiently precise to meet the current requirements. Accordingly, we defer recognition of revenue and the related estimated discounts and allowances 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. Through September 30, 2017, we recognized revenue based on Afrezza prescriptions dispensed, as estimated by syndicated data provided by a third party. We also analyzed 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.

In the fourth quarter of 2017, we obtained new and more comprehensive data regarding the ending inventory in the distribution channel. This data indicated that the quantity of downstream inventory was less than the previously estimated. Because the new data was more comprehensive than the data previously available to us, we adjusted the ending gross deferred revenue balance to match the new estimate. In addition to adjusting the gross deferred revenue balance, we adjusted the ending balances of deferred discounts and deferred cost of goods sold. The net effect of this change was an increase to net income of \$1.2 million or \$0.01 per basic and diluted net income (loss) per share.

Inventory Costing and Recoverability — Inventories are stated at the lower of cost or net 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, 2017, 2016 and 2015. As a result of these assessments, we recorded charges of \$3.0 million and \$36.1 million in the years ended December 31, 2017 and 2015, respectively. There were no write-offs for the year ended December 31, 2016. In the year ended December 31, 2015 we also recorded a charge of \$3.2 million related to the write-off of prepaid deposits related to the purchase of inventory.

Recognized Loss on Purchase Commitments — We assess whether losses on long term purchase commitments should be accrued. Losses that are expected to arise from firm, non-cancellable, commitments for future purchases of inventory items are recognized unless recoverable.

Impairment of Long-Lived Assets — We evaluate long lived assets for impairment at least on a quarterly basis and whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. An impairment loss would be indicated when estimated undiscounted future cash flows from the use and eventual disposition of an asset group, which are identifiable and largely independent of the cash flows of other asset groups, are less than the carrying amount of the asset group.

In connection with our quarterly assessment of impairment indicators, we recorded impairments of \$0.2 million, \$1.2 million, and \$140.4 million for the years ended December 31, 2017, 2016, and 2015, respectively. For further information see Note 4 — Property and Equipment of the Notes to Consolidated Financial Statements included in “Part II, Item 8 — Financial Statements and Supplementary Data”.

Milestone Rights Liability — In connection with the execution of the Facility Agreement, we also issued Milestone Rights to the Milestone Purchasers. We evaluated the Milestone Rights and determined that such rights do not meet the definition of a freestanding derivative. Since we have elected not to apply the fair value option, we recorded the rights at the initial fair value. Upon the achievement of a Milestone Event, the Milestone Payment will be allocated between (i) a reduction of the initial liability and (ii) a return on investment and the gain or loss is recognized at the time the Milestone Event is achieved. 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).

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. 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 based upon the fair value of the awards at the grant date subject to an estimated forfeiture rate. 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.

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, 2017 and December 31, 2016, respectively, we had established a valuation allowance of \$654.3 million and \$914.5 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.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (the “Act”) was signed into law making significant changes to the Internal Revenue Code of 1986, as amended. The changes include, but are not limited to, a corporate tax rate decrease from 35% to 21% effective for tax years beginning after December 31, 2017, a one-time transition tax on the mandatory deemed repatriation of cumulative foreign earnings as of December 31, 2017, and expanded limits on employee remuneration. We have calculated our best estimate of the impact of the Act in our year end income tax provision in accordance with our understanding of the Act and guidance available as of the date of this filing, and as a result, we did not record additional income tax expense in the fourth quarter of 2017, the period in which the legislation was enacted. The provisional amount related to the remeasurement of certain deferred tax assets and liabilities is based on the rates at which they are expected to reverse in the future.

The impact of this Act was a decrease of deferred tax assets approximately \$301 million, offset by a decrease in valuation allowance \$301 million, resulting in no additional income tax expense or benefit. No provisional amount was recorded related to the one-time transition tax on the mandatory deemed repatriation of foreign earnings.

Staff Accounting Bulletin No. 118 ("SAB 118") was issued to address the application of accounting principles generally accepted in the United States in situations when a company does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Act. In accordance with SAB 118, we have determined that the provisional amounts recorded are a reasonable estimate at December 31, 2017. Any subsequent adjustment to these amounts will be recorded when the analysis is complete in 2018.

Results of Operations

Years ended December 31, 2017 and 2016

Revenues

The following table provides a comparison of the revenue categories for the years ended December 31, 2017 and 2016 (dollars in thousands):

	Year Ended December 31,			
	2017	2016	\$ Change	% Change
Revenues:				
Net revenue - commercial product sales:				
Gross revenue from product sales	\$ 12,572	\$ 2,714	\$ 9,858	363%
Gross-to-Net Adjustments:				
Wholesaler distribution fees and prompt pay discounts	(1,653)	(489)	(1,164)	(238%)
Patient discount and co-pay assistance programs	(667)	(196)	(471)	(240%)
Rebates and chargebacks	(1,060)	(134)	(926)	(691%)
Net revenue - commercial product sales	9,192	1,895	7,297	385%
Net revenue - collaboration	250	171,965	(171,715)	(100%)
Revenue - other	2,303	898	1,405	156%
Total revenues	\$ 11,745	\$ 174,758	\$ (163,013)	(93%)

Gross revenue from product sales results from sales of Afrezza. The increase in gross revenue from product sales of \$9.9 million for the year ended December 31, 2017 compared to the prior year is primarily due to an increase in cartridges sold. Total estimated gross-to-net adjustments of \$3.4 million were approximately 27% of gross revenue from product sales for the year ended December 31, 2017, a decrease of approximately 3% of gross revenue from the prior year. This decrease is due primarily to distribution fees paid to Integrated Commercialization Solutions Direct ("ICS") in 2016 as part of an interim agreement that enabled us to distribute product in all necessary jurisdictions while we obtained the necessary licenses. This agreement was terminated on December 15, 2016 and therefore these fees did not recur in 2017.

Net revenue from collaboration for the year ended December 31, 2017 decreased by \$171.7 million from the prior year, primarily because the Sanofi License Agreement was terminated in 2016, which resulted in us recognizing previously deferred revenue from Sanofi, including upfront and milestone payments. The \$0.3 million of collaboration revenue recognized in 2017 is as a result of the collaboration with Receptor, which is more fully described in Note 8 – Collaboration Arrangements of the Notes to the Consolidated Financial Statements included in Part II – Item 8 – Financial Statements and Supplementary Data.

Revenue – other for the year ended December 31, 2017 represents \$1.7 million from sales of bulk insulin to a third party and \$0.6 million from a sale of intellectual property. Revenue – other for the year ended December 31, 2016 represents \$0.9 million from sales of bulk insulin to a third party.

Expenses

The following table provides a comparison of the expense categories for the years ended December 31, 2017 and 2016 (dollars in thousands):

	Year Ended December 31,			
	2017	2016	\$ Change	% Change
Expenses:				
Cost of goods sold	\$ 17,228	\$ 17,121	\$ 107	1%
Cost of revenue - collaboration	—	32,971	(32,971)	(100%)
Research and development	14,118	14,917	(799)	(5%)
Selling	42,571	19,854	22,717	114%
General and administrative	32,388	27,074	5,314	20%
Property and equipment impairment	203	1,259	(1,056)	(84%)
Loss (gain) on foreign currency translation	13,641	(3,433)	17,074	(497%)
(Gain) loss on purchase commitment	(215)	(2,265)	2,050	(91%)
Total expenses	<u>\$ 119,934</u>	<u>\$ 107,498</u>	<u>\$ 12,436</u>	<u>12%</u>

Cost of goods sold includes the costs related to Afrezza product dispensed by pharmacies to patients as well as the following costs, which are recorded as expenses in the period in which they are incurred, rather than as a portion of the inventory cost: current year manufacturing costs in excess of costs capitalized into inventory, the impact of an annual revaluation of inventory and deferred costs of commercial sales to standard cost, write-offs of inventory and deferred costs of commercial sales. The increase in cost of goods sold of \$0.1 million for the year ended December 31, 2017 compared to the prior year is primarily due to increases of \$2.8 million in inventory write offs related to obsolescence and \$1.6 million in cost of goods attributable to commercial product sales. These increases were offset by a decrease of \$4.5 million related to a reduction in current year manufacturing costs in excess of costs capitalized into inventory (resulting from the reduction in work force in the fourth quarter of 2016) and a \$0.3 million gain related to the January 2017 revaluation of inventory to standard costs.

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 for the year ended December 31, 2016. During the year ended December 31, 2017, we did not recognize any collaboration product costs. During the year ended December 31, 2016, we recognized \$33.0 million of collaboration product costs, 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.

Research and development expenses include payroll, employee benefits, stock-based compensation expense, and other headcount-related expenses associated with research and development. Research and development expenses also include third-party clinical spending and clinical grants, manufacturing improvement and Technosphere development. Research and development expenses decreased for the year ended December 31, 2017 by \$0.8 million, or 5% compared with the year ended December 31, 2016, primarily due to a \$3.6 million decrease in research and development expenses associated with a reduction in workforce in 2016 and an FDA submission fee for label expansion of \$1.0 million incurred in 2016. These decreases were offset by a \$2.5 million increase in clinical trial expenses, a \$0.7 million increase in expenses incurred for research and development related to manufacturing automation and improvements, and a \$0.2 million increase in travel expenses.

Selling expenses include payroll, employee benefits, stock-based compensation expense, and other headcount-related expenses associated with sales and marketing personnel, and the costs of advertising, promotions, trade shows, seminars, and other programs. Selling expenses increased for the year ended December 31, 2017 by \$22.7 million, or 114%, compared to the prior year, primarily due to for a full year of marketing Afrezza in 2017 using an internal sales force, versus marketing Afrezza for a partial year in 2016 using a contracted sales force. This resulted in a \$16.0 million increase in expense related to the transition and build-out of our internal sales-force, which was offset by a \$7.7 million decrease in spending on contracted sales efforts. In addition, there was a \$5.0 million increase in product advertising expense, primarily attributed to television advertisements, a \$3.9 million increase in expenses for marketing and branding, a \$3.5 million increase in travel expenses, a \$1.0 million increase in expenses related to promotional materials, a \$0.5 million increase in facilities expense, and a \$0.3 million increase in sponsorship expense.

General and administrative expenses include payroll, employee benefits, stock-based compensation expense, severance expense, and other headcount-related expenses associated with finance, legal, facilities, human resources and other administrative personnel, certain taxes, professional services, and legal and other administrative fees. General and administrative expense increased for the year ended December 31, 2017 by \$5.3 million, or 20%, compared to the prior year, primarily due to increases in salaries of \$2.6 million related to new executives hired in late 2016 and 2017, a \$1.5 million increase in professional fees, primarily related to debt recapitalization, a \$1.4 million increase in expense for consulting services related to accounting, human resources, and business development, a \$0.7 million increase in expenses for performance bonuses, a \$0.5 million increase in expenses associated with executive recruitment and relocation, and a \$0.2 million increase in expenses for software infrastructure. These increases were partially offset by a \$2.1 million decrease in legal expenses.

Under the Insulin Supply Agreement with Amphastar, payment obligations are denominated in Euros. We are 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. The loss on

foreign currency translation for the year ended December 31, 2017 was \$13.6 million as compared to a gain in 2016 of \$3.4 million, resulting in a \$17.1 million net change due to unfavorable U.S. dollar to Euro exchange rates.

(Gain) loss on purchase commitments changed by \$2.1 million as a result of a gain recorded in 2016 of \$2.3 million versus \$0.2 million in 2017. 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 Insulin Supply Agreement).

Other Income (Expense)

The following table provides a comparison of the other income (expense) categories for the years ended December 31, 2017 and 2016 (dollars in thousands):

	Year Ended December 31,			
	2017	2016	\$ Change	% Change
Change in fair value of warrant liability	\$ 5,488	\$ 5,369	\$ 119	2%
Interest income	293	85	208	245%
Interest expense on notes	(9,494)	(15,576)	6,082	(39%)
Interest expense on note payable to principal stockholder	(3,782)	(2,901)	(881)	30%
(Loss) gain on extinguishment of debt	(1,611)	72,024	(73,635)	(102%)
Other income (expense)	13	(597)	610	(102%)
Total other (expense) income	<u>\$ (9,093)</u>	<u>\$ 58,404</u>	<u>\$ (67,497)</u>	<u>(116%)</u>

During the year ended December 31, 2017 we recorded a \$5.5 million change in the fair value of the warrant liability from the beginning of the year through the date the Series A Common Stock Purchase Warrants (“A Warrants”) and Series B Common Stock Purchase Warrants (“B Warrants”) were exchanged, compared to \$5.4 million for the prior year due to the volatility in our stock price. On September 29, 2017, we entered into exchange agreements with the four holders of all outstanding A and B Warrants, pursuant to which we agreed to issue to such holders an aggregate of 1,292,510 shares of our common stock in exchange for such warrants.

The decrease of \$6.1 million in the interest expense on notes for the year ended December 31, 2017 compared to the same period in the prior year was primarily due to the extinguishment of debt under the Sanofi Loan Facility in the fourth quarter of 2016 as a result of the settlement agreement with Sanofi entered into in November 2016 (the “Settlement Agreement”).

The increase of \$0.9 million in the interest expense on note payable to the principal stockholder for the year ended December 31, 2017 compared to the prior year was primarily due to additional borrowings and capitalization of interest under The Mann Group Loan Arrangement in the second quarter of 2017.

(Loss) gain on extinguishment of debt decreased by \$73.6 million. This was due to the \$72.0 million gain from extinguishment of debt in 2016 as a result of the Settlement Agreement and forgiveness of the full outstanding loan balance of the Sanofi Loan Facility and \$1.6 million of losses on conversions of convertible notes into common stock during the current year.

Years ended December 31, 2016 and 2015

Revenues

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

	Year Ended December 31,			
	2016	2015	\$ Change	% Change
Revenues:				
Net revenue - commercial product sales:				
Gross revenue from product sales	\$ 2,714	\$ —	\$ 2,714	100%
Gross-to-Net Adjustments:				
Wholesaler distribution fees and prompt pay discounts	(489)	—	(489)	100%
Patient discount and co-pay assistance programs	(196)	—	(196)	100%
Rebates and chargebacks	(134)	—	(134)	100%
Net revenue - commercial product sales	1,895	—	1,895	100%
Net revenue - collaboration	171,965	—	171,965	100%
Revenue - other	898	—	898	100%
Total revenues	\$ 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.

We began distributing MannKind-branded Afrezza product to wholesalers through ICS Direct in July of 2016. We recognized 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 years ended December 31, 2016 and 2015 (dollars in thousands):

	Year Ended December 31,			
	2016	2015	\$ Change	% Change
Expenses:				
Cost 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	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 commitment	(2,265)	66,167	(68,432)	(103%)
Total expenses	\$ 107,498	\$ 344,655	\$ (237,157)	(69%)

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.

The decrease in cost of goods sold of \$47.6 million for the year ended December 31, 2016 compared to 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 sales 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.

The decrease in research and development expense of \$14.8 million for the year ended December 31, 2016 compared to 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 of \$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.

The increase in selling and marketing expenses of \$18.3 million for the year ended December 31, 2016 compared to 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.

The decrease in general and administrative expenses of \$12.3 million for the year ended December 31, 2016 compared to 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 sales 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 the 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, payment obligations are 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.

The (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 Insulin Supply 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.

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):

	Year 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%
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)	<u>\$ 58,404</u>	<u>\$ (23,790)</u>	<u>\$ 82,194</u>	<u>(345%)</u>

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 year 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 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 prior year was primarily due to a one-time adjustment in 2015 for patents we sold to a third party.

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, under which we can no longer borrow as we have used all amounts available for borrowing, 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 which terminated in 2016.

As of December 31, 2017, we had \$157.8 million principal amount of outstanding debt, consisting of:

- \$23.7 million principal amount of 2021 notes bearing interest at 5.75% per annum and maturing on October 23, 2021;
- The following amounts under the Facility Financing Obligation with Deerfield which are partially convertible as further described below:
- \$39.4 million principal amount of 2019 notes bearing interest at 9.75% per annum. Interest is payable in cash quarterly in arrears on the last business day of March, June, September and December of each year. \$4.4 million principal amount was scheduled to become due on January 19, 2018, \$15.0 million will become due and payable on each of July 2018 and July 2019, and \$5.0 million will become due and payable in December 2019;
- \$15.0 million principal amount of Tranche B notes bearing interest at 8.75% per annum. Interest is payable in cash quarterly in arrears on the last business day of March, June, September and December of each year. The principal amount is due and payable as follows: \$5.0 million in each of May 2018, May 2019, and December 2019; and
- \$79.7 million principal amount of indebtedness under The Mann Group Loan Arrangement bearing interest at a fixed rate of 5.84% per annum and maturing on January 5, 2020. Interest is due and payable quarterly in arrears on the first day of each calendar quarter for the preceding quarter, except that the lender has agreed to defer interest payments until July 1, 2018 unless otherwise permitted under the subordination agreement with Deerfield, and such interest payments are subject to additional deferral beyond July 1, 2018 until our payment obligations to Deerfield have been satisfied in full.

On January 18, 2018, we entered into the Sixth Deerfield Amendment with Deerfield, pursuant to which, among other things, we issued to Deerfield an aggregate of 1,267,972 shares of our common stock in exchange for the cancellation of \$3,157,251 of 2019 notes. In addition, the payment date for the remaining \$1,250,000 in remaining principal amount of the 2019 notes that was previously due to be repaid on January 19, 2018 was extended to May 6, 2018.

The Company has entered into certain transaction related to these borrowings during 2017 and 2018 that are more fully described in in Note 6 – Related Party Arrangements, Note 7- Borrowings, Note 10 – Fair Value of Financial Instruments, Note 14 – Commitments and Contingencies and Note 20 – Subsequent Events in the Notes to Consolidated Financial Statements included in “Part II, Item 8 — Financial Statements and Supplementary Data.

On October 10, 2017, we entered into securities purchase agreements (the “Purchase Agreements”) with certain institutional investors and a charitable foundation (collectively, the “Purchasers”). Pursuant to the terms of the Purchase Agreements, we sold to the Purchasers in a registered offering an aggregate of 10,166,600 shares of our common stock at a purchase price of \$6.00 per share. Included in this offering was 166,600 shares issued to a charitable foundation associated with the Chairman of our board of directors. The net proceeds from the offering were approximately \$57.7 million, after deducting placement agent fees equal to 5.0% of the aggregate gross proceeds from the offering (except for the proceeds received from the sale of 166,600 shares issued to the charitable foundation) and offering expenses payable by us. The offering closed on October 13, 2017.

In November 2017, we sold an aggregate of 173,327 shares of our common stock for aggregate gross proceeds of approximately \$0.5 million pursuant to our At Market Issuance Sales Agreement with B. Riley FBR, Inc. (f/k/a FBR Capital Markets & Co.), dated as of April 26, 2016 (the “FBR Agreement”). On February 27, 2018, we terminated the FBR Agreement and no further sales will made under such agreement.

As described in more detail under Item 9B of this Annual Report, on February 27, 2018 we entered into a Controlled Equity OfferingSM Sales Agreement (the “Sales Agreement”) with Cantor Fitzgerald & Co. (“Cantor Fitzgerald”), as sales agent, pursuant to which we may offer and sell, from time to time, through Cantor Fitzgerald, shares of our common stock having an aggregate offering price of up to \$50.0 million or such other amount as may be permitted by the Sales Agreement. Under the Sales Agreement, Cantor Fitzgerald may sell shares by any method deemed to be an “at the market offering” as defined in Rule 415 under the Securities Act of 1933, as amended.

There can be no assurance that we will have sufficient resources to make any required repayments of principal under the 2021 notes, Facility Financing Obligation, 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 2021 notes, or certain Major Transactions as defined in the Facility Agreement in respect of the Facility Financing Obligation 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.

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 2021 notes and the Facility Financing Obligation, or if we fail to repay or repurchase the 2021 notes, Facility Financing Obligation, or borrowings under The Mann Group Loan Arrangement, 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 on the last day of each fiscal quarter to not be less than \$25.0 million, except for the months of August, September, October and December 2017. In these months the requirement was reduced to \$10.0 million as of the last day of each month if certain conditions were met. We met the required conditions as of the last day of each of these periods. See Note 14 — 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 14 — 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. In 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 us, 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 being required to deliver any insulin for such payment. See Note 8 — Collaboration Arrangements for further information related to the Sanofi agreements.

These factors raise substantial doubt about our ability to continue as a going concern. Our financial statements and related notes thereto included elsewhere in this Annual Report on Form 10-K, do not include adjustments that might result from the outcome of this uncertainty.

Net cash used in operating activities, which consists of net loss adjusted for the various non-cash items, changes in working capital and changes in other balance sheet accounts, totaled \$64.8 million for the year ended December 31, 2017. Net cash used in operating activities totaled \$78.1 million and \$57.2 million for the year ended December 31, 2016 and December 31, 2015, respectively.

During the year ended December 31, 2017, we used \$64.8 million of cash for our operating activities as a result of our net loss of \$117.3 million, offset by a net decrease in operating assets and liabilities of \$27.6 million and non-cash charges of \$25.0 million. The decrease in operating assets and liabilities was primarily as a result of the receipt of \$30.6 million from Sanofi pursuant to the insulin put option in January 2017. The other changes in operating assets and liabilities was a result of increases in accounts payable of \$3.8 million and accrued expenses and other current liabilities of \$2.9 million, offset by decreases in deferred revenue of \$0.4 million, and purchase commitments of \$4.7 million. In addition, there were increases in accounts receivable of \$2.5 million, inventory of \$3.3 million, and deferred costs from commercial product sales of \$0.1 million, offset by a decrease in prepaid expenses of \$1.4 million. The non-cash items included \$5.5 million of a gain in the fair value of the warrant liability, offset by \$13.6 million loss on foreign currency exchange, \$4.8 million of stock-based compensation, \$3.5 million of depreciation, amortization and accretion, \$3.8 million of interest accrued through notes payable to principal stockholder, \$3.0 million of inventory write-offs and \$1.6 million of loss on extinguishment of debt.

During the year ended December 31, 2016, we used \$78.1 million of cash for our operating activities as a result of a net decrease in operating assets and liabilities of \$139.3 million offset by our net income of \$125.7 million, adjusted by non-cash charges of \$64.5 million. The changes in operating assets and liabilities were due to increases in accounts receivable from Sanofi of \$30.5 million, inventory of \$2.3 million, and decreases in accounts payable of \$12.1 million, deferred revenue of \$17.5 million, deferred payments from collaboration of \$134.1 million, offset by a decrease in deferred costs from collaboration of \$13.5 million and increases in recognized loss on purchase commitment of \$40.6 million and deferred revenue of \$3.4 million. The non-cash charges included \$72.0 million gain on extinguishment of debt, \$4.2 million of depreciation and accretion, \$5.1 million of stock-based compensation, \$2.9 million of interest accrued on borrowings from our principal stockholder, and \$4.5 million of interest accrued on borrowings under Sanofi Loan Facility offset by a \$5.4 million non-cash gain from a change in the fair value of warrants, a \$3.4 million gain on foreign currency translation exchange, and \$2.3 million gain on purchase commitments.

During the year ended December 31, 2015, we used \$57.2 million of cash in operating activities as a result of our net loss of \$368.4 million, adjusted by non-cash 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, accretion and stock-based compensation, \$1.7 million interest accrued through borrowings under the Sanofi Loan Facility, \$1.0 million for the loss on extinguishment of debt, with the remainder due to an adjustment for foreign currency 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. This was offset by net decreases in inventory.

Cash provided from investing activities was \$16.7 million for the year ended December 31, 2017 compared to cash used in investing activities of \$1.1 million for the year ended December 31, 2016. The difference was primarily related to net proceeds received during the year ended December 31, 2017 for the sale of certain parcels of real estate owned by us in Valencia, California and certain related improvements, personal property, equipment, supplies and fixtures for \$16.7 million. 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 and 2015 was primarily comprised of purchases of property and equipment of \$1.1 million and \$10.3 million, respectively.

Cash provided from financing activities was \$73.6 million for the year ended December 31, 2017 primarily related to \$57.7 million in net proceeds from the registered direct offering of common stock and \$19.4 million received from borrowings on the note payable to principal stockholder offset by a principal payment of \$4.0 million on the facility financing obligation. Cash provided by financing activities of \$43.0 million for the year ended December 31, 2016 was primarily related to \$47.3 million in net proceeds received from the sale of stock and warrants and a payment on the Deerfield notes of \$5.0 million during the nine months ended December 31, 2016. Financing activities provided \$5.7 million of cash for the year ended December 31, 2015, comprised of a \$64.3 million payment on the outstanding 2015 notes obligation and a \$4.2 million payment associated with the achievement of the second milestone to Deerfield for product launched on February 3, 2015. These outflows were offset by \$34.7 million received in net proceeds from the sale of stock on the Tel Aviv Stock Exchange in November 2015, \$27.8 million net of issuance costs in proceeds from at-the-market sales of stock, and \$14.3 million received in proceeds from exercise of stock options and warrants. Cash inflows were offset by the payment of employment taxes related to vested restricted stock units.

Future Liquidity Needs. As of December 31, 2017, we had \$48.4 million in cash and cash equivalents and restricted cash. Our cash position, together with our short-term debt obligations and anticipated operating expenses, raises substantial doubt about our ability to continue as a going concern. We expect to expend our capital resources for the manufacturing, sales and marketing of Afrezza and to develop our product candidates. We also intend to use our capital resources for general corporate purposes. We will need to raise additional capital before we exhaust our current cash resources in order to continue to fund our research and development, support continued product growth and commercialization efforts, and to fund operations, generally. We will seek to raise additional funds through various potential sources, such as equity and debt financings, or through collaboration and licensing agreements.

If we enter into strategic business collaborations with respect to our product candidates or Afrezza for commercialization outside of the United States, we may, as part of the transaction, 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 when needed or on acceptable terms, 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 plan to continue to fund our operating losses and capital funding needs through public or private equity or debt financings, strategic collaborations, licensing agreements or other arrangements. We cannot provide assurances that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. If planned operating results are not achieved or we are not successful in raising additional capital through equity or debt financing or entering business collaborations, 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.

Off-Balance Sheet Arrangements

As of December 31, 2017, we did not have any off-balance sheet arrangements.

Contractual Obligations

Our contractual obligations represent future cash commitments and liabilities under agreements with third parties, and exclude contingent liabilities for which we cannot reasonably predict future payments. Accordingly, the table below excludes contractual obligations relating to milestone and royalty payments due to third parties, all of which are contingent upon certain future events. The expected timing of payment of the obligations presented (excluding payments in respect of the Milestone Rights) below are estimated based on current information. These contractual obligations consisted of the following at December 31, 2017 (in thousands):

Contractual Obligations	Payments Due in				Total
	Less Than One Year	1-3 Years	4-5 Years	More Than 5 Years	
Open purchase order and commitments (1)	\$ 8,080	\$ 3,187	\$ 533	\$ —	\$ 11,800
Senior convertible notes — long term (2)	1,362	28,034	—	—	29,396
Note payable to principal stockholder (3)	—	91,387	—	—	91,387
Facility financing obligation (4)	28,194	31,851	—	—	60,045
Insulin supply agreement (5)	11,688	51,116	46,469	—	109,273
Operating lease obligations	545	2,969	1,123	—	4,637
Total contractual obligations	\$ 49,869	\$ 208,544	\$ 48,125	\$ —	\$ 306,538

- (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 notes in full upon maturity in 2021.
- (3) The obligation for the note payable to the principal stockholder includes future principal and interest payments related to the \$79.7 million of borrowings as of December 31, 2017. 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 \$39.4 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 €90.3 million at December 31, 2017. Future payments due were estimated by converting to U.S. dollars using the December 31, 2017 Euro-to-dollar exchange rate. 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.

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 2017 and other new accounting standards that have been issued by the FASB but are not effective until after December 31, 2017.

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. See Note 6 – Related Party Arrangements, Note 7- Borrowings, and Note 20 – Subsequent Events in the Notes to Consolidated Financial Statements included in Part II, Item 8 — Financial Statements and Supplementary Data for information about the principal amount of outstanding debt.

The interest rate on amounts borrowed under The Mann Group Loan Arrangement is fixed at 5.84%.. As of December 31, 2017, we also had debt related to the 2021 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, 2017 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, the recognized loss on purchase commitment is converted to U.S. dollars at the then-applicable foreign exchange rate. As a result, our business is affected by fluctuations in exchange rates between the U.S. dollar and foreign currencies. We have not entered into foreign currency hedging transactions to mitigate our exposure to foreign currency exchange risks, but may enter into foreign currency hedging transactions in the future. Exchange rate fluctuations may adversely affect our expenses, results of operations, financial position and cash flows. If 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, 2017 were to occur, this change would have resulted in a foreign currency impact to our pre-tax income (losses) of approximately \$10.8 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.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the Securities and Exchange Commission (“SEC”) is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, we and our 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, our management was required to apply its reasonable judgment.

As required by Rule 13a-15 under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), we carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of our disclosure controls and procedures as of December 31, 2017.

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, 2017.

Management’s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in 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, 2017. In making this assessment, our 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, 2017, our internal control over financial reporting was effective based on those criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2017 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in its report, which is included herein.

Changes in Internal Control over Financial Reporting

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

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of MannKind Corporation

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of MannKind Corporation and subsidiaries (the “Company”) as of December 31, 2017, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2017, of the Company and our report dated February 26, 2018, expressed an unqualified opinion on those financial statements and includes an explanatory paragraph relating to the Company’s ability to continue as a going concern.

Basis for Opinion

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 are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. 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.

Definition and Limitations of Internal Control over Financial Reporting

A company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. 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 its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Deloitte & Touche LLP

Stamford, Connecticut
February 27, 2018

Item 9B. Other Information.

2018 Bonus Goals

Each of our executive officers are eligible to receive annual performance-based cash bonuses. The annual performance-based cash bonuses are intended to compensate our executive officers for achieving our annual goals at the corporate level. Each of our executive officers is assigned a target bonus opportunity expressed as a percentage of base salary, which reflects what we believe are market competitive levels and is subject to modification by our board of directors. Target bonuses are not guaranteed and are subject to achievement of our performance objectives as determined by our board of directors and its compensation committee.

The following table lists our executive officers and their respective target bonuses, expressed as a percentage of their base salary:

<u>Executive Officer</u>	<u>Target Bonus Percentage</u>
Michael E. Castagna, Pharm.D., <i>Chief Executive Officer</i>	60%
Steven B. Binder, <i>Chief Financial Officer</i>	50%
Joseph Kocinsky, <i>Chief Technology Officer</i>	50%
Patrick McCauley, <i>Chief Commercial Officer</i>	50%
David B. Thomson, Ph.D., J.D., <i>General Counsel and Secretary</i>	50%
Stuart A. Tross, Ph.D., <i>Chief People and Workplace Officer</i>	50%
Rosabel R. Alinaya, <i>Senior Vice President, Investor Relations and Treasury</i>	50%
Courtney Barton, <i>Vice President, Chief Compliance and Privacy Officer</i>	50%

On February 21, 2018, our board of directors adopted corporate goals for purposes of determining the eligibility of our executive officers to receive performance-based cash bonuses for 2018. The corporate goals relate to the following categories: Afrezza sales (60%), net cash burn (20%), clinical development and regulatory submissions (15%), and business development (5%). There is no minimum percentage of corporate goals that must be achieved in order to earn a bonus, and each category of performance goals can be achieved at up to 200% of the target level.

2017 Bonuses

On February 21, 2018, our board of directors awarded performance-based cash bonuses to our named executive officers based on its determination, after considering the recommendation of the compensation committee of our board of directors, that corporate performance during 2017 achieved 90% of the corporate objectives previously established for such year. Accordingly, each named executive officer will be paid a cash bonus payment equal to 90% of their individual target bonus opportunity. For executive officers, the target bonus opportunity is generally 50% (60% in the case of individuals who hold the office of chief executive officer) of their base salary earned during the previous year.

Controlled Equity OfferingSM Sales Agreement with Cantor Fitzgerald & Co.

On February 27, 2018, we entered into a Controlled Equity OfferingSM Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor Fitzgerald"), as sales agent, pursuant to which we may offer and sell, from time to time, through Cantor Fitzgerald, shares of our common stock having an aggregate offering price of up to \$50.0 million or such other amount as may be permitted by the Sales Agreement (the "ATM Offering"). The shares will be offered and sold pursuant to our shelf registration statement on Form S-3 (File No. 333-210792).

We are not obligated to sell any shares under the Sales Agreement. Subject to the terms and conditions of the Sales Agreement, Cantor Fitzgerald will use commercially reasonable efforts, consistent with its normal trading and sales practices, applicable state and federal law, rules and regulations and the rules of The NASDAQ Stock Market, to sell shares from time to time based upon our instructions, including any price, time or size limits specified by us. Under the Sales Agreement, Cantor Fitzgerald may sell shares by any method deemed to be an "at the market offering" as defined in Rule 415 under the Securities Act of 1933, as amended. We will pay Cantor Fitzgerald a commission of up to 3.0% of the aggregate gross proceeds from each sale of shares, reimburse legal fees and disbursements and provide Cantor Fitzgerald with customary indemnification and contribution rights. The Sales Agreement may be terminated by Cantor Fitzgerald or us at any time upon notice to the other party, or by Cantor Fitzgerald at any time in certain circumstances, including the occurrence of a material and adverse change in our business or financial condition that makes it impractical or inadvisable to market the shares or to enforce contracts for the sale of the shares.

The foregoing description of the Sales Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Sales Agreement, a copy of which is filed as Exhibit 10.47 to this Annual Report on Form 10-K. The legal opinion of Cooley LLP relating to the shares of common stock being offered pursuant to the Sales Agreement is filed as Exhibit 5.1 to this Annual Report on Form 10-K.

This Annual Report on Form 10-K shall not constitute an offer to sell or the solicitation of an offer to buy any shares under the Sales Agreement nor shall there be any sale of such shares in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

Termination of At Market Issuance Sales Agreement with FBR Capital Markets & Co.

On February 27, 2018, we terminated our At Market Issuance Sales Agreement with B. Riley FBR, Inc. (f/k/a FBR Capital Markets & Co.), dated as of April 26, 2016 (the “FBR Agreement”). No further sales of our common stock will be made under the FBR Agreement.

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 2018 Annual Meeting of Stockholders (the “Proxy Statement”), to be filed with the SEC on or before April 30, 2018, and is incorporated herein by reference.

(c) *Section 16(a) Beneficial Ownership Reporting Compliance* — Section 16(a) of the Exchange Act requires our directors, executive officers and any persons beneficially holding more than 10% of our common stock to report their initial ownership of our common stock and any subsequent changes in that ownership to the SEC. Our executive officers, directors and greater than 10% stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file.

Specific due dates for these reports have been established and we are required to identify those persons who failed to timely file these reports. To our knowledge, based solely on a review of the copies of such reports furnished to us and written representations from our directors and officers that no other reports were required, during the fiscal year ended December 31, 2017, all of our directors, officers and greater than 10% stockholders complied with the Section 16(a) filing requirements; except that Dr. Castagna failed to timely file one Form 4 during the fiscal year ended December 31, 2017. The Form 4 reportable transaction is described below.

On May 29, 2017, in connection with his appointment as our Chief Executive Officer, our board of directors granted Dr. Castagna an option to purchase 191,000 shares of our common stock under our 2013 Equity Incentive Plan (the “Plan”), with 25% of such shares vesting one year after May 25, 2017 and the balance vesting in equal monthly installments over the following 36 months. In accordance with the Plan, the options have an exercise price of \$1.52 per share, which was equal to the closing price of our common stock as reported on The NASDAQ Global Market on May 26, 2017. Due to an administrative oversight, the equity award was not timely reported on Form 4 within the 48-hour time window, but was instead filed on June 14, 2017.

We have adopted a Code of Business Conduct and Ethics Policy that applies to our directors and employees 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.

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:

<u>Report of Independent Registered Public Accounting Firm</u>	61
<u>Consolidated Balance Sheets</u>	62
<u>Consolidated Statements of Operations</u>	63
<u>Consolidated Statements of Comprehensive Income (Loss)</u>	64
<u>Consolidated Statements of Stockholders' Deficit</u>	65
<u>Consolidated Statements of Cash Flows</u>	66
<u>Notes to Consolidated Financial Statements</u>	67

All financial statement schedules have been omitted because the required information is not applicable or not present in amounts sufficient to require submission of the schedule, or because the information required is included in the consolidated financial statements or the notes thereto.

(3) Exhibits. The exhibits listed under Item 15(b) hereof are filed or furnished with, or incorporated by reference into, this Annual Report on Form 10-K. Each management contract or compensatory plan or arrangement is identified separately in Item 15(b) hereof.

(b) Exhibits. The following exhibits are filed or furnished as part of, or incorporated by reference into, this Annual Report on Form 10-K:

Exhibit Number	Description of Document
3.1	<u>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).</u>
3.2	<u>Certificate of Amendment of Amended and Restated Certificate of Incorporation of MannKind Corporation (incorporated by reference to Exhibit 3.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on March 2, 2017).</u>
3.3	<u>Certificate of Amendment of Amended and Restated Certificate of Incorporation of MannKind Corporation (incorporated by reference to Exhibit 3.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on December 13, 2017).</u>
3.4	<u>Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on November 19, 2007).</u>
4.1	Reference is made to Exhibits <u>3.1</u> , <u>3.2</u> , <u>3.3</u> and 3.4.
4.2	<u>Form of common stock certificate (incorporated by reference to Exhibit 4.2 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 16, 2017).</u>
4.3	<u>Form of 9.75% Senior Secured Convertible Promissory Note due 2019 (incorporated by reference Exhibit 99.2 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).</u>
4.4	<u>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).</u>
4.5	<u>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. 000-50856), filed with the SEC on May 12, 2014).</u>
4.6	<u>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 Exhibit 99.3 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).</u>
4.7	<u>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 Exhibit 99.4 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).</u>
4.8	<u>Facility Agreement, dated as of July 1, 2013, by and among MannKind Corporation, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (incorporated by reference to Exhibit 99.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).</u>

Exhibit Number	Description of Document
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	Exchange and Third Amendment to Facility Agreement, dated June 29, 2017 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (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 June 29, 2017).
4.12	Fourth Amendment to Facility Agreement, dated October 23, 2017 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (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 October 23, 2017).
4.13	Fifth Amendment to Facility Agreement, dated January 15, 2018 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, 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 18, 2018).
4.14	Sixth Amendment to Facility Agreement, dated January 18, 2018 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (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 January 18, 2018).
4.15	Indenture, by and between MannKind and U.S. Bank, dated October 30, 2017 (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 October 30, 2017).
4.16	Form of 5.75% Convertible Senior Subordinated Exchange Note due 2021 (incorporated by reference to Exhibit A of Exhibit 4.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on October 30, 2017).
4.17	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).
5.1	Opinion of Cooley LLP.
10.1*	Offer Letter Agreement, dated July 12, 2017, by and between MannKind and Steven B. Binder (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 July 17, 2017).
10.2*	Offer Letter, dated March 9, 2016, by and between MannKind and Michael E. 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).
10.3*	Offer Letter dated December 22, 2016, by and between MannKind and Stuart Tross (incorporated by reference to Exhibit 10.36 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 16, 2017).
10.4*	Offer Letter dated February 17, 2017, by and between MannKind and Courtney Barton.
10.5*	Offer Letter dated June 28, 2017, by and between MannKind and Patrick McCauley.
10.6*	Offer Letter dated February 2, 2018, by and between MannKind and David Kendall.
10.7*	Executive Severance Agreement, dated October 10, 2007, between MannKind and David Thomson (incorporated by reference to Exhibit 99.1 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*	Form of Indemnity Agreement entered into between MannKind and each of its directors and officers (incorporated by reference to Exhibit 10.1 to MannKind's Registration Statement on Form S-1 (File No. 333-115020), filed with the SEC on April 30, 2004, as amended).
10.9*	Form of Change of Control 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 April 7, 2017).
10.10*	Description of Officers' Incentive Program (incorporated by reference to Exhibit 10.5 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 16, 2006).
10.11*	2004 Equity Incentive Plan, as amended (incorporated by reference to Appendix A to MannKind's proxy statement on Schedule 14A (File No. 000-50865), filed with the SEC on April 6, 2012).

Exhibit Number	Description of Document
10.12*	<u>Form of Stock Option Agreement under the 2004 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 MannKind's Registration Statement on Form S-1 (File No. 333-115020), originally filed with the SEC on April 30, 2004, as amended).</u>
10.13*	<u>Form of Phantom Stock Award Agreement under the 2004 Equity Incentive Plan (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 December 14, 2005).</u>
10.14*	<u>2004 Non-Employee Directors' Stock Option Plan and form of stock option agreement there under (incorporated by reference to Exhibit 10.20 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 16, 2006).</u>
10.15*	<u>2004 Employee Stock Purchase Plan and form of offering document there under (incorporated by reference to Exhibit 10.4 to MannKind's Registration Statement on Form S-1 (File No. 333-115020), originally filed with the SEC on April 30, 2004, as amended).</u>
10.16*	<u>Non-Employee Director Compensation Program.</u>
10.17*	<u>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).</u>
10.18*	<u>Form of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the MannKind 2013 Equity Incentive Plan (incorporated by reference to Exhibit 99.2 to MannKind's registration statement on Form S-8 (File No. 000-188790), filed with the SEC on May 23, 2013).</u>
10.19*	<u>Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the MannKind 2013 Equity Incentive Plan (incorporated by reference to Exhibit 99.3 to MannKind's registration statement on Form S-8 (File No. 000-188790), filed with the SEC on May 23, 2013).</u>
10.20*	<u>Acknowledgment and Agreement, dated as of October 31, 2013, by and between MannKind and The Mann Group LLC (incorporated by reference to Exhibit 99.1 MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on November 4, 2013).</u>
10.21	<u>Form of Exchange 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 October 2, 2017).</u>
10.22	<u>Form of Securities Purchase Agreement, dated October 10, 2017 (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 October 11, 2017).</u>
10.23	<u>Engagement Letter, dated October 10, 2017, 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 October 11, 2017).</u>
10.24	<u>Amended and Restated Promissory Note made by MannKind in favor of The Mann Group LLC, dated October 18, 2012 (incorporated by reference to Exhibit 10.2 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on October 19, 2012).</u>
10.25	<u>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 Exhibit 99.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).</u>
10.26	<u>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).</u>
10.27	<u>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).</u>
10.28	<u>Exchange and Third Amendment to Facility Agreement, dated June 29, 2017 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (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 June 29, 2017).</u>
10.29	<u>Fourth Amendment to Facility Agreement, dated October 23, 2017 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (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 October 23, 2017).</u>

Exhibit Number	Description of Document
10.30	<u>Fifth Amendment to Facility Agreement, dated January 15, 2018 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, 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 19, 2018).</u>
10.31	<u>Sixth Amendment to Facility Agreement, dated January 18, 2018 by and among MannKind, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (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 January 19, 2018).</u>
10.32	<u>At Market Issuance Sales Agreement, by and between MannKind and FBR Capital Markets & Co., dated April 26, 2016 (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 April 26, 2016).</u>
10.33	<u>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).</u>
10.34	<u>Exchange Agreement, dated April 18, 2017, by and among MannKind Corporation, MannKind LLC, Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, 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 April 19, 2017).</u>
10.35	<u>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).</u>
10.36	<u>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. (incorporated by reference to Exhibit 10.35 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 16, 2017).</u>
10.37	<u>Agreement, dated June 27, 2017, by and between MannKind and The Mann Group LLC (incorporated by reference to Exhibit 99.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on June 29, 2017).</u>
10.38	<u>Agreement, dated September 13, 2006, between MannKind and Torcon, Inc. (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, 2007).</u>
10.39**	<u>Supply Agreement, dated December 31, 2004, between MannKind and Vaupell, Inc. (incorporated by reference to Exhibit 10.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on February 23, 2005).</u>
10.40**	<u>Letter Agreement, dated June 24, 2011, between MannKind and N.V. Organon (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 August 4, 2011).</u>
10.41**	<u>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).</u>
10.42	<u>First Amendment to Supply Agreement, dated October 31, 2014, by and between MannKind and Amphastar France Pharmaceuticals, S.A.S. and Amphastar Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.32 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 16, 2017).</u>
10.43**	<u>Second Amendment to Supply Agreement, dated November 9, 2016, by and between MannKind and Amphastar Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.33 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 16, 2017).</u>
10.44	<u>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).</u>
10.45	<u>Settlement Agreement, dated November 9, 2016, by and among MannKind, Technosphere International C.V., MannKind Netherlands B.V. and Sanofi-Aventis U.S. LLC (incorporated by reference to Exhibit 10.31 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 16, 2017).</u>
10.46	<u>Office Lease, dated May 5 2017, by and between MannKind and Russell Ranch Road II LLC. (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 August 7, 2017).</u>
10.47	<u>Controlled Equity OfferingSM Sales Agreement, by and between MannKind and Cantor Fitzgerald & Co., dated February 27, 2018.</u>
23.1	<u>Consent of Independent Registered Public Accounting Firm.</u>

Exhibit Number	Description of Document
24.1	Power of Attorney (included on signature page hereto).
31.1	Certification of the Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of the Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of the Chief Executive 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).
32.2	Certification of the 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.

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/ Michael Castagna
Michael E. Castagna
Chief Executive Officer

Dated: February 27, 2018

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Michael E. Castagna and David Thomson, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his 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 might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them or their or his substitute or substituted, may lawfully do or cause to be done by virtue hereof.

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Michael E. Castagna</u> Michael E. Castagna	Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	February 27, 2018
<u>/s/ Steven B. Binder</u> Steven B. Blinder	Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>	February 27, 2018
<u>/s/ Kent Kresa</u> Kent Kresa	Chairman of the Board of Directors	February 27, 2018
<u>/s/ Ronald J. Consiglio</u> Ronald J. Consiglio	Director	February 27, 2018
<u>/s/ Michael Friedman</u> Michael Friedman, M.D.	Director	February 27, 2018
<u>/s/ David H. MacCallum</u> David H. MacCallum	Director	February 27, 2018
<u>/s/ Henry L. Nordhoff</u> Henry L. Nordhoff	Director	February 27, 2018
<u>/s/ James S. Shannon</u> James S. Shannon	Director	February 27, 2018

MANKIND CORPORATION AND SUBSIDIARIES

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of MannKind Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of MannKind Corporation and subsidiaries (the "Company") as of December 31, 2017 and 2016, the related consolidated statements of operations, comprehensive income (loss), stockholders' deficit, and cash flows for each of the three years in the period December 31, 2017 and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2017, in conformity with the accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2017, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 27, 2018 expressed an unqualified opinion on the Company's internal control over financial reporting.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company's available cash resources and continuing cash needs raise substantial doubt about its ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

Stamford, Connecticut
February 27, 2018

We have served as the Company's auditor since 2001.

MANNKIND CORPORATION AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2017	2016
(In thousands except per share data)		
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 43,946	\$ 22,895
Restricted cash	4,409	—
Accounts receivable, net	2,789	302
Receivable from Sanofi	—	30,557
Inventory	2,657	2,331
Asset held for sale	—	16,730
Deferred costs from commercial product sales	405	309
Prepaid expenses and other current assets	3,010	4,364
Total current assets	<u>57,216</u>	<u>77,488</u>
Property and equipment, net	26,922	28,927
Other assets	437	648
Total assets	<u>\$ 84,575</u>	<u>\$ 107,063</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 6,984	\$ 3,263
Accrued expenses and other current liabilities	12,449	7,937
Facility financing obligation	52,745	71,339
Deferred revenue, net	3,038	3,419
Deferred payments from collaboration - current	250	1,000
Recognized loss on purchase commitments - current	12,131	5,093
Total current liabilities	<u>87,597</u>	<u>92,051</u>
Note payable to principal stockholder	79,666	49,521
Accrued interest - note payable to principal stockholder	2,347	9,281
Senior convertible notes	24,411	27,635
Recognized loss on purchase commitments - long term	97,585	95,942
Warrant liability	—	7,381
Deferred payments from collaboration - long term	500	—
Milestone rights liability and other liabilities	7,201	8,845
Total liabilities	<u>299,307</u>	<u>290,656</u>
Commitments and contingencies (Note 14)		
Stockholders' deficit:		
Undesignated preferred stock, \$0.01 par value - 10,000,000 shares authorized; no shares issued or outstanding at December 31, 2017 and 2016	—	—
Common stock, \$0.01 par value - 280,000,000 and 140,000,000 shares authorized, 119,053,414 and 95,680,831 shares issued and outstanding at December 31, 2017 and 2016, respectively	1,192	957
Additional paid-in capital	2,638,992	2,553,039
Accumulated other comprehensive loss	(18)	(24)
Accumulated deficit	<u>(2,854,898)</u>	<u>(2,737,565)</u>
Total stockholders' deficit	<u>(214,732)</u>	<u>(183,593)</u>
Total liabilities and stockholders' deficit	<u>\$ 84,575</u>	<u>\$ 107,063</u>

See notes to consolidated financial statements.

MANKIND CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,		
	2017	2016	2015
	(In thousands except per share data)		
Revenues:			
Net revenue - commercial product sales	\$ 9,192	\$ 1,895	\$ —
Net revenue - collaboration	250	171,965	—
Revenue - other	2,303	898	—
Total revenues	<u>11,745</u>	<u>174,758</u>	<u>—</u>
Expenses:			
Cost of goods sold	17,228	17,121	64,745
Cost of revenue - collaboration	—	32,971	—
Research and development	14,118	14,917	29,674
Selling, general and administrative	74,959	46,928	40,960
Property and equipment impairment	203	1,259	140,412
Loss (gain) on foreign currency translation	13,641	(3,433)	2,697
(Gain) loss on purchase commitments	(215)	(2,265)	66,167
Total expenses	<u>119,934</u>	<u>107,498</u>	<u>344,655</u>
(Loss) income from operations	<u>(108,189)</u>	<u>67,260</u>	<u>(344,655)</u>
Other (expense) income:			
Change in fair value of warrant liability	5,488	5,369	—
Interest income	293	85	18
Interest expense on notes	(9,494)	(15,576)	(21,231)
Interest expense on note payable to principal stockholder	(3,782)	(2,901)	(2,894)
(Loss) gain on extinguishment of debt	(1,611)	72,024	(1,049)
Other income (expense)	13	(597)	1,366
Total other (expense) income	<u>(9,093)</u>	<u>58,404</u>	<u>(23,790)</u>
(Loss) income before income tax expense	<u>(117,282)</u>	<u>125,664</u>	<u>(368,445)</u>
Provision for income taxes	51	—	—
Net (loss) income	<u>\$ (117,333)</u>	<u>\$ 125,664</u>	<u>\$ (368,445)</u>
Net (loss) income per share - basic	<u>\$ (1.13)</u>	<u>\$ 1.37</u>	<u>\$ (4.54)</u>
Net (loss) income per share - diluted	<u>\$ (1.13)</u>	<u>\$ 1.36</u>	<u>\$ (4.54)</u>
Shares used to compute basic net (loss) income per share	<u>104,245</u>	<u>92,053</u>	<u>81,233</u>
Shares used to compute diluted net (loss) income per share	<u>104,245</u>	<u>92,085</u>	<u>81,233</u>

See notes to consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

	Year Ended December 31,		
	2017	2016	2015
	(In thousands)		
Net (loss) income	\$ (117,333)	\$ 125,664	\$ (368,445)
Other comprehensive income (loss):			
Cumulative translation gain (loss)	6	(4)	(6)
Comprehensive (loss) income	\$ (117,327)	\$ 125,660	\$ (368,451)

See notes to consolidated financial statements.

MANKIND CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
(In thousands)						
BALANCE, JANUARY 1, 2015	81,212	\$ 812	\$ 2,420,216	\$ (14)	\$ (2,494,784)	\$ (73,770)
Exercise of stock options	340	3	3,255	—	—	3,258
Issuance of common shares from the release of restricted stock units	144	1	(1)	—	—	0
Issuance of common shares pursuant to warrant exercises	843	8	10,115	—	—	10,123
Issuance of common shares under Employee Stock Purchase Plan	54	1	886	—	—	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	4	7,922	—	—	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	28	34,682	—	—	34,710
Return of loaned common stock	(1,800)	(18)	18	—	—	—
Issuance of common stock pursuant to at-the-market issuances	1,788	18	27,825	—	—	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	857	2,512,063	(20)	(2,863,229)	(350,329)
Exercise of stock options	55	1	466	—	—	467
Issuance of common shares from the release of restricted stock units	131	1	(1)	—	—	0
Issuance of common shares under Employee Stock Purchase Plan	51	1	425	—	—	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	97	49,903	—	—	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	957	2,553,039	(24)	(2,737,565)	(183,593)
Exercise of stock options	5	0	24	—	—	24
Issuance of common shares from the release of restricted stock units	135	2	(1)	—	—	1
Issuance of common shares under Employee Stock Purchase Plan	103	1	235	—	—	236
Stock-based compensation expense	—	—	4,847	—	—	4,847
Restricted stock units taxes paid in cash	—	—	(127)	—	—	(127)
Issuance of shares pursuant to conversion of notes	11,496	115	20,984	—	—	21,099
Issuance of direct placement — common stock	10,167	102	60,898	—	—	61,000
Issuance costs associated with direct placement	—	—	(3,310)	—	—	(3,310)
Issuance of ATM placement	173	2	562	—	—	564
Issuance costs associated with ATM placement	—	—	(17)	—	—	(17)
Reclassification of warrant liability to equity	1,293	13	1,880	—	—	1,893
Amortization of shelf fees	—	—	(22)	—	—	(22)
Cumulative translation loss	—	—	—	6	—	6
Net loss	—	—	—	—	(117,333)	(117,333)
BALANCE, DECEMBER 31, 2017	119,053	\$ 1,192	\$ 2,638,992	\$ (18)	\$ (2,854,898)	\$ (214,732)

See notes to consolidated financial statements.

MANKIND CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
	2017	2016	2015
	(In thousands)		
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net (loss) income	\$ (117,333)	\$ 125,664	\$ (368,445)
Adjustments to reconcile net (loss) income to net cash used in operating activities:			
Depreciation, amortization and accretion	3,528	4,158	13,276
Stock-based compensation expense	4,847	5,135	8,725
Change in fair value of warrant liability	(5,488)	(5,369)	—
Loss (gain) on foreign currency translation	13,641	(3,433)	2,697
Loss (gain) on extinguishment of debt	1,611	(72,024)	1,049
Interest incurred through borrowings under Sanofi Loan Facility	—	4,478	1,652
Interest on note payable to principal stockholder	3,782	2,901	2,894
Series A warrant issuance cost	—	653	—
Other, net	100	19	—
(Gain) loss on sale, abandonment/disposal or impairment of property and equipment	203	1,259	140,582
(Gain) loss on purchase commitments	(215)	(2,265)	66,167
Write-off of inventory	2,971	—	36,104
Changes in operating assets and liabilities:			
Accounts receivable, net	(2,487)	(302)	—
Receivable from Sanofi	30,557	(30,534)	—
Inventory	(3,297)	(2,331)	(26,434)
Receivable from collaboration	—	—	50,413
Deferred costs from commercial product sales	(96)	(309)	—
Deferred costs from collaboration	—	13,539	(13,539)
Prepaid expenses and other current assets	1,354	(346)	13,481
Other assets	188	361	150
Accounts payable	3,800	(12,118)	8,413
Accrued expenses and other current liabilities	2,932	348	(12,467)
Deferred revenue	(381)	3,419	—
Deferred payments from collaboration	(250)	(134,056)	950
Deferred sales from collaboration	—	(17,503)	17,067
Recognized loss on purchase commitments	(4,745)	40,566	—
Milestone rights liability and other liabilities	—	—	33
Net cash used in operating activities	(64,778)	(78,090)	(57,232)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	—	(1,144)	(10,285)
Net proceeds from sale of asset held for sale	16,651	—	—
Proceeds from sale of property and equipment	24	17	82
Net cash provided by (used in) investing activities	16,675	(1,127)	(10,203)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from direct placement of common stock	61,000	50,000	—
Issuance cost associated with direct placement	(3,310)	(2,690)	—
Principal payments on facility financing obligation	(4,000)	(5,000)	—
Payment of employment taxes related to vested restricted stock units	(127)	(165)	(1,858)
Proceeds from issuance of common stock	—	893	4,146
Proceeds from issuance of common stock under Tel Aviv Stock Exchange	—	—	36,142
Issuance cost associated with the Tel Aviv Stock Exchange	—	—	(1,432)
Exercise of warrants for common stock	—	—	10,123
Payment of senior convertible notes	—	—	(64,287)
Payment of debt issuance costs on senior convertible notes	—	—	(831)
Borrowings on note payable to principal stockholder	19,429	—	—
Milestone payment	—	—	(4,219)
Proceeds from issuance of common stock pursuant to at-the-market issuance	564	—	28,392
Issuance costs of at-the-market transactions	(17)	—	(548)
Other	24	—	40
Net cash provided by financing activities	73,563	43,038	5,668
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	25,460	(36,179)	(61,767)
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING OF PERIOD	22,895	59,074	120,841
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, END OF PERIOD	\$ 48,355	\$ 22,895	\$ 59,074
SUPPLEMENTAL CASH FLOWS DISCLOSURES:			
Income taxes paid in cash	\$ 51	\$ —	\$ —
Interest paid in cash, net of amounts capitalized	\$ 7,728	\$ 8,991	\$ 13,355
NON-CASH INVESTING AND FINANCING ACTIVITIES:			
Payment of note obligations and interest through issuance of common stock	\$ 20,593	\$ —	\$ 8,253
Non-cash construction in progress and property and equipment	\$ —	\$ 588	\$ —
Reclassification of deferred payments from collaboration to Sanofi Loan Facility and loss share obligation	\$ —	\$ 5,174	\$ 59,337
Reclassification of property and equipment to asset held for sale	\$ —	\$ 17,294	\$ —
Capitalization of interest on note payable to principal stockholder	\$ 10,716	\$ —	\$ —
Reclassification of warrant liability to additional paid-in capital	\$ 1,880	\$ —	\$ —

See notes to consolidated financial statements.

MANKIND 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 development and commercialization of inhaled therapeutic products for diseases such as diabetes and pulmonary arterial hypertension. The Company’s only approved product, Afrezza (insulin human) inhalation powder, is a rapid-acting inhaled insulin that was approved by the U.S. Food and Drug Administration (the “FDA”) in June of 2014 to improve glycemic control in adults with diabetes. Afrezza became available by prescription in U.S. retail pharmacies in February 2015. Pursuant to a license and collaboration agreement (the “Sanofi License Agreement”) between the Company and Sanofi-Aventis U.S. LLC (“Sanofi”). Sanofi was responsible for global commercial, regulatory and development activities associated with Afrezza from August 2014 to April 2016. After a transition period during which Sanofi continued to fulfill orders for Afrezza, the Company assumed responsibility for worldwide development and commercialization of Afrezza and the Company began distributing MannKind-branded Afrezza to wholesalers in July 2016. During the second half of 2016, 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 its own specialty sales force to promote Afrezza to endocrinologists and certain high-prescribing primary care physicians. The Company’s current strategy for 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.

Basis of Presentation - The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company is not currently profitable and has rarely generated positive net cash flow from operations. As of December 31, 2017, the Company had an accumulated deficit of \$(2.9) billion.

At December 31, 2017, the Company’s capital resources consisted of cash and cash equivalents of \$43.9 million. The Company expects to continue to incur significant expenditures to support commercial manufacturing, sales and marketing of Afrezza and the development of product candidates in the Company’s pipeline. 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”) that resulted in the issuance of 9.75% Senior Convertible Notes due 2019 (“2019 notes”) and the First Amendment to Facility Agreement and Registration Rights Agreement (the “First Amendment”) that resulted in the issuance of an additional tranche of 8.75% Senior Convertible Notes due 2019 (“Tranche B notes”) (see Note 7 — Borrowings) requires the Company to maintain at least \$25.0 million in cash and cash equivalents or available borrowings under the loan arrangement, dated as of October 2, 2007, between the Company and The Mann Group LLC (“The Mann Group”) (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. On June 29, 2017, the Company entered into an Exchange and Third Amendment to the Facility Agreement (the “Third Amendment”) with Deerfield which, among other things, amended such financial covenant to provide that, if certain conditions are met, then the obligation to maintain at least \$25.0 million in cash as of the end of each quarter will be reduced to \$10.0 million as of August 31, 2017, September 30, 2017, October 31, 2017 and December 31, 2017 if certain conditions were met (see Note 7 — Borrowings). We met the conditions at each of these month-ends.

As of December 31, 2017, the Company has \$157.8 million principal amount of outstanding borrowings. The Company has entered into certain transaction related to these borrowings during 2017 and 2018 that are more fully described in Note 6 - Related Party Agreements, Note 7 – Borrowings and Note 20 – Subsequent Events.

The Company’s available cash and financing sources will not be sufficient to meet its current and anticipated cash requirements, accordingly, these factors, among others, raise substantial doubt about the Company’s ability to continue as a going concern.

The Company plans to raise additional capital, whether through a sale of equity or debt securities, a strategic business collaboration with another company, the establishment of other funding facilities, licensing arrangements, asset sales or other means, in order to continue the development and commercialization of Afrezza and other product candidates and to support its other ongoing activities. The Company cannot provide assurances that such additional capital will be available on acceptable terms or at all. Successful completion of these plans is dependent on factors outside of the Company’s control. As such, management cannot be certain that such plans will be effectively implemented within one year after the date that the financial statements are issued. 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.

Reverse Stock Split - On March 1, 2017, following stockholder approval, the Company’s board of directors approved a 1-for-5 reverse stock split of its outstanding common stock. 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 (the “Charter Amendment”) to effect the 1-for-5 reverse stock split of the Company’s outstanding common stock (the “Reverse Stock Split”) 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 a result, prior to March 3, 2017, 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.

Correction of an Immaterial Error — Subsequent to the issuance of the Company’s financial statements for the year ended December 31, 2016 on Form 10-K, the Company determined that the common stock par value as of December 31, 2016 should not have been retrospectively adjusted for the impact of the reverse stock split on March 3, 2017 as described above. Management evaluated the materiality of the errors from a quantitative and qualitative perspective and concluded that this adjustment was not material to the Company’s previously issued financial statements. The Company has elected to revise the historical consolidated financial information presented herein in the consolidated balance sheet and statements of stockholders’ deficit to reflect the correction of this error for the prior periods presented. Since the revisions were not material, no amendments to previously filed reports were required. The revisions had the effect of decreasing common stock and increasing additional paid in capital by \$3.8 million, \$3.4 million, and \$3.2 million as of December 31, 2016 and 2015 and January 1, 2015, respectively. Each affected individual line item within the consolidated statements of stockholders’ deficit relating to issuances of common shares for any reason and the return of loaned common stock in the years ended December 31, 2016 and 2015 have likewise been revised to decrease the common stock and increase the additional paid in capital attributable to each such transaction.

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.

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 and gross-to-net adjustments, assessing long-lived assets for impairment, clinical trial expenses, inventory costing and recoverability, recognized loss on purchase commitment, milestone rights liability, stock-based compensation and the determination of the provision for income taxes and corresponding deferred tax assets and liabilities and the valuation allowance recorded against net deferred tax assets.

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 commercial sales of Afrezza, collaborations, sale of intellectual property and bulk insulin sales, which are described more fully below.

Revenue Recognition – Net Revenue – Commercial Product Sales – The Company currently sells Afrezza through two channels: wholesale distributors and specialty pharmacies as further described below. The Company provides the right of return for unopened product for a period beginning six months prior to and ending twelve months after its expiration date. This right of return is provided to (1) the Company’s wholesale distributors and, through them, to its retail pharmacy customers, and (2) to its specialty pharmacies. Once the product has been prescribed and dispensed to the patient, any right of return ceases to exist.

Sales of Afrezza through Wholesale Distributors - 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”.

The current accounting guidance requires the Company to reliably estimate returns in order to recognize revenue upon shipment. While we can currently estimate returns within a range, it is not sufficiently precise to meet the current requirements. Accordingly, the Company defers recognition of revenue on Afrezza product shipments through wholesale distributors 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. Deferred revenue is presented net of deferred product sales discounts which are further described in *Gross-to-net Adjustments* below. Through the third quarter of 2017, the Company recognized revenue for wholesale distributors based on Afrezza patient prescriptions dispensed as estimated by syndicated data provided by a third party. The Company also analyzed additional data points to ensure that such third-party data was reasonable, including data related to inventory movements within the channel and ongoing prescription demand.

Change in Estimate – In the fourth quarter of 2017, the Company obtained new and more comprehensive data regarding the inventory in the distribution channel. This data indicated that the amount of inventory in the distribution channel was less than previously estimated. Because the new data was more comprehensive than the data that was previously available to the Company, the Company adjusted the ending gross deferred revenue balance to match the new estimate. In addition to adjusting the gross deferred revenue balance, the Company adjusted the ending balances of deferred discounts and deferred cost of goods sold. The net effect of this change was an increase to net income of \$1.2 million or \$0.01 basic and diluted net income (loss) per share for the year ended December 31, 2017.

Sales of Afrezza through Specialty Pharmacies - During the first quarter of 2017, the Company began selling Afrezza to a network of specialty pharmacies. Specialty pharmacies generally purchase product on demand. Title and risk of loss passes to the specialty pharmacies at shipment and our estimated returns are minimal. Therefore, the Company recognizes revenue for sales through specialty pharmacies at the time the product is shipped to the specialty pharmacies, net of *Gross-to-net Adjustments* as described below. For the year ended December 31, 2017, the net amount of revenue recognized from sales to specialty pharmacies was \$0.5 million.

For the years ended December 31, 2017 and 2016, Afrezza net revenue from commercial product sales consisted of \$9.2 million and \$1.9 million of net sales, respectively. As of December 31, 2017 and 2016, the ending balances for net deferred revenue, were \$3.0 million and \$3.4 million, on the Company's consolidated balance sheets which are presented net of \$1.5 million and \$0.8 million in deferred gross-to-net adjustments, respectively. The December 31, 2016 deferred revenue balance includes \$1.7 million of bulk insulin sales which is described more fully under the heading *Revenue Recognition – Revenue – Other* below. For the year ended December 31, 2017, shipments to three wholesale distributors represented 89% of total shipments. For the year ended December 31, 2016, the Company sold directly to ICS and Sanofi and for the year ended December 31, 2015 the Company sold directly to Sanofi.

Gross-to-net Adjustments — Estimated gross-to-net adjustments for Afrezza include wholesaler distribution fees, prompt pay discounts, estimated rebates and chargebacks 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 gross 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, 2017 and 2016, year to date total gross-to-net adjustments were approximately \$3.4 million and \$0.8 million, which represents 27% and 30% of gross revenue from product sales, respectively. Gross-to-net items that are unpaid at the end of each period are presented in discounts and allowances for commercial product sales in accrued expense and other current liabilities.

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 and deferred revenue by the prompt pay discount amount (at the time of shipment to the wholesale distributor). The Company recognizes the cash discounts as a reduction of revenue in the same period the related revenue is recognized.

Rebates and Chargebacks — Most of our rebates are contractual or legislatively mandated. Sales rebates include managed care, Medicare, Medicaid, and various other programs. The Company participates in federal and state government-managed Medicare and Medicaid rebate programs and, as such, is required to provide rebates under these programs. Chargebacks are discounts that occur when customers purchase directly from an intermediary wholesale purchaser.

The Company accounts for these rebates and chargebacks by establishing an accrual based on contractual discount rates, expected utilization under each contract and an estimate of the amount of inventory in the distribution channel that will become subject to such rebates and chargebacks based on historical payor data provided by a third-party vendor along with additional data including forecasted participation rate. From that data, as well as input received from the commercial team, an estimated participation rate for each program is determined and applied at the rate for those sales. Any new information regarding changes in the programs' regulations and guidelines or any changes in the Company's 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 may be paid can be up to approximately six to nine months. As such, continuous monitoring of these estimates will be performed on a periodic basis, and if necessary, adjusted to reflect new facts and circumstances. Rebates and chargebacks 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.

Deferred Costs from Commercial Product Sales — Deferred costs from commercial product sales represents the cost of product (including labor, overhead and shipping costs to third party logistics providers) shipped to wholesale distributors, but not dispensed by pharmacies to patients. If the Company estimates that inventory that has been shipped to wholesale distributors will be returned for credit because there is a risk of product expiry, deferred costs of commercial product sales is reduced and cost of goods sold is increased for the cost of such inventory.

Revenue Recognition — Net Revenue — Collaborations — The Company enters into collaborations under which we must perform certain obligations and receive periodic payments. The Company evaluates 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 — Revenue — Other — In 2017, Revenue-other consists of \$1.7 million of revenue from bulk insulin sales and \$0.6 million related to the sale of intellectual property to Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd ("Fosun"), which is accounted for under the multiple-deliverable revenue recognition guidance and more fully described in Note 9 – Sale of Intellectual Property. Revenue from bulk insulin sales are 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 until such time that all criteria are met. As of December 31, 2016 the ending balance in deferred revenue included amounts related to bulk insulin sales of approximately \$1.7 million. There was no deferred revenue related to bulk insulin sales as of December 31, 2017.

Cost of Goods Sold — Cost of goods sold includes the costs related to Afrezza product dispensed by pharmacies to patients as well as the following costs which are expensed as incurred rather than capitalized into inventory: excess capacity labor and overhead, the impact of the annual revaluation of inventory and deferred costs of commercial sales to standard costs, and write-offs of inventory and deferred costs of commercial sales.

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, 2017 and 2016, cash equivalents were comprised of money market accounts with maturities less than 90 days from the date of purchase.

Restricted Cash — The Company records restricted cash when cash and cash equivalents are restricted as to withdrawal or usage. The Company presents amounts of restricted cash that will be available for use within twelve months of the reporting date as restricted cash in current assets. Restricted cash amounts that will not be available for use in the Company's operations within twelve months of the reporting date are presented as restricted cash in long term assets.

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 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. If the Company estimates that inventory that has been shipped to wholesale distributors will be returned for credit because there is a risk of product expiration, the Company reduces deferred revenue and increases the allowance for returns of such inventory. As of December 31, 2017 and 2016, the allowance for returns was de minimis. As of December 31, 2017 and 2016, there was no allowance for doubtful accounts. As of December 31, 2017 and 2016, the Company had three wholesale distributors representing approximately 93% and 95% of gross accounts receivable, respectively.

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 may become obsolete or are forecasted to 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, 2017 and 2016. As a result of these assessments, the Company recorded a \$3.0 million charge for the year

ended December 31, 2017, to write-off inventory that may expire prior to sale. For the year ended December 31, 2016 there were no write-offs to inventory. For the year ended 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.

Leases – The Company records rent expense for leases that contain scheduled rent increases on a straight-line basis over the lease term. When determining lease terms, the Company begins with the point at which the Company obtains control and possession of the leased property.

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 “State Program”). The State 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 State 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.

During the year ended December 31, 2017, there was no research and development tax credit. During the years ended December 31, 2016 and 2015, research and development expenses were offset by research and development tax credits of \$0.2 million and \$0.7 million, respectively.

Prepaid Expenses and Other Current Assets — As of December 31, 2017 and 2016, 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 \$0.4 million as collateral as required by an agreement with the bank.

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.

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 recognized as an operating loss.

The Company recorded an asset impairment of \$0.2 million, \$1.3 million and \$140.6 million for the years ended December 31, 2017, 2016 and 2015, respectively (see Note 4 — Property and Equipment).

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 are recognized unless recoverable. When making the assessment, the Company also considers whether it is able to renegotiate with its vendors. The recognized loss on purchase commitments is reduced as inventory items are received. If, subsequent to an accrual, a purchase commitment is successfully renegotiated, the gain is recognized in the Company’s consolidated statement of operations.

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. The balance of the recognized loss on insulin purchase commitments is \$109.3 million as of December 31, 2017. No new contracts were identified in 2017 or 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, 2017 and 2016, the remaining liability balance was \$8.9 million.

Fair Value of Financial Instruments — The Company applies various valuation approaches in determining the fair value of its financial assets and liabilities within a hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy is broken down into three levels based on the source of inputs as follows:

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. See Note 16 — Income Taxes for disclosure on the tax laws enacted in December 2017.

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 — 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 grant date subject to an estimated forfeiture rate. 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. 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 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. 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. As of December 31, 2017, the outstanding warrants were de minimis. At December 31, 2016, the outstanding warrants were \$7.4 million.

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 gains and losses resulting from translating cash and cash accounts in foreign currencies 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, development 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.

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 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.

Bonuses — The Company accounts for bonuses that require future service requirements by recognizing the compensation costs pro-rata over the period for which the service is rendered.

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 year ended December 31, 2015 was \$0.1 million. There were no capitalized interest costs for the years ended December 31, 2017 and 2016.

Net Income (Loss) Per Share of Common Stock — Basic net income or loss per share excludes dilution for potentially dilutive securities and is computed by dividing net income or loss by the weighted average number of common shares outstanding during the period. Diluted net income or 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 anti-dilutive.

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)*. The standard requires a company to recognize revenue to depict the transfer of goods or services when transferred to customers in an amount that reflects the consideration it expects to be entitled to receive in exchange for those goods or services. 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 March 2016, the FASB issued additional ASUs which clarified certain aspects of the new guidance. The new guidance also

requires disclosures about the nature, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments.

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 will apply the new guidance using the modified retrospective approach with the cumulative effect of initial application recognized as of January 1, 2018. Based on the expected impacts described below, the Company expects such cumulative effect adjustments to be \$1.7 million decrease to the opening balance of accumulated deficit.

The current accounting guidance requires the Company to reliably estimate returns in order to recognize revenue upon shipment. While we can currently estimate returns within a range, it is not sufficiently precise to meet the current requirements. Accordingly, the Company defers recognition of revenue on Afrezza product deliveries to wholesalers until the right of return no longer exists, which occurs at the earliest of the time Afrezza is dispensed from pharmacies to patients or expiration of the right of return. For deliveries to wholesalers, the Company recognizes revenue based on estimated Afrezza patient prescriptions dispensed, a sell-through model.

Upon adoption of the new guidance, the Company will move from its current sell-through model to a sell-to model for revenue related to commercial sales of Afrezza to wholesalers and will record revenue at the time title and risk of loss passes to its distributors (generally at 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 three months of sales history that it will have obtained by the end of the first quarter of 2018.

For sales of Afrezza to specialty pharmacies, the Company currently recognizes revenue at the time of shipment because specialty pharmacies generally purchase on demand and our estimated returns are minimal. The Company does not expect a material impact upon adoption for sales to specialty pharmacies.

Additionally, the Company has historically entered into collaborative agreements with third parties under which periodic payments have been received. Revenue recognition for certain payments received have 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 all contingencies have been resolved. 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 does not expect a material impact upon adoption for collaborative agreements.

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 adoption of this standard is not expected to materially impact the Company's consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. The new standard requires that all lessees recognize the assets and liabilities that arise from operating leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements. 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.

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 adoption of this standard is not expected to materially impact the Company's 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, 2017, including interim periods within those periods, using a retrospective transition method to each period presented. The Company early adopted ASU 2016-18 in the last quarter of 2017. As a result, restricted cash of approximately \$4.4 million as of December 31, 2017 is included with cash and cash equivalents when reconciling the beginning and ending balances in the statements of cash flows. There were no restricted cash balances prior to 2017.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*. The ASU clarifies the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. ASU 2017-01 is effective for fiscal years beginning after December 15, 2017, including interim periods within those periods. Early adoption is permitted. The Company early adopted ASU 2017-01 in the first quarter of 2017, and it did not result in a material impact on the Company's consolidated financial statements and related disclosures.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting*. This ASU reduces both diversity in practice and cost and complexity when applying *ASC 718* to a change in the terms or conditions of a share-based payment award. *ASU 2017-09* is effective for fiscal years beginning after December 15, 2017, including interim periods within those periods. Early adoption is permitted. The adoption of this standard is not expected to materially impact the Company's consolidated financial statements.

In July 2017, the FASB issued ASU No. 2017-11, *Earnings per Share (Topic 260) and Derivatives and Hedging (Topic 815): Accounting for Certain Financial Instruments with Down Round Provisions*. This ASU addresses the complexity and cost of accounting for certain financial instruments with down round features that require fair value measurement of the entire instrument or conversion option and requires entities that present earnings per share in accordance with Topic 260 to recognize the effect of the down round feature when it is triggered. ASU 2017-11 is effective for fiscal years beginning after December 15, 2018, including interim periods within those periods. The adoption of this standard is not expected to materially impact the Company's consolidated financial statements.

3. Inventories

Inventories consist of the following (in thousands):

	December 31,	
	2017	2016
Raw materials	\$ 572	\$ —
Work-in-process	1,273	2,120
Finished goods	812	211
Total inventory	<u>\$ 2,657</u>	<u>\$ 2,331</u>

Work-in-process and finished goods as of December 31, 2017 and 2016 include conversion costs but not materials cost because the materials used in its production were previously written off. During the years ended December 31, 2017 and 2015, the Company recorded a write-down of inventory of approximately \$3.0 million and \$36.1 million, respectively, for inventory that was forecasted to become obsolete due to expiration which is recorded in costs of goods sold in the accompanying consolidated statements of operations. There was no write-down of inventory for the year ended December 31, 2016.

4. Property and Equipment

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

	Estimated Useful Life (Years)	December 31,	
		2017	2016
Land	—	\$ 875	\$ 875
Buildings	39-40	17,389	17,389
Building improvements	5-40	34,957	34,957
Machinery and equipment	3-15	62,681	62,992
Furniture, fixtures and office equipment	5-10	3,556	3,556
Computer equipment and software	3	8,416	8,531
Construction in progress	—	—	202
		<u>127,874</u>	<u>128,502</u>
Less accumulated depreciation		<u>(100,952)</u>	<u>(99,575)</u>
Total property and equipment, net		<u>\$ 26,922</u>	<u>\$ 28,927</u>

Depreciation and amortization expense related to property and equipment for the years ended December 31, 2017, 2016 and 2015, was \$1.8 million, \$2.4 million and \$11.0 million, respectively.

In 2015, 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.

Based on the evaluation performed it was determined that the probability weighted undiscounted cash flows were not sufficient to recover the carrying value of the Danbury manufacturing facility. 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.

An 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 accompanying consolidated statements of operations, additionally with a \$0.6 million impairment charge related to assets held for sale.

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. This asset in the amount of \$16.7 million was classified as held for sale as of December 31, 2016. The sale and purchase of the Property for \$17.3 million pursuant to the terms of the Purchase Agreement, as amended, was completed on February 17, 2017. Net proceeds were \$16.7 million after deducting broker’s commission and other fees of approximately \$0.6 million paid by the Company. Net proceeds received approximated the carrying value of the asset 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,	
	2017	2016
Salary and related expenses	\$ 7,260	\$ 3,814
Current portion of milestone rights liability	1,643	—
Professional fees	1,007	875
Discounts and allowances for commercial product sales	873	754
Sales and marketing services	147	144
Restructuring	362	1,376
Accrued interest	567	619
Other	590	355
Accrued expenses and other current liabilities	<u>\$ 12,449</u>	<u>\$ 7,937</u>

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, described in the Company’s consolidated balance sheets as Note Payable to Principal Stockholder, 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.

On June 27, 2017, the Company entered into an agreement with The Mann Group, pursuant to which the parties agreed to, among other things, (i) capitalize \$10.7 million of accrued and unpaid interest as of June 30, 2017, resulting in such amount being classified as outstanding principal under The Mann Group Loan Arrangement; (ii) advance to the Company approximately \$19.4 million of cash, the remaining amount available for borrowing by the Company under The Mann Group Loan Arrangement after the foregoing capitalization of accrued and unpaid interest; and (iii) defer all interest payable on the outstanding principal until July 1, 2018, unless such payments are otherwise permitted under the subordination agreement with Deerfield, and subject to further deferral pursuant to the terms of the subordination agreement with Deerfield which terms are more fully disclosed below.

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. The Mann Group can require the Company to prepay up to \$200.0 million in advances that have been outstanding for at least 12 months, less approximately \$105.0 million aggregate principal amount that has been cancelled in connection with two common stock purchase agreements. If The Mann Group exercises this right, the Company will have 90 days after The Mann Group provides written notice, or the number of days to maturity of the note if less than 90 days, to prepay such advances. However, pursuant to a letter agreement entered into in August 2010, The Mann Group has agreed to not require the Company to prepay amounts outstanding under the amended and restated promissory note if the prepayment would require the Company to use its working capital resources. In addition, The Mann Group entered into a subordination agreement with Deerfield pursuant to which The Mann Group agreed with Deerfield not to demand or accept any payment under The Mann Group Loan Arrangement until the Company’s payment obligations to Deerfield under the Facility Agreement have been satisfied in full. Subject to the foregoing, in the event of a default under The Mann Group Loan Arrangement, all

unpaid principal and interest either becomes immediately due and payable or may be accelerated at The Mann Group's option, and the interest rate will increase to the one-year LIBOR 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, 2017 and 2016, the total principal amount outstanding under The Mann Group Loan Arrangement was \$79.7 million and \$49.5 million, respectively. As of December 31, 2017 and 2016, the Company had accrued unpaid interest related to the above note of \$2.3 million and \$9.3 million, respectively. Interest expense for the years ended December 31, 2017, 2016 and 2015 was \$3.8 million, \$2.9 million, and \$2.9 million, respectively. As of December 31, 2017 there were no additional amounts available for future borrowings. As of December 31, 2016 there was \$30.1 million available for future borrowings.

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 was for approximately 12,500 square feet of office space in Valencia, California, which expired in April 2017 and was renewed on a month-to-month basis at a rate of \$20,000 per month until August 31, 2017 when the Company moved into its new corporate headquarters (see Note 14 — Commitments and Contingencies). Lease payments to the Mann Foundation for the years ended December 31, 2017, 2016 and 2015 were \$0.2 million, \$0.3 million, and \$0.2 million, respectively.

The Company has entered into indemnification agreements with each of its directors and executive officers, in addition to the indemnification provided for in its amended and restated certificate of incorporation and amended and restated bylaws (see Note 14 — Commitments and Contingencies).

On October 10, 2017, the Company entered into securities purchase agreements (the "Purchase Agreements") with certain institutional investors and a charitable foundation (collectively, the "Purchasers"). Included in this offering were 166,600 shares issued to a charitable foundation associated with the Chairman of the Company's board of directors.

7. Borrowings

Borrowings consist of the following (in thousands):

	December 31,	
	2017	2016
Facility Financing Obligation (2019 Notes and Tranche B Notes)		
Principal amount	\$ 54,407	\$ 75,000
Unamortized debt issuance costs and debt discount	(1,662)	(3,661)
Net carrying amount	<u>\$ 52,745</u>	<u>\$ 71,339</u>
Senior Convertible Notes (2021 Notes)		
Principal amount	\$ 23,690	\$ 27,690
Unamortized premium	721	426
Unaccrued debt issuance costs	—	(481)
Net carrying amount	<u>\$ 24,411</u>	<u>\$ 27,635</u>
Note payable to principal stockholder - net carrying amount	<u>\$ 79,666</u>	<u>\$ 49,521</u>

Facility Financing Obligation (2019 Notes and Tranche B Notes) – As of December 31, 2017, there were \$39.4 million principal amount of 2019 notes and \$15.0 million principal amount of Tranche B notes outstanding. 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. 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.

On April 18, 2017, the Company entered into an Exchange Agreement with Deerfield pursuant to which the Company agreed to, among other things, (i) repay \$4.0 million principal amount under the Tranche B notes; (ii) exchange \$1.0 million principal amount under the Tranche B notes for 869,565 shares of the Company's common stock (the "Tranche B Exchange Shares"); and (iii) exchange \$5.0 million principal amount under the 2019 notes for 4,347,826 shares of the Company's common stock (together with the "Tranche B Exchange Shares," the "April Exchange Shares"). The exchange price for the Exchange Shares was \$1.15 per share.

The Company determined that, since the principal amount repaid and exchanged under the Tranche B notes and the principal amount exchanged under the 2019 notes represented the principal amount that would have otherwise become due and payable in May and July of 2017 under the Tranche B notes and 2019 notes, respectively, the extinguishment of the May and July 2017 payments was not considered to be a

troubled debt restructuring. Accordingly, the Company accounted for the transaction by recording a loss on extinguishment of debt of \$0.3 million at April 18, 2017 which was calculated as the difference between the reacquisition price and the net carrying value of the related debt. The reacquisition price was calculated using the \$4.0 million cash repayment and the fair value of the April Exchange Shares on April 18, 2017. The fair value of the April Exchange Shares was determined to be \$1.22 per share representing the closing trading price of the Company's common stock on The NASDAQ Global Market on April 18, 2017.

On June 29, 2017, the Company entered into the Third Amendment with Deerfield, pursuant to which the Company agreed to, among other things, (i) exchange \$5.0 million principal amount under the Company's 2019 notes for 3,584,230 shares of the Company's common stock (the "June Exchange Shares") at an exchange price of \$1.395 per share and (ii) amend the Facility Agreement with Deerfield, to (A) defer the payment of \$10.0 million in principal amount of the 2019 notes from the original July 18, 2017 due date to August 31, 2017, which was further deferred to October 31, 2017 upon the Company's delivery on August 31, 2017 and October 30, 2017 of a written certification to Deerfield that certain conditions had been met, including that no event of default under the Facility Agreement had occurred, Michael E. Castagna remains the Company's Chief Executive Officer, the Company received the advance from The Mann Group (see Note 6 — Related-Party Arrangements), the Company had at least \$10.0 million in cash and cash equivalents on hand, no material adverse effect on the Company had occurred, the engagement letter between the Company and Greenhill & Co., Inc. ("Greenhill") remained in full force and effect and Greenhill had remained actively engaged in exploring capital structure and financial alternatives on behalf of the Company in accordance with such engagement letter (collectively, the "Extension Conditions"), and (B) amend the Company's financial covenant under the Facility Agreement to provide that, if the Extension Conditions remain satisfied, the obligation under the Facility Agreement to maintain at least \$25.0 million in cash and cash equivalents as of the end of each quarter, was reduced to \$10.0 million as of August 31, 2017, September 30, 2017, October 31, 2017 and December 31, 2017 if certain conditions were met. We met the conditions at each of these month-ends.

The Company determined that since the principal amount repaid and exchanged under the 2019 notes represented the principal amount that would have otherwise become due and payable under the 2019 notes, the \$5.0 million prepayment was not considered to be a troubled debt restructuring. Accordingly, the Company accounted for the transaction by recording a loss on extinguishment of debt of \$0.5 million on June 29, 2017 which was calculated as the difference between the reacquisition price and the net carrying value of the related debt. The net carrying value of the related debt includes the acceleration of the debt discount and issuance costs amounting to approximately \$0.3 million as a result of the transaction. The reacquisition price was calculated using the fair value of the June Exchange Shares on June 29, 2017. The fair value of the Exchange Shares was determined to be \$1.45 per share representing the closing trading price of the Company's common stock on The NASDAQ Global Market on June 29, 2017.

On October 23, 2017, the Company and MannKind LLC entered into a Fourth Amendment to the Facility Agreement, pursuant to which the parties (i) deferred the payment of \$10.0 million in principal amount (the "October Payment") of the Facility Financing Obligation from October 31, 2017 to January 15, 2018 (further extended to January 19, 2018 under the Fifth Amendment and May 6, 2018 under the Sixth Amendment to the Facility Agreement – See Note 20 - Subsequent Events), with the Company depositing an amount of cash equal to the October Payment into an escrow account until the October Payment has been satisfied in full (subject to early release to the extent that portions of the October Payment are satisfied through the exchange of principal for shares of the Company's common stock), and (ii) amended and restated the Facility Financing Obligation and the Tranche B notes to provide that Deerfield may convert the principal amount under such notes from time to time into an aggregate of up to 4,000,000 shares of the Company's common stock after the effective date of the Fourth Amendment. The conversion price will be the greater of (i) the average of the volume weighted average price per share of the Company's common stock for the three trading day period immediately preceding the date of any election by Deerfield to convert principal amounts of such notes and (ii) \$3.25 per share, subject to adjustment under certain circumstances. Any conversions of principal by Deerfield under such notes will be applied first to reduce the October Payment, and after the October Payment has been satisfied, to reduce other principal payments due under the 2019 notes or the Tranche B notes.

The Company determined that the Fourth Amendment did not include any concessions and that the addition of the conversion option was not substantive and therefore it was not considered to be a troubled debt restructuring. Accordingly, the Company accounted for the transaction as a modification. On November 6, 2017 Deerfield converted 1,720,846 shares under the conversion feature at a price of \$3.25/share, redeeming \$5,592,750 of principal.

As of December 31, 2017, there was \$39.4 million principal amount of 2019 notes and \$15.0 million principal amount of Tranche B notes outstanding. The 2019 notes accrue interest at an 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 payments which began on July 1, 2016 and end on December 9, 2019. As of December 31, 2017, future payments for the years ending December 31, 2018, and 2019 are \$24.4 million and \$30.0 million, respectively.

In connection with the Facility Agreement, on July 1, 2013, the Company entered into a Milestone Rights Purchase Agreement (the "Milestone Agreement") with Deerfield and Horizon Santé FLML SÁRL (collectively, the "Milestone Purchasers"), which requires the Company to make contingent payments to the Milestone Purchasers, totaling up to \$90.0 million, upon the Company achieving specified commercialization milestones (the "Milestone Rights"). The Milestone Rights were initially recorded as a short-term liability equal to \$3.2 million included in accrued expenses and other current liabilities and a long-term liability equal to \$13.1 million included in other liabilities in the accompanying consolidated balance sheets. During the first quarter of 2015, a milestone triggering event was achieved following the Afrezza

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 \$10.0 million milestone payment made in February 2015.

As of December 31, 2017 and 2016, the remaining milestone rights liability balance was \$8.9 million. The Company currently estimates that it will reach the next milestone in the third quarter of 2018, at which point the Company will be required to make a \$5 million payment. The carrying value of the milestone rights liability related to this \$5 million payment is \$1.6 million, which represents the fair value related to this payment that was determined in 2013 (the most recent measurement date). Accordingly, \$1.6 million in value related to the next milestone payment was recorded in accrued expenses and other current liabilities as of December 31, 2017. Furthermore, \$7.2 million and \$8.9 million was recorded in milestone rights liability and other liabilities, which is non-current, in the accompanying consolidated balance sheets as of December 31, 2017 and 2016, respectively.

Accretion of debt issuance cost and debt discount in connection with the Facility Agreement does not include the acceleration of the debt discount and issuance costs related to the transactions disclosed above as the amounts were included in the loss on extinguishment of debt in the consolidated statement of operations. Accretion of debt issuance cost and debt discount during the years ended December 31, 2017, 2016 and 2015 were as follows (in thousands):

	December 31,		
	2017	2016	2015
Accretion expense - debt issuance cost	\$ 31	\$ 35	\$ 35
Accretion expense - debt discount	\$ 1,700	\$ 1,722	\$ 1,553

The Facility Agreement includes customary representations, warranties and covenants, including a restriction on the incurrence of additional indebtedness. 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 Facility Financing Obligation has been classified as a current liability in the accompanying consolidated balance sheets as of December 31, 2017 and 2016. In the event of non-compliance, Deerfield may declare all or any portion of the Facility Financing Obligation 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 initially recorded the Milestone Rights at their estimated fair value.

Security Agreement — In connection with the Facility Agreement and Milestone Agreement, the Company and its subsidiary, MannKind LLC, entered into a Guaranty and Security Agreement (the “Security Agreement”) with Deerfield and Horizon Santé FLML SÀRL (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 Facility Financing Obligation, if applicable, in full.

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. All of the embedded derivatives were determined to have a *de minimis* value as of December 31, 2017 and 2016.

Senior Convertible Notes Due 2021 — On October 23, 2017, the Company entered into exchange agreements with the holders of the Company’s 5.75% Senior Convertible Notes due 2018 (the “2018 notes”), pursuant to which the Company agreed to exchange all of the outstanding 2018 notes in the aggregate principal amount of \$27,690,000 for (i) 23,690,000 aggregate principal amount of Senior Convertible notes due 2021 (the “2021 notes”) and (ii) an aggregate of 973,236 shares of its common stock. In addition, the conversion rate was adjusted from \$34 per share to \$5.15 per share. The 2021 notes were issued at the closing of the exchange on October 23, 2017. The Company analyzed this exchange and concluded that the exchange represents an extinguishment of the 2018 notes and recorded a \$0.8 loss on extinguishment of debt. In addition unamortized debt issuance costs of \$0.3 million and unamortized debt premium of \$0.2 million were also written-off during the last quarter of fiscal year 2017.

The 2021 notes are the Company’s general, unsecured, senior obligations, except that they are subordinated in right of payment to the Facility Financing Obligation. The 2021 notes rank equally in right of payment with the Company’s other unsecured senior debt. The 2021 notes bear interest at the rate of 5.75% per year on the principal amount, payable semiannually in arrears in cash or, at the option of the Company if certain conditions are met, in shares of the Company’s common stock (the “Interest Shares”), on February 15 and August 15 of each year, beginning February 15, 2018, with interest accruing from August 15, 2017. The aggregate number of Interest Shares that the Company may issue

may not exceed 13,648,300, unless the Company receives stockholder approval to issue Interest Shares in excess of such number in accordance with the listing standards of the NASDAQ Global Market. Accrued interest related to these notes is recorded in accrued expenses and other current liabilities on the accompanying consolidated balance sheets.

The 2021 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 194.1748 shares per \$1,000 principal amount of 2021 notes, which is equal to the initial conversion price of approximately \$5.15 per share. The conversion rate is subject to adjustment under certain circumstances described in an indenture governing the 2021 notes.

If the Company undergoes certain fundamental changes, except in certain circumstances, each holder of 2021 notes will have the option to require the Company to repurchase all or any portion of that holder's 2021 notes. The fundamental change repurchase price will be 100% of the principal amount of the 2021 notes to be repurchased plus accrued and unpaid interest, if any.

The Company may elect at its option to cause all or any portion of the 2021 notes to be mandatorily converted in whole or in part at any time prior to the close of business on the business day immediately preceding the maturity date, if the last reported sale price of its common stock exceeds 120% of the conversion price then in effect for at least 10 trading days in any 20 consecutive trading day period, ending within five business days prior to the date of the mandatory conversion notice. The redemption price is equal the sum of 100% of the principal amount of the 2021 notes to be redeemed, plus accrued and unpaid interest. Under the terms of the 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 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 2021 notes under existing commitments. Applying the Company's sequencing policy, the Company performed an analysis at the time of the offering of the 2021 notes and each reporting date since and has concluded that the number of available authorized shares at the time of the offering and each reporting date since was sufficient to deliver the number of shares that could be required to be delivered during the term of the 2021 notes under existing commitments.

The 2021 notes provide that upon an acceleration of certain indebtedness, including the 2019 notes and 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.

As a result of the exchange of the 2021 notes during the last quarter of 2017, the Company recorded approximately \$0.8 million in debt premium, which is recorded with the 2021 notes, in the accompanying consolidated balance sheets. The premium is being accreted to interest expense using the effective interest method over the term of the 2021 notes.

Accretion of debt issuance costs in connection with the 2018 notes during the years ended December 31, 2017 and 2016 was \$0.2 million and \$0.3 million, respectively. Amortization of the 2018 notes premium during the years ended December 31, 2017 and 2016 was \$0.2 million and \$0.2 million, respectively. Amortization of the 2021 notes premium during the year ended December 31, 2017 was \$0.03 million.

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 and Receptor obtained the option to acquire an exclusive license to develop, manufacture and commercialize certain products that use the Company'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, following successful completion of the studies, Receptor exercised its 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 sublicensees' sale of the product; and
- 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 as of December 31, 2016 and will be recognized in net revenue — collaboration over four

years. Recognized revenue related to this license agreement amounted to \$0.3 million for the year ended December 31, 2017. See Note 2 — Summary of Significant Accounting Policies for additional information on the Company's accounting for multiple element arrangements.

On March 15, 2017, the Company entered into a Manufacturing and Supply Agreement with Receptor pursuant to which the Company will provide certain raw materials to Receptor. On March 16, 2017, the Company agreed to provide certain additional research and formulation consulting services to Receptor. For the year ended December 31, 2017 the additional research and formulation services to Receptor were de minimis.

Sanofi License Agreement and Sanofi Supply Agreement — On August 11, 2014, the Company entered into a license and collaboration agreement with Sanofi ("Sanofi License Agreement"), 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 April 4, 2016 the Sanofi License Agreement was terminated. 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 in July 2016.

The Company analyzed the agreements entered into with Sanofi at their inception and determined that 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 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.

During the third quarter of 2016, Sanofi provided 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 a senior secured revolving promissory note and a guaranty and security agreement (collectively, the "Sanofi Loan Facility") 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.

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'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 share for the quarters ended December 31, 2015 and March 31, 2016. The total amount owed to Sanofi at September 30, 2016 was \$71.2 million, which included \$5.8 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, 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 settlement was accounted for in the year ended December 31, 2016, except for a \$30.6 million cash payment received under the insulin put option agreement which reduced the receivable from Sanofi in the first quarter of 2017.

9. Sale of Intellectual Property

On April 12, 2017 the Company entered into an agreement to sell certain oncology assets and patents to Fosun. Fosun paid the Company a one-time nonrefundable payment of \$0.6 million net of taxes in June 2017 and is required to pay royalties on net sales of products by Fosun and its affiliates and other consideration based on revenues from any licensees. The Company determined that the sale of the assets did not constitute a business and accordingly accounted for the transaction as a sale of assets. The Company evaluated the accounting for the payments received in 2017 under the multiple element accounting guidance and recorded the \$0.6 million in payments received in revenue – other in the accompanying consolidated financial statements during the second quarter of 2017 as the deliverables under the agreement were substantially delivered as of June 30, 2017. See Note 2 — Summary of Significant Accounting Policies for additional information on the Company’s accounting for multiple element arrangements. The Company also evaluated the accounting for royalties and other consideration in the agreement. Since the amount of product that Fosun will ultimately be able to sell upon successfully utilizing this technology is uncertain, no royalty revenue will be recognized until such time when Fosun or its affiliates sell product to a third party and royalties are due to the Company.

10. Fair Value of Financial Instruments

The availability of observable inputs can vary among the various types of financial assets and liabilities. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, for financial statement disclosure purposes, the level in the fair value hierarchy within which the fair value measurement is categorized is based on the lowest level input that is significant to the overall fair value measurement.

The carrying amounts reported in the accompanying consolidated financial statements for cash, accounts receivable, accounts payable, and accrued expenses and other current liabilities (excluding the milestone rights liability) approximate their fair value due to their relatively short maturities. The fair value of the cash equivalents, note payable to principal stockholder (also referred to as The Mann Group Loan Arrangement), senior convertible notes, the facility financing obligation, the milestone rights liability and the warrant liability are disclosed in Note 10 – Fair Value of Financial Instruments.

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 — Cash equivalents consist of highly liquid investments with original or remaining maturities of 90 days or less at the time of purchase, that are readily convertible into cash. As of December 31, 2017 and 2016, the Company held \$41.0 million and \$20.5 million, respectively, of cash equivalents, comprised 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, 2017				
	Carrying Amount	Fair Value Measurements Using			Fair Value
Quoted Price in Active Markets for Identical Assets (Level 1)		Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)		
Financial liabilities:					
Senior convertible notes (2021 notes)	\$ 24.4	\$ —	\$ —	\$ 19.8	\$ 19.8
Facility financing obligation	52.7	—	—	54.6	54.6
Milestone rights	8.9	—	—	19.1	19.1
Total financial liabilities	\$ 86.0	\$ —	\$ —	\$ 93.5	\$ 93.5

As of December 31, 2016

	Carrying Value	Fair Value Measurements Using			Fair Value
		Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Financial liabilities:					
Senior convertible notes (2018 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 value)	7.4	—	—	7.4	7.4
Total financial liabilities	<u>\$ 115.2</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 123.2</u>	<u>\$ 123.2</u>

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, 2016	\$ —	\$ —
Additions	12.8	17.3
Changes in fair value	(5.4)	(0.6)
Payments	—	—
Fair value, December 31, 2016	<u>\$ 7.4</u>	<u>\$ 16.7</u>
Additions	—	—
Changes in fair value	(5.5)	—
Settlement through exchange of common shares	(1.9)	—
Payments	—	(16.7)
Fair value, December 31, 2017	<u>\$ —</u>	<u>\$ —</u>

Senior Convertible Notes — The estimated fair value of the 2021 notes was calculated based on model-derived valuations whose inputs were observable, such as the Company’s stock price and yields on U.S. Treasury notes and actively traded bonds, and non-observable, such as the Company’s longer-term historical volatility, and estimated yields implied from any available market trades of the Company’s issued debt instruments. As there was no current active and observable market for the 2021 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 (102%) and recent price quotes and trading information regarding Company issued debt instruments and shares of common stock into which the notes are convertible (Level 3 in the fair value hierarchy).

Facility Financing Obligation — As discussed in Note 7 — Borrowings, the Company issued 2019 notes and subsequently issued Tranche B notes (the “Facility Financing Obligation”) in connection with the Facility Agreement. 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, 2017, the market discount rate was 12-13% for the principal 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 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 progress made to date and assessment of criteria required for achievement, and external data, such as market research studies. The discount rate (14%) was selected based on an estimation of required rate of returns for similar investment opportunities using available market data. As of December 31, 2017, the carrying value of the milestone rights liability was \$8.9 million and the fair value was estimated at \$19.1 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 six months later than in the current forecast, the fair value of the liability would decrease by 4%. If the probabilities of meeting the \$50 to \$200 million milestones were to decrease by 5% or 10%, the fair value of the liability would decrease by 14% and 28%, respectively. Over the long term, these inputs are interrelated because if the Company’s 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.

Warrant Liability— Warrant liabilities were measured at fair value using a Monte Carlo pricing valuation model. The assumptions used in the valuation model for the common stock warrant liabilities were: (a) a risk-free interest rate based on the rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the remaining contractual term of the warrants; (b) an assumed dividend yield of zero percent based on the Company's expectation that it will pay no dividends in the foreseeable future; (c) an expected term based on the remaining contractual term of the warrants; (d) an expected volatility based upon the Company's historical volatility over the remaining contractual term of the warrants; and (e) probability of a dilutive financing that may trigger a price protection clause. 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).

Assets and Liabilities Measured at Fair Value on a Non-recurring Basis— 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, 2017 and 2016.

11. Common and Preferred Stock

On December 13, 2017, the Company approved a proposal to amend the Company's Amended and Restated Certificate of Incorporation to increase the authorized number of shares of the Company's common stock from 140,000,000 to 280,000,000 shares. The Company is authorized to issue 280,000,000 shares of common stock, par value \$0.01 per share, and 10,000,000 shares of undesignated preferred stock, par value \$0.01 per share, issuable in one or more series as designated by the Company's board of directors. No other class of capital stock is authorized. As of December 31, 2017 and 2016, 119,053,414 and 95,680,831 shares of common stock, respectively, were issued and outstanding and no shares of preferred stock were outstanding.

In November 2017, the Company sold an aggregate of 173,327 shares of the Company's common stock at a purchase price of \$3.15 per share pursuant to the Company's At Market Issuance Sales Agreement with FBR Capital Markets & Co. The aggregate gross proceeds from the sales were approximately \$0.5 million.

On October 10, 2017, the Company entered into securities purchase agreements (the "Purchase Agreements") with certain institutional investors and a charitable foundation (collectively, the "Purchasers"). Pursuant to the terms of the Purchase Agreements, the Company sold to the Purchasers in a registered offering an aggregate of 10,166,600 shares of the Company's common stock at a purchase price of \$6.00 per share. Included in this offering was 166,600 shares issued to a charitable foundation associated with the Chairman of the Company's board of directors. The net proceeds to the Company from the offering were approximately \$57.7 million, after deducting placement agent fees equal to 5.0% of the aggregate gross proceeds from the offering (except for the proceeds received from the sale of 166,600 shares issued to the charitable foundation) and offering expenses payable by the Company. The offering closed on October 13, 2017.

On March 1, 2017, the Company effected a 1-for-5 reverse stock split of the Company's outstanding common stock. As a result, prior to March 1, 2017, 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 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 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 approximately 32,000 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, 2017.

The Company's stock was delisted from the TASE in November of 2017.

During 2014, the Company loaned to Bank of America 1,800,000 shares of common stock 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.

For the year ended December 31, 2015, the Company received \$10.1 million in proceeds 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.

12. Net Income (Loss) per Common Share

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 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 (in thousands, except per share amounts):

	Year Ended December 31,		
	2017	2016	2015
Basic EPS:			
Net (loss) income (numerator)	\$ (117,333)	\$ 125,664	\$ (368,445)
Weighted average common shares (denominator)	104,245	92,053	81,233
Net (loss) income per share	\$ (1.13)	\$ 1.37	\$ (4.54)
Diluted EPS:			
Net (loss) income (numerator)	\$ (117,333)	\$ 125,664	\$ (368,445)
Weighted average common shares	104,245	92,053	81,233
Effect of dilutive securities - common shares issuable	—	32	—
Adjusted weighted average common shares (denominator)	104,245	92,085	81,233
Net (loss) income per share	\$ (1.13)	\$ 1.36	\$ (4.54)

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 2021 notes or the Facility Financing Obligation.

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

	December 31,		
	2017	2016	2015
Exercise of common stock options	7,089,440	5,530,256	3,955,845
Conversion of convertible notes into common stock	6,875,272	814,561	814,561
Employee stock purchase plan	136,660	43,672	33,986
Exercise of common stock warrants	31,856	9,740,597	814,919
Vesting of restricted stock units	1,135,216	702,867	360,924
	<u>15,268,444</u>	<u>16,831,953</u>	<u>5,980,235</u>

Subsequent to December 31, 2017, the Company entered into an amendment to the Deerfield Facility Financing Obligation allowing additional principal amounts to be converted into equity. See Note 20 – Subsequent Events for further information.

13. Stock Award Plans

On May 23, 2013, the Company adopted the 2013 Equity Incentive Plan (the “2013 Plan”) as the successor to and continuation of the 2004 Equity Incentive Plan (the “2004 Plan”). The 2013 Plan consists of 4.3 million additional shares and the number of unallocated shares remaining available for grant for new awards under the 2004 Plan. The 2013 Plan provides for the granting of stock awards including stock options and restricted stock units, to employees, directors and consultants. 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, 2017:

	Outstanding Options	Outstanding Restricted Stock Units	Shares Available for Future Issuance
2004 Equity Incentive Plan	1,231,740	—	—
2013 Equity Incentive Plan	5,795,035	1,135,216	1,509,343
2004 Non-Employee Directors’ Stock Option Plan	62,665	—	—
Total	7,089,440	1,135,216	1,509,343

In March 2004, 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 ESPP 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. As of December 31, 2017, 246,205 shares were available for issuance under the ESPP. For the years ended December 31, 2017, 2016 and 2015, the Company sold 199,578, 104,758 and 64,245 shares, respectively, of its common stock to employees participating in the ESPP. The ESPP purchase of 136,660 shares for the year ended December 31, 2017 was initiated prior to year-end but did not settle until January 3, 2018. As a result, the shares sold are reflected in the ESPP share reserves but are excluded from common stock outstanding as of December 31, 2017.

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.

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, 2017, there were options to purchase 23,047 shares of common stock outstanding to consultants.

During the years ended December 31, 2017, 2016 and 2015, the Company recorded stock-based compensation expense of \$4.8 million, \$5.1 million and \$8.7 million, respectively.

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

	Year Ended December 31,		
	2017	2016	2015
Employee-related	\$ 4,847	\$ 5,135	\$ 8,407
Consultant-related	—	—	318
Total	\$ 4,847	\$ 5,135	\$ 8,725

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,		
	2017	2016	2015
Cost of goods sold	\$ 460	\$ 695	\$ —
Research and development	1,010	1,309	3,029
Selling, general and administrative	3,377	3,131	5,696
Total	<u>\$ 4,847</u>	<u>\$ 5,135</u>	<u>\$ 8,725</u>

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, 2017, 2016 and 2015 using the following assumptions:

	Year Ended December 31,		
	2017	2016	2015
Risk-free interest rate	1.83% — 2.13%	1.18% — 1.80%	1.61% — 1.86%
Expected lives	5.41 — 5.78 years	5.13 — 5.82 years	5.79 — 5.86 years
Volatility	83.32% — 90.39%	77.57% — 82.75%	69.76% — 71.84%
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, 2017	5,530,256	\$ 16.10	
Granted	3,335,385	1.60	
Exercised	(5,300)	4.55	
Forfeited	(598,204)	3.17	
Expired	<u>(1,172,697)</u>	<u>22.21</u>	
Outstanding at December 31, 2017	7,089,440	\$ 9.33	\$ 2,484
Vested and expected to vest at December 31, 2017	6,735,675	\$ 9.70	\$ 2,262
Exercisable at December 31, 2017	2,813,227	\$ 19.52	\$ 61

The weighted average grant date fair value of the stock options granted during the years ended December 31, 2017, 2016 and 2015 was \$1.19, \$3.05 and \$12.80 per option, respectively. The total intrinsic value of options exercised during the year ended December 31, 2017 was de minimis. The total intrinsic value of options exercised during the years ended December 31, 2016 and 2015 was \$0.1 million and \$6.2 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, 2017, 2016 and 2015 was approximately \$0.02 million, \$0.5 million and \$3.3 million, respectively. The weighted-average remaining contractual terms for options outstanding, vested and expected to vest and exercisable at December 31, 2017 was 6.87 years, 6.75 years and 3.57 years, respectively.

A summary of restricted stock unit activity for the year ended December 31, 2017 is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value per Share
Outstanding at January 1, 2017	737,966	\$ 8.40
Granted	669,091	1.36
Vested	(192,361)	10.02
Forfeited	(79,480)	5.89
Outstanding at December 31, 2017	<u>1,135,216</u>	<u>\$ 4.08</u>

The total restricted stock units expected to vest as of December 31, 2017 was 939,240 with a weighted average grant date fair value of \$4.28 per share. The total intrinsic value of restricted stock units expected to vest as of December 31, 2017 was \$2.2 million. Intrinsic value of restricted stock units expected to vest is measured using the closing share price at December 31, 2017.

Total intrinsic value of restricted stock units vested during the years ended December 31, 2017, 2016 and 2015 was \$0.4 million, \$0.6 million and \$5.2 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, 2017, 2016 and 2015 was \$1.9 million, \$2.6 million and \$5.5 million, respectively.

As of December 31, 2017, there was \$2.9 million and \$3.2 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 2.3 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, 2017 and 2016, the Company recognized \$0.9 million and \$0.3 million of compensation costs related to the performance-based stock options, respectively. As of December 31, 2017, there was \$3.5 million of unrecognized compensation costs related to performance-based stock options subject to performance conditions.

During the year ended December 31, 2015, there was \$1.6 million of stock compensation expense related to certain executives who entered into severance agreements which resulted in a modification to the terms of their awards. The severance agreements generally allowed for the separated executives to continue to vest under their original award terms for a stated period of time without providing substantive services. There were no modifications in 2017 or 2016.

14. Commitments and Contingencies

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, 2017, the Company believes that the final disposition of such matters will not have a material adverse effect on the financial position, results of operations or cash flows of the Company and no accrual has been recorded. The Company maintains liability insurance coverage to protect the Company's assets from losses arising out of or involving activities associated with ongoing and normal business operations. 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 proceedings and claims as they are incurred.

Following the public announcement of Sanofi's election to terminate the Sanofi License Agreement and the subsequent decline in the Company's stock price, 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 alleged 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 damages. In November 2016, the district court dismissed one of the actions without prejudice. In the remaining action, the district court recently ruled that U.S. law will apply to this case. The Company is in the process of preparing a response to the plaintiff's motion to certify the case as a class action. The Company will vigorously defend against the claims advanced.

Contingencies — In connection with the Facility Agreement, on July 1, 2013, the Company also entered into a the Milestone Agreement with 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).

Commitments — 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 manufactures for and supplies to the Company certain quantities of recombinant human insulin for use in Afrezza. Under the terms of the Insulin Supply Agreement, Amphastar is responsible for manufacturing the insulin in accordance with the Company’s specifications and agreed-upon quality standards.

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 2018 through 2023 total an aggregate purchase price of €90.3 million at December 31, 2017. 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 certain 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:

2018	€	8.9 million
2019	€	11.6 million
2020	€	15.5 million
2021	€	15.5 million
2022	€	19.4 million
2023	€	19.4 million

The Company took delivery of the required amount of insulin under the contract in 2017 but was only obligated to pay for half prior to December 31, 2017. Accordingly, approximately \$1.6 million is included in accounts payable at December 31, 2017 related to the 2017 purchase requirement. The Company also paid cancellation fees of \$1.4 million in 2017, which were previously included in the recognized loss on purchase commitments.

Unless terminated earlier, the term of the Insulin Supply Agreement with Amphastar 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. 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.

At December 31, 2017, the Company has other firm commitments with suppliers for an aggregate of \$0.4 million.

Office Lease — On May 5, 2017, the Company executed an office lease with Russell Ranch Road II LLC for the Company’s corporate headquarters in Westlake Village, California. The office lease commenced in August 2017. The lease requires monthly payments of \$40,951, increased by 3% annually, plus the estimated cost of maintaining the property by the landlord with a five month concession from October 2017 through February 2018. The lease expires January 2023 and provides the Company with a five year renewal option.

On November 29, 2017, the Company executed an office lease with Russell Ranch Road II LLC to expand the office space for the Company’s corporate headquarters in Westlake Village, California. The office lease will commence in October 2018. The lease requires monthly payments of \$35,969, increased by 3% annually, plus the estimated cost of maintaining the property by the landlord. In addition, the Company will be entitled to reimbursement from the landlord of up to \$56,325 for tenant improvements. The lease expires January 2023 and provides the Company with a five year renewal option.

Rent expense under all operating leases including office space and equipment was approximately \$0.4 million for the year ended December 31, 2017, 2016 and 2015, respectively.

Future minimum lease payments are as follows:

2018	\$ 522,000
2019	947,000
2020	976,000
2021	1,005,000
2022	1,035,000
Thereafter	88,000
	<u>\$ 4,573,000</u>

15. Employee Benefit Plans

The Company administers a 401(k) savings retirement plan (the “MannKind Retirement Plan”) for its employees. For the years ended December 31, 2017, 2016 and 2015, the Company contributed \$0.4 million, \$0.4 million and \$0.6 million, respectively, to the MannKind Retirement Plan.

16. Income Taxes

Loss from continuing operations before provision for income tax for the Company’s domestic and international operations was as follows (in thousands):

	December 31,		
	2017	2016	2015
US	\$ (113,679)	\$ 129,361	\$ (358,047)
Foreign	(3,603)	(3,697)	(10,398)
Loss before provision for income taxes	<u>\$ (117,282)</u>	<u>\$ 125,664</u>	<u>\$ (368,445)</u>

At December 31, 2017, 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. The provision for income taxes for the year ended December 31, 2017 was \$0.05 million, and there was no provision for income taxes for the years ended December 31, 2016 and 2015, respectively 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,		
	2017	2016	2015
Current			
U.S. federal	\$ 51	\$ —	\$ —
U.S. state	—	—	—
Non-U.S.	—	—	—
Total current	51	—	—
Deferred			
U.S. federal	244,801	(43,814)	109,512
U.S. state	15,398	(4,311)	(29,394)
Non-U.S.	—	—	—
Total deferred	260,199	(48,125)	80,118
Valuation allowance	(260,199)	48,125	(80,118)
Total	\$ 51	\$ —	\$ —

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, 2017 and 2016, are as follows (in thousands):

	December 31,	
	2017	2016
Deferred tax assets:		
Net operating loss carryforwards	\$ 507,235	\$ 712,124
Research and development credits	83,461	77,998
Capitalized research	1,016	5,117
Milestone Rights	1,908	3,242
Accrued expenses	211	440
Loss on purchase commitment	23,654	36,775
Non-qualified stock option expense	7,004	17,331
Capitalized patent costs	5,194	8,781
Other	795	7,380
Depreciation	23,820	45,310
Total net deferred tax assets	654,298	914,498
Valuation allowance	(654,298)	(914,498)
Net deferred tax assets	\$ —	\$ —

The Company's effective income tax rate differs from the statutory federal income tax rate as follows for the years ended December 31, 2017, 2016 and 2015:

	December 31,		
	2017	2016	2015
Federal tax benefit rate	35.0%	35.0%	35.0%
Permanent items	6.2	(1.9)	—
Intercompany transfer of intellectual property	—	0.9	(1.0)
2017 tax law changes	(265.0)	—	—
Stock based compensation	(5.0)	—	—
Tax attribute expirations	(2.8)	—	—
Valuation allowance	231.6	(34.0)	(34.0)
Effective income tax rate	—%	—%	—%

As of December 31, 2017 and 2016, management assessed the realizability of deferred tax assets. Management evaluated the need for an amount of any valuation allowance for deferred tax assets on a jurisdictional basis. This evaluation utilizes the framework contained in ASC 740,

Income Taxes, wherein management analyzes all positive and negative evidence available at the balance sheet date to determine whether all or some portion of the Company's deferred tax assets will not be realized. Under this guidance, a valuation allowance must be established for deferred tax assets when it is more likely than not (a probability level of more than 50 percent) that the Company may not realize the benefit of its deferred tax assets. In assessing the realization of the Company's deferred tax assets, the Company considers all available evidence, both positive and negative.

In concluding on the evaluation, management placed significant emphasis on guidance in ASC 740, which states that "a cumulative loss in recent years is a significant piece of negative evidence that is difficult to overcome." Based upon available evidence, it was concluded on a more-likely-than-not basis that all deferred tax assets were not realizable as of December 31, 2017. Accordingly, a valuation allowance of \$654.3 million has been recorded to offset this deferred tax asset. During the years ended December 31, 2017 and 2016, the change in the valuation allowance was \$(260.2) million and \$(48.1) million, respectively.

At December 31, 2017, the Company had federal and state net operating loss carryforwards of approximately \$2.0 billion and \$2.2 billion available, respectively, to reduce future taxable income. These losses are available to reduce taxable income and have started expiring, starting in the current year through various future dates for both federal and state purposes.

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, 2017, the Company had research and development credits of \$55.1 million and \$28.4 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 files U.S. federal and state income tax returns in jurisdictions with varying statutes of limitations. In the normal course of business the Company is subject to examination by taxing authorities throughout the country. These audits could include examining the timing and amount of deductions, the allocation of income among various tax jurisdictions and compliance with federal, state and local laws. The Company's tax years since 2012 remain subject to examination by federal, state and foreign tax authorities.

We adopted ASU 2016-09 in the first quarter of 2017. Under the new guidance companies will no longer record excess tax benefits and certain tax deficiencies related to share-based payments to employees in additional paid-in capital (APIC). Instead, the Company will recognize all income tax effects of awards in our income statement when awards vest or are settled. All excess tax benefits not previously recognized were to be recorded to retained earnings as a cumulative effect adjustment upon adoption. Upon adoption, no adjustment to retained earnings was necessary due to the Company's valuation allowance position. Approximately \$10.8 million attributable to excess tax benefits on stock compensation that had not been previously recognized were added to the Net Operating Loss with a corresponding increase to the valuation allowance.

At December 31, 2017 and 2016, the Company has not recognized a liability for unrecognized tax benefits. If any were recognized, it would affect the Company's effective tax rate. The Company does not expect its unrecognized tax benefits to change.

The Company recognizes interest and penalties accrued related to unrecognized tax benefits in income tax expense. During the year ended December 31, 2017, the interest and penalties recognized were not material. During the years ended December 31, 2016 and 2015 the Company recognized and accrued an insignificant amount of interest or penalties related to unrecognized tax benefits.

The Company considers its undistributed earnings of foreign subsidiaries to be permanently reinvested in foreign operations and has not provided for U.S. income taxes on such earnings. As of December 31, 2017 the Company had no undistributed earnings from its foreign subsidiaries.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (the "Act") was signed into law making significant changes to the Internal Revenue Code of 1986, as amended. The changes include, but are not limited to, a corporate tax rate decrease from 35% to 21% effective for tax years beginning after December 31, 2017, a one-time transition tax on the mandatory deemed repatriation of cumulative foreign earnings as of December 31, 2017, and expanded limits on employee remuneration. The Company has calculated its best estimate of the impact of the Act in its year end income tax provision in accordance with its understanding of the Act and guidance available as of the date of this filing, and as a result, the Company recorded no additional income tax expense in the fourth quarter of 2017, the period in which the legislation was enacted. The provisional amount related to the remeasurement of certain deferred tax assets and liabilities is based on the rates at which they are expected to reverse in the future. The impact of this Act was a decrease of deferred tax assets approximately \$301 million, offset by a decrease in valuation allowance of \$301 million, resulting in no additional income tax expense or benefit. No provisional amount was recorded related to the one-time transition tax on the mandatory deemed repatriation of foreign earnings.

Staff Accounting Bulletin No. 118 ("SAB 118") was issued to address the application of US GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Act. In accordance with SAB 118, the Company has determined that the provisional amounts recorded are a reasonable estimate at December 31, 2017. Any subsequent adjustment to these amounts will be recorded to current tax expense in the quarter of 2018 during which the analysis is complete.

17. 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 had an exercise price of \$7.50 per share. The A Warrants became exercisable upon issuance and expired two years thereafter. The B Warrants became exercisable beginning in May 2017 and expired 30 months after the date of issuance. The shares of common stock and the warrants are immediately separable and issued separately.

The Company determined that the A Warrants required 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 a warrant liability in the consolidated balance sheet at issuance and was 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 accounted for such warrants in additional paid in capital.

On September 29, 2017 the Company and four holders of 9.7 million A and B Warrants entered into separate, privately-negotiated exchange agreements, pursuant to which the Company agreed to issue to such holders an aggregate of 1,292,510 shares of the Company's common stock (to be delivered on October 3, 2017) in exchange for such warrants. The warrant liability associated with the exchanged warrants was adjusted to fair value and \$1.9 million, the fair value of the remaining obligation was reclassified into equity as of September 29, 2017.

In addition, as of December 31, 2017, warrants to acquire approximately 32,000 shares of common stock were outstanding. See Note 11 – Common and Preferred Stock, for additional information.

18. Restructuring Charges

As of December 31, 2017 and 2016, the Company had a remaining restructuring liability of \$0.4 million and \$1.4 million, respectively, which is recorded in accrued expenses and other current liabilities in the consolidated balance sheets. The Company expects to substantially pay out the remainder of this obligation by end of first quarter of 2018.

A reconciliation of beginning and ending liability balances for the restructuring charges is as follows (in thousands):

Description	2016	2015	Total
	Restructuring	Restructuring	
Accrual — January 1, 2016	\$ —	\$ 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
Costs incurred and charged to expense	—	—	—
Costs paid or settled	(209)	(805)	(1,014)
Accrual — December 31, 2017	<u>\$ —</u>	<u>\$ 362</u>	<u>\$ 362</u>

19. Selected quarterly financial data (unaudited)

Summarized quarterly financial data for the years ended December 31, 2017 and 2016, are set forth in the following tables:

	March 31	June 30	September 30	December 31
	(In thousands, except per share data)			
2017				
Net revenues	\$ 3,009	\$ 2,163	\$ 2,043	\$ 4,530
Net (loss)	\$ (16,324)	\$ (35,339)	\$ (32,886)	\$ (32,784)
Net (loss) per share — basic	\$ (0.17)	\$ (0.35)	\$ (0.31)	\$ (0.28)
Net (loss) per share — diluted	\$ (0.17)	\$ (0.35)	\$ (0.31)	\$ (0.28)
Weighted average common shares used to compute basic net (loss) per share	95,744	99,864	104,703	116,451
Weighted average common shares used to compute diluted net (loss) per share	95,744	99,864	104,703	116,451
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

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)

In the fourth quarter of 2017, the Company recognized net revenue-commercial product sales of \$1.2 million attributable to a change in estimate (See Note 1 – Description of Business)

20. Subsequent Events

Fifth Amendment to Facility Agreement and First Amendment to Escrow Agreement

On January 15, 2018, the Company and MannKind LLC entered into a Fifth Amendment (the “Fifth Deerfield Amendment”) with Deerfield to the facility Agreement, pursuant to which the parties deferred the payment date for the \$4.4 million remaining October 2017 Tranche 4 Principal Payment from January 15, 2018 to January 19, 2018. Concurrent with this amendment the Company and MannKind LLC entered into a First Amendment to Escrow Agreement to extend the escrow period to January 19, 2018 to align with the amended payment date under the Fifth Deerfield Amendment.

Sixth Amendment to Facility Agreement and Second Amendment to Escrow Agreement

On January 18, 2018, the Company and MannKind LLC entered into an Exchange and Sixth Amendment to Facility Agreement (the “Sixth Deerfield Amendment”) with Deerfield, pursuant to which, among other things, the Company agreed to issue to Deerfield an aggregate of 1,267,972 shares of its common stock, par value \$0.01 per share (the “Exchange Shares”), in exchange for \$3,157,251 of the 2019 Notes, an exchange rate of \$2.49 per share. In addition, the parties deferred the payment date for the \$1,250,000 remaining principal amount of the 2019 Notes (the “Remaining Payment”) from January 19, 2018 to May 6, 2018.

The Company and Deerfield also amended the outstanding 2019 Notes and Tranche B notes to provide that Deerfield may, subject to the terms of the Sixth Deerfield Amendment, convert principal amounts of the 2019 notes and Tranche B notes from time to time into an aggregate of up to 10,000,000 shares of the Company's common stock (excluding the Exchange Shares). The conversion price will be the greater of (i) the average of the volume weighted average price per share of the Company's common stock for the three trading day period immediately preceding the date of any election by Deerfield to convert principal amounts of the 2019 notes and Tranche B notes and (ii) \$2.75 per share, subject to adjustment under certain circumstances described in the 2019 notes and Tranche B notes. Any conversions of principal by Deerfield under the 2019 notes and Tranche B notes will be applied first to reduce the Remaining Payment, and thereafter to reduce other principal payments due under the 2019 notes and Tranche B notes.

In connection with the Sixth Deerfield Amendment, the Company also entered into a Second Amendment to Escrow Agreement, dated January 18, 2018, with Deerfield and US Bank, pursuant to which the parties extended the period of the escrow established thereunder to May 6, 2018, corresponding to the extended payment date under the Facility Agreement.



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

February 27, 2018

MannKind Corporation
30930 Russell Ranch Road, Suite 301
Westlake Village, CA 91362

Ladies and Gentlemen:

You have requested our opinion, as counsel to MannKind Corporation, a Delaware corporation (the "**Company**"), with respect to certain matters in connection with the offering by the Company of \$50,000,000 of shares of the Company's common stock, par value \$0.01 (the "**Shares**"), pursuant to a Registration Statement on Form S-3 (No. 333-210792) (the "**Registration Statement**"), filed with the Securities and Exchange Commission (the "**Commission**") under the Securities Act of 1933, as amended (the "**Act**"), the prospectus included within the Registration Statement (the "**Base Prospectus**"), and the prospectus supplement to be filed with the Commission pursuant to Rule 424(b) of the Rules and Regulations of the Act (the "**Prospectus Supplement**" and together with the Base Prospectus, the "**Prospectus**"). The Shares are to be sold by the Company in accordance with a Controlled Equity OfferingSM Sales Agreement, dated February 27, 2018, between the Company and Cantor Fitzgerald & Co. (the "**Agreement**"), as described in the Prospectus.

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

We have assumed (i) that each sale of Shares will be duly authorized by the Board of Directors of the Company, a duly authorized committee thereof or a person or body pursuant to an authorization granted in accordance with Section 152 of the General Corporation Law of the State of Delaware (the "**DGCL**"), (ii) that no more than 20,000,000 Shares will be sold under the Agreement and (iii) that the price at which the Shares are sold will equal or exceed the par value of the Shares. We express no opinion to the extent that future issuances of securities of the Company and/or anti-dilution adjustments to outstanding securities of the Company cause the number of shares of the Company's common stock outstanding or issuable upon conversion or exercise of outstanding securities of the Company to exceed the number of Shares then issuable under the Agreement.



MannKind Corporation
February 27, 2018
Page 2

Our opinion herein is expressed solely with respect to the General Corporation Law of the State of Delaware. Our opinion is based on these laws as in effect on the date hereof. We express no opinion to the extent that any other laws are applicable to the subject matter hereof and express no opinion and provide no assurance as to compliance with any federal or state securities law, rule or regulation.

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

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

Very truly yours,

Cooley llp

By: /s/ Sean M. Clayton
Sean M. Clayton



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Fax: 203-796-3684
www.mannkindcorp.com

February 17, 2017

Courtney Barton

Revised – 2/23/2017

Dear Courtney:

Congratulations! The MannKind team has been very impressed with your background and credentials, and we are genuinely pleased to offer you full-time employment with MannKind Corporation, in the exempt position Vice President, Chief Compliance Officer, located in Southern California. In this position you will initially report directly to David Thomson, Corporate V.P. & General Counsel.

We will target your employment to commence on March 13, 2017. Please be advised that this offer is contingent upon satisfactory reference and background checks and receipt of results of a satisfactory drug screening test. In the coming days, you will receive an email with information regarding the test, contact and location information for the laboratory as well as the hours of operation. This screening test must be completed no later than two weeks from the date of this letter.

As part of this agreement your primary work location will be Scottsdale, AZ during your initial employment. Once you relocate to California, your primary work location will change to California. We ask that you make every personal effort to complete your physical relocation by July 31, 2017, whether that be to your new residence or to temporary housing. Your relocation benefits will be in effect from one year from your hire date with MannKind.

You will be paid on a bi-weekly basis, on regular payroll schedule, in the amount of \$9615.38, equating to an annualized amount of \$250,000.00. Depending on your date of hire, you may be eligible to participate in the MannKind Employee Bonus Plan, with a target bonus opportunity of 25% of annual earnings. Bonus awards will be based upon company-wide performance and your achievement of mutually agreed-upon milestones.

Courtney Barton

You will be eligible to participate in MannKind's Equity Incentive Plan, under which stock options and restricted stock may be awarded to you at a future date, as approved by the Board of Directors. At the next quarterly Board meeting, we will recommend that you be granted a stock award of 84,800 and RSU's of 61,800, comparable to grants made for other individuals in similar level positions throughout the company. This is not a guarantee for a specific number of restricted stock units, but is only intended to provide you with an understanding of grant guidelines for your position. If your start date is less than two weeks prior to the next quarterly Board meeting, the recommendation will be submitted in the following quarter. Grants will begin vesting based on your hire date.

We have a substantial list of fringe benefits, including the following: 20 days PTO annually, which accrues on a bi-weekly basis; short term and long term disability insurance; company paid life insurance; a 401(k) tax sheltered savings program; flexible spending accounts; health, vision and dental insurance, and 16 paid holidays. The holidays and other time off benefits will be prorated based on your date of hire. All benefits, policies and rules are subject to change from time to time at the Company's discretion. All benefits outlined in this offer letter are contingent on your continuing employment with MannKind Corporation in a benefit eligible status.

Enclosed and included as part of this offer (Attachment One) is information about the main points of the Company's relocation assistance program, which MannKind will provide to you to relocate to the "local area." Upon acceptance of this offer, a representative of NEI will contact you to initiate your relocation benefits.

MannKind will provide relocation assistance to you in good faith, however, should you leave the Company before one year for any reason, except layoff, you will be required to repay the Company all funds paid, either to you or on your behalf, for relocation purposes.

Shortly after we are in receipt of your acceptance, you will receive a welcome email from our onboarding manager, with a link to your personalized onboarding portal. Through this portal you will have access to most of the required MannKind policies and agreements that will require your signature such as, the Employee Proprietary Information and Inventions Agreement, an Arbitration Agreement, a Policy Against Insider Trading, Code of Business Conduct and Ethics, and an Employee Acknowledgement Form, required after reading the MannKind Employee Sourcebook. Of course, the company may require additional policies or agreements to be signed and acknowledged in the future.

Courtney Barton

Employment at MannKind is at will, which means that either you or MannKind can end the employment relationship at any time, and for any reason or for no reason, with or without

cause or notice. The employment terms in this letter supersede any other agreements or promises made to you by anyone, whether oral or written, and cannot be modified or amended except in writing by an officer of the company. As required by law, this offer is subject to satisfactory proof of your right to work in the United States. This at will employment relationship cannot be changed except in writing as approved by the Board of Directors of MannKind.

We appreciate the energy and enthusiasm you demonstrated during our interview and selection process and we look forward to a favorable response to our offer. We have many exciting challenges ahead and believe you can make a significant contribution to MannKind.

At your earliest convenience, please sign and date this letter and return it to Jacqueline Lapotosky, HR Manager @jlapotosky@mannkindcorp.com or mail in the enclosed envelope to indicate your acceptance of this written offer of employment.

If you should have any questions, please don't hesitate to contact me.

Sincerely,

/s/ Jacqueline Lapotosky

Jacqueline Lapotosky
HR Manager

I have carefully read and understand all of the terms of the above letter and freely and voluntarily accept and agree to all of its terms. I represent that, in agreeing to this offer letter, I am not relying on any representations or promises of any kind other than set forth in this letter.

Sincerely,

/s/ Courtney Barton

Courtney Barton

Date Signed

Confirmed Start Date



One Casper Street
Danbury, CT 06810
Main: 203-798-8000
Fax: 203-798-7740
www.mannkindcorp.com

June 27, 2017

Revised: July 11, 2017

Mr. Patrick McCauley

Dear Patrick,

Congratulations! The MannKind team has been very impressed with your background and credentials, and we are genuinely pleased to offer you full-time employment with MannKind Corporation, in the exempt position Chief Commercial Officer located in California. In this position you will initially report directly to Michael Castagna, Chief Executive Officer.

We will target your employment to commence on July 12, 2017. Please be advised that continued employment is contingent upon satisfactory reference and background checks and receipt of results of a satisfactory drug screening test. You will receive an email with information regarding the test, contact and location information for the laboratory as well as the hours of operation. This screening test must be completed within two weeks from the date of this letter.

You will be paid on a bi-weekly basis, on regular payroll schedule, in the amount of \$15,384.62, equating to an annualized amount of \$400,000.12. You will be eligible to participate in the MannKind Discretionary Bonus Plan, with a target bonus opportunity of 50% of annual earnings.

Additionally, you will receive a one-time sign-on bonus in the gross amount of \$50,000.00, less appropriate withholdings and other payroll deductions, payable as a lump sum on the first pay period at the end of the first ninety (90) days of your employment. By accepting this offer, you agree that, in the event that you voluntarily leave the Company, or if you are terminated by the Company for "cause", within the twelve (12) months following receipt of payment, you will repay the full amount of the payment, net any withholdings within thirty (30) days after the last day of your employment. By accepting this offer, you further agree that the Company may deduct this amount from any other amounts The Company owes you should you be obligated to repay this amount.

You will be eligible to participate in the 2017 MannKind Equity Program, under which Performance-based Stock Options will be awarded to you at a future date, as approved by the Board of Directors. At the next quarterly Board meeting after your hire date, we will recommend that you be granted an equity award of 180,100 units of Performance-based Stock Options which is comparable to grants made for other individuals in similar level positions throughout the company. This is not a guarantee for a specific number of stock units, but is only intended to provide you with an understanding of grant guidelines for your position. If your start date is less than two weeks prior to the next quarterly Board meeting, the recommendation will be submitted in the following quarter. Grants will begin vesting based on your hire date and upon the organization reaching specific sales milestones. You will also be eligible for an annual equity grant moving forward.

Included as part of this offer is information about the main points of the Company's relocation assistance program, which MannKind will provide to you to relocate to the "local area." Upon acceptance of this offer, a representative of NEI will contact you to initiate your relocation benefits.

MannKind will provide relocation assistance to you in good faith, however, should you leave the Company before one year for any reason, except layoff, you will be required to repay the Company all funds paid, either to you or on your behalf, for relocation purposes.

We have a substantial list of fringe benefits, including the following: 20 days PTO annually, which accrues on a bi-weekly basis; short term and long term disability insurance; company-paid life insurance; a 401(k) tax deferred savings program; flexible spending accounts; health, vision and dental insurance, Executive Medical Reimbursement plan and paid holidays which includes a full week in July and December for the holiday break. The holidays and other time off benefits will be prorated based on your date of hire. All benefits, policies and rules are subject to change from time to time at the Company's discretion. All benefits outlined in this offer letter are contingent on your continuing employment with MannKind Corporation in a benefit eligible status.

Shortly after we are in receipt of your acceptance, you will receive a welcome email from our onboarding manager, with a link to your personalized onboarding portal. Through this portal you will have access to most of the required MannKind policies and agreements that will require your signature such as, the Employee Proprietary Information and Inventions Agreement, an Arbitration Agreement, a Policy Against Insider Trading, Code of Business Conduct and Ethics, and an Employee Acknowledgement Form, required after reading the MannKind Employee Sourcebook. Of course, the company may require additional policies or agreements to be signed and acknowledged in the future.

Employment at MannKind is at will, which means that either you or MannKind can end the employment relationship at any time, and for any reason or for no reason, with or without cause or notice. The employment terms in this letter supersede any other agreements or promises made to you by anyone, whether oral or written, and cannot be modified or amended except in writing by an officer of the company. As required by law, this offer is subject to satisfactory proof of your right to work in the United States. This at will employment relationship cannot be changed except in writing as approved by the Board of Directors of MannKind.

We appreciate the energy and enthusiasm you demonstrated during our interview and selection process and we look forward to a favorable response to our offer. We have many exciting challenges ahead and believe you can make a significant contribution to MannKind.

At your earliest convenience, please sign and date this letter and return to me to indicate your acceptance of this written offer of employment.

If you should have any questions, please don't hesitate to contact me.

Sincerely,

/s/ Diana Champagne

Diana Champagne
Director, Total Rewards and HR Ops

I have carefully read and understand all of the terms of the above letter and freely and voluntarily accept and agree to all of its terms. I represent that, in agreeing to this offer letter, I am not relying on any representations or promises of any kind other than set forth in this letter.

/s/ Patrick McCauley

Patrick McCauley

June 28, 2017

Date Signed

July 12, 2017

Confirmed Start Date



30930 Russell Ranch Road
Suite 301
Westlake Village, CA 91362
Office: 818.661.5000
Fax: 818.661.5099
www.mannkindcorp.com

January 26, 2018

David Kendall

Dear David,

Congratulations! The MannKind team has been very impressed with your background and credentials, and we are genuinely pleased to offer you full-time employment with MannKind Corporation, in the exempt position of Chief Medical Officer. In this position you will initially report directly to Michael Castagna, Chief Executive Officer.

We will target your employment to commence on February 19, 2018. Please be advised that this offer is contingent upon satisfactory reference and background checks and receipt of results of a satisfactory drug screening test. In the coming days, you will receive an email with information regarding the test, contact and location information for the laboratory as well as the hours of operation. This screening test must be completed no later than two weeks from the date of this letter.

You will be paid on a bi-weekly basis, on regular payroll schedule, in the amount of \$16,346.16, equating to an annualized amount of \$425,000.16.

You will be eligible to participate in the MannKind Employee Bonus Plan, with a target bonus opportunity of 50% of annual earnings. Bonus awards will be based upon company-wide performance and your achievement of mutually agreed-upon milestones.

Additionally, you will receive a sign-on bonus in the gross amount of \$100,000.00. The first installment of \$50,000.00 (less appropriate withholdings and other payroll deductions) will be payable as a lump sum on the first pay period at the end of the first thirty (30) days of your employment. You will receive a second installment of \$50,000.00 (less appropriate withholdings and other payroll deductions) payable as a lump sum on the first pay period following one (1) full year of employment. By accepting this offer, you agree that, in the event that you voluntarily leave the Company, or if you are terminated by the Company for "cause", within the twelve (12) months following receipt of either payment, you will repay the full amount of the installment payment for that twelve (12) month period, net any with-holdings within thirty (30) days after the last day of your employment. By accepting this offer, you further agree that the Company may deduct this amount from any other amounts The Company owes you should you be obligated to repay this amount.

You will be eligible to participate in MannKind's Equity Incentive Plan, under which Stock Options will be awarded to you at a future date, as approved by the Board of Directors. At the next quarterly Board meeting, we will recommend that you be granted an equity award of 180,100 Restricted Stock Units (RSUs) which is comparable to grants made for other individuals in similar level positions throughout the company. This is not a guarantee for a specific number of stock units, but is only intended to provide you with an understanding of grant guidelines for your position. If your start date is less than two weeks prior to the next quarterly Board meeting, the recommendation will be submitted in the following quarter. Grants will begin vesting based on your hire date. You will also be eligible for an annual equity grant moving forward.

Included as part of this offer is information about the main points of the Company's relocation assistance program, which MannKind will provide to you to relocate to the "local area". Upon acceptance of this offer, a representative of NEI will contact you to initiate your relocation benefits. MannKind will provide relocation assistance to you in good faith, however, should you leave the Company before one year for any reason, except layoff, you will be required to repay the Company all funds paid, either to you or on your behalf, for relocation purposes.

We have a substantial list of fringe benefits, including the following: 20 days PTO annually, which accrues on a bi-weekly basis; short term and long term disability insurance; company paid life insurance; a 401(k) tax sheltered savings program; flexible spending accounts; health, vision and dental insurance, Executive Medical Reimbursement plan and paid holidays which includes a full week in July and December for the holiday break. The holidays and other time off benefits will be prorated based on your date of hire. All benefits, policies and rules are subject to change from time to time at the Company's discretion. All benefits outlined in this offer letter are contingent on your continuing employment with MannKind Corporation in a benefit eligible status. Most benefits begin the first of the month following date of hire.

Shortly after we are in receipt of your acceptance, you will receive a welcome email from our onboarding manager, with a link to your personalized onboarding portal. Through this portal you will have access to most of the required MannKind policies and agreements that will require your signature such as, the Employee Proprietary Information and Inventions Agreement, an Arbitration Agreement, a Policy Against Insider Trading, Code of Business Conduct and Ethics, and an Employee Acknowledgement Form, required after reading the MannKind Employee Sourcebook. Of course, the company may require additional policies or agreements to be signed and acknowledged in the future.

Employment at MannKind is at will, which means that either you or MannKind can end the employment relationship at any time, and for any reason or for no reason, with or without cause or notice. The employment terms in this letter supersede any other agreements or promises made to you by anyone, whether oral or written, and cannot be modified or amended except in writing by an officer of the company. As required by law, this offer is subject to satisfactory proof of your right to work in the United States. This at will employment relationship cannot be changed except in writing as approved by the Board of Directors of MannKind.

We appreciate the energy and enthusiasm you demonstrated during our interview and selection process and we look forward to a favorable response to our offer. We have many exciting challenges ahead and believe you can make a significant contribution to MannKind.

At your earliest convenience, please sign and date this letter and return it to me to indicate your acceptance of this written offer of employment.

If you should have any questions, please don't hesitate to contact me.

Sincerely,

/s/ Stuart Tross

Stuart Tross
Chief People and Workplace Officer

I have carefully read and understand all of the terms of the above letter and freely and voluntarily accept and agree to all of its terms. I represent that, in agreeing to this offer letter, I am not relying on any representations or promises of any kind other than set forth in this letter.

/s/ David Kendall

David Kendall

February 2, 2018

Date Signed

February 12, 2018

Confirmed Start Date

MannKind Corporation
Board of Directors Compensation Program for Non-employee Directors
Adopted November 17, 2017

Type of Compensation	Amount
Annual Cash Retainer	\$50,000 (cash)
Equity Vehicle	100% restricted stock unit (Restricted stock units vest immediately, but shares will not be distributed until the director leaves the board.)
Annual Equity Grant	Intended equity value: \$150,000 (The number of shares will be determined using the then-current guideline price for employee equity awards.)
Initial Equity Grant	None.
Independent Chairman Annual Premium	\$32,500 (cash)
Committee Member Annual Compensation	Audit: \$10,000 Compensation: \$7,500 Nominating and Corporate Governance: \$5,000 (cash)
Committee Chair Annual Premiums	Audit: \$15,000 Compensation: \$12,500 Nominating and Corporate Governance: \$5,000 (cash)

MannKind Corporation
Shares of Common Stock
(par value \$0.01 per share)

Controlled Equity OfferingSM

Sales Agreement

February 27, 2018

Cantor Fitzgerald & Co.
499 Park Avenue
New York, NY 10022

Ladies and Gentlemen:

MannKind Corporation, a Delaware corporation (the “**Company**”), confirms its agreement (this “**Agreement**”) with Cantor Fitzgerald & Co. (the “**Agent**”), as follows:

1. **Issuance and Sale of Shares.** The Company agrees that, from time to time during the term of this Agreement, on the terms and subject to the conditions set forth herein, it may issue and sell through the Agent shares of common stock (the “**Placement Shares**”) of the Company, par value \$0.01 per share (the “**Common Stock**”); *provided, however*, that in no event shall the Company issue or sell through the Agent such number or dollar amount of Placement Shares that would (a) exceed the number or dollar amount of shares of Common Stock registered on the effective Registration Statement (as defined below) pursuant to which the offering is being made, (b) exceed the number of authorized but unissued shares of Common Stock, (c) exceed the number or dollar amount of shares of Common Stock permitted to be sold under Form S-3 (including General Instruction I.B.6 thereof, if applicable) or (d) exceed the number or dollar amount of shares of Common Stock for which the Company has filed a Prospectus Supplement (defined below) (the lesser of (a), (b), (c) and (d), the “**Maximum Amount**”). Notwithstanding anything to the contrary contained herein, the parties hereto agree that compliance with the limitations set forth in this **Section 1** on the amount of Placement Shares issued and sold under this Agreement shall be the sole responsibility of the Company and that the Agent shall have no obligation in connection with such compliance. The issuance and sale of Placement Shares through the Agent will be effected pursuant to the Registration Statement filed by the Company and which has been or will be declared effective by the Securities and Exchange Commission (the “**Commission**”), although nothing in this Agreement shall be construed as requiring the Company to use the Registration Statement to issue any Placement Shares.

The Company has filed or will file, in accordance with the provisions of the Securities Act of 1933, as amended (the “**Securities Act**”) and the rules and regulations thereunder (the “**Securities Act Regulations**”), with the Commission a registration statement on Form S-3, including a base prospectus, relating to certain securities, including the Placement Shares to be issued from time to time by the Company, and which incorporates by reference documents that the Company has filed or will file in accordance with the provisions of the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”), and the rules and regulations thereunder. The Company has prepared or will prepare a prospectus or a prospectus supplement to the base

prospectus included as part of the registration statement, which prospectus or prospectus supplement relates to the Placement Shares to be issued from time to time by the Company (the “**Prospectus Supplement**”). The Company will furnish to the Agent, for use by the Agent, copies of the prospectus included as part of such registration statement, as supplemented by the Prospectus Supplement, relating to the Placement Shares to be issued from time to time by the Company. The Company may file one or more additional registration statements from time to time that will contain a base prospectus and related prospectus or prospectus supplement, if applicable (which shall be a Prospectus Supplement), with respect to the Placement Shares. Except where the context otherwise requires, such registration statement(s), including all documents filed as part thereof or incorporated by reference therein, and including any information contained in a Prospectus (as defined below) subsequently filed with the Commission pursuant to Rule 424(b) under the Securities Act Regulations or deemed to be a part of such registration statement pursuant to Rule 430B of the Securities Act Regulations, is herein called the “**Registration Statement**.” The base prospectus or base prospectuses, including all documents incorporated therein by reference, included in the Registration Statement, as it may be supplemented, if necessary, by the Prospectus Supplement, in the form in which such prospectus or prospectuses and/or Prospectus Supplement have most recently been filed by the Company with the Commission pursuant to Rule 424(b) under the Securities Act Regulations, together with the then issued Issuer Free Writing Prospectus(es) (defined below), is herein called the “**Prospectus**.”

Any reference herein to the Registration Statement, any Prospectus Supplement, Prospectus or any Issuer Free Writing Prospectus shall be deemed to refer to and include the documents, if any, incorporated by reference therein (the “**Incorporated Documents**”), including, unless the context otherwise requires, the documents, if any, filed as exhibits to such Incorporated Documents. Any reference herein to the terms “amend,” “amendment” or “supplement” with respect to the Registration Statement, any Prospectus Supplement, the Prospectus or any Issuer Free Writing Prospectus shall be deemed to refer to and include the filing of any document under the Exchange Act on or after the most-recent effective date of the Registration Statement, or the date of the Prospectus Supplement, Prospectus or such Issuer Free Writing Prospectus, as the case may be, and incorporated therein by reference. For purposes of this Agreement, all references to the Registration Statement, the Prospectus or to any amendment or supplement thereto shall be deemed to include the most recent copy filed with the Commission pursuant to its Electronic Data Gathering Analysis and Retrieval System, or if applicable, the Interactive Data Electronic Application system when used by the Commission (collectively, “**EDGAR**”).

2. **Placements.** Each time that the Company wishes to issue and sell Placement Shares hereunder (each, a “**Placement**”), it will notify the Agent by email notice (or other method mutually agreed to in writing by the parties) of the number or amount of Placement Shares to be issued, the time period during which sales are requested to be made, any limitation on the number of Placement Shares that may be sold in any one day and any minimum price below which sales may not be made (a “**Placement Notice**”), in form and substance reasonably satisfactory to the Agent. The Placement Notice shall originate from any of the individuals from the Company set forth on Schedule 2 (with a copy to each of the other individuals from the Company listed on such schedule), and shall be addressed to each of the individuals from the Agent set forth on Schedule 2, as such Schedule 2 may be amended from time to time. The

Placement Notice shall be effective unless and until (i) the Agent declines in writing to accept the terms contained therein for any reason, in its sole discretion, which declination must occur within two (2) business days of the receipt of the Placement Notice, (ii) the entire amount of the Placement Shares thereunder have been sold, (iii) the Company amends, supersedes, suspends or terminates the Placement Notice or (iv) this Agreement has been terminated under the provisions of Section 12. The amount of any discount, commission or other compensation to be paid by the Company to the Agent in connection with the sale of the Placement Shares shall be calculated in accordance with the terms set forth in Schedule 1. It is expressly acknowledged and agreed that neither the Company nor the Agent will have any obligation whatsoever with respect to a Placement or any Placement Shares unless and until the Company delivers a Placement Notice to the Agent and the Agent does not decline such Placement Notice pursuant to the terms set forth above, and then only upon the terms specified therein and herein. In the event of a conflict between the terms of this Agreement and the terms of a Placement Notice, the terms of the Placement Notice will control.

3. Sale of Placement Shares by the Agent.

(a) Subject to the provisions of Section 5(a), the Agent, for the period specified in the Placement Notice, will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of the Nasdaq Stock Market (the “**Exchange**”), to sell the Placement Shares up to the amount specified, and otherwise in accordance with the terms of such Placement Notice. The Agent will provide written confirmation to the Company no later than the opening of the Trading Day (as defined below) immediately following the Trading Day on which it has made sales of Placement Shares hereunder setting forth the number of Placement Shares sold on such day, the compensation payable by the Company to the Agent pursuant to Section 2 with respect to such sales, and the Net Proceeds (as defined below) payable to the Company, with an itemization of the deductions made by the Agent (as set forth in Section 5(b)) from the gross proceeds that it receives from such sales. Subject to the terms of the Placement Notice, the Agent may sell Placement Shares by any method permitted by law deemed to be an “at the market offering” as defined in Rule 415(a)(4) of the Securities Act Regulations, including without limitation sales made directly on the Exchange, on any other existing trading market for the Common Stock or to or through a market maker. Subject to the terms of a Placement Notice, the Agent may also sell Placement Shares by any other method permitted by law, including but not limited to in privately negotiated transactions, subject to the prior written consent by the Company. “**Trading Day**” means any day on which Common Stock is traded on the Exchange.

(b) While a Placement Notice is in effect, neither Agent nor any of its subsidiaries shall, for its own account, engage in (i) any short sale of any security of the Company, as defined in Regulation SHO or (ii) any market making bidding, stabilization or other trading activity with regard to the Common Stock or related derivative securities, in each case, if such activity would be prohibited under Regulation M or other anti-manipulation rules under the Securities Act. For the avoidance of doubt, this restriction shall not apply to transactions by or on behalf of any customer of such Agent or transactions by such Agent to facilitate any such transactions by or on behalf of any customer of such Agent.

4. Suspension of Sales. The Company or the Agent may, upon notice to the other party in writing (including by email correspondence to each of the individuals of the other party set forth on Schedule 2, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply) or by telephone (confirmed immediately by verifiable facsimile transmission or email correspondence to each of the individuals of the other party set forth on Schedule 2), suspend any sale of Placement Shares (a “**Suspension**”); *provided, however*, that such Suspension shall not affect or impair any party’s obligations with respect to any Placement Shares sold hereunder prior to the receipt of such notice. While a Suspension is in effect any obligation under Sections 7(l), 7(m), and 7(n) with respect to the delivery of certificates, opinions, or comfort letters to the Agent, shall be waived. Each of the parties agrees that no such notice under this Section 4 shall be effective against any other party unless it is made to one of the individuals named on Schedule 2 hereto, as such Schedule may be amended from time to time.

5. Sale and Delivery to the Agent; Settlement.

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

(b) Settlement of Placement Shares. Unless otherwise specified in the applicable Placement Notice, settlement for sales of Placement Shares will occur on the second (2nd) Trading Day (or such earlier day as is industry practice for regular-way trading) following the date on which such sales are made (each, a “**Settlement Date**”). The Agent shall notify the Company of each sale of Placement Shares no later than the opening of the Trading Day immediately following the Trading Day on which it has made sales of Placement Shares hereunder. The amount of proceeds to be delivered to the Company on a Settlement Date against receipt of the Placement Shares sold (the “**Net Proceeds**”) will be equal to the aggregate sales price received by the Agent, after deduction for (i) the Agent’s commission, discount or other compensation for such sales payable by the Company pursuant to Section 2 hereof, and (ii) any transaction fees imposed by any governmental or self-regulatory organization in respect of such sales.

(c) Delivery of Placement Shares. On or before each Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Placement Shares

being sold by crediting the Agent's or its designee's account (provided the Agent shall have given the Company written notice of such designee at least one Trading Day prior to the Settlement Date) at The Depository Trust Company through its Deposit and Withdrawal at Custodian System or by such other means of delivery as may be mutually agreed upon by the parties hereto which in all cases shall be freely tradable, transferable, registered shares in good deliverable form. On each Settlement Date, the Agent will deliver the related Net Proceeds in same day funds to an account designated by the Company on, or prior to, the Settlement Date. The Company agrees that if the Company, or its transfer agent (if applicable), defaults in its obligation to deliver Placement Shares on a Settlement Date, through no fault of the Agent, the Company agrees that in addition to and in no way limiting the rights and obligations set forth in Section 10(a) hereto, it will (i) hold the Agent harmless against any loss, claim, damage, or expense (including reasonable and documented legal fees and expenses), as incurred, arising out of or in connection with such default by the Company or its transfer agent (if applicable) and (ii) pay to the Agent (without duplication) any commission, discount, or other compensation to which it would otherwise have been entitled absent such default.

(d) Denominations; Registration. Certificates for the Placement Shares, if any, shall be in such denominations and registered in such names as the Agent may request in writing at least one full Business Day (as defined below) before the Settlement Date. The certificates for the Placement Shares, if any, will be made available by the Company for examination and packaging by the Agent in The City of New York not later than noon (New York time) on the Business Day prior to the Settlement Date.

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

6. Representations and Warranties of the Company. The Company represents and warrants to, and agrees with the Agent that as of the date of this Agreement and as of each Applicable Time (as defined below), unless such representation, warranty or agreement specifies a different time:

(a) Registration Statement and Prospectus. The Company and the transactions contemplated by this Agreement meet the requirements for and comply with the applicable conditions set forth in Form S-3 (including General Instructions I.A and I.B) under the Securities Act. The Registration Statement has been or will be filed with the Commission and has been or will be declared effective by the Commission under the Securities Act prior to the

issuance of any Placement Notices by the Company. The Prospectus Supplement will name the Agent as the agent in the section entitled "Plan of Distribution." The Company has not received, and has no notice of, any order of the Commission preventing or suspending the use of the Registration Statement, or threatening or instituting proceedings for that purpose. The Registration Statement and the offer and sale of Placement Shares as contemplated hereby meet the requirements of Rule 415 under the Securities Act and comply in all material respects with said Rule. Any statutes, regulations, contracts or other documents that are required to be described in the Registration Statement or the Prospectus or to be filed as exhibits to the Registration Statement have been so described or filed. Copies of the Registration Statement, the Prospectus, and any such amendments or supplements and all Incorporated Documents that were filed with the Commission on or prior to the date of this Agreement have been delivered, or are available through EDGAR, to the Agent and its counsel. The Company has not distributed and, prior to the later to occur of each Settlement Date and completion of the distribution of the Placement Shares, will not distribute any offering material in connection with the offering or sale of the Placement Shares other than the Registration Statement and the Prospectus and any Issuer Free Writing Prospectus (as defined below) to which the Agent has consented, any such consent not to be unreasonably withheld, conditioned or delayed. The Common Stock is registered pursuant to Section 12(b) of the Exchange Act and is currently listed on the Exchange under the trading symbol "MNKD." The Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from the Exchange, nor has the Company received any notification that the Commission or the Exchange is contemplating terminating such registration or listing. Except as disclosed in the Registration Statement and the Prospectus, to the Company's knowledge, it is in compliance with all applicable listing requirements of the Exchange.

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

(c) Conformity with Securities Act and Exchange Act. The Registration Statement, the Prospectus, any Issuer Free Writing Prospectus or any amendment or supplement

thereto, and the Incorporated Documents, when such documents were or are filed with the Commission under the Securities Act or the Exchange Act or became or become effective under the Securities Act, as the case may be, conformed or will conform in all material respects with the requirements of the Securities Act and the Exchange Act, as applicable.

(d) Financial Information. The consolidated financial statements of the Company included or incorporated by reference in the Registration Statement, the Prospectus and the Issuer Free Writing Prospectuses, if any, together with the related notes and schedules, present fairly, in all material respects, the consolidated financial position of the Company and the Subsidiaries (as defined below) as of the dates indicated and the consolidated results of operations, cash flows and changes in stockholders' equity of the Company for the periods specified have been prepared in compliance with the requirements of the Securities Act and Exchange Act and in conformity with GAAP (as defined below) applied on a consistent basis during the periods involved (except for such adjustments to accounting standards and practices as are noted therein and except in the case of unaudited financial statements to the extent they may exclude footnotes or may be condensed or summary statements); the summary and selected financial data with respect to the Company and the Subsidiaries (as defined below) contained or incorporated by reference in the Registration Statement, the Prospectus and the Issuer Free Writing Prospectuses, if any, are accurately and fairly presented and prepared on a basis consistent with the financial statements and books and records of the Company; there are no financial statements (historical or pro forma) that are required to be included or incorporated by reference in the Registration Statement, or the Prospectus that are not included or incorporated by reference as required; the Company and the Subsidiaries (as defined below) do not have any material liabilities or obligations, direct or contingent (including any off-balance sheet obligations), not described in the Registration Statement (including the exhibits thereto), and the Prospectus; and all disclosures contained or incorporated by reference in the Registration Statement, the Prospectus and the Issuer Free Writing Prospectuses, if any, regarding "non-GAAP financial measures" (as such term is defined by the rules and regulations of the Commission) comply in all material respects with Regulation G of the Exchange Act and Item 10 of Regulation S-K under the Securities Act, to the extent applicable.

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

(f) Organization. The Company and each of its Subsidiaries has been duly organized, validly existing as a corporation and in good standing under the laws of their respective jurisdictions of organization. The Company and each of its Subsidiaries are, and will be, duly licensed or qualified as a foreign corporation for transaction of business and in good standing under the laws of each other jurisdiction in which their respective ownership or lease of property or the conduct of their respective businesses requires such license or qualification, and have all corporate power and authority necessary to own or hold their respective properties and to conduct their respective businesses as described in the Registration Statement and the Prospectus, except where the failure to be so qualified or in good standing or have such power or authority would not, individually or in the aggregate, have a material adverse effect or would reasonably be expected to have a material adverse effect on or affecting the assets, business,

operations, earnings, properties, condition (financial or otherwise), prospects, stockholders' equity or results of operations of the Company and the Subsidiaries taken as a whole, or prevent or materially interfere with consummation of the transactions contemplated hereby (a "**Material Adverse Effect**").

(g) Subsidiaries. The subsidiaries set forth in Exhibit 21.1 to the Company's most recent Annual Report on Form 10-K (if any) (collectively, the "**Subsidiaries**"), are the Company's only significant subsidiaries (as such term is defined in Rule 1-02 of Regulation S-X promulgated by the Commission). Except as set forth in the Registration Statement and in the Prospectus, the Company owns, directly or indirectly, all of the equity interests of the Subsidiaries free and clear of any lien, charge, security interest, encumbrance, right of first refusal or other restriction, and all the equity interests of the Subsidiaries are validly issued and are fully paid, nonassessable and free of preemptive and similar rights. No Subsidiary is currently prohibited, directly or indirectly, from paying any dividends to the Company, from making any other distribution on such Subsidiary's capital stock, from repaying to the Company any loans or advances to such Subsidiary from the Company or from transferring any of such Subsidiary's property or assets to the Company or any other Subsidiary of the Company.

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

(i) No Material Adverse Change. Subsequent to the respective dates as of which information is given in the Registration Statement, the Prospectus and the Free Writing Prospectuses, if any (including any Incorporated Document), there has not been (i) any Material Adverse Effect or the occurrence of any development that the Company reasonably expects will result in a Material Adverse Effect, (ii) any transaction which is material to the Company and the Subsidiaries taken as a whole, (iii) any obligation or liability, direct or contingent (including any off-balance sheet obligations), incurred by the Company or any Subsidiary, which is material to the Company and the Subsidiaries taken as a whole, (iv) any material change in the capital stock or outstanding long-term indebtedness of the Company or any of its Subsidiaries or (v) any dividend or distribution of any kind declared, paid or made on the capital stock of the Company or any Subsidiary, other than in each case above (A) in the ordinary course of business or (B) as otherwise disclosed in the Registration Statement or Prospectus (including any Incorporated Documents).

(j) Capitalization. The issued and outstanding shares of capital stock of the Company have been validly issued, are fully paid and nonassessable and, other than as disclosed

in the Registration Statement or the Prospectus, are not subject to any preemptive rights, rights of first refusal or similar rights pursuant to the Company's charter, bylaws or any agreement or other instrument to which the Company is a party or by which the Company is bound. The Company has an authorized, issued and outstanding capitalization as set forth in the Registration Statement and the Prospectus as of the dates referred to therein (other than the grant of additional options or other equity awards under the Company's existing equity incentive plans, or changes in the number of outstanding shares of Common Stock of the Company due to the issuance of shares upon the exercise or conversion of securities exercisable for, or convertible into, Common Stock outstanding on the date hereof) and such authorized capital stock conforms to the description thereof set forth in the Registration Statement and the Prospectus. The description of the securities of the Company in the Registration Statement and the Prospectus is complete and accurate in all material respects. Except as disclosed in or contemplated by the Registration Statement or the Prospectus, as of the date referred to therein, the Company does not have outstanding any options to purchase, or any rights or warrants to subscribe for, or any securities or obligations convertible into, or exchangeable for, or any contracts or commitments to issue or sell, any shares of capital stock or other securities.

(k) Authorization; Enforceability. The Company has full legal right, power and authority to enter into this Agreement and perform the transactions contemplated hereby. This Agreement has been duly authorized, executed and delivered by the Company and constitutes a legal, valid and binding agreement of the Company enforceable against the Company in accordance with its terms, except to the extent that (i) enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally and by general equitable principles and (ii) the indemnification and contribution provisions of Section 10 hereof may be limited by federal or state securities laws and public policy considerations in respect thereof.

(l) Authorization of Placement Shares. The Placement Shares, when issued and delivered pursuant to the terms approved by the board of directors of the Company or a duly authorized committee thereof, or a duly authorized executive officer, against payment therefor as provided herein, will be duly authorized, validly issued and fully paid and nonassessable, free and clear of any pledge, lien, encumbrance, security interest or other claim, including any statutory or contractual preemptive rights, resale rights, rights of first refusal or other similar rights, and will be registered pursuant to Section 12 of the Exchange Act. The Placement Shares, when issued, will conform to the description thereof set forth in or incorporated into the Prospectus under the caption "Description of Capital Stock—Common Stock".

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

(n) No Preferential Rights. Except as set forth in the Registration Statement and the Prospectus (including the Incorporated Documents), (i) no person, as such term is defined in Rule 1-02 of Regulation S-X promulgated under the Securities Act (each, a “**Person**”), has the right, contractual or otherwise, to cause the Company to issue or sell to such Person any Common Stock or shares of any other capital stock or other securities of the Company, (ii) no Person has any preemptive rights, resale rights, rights of first refusal, rights of co-sale, or any other rights (whether pursuant to a “poison pill” provision or otherwise) to purchase, from the Company, any Common Stock or shares of any other capital stock or other securities of the Company, (iii) no Person has the right to act as an underwriter or as a financial advisor to the Company in connection with the offer and sale of the Placement Shares, and (iv) no Person has the right, contractual or otherwise, to require the Company to register under the Securities Act any Common Stock or shares of any other capital stock or other securities of the Company, or to include any such shares or other securities in the Registration Statement or the offering contemplated thereby, whether as a result of the filing or effectiveness of the Registration Statement or the sale of the Placement Shares as contemplated thereby or otherwise, which have not been waived with respect to the offering contemplated hereby.

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

(p) Enforceability of Agreements. All agreements between the Company and third parties expressly referenced in the Prospectus are legal, valid and binding obligations of the Company enforceable in accordance with their respective terms, except to the extent that (i) enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors’ rights generally and by general equitable principles and (ii) the indemnification provisions of certain agreements may be limited by federal or state securities laws or public policy considerations in respect thereof.

(q) No Litigation. Except as set forth in the Registration Statement or the Prospectus, there are no pending legal, governmental or regulatory actions, suits, or proceedings, nor, to the Company’s knowledge, any pending legal, governmental or regulatory audits or investigations to which the Company or a Subsidiary is a party or to which any property of the Company or any of its Subsidiaries is the subject that, individually or in the aggregate, would reasonably be expected to have a Material Adverse Effect and, to the Company’s knowledge, no such actions, suits, proceedings, audits or investigations are threatened or contemplated by any legal, governmental or regulatory authority or threatened by others; and (i) there are no current or pending legal, governmental or regulatory audits or investigations, actions, suits or proceedings that are required under the Securities Act to be described in the Prospectus that are not so

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

(r) Consents and Permits. Except as set forth in the Registration Statement and the Prospectus, the Company and each of its Subsidiaries have such permits, licenses, patents, franchises, certificates of need and other approvals and other authorizations (the “**Regulatory Permits**”) issued by the appropriate domestic or foreign regional, federal, state, or local regulatory agencies or bodies necessary to conduct the business of the Company, including, without limitation, any Investigational New Drug Application (an “**IND**”) and/or New Drug Application (an “**NDA**”), as required by the U.S. Food and Drug Administration (the “**FDA**”), or any other authorizations issued by domestic or foreign regional, federal, state, or local agencies or bodies engaged in the regulation of pharmaceuticals such as those being developed by the Company and its Subsidiaries, except for any of the foregoing that would not reasonably be expected to, individually or in the aggregate, have a Material Adverse Effect; the Company is in compliance in all material respects with the requirements of the Regulatory Permits, and all of the Regulatory Permits are valid and in full force and effect, in each case in all material respects, except where any invalidity, individually or in the aggregate, would not reasonably be expected to have a Material Adverse Effect; the Company has not received any written notice of proceedings relating to the revocation, termination, modification or impairment of rights of any of the Regulatory Permits that, individually or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would reasonably be expected to result in a Material Adverse Effect; the Company has not failed to submit to the FDA any IND or NDA necessary to conduct the business of the Company, any such filings that were required to be made were in material compliance with applicable laws when filed, and no material deficiencies have been asserted by the FDA with respect to any such filings or submissions that were made.

(s) Regulatory Filings. Except as disclosed in the Registration Statement and the Prospectus, neither the Company nor any of its Subsidiaries has failed to file with the applicable regulatory authorities (including, without limitation, the FDA, or any foreign, federal, state, provincial or local governmental or regulatory authority performing functions similar to those performed by the FDA) any required filing, declaration, listing, registration, report or submission, except for such failures that, individually or in the aggregate, would not reasonably be expected to have a Material Adverse Effect; except as disclosed in the Registration Statement and the Prospectus, all such filings, declarations, listings, registrations, reports or submissions were in compliance with applicable laws when filed and no deficiencies have been asserted by any applicable regulatory authority with respect to any such filings, declarations, listings, registrations, reports or submissions, except for any deficiencies that, individually or in the aggregate, would not reasonably be expected to have a Material Adverse Effect. The Company has operated and currently is, in all material respects, in compliance with the United States Federal Food, Drug, and Cosmetic Act, all applicable rules and regulations of the FDA and other federal, state, local and foreign governmental bodies exercising comparable authority. The Company has no knowledge of any studies, tests or trials not described in the Prospectus the results of which reasonably call into question in any material respect the results of the studies, tests and trials described in the Prospectus.

(t) Intellectual Property. The Company and each of its Subsidiaries owns, possesses or has valid and enforceable licenses to use, or reasonably believes it can acquire on

reasonable terms, all Intellectual Property (as defined below) necessary for the conduct of the Company's and its Subsidiaries' business as now conducted, except as such failure to own, possess, or acquire such rights would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Effect. Furthermore, except as disclosed in the Registration Statement or the Prospectus (A) to the knowledge of the Company, there is no infringement, misappropriation or violation by third parties of any such Intellectual Property; (B) there is no pending or, to the knowledge of the Company, threatened, action, suit, proceeding or claim by others challenging the Company's or any of its Subsidiaries' rights in or to any such Intellectual Property; (C) the Intellectual Property owned by the Company and its Subsidiaries, and to the knowledge of the Company, the Intellectual Property licensed to the Company and its Subsidiaries, has not been adjudged invalid or unenforceable, in whole or in part, and there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others challenging the validity or scope of any such Intellectual Property; (D) there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others that the Company or any of its Subsidiaries infringes, misappropriates or otherwise violates any Intellectual Property or other proprietary rights of others, and neither the Company nor any of its Subsidiaries has received any written notice of such claim; and (E) to the Company's knowledge, no employee of the Company or any of its Subsidiaries is in or has ever been in violation of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement or any restrictive covenant to or with a former employer where the basis of such violation relates to such employee's employment with the Company or any of its Subsidiaries or actions undertaken by the employee while employed with the Company or any of its Subsidiaries, except, in the case of clauses (A), (B), (C), (D) and (E) above, for any such invalidity, unenforceability, infringement, violation, misappropriation, action, suit, proceeding or claim as would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect. "**Intellectual Property**" shall mean all patents, patent applications, trade and service marks, trade and service mark registrations, trade names, copyrights, licenses, inventions, trade secrets, domain names, technology, know-how and other intellectual property.

(u) Clinical Studies. To the Company's knowledge, the studies, tests and preclinical and clinical investigations conducted by or on behalf of the Company and described in the Prospectus were and, if still pending, are, in all material respects, being conducted in accordance with established protocols, procedures and controls pursuant to, where applicable, accepted professional scientific standards for products or product candidates comparable to those being developed by the Company, and all Applicable Laws and Authorizations, including, without limitation, the Federal Food, Drug, and Cosmetic Act and implementing regulations including good laboratory practice ("**GLP**") regulations (21 C.F.R. Part 58) if any such studies, tests or preclinical and clinical investigations are being conducted pursuant to GLP, and good clinical practice and IND requirements (21 C.F.R. Parts 50, 54, 56, and 312) if any such studies, tests or preclinical and clinical investigations were or are subject to good clinical practice regulations or were or are being conducted under an IND; the descriptions of the results of such studies, tests and trials contained in the Registration Statement and the Prospectus are accurate in all material respects and fairly present the data derived from such studies, tests and trials; except to the extent disclosed in the Registration Statement and the Prospectus, the Company is not aware of any studies, tests or trials the results of which the Company believes reasonably call into question the study, test, or trial results described or referred to in the Registration Statement

and the Prospectus when viewed in the context in which such results are described and the clinical state of development; and neither the Company nor any of its Subsidiaries have received any written notices or correspondence from any Governmental Authority requiring the termination, suspension or material modification of any studies, tests or preclinical or clinical investigations conducted by or on behalf of the Company or any of its Subsidiaries.

(v) Market Capitalization. At the time the Registration Statement was or will be originally declared effective, and at the time the Company's most recent Annual Report on Form 10-K was filed with the Commission, the Company met or will meet the then applicable requirements for the use of Form S-3 under the Securities Act, including, but not limited to, Instruction I.B.1 of Form S-3. The aggregate market value of the outstanding voting and non-voting common equity (as defined in Securities Act Rule 405) of the Company held by persons other than affiliates of the Company (pursuant to Securities Act Rule 144, those that directly, or indirectly through one or more intermediaries, control, or are controlled by, or are under common control with, the Company) (the "**Non-Affiliate Shares**"), was equal to or greater than \$75 million (calculated by multiplying (x) the highest price at which the common equity of the Company closed on the Exchange within 60 days of the date of the latter of (i) the filing of the Registration Statement or (ii) the filing of the Company's most recent Annual Report on Form 10-K times (y) the number of Non-Affiliate Shares). The Company is not a shell company (as defined in Rule 405 under the Securities Act) and has not been a shell company for at least 12 calendar months previously and if it has been a shell company at any time previously, has filed current Form 10 information (as defined in Instruction I.B.6 of Form S-3) with the Commission at least 12 calendar months previously reflecting its status as an entity that is not a shell company.

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

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

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

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

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

(bb) Title to Real and Personal Property. Except as disclosed in the Registration Statement or the Prospectus, the Company and its Subsidiaries have good and marketable title to all real property owned by them, good and valid title to all tangible personal property (other than Intellectual Property, which is covered in Section 6(t) above) described in the Registration Statement or Prospectus as being owned by them that are material to the businesses of the Company or such Subsidiary, in each case free and clear of all liens, encumbrances and claims, except those matters that (i) do not materially interfere with the use made and proposed to be made of such property by the Company and any of its Subsidiaries or (ii) would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. Any real or tangible personal property described in the Registration Statement or Prospectus as being leased by the Company and any of its Subsidiaries is held by them under valid, existing and enforceable leases, except those that (A) do not materially interfere with the use made or proposed to be made of such property by the Company or any of its Subsidiaries or (B) would not be reasonably expected, individually or in the aggregate, to have a Material Adverse Effect. Each of the properties of the Company and its Subsidiaries complies with all applicable codes, laws and regulations (including, without limitation, building and zoning codes, laws and regulations and laws relating to access to such properties), except if and to the extent disclosed in the Registration Statement or Prospectus or except for such failures to comply that would not, individually or in the aggregate, reasonably be expected to interfere in any material respect with the use made and proposed to be made of such property by the Company and its Subsidiaries or otherwise have a Material Adverse Effect. None of the Company or its subsidiaries has received from any governmental or regulatory authorities any notice of any condemnation of, or zoning change affecting, the properties of the Company and its Subsidiaries, and the Company knows of no such condemnation or zoning change which is threatened, except for such that would not reasonably be expected to interfere in any material respect with the use made and proposed to be made of such property by the Company and its Subsidiaries or otherwise have a Material Adverse Effect, individually or in the aggregate.

(cc) Environmental Laws. Except as disclosed in the Registration Statement or the Prospectus, the Company and its Subsidiaries (i) are in compliance with any and all

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

(dd) Disclosure Controls. The Company and each of its Subsidiaries maintain systems of internal accounting controls designed to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company's internal control over financial reporting is effective and the Company is not aware of any material weaknesses in its internal control over financial reporting (other than as set forth in the Prospectus). Since the date of the latest audited financial statements of the Company included in the Prospectus, there has been no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting (other than as set forth in the Prospectus). The Company has established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15 and 15d-15) for the Company and designed such disclosure controls and procedures to provide reasonable assurance that material information relating to the Company and each of its Subsidiaries is made known to the certifying officers by others within those entities, particularly during the period in which the Company's Annual Report on Form 10-K or Quarterly Report on Form 10-Q, as the case may be, is being prepared. The Company's certifying officers have evaluated the effectiveness of the Company's disclosure controls and procedures as of a date within 90 days prior to the filing date of the Form 10-K for the fiscal year most recently ended (such date, the "**Evaluation Date**"). The Company presented in its Form 10-K for the fiscal year most recently ended the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date and the disclosure controls and procedures were effective. Since the Evaluation Date, there have been no significant changes in the Company's internal controls (as such term is defined in Item 307(b) of Regulation S-K under the Securities Act) or, to the Company's knowledge, in other factors that could significantly affect the Company's internal controls.

(ee) Sarbanes-Oxley. There is and has been no failure on the part of the Company or, to the Company's knowledge, any of the Company's directors or officers, in their capacities as such, to comply with any applicable provisions of the Sarbanes-Oxley Act and the rules and regulations promulgated thereunder. Each of the principal executive officer and the principal financial officer of the Company (or each former principal executive officer of the

Company and each former principal financial officer of the Company as applicable) has made all certifications required by Sections 302 and 906 of the Sarbanes-Oxley Act with respect to all reports, schedules, forms, statements and other documents required to be filed by it or furnished by it to the Commission. For purposes of the preceding sentence, “principal executive officer” and “principal financial officer” shall have the meanings given to such terms in the Sarbanes-Oxley Act.

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

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

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

(ii) Operations. The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial record keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all jurisdictions to which the Company or its Subsidiaries are subject, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency having jurisdiction over the Company (collectively, the “**Money Laundering Laws**”); and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its Subsidiaries with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

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

(kk) Underwriter Agreements. The Company is not a party to any agreement with an agent or underwriter for any other “at-the-market” or continuous equity transaction.

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

(mm) Forward-Looking Statements. No forward-looking statement (within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act) (a “**Forward-Looking Statement**”) contained in the Registration Statement and the Prospectus has been made or reaffirmed without a reasonable basis or has been disclosed other than in good faith.

(nn) Agent Purchases. The Company acknowledges and agrees that the Agent has informed the Company that the Agent may, to the extent permitted under the Securities Act and the Exchange Act, purchase and sell Common Stock for its own account while this Agreement is in effect, *provided*, that (i) no such purchase or sales shall take place while a Placement Notice is in effect (except to the extent the Agent may engage in sales of Placement Shares purchased or deemed purchased from the Company as a “riskless principal” or in a similar capacity) and (ii) the Company shall not be deemed to have authorized or consented to any such purchases or sales by the Agent.

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

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

(qq) No Improper Practices. (i) Neither the Company nor the Subsidiaries, nor to the Company’s knowledge, any of their respective executive officers has, in the past five years, made any unlawful contributions to any candidate for any political office (or failed fully to disclose any contribution in violation of law) or made any contribution or other payment to any official of, or candidate for, any federal, state, municipal, or foreign office or other person charged with similar public or quasi-public duty in violation of any law or of the character required to be disclosed in the Prospectus; (ii) no relationship, direct or indirect, exists between

or among the Company or any Subsidiary or any affiliate of any of them, on the one hand, and the directors, officers and stockholders of the Company or any Subsidiary, on the other hand, that is required by the Securities Act to be described in the Registration Statement and the Prospectus that is not so described; (iii) no relationship, direct or indirect, exists between or among the Company or any Subsidiary or any affiliate of them, on the one hand, and the directors, officers, or stockholders of the Company or any Subsidiary, on the other hand, that is required by the rules of FINRA to be described in the Registration Statement and the Prospectus that is not so described; (iv) except as described in the Registration Statement and the Prospectus, there are no material outstanding loans or advances or material guarantees of indebtedness by the Company or any Subsidiary to or for the benefit of any of their respective officers or directors or any of the members of the families of any of them; and (v) the Company has not offered, or caused any placement agent to offer, Common Stock to any person with the intent to influence unlawfully (A) a customer or supplier of the Company or any Subsidiary to alter the customer's or supplier's level or type of business with the Company or any Subsidiary or (B) a trade journalist or publication to write or publish favorable information about the Company or any Subsidiary or any of their respective products or services, and (vi) neither the Company nor any Subsidiary nor, to the Company's knowledge, any employee or agent of the Company or any Subsidiary has made any payment of funds of the Company or any Subsidiary or received or retained any funds in violation of any law, rule or regulation (including, without limitation, the Foreign Corrupt Practices Act of 1977), which payment, receipt or retention of funds is of a character required to be disclosed in the Registration Statement or the Prospectus.

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

(ss) No Misstatement or Omission in an Issuer Free Writing Prospectus. Each Issuer Free Writing Prospectus, as of its issue date and as of each Applicable Time (as defined in Section 23 below), did not, does not and will not, not, through the completion of the Placement for which such Issuer Free Writing Prospectus is used or deemed used, include any information that conflicted, conflicts or will conflict with the information contained in the Registration Statement or the Prospectus, including any Incorporated Document that has not been superseded or modified. The foregoing sentence does not apply to statements in or omissions from any Issuer Free Writing Prospectus based upon and in conformity with written information furnished to the Company by the Agent specifically for use therein.

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

governing documents of the Company, or (y) in any violation of the provisions of any statute or any order, rule or regulation applicable to the Company or of any court or of any federal, state or other regulatory authority or other government body having jurisdiction over the Company, except in the case of clause (y) for such violations as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(uu) Sanctions. (i) The Company represents that, neither the Company nor any of its Subsidiaries (collectively, the “**Entity**”) nor, to the Entity’s knowledge, any director, officer, employee, agent, affiliate or representative of the Entity, is a government, individual, or entity (in this paragraph (uu), “**Person**”) that is, or is owned or controlled by a Person that is:

(A) the subject of any sanctions administered or enforced by the U.S. Department of Treasury’s Office of Foreign Assets Control, the United Nations Security Council, the European Union, Her Majesty’s Treasury, or other relevant sanctions authority (collectively, “**Sanctions**”), nor

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

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

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

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

(iii) The Entity represents and covenants that, except as detailed in the Registration Statement and the Prospectus, for the past 5 years, it has not engaged in, is not now engaging in, and will not engage in, any dealings or transactions with any Person, or in any country or territory, that at the time of the dealing or transaction is or was the subject of Sanctions.

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

(ww) Compliance with Laws. Each of the Company and its Subsidiaries: (A) is and at all times has been in compliance with all statutes, rules, or regulations applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any

product manufactured or distributed by the Company or its Subsidiaries ("**Applicable Laws**"), except as would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect; (B) has not received any FDA Form 483, notice of adverse finding, warning letter, untitled letter or other correspondence or notice from the FDA or any other Governmental Authority alleging or asserting noncompliance in any material respect with any Applicable Laws or any licenses, certificates, approvals, clearances, authorizations, permits and supplements or amendments thereto required by any such Applicable Laws ("**Authorizations**"); (C) possesses all material Authorizations and such Authorizations are valid and in full force and effect and are not in material violation of any term of any such Authorizations; (D) has not received notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any Governmental Authority or third party alleging that any product operation or activity is in violation of any Applicable Laws or Authorizations and has no knowledge that any such Governmental Authority or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding; (E) has not received notice that any Governmental Authority has taken, is taking or intends to take action to limit, suspend, modify or revoke any Authorizations and has no knowledge that any such Governmental Authority is considering such action; and (F) has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and correct in all material respects on the date filed (or were corrected or supplemented by a subsequent submission); and (G) has not, either voluntarily or involuntarily, initiated, conducted, or issued or caused to be initiated, conducted or issued, any recall, market withdrawal or replacement, safety alert, post-sale warning, "dear healthcare provider" letter, or other notice or action relating to the alleged lack of safety or efficacy of any product or any alleged product defect or violation and, to the Company's knowledge, no third party has initiated, conducted or intends to initiate any such notice or action.

(xx) Compliance with Occupational Laws. The Company and each of its Subsidiaries (A) is in compliance, in all material respects, with any and all applicable foreign, federal, state and local laws, rules, regulations, treaties, statutes and codes promulgated by any and all Governmental Authorities (including pursuant to the Occupational Health and Safety Act) relating to the protection of human health and safety in the workplace ("**Occupational Laws**"); (B) has received all material permits, licenses or other approvals required of it under applicable Occupational Laws to conduct its business as currently conducted; and (C) is in compliance, in all material respects, with all terms and conditions of such permit, license or approval. No action, proceeding, revocation proceeding, writ, injunction or claim is pending or, to the Company's knowledge, threatened against the Company or any of its Subsidiaries relating to Occupational Laws and the Company does not have knowledge of any facts, circumstances or developments relating to its operations or cost accounting practices that would reasonably be expected to form the basis for or give rise to such actions, suits, investigations or proceedings, except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

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

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

(a) Registration Statement Amendments. After the date of this Agreement and during any period in which a Prospectus relating to any Placement Shares is required to be delivered by Agent under the Securities Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), (i) the Company will notify the Agent promptly of the time when any subsequent amendment to the Registration Statement, other than documents incorporated by reference, has been filed with the Commission and/or has become effective or any subsequent supplement to the Prospectus, other than documents incorporated by reference, has been filed and of any request by the Commission for any amendment or supplement to the Registration Statement or Prospectus or for additional information; (ii) the Company will prepare and file with the Commission, promptly upon the Agent's reasonable request, any amendments or supplements to the Registration Statement or Prospectus that, in the Agent's reasonable opinion, may be necessary or advisable in connection with the distribution of the Placement Shares by the Agent (*provided, however*, that the failure of the Agent to make such request shall not relieve the Company of any obligation or liability hereunder, or affect the Agent's right to rely on the representations and warranties made by the Company in this Agreement and *provided, further*, that the only remedy the Agent shall have with respect to the failure to make such filing shall be to cease making sales under this Agreement until such amendment or supplement is filed); (iii) the Company will not file any amendment or supplement to the Registration Statement or Prospectus (except for documents incorporated by reference) relating to the Placement Shares or a security convertible into the Placement Shares unless a copy thereof has been submitted to the Agent within a reasonable period of time before the filing and the Agent has not reasonably objected thereto in writing within two (2) Business Days (*provided, however*, that (A) the failure of the Agent to make such objection shall not relieve the Company of any obligation or liability hereunder, or affect the Agent's right to rely on the representations and warranties made by the Company in this Agreement and (B) the Company has no obligation to provide the Agent any advance copy of such filing or to provide the Agent an opportunity to object to such filing, if such filing does not name the Agent and does not reference the transactions contemplated hereunder; and *provided, further*, that the only remedy the Agent shall have with respect to the failure by the Company to obtain such consent shall be to cease making sales under this Agreement) and the Company will furnish to the Agent at the time of filing thereof a copy of any document that upon filing is deemed to be incorporated by reference into the Registration Statement or Prospectus, except for those documents available via EDGAR; and (iv) the Company will cause each amendment or supplement to the Prospectus to be filed with the Commission as required pursuant to the applicable paragraph of Rule 424(b) of the Securities Act or, in the case of any document to be incorporated therein by reference, to be filed with the Commission as required pursuant to the Exchange Act, within the time period prescribed (the determination to file or not file any amendment or supplement with the Commission under this Section 7(a), based on the Company's reasonable opinion or reasonable objections, shall be made exclusively by the Company).

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

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

(c) Delivery of Prospectus; Subsequent Changes. During any period in which a Prospectus relating to the Placement Shares is required to be delivered by the Agent under the Securities Act with respect to the offer and sale of the Placement Shares (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), the Company will use commercially reasonable efforts to comply in all material respects with all requirements imposed upon it by the Securities Act, as from time to time in force, and to file on or before their respective due dates all reports and any definitive proxy or information statements required to be filed by the Company with the Commission pursuant to Sections 13(a), 13(c), 14, 15(d) or any other provision of or under the Exchange Act. If the Company has omitted any information from the Registration Statement pursuant to Rule 430B under the Securities Act, it will use its best efforts to comply with the provisions of and make all requisite filings with the Commission pursuant to said Rule 430B and to notify the Agent promptly of all such filings if not available on EDGAR. If during such period any event occurs as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances then existing, not misleading, or if during such period it is necessary to amend or supplement the Registration Statement or Prospectus to comply with the Securities Act, the Company will promptly notify the Agent to suspend the offering of Placement Shares during such period and the Company will promptly amend or supplement the Registration Statement or Prospectus (at the expense of the Company) so as to correct such statement or omission or effect such compliance; *provided, however*, that the Company may delay any such amendment or supplement if, in the judgment of the Company, it is in the best interests of the Company to do so.

(d) Listing of Placement Shares. Prior to the date of the first Placement Notice, the Company will use its reasonable best efforts to cause the Placement Shares to be listed on the Exchange.

(e) Delivery of Registration Statement and Prospectus. The Company will furnish to the Agent and its counsel (at the expense of the Company) copies of the Registration Statement, the Prospectus (including all Incorporated Documents) and all amendments and supplements to the Registration Statement or Prospectus that are filed with the Commission during any period in which a Prospectus relating to the Placement Shares is required to be delivered under the Securities Act (including all Incorporated Documents filed with the Commission during such period), in each case as soon as reasonably practicable and in such quantities as the Agent may from time to time reasonably request and, at the Agent's request, will also furnish copies of the Prospectus to each exchange or market on which sales of the Placement Shares may be made; *provided, however*, that the Company shall not be required to

furnish any document (other than the Prospectus) to the Agent to the extent such document is available on EDGAR.

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

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

(h) Notice of Other Sales. Without the prior written consent of the Agent, the Company will not, directly or indirectly, offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any Common Stock (other than the Placement Shares offered pursuant to this Agreement) or securities convertible into or exchangeable for Common Stock, warrants or any rights to purchase or acquire, Common Stock during the period beginning on the fifth (5th) Trading Day immediately prior to the date on which any Placement Notice is delivered to the Agent hereunder and ending on the Trading Day immediately following the final Settlement Date with respect to Placement Shares sold pursuant to such Placement Notice (or, if the Placement Notice has been terminated or suspended prior to the sale of all Placement Shares covered by a Placement Notice, the date of such suspension or termination); and will not directly or indirectly in any other "at the market" or continuous equity transaction offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any Common Stock (other than the Placement Shares offered pursuant to this Agreement) or securities convertible into or exchangeable for Common Stock, warrants or any rights to purchase or acquire, Common Stock prior to the later of the termination of this Agreement and the thirtieth (30th) day immediately following the final Settlement Date with respect to Placement Shares sold pursuant to such Placement Notice; *provided, however*, that such restrictions will not apply in connection with the Company's issuance or sale of (i) Common Stock, options to purchase Common Stock, other equity awards to acquire Common Stock, or Common Stock issuable upon the exercise of options or other equity awards, pursuant to any equity incentive or benefits plan, employee stock purchase plan, stock ownership plan or dividend reinvestment plan (but not Common Stock subject to a waiver to exceed plan limits in its dividend reinvestment plan) of the Company whether now in effect or hereafter implemented, (ii) Common Stock issuable upon conversion of securities or the exercise of warrants, options or other rights in effect or outstanding or hereafter implemented, and disclosed in filings by the Company available on EDGAR or otherwise in writing to the Agent and (iii) Common Stock or securities convertible into or exchangeable for shares of Common Stock as consideration for mergers, acquisitions, or other business combinations or strategic alliances occurring after the date of this Agreement which are not issued for capital raising purposes.

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

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

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

(l) Representation Dates; Certificate. (1) On or prior to the date of the first Placement Notice and (2) each time the Company:

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

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

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

(iv) files a current report on Form 8-K containing amended financial information (other than information "furnished" pursuant to Items 2.02 or 7.01 of Form 8-K or to provide disclosure pursuant to Item 8.01 of Form 8-K relating to the reclassification of certain properties as discontinued operations in accordance with Statement of Financial Accounting Standards No. 144) under the Exchange Act (each date of filing of one or more of the documents referred to in clauses (i) through (iv) shall be a "**Representation Date**");

the Company shall furnish the Agent (but in the case of clause (iv) above only if the Agent reasonably determines that the information contained in such Form 8-K is material) with a certificate dated the Representation Date, in the form and substance satisfactory to the Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel, modified, as necessary, to relate to the Registration Statement and the Prospectus as amended or supplemented. The requirement to provide a certificate under this Section 7(l) shall be automatically waived for any Representation Date occurring (1) at a time a Suspension is in

effect, which waiver shall continue until the earlier to occur of the date the Company delivers instructions for the sale of Placement Shares hereunder (which for such calendar quarter shall be considered a Representation Date) and the next occurring Representation Date and (2) at a time at which no Placement Notice is pending, which waiver shall continue until the date the Company delivers a Placement Notice hereunder (which for such calendar quarter shall be considered a Representation Date). Notwithstanding the foregoing, if the Company subsequently decides to sell Placement Shares following a Representation Date when a Suspension was in effect and did not provide the Agent with a certificate under this Section 7(l), then before the Company delivers the instructions for the sale of Placement Shares or the Agent sells any Placement Shares pursuant to such instructions, the Company shall provide the Agent with a certificate in conformity with this Section 7(l) dated as of the date that the instructions for the sale of Placement Shares are issued.

(m) Legal Opinions. (1) On or prior to the date of the first Placement Notice and (2) unless waived by the Agent, within five (5) Trading Days of each Representation Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 7(l) for which no waiver is applicable and excluding the date of this Agreement, the Company shall cause to be furnished to the Agent (A) a written opinion of Cooley LLP (“**Company Counsel**”) and (B) a written opinion of K&L Gates LLP (“**Company IP Counsel**”), or other counsel reasonably satisfactory to the Agent, in form and substance reasonably satisfactory to Agent and its counsel, substantially similar to the form previously provided to the Agent and its counsel, modified, as necessary, to relate to the Registration Statement and the Prospectus as then amended or supplemented; *provided, however*, the Company shall be required to furnish to Agent no more than one opinion from Company Counsel hereunder per calendar quarter and no more than one opinion from Company IP Counsel hereunder per calendar year; *provided, further*, that in lieu of such opinions for subsequent periodic filings under the Exchange Act, counsel may furnish the Agent with a letter (a “**Reliance Letter**”) to the effect that the Agent may rely on a prior opinion delivered under this Section 7(m) to the same extent as if it were dated the date of such letter (except that statements in such prior opinion shall be deemed to relate to the Registration Statement and the Prospectus as amended or supplemented as of the date of the Reliance Letter).

(n) Comfort Letter. (1) On or prior to the date of the first Placement Notice and (2) within five (5) Trading Days of each Representation Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 7(l) for which no waiver is applicable and excluding the date of this Agreement, the Company shall cause its independent registered public accounting firm to furnish the Agent letters (the “**Comfort Letters**”), dated the date the Comfort Letter is delivered, which shall meet the requirements set forth in this Section 7(n); *provided*, that if requested by the Agent, the Company shall cause a Comfort Letter to be furnished to the Agent within ten (10) Trading Days of the date of occurrence of any material transaction or event requiring the filing of a Current Report on Form 8-K containing material financial information, including the restatement of the Company’s financial statements. The Comfort Letter from the Company’s independent registered public accounting firm shall be in a form and substance reasonably satisfactory to the Agent, (i) confirming that they are an independent registered public accounting firm within the meaning of the Securities Act and the PCAOB, (ii) stating, as of such date, the conclusions and findings of such firm with respect to the financial information and other matters ordinarily covered by accountants’ “comfort letters”

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

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

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

(q) No Offer to Sell. Other than an Issuer Free Writing Prospectus approved in advance by the Company and the Agent in its capacity as agent hereunder, neither the Agent nor the Company (including its agents and representatives, other than the Agent in its capacity as such) will make, use, prepare, authorize, approve or refer to any written communication (as defined in Rule 405 under the Securities Act), required to be filed with the Commission, that constitutes an offer to sell or solicitation of an offer to buy Placement Shares hereunder.

(r) Blue Sky and Other Qualifications. The Company will use its commercially reasonable efforts, in cooperation with the Agent, to qualify the Placement Shares for offering and sale, or to obtain an exemption for the Placement Shares to be offered and sold, under the applicable securities laws of such states and other jurisdictions (domestic or foreign) as the Agent may designate and to maintain such qualifications and exemptions in effect for so long as required for the distribution of the Placement Shares (but in no event for less than one year from the date of this Agreement); *provided, however*, that the Company shall not be obligated to file any general consent to service of process or to qualify as a foreign corporation or as a dealer in securities in any jurisdiction in which it is not so qualified or to subject itself to taxation in respect of doing business in any jurisdiction in which it is not otherwise so subject. In each jurisdiction in which the Placement Shares have been so qualified or exempt, the Company will file such statements and reports as may be required by the laws of such jurisdiction to continue such qualification or exemption, as the case may be, in effect for so long as required for the distribution of the Placement Shares (but in no event for less than one year from the date of this Agreement).

(s) Sarbanes-Oxley Act. The Company and the Subsidiaries will maintain and keep accurate books and records reflecting their assets and maintain internal accounting controls in a manner designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and including those policies and procedures that (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company, (ii) provide

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

(t) Secretary's Certificate; Further Documentation. On or prior to the date of the first Placement Notice, the Company shall deliver to the Agent a certificate of the Secretary of the Company and attested to by an executive officer of the Company, dated as of such date, certifying as to (i) the Certificate of Incorporation of the Company, (ii) the By-laws of the Company, (iii) the resolutions of the Board of Directors of the Company, or a duly authorized committee of the Board of Directors, authorizing the execution, delivery and performance of this Agreement and the issuance of the Placement Shares and (iv) the incumbency of the officers duly authorized to execute this Agreement and the other documents contemplated by this Agreement. Within five (5) Trading Days of each Representation Date, the Company shall have furnished to the Agent such further information, certificates and documents as the Agent may reasonably request.

8. Payment of Expenses. The Company will pay all expenses incident to the performance of its obligations under this Agreement, including (i) the preparation and filing of the Registration Statement, including any fees required by the Commission, and the printing or electronic delivery of the Prospectus as originally filed and of each amendment and supplement thereto, in such number as the Agent shall reasonably deem necessary, (ii) the printing and delivery to the Agent of this Agreement and such other documents as may be required in connection with the offering, purchase, sale, issuance or delivery of the Placement Shares, (iii) the preparation, issuance and delivery of the certificates, if any, for the Placement Shares to the Agent, including any stock or other transfer taxes and any capital duties, stamp duties or other duties or taxes payable upon the sale, issuance or delivery of the Placement Shares to the Agent, (iv) the fees and disbursements of the counsel, accountants and other advisors to the Company, (v) the fees and expenses of the Agent including but not limited to the fees and expenses of the counsel to the Agent, payable upon the execution of this Agreement, in an amount not to exceed \$50,000, (vi) the qualification or exemption of the Placement Shares under state securities laws in accordance with the provisions of Section 7(r) hereof, including filing

fees, but excluding fees of the Agent's counsel, (vii) the printing and delivery to the Agent of copies of any Permitted Issuer Free Writing Prospectus and the Prospectus and any amendments or supplements thereto in such number as the Agent shall reasonably deem necessary, (viii) the preparation, printing and delivery to the Agent of copies of the blue sky survey, (ix) the fees and expenses of the transfer agent and registrar for the Common Stock, (x) the filing and other fees incident to any review by FINRA of the terms of the sale of the Placement Shares including the fees of the Agent's counsel (subject to the cap, set forth in clause (v) above), and (xi) the fees and expenses incurred in connection with the listing of the Placement Shares on the Exchange.

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

(a) Registration Statement Effective. The Registration Statement shall have become effective and shall be available for the (i) resale of all Placement Shares issued to the Agent and not yet sold by the Agent and (ii) sale of all Placement Shares contemplated to be issued by any Placement Notice.

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

(c) No Misstatement or Material Omission. The Agent shall not have advised the Company that the Registration Statement or Prospectus, or any amendment or supplement thereto, contains an untrue statement of fact that in the Agent's reasonable opinion, in consultation with outside counsel, is material, or omits to state a fact that in the Agent's

reasonable opinion is material and is required to be stated therein or is necessary to make the statements therein not misleading.

(d) Material Changes. Except as contemplated in the Prospectus, or disclosed in the Company's reports filed with the Commission, there shall not have been any material adverse change in the authorized capital stock of the Company or any Material Adverse Effect or any development that would reasonably be expected to cause a Material Adverse Effect, or a downgrading in or withdrawal of the rating assigned to any of the Company's securities (other than asset backed securities) by any rating organization or a public announcement by any rating organization that it has under surveillance or review its rating of any of the Company's securities (other than asset backed securities), the effect of which, in the case of any such action by a rating organization described above, in the reasonable judgment of the Agent (without relieving the Company of any obligation or liability it may otherwise have), is so material as to make it impracticable or inadvisable to proceed with the offering of the Placement Shares on the terms and in the manner contemplated in the Prospectus.

(e) Legal Opinion. The Agent shall have received the opinions of Company Counsel and Company IP Counsel, as applicable, required to be delivered pursuant to Section 7(m) on or before the date on which such delivery of such opinion is required pursuant to Section 7(m).

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

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

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

(i) Other Materials. On each date on which the Company is required to deliver a certificate pursuant to Section 7(l), the Company shall have furnished to the Agent such appropriate further information, opinions, certificates, letters and other documents as the Agent may reasonably request. All such certificates, opinions, letters and other documents will be in compliance with the provisions hereof.

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

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

the issuance of any Placement Notice and the Exchange shall have reviewed such application and not provided any objections thereto.

(l) FINRA. If applicable, FINRA shall have raised no objection to the terms of this offering and the amount of compensation allowable or payable to the Agent as described in the Prospectus.

(m) No Termination Event. There shall not have occurred any event that would permit the Agent to terminate this Agreement pursuant to Section 12(a).

10. Indemnification and Contribution.

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

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

(ii) against any and all loss, liability, claim, damage and expense whatsoever, as incurred, joint or several, to the extent of the aggregate amount paid in settlement of any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or of any claim whatsoever based upon any such untrue statement or omission, or any such alleged untrue statement or omission; *provided* that (subject to Section 10(d) below) any such settlement is effected with the written consent of the Company, which consent shall not unreasonably be delayed or withheld; and

(iii) against any and all expense whatsoever, as incurred (including the reasonable and documented fees and disbursements of counsel), reasonably incurred in investigating, preparing or defending against any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever based upon any such untrue statement or omission, or any such alleged untrue statement or omission (whether or not a party), to the extent that any such expense is not paid under (i) or (ii) above, *provided, however*, that this indemnity agreement shall not apply to any loss, liability, claim, damage or expense to the extent arising out of any untrue statement or omission or alleged untrue statement or omission made solely in reliance upon and in conformity with the Agent Information (as defined below).

(b) Agent Indemnification. Agent agrees to indemnify and hold harmless the Company and its directors and each officer and director of the Company who signed the

Registration Statement, and each person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act against any and all loss, liability, claim, damage and expense described in the indemnity contained in Section 10(a), as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions, made in the Registration Statement (or any amendments thereto), the Prospectus (or any amendment or supplement thereto) or any Issuer Free Writing Prospectus (or any amendment or supplement thereto) in reliance upon and in conformity with information relating to the Agent and furnished to the Company in writing by the Agent expressly for use therein. The Company hereby acknowledges that the only information that the Agent has furnished to the Company expressly for use in the Registration Statement, the Prospectus or any Issuer Free Writing Prospectus (or any amendment or supplement thereto) are the statements set forth in the fifth and seventh paragraphs under the caption “Plan of Distribution” in the Prospectus (the “**Agent Information**”).

(c) Procedure. Any party that proposes to assert the right to be indemnified under this Section 10 will, promptly after receipt of notice of commencement of any action against such party in respect of which a claim is to be made against an indemnifying party or parties under this Section 10, notify each such indemnifying party of the commencement of such action, enclosing a copy of all papers served, but the omission so to notify such indemnifying party will not relieve the indemnifying party from (i) any liability that it might have to any indemnified party otherwise than under this Section 10 and (ii) any liability that it may have to any indemnified party under the foregoing provision of this Section 10 unless, and only to the extent that, such omission results in the forfeiture of substantive rights or defenses by the indemnifying party. If any such action is brought against any indemnified party and it notifies the indemnifying party of its commencement, the indemnifying party will be entitled to participate in and, to the extent that it elects by delivering written notice to the indemnified party promptly after receiving notice of the commencement of the action from the indemnified party, jointly with any other indemnifying party similarly notified, to assume the defense of the action, with counsel reasonably satisfactory to the indemnified party, and after notice from the indemnifying party to the indemnified party of its election to assume the defense, the indemnifying party will not be liable to the indemnified party for any legal or other expenses except as provided below and except for the reasonable and documented costs of investigation subsequently incurred by the indemnified party in connection with the defense. The indemnified party will have the right to employ its own counsel in any such action, but the fees, expenses and other charges of such counsel will be at the expense of such indemnified party unless (1) the employment of counsel by the indemnified party has been authorized in writing by the indemnifying party, (2) the indemnified party has reasonably concluded (based on advice of counsel) that there may be legal defenses available to it or other indemnified parties that are different from or in addition to those available to the indemnifying party, (3) a conflict or potential conflict exists (based on advice of counsel to the indemnified party) between the indemnified party and the indemnifying party (in which case the indemnifying party will not have the right to direct the defense of such action on behalf of the indemnified party) or (4) the indemnifying party has not in fact employed counsel to assume the defense of such action or counsel reasonably satisfactory to the indemnified party, in each case, within a reasonable time after receiving notice of the commencement of the action; in each of which cases the reasonable and documented fees, disbursements and other charges of counsel will be at the expense of the indemnifying party or parties. It is understood that the indemnifying party or parties shall not, in

connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable and documented fees, disbursements and other charges of more than one separate firm (plus local counsel) admitted to practice in such jurisdiction at any one time for all such indemnified party or parties. All such fees, disbursements and other charges will be reimbursed by the indemnifying party promptly as they are incurred. An indemnifying party will not, in any event, be liable for any settlement of any action or claim effected without its written consent. No indemnifying party shall, without the prior written consent of each indemnified party, settle or compromise or consent to the entry of any judgment in any pending or threatened claim, action or proceeding relating to the matters contemplated by this Section 10 (whether or not any indemnified party is a party thereto), unless such settlement, compromise or consent (1) includes an unconditional release of each indemnified party, in form and substance reasonably satisfactory to such indemnified party, from all liability arising out of such litigation, investigation, proceeding or claim and (2) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party.

(d) Settlement Without Consent if Failure to Reimburse. If an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for reasonable fees and expenses of counsel, such indemnifying party agrees that it shall be liable for any settlement of the nature contemplated by Section 10(a)(ii) effected without its written consent if (1) such settlement is entered into more than 45 days after receipt by such indemnifying party of the aforesaid request, (2) such indemnifying party shall have received notice of the terms of such settlement at least 30 days prior to such settlement being entered into and (3) such indemnifying party shall not have reimbursed such indemnified party in accordance with such request prior to the date of such settlement.

(e) Contribution. In order to provide for just and equitable contribution in circumstances in which the indemnification provided for in the foregoing paragraphs of this Section 10 is applicable in accordance with its terms but for any reason is held to be unavailable from the Company or the Agent, the Company and the Agent will contribute to the total losses, claims, liabilities, expenses and damages (including any investigative, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claim asserted, but after deducting any contribution received by the Company from persons other than the Agent, such as persons who control the Company within the meaning of the Securities Act, officers of the Company who signed the Registration Statement and directors of the Company, who also may be liable for contribution) to which the Company and the Agent may be subject in such proportion as shall be appropriate to reflect the relative benefits received by the Company on the one hand and the Agent on the other hand. The relative benefits received by the Company on the one hand and the Agent on the other hand shall be deemed to be in the same proportion as the total net proceeds from the sale of the Placement Shares (before deducting expenses) received by the Company bear to the total compensation received by the Agent (before deducting expenses) from the sale of Placement Shares on behalf of the Company. If, but only if, the allocation provided by the foregoing sentence is not permitted by applicable law, the allocation of contribution shall be made in such proportion as is appropriate to reflect not only the relative benefits referred to in the foregoing sentence but also the relative fault of the Company, on the one hand, and the Agent, on the other hand, with respect to the statements or omission that resulted in such loss, claim, liability, expense or damage, or action in respect thereof, as well as any other relevant equitable considerations with

respect to such offering. Such relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or the Agent, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and the Agent agree that it would not be just and equitable if contributions pursuant to this Section 10(e) were to be determined by pro rata allocation or by any other method of allocation that does not take into account the equitable considerations referred to herein. The amount paid or payable by an indemnified party as a result of the loss, claim, liability, expense, or damage, or action in respect thereof, referred to above in this Section 10(e) shall be deemed to include, for the purpose of this Section 10(e), any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim to the extent consistent with Section 10(d) hereof. Notwithstanding the foregoing provisions of this Section 10(e), the Agent shall not be required to contribute any amount in excess of the commissions received by it under this Agreement and no person found guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 10(e), any person who controls a party to this Agreement within the meaning of the Securities Act, and any officers, directors, partners, employees or agents of the Agent, will have the same rights to contribution as that party, and each director of the Company and each officer of the Company who signed the Registration Statement will have the same rights to contribution as the Company, subject in each case to the provisions hereof. Any party entitled to contribution, promptly after receipt of notice of commencement of any action against such party in respect of which a claim for contribution may be made under this Section 10(e), will notify any such party or parties from whom contribution may be sought, but the omission to so notify will not relieve that party or parties from whom contribution may be sought from any other obligation it or they may have under this Section 10(e) except to the extent that the failure to so notify such other party materially prejudiced the substantive rights or defenses of the party from whom contribution is sought. Except for a settlement entered into pursuant to the last sentence of Section 10(d) hereof, no party will be liable for contribution with respect to any action or claim settled without its written consent if such consent is required pursuant to Section 10(d) hereof.

11. Representations and Agreements to Survive Delivery. The indemnity and contribution agreements contained in Section 10 of this Agreement and all representations and warranties of the Company herein or in certificates delivered pursuant hereto shall survive, as of their respective dates, regardless of (i) any investigation made by or on behalf of the Agent, any controlling persons, or the Company (or any of their respective officers, directors or controlling persons), (ii) delivery and acceptance of the Placement Shares and payment therefor or (iii) any termination of this Agreement.

12. Termination.

(a) The Agent may terminate this Agreement, by notice to the Company, as hereinafter specified at any time (1) if there has been, since the time of execution of this Agreement or since the date as of which information is given in the Prospectus, any change, or any development or event involving a prospective change, in the condition, financial or otherwise, or in the business, properties, earnings, results of operations or prospects of the

Company and its Subsidiaries considered as one enterprise, whether or not arising in the ordinary course of business, which individually or in the aggregate, in the sole judgment of the Agent is material and adverse and makes it impractical or inadvisable to market the Placement Shares or to enforce contracts for the sale of the Placement Shares, (2) if there has occurred any material adverse change in the financial markets in the United States or the international financial markets, any outbreak of hostilities or escalation thereof or other calamity or crisis or any change or development involving a prospective change in national or international political, financial or economic conditions, in each case the effect of which is such as to make it, in the judgment of the Agent, impracticable or inadvisable to market the Placement Shares or to enforce contracts for the sale of the Placement Shares, (3) if trading in the Common Stock has been suspended or limited by the Commission or the Exchange, or if trading generally on the Exchange has been suspended or limited, or minimum prices for trading have been fixed on the Exchange, (4) if any suspension of trading of any securities of the Company on any exchange or in the over-the-counter market shall have occurred and be continuing for at least three (3) Trading Days, (5) if a major disruption of securities settlements or clearance services in the United States shall have occurred and be continuing, or (6) if a banking moratorium has been declared by either U.S. Federal or New York authorities. Any such termination shall be without liability of any party to any other party except that the provisions of Section 8 (Payment of Expenses), Section 10 (Indemnification and Contribution), Section 11 (Representations and Agreements to Survive Delivery), Section 17 (Governing Law and Time; Waiver of Jury Trial) and Section 18 (Consent to Jurisdiction) hereof shall remain in full force and effect notwithstanding such termination. If the Agent elects to terminate this Agreement as provided in this Section 12(a), the Agent shall provide the required notice as specified in Section 13 (Notices).

(b) The Company shall have the right, by giving ten (10) days' notice as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 8, Section 10, Section 11, Section 17 and Section 18 hereof shall remain in full force and effect notwithstanding such termination.

(c) The Agent shall have the right, by giving ten (10) days' notice as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 8, Section 10, Section 11, Section 17 and Section 18 hereof shall remain in full force and effect notwithstanding such termination.

(d) Unless earlier terminated pursuant to this Section 13, this Agreement shall automatically terminate upon the issuance and sale of all of the Placement Shares through the Agent on the terms and subject to the conditions set forth herein; provided that the provisions of Section 8, Section 10, Section 11, Section 17 and Section 18 hereof shall remain in full force and effect notwithstanding such termination.

(e) This Agreement shall remain in full force and effect unless terminated pursuant to Sections 12(a), (b), (c) or (d) above or otherwise by mutual agreement of the parties; *provided, however*, that any such termination by mutual agreement shall in all cases be deemed to provide that Section 8, Section 10, Section 11, Section 17 and Section 18 shall remain in full force and effect.

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

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

Cantor Fitzgerald & Co.
499 Park Avenue
New York, NY 10022
Attention: Capital Markets/Jeffrey Lumby
Facsimile: (212) 307-3730

with copies to:

Cantor Fitzgerald & Co.
499 Park Avenue
New York, NY 10022
Attention: General Counsel
Facsimile: (212) 829-4708

and with a copy to:

Goodwin Procter LLP
620 8th Avenue
New York, NY 10036
Attention: Seo Salimi
Facsimile: (646) 558-4145

and if to the Company, shall be delivered to:

MannKind Corporation
30930 Russell Ranch Road, Suite 301
Westlake Village, CA 91362
Attention: Chief Financial Officer
cc: General Counsel

with a copy to:

Cooley LLP
4401 Eastgate Mall
San Diego, CA 92121
Attention: Sean M. Clayton
Asa M. Henin

Telephone: (858) 550-6000
Facsimile: (858) 550-6420

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

An electronic communication ("**Electronic Notice**") shall be deemed written notice for purposes of this Section 13 if sent to the electronic mail address specified by the receiving party under separate cover. Electronic Notice shall be deemed received at the time the party sending Electronic Notice receives verification of receipt by the receiving party. Any party receiving Electronic Notice may request and shall be entitled to receive the notice on paper, in a nonelectronic form ("**Nonelectronic Notice**") which shall be sent to the requesting party within ten (10) days of receipt of the written request for Nonelectronic Notice.

14. Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the Company and the Agent and their respective successors and the parties referred to in Section 10 hereof. References to any of the parties contained in this Agreement shall be deemed to include the successors and permitted assigns of such party. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assigns any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement. Neither party may assign its rights or obligations under this Agreement without the prior written consent of the other party; *provided, however*, that the Agent may assign its rights and obligations hereunder to an affiliate thereof without obtaining the Company's consent.

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

16. Entire Agreement; Amendment; Severability; Waiver. This Agreement (including all schedules and exhibits attached hereto and Placement Notices issued pursuant hereto) constitutes the entire agreement and supersedes all other prior and contemporaneous agreements and undertakings, both written and oral, among the parties hereto with regard to the subject matter hereof. Neither this Agreement nor any term hereof may be amended except pursuant to a written instrument executed by the Company and the Agent. In the event that any one or more of the provisions contained herein, or the application thereof in any circumstance, is held invalid, illegal or unenforceable as written by a court of competent jurisdiction, then such provision shall be given full force and effect to the fullest possible extent that it is valid, legal and enforceable, and the remainder of the terms and provisions herein shall be construed as if such invalid, illegal or unenforceable term or provision was not contained herein, but only to the

extent that giving effect to such provision and the remainder of the terms and provisions hereof shall be in accordance with the intent of the parties as reflected in this Agreement. No implied waiver by a party shall arise in the absence of a waiver in writing signed by such party. No failure or delay in exercising any right, power, or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any right, power, or privilege hereunder.

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

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

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

20. **Construction.** The section and exhibit headings herein are for convenience only and shall not affect the construction hereof. References herein to any law, statute, ordinance, code, regulation, rule or other requirement of any Governmental Authority shall be deemed to refer to such law, statute, ordinance, code, regulation, rule or other requirement of any Governmental Authority as amended, reenacted, supplemented or superseded in whole or in part and in effect from time to time and also to all rules and regulations promulgated thereunder.

21. Permitted Free Writing Prospectuses. The Company represents, warrants and agrees that, unless it obtains the prior written consent of the Agent (which consent shall not be unreasonably withheld or delayed), and the Agent represents, warrants and agrees that, unless it obtains the prior written consent of the Company (which consent shall not be unreasonably withheld or delayed), it has not made and will not make any offer relating to the Placement Shares that would constitute an Issuer Free Writing Prospectus, or that would otherwise constitute a “free writing prospectus,” as defined in Rule 405, required to be filed with the Commission. Any such free writing prospectus consented to by the Agent or by the Company, as the case may be, is hereinafter referred to as a “Permitted Free Writing Prospectus.” The Company represents and warrants that it has treated and agrees that it will treat each Permitted Free Writing Prospectus as an “issuer free writing prospectus,” as defined in Rule 433, and has complied and will comply with the requirements of Rule 433 applicable to any Permitted Free Writing Prospectus, including timely filing with the Commission where required, legending and record keeping. For the purposes of clarity, the parties hereto agree that all free writing prospectuses, if any, listed in Exhibit 21 hereto are Permitted Free Writing Prospectuses.

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

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

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

(c) neither the Agent nor its affiliates have provided any legal, accounting, regulatory or tax advice with respect to the transactions contemplated by this Agreement and it has consulted its own legal, accounting, regulatory and tax advisors to the extent it has deemed appropriate;

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

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

provided by the Company to the Agent and the Agent's counsel confidential to the extent not otherwise publicly available; provided, however, the Agent may, if requested by any governmental, regulatory or self-regulatory agency or authority having or asserting jurisdiction over such person or entity or in connection with a legal process, disclose such information or the existence or nature of the Project or discussions between the parties without notice to or consent from the Providing Party, without causing a breach of this Agreement

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

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

"Governmental Authority" means (i) any federal, provincial, state, local, municipal, national or international government or governmental authority, regulatory or administrative agency, governmental commission, department, board, bureau, agency or instrumentality, court, tribunal, arbitrator or arbitral body (public or private); (ii) any self-regulatory organization; or (iii) any political subdivision of any of the foregoing.

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

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

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

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

[Signature Page Follows]

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

Very truly yours,

MANNKIND CORPORATION

By: /s/ Steven Binder

Name: Steven Binder

Title: Chief Financial Officer

SIGNATURE PAGE

MANNKIND CORPORATION SALES AGREEMENT

ACCEPTED as of the date first-above written:

CANTOR FITZGERALD & CO.

By: /s/ Jeffrey Lumby
Name: Jeffrey Lumby
Title: Senior Managing Director

SIGNATURE PAGE

MANNKIND CORPORATION SALES AGREEMENT

SCHEDULE 1

Compensation

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

SCHEDULE 2

Notice Parties

The Company

Michael Castagna mcastagna@mannkindcorp.com

Steven Binder sbinder@mannkindcorp.com

The Agent

Jeffrey Lumby (jlumby@cantor.com)

Josh Feldman (jfeldman@cantor.com)

Sameer Vasudev (svasudev@cantor.com)

With copies to:

CFCControlledEquityOffering@cantor.com

Form of Representation Date Certificate Pursuant to Section 7(l)

The undersigned, the duly qualified and elected [●] of MannKind Corporation, a Delaware corporation (the “Company”), does hereby certify in such capacity and on behalf of the Company, pursuant to Section 7(l) of the Sales Agreement, dated February 27, 2018 (the “Sales Agreement”), between the Company and Cantor Fitzgerald & Co., that to the best of the knowledge of the undersigned:

(i) The representations and warranties of the Company in Section 6 of the Sales Agreement (A) to the extent such representations and warranties are subject to qualifications and exceptions contained therein relating to materiality or Material Adverse Effect, are true and correct on and as of the date hereof with the same force and effect as if expressly made on and as of the date hereof, except for those representations and warranties that speak solely as of a specific date and which were true and correct as of such date, and (B) to the extent such representations and warranties are not subject to any qualifications or exceptions, are true and correct in all material respects as of the date hereof as if made on and as of the date hereof; *provided, however*, that such representations and warranties also shall be qualified by the disclosure included or incorporated by reference in the Registration Statement and Prospectus; and

(ii) The Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied pursuant to the Sales Agreement at or prior to the date hereof.

MANNKIND CORPORATION

By: _____

Name: _____

Title: _____

Date: [●]

Exhibit 21

Permitted Free Writing Prospectus

None.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-117811, 333-127876, 333-137332, 333-149049, 333-160225, 333-176409, 333-182457, 333-188790 and 333-213366 on Form S-8, and Registration No. 333-210792 on Form S-3 of our reports dated February 27, 2018, relating to the consolidated financial statements of MannKind Corporation and subsidiaries ("MannKind Corporation") (which report expresses an unqualified opinion and includes an explanatory paragraph relating to the Company's ability to continue as a going concern), and the effectiveness of MannKind Corporation's internal control over financial reporting, appearing in this Annual Report on Form 10-K of MannKind Corporation for the year ended December 31, 2017.

/s/ Deloitte & Touche LLP

Stamford, CT
February 27, 2018

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

I, Michael E. Castagna, certify that:

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

/s/ Michael E. Castagna

Michael E. Castagna
Chief Executive Officer and Director

Date: February 27, 2018

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

I, Steven B. Binder, certify that:

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

/s/ Steven B. Binder

Steven B. Binder
Chief Financial Officer

Date: February 27, 2018

CERTIFICATION¹

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

1. The Company’s Annual Report on Form 10-K for the period ended December 31, 2017, to which this Certification is attached as Exhibit 32.1 (the “Annual Report”) fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and
2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned has set his hand hereto as of the 27th day of February, 2018.

/s/ Michael E. Castagna

Michael E. Castagna

Chief Executive Officer

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

CERTIFICATION¹

Pursuant to the requirement set forth in Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Steven B. Binder, Chief Financial Officer of MannKind Corporation (the “Company”), hereby certifies that, to the best of his knowledge:

1. The Company’s Annual Report on Form 10-K for the period ended December 31, 2017, to which this Certification is attached as Exhibit 32.2 (the “Annual Report”) fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and
2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned has set his hand hereto as of the 27th day of February, 2018.

/s/ Steven B. Binder

Steven B. Binder
Chief Financial Officer

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

