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, 2019

or

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

For the transition period from _____ to _____

Commission file number: 000-50865

MannKind Corporation

(Exact name of registrant as specified in its charter)

Delaware	**13-3607736**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
30930 Russell Ranch Road, Suite 300 Westlake Village, California	**91362**
(Address of principal executive offices)	**(Zip Code)**

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

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, par value $0.01 per share	MNKD	The Nasdaq Stock Market LLC

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 15(d) of the Securities Exchange Act of 1934. 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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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.

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
		Emerging growth company	☐

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 28, 2019, 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 $194,244,712.

As of February 13, 2020, there were 212,295,318 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 2020 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than April 29, 2020 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, 2019

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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 like “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®, Technosphere® and BluHale® are our trademarks in the United States. We have also applied for or have registered company trademarks in other jurisdictions. 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) Inhalation Powder, is an ultra rapid-acting inhaled insulin that was approved by the U.S. Food and Drug Administration (“FDA”) in June 2014. 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 463 million adults had diabetes in 2019 and approximately 700 million will have diabetes by 2045.

Afrezza

Afrezza is an ultra rapid-acting inhaled insulin used to improve glycemic control in adults with 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.

Currently, we promote Afrezza to endocrinologists and certain high-prescribing primary care physicians through our specialty sales force. To support our sales efforts, we have implemented several patient and physician support programs, including a co-pay assistance and product savings card, a direct purchase program and our MannKind Cares program that supports providers and patients who have questions about insurance coverage, prescription cost and product use. We have also entered into a number of rebate or other agreements with various payors and pharmacy benefit managers that are intended to facilitate more favorable insurance coverage for Afrezza.

In the future, we may seek to supplement our sales force through a co-promotion arrangement with a third party that can be used to promote Afrezza to a greater number of primary care physicians in the United States. Internationally, our strategy is to establish regional partnerships in foreign jurisdictions where there are commercial opportunities, subject to the receipt of necessary foreign regulatory approvals. Our partner in Brazil, Biomm S.A. (“Biomm”), commenced commercialization of Afrezza in January 2020. Our partners in India and Australia are preparing for regulatory submissions and have not yet commenced commercialization in their respective territories.

We have continued to conduct clinical studies of Afrezza, including an open-label, multiple-dose, safety, titration and pharmacokinetics study in two cohorts of pediatric patients with type 1 diabetes (patients aged 13-17 and patients aged 8-12) that completed in 2019. We are currently finalizing with the FDA the study design for a Phase 3 clinical trial to evaluate the safety and efficacy of Afrezza in 8-17 year-old children and adolescents. The pediatric Phase 3 trial is a post-marketing requirement. As part of the approval of Afrezza, the FDA also required us to conduct a five-year, randomized, controlled trial in 8,000-10,000 patients with type 2 diabetes to assess the potential risk of pulmonary malignancy with Afrezza use. We have an ongoing dialogue with the FDA regarding the endpoints and goals for this long-term trial and have not yet commenced this trial. In addition to studies sponsored and conducted by us, we expect to participate in collaborative clinical studies of Afrezza that are sponsored and conducted by independent investigators.

Technosphere Platform

We believe that our proprietary Technosphere formulation technology represents a versatile drug delivery platform that may allow the oral inhalation of a wide range of active pharmaceutical ingredients. 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, fumaryl diketopiperazine (“FDKP”), which is a pH-sensitive organic molecule that self-assembles into small particles under acidic conditions. Certain drugs, such as insulin or treprostinil, can be loaded onto these particles by combining a solution of the drug with a solution or 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 quickly 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 that de-agglomerates the powder while keeping the powder moving relatively slowly. This slow-moving powder effectively navigates the patient’s airways to reach the deep lung with minimal deposition at the back of the throat. Our inhalers show very little change in performance (i.e., efficient cartridge emptying) over a wide range of inhalation efforts.

We advanced an inhaled formulation of treprostinil (internally designated “TreT”) into clinical development, completing a Phase 1 dose-escalation trial in June 2018. In September 2018, we announced a license and collaboration agreement with United Therapeutics Corporation (“United Therapeutics” or “UT”), pursuant to which UT became responsible for global development, regulatory and commercial activities with respect to TreT (the “UT License Agreement”) while we retained responsibility for manufacturing clinical and commercial supplies of TreT. In January 2016, we entered into a collaboration and license agreement with Receptor Life Sciences (“Receptor”), pursuant to which Receptor is responsible for the development, manufacture and commercialization of inhaled formulations of certain cannabinoid compounds utilizing our technology. We have been informed by Receptor that it has evaluated safety, tolerability and pharmacokinetics of prototype powders in initial clinical trials; however, data from these clinical trials has not yet been published or made available to us. In addition to our collaborations, we intend to advance our own pipeline of dry-powder formulations of drugs into feasibility and preclinical studies during the next 12-18 months.

To aid in the development of our oral inhalation products, we have created a number of innovative tools, including a novel inhalation profiling apparatus, known as BluHale, which uses miniature sensors to assess the drug delivery process at the level of an individual inhaler. The BluHale apparatus provides real-time data regarding patient usage and delivery system performance that is transmitted to a user interface, such as a smartphone application. During 2020, we plan to release a BluHale Professional version of the apparatus for use as a training tool in physician’s offices.

Manufacturing and Supply

We use our Danbury, Connecticut facility to formulate both the Afrezza and TreT inhalation powders, fill plastic cartridges with the powders, 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 Afrezza foil-pouched blister packs along with inhalers and the package inserts. The final responsibility for TreT packaging has not yet been determined.

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 is inspected on a regular basis by the FDA, most recently in June 2018. We were also inspected by ANVISA (Brazil National Health Surveillance Agency) in May 2018. Neither of the regulatory inspections in 2018 gave rise to any inspectional observations (known as “483s” in the United States). The FDA and 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 demand for Afrezza and TreT. 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, TreT and other potential products over the next several years.

Currently, the only source of insulin that we have qualified for Afrezza is manufactured by Amphastar France Pharmaceuticals S.A.S. (“Amphastar”). In April 2014, we entered into a supply agreement with Amphastar (as amended, the “Insulin Supply Agreement”) to purchase certain annual minimum quantities with an aggregate purchase commitment of €120.1 million over a term that currently extends through December 31, 2026. As of December 31, 2019, there was €82.0 million remaining in aggregate purchase commitments under this agreement. See additional information in Note 13 – Commitments and Contingencies to the consolidated financial statements for further information related to the Insulin Supply Agreement.

Currently, we purchase FDKP, the primary component of our Technosphere powders, from a major chemical manufacturer with facilities in Europe and North America.

We have a supply agreement with the contract manufacturer that produces the plastic-molded 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.

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 for all inventions in the United States, Europe, Japan and, depending on the nature of the invention, selected other jurisdictions. 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 powder, its manufacture, and its use for pulmonary delivery of drugs. We have additional patent coverage relating to the treatment of diabetes using Afrezza. We have also been granted patent coverage for our inhalers and associated cartridges. Overall, Afrezza is protected by approximately 600 issued patents in the United States and selected jurisdictions around the world, the longest-lived of which will expire in 2032. We also have over 125 applications pending that may provide additional protection for Afrezza if and when they are allowed. Our entire portfolio consists of approximately 1015 issued patents and approximately 240 patent applications that provide protection for our drug delivery platform, Technosphere-based products, the inhalation-profiling apparatus and development tools. Currently, our longest-lived issued patent will expire in 2035. We expect to file further patent applications as our research and development efforts continue.

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 a 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 "ultra rapid-acting" pharmacokinetic profile, i.e., entering the bloodstream in less than one minute, with the first measurable effects occurring approximately 12 minutes after administration, and peak glucose-lowering effects within 35 or 45 minutes after administration of a 4 or 12 unit dose, respectively. There are several formulations of "rapid-acting" insulin analogs that reach their maximum glucose-lowering effect within one to three hours after injection. The principal products in this category are insulin lispro, which is marketed by Eli Lilly & Company as Humalog® and by Sanofi S.A. as Admelog®; insulin aspart, which is marketed by Novo Nordisk A/S as Novolog® and as Fiasp®; and insulin glulisine, which is marketed by Sanofi S.A. as Apidra®.

Inhaled Insulin Delivery Systems

Our drug delivery platform competes with other inhaled delivery systems, including the Dance-501 being developed by Aerami Therapeutics. Dance-501 is a liquid formulation of recombinant human insulin, administered with a small handheld electronic inhaler. Dance-501 has been studied in Phase 2 trials.

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 (Investigational New Drug Application), 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, although the FDA may place trials on hold at any time if it believes the risks to subjects outweigh the potential benefits.
- Approval of clinical protocols by independent institutional review boards ("IRBs") at each of the participating clinical centers conducting a study. The IRBs consider, among other things, ethical factors, the potential risks to individuals participating in the trials and the potential liability of the institution. The IRB also approves the consent form signed by the trial participants.
- Adequate and well-controlled human clinical trials to establish the safety and efficacy of the product. Clinical trials involve the administration of the drug to healthy volunteers or to patients under the supervision of a qualified medical investigator according to an approved protocol. The clinical trials are conducted in accordance with protocols that detail the objectives of the study, the parameters to be used to monitor participant safety and efficacy or other criteria to be evaluated. Each protocol is submitted to the FDA as part of the IND. Human clinical trials are typically conducted in the following four sequential phases that may overlap or be combined:
    - In Phase 1, the drug is initially introduced into a small number of individuals and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. Phase 1 clinical trials are often conducted in healthy human volunteers and such cases do not provide evidence of efficacy. In the case of severe or life-threatening diseases, the initial human testing is often conducted in patients rather than healthy volunteers. Because these patients already have the target disease, these studies may provide initial evidence of efficacy that would traditionally be obtained in Phase 2 clinical trials. Consequently, these types of trials are frequently referred to as Phase 1/2 clinical trials. The FDA receives reports on the progress of each phase of clinical testing and it may require the modification, suspension or termination of clinical trials if it concludes that an unwarranted risk is presented to patients or healthy volunteers.
    - Phase 2 involves clinical trials in a limited patient population to further identify any possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
    - 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 as well as the quality system regulation for medical devices, or QSR. 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 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. On March 23, 2020, our approved NDA for Afrezza, along with all other approved insulins and certain other "biological products" approved as NDAs, will be deemed to be an approved Biologics License Application, or BLA, pursuant to the Biologics Price Competition and Innovation Act of 2009.

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, 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. 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. A 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, industry sponsored scientific and educational activities, and promotional activities involving the Internet, and restrictions on off-label promotion. 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 products and services. 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 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. 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 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 efforts by the Trump administration to repeal or replace certain aspects of the PPACA. President Trump has signed two Executive Orders and other directives designed to eliminate 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. Legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act of 2017 ("Tax Act"), 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". In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the PPACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amends the PPACA, effective January 1, 2019, to increase from 50% to 70% 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". In December 2018, CMS published a new final rule permitting further collections and payments to and from certain PPACA qualified health plans and health insurance issuers under the PPACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the PPACA are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace the PPACA will impact the PPACA.

Other legislative changes have been proposed and adopted in the United States since PPACA. For example, through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, following passage of the BBA, will remain in effect through 2029 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 and enacted federal and 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. For example, at the federal level, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and, at the same, has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. In addition, the Trump administration's budget proposal for fiscal year 2020 contains further drug price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Although a number of these and other measures may require additional authorization to become effective, Congress and the Trump administration have stated that they continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented 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.

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. Similarly, 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.

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

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, which include certain healthcare providers, health plans, and healthcare clearinghouses, 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 HIPAA 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. The recently adopted European General Data Protection Regulation, or GDPR, contains new provisions specifically directed at the processing of health information, higher sanctions and extra-territoriality measures that are intended to bring non-EU companies under the data security and privacy legal framework specified in the regulation. We anticipate that over time we may expand our business operations to include 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

Additionally, effective January 1, 2020, the California Consumer Privacy Act ("CCPA") created individual privacy rights for California consumers (as that word is broadly defined in the law) and placed increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allows for a new cause of action for data breaches. The CCPA will likely impact (possibly significantly) our business activities and exemplifies the vulnerability of our business to not only cyber threats but also the evolving regulatory environment related to personal data and protected health information.

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, comply with industry's compliance guidelines and relevant compliance guidance promulgated by the federal government and register pharmaceutical sales representatives and limit expenditure for, or payments to, individual medical or health professionals. In addition, certain state laws require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in the states; and report pricing with respect to certain drug products.

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 significant criminal, civil and administrative penalties, damages, fines, imprisonment, disgorgement, exclusion from government 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 of which could adversely affect our ability to operate our business and our results of operations.

Ethical Business Practices and Sustainability

Safety of Clinical Trial Participants

Safe clinical trials play a crucial role in the development of new products and our continuing prosperity. We take numerous steps to maximize the safety of our clinical trial participants.

The health of subjects in clinical trials is a priority for us and we are committed to conducting clinical trials according to uniformly high ethical standards. We apply those standards to trials that we sponsor and conduct directly as well as those conducted on our behalf by clinical research organizations. We conduct trials in accordance with all applicable laws, the standards of International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidelines and following the ethical principles that have their origin in the Declaration of Helsinki.

We require that a three-stage informed consent process be implemented in all trials to ensure that participants understand the risks and benefits of the procedures, how personal medical data is collected and used, and that participation in the trial is voluntary, among other information. We retain documentation that all participants in our trials have provided informed consent.

We monitor clinical trials through audits and inspections conducted by us and by third parties. These inspections verify that our policies, good clinical practices and applicable laws are being adhered to.

Our ability to ensure the safety of clinical trial participants is critical to securing regulatory approval and continued product development success. Moreover, our inability to conduct safe and effective clinical trials could increase our development costs over time. We will continue to hold ourselves to high standards in our oversight and management of clinical trials.

Ethical Marketing

We require that our employees abide by our Code of Business Conduct and Ethics, our policy on interactions with healthcare professionals and patients, U.S. federal and state laws and applicable foreign laws. We are committed to protecting the health and well-being of patients by ensuring that medically sound knowledge of the benefits and risks of our products is understood and communicated thoroughly and accurately to patients, physicians and global health authorities.

Our policy on interactions with healthcare professionals and patients prohibits off-label promotion of our products. All sales staff received compliance training upon hire and on an annual basis. We also routinely monitor sales calls. Any case where we promote off-label use of our products has the potential to have a material adverse effect on our reputation, sales and liabilities. We expect that consistent enforcement of, and training on, our Code of Business Conduct and Ethics and our policy on interactions with healthcare professionals and patients will help us to limit the incidence of off-label promotion.

Drug Safety

The safety of our products at all stages – from clinical trials to the administration and use and through to safe disposal – is a key area of attention for us. We acknowledge, however, that there are inherent risks associated with the use of drug products. We attempt to minimize these through stringent adherence to quality control procedures and proactive recall processes whenever a safety concern is identified. To date, we have not issued a recall for any product.

In addition, starting mid-2018, all sales packs of Afrezza that are placed in the distribution chain are serialized in accordance with the requirements of the Drug Quality and Security Act, which requires drug manufacturers to assign a unique identifier to each sales pack (and each aggregate of such sales pack, such as a case or pallet). These identifiers remain on such pack or aggregate through the whole supply chain until its consumption or destruction. This system is intended to improve detection and removal of drugs that may be counterfeit, stolen, contaminated, or otherwise harmful from the drug supply chain.

Corruption and Bribery

Our Code of Business Conduct and Ethics includes clear guidelines on anti-bribery and anti-corruption practices. Currently, we have very limited operations outside the United States; however, as we expand our global reach through collaborations or through our own growth, we acknowledge that certain regions may pose a higher risk for corrupt practices. We intend to continue our internal training programs and oversight over collaborators on anti-bribery, anti-corruption and other unethical practices in order to reduce these risks.

Bribing healthcare professionals to use or recommend our products can create adverse publicity and damage our ability to use a critical channel of influence. We have adopted and implement PhRMA's Code on Interactions with Healthcare Professionals as part of our policy on interactions with healthcare professionals and patients. We believe that training on, and enforcement of, these codes will limit the incidence of unethical interactions between our personnel and healthcare professionals.

Long-Lived Assets

Our long-lived assets are located in the United States and totaled $26.8 million and $25.6 million as of December 31, 2019 and 2018, respectively.

Employees

Our human capital helps us develop and commercialize new products, conduct clinical trials and navigate government regulations. Our ability to recruit, develop and retain highly skilled talent is a significant determinant of our success. Our Code of Business Conduct and Ethics codifies our commitment to diversity and to providing equal opportunity and a positive working environment in all aspects of employment. We also have policies setting forth our expectations for nondiscrimination and a harassment-free work environment.

As of December 31, 2019, we had 233 total employees, of which 232 were full-time. Of our full-time employees, 75 were engaged in manufacturing, 17 in research and development, 43 in general and administrative and 97 in selling and marketing. Thirteen of these employees had a Ph.D. degree and/or M.D. degree and were engaged in activities relating to research and development, manufacturing, quality assurance or business development.

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

Occupational Health and Safety

Hazardous materials are inherent in our operations, and it is not possible to eliminate completely the risk of accidental exposure from our operations. We have established procedures to comply with governmental regulations regarding workplace safety, including training employees to enable them to recognize risks and empower them to learn, discover, work safely, and to minimize injuries, illnesses, environmental impact and regulatory risks. In 2019, our total illness and injury incidence rate was 2.0 per 100 employees compared to the 2018 industry average of 1.6, as reported by the U.S. Department of Labor, and our DART (days away/restricted or job transfer) incident rate was 1.0 per 100 employees compared to the 2018 industry average of 0.9. We will continue our efforts to ensure a high level of workplace safety.

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 300, 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 our websites are not incorporated into this Annual Report. Further, our references to the URLs for these websites are intended to be inactive textual reference only.

Scientific Advisors

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

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

A current listing of our scientific advisors is maintained on our corporate website at www.mannkindcorp.com.

Information about our Executive Officers

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

Name	Age	Position(s)
Michael E. Castagna, Pharm.D.	43	Chief Executive Officer
Steven B. Binder	57	Chief Financial Officer
David M. Kendall, M.D	58	Chief Medical Officer
Joseph Kocinsky	56	Chief Technology Officer
James P. McCauley, Jr.	54	Chief Commercial Officer
Stuart A. Tross, Ph.D.	53	Chief People and Workplace Officer
David B. Thomson, Ph.D., J.D.	53	General Counsel and Secretary
Rosabel R. Alinaya	59	Vice President, Investor Relations and Treasury

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 Pharma D. 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 Stryker 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.

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.

Joseph Kocinsky has been our Chief Technology Officer since October 2015. Mr. Kocinsky has over 30 years of experience in the pharmaceutical industry in technical operations and product development. Prior to joining us in 2003, he held a variety of technical and management positions with increased responsibility at Schering-Plough Corp. Mr. Kocinsky holds a bachelor's degree in chemical engineering and a master's degree in Biomedical Engineering from New Jersey Institute of Technology and a master's degree in Business Administration from Seton Hall University.

James P. McCauley, Jr. 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 J.D. from the South Texas College of Law, and a B.A. in Economics from the University of Notre Dame.

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.Sc. and Ph.D. degrees in Industrial-Organizational Psychology from the Georgia Institute of Technology.

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 B.S degree, M Sc. degree and Ph.D. from Queens University and obtained his J.D. from the University of Toronto.

Rosabel R. Alinaya has been our Vice President, Investor Relations and Treasury since July 2017. Ms. Alinaya also served as Principal Accounting Officer from January 2016 to July 2017 with responsibility for finance, accounting, tax, treasury, investor relations and risk management. Previously, she was our Vice President, Finance since March 2011 after serving as our Corporate Controller since June 2003. Ms. Alinaya began her career at Deloitte & Touche LLP, graduating from California State University, Northridge with a B.S. in Accounting Information Systems.

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 may 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 stockholder's deficit raise substantial doubt about our ability to continue as a going concern. As of December 31, 2019, we had cash and cash equivalents of $29.9 million, short-term investment of $20.0 million and a stockholders' deficit of $190.5 million. We may need to raise additional capital, whether through the sale of equity or debt securities, additional strategic business collaborations, the establishment of other funding facilities, licensing arrangements, asset sales or other means, in order to support our ongoing activities, including the commercialization of Afrezza and the development of our product candidates. It may be difficult for us to raise additional funds on favorable terms, or at all. 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, including through our collaborations;
- the costs of developing and commercializing Afrezza on our own in the United States, including the costs of expanding our commercialization capabilities;
- 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 facility;
- our obligation to make milestone payments;
- our success in establishing additional 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 may also 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 collaboration, 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, borrowing 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 may 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.

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. In addition, we anticipate that revenues from our existing or future licensing arrangements for our Technosphere platform technology that involve license, milestone, royalty or other payments to us will depend on our ability to achieve the performance obligations specified in such arrangements.

Successful commercialization of Afrezza is subject to many risks, including some that are outside our control. 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. We ultimately may be unable to gain widespread market acceptance of Afrezza for a variety of reasons, including the treatment and dosage regimen, potential adverse effects, pricing relative to alternative products, the availability of alternative treatments and lack of coverage or adequate reimbursement. We will need to maintain and enhance 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 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 time-action 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 payor coverage of, and adequate reimbursement 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. We 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.

If we fail to achieve commercialize success with 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 may 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 such jurisdictions, which could limit our commercial revenues. We may not continue to be successful in establishing or maintaining regional partnerships or other arrangements with third parties for the commercialization of Afrezza outside of the United States.

Although Afrezza has been approved in the United States by the FDA and in Brazil by ANVISA, we have not yet obtained approval in any other jurisdiction. In order to market Afrezza in a foreign jurisdiction, we must obtain regulatory approval in each such foreign jurisdiction, and we may never be able to obtain such approvals. The research, testing, manufacturing, labeling, 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 the 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 approval of Afrezza in the United States.

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 commercial opportunities. It may be difficult to find or maintain 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, 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 the development and commercialization of Afrezza, we will likely not be able to advance these programs into clinical development unless we are able to obtain specific funding for these programs or enter into collaborations with third parties.

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.

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

We are not currently profitable and have rarely generated positive net cash flow from operations. As of December 31, 2019, we had an accumulated deficit of $3.0 billion. The accumulated deficit has resulted principally from costs incurred in our research and development programs, the write-off of assets (including 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 our Insulin Supply Agreement with Amphastar, we agreed to purchase certain annual minimum quantities of insulin through 2026. As of December 31, 2019, there was €82.0 million remaining in aggregate purchase commitments under this agreement. We may not have the necessary capital resources 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.

The notes to our consolidated financial statements in this Annual Report on Form 10-K provide details about our various debt obligations. As of December 31, 2019, we had $120.3 million principal amount of outstanding debt, consisting of:

- $40.0 million principal amount under a credit and security agreement with MidCap Financial Trust (as amended, the "MidCap Credit Facility"), bearing interest at an annual rate equal to one-month LIBOR plus 6.75%, subject to a one-month LIBOR floor of 2.00%, and maturing in August 2024;
- $5.0 million principal amount of Convertible Senior Subordinated Exchange Notes due 2024 (the "2024 convertible notes") bearing interest at 5.75% per annum, with interest payable in cash or equity semiannually in arrears on February 15 and August 15 of each year, and maturing in November 2024, all of which is convertible into shares of our common stock at the option of the holder at a conversion price of $3.00 per share;

- $5.2 million in respect of two non-interest bearing promissory notes, each in the amount of $2.6 million, one of which will mature on June 30, 2020 (the "June 2020 note") and the other of which will mature on December 31, 2020 (the "December 2020 note", and together with the June 2020 note, the "2020 notes"); and
- $70.1 million principal amount of indebtedness under two promissory notes (the "Mann Group promissory notes") issued to The Mann Group LLC ("The Mann Group"), each bearing interest at a fixed rate of 7.00% per annum compounded quarterly and maturing in November 2024. The Mann Group promissory notes consist of a $35.0 million note that is convertible into shares of our common stock at the option of The Mann Group at a conversion price of $2.50 per share (the "Mann Group convertible note") and a $35.1 million non-convertible note (the "Mann Group non-convertible note"). Interest is paid-in-kind from August 2019 until the end of 2020, after which we have the option to either pay interest-in-kind or in shares.

Under the MidCap Credit Facility, our interest rate on borrowed amounts is dependent on one-month LIBOR, which is the basic rate of interest used in lending between banks on the London interbank market. LIBOR is widely used as a reference for setting the interest rate on loans globally and is currently scheduled to be phased out in 2021. Before one-month LIBOR is phased out, we may need to renegotiate the MidCap Credit Facility to replace one-month LIBOR with a new standard, which has yet to be established. The consequences of these developments cannot entirely be predicted, but could result in higher interest rates on our loans under the MidCap Credit Facility. We cannot provide assurance that future interest rate changes will not have a material negative impact on our business, financial position, or operating results.

Under the MidCap Credit Facility, we may borrow an additional $10.0 million ("Tranche 2") until April 15, 2020, subject to our satisfaction of certain conditions, including achieving Afrezza net revenue of at least $30.0 million on a trailing twelve month basis. Under the terms of the MidCap Credit Facility, a third advance of $25.0 million ("Tranche 3") will be available to us until June 30, 2021, subject to the satisfaction of certain milestone conditions associated with Afrezza net revenue and certain milestone conditions related to our collaboration with United Therapeutics. We must also comply with a minimum cash covenant of $15.0 million at all times prior to our borrowing of the Tranche 2 advance, and $20.0 million at all times following the funding of Tranche 2 and Tranche 3.

Further, the MidCap Credit Facility requires us, and any debt arrangements we may enter into in the future may require us, to comply with various covenants that limit our ability to, among other things:

- dispose of assets;
- complete mergers or acquisitions;
- incur indebtedness or modify existing debt agreements;
- amend or modify certain material agreements;
- engage in additional lines of business;
- encumber assets;
- pay dividends or make other distributions to holders of our capital stock;
- make specified investments;
- change certain key management personnel or organizational documents; and
- engage in transactions with our affiliates.

The restrictive covenants in the MidCap Credit Facility could prevent us from pursuing business opportunities that we or our stockholders may consider beneficial.

The MidCap Credit Facility also contains a covenant relating to trailing twelve-month minimum Afrezza net revenue, tested on a monthly basis, which are set forth in the MidCap Credit Facility Agreement, as amended. If we fail to meet this covenant, any outstanding borrowings, together with accrued interest, under the MidCap Credit Facility could be declared immediately due and payable.

A breach of any of these covenants could result in an event of default under the MidCap Credit Facility. If we default under our obligations under the MidCap Credit Facility, the lender could proceed against the collateral granted to them to secure our indebtedness or declare all obligations under the MidCap Credit Facility to be due and payable. In certain circumstances, procedures by the lender could result in a loss by us of all of our equipment and inventory, which are included in the collateral granted to the lender. In addition, upon any distribution of assets pursuant to any liquidation, insolvency, dissolution, reorganization or similar proceeding, the holders of secured indebtedness will be entitled to receive payment in full from the proceeds of the collateral securing our secured indebtedness before the holders of other indebtedness or our common stock will be entitled to receive any distribution with respect thereto.

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 2024 convertible notes, the holders of such 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 2024 convertible notes or the MidCap Term Loan, or if we fail to repay or repurchase the 2024 convertible notes, 2020 notes, MidCap Term Loan or borrowings under the Mann Group promissory notes 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.

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.

The rapid rate of scientific discoveries and technological changes could result in Afrezza or one or more of our product candidates becoming obsolete or noncompetitive. Our competitors may develop or introduce new products that render our technology or Afrezza less competitive, uneconomical or obsolete. Our future success may depend not only on our ability to develop our product candidates, but also our ability to improve them and to improve Afrezza in order to 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. 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, FDKP, our Afrezza inhaler, the related cartridges and other materials. Currently, the only source of insulin that we have qualified for Afrezza is manufactured by Amphastar. We must rely on our suppliers 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. 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 a supplier fails to comply with these requirements or the 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, we will need to evaluate that supplier's ability to provide material that meets regulatory requirements, including cGMP or QSR requirements, as well as our specifications and quality requirements, which would require significant time and expense and could delay the production of Afrezza. In general, if any of our suppliers is unwilling or unable to meet its supply obligations or if we encounter delays or difficulties in our relationships with manufacturers or suppliers, 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 both the Afrezza and TreT inhalation powders, fill plastic cartridges with the powders, 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 Afrezza foil-pouched blister packs along with inhalers and the package inserts. The final responsibility for TreT packaging has not yet been determined.

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 support and educate physicians about the benefits and advantages of Afrezza or our other products, 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 reimbursement, as well as pricing 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. In certain foreign markets the pricing of prescription pharmaceuticals is subject to direct governmental control. In the United States, there have been several congressional inquiries and proposed and enacted federal and 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 Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services ("HHS") has solicited feedback on some of these measures and, at the same, has implemented others under its existing authority. For example, in May 2019, the Centers for Medicare & Medicaid Services ("CMS") issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. In addition, the Trump administration's budget proposal for fiscal year 2020 contains further drug price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Although a number of these and other measures may require additional authorization to become effective, Congress and the Trump administration have stated that they will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented 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 third-party payors 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 government health administration authorities 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, which are the 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.

The requirements governing drug pricing vary widely from country to country. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. 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 reimbursement 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.

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 workforce, 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, commercial 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, commercial 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 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 and presentation or classification of cash flows. New pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future and as a result we may be required to make changes in our accounting policies. Any difficulties in adopting or implementing new accounting standards, and updating or modifying 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.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act of 2017 ("Tax Act"), enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to the Tax Act or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future reform legislation could have a material impact on the value of our deferred tax assets and could increase our future U.S. tax expense.

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

As of December 31, 2019 we had federal and state net operating loss carryforwards of $2.1 billion and $1.3 billion, respectively, which we assess annually. A portion of the federal and state net operating loss carryforwards have begun to expire. Net operating loss carryforwards that expire unused will be unavailable to offset future income tax liabilities. Under 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 Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (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. We have completed a Section 382 analysis beginning from the date of our initial public offering through to the end of the previous tax year regarding whether additional limitations may be placed on the net operating loss carryforwards and other tax attributes, and no additional changes in ownership that met Section 382 study ownership change threshold has been identified through December 31, 2019. There is a risk that changes in ownership may occur in tax years after December 31, 2019. If a change in ownership were to occur, our net operating loss carryforwards and other tax attributes could be further limited or restricted. If an ownership change were to occur 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. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Tax authorities may disagree with our positions and conclusions regarding certain tax positions, resulting in unanticipated costs, taxes or non-realization of expected benefits.

A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, the U.S. Internal Revenue Service or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies, including amounts paid with respect to our intellectual property development. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable nexus, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. A tax authority may take the position that material income tax liabilities, interest and penalties are payable by us, in which case, we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable.

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-aventis U.S. LLC's ("Sanofi") 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 appealed this ruling, and following an oral hearing before the Supreme Court of Israel, decided to withdraw his appeal. Subsequently, in November 2018, we filed a motion to dismiss the certification motion. In September 2019, the plaintiff brought a motion to amend his claim, which the court denied in January 2020. We will continue to vigorously defend against the claims advanced. 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.

At least for the foreseeable future, we expect that our manufacturing facility in Danbury, Connecticut will be the sole location for the manufacturing of Afrezza and TreT. 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 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.

Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Legal, political and economic uncertainty surrounding the exit of the U.K. from the European Union may be a source of instability in international markets, create significant currency fluctuations and pose additional risks to our business.

Following the result of a referendum in 2016, the U.K. left the EU on January 31, 2020. This event is commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed to between the U.K. and the EU, the U.K. will be subject to a transition period until December 31, 2020, (the “Transition Period”), during which EU rules will continue to apply. Negotiations between the U.K. and the EU are expected to continue in relation to the customs and trading relationship between the U.K. and the EU following the expiry of the Transition Period.

The uncertainty concerning the U.K’s legal, political and economic relationship with the EU after the Transition Period may be a source of instability in the international markets, create significant currency fluctuations, and/or otherwise adversely affect trading agreements or similar cross-border co-operation arrangements (whether economic, tax, fiscal, legal, regulatory or otherwise). These developments, or the perception that any of them could occur, have had, and may continue to have, a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and limit the ability of key market participants to operate in certain financial markets. In particular, it could also lead to a period of considerable uncertainty in relation to the U.K. financial and banking markets, as well as on the regulatory process in Europe. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility.

Such a withdrawal from the EU is unprecedented, and it is unclear how the U.K's access to the European single market for goods, capital, services and labor within the EU, or single market, and the wider commercial, legal and regulatory environment, will impact our business.

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.

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, with the approval of Afrezza, the FDA has required that we conduct a five-year, randomized, controlled trial in 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. We have an ongoing dialogue with the FDA regarding the endpoints and goals for this long-term trial and have not yet commenced 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 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.

We are required to comply with FDA regulations concerning the advertising and promotion of Afrezza. Failure to comply with these regulations can result in the receipt of warning letters and further liability if off-label promotion is involved. For example, in October 2018, we received a warning letter from the FDA's Office of Prescription Drug Promotion ("OPDP") related to a particular post on our Afrezza Facebook page. The warning letter stated that the post in question failed to adequately disclose the risks associated with the use of Afrezza. As a result, we temporarily inactivated all Afrezza social media accounts (including Facebook, Instagram and Twitter) then, after consultation with OPDP, placed a corrective post on Facebook and Instagram.

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.

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, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, "PPACA") became law in the United States. PPACA substantially changed 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;
- 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 federal Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- A Medicare Part D coverage gap discount program, in which manufacturers must agree to now offer 75% 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;
- Requirements to report annually to CMS certain financial arrangements with physicians, as defined by such law, 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 requirement to annually report drug samples that certain manufacturers and authorized distributors provide to physicians; and
- A Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There remain judicial and congressional challenges to certain provisions of the PPACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the PPACA. President Trump has signed two Executive Orders and other directives designed to eliminate 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 Act includes a provision that repealed, 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". In addition, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the PPACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the PPACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans. In December 2018, CMS published a new final rule permitting further collections and payments to and from certain PPACA qualified health plans and health insurance issuers under the PPACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the PPACA are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace the PPACA will impact the PPACA and 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 2029 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 and enacted legislation 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.

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

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 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 certain 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, in May 2018, the European Union, or EU, 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 CCPA, which has been dubbed the first “GDPR-like” law in the United States;
- The federal Physician Payments Sunshine Act under PPACA, which requires certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to CMS information related to payments and other transfers of value to physicians, as defined by such law, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members; and
- State and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; state laws that require pharmaceutical companies to comply with the industry’s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government that otherwise restricts certain payments that may be made to healthcare providers and entities; state and local laws that require the registration of pharmaceutical sales representatives; 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, marketing expenditures or drug pricing.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. With Afrezza now available in Brazil and as we pursue additional international approvals, we will 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 significant civil, criminal and administrative penalties, damages, fines, imprisonment, disgorgement, exclusion from 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 HHS 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. 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.

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 patients 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, various patents providing protection for the powder component of Afrezza have terms extending into 2026, 2028, 2029 or 2030. In addition, patents providing protection for our inhaler and cartridges have terms extending into 2023, 2031 or 2032. Our method of treatment claims extend into 2026, 2029, 2030 or 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 do not believe that Afrezza infringes any third-party patents, we have identified certain patents having claims that may trigger an allegation of infringement in connection with the commercial manufacture and sale of Afrezza. If a court were to determine that Afrezza was infringing any of these patent rights, we would have to establish with the court that these patents are invalid or unenforceable in order to avoid legal liability for infringement of these patents. However, proving patent invalidity or unenforceability can be difficult because issued patents are presumed valid. Therefore, in the event that we are unable to prevail in a non-infringement or invalidity action we will have to either acquire the third-party patents outright or seek a royalty-bearing license. Royalty-bearing licenses effectively increase production costs and therefore may materially affect product profitability. Furthermore, should the patent holder refuse to either assign or license us the infringed patents, it may be necessary to cease manufacturing the product entirely and/or design around the patents, if possible. In either event, our business, financial condition and results of operations would be harmed and our profitability could be materially and adversely impacted.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public 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, the vesting of restricted stock unit awards and purchases under our employee stock purchase program. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price for our common stock. The issuance or sale of substantial amounts of common stock, or the perception that such issuances or sales may occur, could adversely affect the market price of our common stock and other securities.

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

The trading price of our common stock has been and 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 other products (in addition to Afrezza) based on 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;
- changes in the structure of the healthcare payment systems;
- 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. 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 2016, we 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 reverse stock split in March 2017, 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 convertible debt into, or exercise of our outstanding warrants for, common stock could negatively affect the market price of our common stock and other securities.

As of February 13, 2020, we had 212,295,318 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 2024 convertible notes or the Mann Group promissory notes, or upon issuance of our outstanding warrants, 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 may 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. In addition, pursuant to the MidCap Credit Facility, 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 of 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 has sufficient space to satisfy anticipated commercial demand for Afrezza and TreT. Our obligations under the MidCap Credit Facility are secured by our facility in Danbury, Connecticut and other assets. At the end of December 31, 2019, we leased a total of approximately 24,475 square feet of office space in Westlake Village, California pursuant to a lease that expires in January 2023. This 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 appealed this ruling, and following an oral hearing before the Supreme Court of Israel, decided to withdraw his appeal. Subsequently, in November 2018, we filed a motion to dismiss the certification motion. In September 2019, the plaintiff brought a motion to amend his claim, which the court denied in January 2020. We will continue to vigorously defend against the claims advanced.

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

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

Not applicable.

PART II

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

Common Stock Market

Our common stock has been traded on The Nasdaq Global Market under the symbol "MNKD" since July 28, 2004. The closing sales price of our common stock on The Nasdaq Global Market was $1.47 on February 13, 2020 and there were 107 registered holders of record of our common stock as of that date.

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 MidCap Credit Facility, we are restricted from declaring and distributing a cash dividend to our stockholders.

Recent Sales of Unregistered Securities

None.

Item 6. *Selected Financial Data*

MannKind is a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and is not required to provide information under this item.

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. The Company has elected the presentation requirements under Rule 12b-2 of the Exchange Act as a smaller reporting company and have herein included a two year discussion of our financial condition and results of operations. Please see our Annual Report on Form 10-K filed on February 26, 2019 for similar disclosures on previous years.

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 an ultra rapid-acting inhaled insulin that was approved by the FDA in June 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, 2019, we had an accumulated deficit of $3.0 billion and a stockholders' deficit of $190.5 million. We had net loss of $51.9 million and $87.0 million in the years ended December 31, 2019 and 2018, respectively. To date, we have funded our operations through the sale of equity and convertible debt securities, from the receipt of upfront and milestone payments from certain collaborations, and from borrowings under certain loan arrangements. As discussed below in "Liquidity and Capital Resources," if we are unable to obtain additional funding, there will continue to be substantial doubt about our ability to continue as a going concern.

Our business is subject to significant risks, including but not limited to our need to raise additional capital to fund our operations, our ability to successfully commercialize Afrezza, our ability to manufacture sufficient quantities of Afrezza and competition from other products and technologies. Additional significant risks also include the risks inherent in clinical trials and the regulatory approval process for our product candidates, which in some cases depends upon the efforts of our partners.

Critical Accounting Policies

The preparation of our consolidated financial statements is in accordance with accounting principles generally accepted in the United States of America (GAAP). 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 – Net Revenue – Commercial Product Sales — On January 1, 2018, we adopted Accounting Standards Codification ("ASC") Topic 606 - Revenue from Contracts with Customers ("the new revenue guidance"). We recognize revenue on product sales when a customer obtains control of our product, in an amount that reflects the consideration which we expect to be entitled in exchange for those goods or services. Product revenues are recorded net of applicable reserves for variable consideration, including discounts, rebates, allowances and fees. Management estimates related to revenue from commercial products includes estimates for variable consideration, product returns, government and payor rebates, and other incentives. For further detail refer to Note 2 – Summary of Significant Accounting Policies.

Revenue Recognition – Collaborations and Services — We enter into licensing or research agreements under which we license certain rights to our product candidates to third parties or provide research services to third-parties. The terms of these arrangements may include but are not limited to, payment to us of one or more of the following: up-front license fees; development, regulatory, and commercial milestone payments; payments for manufacturing supply services we provide; and royalties on net sales of licensed products and sublicenses of the rights. As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. We use key assumptions to determine the stand-alone selling price, which may include development timelines, reimbursement rates for personnel costs, discount rates, and probabilities of technical and regulatory success. Given that significant estimates depend on the development plan, these estimates could change and impact the revenue recognition. Consideration received that does not meet the requirements to satisfy the revenue recognition criteria is recorded as deferred revenue in the accompanying consolidated balance sheets based on our best estimate of when such revenue will be recognized. Current deferred revenue consists of amounts that are expected to be recognized as revenue in the next 12 months. Amounts that we expect will not be recognized within the next 12 months are classified as long-term deferred revenue.

Inventory Costing and Recoverability — We determine the cost of inventory using the first-in, first-out or FIFO method. We capitalize inventory costs associated with our products based on judgement that future economic benefits are expected to be realized. 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, 2019 and 2018. As a result of these assessments, we recorded inventory write-offs of $2.2 million in the year ended December 31, 2018. There were no inventory write-offs in the year ended December 31, 2019.

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. The loss on the purchase commitment balance is reduced as material is received. The balance of recognized loss on purchase commitments is primarily associated with insulin purchases. As of December 31, 2019 and 2018 the balance was $92.0 million and $98.3 million, respectively.

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 no impairments for the years ended December 31, 2019 and 2018. 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 July 2013, in conjunction with the execution of a loan agreement (the "Deerfield Credit Facility") with Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (collectively, "Deerfield") that expired following our full satisfaction of our repayment obligations, we issued to Deerfield Private Design Fund II, L.P. and Horizon Santé FLML SÀRL, (the "Milestone Purchasers") certain rights to receive payments of up to $90.0 million upon the occurrence of specified strategic and sales milestones, $70.0 million of which remains payable upon achievement of such milestones (the "Milestone Rights"), pursuant to an agreement (the "Milestone Agreement") that continues beyond the expiration of the loan agreement. 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 GAAP.

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 — 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. We use the Black-Scholes option valuation model to estimate the grant date fair value of employee stock options and the compensatory elements of employee stock purchase plans. Restricted stock units are valued based on the market price on the grant date. We evaluate stock awards with performance conditions as to the probability that the performance conditions will be met and 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.

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. As of December 31, 2019 and 2018, we had established a valuation allowance of $670.6 million and $665.4 million, respectively, 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.

Legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act of 2017 ("Tax Act"), subjects a U.S. shareholder to tax on global intangible low-taxed income ("GILTI") earned by certain foreign subsidiaries. The FASB Staff Q&A, Topic 740, No. 5, Accounting for Global Intangible Low-Taxed Income, states that an entity can make an accounting policy election to either recognize deferred taxes for temporary basis differences expected to reverse as GILTI in future years or to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only. We have elected to account for GILTI in the year the tax is incurred.

Results of Operations

Years ended December 31, 2019 and 2018

Revenues

The following table provides a comparison of the revenue categories for the years ended December 31, 2019 and 2018 (dollars in thousands):

	Year Ended December 31,			
	2019	2018	$ Change	% Change
Net revenue — commercial product sales:				
Gross revenue from product sales	$ 43,492	$ 30,242	$ 13,250	44%
Wholesaler distribution fees, rebates and chargebacks, product returns and other discounts	(18,188)	(12,966)	$ 5,222	40%
Net revenue — commercial product sales	25,304	17,276	$ 8,028	46%
Revenue — collaborations and services	37,734	10,583	$ 27,151	257%
Total revenues	$ 63,038	$ 27,859	$ 35,179	126%

Gross revenue from the sales of Afrezza increased by $13.3 million, or 44%, for the year ended December 31, 2019 compared to the prior year. The increase was primarily driven by higher product demand and price increases, shipments to Biomm (Brazil) as well as a more favorable mix of Afrezza cartridges. The gross-to-net adjustment was $18.2 million (or 42% of gross revenue) for the year ended December 31, 2019, compared to $13.0 million (or 43% of gross revenue) for the prior year. The increase of $5.2 million was primarily due to a $1.8 million increase in wholesaler's fee-for-service, a $1.3 million increase in rebates, chargebacks and patient co-pay assistance programs, and $1.8 million increase in product returns. Shipments to Biomm (Brazil) of $0.7 million which began in 2019 were not subject to gross-to-net adjustments. As a result, net revenue from the sales of Afrezza increased by $8.0 million, or 46%, for the year ended December 31, 2019 compared to the prior year.Net revenue from collaborations and services increased by $27.2 million, or 257%, for the year ended December 31, 2019 compared to the prior year. The increase was primarily driven by $24.8 million in revenue from the UT License Agreement and by $2.3 million in revenue from a separate research agreement with UT that we entered into in the fourth quarter of 2018 (the "UT Research Agreement").

Commercial product gross profit

The following table provides a comparison of the commercial product gross profit categories for the years ended December 31, 2019 and 2018 (dollars in thousands):

	Year Ended December 31,			
	2019	2018	$ Change	% Change
Commercial product gross profit:				
Net revenue — commercial product sales	$ 25,304	$ 17,276	$ 8,028	46%
Less cost of goods sold	(20,078)	(19,392)	$ 686	4%
Commercial product gross profit (loss):	$ 5,226	$ (2,116)	$ 7,342	347%
Gross margin	21%	(12%)		

Commercial product gross profit increased by $7.3 million, or 347%, for the year ended December 31, 2019 from a gross loss of $2.1 million in the prior year. The increase was primarily attributable to higher commercial product sales.

Non-GAAP Measures

To supplement our consolidated financial statements presented under GAAP, we are presenting certain non-GAAP financial measures to disclose additional information to facilitate the comparison of past and present operations, and they are among the indicators management uses as a basis for evaluating our financial performance. We believe that these non-GAAP financial measures, when considered together with our GAAP financial results, provide management and investors with an additional understanding of our business operating results, including underlying trends (dollars in thousands).

	Year Ended December 31,			
	2019	2018	$ Change	% Change
Net revenue — Afrezza	$ 25,304	$ 17,276	$ 8,028	46%
Less cost of goods sold	(20,078)	(19,392)	$ 686	4%
GAAP gross profit (loss) — Afrezza	5,226	(2,116)	$ 7,342	347%
Exclude Amphastar amendment fee	2,750	2,000	$ 750	38%
Non-GAAP gross profit (loss) — Afrezza	$ 7,976	$ (116)	$ 8,092	6,976%
Non-GAAP gross margin	32%	(1%)		

Expenses

The following table provides a comparison of the expense categories for the years ended December 31, 2019 and 2018 (dollars in thousands):

	Year Ended December 31,			
	2019	2018	$ Change	% Change
Expenses:				
Cost of goods sold	$ 20,078	$ 19,392	$ 686	4%
Cost of revenue - collaborations and services	7,901	1,077	$ 6,824	634%
Research and development	6,900	8,737	$ (1,837)	(21%)
Selling	46,373	47,407	$ (1,034)	(2%)
General and administrative	28,296	32,309	$ (4,013)	(12%)
Gain on foreign currency translation	(1,913)	(4,468)	$ (2,555)	(57%)
Total expenses	$ 107,635	$ 104,454	$ 3,181	3%

Cost of goods sold increased by $0.7 million, or 4%, for the year ended December 31, 2019 compared to the prior year. The increase was primarily attributable to higher cost of Afrezza sales of $2.1 million corresponding to higher Afrezza gross sales of $13.3 million and an increase of $0.8 million in fees paid for amendments to our Insulin Supply Agreement in 2018 and 2019, partially offset by a $2.2 million decrease in inventory write-offs as there were no inventory write-offs in 2019.

Cost of goods sold includes the fees incurred to amend our Insulin Supply Agreement, which consisted of approximately $2.8 million and $2.0 million for the years ended December 31, 2019 and 2018, respectively.

Cost of revenue - collaborations and services increased by $6.8 million, or 634%, for the year ended December 31, 2019 compared to the prior year. The increase was attributable to resource costs related to conducting activities under the UT License Agreement and UT Research Agreement, which began in the fourth quarter of 2018.

Research and development expenses decreased by $1.8 million, or 21%, for the year ended December 31, 2019 compared to the prior year. The decrease was primarily attributable to a $1.7 million decrease in personnel related costs and a $0.9 million decrease in clinical trial spending, partially offset by increased expenses of $0.2 million related to the development of our BluHale inhalation profiling apparatus and increased facility remediation and equipment repair costs of $0.5 million.

Selling expenses decreased by $1.0 million, or 2%, for the year ended December 31, 2019 compared to the prior year. The decrease was primarily attributable to a $6.0 million decrease in personnel related costs, a $0.3 million decrease in sponsorships and decreased consulting costs of $0.3 million in 2019, partially offset by a $5.6 million increase in costs for television advertising for Afrezza in 2019.

General and administrative expenses decreased by $4.0 million, or 12%, for the year ended December 31, 2019 compared to the prior year. This decrease was primarily attributable to a $0.6 million decrease in personnel and employee related costs, a $2.2 million net decrease in consulting and professional costs and a $1.2 million decrease in stock-based compensation costs.

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 gain on foreign currency translation decreased $2.6 million, or 57%, for the year ended December 31, 2019 due to the translation impact of the U.S. dollar to Euro exchange rates resulting in a lower gain in 2019 when compared to 2018.

Other Income (Expense)

The following table provides a comparison of the other income (expense) categories for the years ended December 31, 2019 and 2018 (dollars in thousands):

	Year Ended December 31,			
	2019	2018	$ Change	% Change
Interest income	$ 997	$ 501	$ 496	99%
Interest expense on notes	(6,304)	(5,116)	$ 1,188	23%
Interest expense on Mann Group promissory notes	(4,602)	(4,323)	$ 279	6%
Gain (loss) on extinguishment of debt	3,529	(765)	$ 4,294	561%
Other expense	(926)	(437)	$ 489	112%
Total other expense	$ (7,306)	$ (10,140)	$ (2,834)	(28%)

Interest income increased by $0.5 million, or 99%, for the year ended December 31, 2019 compared to the prior year. This increase was primarily attributable to a higher average balance on our money market funds and short-term investments.

Interest expense on notes, which included the MidCap Credit Facility, our previously outstanding $18.7 million aggregate principal amount of 5.75% Convertible Senior Subordinated Exchange Notes due 2021 (the "2021 notes"), our 2024 convertible notes, the Deerfield Credit Facility and the Milestone Rights, increased by $1.2 million, or 23%, for the year ended December 31, 2019 compared to the prior year. The increase was primarily attributable to additional interest of $3.4 million related to our milestone obligation under the Milestone Rights achieved in the third quarter of 2019, partially offset by lower interest as a result of the repayment of the Deerfield Credit Facility, which had an interest rate of 9.75%.

The gain on extinguishment of debt for the year ended December 31, 2019 was primarily due to the cancellation of the 2021 notes in exchange for cash, common stock, 2024 convertible notes and non-interest bearing notes in August 2019 pursuant to an exchange agreement. The loss on extinguishment of debt for the year ended December 31, 2018 was primarily attributable to conversions of convertible debt to common stock under the Deerfield Credit Facility in September 2018.

Other expense increased by $0.5 million, or 112%, for the year ended December 31, 2019 compared to the prior year. Other expense of $0.9 million incurred during 2019 was primarily due to expense recognized for the incremental fair value of warrants issued in December 2018 that were amended in December 2019. Other expense of $0.4 million incurred during 2018 primarily related to a currency loss realized in connection with a foreign exchange contract for purchases under the Insulin Supply Agreement.

Liquidity and Capital Resources

To date, we have funded our operations through the sale of equity and convertible debt securities, from the receipt of upfront and milestone payments from certain collaborations, and from borrowings under certain loan arrangements.

As of December 31, 2019, we had $120.3 million principal amount of outstanding debt consisting of:

- $40.0 million principal amount under the MidCap Credit Facility, bearing interest at an annual rate equal to one-month LIBOR plus 6.75%, subject to a one-month LIBOR floor of 2.00%, and maturing in August 2024;
- $5.0 million principal amount of 2024 convertible notes bearing interest at 5.75% per annum, with interest payable in cash or equity semiannually in arrears on February 15 and August 15 of each year, and maturing in November 2024, all of which is convertible into shares of our common stock at the option of the holder at a conversion price of $3.00 per share;
- $5.2 million principal amount of 2020 notes, half of which mature in June 2020 and half of which mature in December 2020; and
- $70.1 million principal amount of indebtedness under the Mann Group promissory notes bearing interest at a fixed rate of 7.00% per annum compounded quarterly and maturing in November 2024, $35.0 million of which is convertible into shares of our common stock at the option of The Mann Group at a conversion price of $2.50 per share. Interest is paid-in-kind from August 2019 until the end of 2020, after which we have the option to either pay interest in-kind or in shares.

There can be no assurance that we will have sufficient resources to make any required repayments of principal under the MidCap Credit Facility, the 2024 convertible notes, the 2020 notes or the Mann Group promissory notes when required. Further, if we undergo a fundamental change, as that term is defined in the indentures governing the terms of the 2024 convertible notes, the holders of such debt securities will have the option to require us to repurchase all or any portion of such debt securities at a repurchase price of 100% of the principal amount of such debt securities to be repurchased plus accrued and unpaid interest, if any. The 2024 convertible notes and the Mann Group convertible note are fully convertible at any time prior to maturity as further disclosed in Note 7 – Borrowings.

To date, we have been able to timely make our required interest payments, but we cannot guarantee that we will be able to do so in the future. If we fail to pay interest on the 2024 convertible notes or under the MidCap Credit Facility, or if we fail to repay or repurchase the 2024 convertible notes, the 2020 notes, Mann Group promissory notes or borrowings under the MidCap Credit Facility, 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 noteholders initiating bankruptcy proceedings or causing us to cease operations altogether.

In July 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, $70.0 million of which remains payable upon achievement of such milestones. See Note 13 — Commitments and Contingencies and Note 7 — Borrowings for further information related to the Milestone Rights.

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 report do not include adjustments that might result from any unfavorable outcome of this uncertainty.

During the year ended December 31, 2019, we used $88.5 million of cash for our operating activities mainly as a result of our net loss of $51.9 million as well as paid-in-kind interest on the Mann Group promissory notes of $32.8 million and a decrease in deferred revenue of $6.7 million.

During the year ended December 31, 2018, we used $37.7 million of cash for our operating activities mainly as a result of our net loss of $87.0 million, partially offset by a decrease in operating assets and liabilities primarily attributable to our receipt of $57.2 million in cash from

collaboration agreements (revenue recognition of $46.8 million was deferred to future periods. See Note 8 — Collaborations and Licensing Arrangements).

Cash used in investing activities was $22.8 million for the year ended December 31, 2019 compared to cash used in investing activities of $0.2 million for the year ended December 31, 2018. The difference was primarily due to a purchase of treasury bills of $45.0 million, partially offset by proceeds from sales of treasury bills of $25.0 million in 2019. There was no investment in treasury bills for the year ended December 31, 2018.

Cash provided by financing activities was $69.9 million for the year ended December 31, 2019, primarily due to $39.1 million of net proceeds from the Midcap Credit Facility, $31.8 million of net proceeds from the exchange of the Mann Group promissory notes, $9.9 million of net proceeds from the exchange of the senior convertible notes, in addition to proceeds received from the issuance of our common stock associated with the exercise of warrants for $5.9 million and our at-the-market offering for $3.2 million. These net proceeds were partially offset by net payments of $11.1 million for the 2021 notes and $6.9 million for the Deerfield Credit Facility.

Cash provided from financing activities was $61.3 million for the year ended December 31, 2018 primarily related to an aggregate proceeds of $68.0 million in a public offering and a direct placement of common stock and $2.0 million in at-the-market issuance of common stock offset by $5.0 million of principal payment on Facility Financing Obligation and $4.1 million costs associated with the offering and direct placement of common stock.

Future Liquidity Needs

We are not currently profitable and have rarely generated positive net cash flows from operations. In addition, we expect to continue to incur significant expenditures for the foreseeable future in support of our manufacturing operations, sales and marketing costs for Afrezza, and collaboration and development costs for product candidates in our pipeline. As of December 31, 2019, we had an accumulated deficit of $3.0 billion and $120.3 million of total principal amount of outstanding borrowings, with limited capital resources of $29.9 million in cash and cash equivalents and $20.0 million in short-term investments. These financial conditions raise substantial doubt about our ability to continue as a going concern.

Our capital resources may not be sufficient to continue to meet our current and anticipated obligations over the next twelve months if we cannot increase our operating cash inflows by growing our prescription and revenue base and/or obtain access to the remaining $35.0 million borrowings that may become available under the MidCap Credit Facility. In the event these capital resources are not sufficient, we may need to raise additional capital by selling equity or debt securities, entering into strategic business collaboration agreements with other companies, seeking other funding facilities or licensing arrangements, selling assets or by other means. However, we cannot provide assurances that additional capital will be available on acceptable terms or at all. 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.

If we are unable to meet our current and anticipated obligations over the next twelve months through our existing capital resources, or obtain new sources of capital when needed, we may have to delay or reduce the scope of our manufacturing operations, reduce or eliminate one or more of our development programs, or make significant changes to our operating plan. These factors raise substantial doubt about our ability to continue as a going concern.

Off-Balance Sheet Arrangements

As of December 31, 2019 and 2018, we did not have any off-balance sheet arrangements.

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 2019 and other new accounting standards that have been issued by the FASB but are not effective until after December 31, 2019.

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

Interest Rate Risk

Interest on borrowings under the MidCap Credit Facility is determined, for any one-month period, on the basis of one-month LIBOR in effect at the beginning of such period plus 6.75%, subject to a one-month LIBOR floor of 2.00%. Accordingly, our interest expense under the MidCap Credit Facility is subject to changes in the one-month LIBOR rate. All other debt has fixed interest rates, so the interest expense associated with such debt is not exposed to changes in market interest rates. Specifically, the interest rate on amounts borrowed under the Mann Group promissory notes is fixed at 7.00% and the interest rate under the 2024 convertible notes is fixed at 5.75%. See Note 7 – Borrowings for information about the principal amount of outstanding debt.

If a change in the one-month LIBOR interest rate equal to 10% of the one-month LIBOR interest rate on December 31, 2019 were to have occurred, this change would not have a material effect on our interest payment obligation.

Our current policy requires us to maintain a highly liquid short-term investment portfolio consisting mainly of U.S. money market funds, U.S. Treasury bills or notes 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, 2019 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 Insulin Supply Agreement with Amphastar. Such obligations are denominated in Euros. At the end of each reporting period, the recognized gain or 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 the Euro. In 2019, we entered into two 90-day foreign currency hedging transactions to mitigate our exposure to foreign currency exchange risks associated with then-existing insulin purchase commitments. We realized a *de minimis* currency loss for these transactions, which we recorded in other income and expense.

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, 2019 were to have occurred, this change would have resulted in a foreign currency impact to our pre-tax loss of approximately $9.2 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, 2019.

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, 2019.

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, 2019. 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, 2019, 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, 2019 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, 2019, 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, 2019, 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, 2019, of the Company and our report dated February 25, 2020, 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

Los Angeles, California
February 25, 2020

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

None.

PART III

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

(a) *Executive Officers* — For information regarding the identification and business experience of our executive officers, see "Information about our Executive Officers" in Part I, Item 1 of this Annual Report on Form 10-K.

(b) *Directors* — The information required by this Item regarding the identification and business experience of our directors and corporate governance matters 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 2020 Annual Meeting of Stockholders (the "Proxy Statement"), to be filed with the SEC on or before April 29, 2020, and is incorporated herein by reference.

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 and 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 51:

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

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

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

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on August 9, 2016).
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation 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).
3.3	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).
3.4	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).
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3 and 3.4.
4.2	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).
4.3	Description of Common Stock.
4.4	Milestone Rights Purchase Agreement, dated as of July 1, 2013, by and among MannKind, Deerfield Private Design Fund II, L.P. and Horizon Santé FLML SÁRL (incorporated by reference to Exhibit 99.3 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on July 1, 2013).
4.5	Form of Warrant to Purchase Common Stock issued November 16, 2015 (incorporated by reference to Exhibit 4.17 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 15, 2016).
4.6	Form of Common Stock Purchase Warrant issued December 26, 2018 (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 December 21, 2018).
4.7	Amendment to Common Stock Purchase Warrant, dated December 22, 2019, by and between MannKind Corporation and CVI Investments, Inc. (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 December 23, 2019).
4.8	Form of Warrant to Purchase Stock issued to MidCap Financial Trust on August 6, 2019 (incorporated by reference to Exhibit 4.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on August 7, 2019).
4.9	Form of 5.75% Convertible Senior Subordinated Exchange Notes Due 2024 (incorporated by reference to Exhibit 4.2 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on August 7, 2019).
4.10	Indenture, dated as of August 6, 2019, by and between MannKind Corporation and U.S. Bank National Association (incorporated by reference to Exhibit 4.3 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on August 7, 2019).

Exhibit Number	Description of Document
4.11	Promissory Note due June 30, 2020 made by MannKind Corporation in favor of Bruce & Co., Inc., dated August 6, 2019 (incorporated by reference to Exhibit 4.4 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on August 7, 2019).
4.12	Promissory Note due December 31, 2020 made by MannKind Corporation in favor of Bruce & Co., Inc., dated August 6, 2019 (incorporated by reference to Exhibit 4.5 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on August 7, 2019).
4.13	Convertible Promissory Note made by MannKind Corporation in favor of The Mann Group LLC, dated August 6, 2019 (incorporated by reference to Exhibit 4.6 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on August 7, 2019).
4.14	Promissory Note made by MannKind Corporation in favor of The Mann Group LLC, dated August 6, 2019 (incorporated by reference to Exhibit 4.7 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on August 7, 2019).
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 June 28, 2017, by and between MannKind and Patrick McCauley (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 February 27, 2018).
10.5*	Offer Letter dated February 2, 2018, by and between MannKind and David Kendall (incorporated by reference to Exhibit 10.6 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on February 27, 2018).
10.6*	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).
10.7*	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).
10.8*	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).
10.9*	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).
10.10*	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).
10.11*	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).
10.12*	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).
10.13*	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).
10.14*	Non-Employee Director Compensation Program (incorporated by reference to Exhibit 10.15 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on February 26, 2019).
10.15*	MannKind Corporation 2013 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on August 9, 2016).
10.16*	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).
10.17*	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).
10.18*	MannKind Corporation 2018 Equity Incentive Plan (incorporated by reference to Exhibit 99.1 to MannKind's registration statement Form S-8 (File No. 333-226648), filed with the SEC on August 7, 2018).
10.19*	Form of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the MannKind 2018 Equity Incentive Plan (incorporated by reference to Exhibit 99.2 to MannKind's registration statement on Form S-8 (File No. 333-226648), filed with the SEC on August 7, 2018).

Exhibit Number	Description of Document
10.20*	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the MannKind 2018 Equity Incentive Plan (incorporated by reference to Exhibit 99.3 to MannKind's registration statement on Form S-8 (File No. 333-226648), filed with the SEC on August 7, 2018).
10.21*	MannKind Corporation 2004 Employee Stock Purchase Plan, as amended (incorporated by reference to Exhibit 99.4 to MannKind's registration statement Form S-8 (File No. 333-226648), filed with the SEC on August 7, 2018).
10.22*	MannKind Corporation Market Price Stock Purchase Plan (incorporated by reference to Exhibit 99.1 to MannKind's registration statement Form S-8 (File No. 333-225428), filed with the SEC on June 5, 2018).
10.23**	Supply Agreement, dated as of July 31, 2014, by and between MannKind and Amphastar France Pharmaceuticals S.A.S. (incorporated by reference to Exhibit 10.3 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on November 10, 2014).
10.24	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).
10.25**	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).
10.26**	Third Amendment to Supply Agreement, dated April 11, 2018, by and between MannKind and Amphastar Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.8 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on May 9, 2018).
10.27**	Fourth Amendment to Supply Agreement, dated December 24, 2018, by and between MannKind and Amphastar Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.50 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on February 26, 2019).
10.28***	Fifth Amendment to Supply Agreement, dated August 2, 2019, by and between MannKind Corporation and Amphastar Pharmaceuticals, Inc. (incorporated by reference to Exhibit 99.5 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on August 7, 2019).
10.29	Sublease Agreement, dated May 1, 2015, by and between MannKind and the Alfred Mann Foundation for Scientific Research (incorporated by reference to Exhibit 10.37 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on March 15, 2016).
10.30	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).
10.31	Controlled Equity Offering℠ Sales Agreement, by and between MannKind and Cantor Fitzgerald & Co., dated February 27, 2018 (incorporated by reference to Exhibit 10.47 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on February 27, 2018).
10.32**	License and Collaboration Agreement, dated September 3, 2018 by and between MannKind and United Therapeutics Corporation (incorporated by reference to Exhibit 10.8 to MannKind's Quarterly Report on Form 10-Q (file No. 000-50865), filed with the SEC on November 1, 2018).
10.33**	Research Agreement, dated September 3, 2018 by and between MannKind and United Therapeutics Corporation (incorporated by reference to Exhibit 10.9 to MannKind's Quarterly Report on Form 10-Q (file No. 000-50865), filed with the SEC on November 1, 2018).
10.34	Exchange Agreement, dated July 18, 2019, 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 July 18, 2019).
10.35	Exchange Agreement, dated August 5, 2019, by and between MannKind Corporation and The Mann Group LLC (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 August 7, 2019).
10.36	Exchange Agreement, dated August 6, 2019, 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 99.4 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on August 7, 2019).
10.37	Exchange Agreement, dated August 6, 2019, by and between MannKind Corporation and Bruce & Co., Inc. (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 August 7, 2019).
10.38***	Credit and Security Agreement, dated August 6, 2019, by and among MannKind Corporation, MannKind LLC, the lenders party thereto from time to time and MidCap Financial Trust, as agent (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 August 7, 2019).

Exhibit Number	Description of Document
10.39	Amendment No. 1 to Credit and Security Agreement, dated December 18, 2019, by and among MannKind Corporation, MannKind LLC, the lenders party thereto from time to time and MidCap Financial Trust, as agent (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 18, 2019).
23.1	Consent of Independent Registered Public Accounting Firm.
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.
*** Certain portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

Item 16. ***Form 10-K Summary***

None.

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 E. Castagna
Michael E. Castagna
Chief Executive Officer

Dated: February 25, 2020

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.

Signature	Title	Date
/s/ Michael E. Castagna Michael E. Castagna	Chief Executive Officer and Director *(Principal Executive Officer)*	February 25, 2020
/s/ Steven B. Binder Steven B. Blinder	Chief Financial Officer *(Principal Financial and Accounting Officer)*	February 25, 2020
/s/ Kent Kresa Kent Kresa	Chairman of the Board of Directors	February 25, 2020
/s/ Ronald J. Consiglio Ronald J. Consiglio	Director	February 25, 2020
/s/ Michael Friedman Michael Friedman, M.D.	Director	February 25, 2020
/s/ Anthony C. Hooper Anthony C. Hooper	Director	February 25, 2020
/s/ Christine Mundkur Christine Mundkur	Director	February 25, 2020
/s/ James S. Shannon James S. Shannon, M.D., MRCP (UK)	Director	February 25, 2020

MANNKIND CORPORATION AND SUBSIDIARIES

INDEX TO FINANCIAL STATEMENTS

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, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, stockholders' deficit, and cash flows for each of the two years in the period ended December 31, 2019 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, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, 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, 2019, 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 25, 2020 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

Los Angeles, California
February 25, 2020

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

MANNKIND CORPORATION AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2019	2018
	(In thousands except per share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 29,906	$ 71,157
Restricted cash	316	527
Short-term investments	19,978	—
Accounts receivable, net	3,513	4,017
Inventory	4,155	3,597
Prepaid expenses and other current assets	2,889	2,556
Total current assets	60,757	81,854
Property and equipment, net	26,778	25,602
Other assets	6,190	249
Total assets	$ 93,725	$ 107,705
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 4,789	$ 5,379
Accrued expenses and other current liabilities	15,904	15,022
Facility financing obligation	—	11,298
Short-term note payable	5,028	—
Deferred revenue — current	32,503	36,885
Recognized loss on purchase commitments — current	7,394	6,657
Total current liabilities	65,618	75,241
Promissory notes	70,020	72,089
Accrued interest — promissory notes	2,002	6,835
Long-term Midcap credit facility	38,851	—
Senior convertible notes	5,000	19,099
Recognized loss on purchase commitments — long term	84,639	91,642
Operating lease liability	2,514	—
Deferred revenue — long term	8,344	10,680
Milestone rights liability	7,263	7,201
Total liabilities	284,251	282,787
Commitments and contingencies (Note 13)		
Stockholders' deficit:		
Undesignated preferred stock, $0.01 par value — 10,000,000 shares authorized; no shares issued or outstanding at December 31, 2019 and 2018	—	—
Common stock, $0.01 par value — 280,000,000 shares authorized, 211,787,573 and 187,029,967 shares issued and outstanding at December 31, 2019 and 2018, respectively	2,118	1,870
Additional paid-in capital	2,799,278	2,763,067
Accumulated other comprehensive loss	(19)	(19)
Accumulated deficit	(2,991,903)	(2,940,000)
Total stockholders' deficit	(190,526)	(175,082)
Total liabilities and stockholders' deficit	$ 93,725	$ 107,705

See notes to consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2019	2018
	(In thousands except per share data)	
Revenues:		
Net revenue — commercial product sales	$ 25,304	$ 17,276
Revenue — collaborations and services	37,734	10,583
Total revenues	63,038	27,859
Expenses:		
Cost of goods sold	20,078	19,392
Cost of revenue — collaborations and services	7,901	1,077
Research and development	6,900	8,737
Selling, general and administrative	74,669	79,716
Gain on foreign currency translation	(1,913)	(4,468)
Total expenses	107,635	104,454
Loss from operations	(44,597)	(76,595)
Other (expense) income:		
Interest income	997	501
Interest expense on notes	(6,304)	(5,116)
Interest expense on promissory notes	(4,602)	(4,323)
Gain (loss) on extinguishment of debt	3,529	(765)
Other expense	(926)	(437)
Total other expense	(7,306)	(10,140)
Loss before income tax expense	(51,903)	(86,735)
Provision for income taxes	—	240
Net loss	$ (51,903)	$ (86,975)
Net loss per share — basic and diluted	$ (0.27)	$ (0.60)
Shares used to compute net loss per share — basic and diluted	195,584	144,136

See notes to consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Year Ended December 31,	
	2019	2018
	(In thousands)	
Net loss	$ (51,903)	$ (86,975)
Other comprehensive loss:		
Cumulative translation loss	—	(1)
Comprehensive loss	$ (51,903)	$ (86,976)

See notes to consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Capital	Loss	Deficit	Total
			(In thousands)			
BALANCE, JANUARY 1, 2018	119,053	$ 1,192	$ 2,638,992	$ (18)	$ (2,854,898)	$ (214,732)
Exercise of stock options	7	—	7	—	—	7
Issuance of common stock from the release of restricted stock units	193	2	(1)	—	—	1
Issuance of common stock under Employee Stock Purchase Plan	400	3	342	—	—	345
Stock-based compensation expense	—	—	6,857	—	—	6,857
Issuance of common stock pursuant to conversion of Note Payable to Related Party	3,000	30	8,130	—	—	8,160
Issuance of common stock pursuant to conversion of Facility Financing Obligation	19,726	197	37,931	—	—	38,128
Issuance of common stock — direct placement	14,000	140	27,860			28,000
Issuance costs associated with direct placement			(1,610)	—	—	(1,610)
Issuance of common stock — public offering	26,667	267	39,733	—	—	40,000
Issuance cost associated with public offering	—	—	(2,538)	—	—	(2,538)
Issuance of common stock pursuant to conversion of Senior Convertible Notes	2,726	27	4,953	—	—	4,980
Issuance of at-the-market placement	1,028	10	2,079	—	—	2,089
Issuance costs associated with at-the-market placement	—	—	(84)	—	—	(84)
Issuance of common stock under Market Price Stock Purchase Plan	230	2	428	—	—	430
Amortization of shelf fees	—	—	(12)	—	—	(12)
Cumulative translation loss	—	—	—	(1)	—	(1)
Adjustment to adopt ASU 2014-09 (Topic 606)	—	—	—	—	1,873	1,873
Net loss	—	—	—	—	(86,975)	(86,975)
BALANCE, DECEMBER 31, 2018	187,030	$ 1,870	$ 2,763,067	$ (19)	$ (2,940,000)	$ (175,082)
Exercise of stock options	68	1	123	—	—	124
Issuance of common stock under Employee Stock Purchase Plan	653	7	649	—	—	656
Stock-based compensation expense	—	—	6,203	—	—	6,203
Issuance of common stock pursuant to conversion of Deerfield Credit Facility	4,193	42	4,533	—	—	4,575
Issuance of common stock from the release of restricted stock units	705	7	(9)	—	—	(2)
Issuance of common stock pursuant to conversion of Mann Group promissory notes	7,143	71	7,929	—	—	8,000
Issuance of common stock pursuant to conversion of senior convertible notes	4,911	49	5,526	—	—	5,575
Issuance of common stock in at-the-market offering	2,585	26	3,173	—	—	3,199
Issuance cost associated with at-the-market offering	—	—	(60)	—	—	(60)
Issuance of warrants pursuant to MidCap Credit Facility	—	—	1,854	—	—	1,854
Issuance of common stock from the exercise of warrants	4,500	45	5,855	—	—	5,900
Warrant modification	—	—	688	—	—	688
Repurchase of warrants	—	—	(253)	—	—	(253)
Net loss	—	—	—	—	(51,903)	(51,903)
BALANCE, DECEMBER 31, 2019	211,788	$ 2,118	$ 2,799,278	$ (19)	$ (2,991,903)	$ (190,526)

See notes to consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2019	2018
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (51,903)	$ (86,975)
Adjustments to reconcile net loss to net cash used in operating activities:		
Payment-in-kind interest on promissory notes	(32,822)	—
Interest expense on promissory notes	4,712	4,488
Stock-based compensation expense	6,203	6,857
Gain on foreign currency translation	(1,913)	(4,468)
(Gain) loss on extinguishment of debt	(3,529)	765
Amortization of right-of-use assets	1,182	—
Depreciation, amortization and accretion	972	2,857
Loss on warrant transactions	868	—
Gain on sale, abandonment/disposal or impairment of property and equipment	—	(114)
Write-off of inventory	—	2,212
Other, net	107	(35)
Changes in operating assets and liabilities:		
Accounts receivable, net	504	(1,339)
Inventory	(558)	(3,152)
Prepaid expenses and other current assets	(333)	454
Other assets	(549)	200
Accounts payable	(593)	(1,605)
Accrued expenses and other current liabilities	3,498	2,249
Deferred revenue	(6,717)	46,814
Recognized loss on purchase commitments	(4,395)	(6,939)
Operating lease liabilities	(1,672)	—
Accrued interest on Mann Group promissory notes	(1,545)	—
Net cash used in operating activities	(88,483)	(37,731)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of treasury bills	(44,971)	—
Proceeds from sale of treasury bills	24,993	—
Purchase of property and equipment	(2,565)	(354)
Proceeds from sale of property and equipment	—	120
Purchase of limited liability company ownership interest	(300)	—
Net cash used in investing activities	(22,843)	(234)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from promissory notes	70,051	—
Proceeds from MidCap Credit Facility	40,000	—
Proceeds from senior convertible notes	9,910	—
Principal payments on Mann Group promissory notes	(38,264)	—
Principal payments on senior convertible notes	(11,081)	—
Principal payments on facility financing obligation	(6,920)	(5,000)
Issuance of common stock from the exercise of warrants	5,900	—
Proceeds from at-the-market offering	3,199	2,089
Milestone payment	(1,643)	—
Issuance cost associated with MidCap Credit Facility	(886)	—
Issuance cost associated with Mann Group promissory notes	(33)	—
Issuance costs associated with at-the-market offering	(60)	(84)
Repurchase of warrants	(433)	—
Exercise of stock options	124	—
Proceeds from public offering	—	40,000
Proceeds from direct placement	—	28,000
Proceeds from market price stock purchase plan	—	430
Issuance cost associated with public offering	—	(2,538)
Issuance cost associated with direct placement	—	(1,610)
Other	—	7
Net cash provided by financing activities	69,864	61,294
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	(41,462)	23,329
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING OF PERIOD	71,684	48,355
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, END OF PERIOD	$ 30,222	$ 71,684
SUPPLEMENTAL CASH FLOWS DISCLOSURES:		
Interest paid in cash, net of amounts capitalized	$ 1,757	$ 3,759
Income taxes paid in cash	—	240
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Payment on promissory notes through issuance of common stock	8,000	8,160
Addition of right-of-use assets upon adoption of new lease guidance	5,192	—
Payment of facility obligation through common stock issuance	4,575	37,912
Payment of senior convertible notes through common stock issuance	4,500	5,000
Payment of interest on senior convertible notes through common stock issuance	1,075	—
Common stock issuance to settle employee stock purchase plan liability	656	—
Issuance of warrants associated with MidCap Credit Facility	1,854	—

See notes to consolidated financial statements.

1. Description of Business

Business — MannKind Corporation and its 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 an ultra rapid-acting inhaled insulin that was approved by the U.S. Food and Drug Administration (the "FDA") in June 2014 to improve glycemic control in adults with diabetes. Afrezza became available by prescription in United States retail pharmacies in February 2015. Currently, the Company promotes Afrezza to endocrinologists and certain high-prescribing primary care physicians in the United States through its specialty sales force. In addition, the Company's partner in Brazil, Biomm, commenced commercialization of Afrezza in January 2020 and the Company's partners in India and Australia are preparing for regulatory submissions and have not yet commenced commercialization in their respective territories.

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. In addition, the Company expects to continue to incur significant expenditures for the foreseeable future in support of its manufacturing operations, sales and marketing costs for Afrezza, and development costs for product candidates in the Company's pipeline. As of December 31, 2019, the Company had an accumulated deficit of $3.0 billion and $120.3 million of total principal amount of outstanding borrowings, with limited capital resources of $29.9 million in cash and cash equivalents and $20.0 million in short-term investments. These financial conditions raise substantial doubt about the Company's ability to continue as a going concern.

In August 2019, the Company and MannKind LLC entered into a credit and security agreement with MidCap Financial Trust (as amended, the "MidCap Credit Facility") to recapitalize its debt structure (the "recapitalization") (Refer to Note 7 – Borrowings for further details). The MidCap Credit Facility provides a secured term loan facility in an aggregate principal amount of up to $75.0 million, of which $40.0 million was outstanding as of December 31, 2019 and the remaining $35.0 million will become available under the following conditions: (1) $10.0 million will be available to the Company until April 15, 2020, subject to the satisfaction of certain conditions, including achieving Afrezza net revenue of at least $30.0 million on a trailing twelve month basis, and (2) the remaining $25.0 million will be available to the Company until June 30, 2021, subject to the satisfaction of certain milestone conditions associated with Afrezza net revenue and certain milestone conditions related to the Company's collaboration with United Therapeutics (see Note 8 – Collaborations and Licensing Arrangements).

Principal payments on the MidCap Credit Facility began in September 2021. In addition, the MidCap Credit Facility contains certain covenants, one of which includes a requirement to maintain a minimum of $15.0 million of unrestricted cash and cash equivalents. This amount will increase to $20.0 million if the Company draws the aforementioned additional funding that may be made available.

As part of the recapitalization, the Company converted shares of common stock, made repayments on outstanding borrowings, and used some of the proceeds from the MidCap Credit Facility proceeds to:

1) Fully repay the remaining $5.0 million due on its financing facility with Deerfield Private Design Fund II L.P. and Deerfield Private Design International I L.P.

2) Pay down the Company's obligations under the Mann Group promissory notes, including accrued interest, by $11.0 million and restructure the remaining $70.1 million of debt into the $35.0 million note that is convertible into shares of the Company's common stock at $2.50 per share (the "Mann Group convertible note") and the $35.1 million non-convertible note (the "Mann Group non-convertible note").

3) Reduce the 5.75% Convertible Senior Subordinated Exchange Notes due 2021 (the "2021 notes") by $8.5 million and restructure the remaining $10.2 million to the $2.6 million due June 2020 (the "June 2020 note"), $2.6 million due December 2020 (the "December 2020 note", and together with the June 2020 note, the "2020 notes"), and the $5.0 million 5.75% Convertible Senior Subordinated Exchange Notes due November 2024 (the "2024 convertible notes") which are convertible into shares of our common stock at $3.00 per share.

The Company's capital resources may not be sufficient to continue to meet its current and anticipated obligations over the next twelve months if the Company cannot increase its operating cash inflows by growing its prescription and revenue base and/or obtain access to the remaining $35.0 million borrowings that may become available under its MidCap Credit Facility. In the event these capital resources are not sufficient, the Company may need to raise additional capital by selling equity or debt securities, entering into strategic business collaboration agreements with other companies, seeking other funding facilities or licensing arrangements, selling assets or by other means. However, the Company cannot provide assurances that additional capital will be available on acceptable terms or at all.

If the Company is unable to meet its current and anticipated obligations over the next twelve months through its existing capital resources, or obtain new sources of capital when needed, the Company may have to delay, reduce the scope of its manufacturing operations, reduce or eliminate one or more of its development programs, and/or make significant changes to its operating plan. These factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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. Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications had no effect on the reported Consolidated Balance Sheets or Statements of Operations. An adjustment has been made to the Consolidated Statements of Cash Flows for the fiscal year ended December 31, 2018 to separately identify the disclosures of non-cash investing and financing activities related to the payment of facility obligation through common stock issuance and senior convertible notes through common stock issuance. This change in classification does not affect previously reported cash flows from operating, investing or financing activities. In addition, an adjustment has been made to reclassify certain immaterial amounts of professional fees to other accrued expenses within the table of accrued expenses in Note 5 — Accrued Expenses and Other Current Liabilities as of December 31, 2018 for consistency with the current year presentation.

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 — The Company adopted Accounting Standards Codification ("ASC") Topic 606 - *Revenue from Contracts with Customers* ("the new revenue guidance"), on January 1, 2018. Under Topic 606, the Company recognizes revenue when its customers obtain control of promised goods or services, in an amount that reflects the consideration which the Company expects to be entitled in exchange for those goods or services.

To determine revenue recognition for arrangements that are within the scope of Topic 606, the Company performs the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to arrangements that meet the definition of a contract under Topic 606, including when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer.

At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract, determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company has two types of contracts with customers: (i) contracts for commercial product sales with wholesale distributors and specialty pharmacies and (ii) collaboration arrangements.

Revenue Recognition – Net Revenue – Commercial Product Sales – The Company sells Afrezza to a limited number of wholesale distributors and specialty pharmacies in the U.S. (collectively, its "Customers"). Wholesale distributors subsequently resell the Company's products to retail pharmacies and certain medical centers or hospitals. Specialty pharmacies sell directly to patients. In addition to distribution agreements with Customers, the Company enters into arrangements with payors that provide for government mandated and/or privately negotiated rebates, chargebacks, and discounts with respect to the purchase of the Company's products.

The Company recognizes revenue on product sales when the Customer obtains control of the Company's product, which occurs at delivery for wholesale distributors and at shipment for specialty pharmacies. Product revenues are recorded net of applicable reserves for variable consideration, including discounts and allowances.

Free Goods Program – From time to time, the Company offers programs to potential new patients that allow them to obtain free goods (prescription fills) from a pharmacy. On a net basis, it is not probable that the Company will receive the consideration from these products. Therefore, the Company excludes such amounts from both gross and net revenue. The cost of product associated with the free goods program is included in cost of goods sold.

Reserves for Variable Consideration — Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established. Components of variable consideration include trade discounts and allowances, product returns, provider chargebacks and discounts, government rebates, payor rebates, and other incentives, such as voluntary patient assistance, and other allowances that are offered within contracts between the Company and its Customers, payors, and other indirect customers relating to the Company's sale of its products. These reserves, as detailed below, are based on the amounts earned, or to be claimed on the related sales, and result in a reduction of accounts receivable or establishment of a current liability.

Where appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted in accordance with the expected value method in Topic 606 for relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying and payment patterns. Overall, these reserves reduce recognized revenue to the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts.

The amount of variable consideration which is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. The Company's analysis also contemplates application of the constraint in accordance with the guidance, under which it determined a material reversal of revenue would not occur in a future period for the estimates detailed below as of December 31, 2019 and, therefore, the transaction price was not reduced further during the year ended December 31, 2019. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net revenue – commercial product sales and earnings in the period such variances become known.

Trade Discounts and Allowances — The Company generally provides Customers with discounts which include incentives, such as prompt pay discounts, that are explicitly stated in the Company's contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized. In addition, the Company compensates (through trade discounts and allowances) its Customers for sales order management, data, and distribution services. However, the Company has determined such services received to date are not distinct from the Company's sale of products to the Customer and, therefore, these payments have been recorded as a reduction of revenue and as a reduction to accounts receivable, net.

Product Returns —Consistent with industry practice, the Company generally offers Customers a right of return for unopened product that has been purchased from the Company for a period beginning six months prior to and ending 12 months after its expiration date, which lapses upon shipment to a patient. The Company estimates the amount of its product sales that may be returned by its Customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized, as well as reductions to accounts receivable, net. The Company currently estimates product returns using available industry data and its own sales information, including its visibility into the inventory remaining in the distribution channel. The Company's current return reserve percentage is estimated to be in the single digits.

Provider Chargebacks and Discounts — Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to Customers who directly purchase the product from the Company. Customers charge the Company for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is recorded in accrued expenses and other current liabilities. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by Customers, and the Company generally issues credits for such amounts within a few weeks of the Customer's notification to the Company of the resale. Reserves for chargebacks consist of credits that the Company expects to issue for units that remain in the distribution channel inventories at each reporting period-end that the Company expects will be sold to qualified healthcare providers, and chargebacks that Customers have claimed, but for which the Company has not yet issued a credit.

Government Rebates — The Company is subject to discount obligations under Medicare and state Medicaid programs. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

Payor Rebates — The Company contracts with certain private payor organizations, primarily insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of its products. The Company estimates these rebates and records such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities.

Other Incentives — Other incentives which the Company offers include voluntary patient support programs, such as the Company's co-pay assistance program, which are intended to provide financial assistance to qualified commercially-insured patients with prescription drug co-payments required by payors. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with the product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period. The adjustments are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities.

Revenue Recognition — Revenue — Collaborations and Services — The Company enters into licensing or research agreements under which the Company licenses certain rights to its product candidates to third parties or conducting research services to third parties. The terms of these arrangements may include, but are not limited to payment to the Company of one or more of the following: up-front license fees; development, regulatory, and commercial milestone payments; payments for manufacturing commercial and clinical supply services the Company provides; and royalties on net sales of licensed products and sublicenses of the rights. As part of the accounting for these arrangements, the Company must develop assumptions that require judgment such as determining the performance obligation in the contract and determining the stand-alone selling price for each performance obligation identified in the contract. If an arrangement has multiple performance obligations, the allocation of the transaction price is determined from observable market inputs, and the Company uses key assumptions to determine the stand-alone selling price, which may include development timelines, reimbursement rates for personnel costs, discount rates, and probabilities of technical and regulatory success. Revenue is recognized based on the measurement of progress as the performance obligation is satisfied and consideration received that does not meet the requirements to satisfy the revenue recognition criteria is recorded as deferred revenue. Current deferred revenue consists of amounts that are expected to be recognized as revenue in the next 12 months. For further information see Note 8 — Collaboration and Licensing Agreements.

The Company recognizes upfront license payments as revenue upon delivery of the license only if the license is determined to be a separate unit of accounting from the other undelivered performance obligations. The undelivered performance obligations typically include manufacturing or development services or research and/or steering committee services. If the license is not considered as a distinct performance obligation, then the license and other undelivered performance obligations would be evaluated to determine if such should be accounted for as a single unit of accounting. If concluded to be a single performance obligation, the transaction price for the single performance obligation is recognized as revenue over the estimated period of when the performance obligation is satisfied.

Whenever the Company determines that an arrangement should be accounted for over time, the Company determines the period over which the performance obligations will be performed, and revenue will be recognized over the period the Company is expected to complete its performance obligations. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company is expected to complete its performance obligations under an arrangement.

The Company's collaboration agreements typically entitle the Company to additional payments upon the achievement of development, regulatory and sales milestones. If the achievement of a milestone is considered probable at the inception of the collaboration, the related milestone payment is included with other collaboration consideration, such as upfront fees and research funding, in the Company's revenue calculation. If these milestones are not considered probable at the inception of the collaboration, the milestones will typically be recognized in one of two ways depending on the timing of when the milestone is achieved. If the milestone is improbable at inception and subsequently deemed probable of achievement, such will be added to the transaction price, resulting in a cumulative adjustment to revenue. If the milestone is achieved after the performance period has completed and all performance obligations have been delivered, the Company will recognize the milestone payment as revenue in its entirety in the period the milestone was achieved.

The Company's collaborative agreements, for accounting purposes, represent contracts with customers and therefore are not subject to accounting literature on collaborative agreements. The Company grants licenses to its intellectual property, supplies raw materials or finished goods and provides research and development services, all of which are outputs of the Company's ongoing activities, in exchange for consideration. The Company does not develop assets jointly with collaboration partners, and does not share in significant risks of their development or commercialization activities. Accordingly, the Company concluded that its collaborative agreements must be accounted for pursuant to Topic 606, Revenue from Contracts with Customers.

For collaboration agreements that allow collaboration partners to select additional optioned products or services, the Company evaluates whether such options contain material rights (i.e., have exercise prices that are discounted compared to what the Company would charge for a similar product or service to a new collaboration partner). The exercise price of these options includes a combination of licensing fees, event-based milestone payments and royalties. When these amounts in aggregate are not offered at a discount that exceeds discounts available to other customers, the Company concludes the option does not contain a material right, and therefore is not included in the transaction price at contract inception. Rather, the Company evaluates grants of additional licensing rights upon option exercises to determine whether such should be accounted for as separate contracts. The Company concluded there is no material right in these options.

The Company follows detailed accounting guidance in measuring revenue and certain judgments affect the application of its revenue policy. For example, in connection with its existing collaboration agreements, the Company has recorded on its consolidated balance sheets short-term and long-term deferred revenue based on its best estimate of when such revenue will be recognized. Short-term deferred revenue consists of amounts that are expected to be recognized as revenue in the next 12 months. Amounts that the Company expects will not be recognized within the next 12 months are classified as long-term deferred revenue. However, this estimate is based on the Company's current project development plan and, if the development plan should change in the future, the Company may recognize a different amount of deferred revenue over the next 12-month period.

The activity related to deferred revenue and the related revenue recognized for collaborations and services is as follows (in thousands):

	December 31,	
	2019	2018
Deferred revenue:		
Beginning balance	$ 47,565	$ 750
Upfront and milestone payments	25,000	55,000
Pass through payments	6,016	2,398
Revenue — collaborations and services	(37,734)	(10,583)
Ending balance	$ 40,847	$ 47,565

Milestone Payments — At the inception of each arrangement that includes development milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the customer, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as, or when, the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company will re-evaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration, other revenue, and earnings in the period of adjustment.

Cost of Goods Sold — Cost of goods sold includes material, labor costs and manufacturing overhead. Cost of goods sold also includes a significant component of current period manufacturing costs in excess of costs capitalized into inventory (excess capacity costs). These costs, in addition to the impact of the annual revaluation of inventory to standard costs and write-offs of inventory are recorded as expenses in the period in which they are incurred, rather than as a portion of inventory costs. All insulin inventory on hand and the full purchase commitment contract to purchase future insulin was written off as of the end of 2015. Therefore, cost of goods sold excludes the cost of insulin purchased under our Insulin Supply Agreement, except for the contract amendment fees of approximately $2.8 million and $2.0 million for the years ended December 31, 2019 and 2018, respectively (see Note 13 – Commitments and Contingencies).

Cash and Cash Equivalents and Restricted Cash – 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, 2019 and 2018, cash equivalents were comprised of money market accounts with maturities less than 90 days from the date of purchase.

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 12 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 12 months of the reporting date are presented as restricted cash in long term assets.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported on the consolidated balance sheets that sum to amounts reported on the consolidated statement of cash flows (in thousands):

	December 31,	
	2019	2018
Cash and cash equivalents	$ 29,906	$ 71,157
Restricted cash	316	527
Total cash, cash equivalents, and restricted cash	$ 30,222	$ 71,684

Short-term Investments — The Company's short-term investments consist of U.S. Treasury securities stated at amortized cost which the Company intends to hold until maturity. Those with maturities less than 12 months are included in short-term investments and any investments with maturities in excess of twelve months are included in long-term investments in our consolidated balance sheets. The Company did not record any material gains or losses on these securities during the years ended December 31, 2019 and 2018.

Concentration of Credit Risk — Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents and short-term investments. Cash and cash equivalents are held in high credit quality institutions. Cash equivalents consist of interest-bearing money market accounts and U.S. Treasury securities, which are regularly monitored by management. Short-term investments consist of U.S. Treasury securities with a maximum maturity of twelve months.

Accounts Receivable and Allowance for Doubtful Accounts — Accounts receivable are recorded at the invoiced amount and are not interest bearing. Accounts receivable are presented net of an allowance for doubtful accounts if there are 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. Accounts receivable are also presented net of an allowance for product returns and trade discounts and allowances because the Company's customers have the right of setoff for these amounts against the related accounts receivable.

Accounts receivable, net consists of the following (in thousands):

	December 31,	
	2019	2018
Accounts Receivable, gross	$ 6,925	$ 5,198
Wholesaler distribution fees and prompt pay discounts	(1,767)	(868)
Reserve for returns	(1,645)	(313)
Accounts receivable, net	$ 3,513	$ 4,017

As of December 31, 2019 and December 31, 2018, the allowance for doubtful accounts was de minimis. As of December 31, 2019 and December 31, 2018, the Company had three wholesale distributors representing approximately 96% and 89% of sales, respectively.

Pre-Launch Inventory — An improvement to the manufacturing process for the Company's primary excipient FDKP was demonstrated to be viable and management expects to realize an economic benefit in the future as a result of such process improvement. Accordingly, the Company is required to assess whether to capitalize inventory costs related to such excipient prior to regulatory approval of the new supplier and the improved manufacturing process. In doing so, management must consider a number of factors in order to determine the amount of inventory to be capitalized, including the historical experience of achieving regulatory approvals for the Company's manufacturing process, feedback from regulatory agencies on the changes being effected and the amount of inventory that is likely to be used in commercial production. The shelf life of the excipient will be determined as part of the regulatory approval process; in the interim, the Company must assess the available stability data to determine whether there is likely to be adequate shelf life to support anticipated future sales occurring beyond the expected approval date of the new raw material. If management is aware of any specific material risks or contingencies other than the normal regulatory review and approval process, or if the criteria for capitalizing inventory produced prior to regulatory approval are otherwise not met, the Company would not capitalize such inventory costs, choosing instead to recognize such costs as a research and development expense in the period incurred.

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 incurred 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 analyzes its inventory levels to identify inventory that may expire or has a cost basis in excess of its estimated realizable value. The Company performs an assessment of projected sales and evaluates the lower of cost or net realizable value and the potential excess inventory on hand at the end of each reporting period.

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 zero asset impairments for the years ended December 31, 2019 and 2018 (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. The liability balance of the recognized loss on insulin purchase commitments as of December 31, 2019 and 2018 was $92.0 million and $98.3 million, respectively.

Milestone Rights Liability — On July 1, 2013, in conjunction with the execution of the Facility Agreement, the Company 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, of which $70.0 million remain payable as of December 31, 2019, upon the occurrence of specified strategic and sales milestones, including the achievement of specified net sales figures. The Company analyzed the Milestone Rights and determined that the Milestone 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 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, 2019 and 2018, the remaining liability balance was $7.3 million and $8.9 million, respectively.

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.

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. 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.

Clinical Trial Expenses — Clinical trial expenses, which are primarily 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.

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 Adopted Accounting Standards — Leases —The Company adopted Accounting Standards Codification ("ASC") Topic 842 – Leases ("ASC 842") on January 1, 2019. Under ASC 842, the Company is required to recognize the assets and liabilities that arise from most operating leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements.

Upon adoption of ASC 842, the Company recognized a lease liability to make lease payments and a right-of-use-asset representing its right to use the underlying asset for the applicable lease term using the optional transition method. In doing so, the Company elected the package of three practical expedients permitted under the transition guidance within the new standard, which among other things, allowed the Company to carry forward the historical lease classification. The Company also elected the practical expedient that permits not separating lease and non-lease components for all classes of underlying assets. For short-term leases, the Company has elected not to apply the recognition requirements of this guidance. The Company did not elect to use the hindsight practical expedient.

Upon the adoption as of January 1, 2019, the impact on total assets and total liabilities was an increase of $5.2 million. The standard did not materially impact net earnings and had no impact on cash flow. See Note 13 — Commitments and Contingencies for further information related to leases.

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 January 1, 2019, including interim periods within those periods. The adoption of this standard did not materially impact the Company's consolidated financial statements.

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 December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740)* to simplify and reduce the cost of accounting for income taxes. The pronouncement calls for removing exceptions to the incremental approach for intraperiod tax allocations, exceptions to the requirement to recognize a deferred tax liability for equity method investment when a foreign subsidiary becomes an equity method investment, exception to the ability to not recognize a deferred tax liability for a foreign subsidiary when a foreign equity method investment becomes a subsidiary and exception to the general methodology for calculating income taxes in an interim period when a year-to-date loss exceeds the anticipated loss for the year. ASU 2019-12 is effective for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. Early adoption is permitted. We are currently assessing the effect the adoption of this standard will have on the Company's consolidated financial statements.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808)* to clarify when transactions between participants in a collaborative arrangement under ASC 808 are within the scope of the new revenue guidance when the collaborative arrangement participant is a customer. ASU 2018-18 is effective for fiscal years beginning after December 15, 2020, and interim periods within fiscal years beginning after December 15, 2021. Early adoption is permitted. The Company does not expect the adoption of this standard to have a materially impact on the Company's consolidated financial statements.

3. Inventories

Inventories consist of the following (in thousands):

	December 31,	
	2019	2018
Raw materials	$ 1,751	$ 1,337
Work-in-process	1,432	1,605
Finished goods	972	655
Total inventory	$ 4,155	$ 3,597

Work-in-process and finished goods as of December 31, 2019 and 2018 include conversion costs and exclude the cost of insulin. All insulin inventory on hand was written off and the projected loss on the purchase commitment contract to purchase future insulin was accrued as of the end of 2015. Raw materials inventory included $0.8 million of pre-launch inventory as of December 31, 2019, which consisted of FDKP received in November 2019 that will be used to manufacture Afrezza under an enhanced manufacturing process for FDKP. Approximately 2% of the material received in November 2019 was recognized as a research and development expense and will be used by the Company for stability studies and other tests. The Company expects to receive FDA approval of the new source of FDKP in mid-2021, after which the pre-launch raw materials inventory will be reclassified as raw materials inventory for use in the manufacturing of Afrezza. The Company did not have any pre-launch raw materials inventory as of December 31, 2018.

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 also 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, 2019 and 2018. Inventory that was forecasted to become obsolete due to expiration is recorded in costs of goods sold in the accompanying consolidated statements of operations. During the year ended December 31, 2018, the Company recorded a write-down of inventory of approximately $2.2 million. There were no inventory write-offs for the year ended December 31, 2019.

4. Property and Equipment

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

	Estimated Useful Life (Years)	December 31,	
		2019	2018
Land	—	$ 875	$ 875
Buildings	39-40	17,389	17,389
Building improvements	5-40	37,543	34,967
Machinery and equipment	3-15	54,982	61,217
Furniture, fixtures and office equipment	5-10	3,005	2,954
Computer equipment and software	3	8,234	8,355
Construction in progress	—	114	342
		122,142	126,099
Less accumulated depreciation		(95,364)	(100,497)
Total property and equipment, net		$ 26,778	$ 25,602

Depreciation expense related to property and equipment for the years ended December 31, 2019 and 2018 was $1.6 million and $1.7 million, respectively. During the year ended December 31, 2019, the Company retired $6.7 million of manufacturing equipment and computer hardware as it was no longer in service. During the year ended December 31, 2018, the Company disposed of $2.1 million of furniture and fixtures, manufacturing equipment and laboratory equipment as it was no longer in service. The net book value for the disposed assets was *de minimis*.

5. Accrued Expenses and Other Current Liabilities

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

	December 31,	
	2019	2018
Salary and related expenses	$ 8,835	$ 8,110
Discounts and allowances for commercial product sales	3,162	2,656
Deferred lease liability	1,433	257
Professional fees	620	457
Accrued interest	409	492
Sales and marketing services	147	88
Other	1,298	1,319
Current portion of milestone rights liability	—	1,643
Accrued expenses and other current liabilities	$ 15,904	$ 15,022

6. Loan Arrangement with Former Related Party

In October 2007, the Company entered into a loan agreement with The Mann Group LLC (“The Mann Group”), which has been amended from time to time (including in August 2019 – see Note 7 – Borrowings). During his lifetime, Alfred Mann controlled The Mann Group, and also served as the Company’s chief executive officer until January 2015 and chairman until February 2016. Following Mr. Mann’s death in February 2016, control of The Mann Group was assumed by the trustees of the Alfred E. Mann Living Trust (the sole member and managing director of The Mann Group). None of the trustees is a member of the Company’s management or has the ability to influence the Company.

At the time of Mr. Mann’s death, he beneficially owned approximately 36% of the outstanding shares of the Company’s common stock, including those held by The Mann Group. Over the three years following Mr. Mann’s death, the trustees of The Mann Group disposed of a substantial portion of these holdings. The Company has been informed that The Mann Group currently holds approximately 9.3 million shares as of December 31, 2019, which represents less than 5% of the Company’s outstanding common stock. The Company reserved an additional 14,000,000 shares for issuance to The Mann Group upon the conversion of outstanding amounts under the Mann Group convertible note. The Mann Group convertible note contains a provision that limits conversion to the extent that doing so would result in The Mann Group beneficially owning in excess of 9.99% (19.99% upon 65 days’ written notice from The Mann Group) of the outstanding shares of the Company’s common stock.

Given that the trustees of the Alfred Mann Living Trust have no influence over, or involvement in the operations of, the Company, the Company has ceased to identify The Mann Group as a related party in its consolidated financial statements. Specifically, the consolidated balance sheet reflects $70.0 million in carrying amount in respect of the Mann Group promissory notes whereas the Company’s Form 10-K filed on February 26, 2019 reflected $72.1 million as related party notes and $6.8 million as accrued interest due to related party in the corresponding consolidated balance sheet as of December 31, 2018.

7. Borrowings

Carrying amount of borrowings consist of the following (in thousands):

	December 31,	
	2019	2018
Mann Group promissory notes	$ 70,020	$ 72,089
MidCap Credit Facility	38,851	—
Senior notes	10,028	19,099
Deerfield Credit Facility	—	11,298
Total debt — net carrying amount	$ 118,899	$ 102,486

During the year ended December 31, 2019, the Company discharged its obligations under the Deerfield Credit Facility, entered into the MidCap Credit Facility and restructured the obligations owed to its other lenders. The following table provides a summary of the Company's debt and key terms:

	December 31,							
	2019				2018			
	Amount Due	Annual interest rate	Maturity date	Conversion price	Amount Due	Annual interest rate	Maturity date	Conversion price
Mann Group convertible note	$35.0 million (plus $1.0 million accrued interest paid-in-kind)	7.00%	November 2024	$2.50 per share	$71.5 million (plus $6.8 million accrued interest paid-in-kind)	5.84%	July 2021	$4.00 per share
Mann Group non-convertible note	$35.1 million (plus $1.0 million accrued interest paid-in-kind)	7.00%	November 2024	N/A	—	—	—	—
MidCap Credit Facility	$40.0 million	one-month LIBOR (2% floor) plus 6.75%	August 2024	N/A	—	—	—	—
2024 convertible notes	$5.0 million	5.75%	November 2024	$3.00 per share	$18.7 million	5.75%	October 2021	$5.15 per share
June 2020 note	$2.6 million	—	June 2020	N/A	—	—	—	—
December 2020 note	$2.6 million	—	December 2020	N/A	—	—	—	—
Deerfield Credit Facility	—	—	—	—	$4.0 million	9.75%	July 2019	N/A
	—	—	—	—	$5.0 million	9.75%	August 2019	N/A
	—	—	—	—	$2.5 million	8.75%	May 2019	N/A

The maturities of our borrowings as of December 31, 2019 are as follows (in thousands):

	Amounts
2020	$ 5,262
2021	4,444
2022	13,333
2023	13,333
2024	83,940
Thereafter	—
Total principal payments	120,312
Unamortized discount	(539)
Debt issuance costs	(874)
Total debt	$ 118,899

Deerfield Facility Financing Obligation – On July 1, 2013, the Company entered into a facility agreement (the "Deerfield Credit Facility") with Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (collectively, "Deerfield"), which permitted it to borrow $160.0 million through the issuance of 9.75% notes due 2019 ("2019 notes"), $100.0 million of which were converted into shares of the Company's common stock during 2013 and 2014. The Company and Deerfield amended the Deerfield Credit Facility in 2014 to permit the Company to borrow an additional $20.0 million through the issuance of 8.75% notes ("Tranche B notes"). The remaining $80.0 million in principal amount that was not converted during 2013 and 2014 ($60.0 million in 2019 notes and $20.0 million in Tranche B notes) was subject to a repayment schedule that began in July 2016 and ended in August 2019. By June 30, 2019, the Company had repaid all amounts owed under the Tranche B notes and owed approximately $9.0 million in respect of outstanding 2019 notes. On July 18, 2019, the Company entered into an exchange agreement with Deerfield pursuant to which, among other things, the Company (i) repaid approximately $2.4 million in aggregate principal amount of 2019 notes plus all accrued and unpaid interest, and (ii) issued an aggregate of 1,514,423 shares of the Company's common stock to Deerfield in exchange for approximately $1.6 million in aggregate principal amount of 2019 notes.

On August 6, 2019, the Company entered into an exchange agreement with Deerfield pursuant to which, among other things, the Company (i) repaid $2.0 million of the aggregate principal amount of 2019 notes plus accrued and unpaid interest, (ii) issued an aggregate of 2,678,571 shares of the Company's common stock to Deerfield in exchange for $3.0 million in aggregate principal amount of 2019 notes and (iii) canceled the 2019 notes.

As of December 31, 2019, the Deerfield Credit Facility was paid in full. The unamortized debt issuance costs and debt discount were zero and $0.2 million as of December 31, 2019 and 2018, respectively.

Milestone Rights — As of December 31, 2019 and 2018, the remaining Milestone Rights liability balance was $7.3 million and $8.9 million, respectively, which was based on initial fair value estimates calculated using the income approach and reduced by milestone achievement payments made. During the third quarter of 2019, the Company achieved the first Afrezza net sales milestone specified in the Milestone Agreement. As a result, the Company delivered a milestone event notice to the Milestone Purchasers and made a payment of $5.0 million in the fourth quarter of 2019. The carrying value of this Milestone Rights liability was $1.6 million, which represented the fair value related to this payment, determined in 2013 (the most recent measurement date). Accordingly, $1.6 million was recorded as a reduction to the current Milestone Rights liability and $3.4 million was recognized as interest expense. The remaining Milestone Right liability of $7.3 million remains non-current as of December 31, 2019.

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.

MidCap Credit Facility — In August 2019, the Company closed the MidCap Credit Facility, which provides a secured term loan facility in an aggregate principal amount of up to $75.0 million. The Company borrowed the first advance of $40.0 million ("Tranche 1") on August 6, 2019. Under the terms of the MidCap Credit Facility, the second advance of $10.0 million ("Tranche 2") will be available to the Company until April 15, 2020, subject to the satisfaction of certain conditions, including achieving Afrezza net revenue of at least $30.0 million on a trailing twelve month basis. Under the terms of the MidCap Credit Facility, the third advance of $25.0 million ("Tranche 3") will be available to the Company until June 30, 2021, subject to the satisfaction of certain milestone conditions associated with Afrezza net revenue and certain milestone conditions related to the Company's collaboration with United Therapeutics (see Note 8 – Collaborations and Licensing Arrangements). In addition, unamortized debt issuance costs were $0.8 million and unamortized debt discount was $0.3 million as of December 31, 2019.

In December 2019, the Company entered into an Amendment No. 1 to the MidCap Credit Facility, pursuant to which the parties agreed to (i) amend the financial covenant relating to trailing twelve month minimum Afrezza Net Revenue (as defined in the MidCap Credit Facility) requirements, (ii) add a condition to the third advance of $25.0 million that requires the Company achieve certain amounts of Afrezza Net Revenue, and (iii) increase the exit fee from 6.00% to 7.00% of the principal amount of all term loans advanced to the Company under the MidCap Credit Facility.

Tranche 1 and, if borrowed, Tranche 2 and Tranche 3, each accrue interest at an annual rate equal to one-month LIBOR plus 6.75%, subject to a one-month LIBOR floor of 2.00%. Interest on each term loan advance is due and payable monthly in arrears. Principal on each term loan advance under Tranche 1 and Tranche 2 is payable in 36 equal monthly installments beginning September 1, 2021, until paid in full on August 1, 2024, and principal on each term loan advance under Tranche 3 is payable beginning on the later of (i) September 1, 2021, and (ii) the first day of the first full calendar month immediately following such term loan advance, in an amount equal to the outstanding term loan advance in respect of Tranche 3 divided by the number of full calendar months remaining before August 1, 2024. The Company has the option to prepay the term loans, in whole or in part, subject to early termination fees in an amount equal to 3.00% of principal prepaid if prepayment occurs on or prior to the first anniversary of the closing date, 2.00% of principal prepaid if prepayment occurs after the first anniversary of the closing date but on or prior to the second anniversary of the closing date, and 1.00% of principal prepaid if prepayment occurs after the second anniversary of the closing date and prior to or on the third anniversary of the closing date. In connection with execution of the MidCap Credit Facility, the Company paid MidCap a $0.4 million origination fee.

The Company's obligations under the MidCap Credit Facility are secured by a security interest on substantially all of its assets, including intellectual property.

The MidCap Credit Facility contains customary affirmative covenants and customary negative covenants limiting the Company's ability and the ability of the Company's subsidiaries to, among other things, dispose of assets, undergo a change in control, merge or consolidate, make acquisitions, incur debt, incur liens, pay dividends, repurchase stock and make investments, in each case subject to certain exceptions. The Company must also comply with a financial covenant relating to trailing twelve month minimum Afrezza net revenue, tested on a monthly basis, and a minimum cash covenant of $15.0 million at all times prior to the funding of Tranche 2, and $20.0 million at all times following the funding of Tranche 2 and Tranche 3. As of December 31, 2019, the Company was in compliance with the financial and minimum cash covenants.

The MidCap Credit Facility also contains customary events of default relating to, among other things, payment defaults, breaches of covenants, a material adverse change, listing of the Company's common stock, bankruptcy and insolvency, cross defaults with certain material indebtedness and certain material contracts, judgments, and inaccuracies of representations and warranties. Upon an event of default, the agent and the lenders may declare all or a portion of the Company's outstanding obligations to be immediately due and payable and exercise other rights and remedies provided for under the MidCap Credit Facility. During the existence of an event of default, interest on the term loans could be increased by 2.00%.

The Company also agreed to issue warrants to purchase shares of the Company's common stock (the "MidCap warrants") upon the drawdown of each term loan advance under the MidCap Credit Facility in an aggregate amount equal to 3.25% of the amount drawn, divided by the exercise price per share for that tranche. The exercise price per share is equal to the volume-weighted average closing price of the Company's common stock for the ten business days immediately preceding the second business day before the issue date. As a result of Tranche 1, the Company issued warrants to purchase an aggregate of 1,171,614 shares of the Company's common stock, at an exercise price equal to $1.11 per share. The MidCap warrants are immediately exercisable and expire on the earlier to occur of the seventh anniversary of the respective issue date or, in certain circumstances, the closing of a merger, sale or other consolidation transactions in which the consideration is cash, stock of a publicly traded acquirer, or a combination thereof. The Company determined that these warrants met the criteria for equity classification and accounted for such warrants in additional paid-in capital.

Senior Notes — As of December 31, 2019 and 2018, there was $10.2 million and $18.7 million, respectively, of principal amount of senior notes outstanding.

In August 2019, the Company entered into a privately-negotiated exchange agreement with the 2021 notes, pursuant to which, among other things, the Company (i) repaid $1.5 million in cash to such holder, (ii) issued 4,017,857 shares of the Company's common stock to such holder (at a conversion price of $1.12 per share), (iii) issued the 2024 convertible notes to such holder in the principal amount of $5.0 million and (iv) issued the 2020 notes in the aggregate principal amount of $5.2 million, all in exchange for the cancellation of the $18.7 million in principal amount of the 2021 notes. The 2020 notes may be prepaid at any time on or prior to their respective maturity dates of June 30, 2020 and December 31, 2020 at the option of the Company. In addition, the Company may elect to pay the 2020 notes at any time on or prior to their respective maturity dates, if certain conditions are met, in shares of the Company's common stock at a price per share equal to the last reported sale price on the trading day immediately prior to the payment date.

The 2024 convertible notes were issued pursuant to an indenture, dated as of August 6, 2019, between the Company and U.S. Bank National Association, as trustee (the "Indenture"). The 2024 convertible notes are the Company's general, unsecured obligations, and are subordinated in right of payment to the indebtedness incurred pursuant to the MidCap Credit Facility. The 2024 convertible notes rank equally in right of payment with the Company's other unsecured senior debt. The 2024 convertible Notes accrue interest at the rate of 5.75% per year on the principal amount, payable semiannually in arrears on February 15 and August 15 of each year, beginning February 15, 2020, with interest accruing from August 6, 2019. Interest on the 2024 convertible notes will be payable in cash or, at the option of the Company if certain conditions are met, in shares of the Company's common stock at a price per share equal to the last reported sale price on the trading day immediately prior to the interest payment date. The 2024 convertible notes will mature on the earlier of (i) November 4, 2024 or (ii) the 91st day after the payment in full of, and termination and discharge of all obligations (other than contingent indemnity obligations) under the MidCap Credit Facility.

The 2024 convertible notes will be 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 a conversion rate of 333.3333 shares per $1,000 principal amount of 2024 convertible notes, which is equal to a conversion price of approximately $3.00 per share.

If certain bankruptcy and insolvency-related events of default occur, the principal of, and accrued and unpaid interest on, all of the then outstanding 2024 convertible notes shall automatically become due and payable. If an event of default other than certain bankruptcy and insolvency-related events of defaults occurs and is continuing, the Trustee or the holders of at least 25% in aggregate principal amount of the then-outstanding 2024 convertible notes, by written notice to the Trustee, may declare the 2024 convertible notes due and payable at their principal amount plus any accrued and unpaid interest, and thereupon the Trustee may, at its discretion, proceed to protect and enforce the rights of the holders by the appropriate judicial proceedings. Notwithstanding the foregoing, the Indenture provides that, to the extent the Company elects, the sole remedy for an event of default relating to certain failures by the Company to comply with certain reporting covenants in the Indenture will, for the first 180 days after such event of default, consist exclusively of the right to receive additional interest on the 2024 convertible notes.

If the Company undergoes certain fundamental changes, except in certain circumstances, each holder of 2024 convertible notes will have the option to require the Company to repurchase all or any portion of that holder's 2024 convertible notes. The fundamental change repurchase price will be 100% of the principal amount of the 2024 convertible 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 2024 convertible 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 equals or exceeds 120% of the conversion price then in effect for at least 10 trading days in any 20 trading day period, ending within five business days prior to the date of the mandatory conversion notice.

As a result of the exchange of the senior convertible notes, the Company recorded $3.1 million as an extinguishment gain. The unamortized premium was zero and $0.4 million as of December 31, 2019 and 2018, respectively.

Mann Group promissory notes — In August 2019, the Company entered into a privately-negotiated exchange agreement with The Mann Group, pursuant to which, among other things, the Company (i) repaid $3.0 million in cash to The Mann Group, (ii) issued 7,142,857 shares of the Company's common stock to The Mann Group (at a conversion price of $1.12 per share), (iii) issued the Mann Group convertible note to the Mann Group in an aggregate principal amount of $35.0 million and (iv) issued a new non-convertible promissory note the Mann Group non-convertible note to the Mann Group in an aggregate principal amount of $35.1 million, all in exchange for the cancellation of the $71.5 million in principal and approximately $9.5 million in accrued interest paid-in-kind under the Mann Group loan arrangement.

The Mann Group convertible note and Mann Group non-convertible note each accrue interest at the rate of 7.00% per year on the principal amount, payable quarterly in arrears on the first day of each calendar quarter beginning October 1, 2019.

The Mann Group convertible note will mature on November 3, 2024. The principal and any accrued and unpaid interest under the Mann Group convertible note may be converted, at the option of the Mann Group, 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 a conversion rate of 400 shares per $1,000 of principal and/or accrued and unpaid interest, which is equal to a conversion price of $2.50 per share. The conversion rate will be subject to adjustment under certain circumstances described in the Mann Group convertible note. Interest on the Mann Group convertible note will be payable in kind by adding the amount thereof to the principal amount; provided that with respect to interest accruing from and after January 1, 2021, the Company may, at its option, elect to pay any such interest on any interest payment date, if certain conditions are met, in shares of the Company's common stock at a price per shall equal to the last reported sale price on the trading day immediately prior to the payment date.

The Mann Group non-convertible note will mature on the earlier of (i) November 3, 2024 or (ii) the 90th day after the repayment in full, and termination and discharge of all obligations (other than contingent indemnity obligations) under the MidCap Credit Facility. Interest on the Mann Group non-convertible note will be payable in kind by adding the amount thereof to the principal amount; provided that the Company may, at its option, elect to pay any such interest on any interest payment date, if certain conditions are met, in shares of the Company's common stock at a price per shall equal to the last reported sale price on the trading day immediately prior to the interest payment date.

The Company recorded $0.4 million as an extinguishment gain. The unamortized premium and unaccreted debt issuance costs was zero and $0.6 million as of December 31, 2019 and 2018, respectively.

Amortization of the premium and accretion of debt issuance costs related to all borrowings for the years ended December 31, 2019 and 2018 are as follows (in thousands):

	Year Ended December 31,	
	2019	2018
Amortization of debt premium	$ (1,049)	$ (339)
Amortization of debt discount	295	1,155
Accretion expense — debt issuance cost	(111)	(69)

See Note 6 — Loan Arrangement with Former Related Party for additional information on the Company's loan arrangements with the Mann Group.

8. Collaboration and Licensing Arrangements

Revenue from collaborations and services for the years ended December 31, 2019 and 2018 are as follows (in thousands):

	Year Ended December 31,	
	2019	2018
UT License Agreement	$ 31,229	$ 6,386
UT Research Agreement	6,032	3,758
Receptor CLA	250	341
Cipla distribution agreement	148	98
Biomm distribution agreement	75	—
Total revenue from collaborations and services	$ 37,734	$ 10,583

United Therapeutics License Agreement – In September 2018, the Company and United Therapeutics Corporation ("United Therapeutics" or "UT") entered into an exclusive global license and collaboration agreement (the "UT License Agreement") for the rights to the Company's dry powder formulation of treprostinil ("TreT") and associated inhalation delivery devices. Under the UT License Agreement, UT is responsible for global development, regulatory and commercial activities with respect to TreT. The Company is responsible for manufacturing clinical supplies and commercial supplies of TreT.

Under the terms of the UT License Agreement, the Company received an upfront payment of $45.0 million in October 2018 and two $12.5 million milestone payments in 2019. The Company may receive additional milestone payments of up to $25.0 million upon the achievement of specified development targets. The Company will also be entitled to receive low double-digit royalties on net sales of TreT. UT, at its option, may expand the scope of the products covered by the UT License Agreement to include products with certain other active ingredients for the treatment of pulmonary arterial hypertension. Each such optioned product would be subject to UT's payment to the Company of up to $40.0 million in additional option exercise and development milestone payments, as well as a low double-digit royalty on net sales of any such product. The Company recognizes revenue on a ratable basis from October 2018 through December 2021 — the estimated date when its performance obligations for development activities under the UT License Agreement will be substantially completed.

At the inception of the agreement, the Company identified one distinct performance obligation. The Company determined that the key deliverables include the license, supply of product to be used in clinical development, and certain research services upon achievement of specified development targets. Due to the specialized and unique nature of these services and their direct relationship with the license, the Company has determined that these deliverables represent one distinct bundle and thus, one performance obligation. The Company also determined that UT's option to expand the scope of the products to include products with other active ingredients is not a material right, and thus, not a performance obligation at the onset of the agreement. The consideration for the option will be accounted for upon exercise of the option.

The Company expects to complete the activities specified in the development plan and to achieve the remaining milestone events for total consideration of approximately $101.4 million, which includes an upfront payment, four milestone payments and various pass-through costs. Future commercial supply remains at UT's option and is valued at a stand-alone selling price and, therefore, is not accounted for under the current arrangement. The Company believes that this method best reflects the measure of progress toward complete satisfaction of the performance obligation.

Deferred revenue related to the UT License Agreement is being recognized in net revenue – collaborations over a 13-quarter period ending December 31, 2021, which represents the estimated period to satisfy the performance obligation. As of December 31, 2019, the total deferred revenue for the UT License Agreement consisted of $38.4 million, of which $31.9 million is current and $6.5 million is long term. Deferred revenue is classified as part of current or long-term liability in the accompanying consolidated balance sheets based on the Company's estimate of the portion of the performance obligation that will be completed within the next 12 months, and includes payments received as well as payments receivable.

United Therapeutics Research Agreement – In September 2018, the Company and UT also entered into a research agreement ("UT Research Agreement") for the conduct of research and consulting services in connection with multiple potential products, including evaluating the feasibility of preparing a dry powder formulation of a compound for the treatment of pulmonary hypertension outside the scope of the UT License Agreement. In addition, UT, at its option, may obtain a license to develop, manufacture and commercialize products based on specified compounds within the drug classes covered by the UT Research Agreement. Each specified compound advanced into development and commercialization under such a license would be subject to the payment to the Company of additional milestone payments of up to $30.0 million and a low double-digit royalty on net sales of such products. The Company received an upfront payment of $10.0 million in September 2018.

At the inception of the UT Research Agreement, the Company identified two distinct performance obligations. The Company determined that the key deliverables of each performance obligation include (i) the development of a product prototype (including a technical feasibility report) and (ii) engineering consulting services. Due to the separately identifiable nature of these obligations, the Company has determined that these deliverables represent two distinct performance obligations. The Company also determined that UT's option to expand the scope to include specific drug classes covered by the agreement is not a material right, and thus, not a performance obligation at the onset of the agreement. The consideration for the option will be accounted for upon exercise of the option.

The Company allocated the total $10.0 million transaction price to its two distinct performance obligations based on available observable market inputs. A transaction price of $9.0 million was allocated to the product prototype and a transaction price of $1.0 million was allocated to engineering consulting services. The revenue for the product prototype is recognized using an output method (based on project milestones achieved and surveys of performance completed to date). The Company believes that this method best reflects the measure of progress toward complete satisfaction of the performance obligation. The revenue for the engineering consulting services was recognized using a ratable method until the obligation was satisfied. The Company believes that this method best reflects the measure of progress toward complete satisfaction of the performance obligation.

As of December 31, 2019, the deferred revenue balance was $0.2 million, which was classified as a current liability in the accompanying consolidated balance sheets.

Receptor Collaboration and License Agreement — In 2016, the Company entered into a collaboration and license agreement (the "CLA") with Receptor Life Sciences, Inc. ("Receptor") pursuant to which Receptor acquired an exclusive license to develop, manufacture and commercialize products that use the Company's technology to deliver certain compounds via oral inhalation in exchange for upfront license fees, milestone payments upon the completion of certain technology transfer activities and the achievement of specified sales targets as well as royalties upon Receptor's and its sublicensees' sale of products.

A $1.0 million license fee received in 2016 was recorded in deferred revenue from collaborations as of December 31, 2016 and is being recognized in net revenue — collaborations over four years, the estimated period over which the Company is required to satisfy the remaining performance obligations. The remaining performance obligations are to provide certain technology transfer activities. As of December 31, 2019, the deferred revenue balance was $0.3 million, which was classified as a current liability in the accompanying consolidated balance sheets.

The additional payments referred to above represent variable consideration for which the Company has not recognized any revenue because it is uncertain that Receptor will be able to successfully develop, manufacture or sell product related to this license. There was no change to the accounting for this contract as a result of the initial application of the new revenue guidance since (i) the receipt of such payments is highly susceptible to factors outside of the Company's influence, (ii) the uncertainty regarding the receipt of these payments is not expected to be resolved for years, and (iii) the Company has limited experience with similar contracts. See Note 1 – Description of Business and Note 2 –Summary of Significant Accounting Policies for additional information on the Company's revenue recognition accounting policy.

In 2017, the Company entered into a manufacturing and supply agreement with Receptor pursuant to which the Company agreed to provide certain raw materials and certain additional research and formulation consulting services to Receptor. For the years ended December 31, 2019 and 2018, the additional research and formulation services provided to Receptor were *de minimis*.

Biomm Supply and Distribution Agreement – In May 2017, the Company and Biomm entered into a supply and distribution agreement for the commercialization of Afrezza in Brazil. Under this agreement, Biomm was responsible for pursuing regulatory approvals of Afrezza in Brazil, including from the Agência Nacional de Vigilância Sanitária ("ANVISA") and, with respect to pricing matters, from the Camara de Regulação de Mercado de Medicamentos ("CMED"), both of which have now been received. In September 2019, the Company delivered its first shipment of Afrezza to Biomm and recognized $0.7 million as commercial product sales in advance of the launch of the product in Brazil. Biomm commenced product sales in January 2020.

Cipla License and Distribution Agreement — In May 2018, the Company and Cipla Ltd. ("Cipla") entered into an exclusive agreement for the marketing and distribution of Afrezza in India and the Company received a $2.2 million nonrefundable license fee. Under the terms of the agreement, Cipla will be responsible for obtaining regulatory approvals to distribute Afrezza in India and for all marketing and sales activities of Afrezza in India. The Company is responsible for supplying Afrezza to Cipla. The Company has the potential to receive certain additional regulatory milestone payments, minimum purchase commitment revenue and royalties on Afrezza sales in India once cumulative gross sales have reached a specified threshold.

The nonrefundable licensing fee was recorded in deferred revenue and is being recognized in net revenue – collaborations over 15 years, representing the estimated period to satisfy the performance obligation. The additional milestone payments represent variable consideration for which the Company has not recognized any revenue because of the uncertainty of obtaining marketing approval. The Company also recognized $0.2 million as income tax expense for a payment made to the India tax authority in 2018. As of December 31, 2019, the deferred revenue balance was $1.9 million, of which $0.1 million is classified as current and $1.8 million is classified as long term in the accompanying consolidated balance sheets.

AMSL Distribution Agreement – In May 2019, the Company entered into an exclusive marketing and distribution agreement with the AMSL Diabetes division of Australasian Medical & Scientific Ltd. ("AMSL Diabetes") for the commercialization of Afrezza in Australia. Under the terms of this agreement, AMSL Diabetes is responsible for obtaining regulatory and reimbursement approvals to distribute Afrezza in Australia. Upon regulatory approval, AMSL Diabetes will conduct sales, marketing, and customer support and distribution activities whereas the Company will be responsible for the supply and manufacturing of Afrezza.

9. 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 Company uses the exit price method for estimating the fair value of loans for disclosure purposes.

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, MidCap Credit Facility, Mann Group promissory notes, 2024 convertible notes, 2020 notes, and Milestone Rights liabilities are disclosed below.

Cash Equivalents and Restricted Cash — 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, 2019 and 2018, the Company held $29.9 million and $71.2 million, respectively, of cash and cash equivalents. The Company held $0.3 million and $0.5 million in restricted cash as of December 31, 2019 and 2018, respectively. Both are comprised of money market funds. Restricted cash is used to collateralize a letter of credit. 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).

Short-term investments— Short-term investments consist of highly liquid investments that are intended to facilitate liquidity and capital preservation. As of December 31, 2019, the Company held $20.0 million of short-term investments in U.S. Treasury bills or notes. The Company did not have short-term investments as of December 31, 2018. The fair value of short-term investments approximate their carrying value. The fair value measurement is based on a market approach using quoted market values (Level 1 in the fair value hierarchy).

The fair value measurement of debt instruments is based on a discounted cash flow model and is sensitive to the change in yield (Level 3 in the fair value hierarchy):

		Hypothetical Change in Yield			Hypothetical Change in Notes Payable		
	Yield	% Change	Hypothetical Yield	FV of Notes	FV	$ Change	% Change
					(in millions)		
Mann Group promissory notes:							
(with conversion feature)	29.0%	2%	31.0%	$ 46.2	$ 44.1	$ (2.1)	-4.5%
	29.0%	-2%	27.0%	$ 46.2	$ 48.5	$ 2.3	5.0%
	29.0%	4%	33.0%	$ 46.2	$ 42.2	$ (4.0)	-8.7%
	29.0%	-4%	25.0%	$ 46.2	$ 51.0	$ 4.8	10.4%
Senior notes:							
(with conversion feature)	29.0%	2%	31.0%	$ 8.0	$ 7.8	$ (0.2)	-2.5%
	29.0%	-2%	27.0%	$ 8.0	$ 8.2	$ 0.2	2.5%
	29.0%	4%	33.0%	$ 8.0	$ 7.6	$ (0.4)	-5.0%
	29.0%	-4%	25.0%	$ 8.0	$ 8.4	$ 0.4	5.0%
MidCap Credit Facility							
	11.5%	1%	12.5%	$ 40.0	$ 39.0	$ (1.0)	-2.5%
	11.5%	-1%	10.5%	$ 40.0	$ 41.0	$ 1.0	2.5%
	11.5%	2%	13.5%	$ 40.0	$ 38.1	$ (1.9)	-4.8%
	11.5%	-2%	9.5%	$ 40.0	$ 42.1	$ 2.1	5.3%

Financial Liabilities — The following tables set forth the fair value of the Company's financial instruments as of December 31, 2019 and 2018 (in millions):

	December 31, 2019		
		Fair Value	
	Carrying Amount	Significant Unobservable Inputs (Level 3)	Total Fair Value
Financial liabilities:			
MidCap Credit Facility	$ 38.9	$ 40.0	$ 40.0
2024 convertible notes	5.0	3.7	3.7
June 2020 note	2.5	2.3	2.3
December 2020 note	2.5	2.0	2.0
Mann Group promissory notes	70.0	46.2	46.2
Milestone Rights	7.3	16.4	16.4
Total financial liabilities	$ 126.2	$ 110.6	$ 110.6

	December 31, 2018		
		Fair Value	
	Carrying Value	Significant Unobservable Inputs (Level 3)	Total Fair Value
Financial liabilities:			
Deerfield Credit Facility	$ 11.3	$ 11.4	$ 11.4
Senior convertible notes	19.1	17.5	17.5
Mann Group promissory notes	72.1	55.0	55.0
Milestone Rights	8.9	18.1	18.1
Total financial liabilities	$ 111.4	$ 102.0	$ 102.0

Milestone Rights Liability — The fair value measurement of the Milestone Rights liability is sensitive to the discount rate and the timing of achievement of milestones. The Company utilized Monte-Carlo Simulation Method to simulate the Net Sales under a neutral framework to estimate the payment. The Company then discounted the future expected payments at cost of debt with a term equal to the simulated time to payout based on cumulative sales.

Embedded Derivatives — The Company identified and evaluated a number of embedded features in the notes issued under the Deerfield Credit Facility 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 at December 31, 2018 and no value as of December 31, 2019 due to the repayment of the Deerfield Credit Facility in August 2019.

10. Common and Preferred Stock

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, 2019 and 2018, 211,787,573 and 187,029,967 shares of common stock, respectively, were issued and outstanding and no shares of preferred stock were outstanding.

In February 2018, the Company entered into a controlled equity offering sales agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor Fitzgerald"), as sales agent, pursuant to which the Company may offer and sell, from time to time, through Cantor Fitzgerald, shares of the Company's 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. For the year ended December 31, 2019, the Company sold an aggregate of 2,584,964 shares of the Company's common stock at an average purchase price of $1.24 per share for an aggregate gross proceeds of approximately $3.2 million pursuant to the Sales Agreement. For the year ended December 31, 2018, the Company sold an aggregate of 1,028,432 shares of the Company's common stock at an average purchase price of $2.03 per share for an aggregate gross proceeds of approximately $2.1 million pursuant to the Sales Agreement.

In April 2018, the Company entered into securities purchase agreements with certain institutional investors. Pursuant to the terms of the purchase agreements, the Company sold to the purchasers in a registered offering an aggregate of 14,000,000 shares of the Company's common stock and warrants to purchase up to an aggregate of 14,000,000 shares of the Company's common stock at a combined purchase price of $2.00 per share and accompanying warrant. The shares of common stock and the warrants were immediately separable. The warrants became exercisable at a price of $2.38 per share beginning on October 9, 2018 and expired unexercised on April 9, 2019. The net proceeds to the Company from the offering were approximately $26.4 million. The offering closed on April 9, 2018.

In December 2018, the Company entered into an underwriting agreement with Leerink Partners LLC relating to the issuance and sale in a public offering of 26,666,667 shares of the Company's common stock and warrants to purchase up to an aggregate of 26,666,667 shares of the Company's common stock (the "December warrants") at a combined purchase price of $1.50 per share and accompanying warrant. The shares of common stock and the December warrants were immediately separable. The December warrants were immediately exercisable at issuance at a price of $1.60 per share and had an expiry date of December 26, 2019. The net proceeds to the Company from the offering were approximately $37.3 million. The Company determined that the December warrants met the criteria for equity classification and accounted for such warrants in additional paid-in capital. In July 2019, the Company repurchased 3,333,334 December warrants for consideration of approximately $0.4 million, for which $0.2 million was recognized as a reduction to additional paid-in capital on the consolidated balance sheet and $0.2 million was recognized as other expense on the consolidated statement of operations for cash paid in excess of fair value. On December 23, 2019, the Company and one holder of a December warrant to purchase 11,750,000 shares of the Company's common stock (the "Warrant Shares") agreed to amend their December warrant to provide that (i) the exercise price per share for 4,500,000 Warrant Shares would be equal to $1.311 but only with respect to a cash exercise of such December warrant on December 23, 2019 and (ii) if the holder purchased at least 4,500,000 Warrant Shares pursuant to a timely cash exercise of such December warrant, the termination date of such December warrant would be extended to June 26, 2020. The Company determined that the modified December warrants met the criteria for equity classification and the incremental fair value of approximately $0.7 million was recognized as additional paid-in capital. On December 23, 2019, 4,500,000 Warrant Shares were exercised by the holder at $1.311 per share for an aggregate exercise price of $5.9 million. On December 26, 2019, 11,583,333 December warrants expired unexercised. As of December 31, 2019, 7,250,000 Warrant Shares remained available for purchase by such holder until June 26, 2020 at a price of $1.60 per share.

For the year ended December 31, 2018, the Company received $0.4 million from the market price stock purchase plan for 230,445 shares. There were no market price stock purchase plan transactions for the year ended December 31, 2019.

11. Earnings per Common Share ("EPS")

Basic EPS 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 EPS 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 EPS as they would be antidilutive.

The following tables summarize the components of the basic and diluted EPS computations (in thousands, except per share amounts):

	Year Ended December 31,	
	2019	2018
EPS — basic and diluted:		
Net loss (numerator)	$ (51,903)	$ (86,975)
Weighted average common shares (denominator)	195,584	144,136
Net loss per share	$ (0.27)	$ (0.60)

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

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

	Year Ended December 31,	
	2019	2018
Exercise of common stock options	14,135,681	10,976,118
Conversion of convertible notes payable to former related party into common stock	14,000,000	21,909,541
Exercise of warrants associated with public offering	7,250,000	26,666,667
Exercise of warrants associated with Midcap Credit Facility	1,171,614	—
Conversion of convertible notes into common stock	1,666,667	3,629,627
Vesting of restricted stock units	1,057,047	691,266
Employee stock purchase plan	369,979	307,395
Exercise of common stock warrants	31,851	31,851
Exercise of warrants associated with direct placement	—	14,000,000
Total	39,682,839	78,212,465

12. Stock Award Plans

On May 16, 2018, the Company adopted the 2018 Equity Incentive Plan (the "2018 Plan") as the successor to and continuation of the 2013 Equity Incentive Plan (the "2013 Plan") and the 2004 Equity Incentive Plan (the "2004 Plan"). The 2018 Plan consists of 12.0 million additional shares and the number of unallocated shares remaining available for grant for new awards under the 2013 Plan and the 2004 Plan. The 2018 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 2013 Plan, the 2004 Plan or the 2004 Non-Employee Directors' Stock Option Plan (the "NED Plan") as all future awards will be made out of the 2018 Plan.

The Company's board of directors determines eligibility, vesting schedules and criteria, and exercise prices for stock awards granted under the 2018 Plan. Options and restricted stock unit awards under the 2018 Plan, the 2013 Plan and the 2004 Plan expire not more than ten years from the date of the grant and are exercisable upon vesting. Stock options that vest over time generally vest over four years. Current time-based vesting stock option grants vest and become exercisable at the rate of 25% after one year and ratably on a monthly basis over a period of 36 months thereafter. Restricted stock units with time-based vesting generally vest at a rate of 25% per year over four years with consideration satisfied by service to the Company. The Company also issues stock awards with performance conditions.

The following table summarizes information about the Company's stock-based award plans as of December 31, 2019:

	Outstanding Options	Outstanding Restricted Stock Units	Shares Available for Future Issuance
2004 Equity Incentive Plan	451,149	—	—
2013 Equity Incentive Plan	4,714,169	393,309	—
2018 Equity Incentive Plan	8,934,586	663,738	4,710,565
2004 Non-Employee Directors' Stock Option Plan	35,777	—	—
Total	14,135,681	1,057,047	4,710,565

Share-based payment transactions are recognized as compensation cost based on the fair value of the instrument on the date of grant. 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.

During the years ended December 31, 2019 and 2018, the Company recorded stock-based compensation expense of $6.2 million, $6.9 million, respectively.

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,	
	2019	2018
Cost of goods sold	$ 601	$ 379
Research and development	356	1,203
Selling, general and administrative	4,508	5,275
Cost of revenue — collaborations and services	738	—
Total	$ 6,203	$ 6,857

The expected volatility assumption used in the Company's Black-Sholes option valuation model is based on an assessment of the historical 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, 2019 and 2018 using the following assumptions:

	Year Ended December 31,	
	2019	2018
Risk-free interest rate	1.52% — 2.51%	2.63% — 3.11%
Expected lives	6.20 — 9.37 years	5.90 — 7.19 years
Volatility	93.05% — 94.25%	92.68% — 93.62%
Dividends	—	—

The following table summarizes information about stock options outstanding:

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value ($000)
Outstanding at January 1, 2019	10,976,118	$ 5.75	7.83	$ —
Granted	5,613,253	1.32		
Exercised	(67,461)	1.10		
Forfeited	(1,395,644)	2.25		
Expired	(990,585)	17.07		
Outstanding at December 31, 2019	14,135,681	$ 3.09	7.84	$ 182
Exercisable at December 31, 2019	4,554,661	$ 6.20	6.00	$ 86

The weighted average grant date fair value of the stock options granted during the years ended December 31, 2019 and 2018 was $1.32 and $1.51, respectively. The total intrinsic value of options exercised during the year ended December 31, 2019 and 2018 was *de minimis*. 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 year ended December 31, 2019 was approximately $0.1 million and for the year ended December 31, 2018 the cash received was *de minimis*.

As of December 31, 2019 and 2018, the Company recognized a *de minimis* amount and $1.9 million, respectively, of compensation costs related to the performance-based stock options. As of December 31, 2019, there was $1.1 million of unrecognized compensation costs related to performance-based stock options subject to performance conditions.

A summary of restricted stock unit activity for the year ended December 31, 2019 is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value per Share
Outstanding at January 1, 2019	691,266	$ 3.72
Granted	1,293,690	1.42
Vested	(804,105)	2.33
Forfeited	(123,804)	2.06
Outstanding at December 31, 2019	1,057,047	2.16

Total fair value of restricted stock units vested during the years ended December 31, 2019 and 2018 was $1.1 million and $1.4 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 outstanding as of December 31, 2019 and 2018 was $2.3 million and $2.4 million, respectively.

As of December 31, 2019, there was $9.9 million of unrecognized compensation expense related to options and performance-based options and $0.6 million of unrecognized compensation expense related to restricted stock units, which are expected to be recognized over the weighted average vesting period of 1.0 to 2.9 years. The Company evaluates stock awards with performance conditions as to the probability that the performance conditions will be met and uses that information to estimate the date at which those performance conditions will be met in order to properly recognize stock-based compensation expense over the requisite service period.

13. 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, 2019, 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 in January 2016 of the election by sanofi-aventis U.S. LLC ("Sanofi") to terminate a license and collaboration agreement (the "Sanofi License Agreement") between the Company and Sanofi 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 allege that the Company and certain of its officers and directors violated Israeli and U.S. securities laws by making materially false and misleading statements regarding the prospects for Afrezza, thereby artificially inflating the price of its common stock. The plaintiffs are seeking monetary 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 appealed this ruling, and following an oral hearing before the Supreme Court of Israel, decided to withdraw his appeal. Subsequently, in November 2018, the Company filed a motion to dismiss the certification motion. In September 2019, the plaintiff brought a motion to amend his claim, which the court denied in January 2020. The Company will continue to vigorously defend against the claims advanced.

Contingencies — In July 2013, the Company also entered into a Milestone Agreement with the Milestone Purchasers, pursuant to which the Company granted such Milestone Purchasers rights to receive payments up to $90.0 million upon the occurrence of specified strategic and sales milestones, $70.0 million of which remains payable upon achievement of such milestones (see Note 7 — Borrowings).

Commitments — In July 2014, the Company entered into the Insulin Supply Agreement with 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.

In August 2019, the Company and Amphastar amended the Insulin Supply Agreement to extend the term to 2026 and to restructure the annual purchase commitments. The annual purchase requirements under the amended contract are as follows:

	Minimum Commitment	
2020	€	6.6 million
2021	€	6.6 million
2022	€	8.5 million
2023	€	10.8 million
2024	€	14.6 million
2025	€	15.5 million
2026	€	19.4 million

During the year ended December 31, 2019 and 2018, the Company paid amendment fees of $2.8 million and $2.0 million, respectively, which were recognized as cost of goods sold.

Unless terminated earlier, the term of the Insulin Supply Agreement expires on December 31, 2026 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 a 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. In 2019, the Company entered into two 90-day foreign currency hedging transactions to mitigate its exposure to foreign currency exchange risks associated with then-existing insulin purchase commitments. The Company realized a *de minimis* currency loss for these transactions, which was recorded in other income and expense.

Warrants - In December 2018, the Company issued the December warrants to purchase up to an aggregate of 26,666,667 shares of the Company's common stock at an exercise price of $1.60 per share. During 2019, the Company repurchased 3,333,334 December warrants and modified 11,750,000 December warrants, of which 4,500,000 were subsequently exercised. In December 2019, 11,583,333 December warrants expired unexercised. As of December 31, 2019, 7,250,000 December warrants remain exercisable until June 26, 2020 at an exercise price of $1.60 per share.

On August 6, 2019, in connection with the MidCap Credit Facility, the Company issued warrants to purchase an aggregate of 1,171,614 shares of the Company's common stock, at an exercise price equal to $1.11 per share, to the lenders. Additional MidCap warrants will be issued if the Company accesses additional tranches under the MidCap Credit Facility (see Note 7 — Borrowings).

Vehicle Leases – During the second quarter of 2018, the Company entered into a lease agreement with Enterprise Fleet Management Inc. for the lease of 119 vehicles. The lease requires monthly payments of approximately $83,000 per month including the cost of maintaining the vehicles, taxes and insurance. The lease commenced when the Company took possession of the majority of the vehicles in the second quarter of 2018 and expires 48 months after the delivery date.

As of December 31, 2019, 29 vehicles were removed from the fleet, resulting in a fleet size of 90 vehicles; no gain or loss was recorded. The revised monthly payment inclusive of maintenance fees, insurance and taxes is $65,000 and the reduction of the right of use asset and lease obligation is approximately $0.4 million in our consolidated balance sheets. The lease expense is included in selling, general and administrative expenses in the accompanying consolidated statement of operations for the year ended December 31, 2019.

Upon adoption of ASC 842, the agreement was classified as an operating lease which resulted in recording right-of-use assets and lease liabilities of approximately $1.6 million and $1.9 million, respectively, as of January 1, 2019. These amounts included approximately $1.6 million of non-current other assets and approximately $0.6 million and $1.3 million of other current liabilities and operating lease liabilities, respectively.

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 Company agreed to pay initial monthly lease payments of $40,951, subject to 3% annual increases, plus the estimated cost of maintaining the property and common areas by the landlord, with a five month concession from October 2017 through February 2018. The lease also provides for allowances for tenant alterations and maintenance. The lease expires in January 2023 and provides the Company with a five year renewal option. The lease expense is included in selling, general and administrative expenses in the accompanying consolidated statement of operations for year ended December 31, 2019.

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 commenced in October 2018. The Company agreed to pay initial monthly lease payments of $35,969, subject to a 3% annual increase, plus the estimated operating cost of maintaining the property by the landlord, which are allocable based an annual assessment made by the landlord. In addition, the Company received reimbursement from the landlord of $56,325 for tenant improvements and was not required to pay a first-year common area maintenance fee. The lease expires in January 2023 and provides the Company with a five year renewal option.

Upon adoption of ASC 842, this lease was classified as an operating lease which resulted in recording right-of-use assets and lease liabilities of approximately $3.2 million and $3.5 million, respectively, as of January 1, 2019. These amounts included approximately $0.9 million and $2.6 million of other current liabilities and operating lease liabilities, respectively.

Operating lease costs under all operating leases including office space and equipment for the year ended December 31, 2019 was approximately $1.5 million. Cash paid for all operating leases for the year ended December 31, 2019 was $1.8 million. Variable lease costs were approximately $0.4 million for the year ended December 31, 2019. The weighted average discount rate used was 7.5%. The weighted-average remaining lease term for all operating leases is 3.0 years.

Rent expense under all operating leases for the year ended December 31, 2018, including office space and equipment, was approximately $0.5 million prior to the adoption of ASC topic 842.

Future minimum office and vehicle lease payments as of December 31, 2019 and 2018 were as follows:

	December 31,	
	2019	2018
2019	$ —	$ 1,595,421
2020	1,470,217	1,623,835
2021	1,499,484	1,653,101
2022	1,241,089	1,305,096
2023	87,957	87,957
Total	$ 4,298,747	$ 6,265,410

The 2018 amounts above are inclusive of office and vehicle lease payments in order to conform to the current year's presentation.

14. Employee Benefit Plans

The Company administers a 401(k) savings retirement plan for its employees. The Company contributed $1.5 million and $1.0 million for the years ended December 31, 2019 and 2018, respectively.

15. Income Taxes

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

	Year Ended December 31,	
	2019	2018
United States	$ (51,044)	$ (84,207)
Foreign	(859)	(2,528)
Loss before provision for income taxes	$ (51,903)	$ (86,735)

At December 31, 2019, the Company has concluded that it is more likely than not that the Company may not realize the benefit of its deferred tax assets due to its history of losses. There was no provision for income tax recorded for the year ended December 31, 2019 as a result of the current year losses. The provision for income taxes for the year ended December 31, 2018 was $0.2 million. The provision for income taxes relates only to withholding taxes for the year ended December 31, 2018 because the Company has 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,	
	2019	2018
Current		
U.S. federal	$ —	$ —
U.S. state	—	—
Non-U.S.	—	240
Total current	—	240
Deferred		
U.S. federal	(8,551)	(9,164)
U.S. state	3,299	(1,903)
Non-U.S.	—	—
Total deferred	(5,252)	(11,067)
Valuation allowance	5,252	11,067
Total	$ —	$ 240

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, 2019 and 2018, are as follows (in thousands):

	December 31,	
	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	$ 531,970	$ 524,377
Research and development credits	80,488	81,583
Capitalized research	44	557
Milestone Rights	1,528	3,521
Accrued expenses	1,951	1,156
Loss on purchase commitment	22,167	23,194
Non-qualified stock option expense	3,128	2,551
Capitalized patent costs	4,964	5,090
Other	147	669
Lease liability	827	—
Interest expense limitation	1,167	—
Depreciation	21,132	22,560
Deferred Product Revenue & Costs	2,062	107
Total net deferred tax assets	671,575	665,365
Valuation allowance	(670,617)	(665,365)
Net deferred tax assets	$ 958	$ —
Deferred tax liabilities:		
Right of use asset	$ (751)	$ —
Other prepaids	(207)	—
Total deferred tax liabilities	(958)	—
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, 2019 and 2018:

	Year Ended December 31,	
	2019	2018
Federal tax benefit rate	21.0%	21.0%
Permanent items	(3.3)	1.0
Tax law changes	(2.7)	(0.7)
Stock based compensation	(0.9)	(6.5)
Tax attribute expirations	(4.0)	(1.6)
Foreign withholding tax	—	(0.3)
Valuation allowance	(10.1)	(13.2)
Effective income tax rate	0.0%	-0.3%

As of December 31, 2019 and 2018, 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%) 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, 2019. Accordingly, a valuation allowance of $670.6 million has been recorded to offset this deferred tax asset. During the years ended December 31, 2019 and 2018, the change in the valuation allowance was $5.3 million and $11.1 million, respectively.

At December 31, 2019, the Company had federal and state net operating loss carryforwards of approximately $2.1 billion and $1.3 billion available, respectively, to reduce future taxable income. $117.8 million of the federal losses do not expire and the remaining federal and state losses have started expiring, beginning in the current year through various future dates.

Pursuant to Internal Revenue Code (“IRC”) Sections 382 and 383, annual use of the Company’s federal and state net operating loss and research and development credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. 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 carryforwards 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. We have completed a Section 382 analysis beginning from the date of our initial public offering through to the end of the previous tax year regarding whether additional limitations may be placed on the net operating loss carryforwards and other tax attributes, and no additional changes in ownership that met Section 382 study ownership change threshold has been identified through December 31, 2019. There is a risk that changes in ownership may occur in tax years after December 31, 2019. If a change in ownership were to occur, our net operating loss carryforwards and other tax attributes could be further limited or restricted. If limited, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance. Due to the existence of the valuation allowance, limitations created by future ownership changes, if any, related to the Company’s operations in the U.S. will not impact the Company’s effective tax rate.

At December 31, 2019, the Company had $54.2 million of U.S. federal research and development credits which expire beginning in 2024, and $26.3 million of state research and development credits. The California credits do not expire and the New Jersey credits will begin to expire in 2020. The Company also had two types of credits in Connecticut of which $15.7 million do not expire and $0.9 million will begin to expire in 2020. Due to the existence of the valuation allowance, the expiration of the research and development credits will not impact the Company’s consolidated statements of operations.

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 2015 remain subject to examination by federal, state and foreign tax authorities.

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, 2019 the Company had no undistributed earnings from its foreign subsidiaries.

The Company adopted Accounting Standards Codification (“ASC”) Topic 842 – Leases, on January 1, 2019. Under Topic 842, the Company is required to recognize the assets and liabilities that arise from most operating leases on the balance sheet. Upon adoption, no change in retained earnings was recorded related to income taxes as the Company maintains a full valuation allowance. As of the implementation date, an adjustment of $0.7 million was recorded as a deferred tax liability and an adjustment of $0.7 million was recorded as a deferred tax asset. See above for more information about the non-income tax impact of the adoption of the new leasing standard.

Legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act of 2017, subjects a U.S. shareholder to tax on global intangible low-taxed income (“GILTI”) earned by certain foreign subsidiaries. The FASB Staff Q&A, Topic 740, No. 5, Accounting for Global Intangible Low-Taxed Income, states that an entity can make an accounting policy election to either recognize deferred taxes for temporary basis differences expected to reverse as GILTI in future years or to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only. The Company has elected to account for GILTI in the year the tax is incurred.

16. Selected quarterly financial data (unaudited)

Summarized quarterly financial data for the years ended December 31, 2019 and 2018, are set forth in the following tables:

	March 31	June 30	September 30	December 31
	(In thousands, except per share data)			
2019				
Net revenues	$ 17,448	$ 15,002	$ 14,595	$ 15,993
Net loss	$ (14,883)	$ (12,387)	$ (10,370)	$ (14,263)
Net loss per share — basic and diluted	$ (0.08)	$ (0.07)	$ (0.05)	$ (0.07)
Weighted average common shares used to compute net loss per share — basic and diluted	187,434	188,054	199,906	206,689
2018				
Net revenues	$ 3,465	$ 3,893	$ 4,469	$ 16,031
Net loss	$ (30,385)	$ (22,675)	$ (24,168)	$ (9,747)
Net loss per share — basic and diluted	$ (0.25)	$ (0.16)	$ (0.16)	$ (0.06)
Weighted average common shares used to compute net loss per share — basic and diluted	120,911	140,054	153,597	161,397

Exhibit 4.3

DESCRIPTION OF COMMON STOCK

General

Our authorized capital stock consists of 280,000,000 shares of common stock, $0.01 par value, and 10,000,000 shares of preferred stock, $0.01 par value. All of our authorized preferred stock is undesignated. Our board of directors is authorized, without stockholder approval except as required by the listing standards of The Nasdaq Stock Market LLC, to issue additional shares of our capital stock.

The following summary description of our common stock is based on the provisions of our amended and restated certificate of incorporation, as amended, or our Certificate of Incorporation, and amended and restated bylaws, or our Bylaws, and the applicable provisions of the Delaware General Corporation Law, or DGCL. This information is qualified entirely by reference to the applicable provisions of our Certificate of Incorporation, Bylaws and the DGCL.

Voting Rights

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of our stockholders, including the election of our directors. Under our Certificate of Incorporation and Bylaws, our stockholders will not have cumulative voting rights. Accordingly, the holders of a majority of our outstanding shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose. In all other matters, an action by our common stockholders requires the affirmative vote of the holders of a majority of our outstanding shares of common stock entitled to vote.

Dividends

Subject to preferences that may be applicable to any outstanding shares of our preferred stock, holders of our common stock are entitled to receive ratably any dividends our board of directors declares out of funds legally available for that purpose. Any dividends on our common stock will be non-cumulative.

Liquidation, Dissolution or Winding Up

If we liquidate, dissolve or wind up, the holders of our common stock are entitled to share ratably in all assets legally available for distribution to our stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any outstanding shares of our preferred stock.

Rights and Preferences

Our common stock has no preemptive, conversion or subscription rights. There are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of any outstanding shares of our preferred stock, which we may designate and issue in the future.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

Listing on The Nasdaq Global Market

Our common stock is listed on The Nasdaq Global Market under the symbol “MNKD.”

Anti-Takeover Effects of Provisions of Our Certificate of Incorporation, Our Bylaws and Delaware Law

Delaware Anti-Takeover Law

We are subject to Section 203 of the DGCL, which generally prohibits a public Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding upon consummation of the transaction, excluding for purposes of determining the number of shares outstanding (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the consummation of the transaction, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 of the DGCL defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 of the DGCL defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Certificate of Incorporation and Bylaws

Provisions of our Certificate of Incorporation and Bylaws, may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our Certificate of Incorporation and Bylaws:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that, subject to the rights of the holders of any outstanding series of preferred stock, all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- provide that our board of directors may fix the number of directors by resolution;

- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent or electronic transmission;

- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide timely notice in writing and also specify requirements as to the form and content of a stockholder's notice;

- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose); and

- provide that special meetings of our stockholders may be called only by the Chairman of our board of directors, by our Chief Executive Officer, by our board of directors upon a resolution adopted by a majority of the total number of authorized directors or, under certain limited circumstances, by the holders of at least 5% of our outstanding voting stock.

Exhibit 23.1

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, 333-213366, 333-225428 and 333-226648 on Form S-8, and Registration Statement Nos. 333-210792 and 333-230633 on Form S-3 of our reports dated February 25, 2020, 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, 2019.

/s/ Deloitte & Touche LLP

Los Angeles, CA
February 25, 2020

Exhibit 31.1

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 25, 2020

Exhibit 31.2

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 25, 2020

Exhibit 32.1

CERTIFICATION[1]

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, 2019, 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 25th day of February, 2020.

/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.

Exhibit 32.2

CERTIFICATION[1]

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, 2019, 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 25th day of February, 2020.

/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.