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, 2020

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 Section 15(d) of the Act. Yes ☐ No ☒

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

Indicate by check mark whether the registrant has submitted electronically 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

As of June 30, 2020, the aggregate market value of the voting and non-voting common equity 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 $358,189,732.

As of February 12, 2021, there were 247,158,297 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 2021 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than April 30, 2021 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, 2020

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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; scientific studies and the conclusions we draw from them; and the transaction and the terms thereof contemplated by our non-binding letter of intent with a third party to sell and lease back a portion of our Danbury manufacturing facility and administrative offices. 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.

Risk Factor Summary

Below is a summary of the material factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found under the heading "Risk Factors" in Part I of this Annual Report on Form 10-K and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the Securities and Exchange Commission ("SEC") before making investment decisions regarding our common stock.

RISKS RELATED TO OUR BUSINESS

- We will need to raise additional capital to fund our operations, and there is substantial doubt about our ability to continue as a going concern.
- We are currently 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.
- If we fail as an effective manufacturing organization, we may be unable to support commercialization of Afrezza or Tyvaso DPI.
- 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 business, product sales, results of operations and ability to access capital could be adversely affected by the effects of health pandemics or epidemics, including the recent ongoing COVID-19 pandemic, in regions where we or third parties distribute our products or where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations. The COVID-19 pandemic could materially affect our operations, including at our headquarters in California and at our manufacturing facility in Connecticut and with respect to our sales force and their ability to interact with health care professionals, as well as the business or operations of our suppliers, distributors or other third parties with whom we conduct business.
- 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.
- We may not be successful in our efforts to develop and commercialize our product candidates.
- We have a history of operating losses, we expect to incur losses in the future and we may not generate positive cash flow from operations in the future.
- We have a substantial amount of debt, and we may be unable to make required payments of interest and principal as they become due.
- 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.
- Afrezza or our product candidates may be rendered obsolete by rapid technological change.
- 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.
- If our suppliers fail to deliver materials and services needed for commercial manufacturing 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.
- If Afrezza or any other product that we develop does not become widely accepted by physicians, patients, third-party payers and the healthcare community, we may be unable to generate significant revenue, if any.
- If third-party payers 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.
- 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.

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.
- 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.
- We are subject to stringent, ongoing government regulation.
- 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.

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

GENERAL RISK FACTORS

- 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.

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 endocrine and orphan lung diseases. Our development team is capable of taking a compound from early formulation feasibility studies to a full commercial-scale manufacturing operation. Our commercial team includes a specialty sales force that calls on endocrinologists and selected primary care physicians as well as supporting functions that are directed to improving market access and delivering patient and physician support programs.

Endocrine diseases

Our lead product is Afrezza (insulin human) Inhalation Powder, which was approved by the U.S. Food and Drug Administration (“FDA”) in June 2014. Afrezza is an ultra rapid-acting inhaled insulin indicated to improve glycemic control in adults with diabetes. According to the Centers for Disease Control and Prevention, 34.2 million people in the United States had diabetes in 2018. 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 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.

In the U.S., we are solely responsible for the commercialization of Afrezza. Outside of the U.S., our strategy has been 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 engaged in activities to prepare for regulatory submissions and have not yet commenced commercialization in their respective territories.

As part of the approval of Afrezza, the FDA required us to conduct certain additional clinical studies of Afrezza. We expect to initiate one of these studies, a Phase 3 clinical trial to evaluate the safety and efficacy of Afrezza in 8-17 year-old children and adolescents, later in 2021, subject to the easing of restrictions due to COVID-19. We are also required 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.

In December 2020, we entered into a sales and marketing collaboration agreement with an affiliate of Vertice Pharma, pursuant to which we will co-promote Thyquidity™ (levothyroxine sodium) oral solution through our sales force to adult endocrinologists, pediatric endocrinologists and other U.S. healthcare providers who treat hypothyroidism. Thyquidity is indicated as a replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism. Under this agreement, Vertice will book all sales of Thyquidity. In consideration of our sales and marketing efforts, Vertice will make a specified quarterly payment to us and will pay us royalties on gross profit resulting from all sales of Thyquidity. We believe that this arrangement with Vertice Pharma will allow us to strengthen our relationships with our current physician customers, expand into pediatric endocrinology and leverage the capabilities of our sales force and reimbursement support systems. We expect to begin promoting Thyquidity in collaboration with Vertice Pharma in the first quarter of 2021.

Orphan Lung Diseases

Afrezza utilizes our proprietary Technosphere formulation technology, which we believe 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 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 up (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 Technosphere (initially known as “TreT”) into clinical development, completing a Phase 1 dose-escalation trial in June 2018. In September 2018, we entered into 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. UT subsequently branded TreT as “Tyvaso DPI” subject to FDA review. In January 2021, UT disclosed that it intends to submit a new drug application (“NDA”) for Tyvaso DPI to the FDA in April 2021. This NDA will seek approval for Tyvaso DPI for the indications of pulmonary arterial hypertension and pulmonary hypertension associated with interstitial lung disease. UT has announced that it plans to apply a priority review voucher to the Tyvaso DPI NDA, which would provide for an expedited FDA review period. One of our key focuses during 2021 will be to support the NDA submission by UT and to prepare our facility for the potential commercial production of Tyvaso DPI. Under the UT License Agreement, we are entitled to receive a margin on commercial supplies that we manufacture for UT and low double-digit royalties on all net sales of Tyvaso DPI.

In December 2020, we acquired QrumPharma, Inc., a privately held pharmaceutical company developing inhalation treatments for severe chronic and recurrent pulmonary infections, including nontuberculous mycobacterial (NTM) lung disease. QrumPharma is now our wholly owned subsidiary. Its lead program (QRM-003) is an inhaled, nebulized formulation of clofazimine, which could potentially provide several clinical advantages over the current solid oral dosage form of this drug, that is currently in preclinical development. The FDA has designated QRM-003 as both an orphan drug and a qualified infectious disease product for the treatment of pulmonary NTM infections. In addition to continuing the development of QRM-003, we intend to evaluate the feasibility of developing a dry-powder formulation of clofazimine using our Technosphere technology.

We have formulated other drugs and biologics for the treatment of orphan lung disease and plan to continue their development as dictated by the results achieved in preclinical studies and by resource requirements. For diseases outside of our areas of focus, our current intention is to seek partnerships to continue the development of our dry-powder formulations. As an example of one such partnership, in January 2016, we entered into a collaboration and license agreement with Receptor Life Sciences (“Receptor”), pursuant to which Receptor assumed responsibility for the development, manufacture and commercialization of inhaled formulations of certain cannabinoid compounds utilizing our technology. We have been informed that Receptor’s most advanced program, a dry-powder Technosphere formulation of cannabidiol, was reviewed with the FDA in a pre-IND meeting and that an investigational new drug (“IND”) submission is planned for 2021.

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 that 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 released a BluHale Professional version of the apparatus for use as a training tool in certain physician’s offices. New versions of the apparatus, with additional features, are in development.

Manufacturing and Supply

We use our Danbury, Connecticut facility to formulate both the Afrezza and Tyvaso DPI 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 Tyvaso DPI packaging has not yet been determined.

The quality management systems of our Connecticut facility have been certified to be in conformance with the ISO 13485:2016 standard. 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). ANVISA renewed its certificate in 2020 on the basis of a virtual inspection. 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 Tyvaso DPI. 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, Tyvaso DPI 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, 2020, there was €77.9 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.

The treprostinil used to produce Tyvaso DPI is supplied to us by our partner, United Therapeutics.

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 of treatment and manufacturing processes flowing from our research and development efforts.

Our Technosphere drug delivery platform, including Afrezza, enjoys patent protection relating to the powder, its manufacture, its use for pulmonary delivery of drugs as well as protection related to our inhalers and associated cartridges. We have additional patent coverage relating to methods for the treatment of diabetes using Afrezza. Overall, Afrezza is protected by approximately 630 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 110 applications pending that may provide additional protection for Afrezza if and when they are allowed. Similarly, Tyvaso DPI is protected by approximately 330 issued patents in the United States and elsewhere and an additional 60 pending applications. The longest-lived patent protection for Tyvaso DPI will expire in 2035. Our entire portfolio consists of approximately 1,050 issued patents and approximately 215 patent applications that provide protection for our drug delivery platform, Technosphere-based products, our BluHale inhalation-profiling apparatus and various development tools. 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. For some of our inventions, particularly manufacturing processes and improvements, we have chosen to rely on trade secrets and know-how, which are not protected by patents, to maintain our competitive position.

We use trademarks and service marks to protect our corporate brand as well as the branding associated with Afrezza, our Technosphere formulation technology, our device platform and the product support programs that we have developed. Our current portfolio consists of 136 registered trademarks and 65 applications in the U.S. and selected foreign jurisdictions. We routinely monitor competing trademarks and, when necessary, oppose marks that we believe would be confusing to consumers. We also enforce against the unauthorized use or misappropriation of our marks.

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.

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 insulin glulisine, which is marketed by Sanofi S.A. as Apidra®. New formulations of two of these products – Fiasp®, a version of insulin aspart from Novo Nordisk, and Lyumjev™, a version of insulin lispro from Eli Lilly & Company – have been positioned by their manufacturers as fast(er) insulins. According to prescribing information, these products have their first measurable effects within 17-30 minutes after administration and reach peak glucose-lowering effects after 90-120 minutes.

Inhaled Drug Delivery Systems

Our drug delivery platform competes with other inhaled delivery systems, including AER-901 being developed by Aerami Therapeutics. AER-901 is a formulation of imatinib, administered with a small handheld electronic inhaler that is being developed for the treatment of pulmonary arterial hypertension.

Government Regulation

The FDA and comparable regulatory agencies in state and local 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, to the extent that our products are marketed abroad, they are also 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, including warning letters, hold letters on clinical research, product recalls or seizures, 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, civil or criminal fines or other penalties.

With 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 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. All manufacturing sites are subject to inspection by the FDA and other national regulatory bodies and must comply with current good manufacturing practices (“cGMPs”), quality system regulations for medical devices (“QSR”) and other requirements enforced by these regulatory bodies. As a result, our drug-manufacturing facility in Connecticut is subject to federal registration and listing requirements and, if applicable, to state licensing requirements and so too are the facilities of our insulin supplier and the supplier(s) of FDKP. Likewise, the supplier of our inhaler and cartridges is subject to QSR, which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process of medical devices, among other requirements. 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. 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 regulation 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 are also 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.

Pricing and Reimbursement

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 payers, 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 payers 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 payers 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 payers 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 signed 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. 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, several 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 eliminated the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended 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. In December 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, in December 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. The U.S. Supreme Court is currently reviewing this case, but it is unknown when a decision will be reached. Although the U.S. Supreme Court has not yet ruled on the constitutionality of the PPACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the PPACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the PPACA. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the PPACA and our business.

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, remained in effect through 2020 unless additional Congressional action is taken. However, COVID-19 relief support legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2021. 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 previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained 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. In addition, the Trump administration's budget proposal for fiscal year 2021 included a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. Further, on March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. On July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of this rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. However, it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. 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, it is possible that additional government action will be taken in response to the COVID-19 pandemic.

Health Care Fraud and Abuse and Transparency Laws

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 federal healthcare Anti-Kickback Statute prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid.

In addition, federal civil and criminal false claims laws, including the civil False Claims Act, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalty laws impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment or approval that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government.

The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services.

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 (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) 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. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year.

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 and local 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; register pharmaceutical sales representatives, and report pricing with respect to certain drug products.

Privacy

We are 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.

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.

Other regulation

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, safe working conditions, manufacturing practices, environmental protection and fire hazard control.

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

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, 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.

Safety of Clinical Trial Participants

When we are actively conducting clinical trials, the safety of our clinical trials plays 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.

Corruption and Bribery

Our Code of Business Conduct and Ethics includes clear guidelines on anti-bribery and anti-corruption practices. In addition, we have adopted an anti-corruption policy. 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 implemented 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 $25.9 million and $26.8 million as of December 31, 2020 and 2019, 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, 2020, we had 241 total employees, of which 240 were full-time. Of our full-time employees, 76 were engaged in manufacturing, 16 in research and development, 38 in general and administrative and 110 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. In managing our business, we monitor several human capital measures, including:

- performance against a set of specified corporate objectives for each calendar year, some of which are milestone-based, such as achieving deliverables under our collaboration agreements, and some of which are quantitative, such as achieving target net sales of Afrezza. These objectives are intended to stretch employees and serve as development opportunities but also form the basis for our incentive compensation programs.
- churn rate – the number of new hires and terminations each month as a percentage of the employee base – as well as the number of regrettable losses. These metrics help us to identify areas within the company where there may be a need for greater management attention and intervention.
- responses to periodic employee surveys, which are designed to give us insight into employees' perception of company culture and areas where management's efforts are perceived positively or negatively as well as open-ended feedback in the form of anonymous comments and questions.

We offer our employees a portfolio of rewards (our "Total Rewards Program") to recruit and retain a high level of talent across the Company. Our Total Rewards program is offered to each employee and currently consists of the seven offerings:

- Base salary – We offer a market-competitive base salary.
- Annual bonus program – We offer quarterly sales incentive bonuses to our sales force and annual bonuses to the remainder of our employees.
- Annual equity program – we offer a new hire and annual equity awards that consist of time- and, in some cases, performance-based restricted stock units and non-qualified stock options.
- Health and wellness program – A variety of insurance plans that allow employees to select among different options, including a health maintenance organization, a preferred provider organization and a high-deductible health plan, as well as flexible spending and health savings accounts.
- Paid time off program – In addition to the paid time off that is accrued throughout the year, we offer paid holidays, including two week-long company shutdowns in July and December.
- Retirement savings program – A 401(k) retirement plan pursuant to which we match 50% of employee contributions up to a specified limit on their annual eligible earnings.
- Employee stock purchase plan ("ESPP") program – The ESPP provides the opportunity to purchase shares of our common stock through payroll deductions every six months at a 15% discount to the market price at the beginning or end of each offering period, whichever is lower.

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 2020, our total illness and injury incidence rate was 2.9 per 100 employees compared to the 2019 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 0.0 per 100 employees compared to the 2019 industry average of 1.0. 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 endocrinology, pulmonology and other areas of scientific or clinical interest. 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 partial listing of our current 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.	44	Chief Executive Officer
Steven B. Binder	58	Chief Financial Officer
Alejandro Galindo	49	Chief Commercial Officer
Joseph Kocinsky	57	Chief Technology Officer
Stuart A. Tross, Ph.D.	54	Chief People and Workplace Officer
David B. Thomson, Ph.D., J.D.	54	General Counsel and Secretary

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.

Alejandro Galindo has been our Chief Commercial Officer since August 2020. Before joining us, he served as Vice President and President of the Advanced Insulin Management Business Unit at Medtronic from 2014 to 2020. Prior to Medtronic, Mr. Galindo spent nine years at General Electric (GE) Healthcare in a variety of leadership roles, leading emerging markets, strategic corporate development and global supply chain operations. Prior to joining GE's Healthcare division, he spent eleven years in various global leadership positions for the company's energy and appliance sectors, overseeing advanced manufacturing engineering and product development. Mr. Galindo received a B.Sc. in Industrial & Systems Engineering from Monterrey Institute of Technology, Mexico and M.B.A. and M.S. degrees from Indiana University.

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.

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. Mr. Tross 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.

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

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

RISKS RELATED TO OUR BUSINESS

We will need to raise additional capital to fund our operations, and there is substantial doubt about our ability to continue as a going concern.

This report includes disclosures stating that our existing cash resources and our accumulated deficit raise substantial doubt about our ability to continue as a going concern. As of December 31, 2020, we had cash and cash equivalents of $67.0 million and accumulated deficit of $3.0 billion. We will need to raise additional capital, whether through the sale of equity or debt securities, additional strategic business collaborations, the establishment of other funding facilities, licensing arrangements, asset sales or other means, in order to support our ongoing activities, including the commercialization of Afrezza and the development of our product candidates. 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 revenue from Afrezza exceeds or does not exceed the minimum revenue covenants under the MidCap Credit Facility;
- 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;
- our ability to satisfy the milestone conditions necessary to access additional borrowing under the MidCap Credit Facility;
- 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. In addition, the COVID-19 pandemic continues to have the potential for disruption of global financial markets. This disruption, if sustained or recurrent, could prevent us or make it more difficult for us to access capital or make it difficult to comply with the covenants contained in the MidCap Credit Facility, which could negatively affect our liquidity.

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.

We are currently 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 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 and availability relative to alternative products and lack of coverage or adequate reimbursement by payers. We will need to maintain and potentially 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 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 payer 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 commercial success with Afrezza in the United States, our business, financial condition and results of operations will be materially and adversely affected.

If we fail as an effective manufacturing organization, we may be unable to support commercialization of Afrezza or Tyvaso DPI.

We use our Danbury, Connecticut facility to formulate both the Afrezza and Tyvaso DPI 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 responsibility for Tyvaso DPI 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 production to commercial batch sizes, which is the stage of production that we have now reached with Tyvaso DPI. These problems include difficulties with production costs and yields, quality control and assurance and shortages of qualified personnel. There is also a need to comply with strictly enforced federal, state and foreign regulations, including inspections. We anticipate that our facility will need to undergo a pre-approval inspection related to Tyvaso DPI before the FDA will approve the NDA for that product. If the FDA makes any major inspectional observations, the approval and launch of Tyvaso DPI may be delayed.

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 drug products 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 such drug products and we would lose potential revenues.

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

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

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

Our business, product sales, results of operations and ability to access capital could be adversely affected by the effects of health pandemics or epidemics, including the recent ongoing COVID-19 pandemic, in regions where we or third parties distribute our products or where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations. The COVID-19 pandemic could materially affect our operations, including at our headquarters in California and at our manufacturing facility in Connecticut and with respect to our sales force and their ability to interact with health care professionals, as well as the business or operations of our suppliers, distributors or other third parties with whom we conduct business.

Our business could be adversely affected by the effects of health pandemics or epidemics in regions where we have business operations, and could cause significant disruption in the operations of third-party manufacturers and distributors upon whom we rely.

The ongoing COVID-19 pandemic has resulted in a number of restrictions to reduce the spread of the disease, including executive orders in California and Connecticut, and several other state and local orders across the country, which, among other things, directed individuals to shelter at their places of residence, directed schools, businesses and governmental agencies to cease non-essential operations at physical locations, prohibited certain non-essential gatherings, and ordered cessation of non-essential travel. In some places, these orders have been lifted whereas other locations, including Los Angeles County where our headquarters is located, continue to be subject to significant restrictions. The emergence of new variants of the SARS-CoV-2 virus raises the possibility that recurring cycles of restrictions will be imposed in the future, notwithstanding vaccination efforts. The effects of state and local stay-at-home orders and our own work-from-home policies may negatively impact productivity, disrupt our business and delay our development programs, regulatory and commercialization timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations due to the COVID-19 pandemic could negatively impact our business, operating results and financial condition.

Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. Although we believe we have sufficient quantities of raw materials for planned manufacturing operations in 2021, a prolonged supply interruption of certain components could adversely affect our ability to conduct commercialization activities and planned clinical trials. In addition, we believe that the severity of the COVID-19 pandemic in Brazil has the potential to negatively impact the distribution of Afrezza by our partner in that country.

Sales and demand for Afrezza have been adversely affected by the global COVID-19 pandemic, and we expect that the COVID-19 pandemic will continue to negatively impact near-term revenues from Afrezza. Our sales representatives have not fully returned to conducting in-person office visits with healthcare providers, which impacts their productivity. Disruptions in the prescription volume of Afrezza could also occur:

- if patients are physically quarantined or are unable or unwilling to visit healthcare providers,
- if physicians restrict access to their facilities for a material period of time,

- if healthcare providers prioritize treatment of acute or communicable illnesses over diabetes management,
- if pharmacies are closed or suffering supply chain disruptions,
- if patients lose access to employer-sponsored health insurance due to period of high unemployment, or
- as a result of general disruptions in the operations of payers, distributors, logistics providers and other third parties that are necessary for Afrezza to be prescribed and reimbursed.

In addition, our planned clinical trials of Afrezza and those of our partner for Tyvaso DPI may be affected by the COVID-19 pandemic. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. Some patients may not be able or willing to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 would adversely impact our clinical trial operations.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, the pandemic continues to have the potential for disruption of global financial markets. This disruption, if sustained or recurrent, could make it more difficult for us to access capital or to comply with the covenants contained in the MidCap Credit Facility, which could negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

We are still in the midst of the COVID-19 pandemic. The ultimate impact of the COVID-19 pandemic or a similar health pandemic or epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, commercialization efforts, healthcare systems or to the global economy as a whole. These effects could have a material impact on our operations. We will continue to monitor the COVID-19 situation closely.

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. Other than Tyvaso DPI, which UT is expected to be submitted for regulatory approval in April 2021 according to disclosures from United Therapeutics, 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, our need to support the regulatory submission and launch preparations of Tyvaso DPI and our ongoing attention 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.

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, 2020, 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, 2020, there was €77.9 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, 2020, we had $122.9 million principal amount of outstanding debt, consisting of:

- $50.0 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 payable in equal monthly installments beginning in September 2022 through maturity in August 2024;
- $5.0 million principal amount of 2024 convertible notes bearing interest at 5.75% per annum ("2024 convertible notes"), 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 was convertible into shares of our common stock at the option of the holder at a conversion price of $3.00 per share. The 2024 convertible notes provided that, under certain circumstances, at our option, we may elect to cause all or any portion of the 2024 convertible notes to be mandatorily converted;
- $63.0 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, $28.0 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.
- $4.9 million from a loan under the Paycheck Protection Program of the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), all or a portion of which may be forgiven. The Paycheck Protection Program loan ("PPP Loan") matures in April 2022 and bears interest at a rate of 0.98% per annum. Principal and interest payments can be deferred up to the date the SBA remits the borrower's loan forgiveness amount to the lender. In the event the SBA does not authorize loan forgiveness, the deferred principal and interest will be payable to the lender and the Company will then make equal monthly payments as required to fully amortize the remaining principal amount by April 9, 2022.

In February 2021, we elected to convert the $5.0 million principal amount of 2024 convertible notes into 1,666,667 shares of our common stock in accordance with the terms of the 2024 convertible notes. All or a portion of the PPP Loan may be forgiven by the SBA upon application to our lender by us beginning 60 days after loan approval up to 24 weeks after the date of the loan disbursement (the "covered period"), but not later than ten months after the end of our covered period, and upon documentation of expenditures in accordance with the SBA requirements. Under the CARES Act, loan forgiveness is available for the sum of documented payroll costs, covered rent payments, covered interest and covered utilities during the 24 week period (or eight-week period at our option) beginning on the date of loan approval. Not more than 40% of the forgiven amount may be for non-payroll costs. The amount of the PPP Loan eligible to be forgiven will be reduced if our full-time headcount declines, or if salaries and wages for employees with salaries of $100,000 or less annually are reduced by more than 25%. We will be required to repay any portion of the outstanding principal that is not forgiven, along with accrued interest, in accordance with the amortization schedule described above, and we cannot provide any assurance that we will be eligible for loan forgiveness or that any amount of the PPP Loan will ultimately be forgiven by the SBA. Furthermore, on April 28, 2020, the Secretary of the U.S. Department of the Treasury stated that the SBA will perform a full review of any PPP loan over $2.0 million before forgiving the loan.

The PPP Loan application required us to certify, among other things, that the current economic uncertainty made the PPP Loan request necessary to support our ongoing operations. While we made this certification in good faith after analyzing, among other things, our financial situation and access to alternative forms of capital, and believe that we satisfied all eligibility criteria for the PPP Loan, and that our receipt of the PPP Loan is consistent with the broad objectives of the PPP, the certification described above does not contain any objective criteria. In addition, the SBA has stated that it is unlikely that a public company with substantial market value and access to capital markets will be able to make the required certification in good faith. The lack of clarity regarding loan eligibility under the PPP has resulted in significant media coverage and controversy with respect to public companies applying for and receiving loans. If, despite our good-faith belief that we satisfied all eligible requirements for the PPP Loan, we are found to be in violation of any of the laws or governmental regulations that apply to us in connection with the PPP Loan, including the False Claims Act, or it is otherwise determined that we were not eligible to receive the PPP Loan, we may be subject to penalties, including significant civil, criminal and administrative penalties and could be required to repay the PPP Loan. In addition, our receipt of the PPP Loan may result in adverse publicity and damage to our reputation, and a review or audit by the SBA or other government entity or claims under the False Claims Act could consume significant financial and management resources. If we fail to take all actions necessary and promptly file all required reporting to ensure than no less than 90% of the PPP Loan is forgiven in accordance with the loan forgiveness provisions of the PPP, we will be in violation of the consent given by MidCap with respect to such additional

indebtedness, which could lead to an event of default under the MidCap Credit Facility. Any of these events could have a material adverse effect on our business, results of operations and financial condition.

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, an advance of $25.0 million will be available to us between October 1, 2021 and March 31, 2022, subject to the satisfaction of certain milestone conditions associated with Tyvaso DPI.

Under the MidCap Credit Facility, we must comply with a minimum cash covenant of $30.0 million at all times and, if the third advance of $25.0 million is funded, we must ensure that our partner is actively marketing and (after the first commercial sale) generating revenue from Tyvaso DPI. 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.

We expect that the COVID-19 pandemic will continue to negatively impact near-term revenues from Afrezza, which could also affect our compliance with a covenant relating to trailing twelve-month minimum Afrezza net revenue, tested on a monthly basis, which is set forth in the MidCap Credit Facility Agreement, as amended. If we fail to meet this covenant or the minimum cash 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. 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 our outstanding term loan under the MidCap Credit Facility (the “MidCap Term Loan”), or if we fail to repay or repurchase the MidCap Term Loan, PPP 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;
- actions by regulators; and
- disruptions caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including, for example, the COVID-19 pandemic.

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;

- 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; and
- disruptions caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including, for example, the COVID-19 pandemic.

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 commercial manufacturing 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 inhaled drug products, we need access to sufficient, reliable and affordable supplies of FDKP, the inhaler, the related cartridges and other materials. For Afrezza, we also require a supply of insulin. Currently, the only source of insulin that we have qualified for Afrezza is manufactured by Amphastar. We must rely on all of 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 Afrezza or any other product that we develop does not become widely accepted by physicians, patients, third-party payers 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 payers 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 following:

- 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 payers, 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 payers 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 payers 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's budget proposal for the fiscal year 2021 included a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Moreover, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained 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. On July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of this rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. However, it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. 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 payers may take in response to any drug pricing and reimbursement reform proposals or legislation. For example, it is possible that additional governmental action is taken in response to the COVID-19 pandemic. 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 payers, such as government health administration authorities and private insurance plans. Third-party payers 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 payers' drug formularies, which are the lists of medications for which third-party payers 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 payers 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 payer 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 payer 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 and maintain coverage of, and adequate payment levels reimbursement for, Afrezza or any of our other product candidates that receive marketing approval from third-party payers, 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, 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.

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, the 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. For example, the CARES Act modified certain provisions of the Tax Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES 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, 2020 we had federal and state net operating loss carryforwards of $2.4 billion and $1.3 billion, respectively, which we assess annually. A portion of our 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 the Tax Act as modified by the CARES

Act, federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses in tax years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act. 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 December 31, 2020, to determine whether additional limitations may be placed on our net operating loss carryforwards and other tax attributes, and no additional changes in ownership that met the Section 382 ownership change threshold were identified through December 31, 2020. There is a risk that changes in ownership may occur in tax years after December 31, 2020. 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. For example, California imposed limits on the usability of California state net operating losses to offset taxable income in tax years beginning after 2019 and before 2023. As a result, if we earn net taxable income, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could potentially result in increased future tax liability to us and adversely affect our future cash flows.

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'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. The plaintiff has appealed this denial to the Supreme Court of Israel. 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 Tyvaso DPI. 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, public health pandemics or epidemics (including, for example, the ongoing COVID-19 pandemic), 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. Additionally, natural disasters, public health pandemics or epidemics (including, for example, the COVID-19 pandemic), terrorism, war and telecommunication and electrical failures may result in damage to or the interruption or impairment of key business processes, or the loss or corruption of confidential information, including intellectual property, proprietary business information and personal information. 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.

The withdrawal of the United Kingdom from the European Union, commonly referred to as "Brexit," may adversely impact our ability to obtain regulatory approvals of our product candidates in the European Union, result in restrictions or imposition of taxes and duties for importing our product candidates into the European Union, and may require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the European Union.

Following the result of a referendum in 2016, the United Kingdom left the European Union on January 31, 2020, commonly referred to as "Brexit." Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the European Union, the United Kingdom was subject to a transition period that ended December 31, 2020, or the Transition Period, during which EU rules continued to apply. A trade and cooperation agreement, or the Trade and Cooperation Agreement, that outlines the future trading relationship between the United Kingdom and the European Union was agreed in December 2020.

Since a significant proportion of the regulatory framework in the United Kingdom applicable to our business and our product candidates is derived from EU directives and regulations, Brexit has had, and may continue to have, a material impact upon the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the United Kingdom or the European Union. For example, Great Britain is no longer covered by the centralized procedures for obtaining EU-wide marketing authorization from the EMA and, and a separate marketing authorization will be required to market our product candidates in Great Britain. It is currently unclear whether the Medicines & Healthcare products Regulatory Agency, or MHRA, in the U.K. is sufficiently prepared to handle the increased volume of marketing authorization applications that it is likely to receive. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom or the European Union and restrict our ability to generate revenue and achieve and sustain profitability.

While the Trade and Cooperation Agreement provides for the tariff-free trade of medicinal products between the UK and the EU there may be additional non-tariff costs to such trade which did not exist prior to the end of the Transition Period. Further, should the UK diverge from the EU from a regulatory perspective in relation to medicinal products, tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses (when compared to the position prior to the end of the Transition Period) to

operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the UK It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the EU These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the United Kingdom.

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, as part of the approval of Afrezza, the FDA required us to conduct certain additional clinical studies of Afrezza. We expect to initiate one of these studies, a Phase 3 clinical trial to evaluate the safety and efficacy of Afrezza in 8-17 year-old children and adolescents, later in 2021, subject to the easing of restrictions due to COVID-19. In addition, 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.

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 significant 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;
- revisions to the approved labeling to add new safety information;
- 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. Prescription drugs may be promoted only for the approved indications in accordance with the approved label. 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. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments but the FDA does restrict manufacturer’s communications on the subject of off-label use of their products. Enforcement action may include product seizures, injunctions, significant 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, delay the submission or review of an application or require additional expenditures by us. 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. 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.

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, certain other healthcare professionals, and teaching hospitals, 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, as described in more detail below;
- 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 signed 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. 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, several 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 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, 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. The United States Supreme Court is currently reviewing this case, but it is unknown when a decision will be reached. Although the United States Supreme Court has yet ruled on the constitutionality of the PPACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the PPACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the PPACA. It is unclear how the Supreme Court rule, other such litigation, the healthcare reform measures of the Biden administration 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 2030 unless additional Congressional action is taken. However, COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2021. 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.

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. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private third-party payers. 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 payers, 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 as well as their covered subcontractors. 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 California Consumer Privacy Act ("CCPA"), which 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;
- 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 (defined to include defined to include doctors, dentists, optometrists, podiatrists and chiropractors), and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year; 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 payer, 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 payers 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 payers. 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.

Furthermore, patents already issued to us or our pending applications may become subject to disputes that could be resolved against us. In the United States and certain other countries, applications are generally published 18 months after the application's priority date. 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"), the United States moved to a first inventor to file system. In general, the AIA 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 2020, 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. 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. Thus, 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 AIA 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, if a plaintiff was to allege that Afrezza infringed their patent rights, we would have to establish with the court that their 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.

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 COVID-19 pandemic, for example, has negatively affected the stock market and investor sentiment and has resulted in significant volatility.

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;
- future estimates of Afrezza sales, Tyvaso DPI royalties, 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;
- disruptions caused by man-made or natural disasters or public health pandemics or epidemics or other business interruptions, including, for example, the COVID-19 pandemic;
- 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, Tyvaso DPI 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, Tyvaso DPI, 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.

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 12, 2021, we had 247,158,297 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 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.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America are the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated bylaws provide that, to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants, the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action or proceeding asserting a breach of fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders;
- any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and certificate of incorporation or amended and restated bylaws;
- any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws;
- any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and
- any action asserting a claim against us or any of our directors, officers or other employees that is governed by the internal affairs doctrine.

This provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act of 1933, as amended, or the Securities Act, creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated bylaws further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated bylaws. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

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.

GENERAL RISK FACTORS

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.

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.

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. We believe the Connecticut facility has sufficient space, including unimproved manufacturing space, to satisfy anticipated commercial demand for Afrezza and Tyvaso DPI. Our obligations under the MidCap Credit Facility are secured by our facility in Danbury, Connecticut and other assets. As of December 31, 2020, 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.

In February 2021, we entered into a non-binding letter of intent ("LOI") with a third party to sell and lease-back a portion of our Danbury manufacturing facility and administrative offices. The terms of the LOI include a sales price of approximately $95 million to $105 million, a lease term of 20 years with four five-year renewal options, and annual rent of approximately $10 million to $11 million at the beginning of the lease. If the transaction is completed, we intend to use the proceeds for general corporate purposes, and may also pay down a portion of our senior secured debt. The completion of the transactions contemplated by the LOI is subject to certain conditions, including the negotiation of satisfactory definitive agreements and satisfactory results of the buyer's inspections and other investigations, all of which are anticipated to be completed during the first quarter of 2021. However, there can be no assurances that this proposed transaction will be completed in the timeframe or on the principal terms set forth above, or at all.

Item 3. ***Legal Proceedings***

See Note 13 – Commitments and Contingencies in the consolidated financial statements included in Part II, Item 8 – Financial Statements and Supplementary Data.

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

Not applicable.

PART II

Item 5. *Market for 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 $5.41 on February 12, 2021 and there were 112 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

In August 2019 we issued a $2.6 million note due June 2020 (the "June 2020 note") and a $2.6 million note due December 2020 (the "December 2020 note." On October 9, 2020, we prepaid the December 2020 note with the issuance of 1,377,356 shares of our common stock, in accordance with the terms of the December 2020 note. On November 15, 2020, the Mann Group converted $3.0 million of accrued interest and $2.0 million of principal under the Mann Group Note into 2,000,000 shares of our common stock in accordance with the terms of the Mann Group Note. On December 28, 2020, the Mann Group converted an additional $5.0 million of principal under the Mann Group Note into 2,000,000 shares of our common stock in accordance with the terms of the Mann Group Note.

We relied on an exemption from registration provided by Section 3(a)(9) of the Securities Act of 1933, as amended, for the issuance of the shares described above.

Item 6. *Selected Financial Data*

Not required.

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. We have 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.

Overview

We are a biopharmaceutical company focused on the development and commercialization of inhaled therapeutic products for endocrine and orphan lung diseases. Our lead product, is Afrezza (insulin human) Inhalation Powder, which was approved by the FDA in June 2014. Afrezza is an ultra rapid-acting inhaled insulin indicated to improve glycemic control in adults with diabetes. Afrezza became available by prescription in United States retail pharmacies in February 2015. Since September 2018, we have been collaborating with United Therapeutics to develop an inhaled formulation of treprostinil known as Tyvaso DPI. Our partner has disclosed that it intends to submit an NDA for Tyvaso DPI to the FDA in April 2021.

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 commercialize Afrezza successfully and our ability to manufacture sufficient quantities of Afrezza and Tyvaso DPI. Other 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.

We continue to manage the risk to our business posed by the global COVID-19 pandemic. Our sales representatives have resumed in-person sales calls to the extent permitted by state and local public health authorities and by the policies of individual healthcare providers on their call lists. Our offices in California and Connecticut have remained open for essential personnel and, as public health orders allow, have reopened to non-essential personnel, although many employees continue to work from home for a portion of each workweek. Although our productivity has been impacted by the global pandemic, we have suitably adapted to the changed business environment that now exists.

The COVID-19 pandemic continues to evolve rapidly and its ultimate impact remains highly uncertain. We do not yet know the full extent of potential delays or impacts on our business, our collaboration arrangements, commercialization efforts, healthcare systems or to the global economy as a whole. We expect the COVID-19 pandemic to continue to negatively impact our near-term revenues from Afrezza and believe it has the potential to have additional adverse impacts on our operations. We will continue to monitor the COVID-19 situation closely.

As of December 31, 2020, we had an accumulated deficit of $3.0 billion and a stockholders' deficit of $180.4 million. We had net loss of $57.2 million and $51.9 million in the years ended December 31, 2020 and 2019, 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.

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 — We sell Afrezza to a limited number of wholesale distributors and specialty pharmacies in the U.S. (collectively, its "Customers"). Wholesale distributors subsequently resell our products to retail pharmacies and certain medical centers or hospitals. Specialty pharmacies sell directly to patients. In addition to distribution agreements with Customers, we enter into arrangements with payers that provide for government mandated and/or privately negotiated rebates, chargebacks, and discounts with respect to the purchase of our products.

We recognize revenue on product sales when the Customer obtains control of our product, which occurs at delivery for wholesale distributors and generally at delivery for specialty pharmacies. Product revenues are recorded net of applicable reserves for variable consideration. Components of variable consideration include trade discounts and allowances, product returns, provider chargebacks and discounts, government rebates, payer rebates, and other incentives, such as voluntary patient assistance, and other allowances that are offered within contracts between the Company and its Customers, payers, and other indirect customers relating to the Company's sale of its products. These reserves are further detailed under Reserves for Variable Consideration 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 – Collaborations and Services — We enter into licensing or research agreements under which we license certain rights to our product candidates to third parties or conduct 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 commercial and clinical 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 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 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. 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. 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 judgment 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.

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.

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.

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, 2020 and 2019, we had established a valuation allowance of $675.5 million and $670.6 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.

On March 27, 2020, the U.S. government enacted the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, a $2 trillion relief package comprising a combination of tax provisions and other stimulus measures. The CARES Act broadly provides entities tax payment relief and significant business incentives and makes certain technical corrections to the Tax Act. The tax relief measures for entities include a five-year net operating loss carry back, increased interest expense deduction limits, acceleration of alternative minimum tax credit refunds, payroll tax relief, and a technical correction to allow accelerated deductions for qualified improvement property. The Act also provides other non-income tax benefits, including federal funding for a range of stabilization measures and emergency funding to assist those impacted by the COVID-19 pandemic. Similar legislation is being enacted in other jurisdictions in which the Company operates. Accounting Standards Codification Topic 740, *Income Taxes*, requires the effect of changes in tax rates and laws on deferred tax balances to be recognized in the period in which new legislation is enacted. The enactment of the CARES Act and similar legislation in other jurisdictions in which the Company operates was not material to the Company's income tax benefit for the year ended December 31, 2020.

Results of Operations

Years ended December 31, 2020 and 2019

Revenues

The following table provides a comparison of the revenue categories for the years ended December 31, 2020 and 2019 (dollars in thousands):

	Year Ended December 31,			
	2020	2019	$ Change	% Change
Net revenue — commercial product sales:				
Gross revenue from product sales	$ 54,457	$ 43,492	$ 10,965	25%
Wholesaler distribution fees, rebates and chargebacks, product returns and other discounts	(22,133)	(18,188)	$ 3,945	22%
Net revenue — commercial product sales	32,324	25,304	$ 7,020	28%
Revenue — collaborations and services	32,820	37,734	$ (4,914)	(13%)
Total revenues	$ 65,144	$ 63,038	$ 2,106	3%

Gross revenue from the sales of Afrezza increased by $11.0 million, or 25%, for the year ended December 31, 2020 compared to the prior year. The increase was primarily driven by higher product demand with a more favorable mix of Afrezza cartridges and a price increase, partially offset by a reduction in sales to Biomm (Brazil). The gross-to-net adjustment was $22.1 million (or 41% of gross revenue) for the year ended December 31, 2020, compared to $18.2 million (or 42% of gross revenue) for the prior year. The increase of $3.9 million was primarily driven by an increase in commercial product sales and a decrease in rebates and wholesaler fees, partially offset by an increase in the utilization of our patient co-pay assistance program. As a result, net revenue from the sales of Afrezza increased by $7.0 million, or 28%, for the year ended December 31, 2020 compared to the prior year. The stay-at-home orders implemented around the country in response to the COVID-19 pandemic negatively impacted the sales of Afrezza by limiting the access of our sales force to physicians. The COVID-19 pandemic is expected to continue to negatively impact our near-term revenues from Afrezza.

Net revenue from collaborations and services decreased by $4.9 million, or 13%, for the year ended December 31, 2020 compared to the prior year. This was primarily driven by a $5.8 million decrease in revenue recognized from the UT Research Agreement, which was substantially completed in the second quarter of 2019. During the third quarter of 2020, we sold clinical supplies to UT. See Note 8 – Collaboration, Licensing and Other Arrangements in the consolidated financial statements included in Part II, Item 8 – Financial Statements and Supplementary Data.

Commercial product gross profit

The following table provides a comparison of the commercial product gross profit categories for the years ended December 31, 2020 and 2019 (dollars in thousands):

	Year Ended December 31,			
	2020	2019	$ Change	% Change
Commercial product gross profit:				
Net revenue — commercial product sales	$ 32,324	$ 25,304	$ 7,020	28%
Less cost of goods sold	(15,084)	(20,078)	$ (4,994)	(25%)
Commercial product gross profit (loss):	$ 17,240	$ 5,226	$ 12,014	230%
Gross margin	53%	21%		

Commercial product gross profit for the year ended December 31, 2020 increased by $12.0 million, or 230%, compared to the prior year. Gross margin for the year ended December 31, 2020 increased to 53% from 21% for the prior year. The increase in gross profit and gross margin was attributable to higher commercial product sales combined with a reduction in cost of goods sold. Cost of goods sold decreased by $5.0 million, or 25%, for the year ended December 31, 2020 compared to the prior year. The reduction in cost of goods sold was primarily attributable to a $2.8 million amendment fee associated with our Insulin Supply Agreement with Amphastar in 2019, $1.7 million in reduced manufacturing-related spending and $1.0 million of increased manufacturing activities, which resulted in a greater amount of costs capitalized to inventory, partially offset by $0.5 million of inventory write-offs.

Expenses

The following table provides a comparison of the expense categories for the years ended December 31, 2020 and 2019 (dollars in thousands):

	Year Ended December 31,			
	2020	2019	$ Change	% Change
Expenses:				
Cost of goods sold	$ 15,084	$ 20,078	$ (4,994)	(25%)
Cost of revenue — collaborations and services	9,557	7,901	$ 1,656	21%
In-process research and development	13,233	—	$ 13,233	100%
Research and development	6,248	6,900	$ (652)	(9%)
Selling	34,365	46,373	$ (12,008)	(26%)
General and administrative	24,675	28,296	$ (3,621)	(13%)
Impairment of commitment asset	1,889	—	$ 1,889	100%
Loss (gain) on foreign currency translation	8,006	(1,913)	$ 9,919	519%
Total expenses	$ 113,057	$ 107,635	$ 5,422	5%

Cost of revenue - collaborations and services increased by $1.7 million, or 21%, for the year ended December 31, 2020 compared to the prior year. The increase was attributable to resource costs related to conducting activities for our collaboration partner, UT, in addition to the cost of clinical supplies.

In-process research and development expense of $13.2 million for the year ended December 31, 2020 related to the acquisition of QrumPharma for total consideration of approximately $12.7 million and transaction costs of approximately $0.5 million. The acquisition of QrumPharma was accounted for as an asset acquisition and expensed on the date of acquisition as substantially all of the fair value of the assets acquired was concentrated in a single asset that consisted of in-process research and development in a pre-clinical development state. See Note 3 – Acquisition in the consolidated financial statements included in Part II, Item 8 – Financial Statements and Supplementary Data.

Research and development expenses decreased by $0.7 million, or 9%, for the year ended December 31, 2020 compared to the prior year. The decrease was mainly attributable to lower clinical trial spending.

Selling expenses decreased by $12.0 million, or 26%, for the year ended December 31, 2020 compared to the prior year. The decrease was primarily attributable to a $9.3 million decrease in costs for television advertising for Afrezza and a $4.1 million decrease from a reduction in promotional and marketing activities in response to the COVID-19 pandemic, partially offset by a $0.8 million increase in personnel-related costs and a $0.5 million increase in costs associated with AfrezzaAssist, our new patient support platform.

General and administrative expenses decreased by $3.6 million, or 13%, for the year ended December 31, 2020 compared to the prior year. This decrease was primarily attributable to a $2.5 million decrease in professional fees, $0.6 million decrease in personnel and employee-related costs and a $0.2 million reduction in property taxes.

During the year ended December 31, 2020, an impairment of $1.9 million was recognized for a commitment asset and debt issuance costs related to the future funding commitments of the MidCap Credit Facility (see Note 1 – Description of Business and Note 7 – Borrowings in the consolidated financial statements included in Part II, Item 8 – Financial Statements and Supplementary Data. There were no asset impairments for the year ended December 31, 2019.

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 gain or loss on purchase commitments. The foreign currency translation resulted in a loss of $8.0 million for the year ended December 31, 2020 compared to a gain of $1.9 million for the prior year. This impact was due to the translation of the U.S. dollar to Euro exchange rates.

Other Income (Expense)

The following table provides a comparison of the other income (expense) categories for the years ended December 31, 2020 and 2019 (dollars in thousands):

	Year Ended December 31,			
	2020	2019	$ Change	% Change
Interest income	$ 167	$ 997	$ (830)	(83%)
Interest expense on notes	(4,316)	(6,304)	$ (1,988)	(32%)
Interest expense on promissory notes	(5,155)	(4,602)	$ 553	12%
(Loss) gain on extinguishment of debt	(264)	3,529	$ (3,793)	107%
Other expense	23	(926)	$ (949)	(102%)
Total other expense	$ (9,545)	$ (7,306)	$ 2,239	31%

Interest income decreased by $0.8 million, or 83%, for the year ended December 31, 2020 compared to the prior year primarily due to lower short-term interest rates.

Interest expense on notes decreased $2.0 million, or 32%, for the year ended December 31, 2020 compared to the prior year. The decrease was primarily due to a $3.4 million milestone obligation that was achieved in the third quarter of 2019 and a decrease of $0.8 million of interest expense related to the Deerfield Credit Facility, which was extinguished in the third quarter of 2019, partially offset by an increase in interest expense from the MidCap Credit Facility of $2.3 million in 2020.

The loss on extinguishment of debt for the year ended December 31, 2020 was primarily due to the third amendment to the MidCap Credit Facility, in addition to the prepayment of the 2020 notes. 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.

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, 2020, we had $122.9 million principal amount of outstanding debt, consisting of:

- $50.0 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%, payable in equal monthly installments beginning in September 2022 through maturity in August 2024;
- $5.0 million principal amount of 2024 convertible notes, 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 was convertible into shares of our common stock at the option of the holder at a conversion price of $3.00 per share. The 2024 convertible notes provided that, under certain circumstances, at our option, we may elect to cause all or any portion of the 2024 convertible notes to be mandatorily converted;
- $63.0 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, $28.0 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.
- $4.9 million from a loan under the Paycheck Protection Program of the CARES Act, all or a portion of which may be forgiven. The PPP Loan matures in April 2022 and bears interest at a rate of 0.98% per annum. Principal and interest payments can be deferred up to ten months after the end of a 24 week covered period unless we are is notified earlier of our loan forgiveness status. In the event the SBA does not authorize loan forgiveness, the deferred principal and interest will be payable to the lender and we will then make equal monthly payments as required to fully amortize the remaining principal amount by April 9, 2022.

In February 2021, we elected to convert the $5.0 million principal amount of 2024 convertible notes into 1,666,667 shares of our common stock in accordance with the terms of the 2024 convertible notes. There can be no assurance that we will have sufficient resources to make any required repayments of principal under the MidCap Credit Facility, the Mann Group promissory notes, or unforgiven amounts of the PPP Loan. The Mann Group convertible note is 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 under the MidCap Credit Facility, or if we fail to repay the Mann Group promissory notes, borrowings under the MidCap Credit Facility or unforgiven amounts of the PPP Loan, 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 liabilities and other 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, 2020, we used $28.1 million of cash for our operating activities, which reflects our net loss of $57.2 million, partially offset by non-cash charges of $38.9 million (including $13.2 million for the write-off of in-process research and development related to the acquisition of QrumPharma). The net change in operating asset and liabilities was primarily a result of the recognition of deferred revenue of $32.8 million, which was partially offset by the receipt of milestone payments from UT of $25.0 million and pass-through payments of $1.9 million.

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.

Cash provided by investing activities of $15.2 million for the year ended December 31, 2020 was primarily due to the proceeds from the sale of treasury bills of $20.0 million, partially offset by $4.0 million of cash consideration paid for the acquisition of QrumPharma, net of $0.2 million of cash acquired, in addition to $0.5 million of related transaction costs.

Cash used in investing activities was $22.8 million for the year ended December 31, 2019, which consisted of a purchase of treasury bills of $45.0 million, partially offset by proceeds from sales of treasury bills of $25.0 million.

Cash provided by financing activities of $49.9 million for the year ended December 31, 2020 was primarily due to the receipt of $23.5 million in gross proceeds from at the market offerings, the exercise of outstanding warrants to purchase shares of our common stock of $11.6 million, proceeds from the MidCap Credit Facility of $10.0 million and proceeds from the PPP Loan of $4.9 million.

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.

Future Liquidity Needs and Going Concern

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, 2020, we had an accumulated deficit of $3.0 billion and $122.9 million of total principal amount of outstanding borrowings, with limited capital resources of $67.0 million in cash and cash equivalents. 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 $25.0 million borrowings that may become available under the MidCap Credit Facility (which, in turn, requires us to grow Afrezza revenue before we can access such funds). The various stay-at-home orders implemented around the country in response to the COVID-19 pandemic have negatively impacted the sales of Afrezza by limiting the access of our sales force to physicians. The COVID-19 pandemic is expected to continue to negatively impact our near-term revenues from Afrezza.

Our ability to draw the $25.0 million Tranche 3 of the MidCap Credit Facility depends on the satisfaction of certain milestone conditions associated with Tyvaso DPI and other financial covenants. In the event the milestone conditions are not achieved or our capital resources are not sufficient, we may need to raise additional capital by either 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. In addition, the COVID-19 pandemic continues to have the potential for disruption of global financial markets. This disruption, if it occurs, could prevent us or make it more difficult for us to access capital or make it difficult to comply with the covenants contained in the MidCap Credit Facility, which could negatively affect our liquidity. 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.

The impact of the COVID-19 pandemic on Afrezza sales also increased the risk of non-compliance with a covenant relating to trailing twelve-month minimum Afrezza net revenue, tested on a monthly basis, which is set forth in the MidCap Credit Facility Agreement, as amended. In November 2020, we entered into an amendment to the MidCap Credit Facility, pursuant to which the minimum cash requirement was increased to $30.0 million. If we fail to meet the minimum Afrezza net revenue covenant, any outstanding borrowings, together with accrued interest, under the MidCap Credit Facility could be declared immediately due and payable. 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.

We may not have sufficient resources to make any required repayments of principal under the terms of our indebtedness when required. 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 MidCap Term Loan, or if we fail to repay or repurchase the MidCap Term Loan, PPP 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 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, 2020 and 2019, 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 2020 and other new accounting standards that have been issued by the FASB but are not effective until after December 31, 2020.

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%, the interest rate under the 2024 convertible notes was fixed at 5.75%, and the interest rate under the PPP Loan is fixed at 0.98%. See Note 7 – Borrowings for information about the principal amount of outstanding debt.

If a change in one-month LIBOR interest rates equal to 10% of the one-month LIBOR interest rates on December 31, 2020 were to have occurred, this change would not have had a material effect on our interest payment obligation.

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. For the year ended December 31, 2020, we realized an $8.0 million currency loss, which was included in loss on foreign currency translation in the accompanying consolidated statements of operations.

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, 2020 were to have occurred, this change would have resulted in a foreign currency impact to our pre-tax loss of approximately $9.5 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, 2020.

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, 2020.

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, 2020. 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, 2020, our internal control over financial reporting was effective based on those criteria.

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.

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 2021 Annual Meeting of Stockholders (the "Proxy Statement"), to be filed with the SEC on or before April 30, 2021, and is incorporated herein by reference.

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

Item 11. ***Executive Compensation***

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

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

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

Item 13. ***Certain Relationships 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 Accountant 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 and 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 55:

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
2.1	Purchase Agreement, dated December 7, 2020 by and among the Company, the Acquired Company, the Sellers and the Securityholders' Representative (incorporated by reference to Exhibit 2.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on December 7, 2020).
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	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 May 27, 2020).
3.5	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on May 27, 2020).
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3, 3.4 and 3.5.
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 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).
4.6	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).
4.7	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
4.8	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).
4.9	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).
4.10	Promissory Note, dated April 9, 2020, by and between MannKind Corporation and JPMorgan Chase Bank, N.A. (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 15, 2020).
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 May 7, 2020 by and between MannKind and Alejandro Galindo.
10.5*	Offer Letter, dated August 11, 2003, by and between MannKind and Joseph Kocinsky.
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, 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 5, 2020).
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).
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).

Exhibit Number	Description of Document
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.
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***	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).
10.35	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).
10.36	Amendment No. 2 to Credit and Security Agreement, dated August 21, 2020, by and among MannKind Corporation, MannKind LLC and MidCap Financial Trust (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 25, 2020).
10.37	Amendment No. 3 to Credit and Security Agreement, dated November 30, 2020, by and among MannKind Corporation, MannKind LLC and MidCap Financial Trust (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 1, 2020).
10.38	Amendment No. 4 to Credit and Security Agreement, dated December 7, 2020 by and among the Company, MannKind LLC and MidCap Financial Trust (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 7, 2020).
10.39	Omnibus Joinder and Amendment No. 5 to Credit and Security Agreement and Amendment No. 1 to Pledge Agreement, dated December 29, 2020 by and among MannKind Corporation, MannKind LLC, QrumPharma, Inc., and MidCap Financial Trust (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 30, 2020).
23.1	Consent of Independent Registered Public Accounting Firm.

Exhibit Number	Description of Document
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.
104	The cover page has been formatted in Inline XBRL.

* 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, 2021

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, 2021
/s/ Steven B. Binder Steven B. Blinder	Chief Financial Officer *(Principal Financial and Accounting Officer)*	February 25, 2021
/s/ James S. Shannon James S. Shannon, M.D., MRCP (UK)	Chairman of the Board of Directors	February 25, 2021
/s/ Ronald J. Consiglio Ronald J. Consiglio	Director	February 25, 2021
/s/ Michael Friedman Michael Friedman, M.D.	Director	February 25, 2021
/s/ Jennifer Grancio Jennifer Grancio	Director	February 25, 2021
/s/ Anthony C. Hooper Anthony C. Hooper	Director	February 25, 2021
/s/ Sabrina Kay Sabrina Kay	Director	February 25, 2021
/s/ Kent Kresa Kent Kresa	Director	February 25, 2021
/s/ Christine Mundkur Christine Mundkur	Director	February 25, 2021

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, 2020 and 2019, 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, 2020 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, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with the accounting principles generally accepted in the United States of America.

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. Management's plans in regard to these matters are also described in Note 1. 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing and opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Net Revenue – Commercial Product Sales – Government and Payer Rebates Refer to Note 2 to the financial statements

Critical Audit Matter Description

As more fully disclosed in Note 2 to the financial statements, the Company recognizes revenue for commercial product sales net of applicable reserves for variable consideration, including trade discounts and allowances, product returns, provider chargebacks and discounts, government rebates, payer rebates, and other incentives, such as voluntary patient assistance. Government rebates are provided to Medicare and state Medicaid programs. Payer rebates are provided to certain private payer organizations, primarily insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of the Company's products. Government and payer rebates involve the use of significant assumptions and judgments to estimate claims from prior quarters for which an invoice has not yet been received, estimate claims for the current quarter, and estimate future claims that will be made for product that has been sold to the distributor and recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period. These significant assumptions and judgments include consideration of legal interpretations of applicable laws and regulations, historical claims experience, payer channel mix, current contract prices under applicable programs, unbilled claims, processing time lags and inventory in the distribution channel.

Given the complexity involved in determining the significant assumptions and judgments used in estimating the government and payer rebates, auditing such estimates required a high degree of auditor judgment and increased extent of audit effort.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to management's estimates of government and payer rebates included the following, among others:

- We evaluated key inputs used in management's analysis of the government and payer rebate estimates.
- We inspected contractual documents associated with the government and payer rebates and evaluated the consistency of the methodology with the Company's obligations under such contractual documents.
- We tested the mathematical accuracy of the Company's calculation of the estimates for government and payer rebates.
- We performed the following procedures to evaluate the significant assumptions and judgments used by management to estimate government and payer rebates:
    - Evaluated the reasonableness of government and payer rebates by comparing the underlying data to historical adjustments.
    - Compared management's assumptions of expected government and payer rebates to actuals incurred subsequent to year end to identify potential bias in the determination of government and payer rebates.

/s/ Deloitte & Touche LLP

Los Angeles, California
February 25, 2021

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

MANNKIND CORPORATION AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2020	2019
	(In thousands except share and per share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 67,005	$ 29,906
Restricted cash	158	316
Short-term investments	—	19,978
Accounts receivable, net	4,218	3,513
Inventory	4,973	4,155
Prepaid expenses and other current assets	3,122	2,889
Total current assets	79,476	60,757
Property and equipment, net	25,867	26,778
Other assets	3,265	6,190
Total assets	$ 108,608	$ 93,725
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 5,582	$ 4,789
Accrued expenses and other current liabilities	19,707	15,904
Paycheck Protection Program loan — current	4,061	—
Short-term note payable	—	5,028
Deferred revenue — current	33,275	32,503
Recognized loss on purchase commitments — current	11,080	7,394
Total current liabilities	73,705	65,618
Promissory notes	63,027	70,020
Accrued interest — promissory notes	4,150	2,002
Long-term Midcap credit facility	49,335	38,851
Senior convertible notes	5,000	5,000
Recognized loss on purchase commitments — long term	84,208	84,639
Operating lease liability	1,202	2,514
Deferred revenue — long term	1,662	8,344
Milestone rights liability	5,926	7,263
Paycheck Protection Program loan — long term	812	—
Total liabilities	289,027	284,251
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, 2020 and 2019	—	—
Common stock, $0.01 par value — 400,000,000 and 280,000,000 shares authorized, 242,117,089 and 211,787,573 shares issued and outstanding at December 31, 2020 and 2019, respectively	2,421	2,118
Additional paid-in capital	2,866,303	2,799,278
Accumulated other comprehensive loss	—	(19)
Accumulated deficit	(3,049,143)	(2,991,903)
Total stockholders' deficit	(180,419)	(190,526)
Total liabilities and stockholders' deficit	$ 108,608	$ 93,725

See notes to consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2020	2019
	(In thousands except per share data)	
Revenues:		
Net revenue — commercial product sales	$ 32,324	$ 25,304
Revenue — collaborations and services	32,820	37,734
Total revenues	65,144	63,038
Expenses:		
Cost of goods sold	15,084	20,078
Cost of revenue — collaborations and services	9,557	7,901
In-process research and development	13,233	—
Research and development	6,248	6,900
Selling, general and administrative	59,040	74,669
Impairment of commitment asset	1,889	—
Loss (gain) on foreign currency translation	8,006	(1,913)
Total expenses	113,057	107,635
Loss from operations	(47,913)	(44,597)
Other (expense) income:		
Interest income	167	997
Interest expense on notes	(4,316)	(6,304)
Interest expense on promissory notes	(5,155)	(4,602)
(Loss) gain on extinguishment of debt	(264)	3,529
Other expense	23	(926)
Total other expense	(9,545)	(7,306)
Loss before income tax expense	(57,458)	(51,903)
Benefit from income taxes	218	—
Net loss	$ (57,240)	$ (51,903)
Net loss per share — basic and diluted	$ (0.26)	$ (0.27)
Shares used to compute net loss per share — basic and diluted	222,585	195,584

See notes to consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Year Ended December 31,	
	2020	2019
	(In thousands)	
Net loss	$ (57,240)	$ (51,903)
Other comprehensive loss:		
Cumulative translation loss	(19)	—
Comprehensive loss	$ (57,259)	$ (51,903)

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, 2019	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)
Net issuance of common stock in association with stock options and restricted stock units	653	6	227	—	—	233
Payment of principal on senior convertible notes through common stock issuance	2,612	26	5,235	—	—	5,261
Payment of interest on senior convertible notes through common stock issuance	188	2	286	—	—	288
Issuance of common stock pursuant to conversion of Mann Group convertible note principal	2,800	28	6,972	—	—	7,000
Issuance of common stock pursuant to conversion of the Mann Group convertible note interest	1,200	12	2,988	—	—	3,000
Issuance of common stock in at-the-market offering	11,853	118	23,412	—	—	23,530
Issuance cost associated with at-the-market offering	—	—	(519)	—	—	(519)
Issuance of common stock under Employee Stock Purchase Plan	627	6	678	—	—	684
Issuance of common stock from acquisition	3,067	31	9,219	—	—	9,250
Stock-based compensation expense	—	—	6,511	—	—	6,511
Issuance of common stock from the exercise of warrants	7,250	73	11,527	—	—	11,600
Issuance of common stock from market price stock purchase	80	1	214	—	—	215
Issuance of warrants pursuant to Midcap Credit Facility	—	—	275	—	—	275
Cumulative translation loss	—	—	—	19	—	19
Net loss	—	—	—	—	(57,240)	(57,240)
BALANCE, DECEMBER 31, 2020	242,118	$ 2,421	$ 2,866,303	$ —	$ (3,049,143)	$ (180,419)

See notes to consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2020	2019
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (57,240)	$ (51,903)
Adjustments to reconcile net loss to net cash used in operating activities:		
In-process research and development	13,233	—
Payment-in-kind interest on promissory notes	—	(32,822)
Interest expense on promissory notes	5,148	4,712
Stock-based compensation expense	6,511	6,203
Asset impairment	1,889	—
Loss (Gain) on foreign currency translation	8,006	(1,913)
Loss (Gain) on extinguishment of debt	264	(3,529)
Amortization of right-of-use assets	1,177	1,182
Depreciation, amortization and accretion	2,149	972
Loss on warrant transactions	—	868
Write-off of inventory	496	—
Other, net	19	107
Changes in operating assets and liabilities:		
Accounts receivable, net	(705)	504
Inventory	(1,314)	(558)
Prepaid expenses and other current assets	(154)	(333)
Other assets	227	(549)
Accounts payable	793	(593)
Accrued expenses and other current liabilities	3,346	2,821
Deferred revenue	(5,910)	(6,717)
Recognized loss on purchase commitments	(4,751)	(4,395)
Operating lease liabilities	(1,312)	(995)
Accrued interest on Mann Group promissory notes	—	(1,545)
Net cash used in operating activities	(28,128)	(88,483)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of treasury bills	20,000	24,993
Acquisition of in-process research and development, net of cash acquired	(3,983)	—
Purchase of treasury bills	—	(44,971)
Purchase of property and equipment	(801)	(2,565)
Purchase of limited liability company ownership interest	—	(300)
Net cash provided by (used in) investing activities	15,216	(22,843)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from at the market offering	23,450	3,199
Issuance costs associated with at the market offering	(518)	(60)
Issuance of common stock from the exercise of warrants	11,600	5,900
Proceeds from MidCap Credit Facility	10,000	40,000
Proceeds from Paycheck Protection Program Loan	4,873	—
Payment of employment taxes related to vested restricted stock units and exercise of stock options	233	124
Proceeds from market price stock purchase plan	215	—
Proceeds from promissory notes	—	70,051
Proceeds from senior convertible notes	—	9,910
Principal payments on promissory notes	—	(38,264)
Principal payments on senior convertible notes	—	(11,081)
Principal payments on facility financing obligation	—	(6,920)
Milestone payment	—	(1,643)
Issuance cost associated with MidCap Credit Facility	—	(886)
Repurchase of warrants	—	(433)
Issuance cost associated with promissory notes	—	(33)
Net cash provided by financing activities	49,853	69,864
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	36,941	(41,462)
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING OF PERIOD	30,222	71,684
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, END OF PERIOD	$ 67,163	$ 30,222
SUPPLEMENTAL CASH FLOWS DISCLOSURES:		
Interest paid in cash, net of amounts capitalized	$ 3,558	$ 1,757
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Issuance of common stock for acquisition of in-process research and development	9,250	—
Payment on promissory notes through issuance of common stock	7,000	8,000
Payment on interest of promissory notes through issuance of common stock	3,000	—
Payment of senior convertible notes through common stock issuance	5,261	4,500
Common stock issuance to settle employee stock purchase plan liability	684	656
Payment of interest on senior convertible notes through common stock issuance	288	1,075
Issuance of warrants associated with MidCap Credit Facility	275	1,854
Receivable from at the market offering	226	—
Non-cash construction in progress and property and equipment	92	—
Addition of right-of-use assets upon adoption of new lease guidance	—	5,192
Payment of facility obligation through common stock issuance	—	4,575

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 patients with endocrine and orphan lung diseases. The Company's development team is capable of taking a compound from early formulation feasibility studies to a full commercial-scale manufacturing operation. The Company's commercial team includes a specialty sales force that calls on endocrinologists and selected primary care physicians, as well as supporting functions that are directed to improving market access and delivering patient and physician support programs.

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, 2020, the Company had an accumulated deficit of $3.0 billion and $122.9 million of total principal amount of outstanding borrowings, with limited capital resources of $67.0 million in cash and cash equivalents. Further, the ongoing COVID-19 pandemic has adversely impacted the Company's Afrezza net sales and could impact the ability to access capital and comply with covenants under debt covenants. These financial conditions raise substantial doubt about the Company's ability to continue as a going concern.

In August 2019, the Company and its wholly owned subsidiaries, entered into a credit and security agreement with MidCap Financial Trust (as amended, the "MidCap Credit Facility") to restructure its existing debts and to provide additional operating capital (the "recapitalization") (Refer to Note 7 – Borrowings for further details). The MidCap Credit Facility provides a secured term loan facility with an aggregate principal amount of up to $75.0 million, of which $50.0 million was outstanding as of December 31, 2020. The remaining $25.0 million will be available to the Company between October 1, 2021 and March 31, 2022, subject to the satisfaction of certain milestone conditions associated with Tyvaso DPI through the Company's collaboration with United Therapeutics (see Note 8 – Collaboration, Licensing and Other Arrangements for more information on the collaboration agreement with United Therapeutics).

Principal payments on the MidCap Credit Facility will begin in September 2022. Under the MidCap Credit Facility, the Company must comply with certain covenants, which includes requirements to maintain a minimum of $30.0 million of unrestricted cash and cash equivalents as well as meet certain minimum Afrezza net revenue trailing twelve-month thresholds, tested on a monthly basis.

The Company's capital resources may not be sufficient to continue to meet its current and anticipated obligations, including the need to maintain compliance with its debt covenants, over the next twelve months if the Company cannot increase its operating cash inflows by growing its revenue or obtaining access to the remaining $25.0 million in 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 reduce the scope of its commercial 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. Changes were made to Note 12 – Stock Award Plans to separately disclose the stock-based compensation expense related to the employee stock purchase plan from the expense for restricted stock units ("RSUs") and stock options for 2019. In addition, changes were made to the consolidated statements of cash flows for 2019 to reclassify operating lease payments from operating lease liabilities to accrued expenses and other current liabilities.

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 or assumptions. 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 and the COVID-19 pandemic has increased the level of judgment used by management in developing these estimates and assumptions. The COVID-19 pandemic continues to rapidly evolve and the ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. These effects could have a material impact on the estimates and assumptions used in the preparation of the accompanying consolidated financial statements. The more significant estimates 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 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 Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers*, 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 payers 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 generally at delivery for specialty pharmacies. Product revenues are recorded net of applicable reserves including discounts, allowances, rebates, returns and other incentives. See *Reserves for Variable Consideration* below.

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. The Company excludes such amounts related to these programs from both gross and net revenue. The cost of product associated with the free goods program is recognized as cost of goods sold in the consolidated statements of operations.

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, payer rebates, and other incentives, such as voluntary patient assistance, and other allowances that are offered within contracts between the Company and its Customers, payers, and other indirect customers relating to the Company's sale of its products. These reserves, as further 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. Significant judgments are required in making these estimates.

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 that 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, 2020 and, therefore, the transaction price was not reduced further during the year ended December 31, 2020. 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.

Significant judgment is required in estimating gross-to-net adjustments considering legal interpretations of applicable laws and regulations, historical experience, payer channel mix, current contract prices under applicable programs, unbilled claims, processing time lags and inventory levels in the distribution channel.

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. Adjustments to the returns reserve have been made in the past and may be necessary in the future based on revised estimates to our assumptions.

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 that 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 that is included in accrued expenses and other current liabilities. Estimates around Medicaid have historically required significant judgment due to timing lags in receiving invoices for claims from states. 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. The Company's estimates include consideration of historical claims experience, payer channel mix, current contract prices, unbilled claims, claim submission time lags and inventory in the distribution channel.

Payer Rebates — The Company contracts with certain private payer 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, including estimates for product that has been recognized as revenue, but which remains in the distribution channel, 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. The Company's estimates include consideration of historical claims experience, payer channel mix, current contract prices, unbilled claims, claim submission time lags and inventory in the distribution channel.

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 payers. 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 that 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 conduct 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. Amounts that the Company expects will not be recognized within the next 12 months are classified as long-term deferred revenue. For

further information see Note 8 – Collaboration, Licensing and Other Arrangements.

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, provides research and development services and offers sales support for the co-promotion of products, 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,	
	2020	2019
Deferred revenue:		
Beginning balance	$ 40,847	$ 47,565
Upfront and milestone payments	25,000	25,000
Pass through payments	1,910	6,016
Revenue — collaborations and services	(32,820)	(37,734)
Ending balance	$ 34,937	$ 40,847

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.

Paycheck Protection Program Loan — On April 10, 2020, the Company received the proceeds from a loan in the amount of approximately $4.9 million (the "PPP Loan") from JPMorgan Chase Bank, N.A., as lender, pursuant to the Paycheck Protection Program ("PPP") of the CARES Act. The Company accounted for the PPP Loan as a financial liability in accordance with ASC Topic 470, *Debt*. Accordingly, the PPP Loan was recognized as current and long-term debt in the Company's consolidated balance sheets and is included as Paycheck Protection Program loan — current and Paycheck Protection Program loan — long term. In addition, a *di minimis* amount of accrued interest is included in accrued expenses and other current liabilities. See Note 7 – *Borrowings* for additional information.

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. The cost of goods sold excludes the cost of insulin purchased under our Insulin Supply Agreement. All insulin inventory on hand was written off and the full purchase commitment contract to purchase future insulin was accrued as a recognized loss on purchase commitments as of the end of 2015.

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, 2020 and 2019, 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,	
	2020	2019
Cash and cash equivalents	$ 67,005	$ 29,906
Restricted cash	158	316
Total cash, cash equivalents, and restricted cash	$ 67,163	$ 30,222

Short-term Investments — The Company's short-term investments consist of U.S. Treasury securities stated at amortized cost that 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. As of December 31, 2020, the Company did not hold any short-term investments. Short-term investments as of December 31, 2019 were $20.0 million. The Company did not record any material gains or losses on these investment securities during the year ended December 31, 2019.

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.

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,	
	2020	2019
Accounts Receivable, gross	$ 8,090	$ 6,925
Wholesaler distribution fees and prompt pay discounts	(1,205)	(1,767)
Reserve for returns	(2,667)	(1,645)
Accounts receivable, net	$ 4,218	$ 3,513

As of December 31, 2020 and December 31, 2019, the allowance for doubtful accounts was *de minimis*. As of December 31, 2020 and December 31, 2019, the Company had three wholesale distributors representing approximately 86% and 96% of gross sales and 90% and 94% of accounts receivable, 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 is considered to be unrecoverable.

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.

In August 2019, the Company recorded a $1.5 million commitment asset and a $0.4 million other asset for deferred debt issuance costs related to the future funding commitments of the MidCap Credit Facility. A quarterly assessment was performed to determine if the Company was on target to achieve certain required milestone conditions in order for the Company to access further borrowings under the MidCap Credit Facility. The Company determined that such milestone conditions related to Afrezza trailing net revenue were unlikely to be achieved. As a result, an asset impairment of $1.9 million was recognized during the second quarter of 2020 and is reflected in the Company's consolidated statement of operations. See Note 7 – *Borrowings* for further information on the MidCap Credit Facility.

The Company recorded no asset impairments for the year ended December 31, 2019.

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, 2020 and 2019 was $95.3 million and $*92.0* million, respectively. No new contracts were identified in 2020 that required a new loss on purchase commitment accrual.

Milestone Rights Liability — On July 1, 2013, in conjunction with the execution of a financing facility with Deerfield Private Design Fund II L.P. and Deerfield Private Design International I L.P, the Company issued to Deerfield Private Design Fund II, L.P. and Horizon Santé FLML SÁRL (the "Milestone Purchasers") certain rights to receive payments of up to $90.0 million, of which $70.0 million remains payable as of December 31, 2020, upon the occurrence of specified strategic and sales milestones, including the achievement of specified net sales figures (the "Milestone Rights"). The Company analyzed the Milestone Rights and determined that they did not meet the definition of a freestanding derivative. Since the Company has not elected to apply the fair value option to the Milestone Rights, the Company recorded them 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).

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.

For uncertain tax positions, the Company determines whether it is "more likely than not" that a tax position will be sustained upon examination by the appropriate taxing authorities before any part of the benefit can be recorded in the financial statements. For those tax positions where it is "not more likely than not" that a tax benefit will be sustained, no tax benefit is recognized. Penalties, if probable and reasonably estimable, are recognized as a component of income tax expense. The Company has reduced its deferred tax assets for uncertain tax positions but has not recorded liabilities for income tax expense, penalties, or interest.

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, RSUs, performance-based non-qualified stock options awards ("PNQs"), restricted stock units with market conditions ("Market RSUs") 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. RSUs 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 — In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326)*, The Company adopted this standard as of January 1, 2020. This update introduces the current expected credit loss (CECL) model, which requires an entity to measure credit losses for certain financial instruments and financial assets, including trade receivables. Under this update, on initial recognition and at each reporting period, an entity is required to recognize an allowance that reflects the entity's current estimate of credit losses expected to be incurred over the life of the financial instrument. The adoption of this standard did not have a material impact 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 Topic 808 are within the scope of the new revenue guidance when the collaborative arrangement participant is a customer. The Company adopted this pronouncement in 2020 with no impact on the consolidated financial statements.

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. The Company adopted this pronouncement in 2020 with no impact on the 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 March 2020, the FASB issued a new accounting standard to ease the financial reporting burdens of the expected market transition from the London Interbank Offered Rate (LIBOR) and other interbank offered rates to alternative reference rates, commonly referred to as reference rate reform. The new standard provides temporary optional expedients and exceptions to current GAAP guidance on contract modifications and hedge accounting. Specifically, a modification to transition to an alternative reference rate is treated as an event that does not require contract remeasurement or reassessment of a previous accounting treatment. We are currently evaluating the impact on our consolidated financial statements.

3. Acquisition

On December 7, 2020, the Company acquired QrumPharma, Inc., a privately held pharmaceutical company developing inhalation treatments for severe chronic and recurrent pulmonary infections, including Nontuberculous Mycobacterial (NTM) lung disease. The Company purchased all of the outstanding capital stock of QrumPharma for consideration consisting of cash and shares of the Company's common stock, subject to adjustment for cash on hand, unpaid indebtedness, unpaid transaction expenses, and net working capital as follows (in thousands):

Consideration		
Cash consideration	$	3,574
Stock consideration (3,067,179 shares at $3.01 per share)		9,250
Transaction costs		531
Repayment of debt		11
Liabilities assumed		22
Cash acquired		(155)
Total consideration paid for IPR&D	$	13,233

The stock purchase of QrumPharma was accounted for under ASC 805, *Business Combinations*, as an asset acquisition since the transaction did not include the acquisition of inputs or processes and the fair value of the assets acquired were concentrated in a single identifiable asset, QRM-003 (a nebulized version of clofazimine), which consisted of an in-process research and development asset ("IPR&D"). Under ASC 805, an entity that acquires IPR&D in an asset acquisition should follow the guidance in ASC 730, Research and Development, which requires that both tangible and intangible identifiable research and development assets with no alternative future use be allocated a portion of the consideration transferred and charged to expense at the acquisition date. Due to the stage of development of QRM-003 at the date of acquisition, significant risk remained that the product would not obtain regulatory approval and it was not yet probable that there would be future economic benefit for the Company. Absent successful clinical results and regulatory approval, it was determined that there was no alternative future use associated with QRM-003. Accordingly, the value of this asset was expensed at the time of acquisition and the total accumulated cost of $13.2 million, was allocated to the IPR&D asset using a relative fair value basis and the total consideration was recognized as in-process research and development expense in the consolidated statement of operations.

The acquisition of QrumPharma also included a potential future royalty payment of 1.5% of net sales in each of the calendar years in which the total annual and global adjusted net sales of specified products exceeds $50 million and a royalty payment of 1.0% of net sales in each of the calendar years in which the total annual and global adjusted net sales of nebulized clofazimine are greater than or equal to $200 million. The contingent consideration in the form of royalty payments will be expensed as incurred since the probability of QRM-003 obtaining FDA approval and generating net sales that exceed the specified thresholds could not be reasonably estimated on the date of acquisition.

4. Inventories

Inventories consist of the following (in thousands):

	December 31,	
	2020	**2019**
Raw materials	$ 1,393	$ 1,751
Work-in-process	2,484	1,432
Finished goods	1,096	972
Total inventory	$ 4,973	$ 4,155

Work-in-process and finished goods as of December 31, 2020 and 2019 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, 2020 and 2019, which consisted of FDKP received in November 2019 that will be used to manufacture Afrezza under an enhanced manufacturing process for FDKP. The Company expects to receive FDA approval of the new source of FDKP in 2023, after which the pre-launch raw materials inventory will be reclassified as raw materials inventory for use in the manufacturing of Afrezza and Tyvaso DPI.

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, 2020 and 2019. Inventory that was forecasted to become obsolete due to expiration is recorded in costs of goods sold in the accompanying consolidated statements of operations. For the year ended December 31, 2020, there was an inventory write-off of $0.5 million as a result of this assessment. There was no inventory write-off for the year ended December 31, 2019.

5. Property and Equipment

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

	Estimated Useful Life (Years)	December 31, 2020	December 31, 2019
Land	—	$ 875	$ 875
Buildings	39-40	17,389	17,389
Building improvements	5-40	37,543	37,543
Machinery and equipment	3-15	55,054	54,982
Furniture, fixtures and office equipment	5-10	3,004	3,005
Computer equipment and software	3	8,319	8,234
Construction in progress	—	503	114
		122,687	122,142
Less accumulated depreciation		(96,820)	(95,364)
Total property and equipment, net		$ 25,867	$ 26,778

Depreciation expense related to property and equipment for the years ended December 31, 2020 and 2019 was $1.8 million and $1.6 million, respectively. During the year ended December 31, 2020, the Company retired $0.3 million of manufacturing and lab equipment as it was no longer in service. During the year ended December 31, 2019, the Company retired of $6.7 million of manufacturing equipment and computer hardware as it was no longer in service. The net book value for the disposed assets was *de minimis*.

6. Accrued Expenses and Other Current Liabilities

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

	December 31, 2020	December 31, 2019
Salary and related expenses	$ 11,250	$ 8,835
Discounts and allowances for commercial product sales	3,688	3,162
Deferred lease liability	1,422	1,433
Professional fees	533	620
Accrued interest	519	409
Sales and marketing services	99	147
Other	859	1,298
Current portion of milestone rights liability	1,337	—
Accrued expenses and other current liabilities	$ 19,707	$ 15,904

Included in salary and related expenses is $1.0 million of deferred social security taxes as permitted under the CARES Act. The Company is permitted to defer the employer share of social security taxes otherwise owed on dates beginning March 27, 2020 and ending December 31, 2020. Half of the total deferred payments are payable on December 31, 2021 and the remaining half are payable on December 31, 2022. The amount of the deferral is based on wages paid from April through December 2020. This deferral option is no longer available if the Company receives forgiveness for its PPP Loan as discussed in Note 7 – Borrowings.

7. Borrowings

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

	December 31, 2020	December 31, 2019
Mann Group promissory notes	$ 63,027	$ 70,020
MidCap Credit Facility	49,335	38,851
Senior notes (2024 convertible notes)	5,000	10,028
PPP Loan	4,873	—
Total debt — net carrying amount	$ 122,235	$ 118,899

The following table provides a summary of the Company's debt and key terms:

	Amount Due		Terms		
	December 31, 2020	December 31, 2019	Annual Interest Rate	Maturity Date	Conversion Price
Mann Group convertible note	$28.0 million (plus $0.6 million accrued interest paid-in-kind)	$35.0 million (plus $1.0 million accrued interest paid-in-kind)	7.00%	November 2024	$2.50 per share
Mann Group non-convertible note	$35.1 million (plus $3.6 million accrued interest paid-in-kind)	$35.1 million (plus $1.0 million accrued interest paid-in-kind)	7.00%	November 2024	N/A
MidCap Credit Facility	$50.0 million	$40.0 million	one-month LIBOR (2% floor) plus 6.75%	August 2024	N/A
2024 convertible notes	$5.0 million	$5.0 million	5.75%	November 2024	$3.00 per share
June 2020 note	—	$2.6 million	—	June 2020	N/A
December 2020 note	—	$2.6 million	—	December 2020	N/A
PPP Loan	$4.9 million	—	0.98%	April 2022	N/A

The maturities of our borrowings as of December 31, 2020 are as follows (in thousands):

	Amounts
2021	4,061
2022	9,145
2023	25,000
2024	84,718
Total principal payments	122,924
Unamortized discount	(665)
Debt issuance costs	(24)
Total debt	$ 122,235

MidCap Credit Facility — In August 2019, the Company closed the MidCap Credit Facility, which provides a secured term loan facility with an aggregate principal amount of up to $75.0 million. The Company borrowed the first advance of $40.0 million ("Tranche 1") in August 2019 and the second advance of $10.0 million ("Tranche 2") in December 2020. Under the terms of the MidCap Credit Facility, the third advance of $25.0 million ("Tranche 3") will be available to the Company between October 1, 2021 and March 31, 2022, subject to the satisfaction of certain milestone conditions associated with Tyvaso DPI through the Company's collaboration with United Therapeutics (see Note 8 – Collaboration, Licensing and Other Arrangements).

In December 2019, the Company entered into the first amendment 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.

In August 2020, the Company entered into the second amendment to the MidCap Credit Facility, pursuant to which the parties agreed that no breach of the minimum Afrezza net revenue covenant for any trailing twelve-month reporting period between July 31, 2020 and November 30, 2020 will be deemed to occur if the Company delivers satisfactory evidence that it had unrestricted cash of at least $40.0 million. Without this amendment, the Company would have been in violation of the minimum Afrezza net revenue covenant as of September 30, 2020.

In November 2020, the Company entered into the third amendment to the MidCap Credit Facility, pursuant to which the parties agreed to (i) amend the conditions to draw Tranche 2, which had become unavailable, such that the advance became available and was, in fact, funded to the Company on December 1, 2020, (ii) amend the conditions to the third advance of $25.0 million such that the third advance is available upon the satisfaction of certain conditions, including certain milestone conditions associated with Tyvaso DPI, (iii) add a covenant that requires the marketing of Tyvaso DPI if the third advance of $25.0 million is funded, (iv) amend the financial covenant relating to trailing twelve month minimum Afrezza Net Revenue (as defined in the MidCap Credit Facility) requirements, (v) increase the minimum cash covenant to $30.0 million at all times, (vi) extend the interest only period until September 1, 2022, at which time principal on each term loan advance is payable in 24 equal monthly installments, and (vii) amend the prepayment fees.

In connection with the extension of the interest only period for the $40.0 million drawn under Tranche 1, a $0.2 million loss on extinguishment was recognized in the consolidated statement of operations for the year ended December 31, 2020. The funding of $10.0 million under Tranche 2 resulted in the recognition of approximately $0.3 million of debt discount and a *de minimis* amount of debt issuance costs. As of December 31, 2020, the unamortized debt discount was $0.4 million for Tranche 1 and $0.3 million for Tranche 2.

In December 2020, the Company entered into the fourth and fifth amendments to the MidCap Credit Facility. Pursuant to the fourth amendment, MidCap consented to the acquisition by the Company of QrumPharma (see Note 3 – Acquisition). Pursuant to the omnibus joinder and fifth amendment, QrumPharma was joined as a borrower to the MidCap Credit Facility and to certain related financing documents.

Tranche 1, Tranche 2 and, if borrowed, Tranche 3, each accrues interest at an annual rate equal to the 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 24 equal monthly installments beginning September 1, 2022, until paid in full on August 1, 2024, and the principal on the term loan advance under Tranche 3 is payable beginning on the later of (i) September 1, 2022, 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 2.00% of principal prepaid if prepayment occurs on or prior to June 30, 2021; 4.00% of principal prepaid if prepayment occurs on or after July 1, 2021 through and including June 30, 2022; 3.00% of principal prepaid if prepayment occurs on or after July 1, 2022 through and including June 30, 2023; and 2.00% of principal prepaid if prepayment occurs on or after July 1, 2023 through the maturity 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, as amended, 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 $30.0 million at all times. As of December 31, 2020, 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. As a result of Tranche 2, the Company issued warrants to purchase an aggregate of 111,853 shares of the Company’s common stock, at an exercise price equal to $2.91 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, 2020 and 2019, there was $5.0 million and $10.2 million, respectively, of principal amount of senior notes outstanding.

In August 2019, the Company entered into a privately-negotiated exchange agreement with the holder of the 5.75% Convertible Senior Subordinated Exchange Notes due 2021 (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 5.75% Convertible Senior Subordinated Exchange Notes due November 2024 (the "2024 convertible notes") to such holder in the principal amount of $5.0 million and (iv) issued a $2.6 million note due June 2020 (the "June 2020 note"), a $2.6 million note due December 2020 (the "December 2020 note", and together with the June 2020 note, the "2020 notes"), all in exchange for the cancellation of the $18.7 million in principal amount of the 2021 notes. The 2020 notes were permitted to 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. On June 24, 2020, the Company prepaid the $2.6 million June 2020 note with the issuance of 1,235,094 shares of the Company's common stock (at a conversion price of $2.13 per share), pursuant to the Company's election and in accordance with the terms of the June 2020 note. On October 9, 2020, the Company prepaid the $2.6 million December 2020 note with the issuance of 1,377,356 shares of the Company's common stock (at a conversion price of $1.91 per share), pursuant to the Company's election and in accordance with the terms of the December 2020 note. The number of shares issued for the prepayments on June 24, 2020 and October 9, 2020 were determined based on the Company's closing stock price on the settlement date. As a result of the prepayments, the Company recognized a *de minimis* amount of loss on extinguishment related to unamortized debt discounts.

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 were the Company's general, unsecured obligations, and were subordinated in right of payment to the indebtedness incurred pursuant to the MidCap Credit Facility. The 2024 convertible notes ranked 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 was 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 are convertible, at the option of the holder, at any time on or prior to the close of business on the business day immediately preceding the stated maturity date, into shares of the Company's common stock at 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 occurred while the 2024 convertible notes were outstanding, the principal of, and accrued and unpaid interest on, all of the then outstanding 2024 convertible notes would automatically become due and payable. If an event of default other than certain bankruptcy and insolvency-related events of defaults occurred and continued, 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, could 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. The 2024 convertible notes also contain certain cross default provisions related to other debt obligations.

If the Company underwent certain fundamental changes, except in certain circumstances, each holder of 2024 convertible notes would have had the option to require the Company to repurchase all or any portion of that holder's 2024 convertible notes. The fundamental change repurchase price would 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. Pursuant to this option, subsequent to December 31, 2020, the Company converted the $5.0 million 2024 convertible notes with the issuance of 1,666,667 shares of the Company's common stock, pursuant to the Company's election and in accordance with the terms of the 2024 convertible notes.

Mann Group promissory notes — In August 2019, the Company entered into a privately-negotiated exchange agreement with The Mann Group LLC ("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 a $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 (iv) issued a non-convertible note to the Mann Group in an aggregate principal amount of $35.1 million (the "Mann Group non-convertible note" and, together with the Mann Group convertible note, the "Mann Group promissory notes"), 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 existing Mann Group loan arrangement.

The Mann Group promissory notes 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.

Pursuant to the terms of the Mann Group convertible note, the Mann Group converted $3.0 million of accrued interest and $7.0 million of principal into 1.2 million shares and 2.8 million shares, respectively, of the Company's common stock in the fourth quarter of 2020. Subsequent to December 31, 2020, the Mann Group converted $0.4 million of interest and $9.6 million of principal into 4.0 million shares of common stock.

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.

PPP Loan – On April 10, 2020, the Company received the proceeds from the PPP Loan from JPMorgan Chase Bank, N.A., as lender, in the amount of approximately $4.9 million pursuant to the PPP of the CARES Act. The PPP Loan matures on April 9, 2022 and bears interest at a rate of 0.98% per annum. The PPP Loan is evidenced by a promissory note dated April 9, 2020, which contains customary events of default relating to, among other things, payment defaults and breaches of representations and warranties. The PPP Loan may be prepaid by the Company at any time prior to maturity with no prepayment penalties. All or a portion of the PPP Loan may be forgiven by the U.S. Small Business Administration ("SBA") upon application to the lender by the Company beginning 60 days after loan approval or up to 24 weeks after the date of the loan disbursement (the "covered period"), but not later than ten months after the end of the 24 week covered period, and upon documentation of expenditures in accordance with the SBA requirements. Principal and interest payments can be deferred up to the date the SBA remits the borrower's loan forgiveness amount to the lender. In the event the SBA does not authorize loan forgiveness, the deferred principal and interest will be payable to the lender and the Company will then make equal monthly payments as required to fully amortize the remaining principal amount by April 9, 2022.

Under the CARES Act, loan forgiveness is available for the sum of documented payroll costs, covered rent payments, covered interest and covered utilities during the 24-week period (or eight-week period at the Company's option) beginning on the date of loan approval. For purposes of the CARES Act, payroll costs exclude compensation of an individual employee in excess of $100,000, prorated annually. Not more than 40% of the forgiven amount may be for non-payroll costs. Forgiveness is reduced if full-time headcount declines, or if salaries and wages for employees with salaries of $100,000 or less annually are reduced by more than 25%. In the event the PPP Loan, or any portion thereof, is forgiven pursuant to the PPP, the amount forgiven is applied to outstanding principal. Any unforgiven portion of the PPP Loan will be payable in accordance with the terms of the promissory note as described above.

The Company used all proceeds from the PPP Loan to retain employees, maintain payroll and make lease, interest and utility payments.

Amortization of the premium and accretion of debt issuance costs related to all borrowings for the years ended December 31, 2020 and 2019 are as follows (in thousands):

	Year Ended December 31,	
	2020	2019
Amortization of debt premium	$ —	$ (1,049)
Amortization of debt discount	268	295
Accretion expense — debt issuance cost	(101)	(111)

Milestone Rights — As of December 31, 2020 and 2019, the remaining Milestone Rights liability balance was $7.3 million, 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 by the Milestone Rights. The Company currently estimates that it will reach the next milestone in the first quarter of 2021, at which point the Company will be required to make a $5.0 million payment in the following quarter. The carrying value of the Milestone Rights liability related to this $5.0 million payment is approximately $1.3 million, which represented the fair value related to this payment, that was determined in 2013 (the most recent measurement date). Accordingly, approximately $1.3 million in value related to the next milestone payment was recorded in accrued expenses and other current liabilities and the remaining long-term portion of $5.9 million is included as Milestone Rights liability in the accompanying consolidated balance sheets as of December 31, 2020.

The agreement with the Milestone Purchasers that provides for the Milestone Rights 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 such agreement.

8. Collaboration, Licensing and Other Arrangements

Revenue from collaborations and services for the years ended December 31, 2020 and 2019 are as follows (in thousands):

	Year Ended December 31,	
	2020	2019
UT License Agreement	$ 32,213	$ 31,229
UT Research Agreement	210	6,032
Receptor CLA	250	250
Cipla License and Distribution Agreement	147	148
Biomm Distribution Agreement	—	75
Total revenue from collaborations and services	$ 32,820	$ 37,734

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 ("Tyvaso DPI") and associated inhalation delivery devices. Under the UT License Agreement, UT is responsible for global development, regulatory and commercial activities with respect to Tyvaso DPI. The Company is responsible for manufacturing clinical supplies and commercial supplies of Tyvaso DPI.

Under the terms of the UT License Agreement, the Company received an upfront payment of $45.0 million in October 2018 and four $12.5 million milestone payments between April 2019 and November 2020. The Company will also be entitled to receive low double-digit royalties on net sales of Tyvaso DPI as well as a manufacturing margin on commercial supplies of the product. 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. During the third quarter of 2020, the Company sold $0.4 million of clinical supplies to UT for use in their clinical study, which was recognized as deferred revenue in the accompanying consolidated balance sheet. 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 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 (including a $2.7 million increase in total consideration pursuant to an agreement executed in December 2020) for total consideration of approximately $105.8 million, which includes an upfront payment, four milestone payments, various pass-through costs and payments for clinical supplies. 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, 2020, the deferred revenue for the UT License Agreement consisted of $33.1 million, which was classified as current in our consolidated balance sheet.

The total consideration for the UT License Agreement, includes $1.2 million related to the manufacturing of clinical supplies, which was included in the current portion of deferred revenue on our consolidated balance sheet as of December 31, 2020.

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. In connection with the UT Research Agreement, 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 was recognized using an output method (based on project milestones achieved and surveys of performance completed to date). The Company believed that this method best reflected 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 believed that this method best reflected the measure of progress toward complete satisfaction of the performance obligation. The performance obligations for engineering consulting services and the product prototype were completed in April 2020 and June 2019, respectively.

Vertice Pharma Sales and Marketing Collaboration Agreement — In December 2020, the Company entered into a co-promotion agreement with Vertice Pharma where the Company's sales force will promote Thyquidity to adult endocrinologists, pediatric endocrinologists and other healthcare providers who treat hypothyroidism. Following the commercial launch of Thyquidity, in consideration of the sales and promotional activities provided by the Company's sales force, Vertice will be obligated to pay fixed quarterly payments to the Company, as well as royalties on gross profits resulting from all sales of Thyquidity. The Company expects to launch Thyquidity in collaboration with Vertice Pharma in the first quarter of 2021.

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 was being recognized in net revenue — collaborations over four years, the estimated period over which the Company was required to satisfy the remaining performance obligations. The remaining performance obligations to provide certain technology transfer activities were completed as of December 31, 2020.

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 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, 2020 and 2019, 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. Biomm commenced product sales in January 2020.

In September 2019, the Company delivered its first shipment of Afrezza to Biomm and recorded it as net revenue — commercial product sales for $0.7 million, in advance of the planned launch of the product in Brazil by Biomm. During the second quarter of 2020, the Company sold $0.2 million of product to Biomm. No additional shipments were made in 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 an additional regulatory milestone payment, 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. As of December 31, 2020, the deferred revenue balance was $1.8 million, of which $0.1 million is classified as current and $1.7 million is classified as long term in the accompanying consolidated balance sheets. The Company also recognized $0.2 million as income tax expense for a payment made to the India tax authority in 2018. The Company received a tax refund from the India tax authority in October 2020 and recognized an income tax benefit in the accompanying statement of operations for the year ended December 31, 2020.

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, 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, 2020 and 2019, the Company held $67.0 million and $29.9 million, respectively, of cash and cash equivalents. The Company held $0.2 million and $0.3 million in restricted cash as of December 31, 2020 and 2019, respectively, which 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. The fair value of short-term investments approximate their carrying value. The measurement of which is based on a market approach using quoted market values (Level 1 in the fair value hierarchy). As of December 31, 2020, the Company did not hold any short-term investments.

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	18.0%	1%	19.0%	$ 78.9	$ 77.4	$ (1.5)	-1.9%
on $28.0 million)	18.0%	-1%	17.0%	$ 78.9	$ 80.4	$ 1.5	1.9%
	18.0%	2%	20.0%	$ 78.9	$ 76.0	$ (2.9)	-3.7%
	18.0%	-2%	16.0%	$ 78.9	$ 82.0	$ 3.1	3.9%
Senior notes:							
(with conversion feature)	18.0%	1%	19.0%	$ 7.0	$ 6.9	$ (0.1)	-1.4%
	18.0%	-1%	17.0%	$ 7.0	$ 7.1	$ 0.1	1.4%
	18.0%	2%	20.0%	$ 7.0	$ 6.8	$ (0.2)	-2.9%
	18.0%	-2%	16.0%	$ 7.0	$ 7.2	$ 0.2	2.9%
MidCap Credit Facility							
	7.5%	1%	8.5%	$ 55.4	$ 54.1	$ (1.3)	-2.3%
	7.5%	-1%	6.5%	$ 55.4	$ 56.6	$ 1.2	2.2%
	7.5%	2%	9.5%	$ 55.4	$ 52.9	$ (2.5)	-4.5%
	7.5%	-2%	5.5%	$ 55.4	$ 57.9	$ 2.5	4.5%

Financial Liabilities — The following tables set forth the fair value of the Company's financial instruments:

	December 31, 2020		
		Fair Value	
	Carrying Amount	Significant Unobservable Inputs (Level 3)	Total Fair Value
Financial liabilities:			
MidCap Credit Facility	$ 49.3	$ 55.4	$ 55.40
Senior convertible notes	5.0	7.0	7.0
Mann Group promissory notes	63.0	78.9	78.9
PPP loan	4.9	4.7	4.7
Milestone Rights	7.3	19.8	19.8
Total financial liabilities	$ 129.5	$ 165.8	$ 165.8

	December 31, 2019		
		Fair Value	
	Carrying Value	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

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.

10. Common and Preferred Stock

The Company is authorized to issue 400,000,000 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, 2020 and 2019, 242,117,089 and 211,787,573 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, 2020, the Company sold an aggregate of 11,851,566 shares of the Company's common stock at an average purchase price of $1.99 per share for an aggregate gross proceeds of approximately $23.5 million pursuant to the Sales Agreement. 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.

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 and 7,250,000 remained available for purchase at a price of $1.60 per share, which were subsequently exercised in June 2020.

On June 24, 2020, the Company prepaid the June 2020 note with the issuance of 1,235,094 shares of the Company's common stock, in accordance with the terms of the June 2020 note. On October 9, 2020, the Company prepaid the December 2020 note with the issuance of 1,377,356 shares of the Company's common stock, in accordance with the terms of the December 2020 note. The number of shares issued for the prepayments on June 24, 2020 and October 9, 2020 were determined based on the Company's closing stock price on the day preceding the settlement date. See Note 7 – Borrowings.

In the fourth quarter of 2020, the Mann Group converted $3.0 million of accrued interest and $7.0 million of principal under the Mann Group convertible note into 1.2 million shares and 2.8 million shares, respectively, of the Company's common stock, in accordance with the terms of the convertible note. Subsequent to December 31, 2020, the Mann Group converted $0.4 million of interest and $9.6 million of principal into 4.0 million shares of common stock. See Note 7 – Borrowings.

In December 2020, the Company issued 111,853 warrants to purchase shares of the Company's common stock in connection with the third amendment to the Midcap Credit Facility. The warrants are set to expire on the earlier of December 1, 2027 or upon acquisition of the Company. See Note 7 – Borrowings.

In December 2020, the Company issued 3,067,179 shares of the Company's common stock as consideration for the acquisition of QrumPharma. See Note 3 – Acquisition.

In February 2021, the Company converted $5.0 million principal amount of 2024 convertible notes into 1.7 million shares of the Company's common stock.

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,	
	2020	2019
EPS — basic and diluted:		
Net loss (numerator)	$ (57,240)	$ (51,903)
Weighted average common shares (denominator)	222,585	195,584
Net loss per share	$ (0.26)	$ (0.27)

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,	
	2020	2019
Exercise of common stock options	12,264,616	14,135,681
Conversion of convertible promissory note into common stock	11,200,000	14,000,000
Exercise of warrants associated with public offering	—	7,250,000
Exercise of warrants associated with Midcap Credit Facility	1,283,467	1,171,614
Conversion of convertible notes into common stock	1,666,667	1,666,667
Vesting of restricted stock units	6,037,542	1,057,047
Employee stock purchase plan	292,981	369,979
Exercise of common stock warrants	—	31,851
Total	32,745,273	39,682,839

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"). The 2018 Plan initially consisted of 12,000,000 new shares plus the number of unallocated shares remaining available for grant for new awards under the 2013 Plan. In May 2020, the 2018 Plan was amended to increase the number of shares of common stock that may be issued under the 2018 Plan by 12,500,000 shares.

Effective upon the approval of the 2018 Plan by the Company's stockholders in May 2018, no additional awards have been or may be granted under the 2013 Plan. Any Prior Plans' returning shares will increase the number of shares issuable under the 2018 Plan. The Prior Plans' returning shares are shares subject to outstanding stock awards granted under the 2013 Plan or the 2004 Equity Incentive Plan (collectively, "Prior Plans") that, from and after the effective date of the 2018 Plan, (i) expire or terminate for any reason prior to exercise or settlement, (ii) are forfeited, cancelled or otherwise returned to the Company because of the failure to meet a contingency or condition required for the vesting of such shares, or (iii) other than with respect to outstanding stock options and stock appreciation rights granted under the Prior Plans with an exercise or strike price of at least 100% of the fair market value of the underlying common stock on the date of grant, are reacquired or withheld (or not issued) by the Company to satisfy a tax withholding obligation in connection with a stock award.

The 2018 Plan provides for the granting of stock awards including stock options and restricted stock units to employees, directors and consultants.

The Company's board of directors or its compensation committee 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, or the Prior Plans 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. The Company also issues PNQ awards with performance conditions. For PNQs, the Company evaluates the probability that the performance conditions will be met and estimates the service period for recognition of the associated expense. RSUs with time-based vesting generally vest at a rate of 25% per year over four years with consideration satisfied by service to the Company. Certain RSUs issued to nonemployee directors vest immediately upon grant, but the underlying shares of common stock will not be delivered until there is a separation of service such as resignation, retirement or death. The Company also issued restricted stock units with market conditions ("Market RSUs"). The grant date fair value and the effect of the market conditions was estimated using a Monte Carlo valuation.

Market RSUs issued during the year ended December 31, 2020 had a grant date fair value of $3.77 per share and will vest on May 22, 2023 provided that the closing price of the Company's common stock on such vesting date is not less than the closing price on August 27, 2020. The fair value of the Market RSUs was determined using a share price of $1.70, risk-free interest rate of 0.18%, volatility of 95%, and a dividend yield of 0%. The number of shares delivered on the vesting date is determined by the percentile ranking of MannKind total shareholder return (TSR) over the period from August 27, 2020 until May 22, 2023 related to the TSR of the Russell 3000 Pharmaceutical & Biotechnology Index over the same period, as follows: less than 25th percentile=0% of target, 25th percentile=50% of target, 50th percentile=100% of target, 75th percentile=200% percent of target, 90th percentile or higher=300% maximum. Payout values will be interpolated between the percentile rankings above. The resulting stock-based compensation expense will be recognized over the service period regardless of whether the market conditions are achieved, as long as the service condition is rendered.

The following table summarizes information about the Company's stock-based award plans as of December 31, 2020:

	Outstanding Options	Outstanding Restricted Stock Units	Shares Available for Future Issuance
2004 Equity Incentive Plan	392,180	—	—
2013 Equity Incentive Plan	4,318,058	148,150	—
2018 Equity Incentive Plan	7,533,823	5,889,392	7,717,480
2004 Non-Employee Directors' Stock Option Plan	20,555	—	—
Total	12,264,616	6,037,542	7,717,480

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. The Company recognizes forfeitures as they occur. During the years ended December 31, 2020 and 2019, the Company recorded RSU and option based stock compensation expense of $6.2 million, $5.8 million and employee stock purchase plan compensation of $0.3 million and $0.4 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,	
	2020	2019
Cost of goods sold	$ 446	$ 601
Cost of revenue — collaborations and services	626	738
Research and development	338	356
Selling, general and administrative	5,101	4,508
Total	$ 6,511	$ 6,203

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, 2020 and 2019 using the following assumptions:

	Year Ended December 31,	
	2020	2019
Risk-free interest rate	0.39% — 1.52%	1.52% — 2.51%
Expected lives	5.67 — 7.0 years	6.20 — 9.37 years
Volatility	93.83% — 94.25%	93.05% — 94.25%
Dividends	—	—

The following table summarizes information relating to stock options:

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value ($000)
Outstanding at January 1, 2020	14,135,681	$ 3.09	7.84	$ 182
Granted	196,400	1.30		
Exercised	(432,166)	1.40		
Forfeited	(1,451,403)	1.55		
Expired	(183,896)	9.86		
Outstanding at December 31, 2020	12,264,616	$ 3.41	6.45	$ 15,414
Exercisable at December 31, 2020	7,493,851	$ 4.56	5.62	$ 8,079

The weighted average grant date fair value of the stock options granted during the years ended December 31, 2020 and 2019 was $0.97 and $1.32, respectively. Total fair value of stock options vested during the years ended December 31, 2020 and 2019 was $4.5 million and $3.4 million, respectively. The total intrinsic value of options exercised during the year ended December 31, 2020 was $0.5 million. The total intrinsic value of options exercised during the year ended December 31, 2019 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 years ended December 31, 2020 and December 31, 2019 was approximately $0.6 million and $0.1 million, respectively.

As of December 31, 2020 and 2019, the Company recognized a $0.2 million and *de minimis* amount, respectively, of compensation costs related to the performance-based stock options. As of December 31, 2020, there was $0.4 million of unrecognized compensation costs related to performance-based stock options subject to performance conditions.

The following table summarizes information relating to restricted stock units:

	Number of Shares	Weighted Average Grant Date Fair Value per Share
Outstanding at January 1, 2020	1,057,047	$ 2.16
Granted	7,009,997	2.08
Vested	(1,731,076)	1.81
Forfeited	(298,426)	1.39
Outstanding at December 31, 2020	6,037,542	2.20

Total fair value of restricted stock units vested during the years ended December 31, 2020 and 2019 was $2.5 million and $1.1 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, 2020 and 2019 was $13.3 million and $2.3 million, respectively.

As of December 31, 2020, there was $4.8 million of unrecognized compensation expense related to options and performance-based non-qualified options and $11.0 million of unrecognized compensation expense related to restricted stock units and market based stock units, which are expected to be recognized over the weighted average period of 2.08 to 3.0 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.

Employee Stock Purchase Plan

The Company provides all employees, including executive officers, the ability to purchase our common stock at a discount under our 2004 employee stock purchase plan (the "ESPP"). The ESPP is designed to comply with Section 423 of the Internal Revenue Code and provides all employees with the opportunity to purchase up to $25,000 worth of our common stock (based on the undiscounted fair market value at the commencement of the offering period) each year at a purchase price that is the lower of 85% of the fair market value of the common stock on either the date of purchase or the commencement of the offering period. An employee may not purchase more than 5,000 shares of common stock on any purchase date. The executives' rights under the ESPP are identical to those of all other employees.

The Company issued 0.6 million and 0.7 million shares of common stock pursuant to the ESPP for the years ended December 31, 2020 and 2019, respectively. There were approximately 1.6 million shares of common stock available for issuance under the ESPP as of December 31, 2020.

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, 2020, 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 plaintiff has appealed this denial to the Supreme Court of Israel. The Company will continue to vigorously defend against the claims advanced.

Contingencies — In July 2013, the Company entered into an agreement with the Milestone Purchasers, pursuant to which the Company granted the Milestone 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). The fair value of the Milestone Rights is recorded in the consolidated balance sheet, including $1.3 million in accrued expenses and other current liabilities and $5.9 million in milestone rights and other liabilities.

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. As of December 31, 2020, the remaining purchase requirements are as follows:

	Minimum Commitment	
2021	€	9.1 million
2022	€	8.5 million
2023	€	10.9 million
2024	€	14.6 million
2025	€	15.5 million
2026	€	19.4 million

During the year ended December 31, 2019, the Company paid amendment fees of $2.8 million which were recognized as cost of goods sold. There were no amendment fees paid in 2020.

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 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. On December 26, 2019, 11,583,333 December warrants expired unexercised and 7,250,000 remained available for purchase at a price of $1.60 per share, which were subsequently exercised in June 2020.

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. On November 30, 2020, in connection with the third amendment to the MidCap Credit Facility, the Company issued warrants to purchase an aggregate of 111,853 shares of the Company's common stock, at an exercise price of $2.91 per share.

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. An additional vehicle was removed from the fleet in 2020. No gain or loss was recorded. The revised monthly payment inclusive of maintenance fees, insurance and taxes is $70,000. The lease expense is included in selling, general and administrative expenses in the accompanying consolidated statement of operations.

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 — In May 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.

In November 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, 2020 was approximately $1.4 million. Cash paid for all operating leases for the year ended December 31, 2020 was $1.8 million. Variable lease costs were approximately $0.4 million for the year ended December 31, 2020. The weighted average discount rate used was 7.5%. The weighted-average remaining lease term for all operating leases is 1.9 years.

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.

Future minimum office and vehicle lease payments as of December 31, 2020 and 2019 were as follows:

	December 31,	
	2020	2019
2020	$ —	$ 1,470,217
2021	1,493,988	1,499,484
2022	1,238,799	1,241,089
2023	87,957	87,957
Total	$ 2,820,744	$ 4,298,747

14. Employee Benefit Plans

The Company administers a defined contribution 401(k) savings retirement plan for its employees. The Company may make discretionary matching contributions. For the year ended December 31, 2020, the Company matched each participant's deferral at the rate of 50% of each participant's deferral up to the first 6% of compensation. Participants hired after March 31, 2020 became vested in Company contributions at 100% after two years of service. For the year ended December 31, 2019, the Company matched each participant's deferral at the rate of 75% of each participant's deferral up to the first 8% of compensation. Participants are vested in Company contributions at 50% after one year of service and are 100% vested after two years of service.

The Company's total discretionary matching contributions were $0.9 million and $1.5 million for the years ended December 31, 2020 and 2019, 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,	
	2020	2019
United States	$ (57,458)	$ (51,044)
Foreign	—	(859)
Loss before provision for income taxes	$ (57,458)	$ (51,903)

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. For the year ended December 31, 2020 there was an income tax benefit of $0.22 million. The income tax benefit relates to a refund of previously paid withholding taxes in a foreign jurisdiction 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,	
	2020	2019
Current		
U.S. federal	$ —	$ —
U.S. state	—	—
Non-U.S.	(218)	—
Total current	(218)	—
Deferred		
U.S. federal	(4,377)	(8,551)
U.S. state	(469)	3,299
Non-U.S.	—	—
Total deferred	(4,846)	(5,252)
Valuation allowance	4,846	5,252
Total	$ (218)	$ —

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, 2020 and 2019, are as follows (in thousands):

	December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 533,448	$ 531,970
Research and development credits	79,455	80,488
Capitalized research	—	44
Milestone Rights	1,547	1,528
Accrued expenses	1,436	1,951
Loss on purchase commitment	23,864	22,167
Non-qualified stock option expense	3,766	3,128
Capitalized patent costs	5,273	4,964
Other	2093	147
Lease liability	559	827
Interest expense limitation	2,460	1,167
Depreciation	20,735	21,132
Deferred Product Revenue & Costs	1,569	2,062
Total net deferred tax assets	676,205	671,575
Valuation allowance	(675,463)	(670,617)
Net deferred tax assets	$ 742	$ 958
Deferred tax liabilities:		
Right of use asset	$ (510)	$ (751)
Other prepaids	(232)	(207)
Total deferred tax liabilities	(742)	(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, 2020 and 2019:

	Year Ended December 31,	
	2020	2019
Federal tax benefit rate	21.0%	21.0%
Permanent items	(6.1)	(3.3)
Tax law changes	—	(2.7)
Stock based compensation	(0.5)	(0.9)
Tax attribute expirations	(6.6)	(4.0)
Foreign withholding tax	0.4	—
Valuation allowance	(7.8)	(10.1)
Effective income tax rate	0.4%	0.0%

As of December 31, 2020 and 2019, 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, 2020. Accordingly, a valuation allowance of $675.5 million has been recorded to offset this deferred tax asset. During the years ended December 31, 2020 and 2019, the change in the valuation allowance was $4.8 million and $5.3 million, respectively.

At December 31, 2020, the Company had federal and state net operating loss carryforwards of approximately $2.4 billion and $1.3 billion available, respectively, to reduce future taxable income. $395.2 million of the federal losses do not expire and the remaining federal and state losses have started expiring, beginning in 2020 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 December 31, 2020, to determine 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, 2020. There is a risk that changes in ownership may occur in tax years after December 31, 2020. 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, 2020, the Company had $54.2 million of U.S. federal research and development credits which expire beginning in 2024, and $25.3 million of state research and development credits. The California credits do not expire and the New Jersey credits began to expire in 2020. The Company also had two types of credits in Connecticut of which $15.7 million do not expire and $0.1 million of $1.0 million expired at the end of 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.

A reconciliation of beginning and ending amounts of unrecognized tax benefits in 2020 and 2019, respectively, was as follows (in thousands):

	Year Ended December 31,	
	2020	2019
Gross unrecognized Tax benefit as of 1/1/2020	$ —	$ —
Gross increases for tax positions of prior years	268,902	—
Gross decreases for tax positions of current year	—	—
Settlements	—	—
Lapse of statute of limitations	—	—
Gross unrecognized tax benefits as of 12/31/2020	$ 268,902	$ —

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 2016 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, 2020 the Company had no undistributed earnings from its foreign subsidiaries.

The Company adopted ASC Topic 842, *Lease*s, 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.

The 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. The Company has elected to account for GILTI in the year the tax is incurred.

On March 27, 2020, the U.S. government enacted the CARES Act, a $2 trillion relief package comprising a combination of tax provisions and other stimulus measures. The CARES Act broadly provides entities tax payment relief and significant business incentives and makes certain technical corrections to the Tax Act. The tax relief measures for entities include a five-year net operating loss carry back, increased interest expense deduction limits, acceleration of alternative minimum tax credit refunds, payroll tax relief, and a technical correction to allow accelerated deductions for qualified improvement property. The Act also provides other non-income tax benefits, including federal funding for a range of stabilization measures and emergency funding to assist those impacted by the COVID-19 pandemic. Similar legislation is being enacted in other jurisdictions in which the Company operates. ASC Topic 740, *Income Taxes*, requires the effect of changes in tax rates and laws on deferred tax balances to be recognized in the period in which new legislation is enacted. The enactment of the CARES Act and similar legislation in other jurisdictions in which the Company operates was not material to the Company's income tax benefit for the year ended December 31, 2020.

16. Subsequent Event

Subsequent to December 31, 2020, the Company entered into a non-binding letter of intent ("LOI") with a third party to sell and lease back a portion of the Company's Danbury manufacturing facility and administrative offices. The terms of the LOI include a sales price of approximately $95 million to $105 million, a lease term of 20 years with four five-year renewal options, and annual rent of approximately $10 million to $11 million at the beginning of the lease. If the transaction is completed, the Company intends to use the proceeds for general corporate purposes, and may also pay down a portion of its senior secured debt. The completion of the transactions contemplated by the LOI is subject to certain conditions, including the negotiation of satisfactory definitive agreements and satisfactory results of the buyer's inspections and other investigations, all of which are anticipated to be completed during the first quarter of 2021. However, there can be no assurances that this proposed transaction will be completed in the timeframe or on the principal terms set forth above, or at all.

Exhibit 4.3

DESCRIPTION OF COMMON STOCK

General

Our authorized capital stock consists of 400,000,000 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. With respect to the 10,000,000 shares of preferred stock, par value $0.01 per share, all of which is undesignated, our board of directors has the authority, without further action by stockholders, to designate up to in one or more series and to fix the rights, preferences, privileges, qualifications and restrictions granted to or imposed upon the preferred stock, including dividend rights, conversion rights, voting rights, rights and terms of redemption, liquidation preference and sinking fund terms, any or all of which may be greater than the rights of our common stock. The issuance of preferred stock could adversely affect the voting power of holders of common stock and reduce the likelihood that common stockholders will receive dividend payments and payments upon liquidation. The issuance could also have the effect of decreasing the market price of the common stock. The issuance of preferred stock also could have the effect of delaying, deterring or prevent a change in control of us.

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 10.4

May 7th, 2020

Dear Alejandro

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

We will target your employment to commence on August 4th, 2020. Please be advised that this offer is contingent upon satisfactory reference and background checks and receipt of results of a satisfactory drug screening test, and execution of pre-hire documents set forth herein. In the coming days, you will receive an email with information regarding the test, contact and location information for the laboratory as well as the hours of operation. This screening test must be completed no later than one week from the date of this letter.

You will be paid on a bi-weekly basis, on regular payroll schedule, in the amount of $16,153.85 equating to an annualized amount of $420,000.10.

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

You will be eligible to participate in MannKind's Equity Incentive Plan, under which stock options and restricted stock may be awarded to you at a future date, as approved by the Board of Directors. At the next quarterly Board meeting, we will recommend that you be granted an equity award of 305,000 units of Time-Based Stock Options which is comparable to grants made for other individuals in similar level positions throughout the company. This is not a guarantee for a specific number of stock units, but is only intended to provide you with an understanding of grant guidelines for your position. If your start date is less than two weeks prior to the next quarterly Board meeting, the recommendation will be submitted in the following quarter. Grants will begin vesting based on your hire date.

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

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

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

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

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

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

Sincerely,

/s/ Brandi Santogatta
Brandi Santogatta
Sr. Manager, Recruiting & Onboarding
203-297-0435

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

/s/ Alejandro Galindo
Alejandro Galindo

5/7/2020
Date Signed

Exhibit 10.5

August 11, 2003

Dear Joe:

I am pleased to confirm MannKind's offer to you for full-time employment in the position of **Senior Director, Pharmaceutical Manufacturing**, effective September 1, 2003. In this position, you will report directly to me.

You will be paid on a bi-weekly basis, along with our regular payroll schedule, equating to an annualized amount of $175,000. You will be eligible to participate in the MannKind Stock Option Plan, under which we will recommend to the Board of Directors an award for you of 25,000 options.

In addition, you will be eligible to earn a performance bonus of up to 20% of your base salary. Specific criteria required to earn this bonus will be based upon the successful achievement of agreed upon yearly objectives. In general, it will be based upon corporate objectives, your individual contributions and significant accomplishments focused primarily on leading and organizing MannKind's Pharmaceutical Manufacturing Department in a manner that enables it to function at peak capacity, while meeting all critical timelines associated with the production of clinical supplies for the upcoming trials.

As a full-time employee, you will also be eligible to participate in MannKind's group medical, dental, life, disability insurance and 401(k) plan, and any other benefits that become generally available to full-time employees.

As a condition of employment, you will be required to sign an Employee Proprietary Information and Inventions Agreement, a Computer Use and Email Policy and any other future policies or agreements required by the company.

Please be advised that the employment relationship between you and MannKind Corporation is *at will.* As such, you or the company can exercise the right to terminate the relationship at any time, for any reason, with or without cause or prior notice.

We hope you will accept this offer to join the MannKind team. I believe you have the ability to become a key member of the executive group and we certainly look forward to working with you. Once you have signed the acceptance below, please be sure to return one copy of this letter to me as soon as possible.

Sincerely, Offer accepted:

/s/ Dan Burns /s/ Joseph Kocinsky

August 15, 2003

Exhibit 10.23

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE MANNKIND CORPORATION HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO MANNKIND CORPORATION IF PUBLICLY DISCLOSED.

28903 North Avenue Paine, Valencia, California 91355 USA
61 South Paramus Road, Paramus, New Jersey 07652 USA
One Casper Street, Danbury, Connecticut 06810 USA
www.mannkindcorp.com

SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT (the "***Agreement***") is made as of the 31st day of July, 2014 (the "***Effective Date***") by and between MannKind Corporation, a Delaware corporation ("***MannKind***"), with its principal office and place of business at 28903 North Avenue Paine, Valencia, CA 91355, U.S.A., and Amphastar France Pharmaceuticals S.A.S., a French corporation ("***AFP***"), with its principal office and place of business at Usine Saint-Charles, 60590 Eragny-Sur-Epte, France (each of MannKind and AFP, a "***Party***" and together, the ***"Parties"***).

RECITALS

WHEREAS, MannKind has developed and obtained marketing approval for its product AFREZZA® ("***MannKind Product***"); and

WHEREAS, AFP is in the business of manufacturing and supplying recombinant human insulin, an active pharmaceutical ingredient ("***API***"); and

WHEREAS, MannKind and AFP desire to enter into this Agreement to provide the terms and conditions upon which AFP shall manufacture for and supply to MannKind recombinant human insulin API, SIHR Insulin ("***Product***").

AGREEMENT

NOW THEREFORE, in consideration for the representations, warranties and covenants set forth below, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as set forth below.

1. CERTAIN DEFINITIONS.

1.1 "Affiliate" means, with respect to any Party, another entity or person which directly or indirectly, is controlled by, or controls, or is under common control with such Party, where, for purposes of this definition, the term "control" means ownership, directly or indirectly, of more than 50% of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or more than 50% of the equity interests in the case of any other type of legal entity, status as a general partner in any partnership, or any other arrangement whereby a Party controls or has the right to control the Board of Directors or equivalent governing body of a corporation or other entity, or if such level of ownership or control is prohibited in any country, any entity owning

or controlling at the maximum control or ownership right permitted in the country where such entity exists.

1.2 "Confidential Information" means any confidential or proprietary information of a Party disclosed to the other Party or generated in the course of this Agreement, including inventions, know-how, works of authorship, software, data, software tools, designs, schematics, plans or other information relating to any work in process, future development, engineering, manufacturing, marketing or business plan, or financial or personnel matters relating to either Party, its present or future products, sales, suppliers, customers, employees, investors or business.

1.3 "Current Good Manufacturing Practices" or "**cGMP**" means the methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug or API to assure that such drug or API meets the regulatory requirements of the FDA and as further defined in 21 C.F.R. Parts 210 and 211 and the guidance of the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research and the European Commission Directive 2003/94/EC of October 8, 2003.

1.4 "Excluded Countries" means [***].

1.5 "FDA" means the United States Food and Drug Administration or any successor agency in the United States.

1.6 "Intellectual Property Rights" means any and all rights in and to discoveries, concepts, ideas, Technical Information, developments, specifications, methods, drawings, designs, flow charts, diagrams, models, formulae, procedures, processes, schematics, specifications, algorithms, apparatus, inventions, ideas, know-how, materials, techniques, methodologies, modifications, improvements, works of authorship and data (whether or not protectable under patent, copyright, trade secrecy or similar laws), including patents, copyrights, trade secrets, manufacturing documentation, and any other form of protection afforded by law to inventions, works of authorship, databases or technical information and applications and registrations with respect thereto.

1.7 "Non-conforming Product" means Product that does not conform to the Specifications, the Quality/Technical Agreement, or does not conform to cGMP, or is not free from defect, adulteration or contamination, or is not free and clear of all liens, claims and encumbrances upon delivery.

1.8 "Project Team" has the meaning set forth in § 2.2(a).

1.9 "**Purchase Commitment Quantities**" has the meaning set forth in § 6.1.

1.10 "Purchase Order" means a purchase order that is issued by MannKind and accepted by AFP for the purpose of obtaining the Product under this Agreement.

1.11 "Quality/Technical Agreement" or "**QTA**" means a separate agreement, executed subsequent to this Agreement, between the Parties which shall be incorporated herein by reference, and which sets forth, among other things, the quality control and quality assurance terms for the Product. In case of a discrepancy between this Agreement and the Quality/Technical Agreement,

as to quality and technical matters the terms of the Quality/Technical Agreement shall govern, otherwise the provisions of this Agreement shall prevail.

1.12 "**Quarter**" shall mean a period of three consecutive months during a calendar year beginning on and including January 1st, April 1st, July 1st and October 1st.

1.13 "**Specifications**" means the technical specifications for the Product, as further described in the **QTA**.

1.14 **"Technical Information"** means either Party's pre-existing technical documentation and information relating to manufacture of the Product, or to human insulin for use in the manufacture of the MannKind Product.

1.15 **"Territory"** means all countries in the world except the Excluded Countries.

2. Performance Obligations

2.1 **Supply**.

(a) **Performance.** AFP shall manufacture and supply the Product in accordance with the Specifications, Quality/Technical Agreement, and all applicable laws of the United States and European Union. AFP shall perform its activities in accordance with professional standards and practices including, but not limited to cGMP. AFP shall provide cGMP facilities as well as resources for such services including, but not limited to testing, release, storage, and manufacture of the Product. MannKind shall provide AFP, upon request and only for use in accordance with the terms of this Agreement, with any and all Technical Information of MannKind that AFP reasonably determines it may need to manufacture and supply the Product. Any distribution or sales by MannKind of the Product or the MannKind Product made using the Product shall be limited to the Territory until such time, if ever, as the geographical restrictions on the distribution and sale of the Product are no longer applicable under any third party license agreement with AFP.

(b) **Manufacturing Site; Subcontracting.** AFP shall manufacture the Product only at its facility in Eragny-Sur-Epte, France and shall not manufacture Product at any other site, except with MannKind's prior written consent, which it may withhold in its reasonable discretion. AFP shall not delegate or subcontract the performance of activities under this Agreement to third party subcontractors, except with MannKind's prior written consent, which it may withhold in its reasonable discretion, provided that, if MannKind provides consent to allow AFP to delegate or subcontract the performance of any such activities to a third party, such consent shall be subject to the condition that AFP shall control the performance of such activities and remains fully responsible to MannKind for the performance of such activities and any material breach of this Agreement by such third party subcontractor, and require that such third party subcontractor agrees in writing to comply with confidentiality restrictions at least as stringent as those set forth in this Agreement.

2.2 Project Team.

(a) Formation; Composition. The Parties shall form a team ("***Project Team***"), which shall be responsible for oversight of the activities under this Agreement. Each Party shall appoint to the Project Team an equal number of team members that have the requisite skills in the disciplines necessary for performance of activities under this Agreement. Each Party may change its Project Team members at any time by written notice to the other.

(b) Meetings. The Project Team shall meet at such times and locations as are agreeable to a majority of the Project Team members, but no less than once per year. Project Team meetings may take place in person or through video or telephone communications. At the initial meeting of the Project Team, the Project Team shall establish operating procedures for its meetings and activities. At each meeting of the Project Team, the Parties shall provide an update on the status of the activities conducted under this Agreement. Other personnel of each Party may attend Project Team meetings. Each Party shall bear the expense of participation of its respective Project Team members and other personnel in Project Team meetings. Written minutes shall be kept of all Project Team meetings and shall include material decisions made at such meetings.

2.3 Regular Communication. Each Party shall be available to the other Party for a reasonable number of telephone and written consultations on a schedule to be determined by mutual arrangement between the Parties. Each Party shall respond to all telephone and written (e.g. letters, e-mail, fax) communications within five (5) business days.

2.4 Regulatory Matters. The Parties shall cooperate diligently and in good faith to obtain any and all necessary approvals and permits for the manufacture and supply of the Product. The Parties shall bear their respective costs and shall pay all costs, consistent with industry practice, associated with obtaining such approvals or permits for the Product. The Parties shall provide such technical assistance to each other as is commercially reasonable for this purpose. AFP will provide MannKind with such information and data regarding the manufacture of Product to the extent necessary for MannKind and its Affiliates and licensees to prepare and defend any inquiries from regulatory authorities to satisfy regulatory requirements with respect to the Product. Only in the event that AFP needs to obtain third party services in order to support MannKind, its Affiliates, and licensee(s) to obtain or maintain approvals or permits with respect to the Product, as it specifically relates to theMannKind Product, MannKind and AFP agree to negotiate in good faith such services and the costs therefore.

2.5 Regulatory Compliance. In performing its obligations hereunder AFP shall comply with all applicable U.S. and foreign federal, state, municipal, or local laws, rules, regulations, orders, decisions or permits of any relevant jurisdiction relating to matters including, but not limited to employment, safety, health, environmental standards and requirements, non-discrimination, equal employment opportunity, import/export and privacy protection. Such laws include, but are not limited to the U.S. Occupational Safety and Health Act, the U.S. Fair Labor Standards Act, and the U.S. Food and Drug Cosmetic Act and all applicable laws of France.

3. SALE AND PURCHASE TERMS

3.1 Purchase. Subject to contractual obligations of MannKind and subject to the other provisions of this Agreement, AFP shall sell to MannKind and its Affiliates, and MannKind and its Affiliates shall purchase from AFP, at least the quantities of Product described in § 6.1.

3.2 Schedule for Delivery. Each year during the term of this Agreement, no later than December 1st, MannKind shall provide to AFP a schedule for delivery of the following calendar year's annual Product Purchase Commitment Quantities. Annual Product quantities must be requested with multiple delivery dates, and in all cases, the deliveries requested for the quantities shall be whole batch quantities (or multiples thereof, as applicable). Such requested deliveries shall not exceed quantity of [***] kg of Product per delivery. AFP shall be deemed to have satisfied its obligations with respect to quantity of Product if the actual quantity of Product supplied is within plus or minus [***] percent (+/- [***]%) of the quantity set forth in the applicable Purchase Order. No later than fifteen (15) calendar days prior to the end of each Quarter during the Term, MannKind shall provide AFP with the forecasted schedule of delivery of the Product for the next successive four (4) Quarters (or until the Term ends if shorter), on a rolling basis, the first two (2) Quarters of which shall be broken down on a month-by-month basis (the "***Forecast***"). Each Forecast shall be deemed to be an update of any Forecast previously provided by MannKind to AFP during the Term. The first two (2) Quarters of each Forecast shall be binding (the "***Firm Order Period***") and simultaneously with submission of the Forecast, MannKind shall submit any Purchase Order(s) for the quantities of the Product to be delivered during the second (2nd) Quarter of such Forecast (i.e., the last Quarter of the Firm Order Period). AFP will deliver the designated quantities to MannKind on the dates specified. Time is of the essence for delivery dates and quantities. If AFP cannot meet the dates specified or proposes alternate delivery dates, it must notify MannKind in writing within fifteen (15) calendar days after receipt of MannKind's most recent Forecast. In no event shall any delivery be later than one (1) month beyond MannKind's requested delivery date as long as the delivery per quarter of the Purchase Commitment Quantities does not exceed [***] kilograms ([***] kg).

Notwithstanding the foregoing, for the Purchase Commitment Quantity to be delivered in the 4th Quarter of 2014 and the 1st Quarter of 2015, MannKind shall issue a Purchase Order no later than thirty calendar days after execution of this Agreement ("Initial Order"). The Purchase Commitment Quantity of the Initial Order shall not be less than [***] kg for the 4th Quarter of 2014, except that the Purchase Commitment Quantity actually delivered under the Initial Order for the 4th Quarter of 2014 shall be limited by the amount that AFP can deliver in the 4th Quarter of 2014. The Purchase Commitment Quantity of the Initial Order for the 1st Quarter of 2015 shall not be less than [***] kg. For avoidance of doubt, the Purchase Commitment Quantity of the Initial Order shall not be less than [***] kg in total. MannKind and AFP shall mutually agree on specific delivery dates under the Initial Order, and, in the event AFP is unable to deliver the Purchase Commitment Quantity recited in the Initial Order for the 4th Quarter of 2014, MannKind and AFP shall mutually agree upon an altered quantity allocation of Product as between the 4th Quarter of 2014 and the 1st Quarter of 2015, which shall not be less than [***] kg total in any event..

3.3 Purchase Orders. MannKind shall issue Purchase Orders to AFP based on the Forecast provided to AFP in accordance with the terms of § 3.2. All orders shall be evidenced by

specific and separate Purchase Orders issued by MannKind to AFP pursuant to this § 3.3. Purchase Orders for Product may be submitted by MannKind to AFP in writing, or electronically pursuant to a mutually agreed upon process. All Purchase Orders shall contain: (a) the quantities ordered; (b) the purchase price for Product ordered in accordance with § 6; (c) delivery dates; and (d) delivery address as well as any other appropriate instructions. If MannKind issues any such Purchase Orders, AFP shall inform MannKind in writing of its acceptance or rejection thereof; provided that AFP may not reject any Purchase Order for quantities ordered in accordance with § 6.1 where the delivery dates are in accordance with the terms of § 3.2. Any deviation from an agreed upon scheduled delivery date for Product shall occur only upon written approval by the Parties. For the avoidance of doubt, this Agreement shall take precedence over the terms and conditions set forth in any Purchase Order; in other words, no additional, ambiguous or inconsistent terms in any Purchase Orders or Purchase Order acknowledgements shall have any legal effect.

3.4 Notice of Potential Product Delivery Delays. If AFP is unable to provide to MannKind the quantities of Product in accordance with the provisions of this Agreement, during any calendar year, then AFP shall inform MannKind in writing within ten (10) days of learning of such event. Such notice shall in no event be received by MannKind later than forty five (45) days prior to any delivery date, and AFP shall use commercially reasonable efforts to resolve the condition that caused such delay.

3.5 Additional Quantity. MannKind may submit a written request to AFP for quantities of Product in addition to the quantities set forth in § 6.1 of this Agreement. AFP will use commercially reasonable efforts to attempt to supply such additional quantities. AFP will respond in writing, within thirty (30) days, whether it can meet the additional quantities of Product. Upon agreement between AFP and MannKind of a specific quantity and delivery time, MannKind will submit a Purchase Order for such additional quantities of Product in accordance with the terms of § 3.3. The Parties shall negotiate in good faith the pricing for such additional quantities in no event shall the pricing be more than the amount as set forth in § 6.1.

4. MANUFACTURE

4.1 Raw Materials. AFP shall be responsible for obtaining, and shall store at no cost to MannKind, any and all materials required for the manufacture of the Product, in reasonable quantities consistent with MannKind's designated quantities and orders for the Product. AFP shall use and rotate all stock of materials on a first-in, first-out basis. AFP shall conduct on-site quality audits of its inclusion bodies supplier on a regular basis, but shall not be obligated to conduct more than one (1) such audit every calendar year. AFP represents and warrants that AFP has a long-term supply agreement with [***] to support AFP's obligations with respect to the Purchase Commitment Quantities and Purchase Price (without resorting to § 6.1(b)) under this Agreement and covenants that during the term of this Agreement AFP shall not unreasonably terminate such agreement or amend such agreement in a manner that would adversely affect AFP's ability to perform its obligations under this Agreement. If during the term of this Agreement AFP intends to qualify an appropriate alternate source of [***]. then AFP must notify MannKind in writing and AFP agrees that such change shall not adversely affect AFP's ability to perform its obligations under this Agreement. AFP has provided or will provide to MannKind and its potential licensee(s) the opportunity to review a true and correct copy of such agreement, at AFP's location or

Amphastar Pharmaceuticals, Inc.'s location, as in effect as of the Effective Date (as redacted to protect any proprietary information of AFP or [***])

4.2 Manufacture of Product. AFP shall reserve sufficient production capacity and inventory of Product in order to be able to supply to MannKind pursuant to the terms of this Agreement. AFP shall manufacture Product in accordance with § 2.1, § 2.5, and United States and European Union regulations applicable to the transportation, storage, use, handling and disposal of hazardous materials. Each Party shall promptly notify the other of any new instructions or specifications with respect to the Product required under any applicable laws and shall confer with each other with respect to the best means to comply with such requirements. AFP represents and warrants to MannKind that it has, and shall maintain during the term of this Agreement, all government permits, including without limitation health, safety and environmental permits, necessary for the conduct of the actions and procedures that it undertakes pursuant to this Agreement.

4.3 Product Specifications; Testing. Product supplied hereunder shall conform to the Specifications and the warranty set forth in § 7.2. AFP or applicable qualified contract laboratories shall perform quality control testing and quality oversight on the Product to be delivered to MannKind or its designee hereunder.

4.4 Audits. Upon MannKind's written request to AFP, which shall be not less than thirty (30) days in advance, MannKind, or its licensee(s) identified in such a written request, shall have the right to have its representatives visit AFP's facility during normal business hours to review and inspect AFP's manufacturing operations and quality systems related to the Product and to discuss any related issues with AFP's manufacturing and management personnel. Such audits of AFP shall not exceed one (1) time per calendar year for MannKind and shall not exceed one (1) time per year for MannKind's sole licensee. If MannKind adds additional licensee(s), only one (1) licensee is entitled to an audit per calendar year. For the avoidance of doubt, only two (2) audits total are allowed per calendar year. MannKind, or its licensee(s) will be entitled to perform additional audits, upon shorter notice, if Non-conforming Products are produced by AFP or complaints or other inquiries by regulatory authorities relating to the Products produced hereunder are received by either Party, or for any additional reasons where good cause is articulated in writing by MannKind.

4.5 Change in Manufacturing Process. AFP shall provide prior written notice to MannKind before AFP implements any change in the materials, suppliers, contract laboratories, equipment, processes, procedures, or test methods used to manufacture the Product, but only to the extent that such changes affect AFP's United States Drug Master File of the Product or any other regulatory filing throughout the Territory. If MannKind does not notify AFP of an objection within ten (10) business days of receipt of AFP's notice and, as far as AFP is aware having made due inquiry, such change would not require approval or notification of the applicable regulatory authorities with respect to the MannKind Product, then AFP may proceed with the change without the prior written approval of MannKind. If MannKind notifies AFP within such ten (10) business day period that such change would require approval or notification of the applicable regulatory authorities with respect to the MannKind Product, then AFP shall not make such change without the prior written consent of MannKind, which prior written consent shall not be unreasonably withheld. With respect to any changes that would not require approval or notification of the

applicable regulatory authorities in connection with the MannKind Product, if MannKind notifies AFP of an objection to such change within such ten (10) business day period, the Parties will discuss the change in good faith for up to an additional ten (10) business days (or longer, if agreed by the Parties) in the interest of reaching a mutually agreeable resolution; provided, that if agreement is not reached on such change (and that change does not require notification or approval of the applicable regulatory authorities with respect to the MannKind Product) then AFP may proceed with such change following such discussions.

4.6 Documentation. AFP shall keep complete, accurate and authentic accounts, notes, data and records of the work performed under this Agreement adequate to comply with all applicable laws. AFP shall maintain complete and adequate records pertaining to the methods and facilities used by it for the manufacture, testing and supply of the Product. Upon MannKind's written request, AFP shall make these documents available for MannKind on-site review at AFP's facility. MannKind acknowledges that all of AFP's manufacturing records shall be protected under the confidentiality provisions of § 11.

4.7 Recall of Product. In the event that: (a) any regulatory authority issues a request, directive or order that the Product be recalled or retrieved; (b) a court of competent jurisdiction orders that the Product be recalled or retrieved; or (c) AFP determines that the Product should be recalled or retrieved, AFP shall promptly notify MannKind, in writing, of such event and shall conduct such activity and take appropriate corrective actions, at AFP's expense.

5. Delivery and Acceptance

5.1 Time and Place of Delivery. AFP shall deliver the Product to MannKind DAT ("Delivered at Terminal," as such term is defined in INCOTERMS 2010) to John F. Kennedy International Airport ("***JFK***"), or other designated terminal within the United States ("Alternate Designated Terminal") at MannKind's reasonable discretion upon reasonable written notice to AFP, to arrive on or before the scheduled date as set forth in the Purchase Orders. AFP shall ensure that the shipping, handling and storage conditions are sufficiently maintained so that there is no adverse impact to Product quality. Upon delivery to MannKind, AFP shall ensure Product will have a remaining expiry date of not less than four (4) years.

5.2 Risk of Loss. AFP shall bear the risk of loss for the Product through delivery to, and unloading at, JFK or Alternate Designated Terminal, at which time title to the Product and the risk of loss shall pass to MannKind.

5.3 Documents. Each shipment of the Product shall be accompanied by relevant certificates of analysis and a copy of the invoice. Each certificate of analysis shall certify with respect to each shipment and batch (identified by batch number) (a) the quantity of the shipment, and (b) that Product delivered conforms to Specifications, as well as any further information required by the relevant regulatory authorities that MannKind may have previously notified AFP is necessary. MannKind shall be under no obligation to accept any shipment of Product without an accompanying certificate of analysis.

5.4 Inspection, Acceptance and Rejection. MannKind shall have the right to inspect the Product as follows:

(a) Delivery Inspection. Upon delivery at MannKind's designated facility, MannKind shall perform testing to determine whether the Product is acceptable to MannKind, conforms with the Specifications and cGMPs, is free from defect, adulteration and contamination and is free and clear of all liens, claims and encumbrances.

(b) Acceptance; Rejection. If, after performing such testing MannKind determines and informs AFP in writing that any Product delivered is a Non-conforming Product, MannKind shall so notify AFP in writing within forty-five (45) days from receipt of the shipment. In the event that AFP agrees that the Product is Non-conforming Product, MannKind may, at its option, return such Non-conforming Product to AFP or request replacement of the Non-conforming Product at AFP's sole cost and at the earliest possible timeframe that is commercially reasonable. If MannKind exercises such return rights, MannKind shall return any such Non-conforming Product in accordance with AFP's then current return procedures, and AFP shall replace such Non-conforming Product. If AFP does not replace such Non-conforming Product so as to remedy any reported non-conformity within forty-five (45) days after such non-conformity is reported to AFP, then MannKind may reject such Non-conforming Product by providing prompt written notice of such rejection to AFP. In the event of such rejection of any Non-conforming Product, AFP shall promptly credit or refund the net purchase price paid by MannKind. MannKind may charge AFP for all costs of shipment of Non-conforming Product and for the cover costs of the Product. If MannKind does not notify AFP that any Product is a Non-conforming Product during the forty-five (45) day period following delivery of such Product at MannKind's designated facility, or does not reject any Non-conforming Product in accordance with the procedure described above, such Product shall be deemed to have been accepted by MannKind. Acceptance or deemed acceptance under this § 5.4 shall not limit AFP's warranty obligations or MannKind's warranty rights under § 7.2.

In the event of a discrepancy between MannKind and AFP as to whether the Product is Non-conforming Product or there otherwise exists a dispute between the Parties over the extent to which such non-conformity is attributable to a given Party, the Parties shall cause an independent laboratory promptly to review records, test data and perform comparative tests and analyses on samples of the Product that allegedly is Non-conforming. Such independent laboratory shall be mutually agreed upon by the Parties. The independent laboratory's results shall be in writing and shall be final and binding save for manifest error. Unless otherwise agreed to by the Parties in writing, the costs associated with such testing and review shall be borne by the Party against whom the independent laboratory rules.

6. PRICING; QUANTITIES; AND PAYMENT

6.1 Purchase Commitment and Purchase Price. MannKind shall purchase from AFP the minimum quantities of Product (the "***Purchase Commitment Quantities***") at the purchase price per gram (the "***Purchase Price***") in each calendar year as provided in the table set forth below. In the event that MannKind fails to meet the Purchase Commitment Quantities in any given calendar year, MannKind shall pay AFP for the difference in the amount of the Purchase Commitment Quantities and the actual amount purchased for the corresponding calendar year (such difference, the "***Purchase Commitment Difference***"). AFP shall issue an invoice and MannKind shall pay the Purchase Commitment Difference no later than thirty (30) days after the close of the corresponding calendar year.

Calendar Year	Purchase Commitment Quantities (kg)	Purchase Price (per gram)	Comment
2015	[***]	EUR [***]	Up to [***] kg to be delivered in the fourth quarter of 2014.
2016	[***]	EUR [***]	
2017	[***]	EUR [***]	
2018	[***]	EUR [***]	
2019	[***]	EUR [***]	

All amounts due under this § 6.1 shall be due and payable by MannKind to AFP in EUR in accordance with § 6.2. In calendar year 2016 and thereafter, the Purchase Price shall be subject to adjustment as follows:

(a) The Purchase Price will be subject to an obligatory annual adjustment on January 1 of each calendar year equal to the percentage change in the [***] (the "***Index***"), where the annual adjustment is calculated using the historical twelve (12) month percentage change of the Index, as of December 1 of the immediate prior year; provided, however, that if the percentage change (either increase or decrease, as applicable) of the Index equals or exceeds [***] percent (i.e., +/- [***]%), the Purchase Price adjustment shall not be obligatory, but instead the Parties shall attempt in good faith to negotiate an adjusted Purchase Price based on such change, which attempted negotiations shall be concluded no later than February 15 of that calendar year.

(b) In addition to any adjustment to the Purchase Price pursuant to §6.1(a), if for causes beyond AFP's reasonable control (including market shortage, market embargo, etc.), AFP has incurred any price increase(s) in its aggregate material and service costs (such increased costs measured on a per gram basis of Product, the "***Cost Excess***") which are in excess of [***] percent ([***]%) of the Purchase Price in a given calendar year, then the Purchase Price for the

next calendar year shall be increased by the percentage increase of the Cost Excess as compared to the aggregate costs for such materials and services during the prior calendar year.

(c) If AFP delivers any Product Purchase Commitment Quantities, as defined in the Firm Order Period through a Purchase Order accepted by AFP, beyond sixty (60) days after the committed delivery date, then such quantities shall be subject to a [***] percent ([***]%) discount off the Purchase Price.

6.2 Payment. MannKind shall pay AFP for the Product within forty-five (45) days from shipment date of the Product. In the event the Product is detained due to Customs or FDA then MannKind shall notify AFP of such delay and the period for payment shall be extended for the period commensurate with such delay. AFP shall submit an invoice electronically to MannKind, Attention: Accounts Payable, valenciaap@mannkindcorp.com. If any portion of an invoice is disputed then MannKind shall pay the undisputed amount and the Parties shall use good faith efforts to reconcile the disputed amount as soon as practicable. AFP shall not suspend work or seek to terminate this Agreement or any Purchase Order solely on account of MannKind's failure to pay any invoiced amount which is the subject of a good faith bona fide dispute, provided that MannKind pays all non-disputed amounts.

6.3 Reservation Fee. No later than five (5) days after the Effective Date, MannKind shall make payment to AFP in the amount of EUR [***], which will be considered as partial payment for the calendar year 2015 Purchase Commitment Quantities of [***] kilograms of Product. This reservation fee is non-refundable and deemed fully earned by, and to be the property of AFP in all events, including but not limited to the event that MannKind fails to purchase the calendar year 2015 Purchase Commitment Quantities, except for and excluding only the event of a material breach of AFP's obligations under this Agreement that occurs prior to the delivery of the full amount of calendar year 2015 Purchase Commitment Quantities. Any invoice(s) for the calendar year 2015 designated quantities will be adjusted to reflect a credit for the reservation fee. For avoidance of doubt, this Reservation Fee will only be adjusted against the purchase of quantity that is delivered in calendar year 2015, and not calendar year 2014 or in any other calendar year.

6.4 Taxes. The Party receiving payments under this Agreement shall pay any and all taxes levied on account of such payment. If any taxes are required to be withheld by the paying Party, it shall (a) deduct such taxes from the remitting payment, (b) timely pay the taxes to the proper taxing authority, and (c) send proof of payment to the other Party and certify its receipt by the taxing authority within sixty (60) calendar days following such payment. AFP shall ensure that the proper harmonized code is used for Customs shipping documentation in accordance with 19 CFR 152.11.

7. Representations And Warranties; Covenants

7.1 General Representations and Warranties. Each Party represents and warrants:

(a) Corporate Power and Authorization. It is duly organized and validly existing under the laws of the state of its incorporation, and has full corporate power and authority to execute and deliver this Agreement and to perform all of its obligations hereunder; and

(b) Binding Agreement. This Agreement is a legal and valid obligation binding upon it and enforceable in accordance with its terms; and

(c) No Conflict. The execution, delivery and performance of this Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any law or regulation of any court, governmental body, or administrative or other agency having jurisdiction over it; and

(d) Resources. It has adequate resources, both financial and otherwise, to perform its duties hereunder.

7.2 AFP Warranty. AFP represents and expressly warrants that the Product provided hereunder shall be in compliance with all applicable laws and regulations, free from defect, adulteration and contamination and free and clear of all liens, claims and encumbrances upon delivery. In addition to § 5.4 upon any breach of the warranty AFP shall at AFP's sole expense promptly (and in no event longer than sixty (60) days) correct, at no cost to MannKind, and at MannKind's request, any such breach by replacement of any Non-conforming Product and shall provide technical assistance to MannKind to address the Product non-conformity issues. Any replacement shall be considered a new Product for purposes of this § 7.2.

AFP represents and expressly warrants that the Product provided hereunder shall conform to the Specifications, shall be supplied in compliance with the QTA and instructions from MannKind, except where MannKind has failed to notify AFP of any Product that does not so conform pursuant to the terms of § 5.4(b); provided, however, that AFP shall remain liable for Product having latent defects that could not have been discovered by MannKind within the applicable period described in § 5.4(b) despite reasonable inspection by MannKind.

AFP represents and expressly warrants that it has and shall at all times throughout the term of this Agreement has, whether by right, title, interest, including by license or otherwise, the Intellectual Property Rights that are required to use, manufacture, market, offer to sell, sell, import and export the Product, and that this Agreement shall not infringe any third party patent rights.

7.3 Limitation of Liability. THE EXPRESS WARRANTIES AND REPRESENTATIONS SET FORTH IN SECTION 7.2, AND ANY OTHER AFP WRITTEN PROMISE OR STATEMENT EXPRESSLY REFERRED TO AS A WARRANTY, REPRESENTATION OR COVENANT IN THE AGREEMENT, ARE IN LIEU OF ALL OTHER WARRANTIES AND REPRESENTATIONS, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE WHICH ARE HEREBY DISCLAIMED AND EXCLUDED BY AFP, INCLUDING ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR USE, AND NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, INCLUDING PATENT RIGHTS.

7.4 Disclaimer of Consequential Damages. As used in this Section 7.4, the term "**AFP LIABILITY"** MEANS LIABILITY OF AFP OF ANY KIND, WHETHER UNDER CONTRACT, WARRANTY, TORT (INCLUDING LIABILITY FOR NEGLIGENCE), STRICT LIABILITY, STATUTE, OR ANY OTHER LEGAL OR EQUITABLE THEORY OF LIABILITY, ARISING OUT OF, CONNECTED WITH, OR RELATING IN ANY MANNER

TO THIS AGREEMENT. TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW AND NOTWITHSTANDING THAT ANY REMEDY REFERRED TO, OR LIMITATION OF CUMULATIVE LIABILITY SET FORTH, WITH THE EXCEPTION OF ANY WILLFUL MISCONDUCT, IN NO EVENT WILL AFP LIABILITY INCLUDE, AND AFP SHALL NOT BE LIABLE FOR, ANY SPECIAL, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL LOSSES OR DAMAGES (INCLUDING LOSS OF PROFIT OR REVENUES, INJURY TO GOODWILL, LOSS OF THE USE OF GOODS OR EQUIPMENT, DAMAGE TO ANY ASSOCIATED EQUIPMENT, COST OF CAPITAL, DOWNTIME COSTS, OR CLAIMS OF MANNKIND'S CUSTOMERS, AFFILIATES, LICENSEES, DISTRIBUTORS OR OTHER THIRD PARTIES FOR SUCH DAMAGES OR LOSSES) EVEN IF AFP WAS ADVISED OF THE POSSIBILITY OF SUCH POTENTIAL DAMAGE OR LOSS;

7.5 Cumulative Liability. TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, AFP LIABILITY WILL BE LIMITED TO DAMAGES AND LOSSES NOT TO EXCEED IN THE AGGREGATE [***] EUROS (EU [***]) . IT IS UNDERSTOOD THAT THE FOREGOING MONETARY LIMITATION OF LIABILITY REPRESENTS AFP'S TOTAL AND CUMULATIVE LIABILITY FOR ALL AFP LIABILITY.

7.6 No Debarred or Disqualified Persons. AFP represents and warrants that it shall not employ, contract with, or retain any person directly or indirectly to perform any activities relating to the manufacture or supply of Product if such a person (a) is under investigation by the FDA for debarment or is presently debarred by the FDA pursuant to 21 U.S.C. § 335a or its successor provisions or by the applicable regulatory authority in any country or jurisdiction outside the United States under comparable regulations, or (b) has a disqualification hearing pending or has been disqualified by the FDA pursuant to 21 C.F.R. § 312.70 or its successor provisions or by the applicable regulatory authority in any other country or jurisdiction outside the United States under comparable regulations. In addition, AFP represents and warrants that it has not engaged in any conduct or activity which could lead to any of the above-mentioned disqualification or debarment actions. If, during the term of this Agreement, AFP or any person employed or retained by it to perform any activities relating to the manufacture or supply of Product (i) comes under investigation by the FDA or by the applicable regulatory authority in any country or jurisdiction outside the United States for a debarment action or disqualification, (ii) is debarred or disqualified, or (iii) engages in any conduct or activity that could lead to any of the above-mentioned disqualification or debarment actions, AFP shall immediately notify MannKind of same.

7.7 Covenants. Contemporaneous with the Effective Date, the Parties hereby agree to negotiate in good faith the execution of a Quality/Technical Agreement, incorporated hereby by reference, which sets forth, among other things, the quality control and quality assurance terms for the Product. Such Quality/Technical Agreement shall be mutually agreed to in writing prior to placement of any Purchase Order for the Product.

8. INDEMNIFICATION

8.1 Mutual Indemnification. Each Party (the "***Indemnifying Party***") shall indemnify and hold harmless the other Party and its Affiliates, and their respective directors, employees, consultants and agents (the "***Indemnified Parties***") from and against any and all liabilities, losses, damages, costs, and other expenses (including attorneys' and expert witnesses' costs and fees)

(***"Losses"***) incurred by the Indemnified Parties as a result of any claim, demand, action or proceeding by any third party (a ***"Claim"***) to the extent arising from or relating to any breach of any representation, warranty, covenant, or obligation of the Indemnifying Party under this Agreement or any intentional misconduct or gross negligence by the Indemnifying Party or any of its employees, agents, or subcontractors, except, in each case, to the extent such Losses result from the intentional misconduct or gross negligence of, any of the Indemnified Parties.

8.2 Indemnification Procedures. In the event of any Claim for which any Indemnified Party is or may be entitled to indemnification hereunder, the Indemnified Party may, at its option, require the Indemnifying Party to defend such Claim at the Indemnifying Party's sole expense. Indemnifying Party may not settle any such Claim without the Indemnified Party's express prior written consent.

8.3 Failure to Defend or Settle. If the Indemnifying Party fails or wrongfully refuses to defend or settle any Claims, then the Indemnified Party shall, upon written notice to the Indemnifying Party, have the right to defend or settle (and control the defense of) such Claims. In such case, the Indemnifying Party shall cooperate, at its own expense, with the Indemnified Party and its counsel in the defense and settlement of such Claims, and shall pay, as they become due, all costs, damages, and reasonable legal fees incurred therefore.

9. INSURANCE PROTECTION. Each Party shall obtain and maintain during the term of this Agreement liability, comprehensive, and workers' compensation insurance with a reputable insurance company to help protect against those insurable risks that such Party may incur in connection with the performance of its obligations under this Agreement. Each Party shall provide, upon request, to the other Party any such policies of such insurance, and the premium receipt(s) and insurance certificate(s) therefore.

10. TERM; TERMINATION

10.1 Term. This Agreement shall begin on the Effective Date and, unless terminated sooner as provided in § 10.2, expire on December 31, 2019. The Parties may renew this Agreement for additional, successive two (2) year terms upon twelve (12) months written notice, given prior to the end of the initial or any additional two (2) year term.

10.2 Termination Events

(a) For Cause. A Party shall have the right to terminate this Agreement for cause if the other Party materially breaches this Agreement and fails to cure such breach within sixty (60) days after receiving written notice that specifies the particulars of such breach.

(b) Force Majeure. A Party shall have a right to terminate this Agreement in accordance with § 12.14.

(c) Without Cause. MannKind shall have the right to terminate this Agreement without cause upon two (2) years' prior written notice to AFP.

(d) Business Circumstances. A Party shall have the right to terminate this Agreement in the event of the other Party's liquidation, bankruptcy or state of insolvency upon written notice to such other Party.

(e) Regulatory Decisions. MannKind may terminate this Agreement upon a thirty (30) day written notice to AFP if a controlling regulatory authority withdraws approval of the MannKind Product.

10.3 Effects of Termination. Upon the expiration or earlier termination of this Agreement: (a) MannKind shall pay to AFP all amounts due to AFP under this Agreement, including any unpaid Purchase Commitment Difference within sixty (60) days of the effective date of such expiration or earlier termination; provided however, only in the event of a termination by MannKind pursuant to §10.2(c) or §10.2(e), MannKind shall pay to AFP within sixty (60) calendar days of the effective date of such expiration or earlier termination, the full payment for all remaining Purchase Commitment Quantities as provided in the table set forth in §6.1, as well as any unpaid Purchase Commitment Difference; and (b) each Party shall return to the other Party, upon the other Party's request, all tangible items of the other Party in its possession or under its control evidencing the Confidential Information of the other Party, if applicable. The expiration or earlier termination of this Agreement shall not affect any rights or claims of a Party hereunder that accrued prior to the date of such expiration or earlier termination.

10.4 Survival. Sections (§): § 1, §2.4, §2.5, §3.1, §6.1, §4.4, §4.6, §4.7, §7, §8, §9, §10.3, §10.4, §11, §12 shall survive the expiration or termination of this Agreement.

11. CONFIDENTIAL INFORMATION

11.1 Confidentiality Obligations. Each Party shall at all times, and notwithstanding any termination or expiration of this Agreement, hold in confidence and not disclose to any third party Confidential Information of the other Party, except as approved in writing by the other Party to this Agreement, and shall use the Confidential Information for no purpose other than the purposes expressly permitted by this Agreement. For clarification, all MannKind Intellectual Property Rights, shall be Confidential Information of MannKind. For clarification, all AFP Intellectual Property Rights shall be the Confidential Information of AFP. Each Party shall only permit access to Confidential Information of the other Party to those of its and its Affiliates' employees, consultants, agents, and attorneys and, in the case of MannKind, to its licensee of rights to the MannKind Product, in each case who have a need to know and are bound by confidentiality obligations at least as restrictive as those contained herein. The obligations in this § 11.1 shall terminate five years from the date of expiration or termination of this Agreement in accordance with § 10.

11.2 Exceptions to Confidentiality Obligations. A Party's obligations under this Agreement with respect to any portion of the other Party's Confidential Information shall terminate when the Party that is subject to such obligations can document in writing that such information: (a) entered the public domain through no fault of such Party; (b) was in such Party's possession free of any obligation of confidence at the time it was communicated to such Party by the other Party; (c) was rightfully communicated to such Party free of any obligation of confidence subsequent to the time it was communicated to such Party by the other Party; or (d) was developed

by employees or agents of such Party independently of and without reference to any information communicated to such Party by the other Party.

11.3 Authorized Disclosure. Notwithstanding anything to the contrary, a Party shall not be in violation of § 11.1 with regard to a disclosure of the other Party's Confidential Information that is in response to a valid order by a court or other governmental body or necessary to comply with applicable law or governmental regulations, provided that if such Party is required to make any such disclosure of the other Party's Confidential Information it shall to the extent practicable give reasonable advance notice to the other Party of such disclosure requirement in order to permit the other Party to seek confidential treatment of or to limit the Confidential Information required to be disclosed.

11.4 Previous Confidential Disclosure Agreements. As of the Effective Date, the terms of this § 11 shall supersede any prior confidential disclosure agreements between the Parties dealing with the subject of this Agreement. Any information disclosed under such prior agreements shall be deemed disclosed under this Agreement.

11.5 Publicity; Filing of Agreement. Each Party shall have the right to issue from time to time press releases that disclose the relationship of the Parties under this Agreement upon the agreement of the Parties, which agreement shall not be unreasonably withheld, delayed, or conditioned. Any press releases that are to be issued by either Party shall be in a form and substance as may be mutually agreed upon by the Parties. The Parties will coordinate in advance with each other in connection with the filing of this Agreement (including redaction of certain provisions of this Agreement) with the U.S. Securities and Exchange Commission (the "***SEC***"), the NASDAQ stock exchange or any other stock exchange or governmental agency on which securities issued by a Party or its Affiliate are traded, and each Party will use reasonable efforts to seek confidential treatment for the terms proposed to be redacted; provided, that each Party will ultimately retain control over what information to disclose to the SEC, the NASDAQ stock exchange or any other stock exchange or governmental agency, as the case may be, and provided further that the Parties will use their reasonable efforts to file redacted versions with any governing bodies which are consistent with redacted versions previously filed with any other governing bodies. Other than such obligation, neither Party (nor its Affiliates) will be obligated to consult with or obtain approval from the other Party with respect to any filings to the SEC, the NASDAQ stock exchange or any other stock exchange or governmental agency.

12. MISCELLANEOUS

12.1 Assignment. Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld); provided, however, that either Party may assign this Agreement and its rights and obligations hereunder without the other Party's consent (a) in connection with the transfer or sale of all or substantially all of the business of such Party to which this Agreement relates to a third party, whether by merger, sale of stock, sale of assets or otherwise, including, for greater certainty, by MannKind to its licensee(s) of the MannKind Product in connection with the transfer of manufacturing responsibility for the MannKind Product to such licensee, or (b) to any Affiliate. Notwithstanding the foregoing, any such assignment to an Affiliate or licensee(s) shall not relieve

the assigning Party of its responsibilities for performance of its obligations under this Agreement, and the assigning Party hereby guarantees the performance of this Agreement by such Affiliate or licensee(s). The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties. Any assignment not in accordance with this Agreement shall be void.

12.2 Ownership Rights. Each Party shall retain ownership and control of their respective works of authorship, inventions, know-how, information, data, and all Intellectual Property Rights therein that were in existence as of the Effective Date or are created thereafter, whether or not in the course of the performance of its obligations under this Agreement. The Parties hereby acknowledge that neither Party has, nor shall it acquire, any interest in any of the other party's Intellectual Property Rights, unless otherwise expressly agreed to in writing.

12.3 Relationship of the Parties. It is expressly agreed that AFP and MannKind shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture or agency of any kind. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

12.4 Amendment. Unless otherwise provided herein, this Agreement may not be changed, waived, discharged, or terminated orally, but instead only by a written document that is signed by the duly authorized officers of both Parties.

12.5 Waiver. No failure or delay by either Party in exercising any right, power, or privilege under this Agreement shall operate as a waiver thereof, nor shall any single or partial waiver thereof include any other or further exercise thereof or the exercise of any other right, power, or privilege.

12.6 Severability. Whenever possible, each provision of the Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any term or provision of this Agreement is held to be prohibited by or invalid under applicable law, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of the Agreement and this Agreement shall be interpreted and construed as if such provision had never been contained herein.

12.7 Notices. All notices and statements to be given (which shall be in writing) and all payments to be made hereunder shall be given or made at the respective addresses of the Parties as set forth above, unless notification of a change of address is given. All notices, payments and statements to be made hereunder shall be mailed by certified or registered mail, return receipt requested, or sent by overnight courier, or by facsimile or other electronic means. Any notice given pursuant to this Agreement by mail shall be considered effective three (3) business days after mailing. Any notice sent by overnight courier shall be considered effective one day after mailing. The date of transmission of any notice sent by electronic means shall be deemed to be the date the notice or statement is transmitted.

12.8 Construction. The section headings of this Agreement are inserted only for ease of reference only, and shall not be used to interpret, define, construe, or describe the scope or

extent of any aspect of this Agreement. Unless otherwise expressly stated, when used in this Agreement the word "including" means "including but not limited to." References to "days" shall mean calendar days unless reference to business days is made expressly. Each Party represents that it has had the opportunity to participate in the preparation of this Agreement and hence the Parties agree that the rule of construction that ambiguities be resolved against the drafting Party shall not apply to this Agreement.

12.9 No Third Party Beneficiaries. Unless expressly provided, no provisions of this Agreement are intended or shall be construed to confer upon or give to any person other than MannKind and AFP any rights, remedies, or other benefits under or by reason of this Agreement.

12.10 Dispute Resolution. If a dispute arises under this Agreement, the Parties shall use reasonable efforts to attempt to resolve such dispute, including escalation of discussions to the appropriate level of management, as provided in § 12.13, prior to exercising any remedies that may exist before commencing an action against the other Party. Notwithstanding the foregoing, either Party may at any time seek equitable relief under § 12.11 without first attempting to resolve a dispute under this § 12.10 provided, however, that such Party notifies the other Party promptly after it files any such action.

12.11 Equitable Relief. Each Party acknowledges and agrees that any breaches or violations of § 3 or § 11 may cause the non-breaching Party irreparable damage for which the award of monetary damages would be inadequate. Consequently, the non-breaching Party may seek to enjoin the breaching Party from any and all acts in violation of any such provisions, which remedy shall be cumulative and not exclusive, and a Party may seek the entry of an injunction enjoining any breach or threatened breach of such provisions, in addition to any other relief to which the non-breaching Party may be entitled at law or in equity.

12.12 Governing Law. This Agreement shall be governed by and interpreted under the laws the State of Delaware, without regard to its conflict or choice of law provisions. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.

12.13 Alternative Dispute Resolution. The Parties shall attempt by direct negotiation, between the Project Team, or pertinent members, in good faith to resolve promptly any dispute arising out of or relating to this Agreement. If the matter cannot be resolved in the normal course of business either Party shall give the other Party written notice of any such dispute not resolved at which time the dispute shall be referred to the senior management of the respective Parties who shall likewise attempt to resolve the dispute.

If the dispute has not been resolved by negotiation as detailed above, or if the Parties fail to meet, within twenty (20) business days from such notice, either party may submit the dispute to arbitration to the International Institute for Conflict Prevention & Resolution ("CPR") for resolution in accordance with the CPR Arbitration Rules and Commentary. A single, impartial arbitrator mutually acceptable to the Parties shall conduct the arbitration. In the event the Parties cannot agree on an arbitrator within ten (10) business days after the end of the aforesaid twenty (20) business days, either Party may have an arbitrator appointed by the CPR.

The location of the arbitration shall be in New York, NY, USA, unless the Parties agree otherwise. As a condition of appointment of the arbitrator, said arbitrator shall agree to use her/his best efforts to conclude the proceeding within thirty (30) business days. Said arbitrator shall further have the authority to limit the volume of evidence and documents to be submitted by the Parties. Any court having jurisdiction thereof may enter judgment upon the award rendered by the arbitrator. This Section shall, however, not be construed to limit or to preclude either Party from bringing any action in any court of competent jurisdiction for injunctive or other provisional relief as necessary or appropriate.

12.14 Force Majeure. AFP shall not be liable to MannKind for any failure or delay in the performance of any of its obligations under this Agreement arising out of any event or circumstance beyond its reasonable control, including war, rebellion, terrorism, civil commotion, strikes, lock-outs or industrial or labor disputes; fire, explosion, earthquake, acts of God, flood, drought, or bad weather; or requisitioning or other act or order by any government or regulatory authority. If such failure or delay occurs, then AFP shall give MannKind notice of the circumstances causing such failure or delay, and AFP shall be excused from the performance of such of its obligations that it is thereby disabled from performing for so long as it is disabled and for sixty (60) calendar days thereafter; provided, however, that AFP commences and continues to take reasonable and diligent actions to cure such failure or delay. Notwithstanding the foregoing, if AFP is disabled from the performance of any material obligation under this Agreement for a period of ninety (90) calendar days or more, then MannKind shall have the right to terminate this Agreement upon written notice to AFP, in which event the provisions of § 10.3 shall apply.

12.15 Attorneys' Fees. If any claim, action, or dispute arises between the parties with respect to any matter covered by this Agreement that leads to a proceeding before a court of competent jurisdiction to resolve such claim, the Prevailing Party in such proceeding shall be entitled to receive from the other Party its reasonable attorneys' fees, expert witness fees, court costs and other out-of-pocket costs incurred in connection with such proceeding, in addition to any other relief that it may be awarded. For purposes of this Section, the term "Prevailing Party" means that Party in whose favor any monetary or equitable award is made or in whose favor any dispute is resolved, regardless of any settlement offers.

12.16 Entire Agreement. This Agreement includes all exhibits attached hereto and any Specifications that are executed by authorized representatives of the Parties, and constitutes the entire agreement by and between the Parties as to the subject matter hereof. This Agreement supersedes and replaces in its entirety all prior agreements, understandings, letters of intent, and memoranda of understanding by and between the Parties hereto, in either written or oral form. No amendment or modification of this Agreement shall be valid unless set forth in writing referencing this Agreement and executed by authorized representatives of both Parties.

12.17 English Language. This Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties regarding this Agreement, or delivered pursuant to the terms of this Agreement, shall be in the English language. Any proceedings related to dispute resolution including, but not limited to legal, equitable, or alternative dispute resolution, shall be conducted in the English language.

12.18 Counterparts; Electronic or Facsimile Signatures. This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument. This Agreement may be executed and delivered electronically or by facsimile and upon such delivery such electronic or facsimile signature will be deemed to have the same effect as if the original signature had been delivered to the other Party.

12.19 Reservation of Rights. Except for the rights expressly provided in this Agreement, no other rights are granted by either Party to the other Party. Notwithstanding anything to the contrary, no rights or licenses are granted under this Agreement by either Party to the other for the use of any trade names, trademarks, and service marks.

In Witness Whereof, the Parties hereto have this day caused this Agreement to be executed by their duly authorized officers.

Amphastar France Pharmaceuticals S.A.S.		**MannKind Corporation**	
By:	/s/ Franck Vitali	By:	/s/ Matthew Pfeffer
Name:	Franck Vitali	Name:	Matthew Pfeffer
Title:	Plant Manager	Title:	CFO

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, 333-225428, 333-226648, and 333-242367 on Form S-8, and Registration Statement No. 333-230633 on Form S-3 of our report dated February 25, 2021, relating to the financial statements of MannKind Corporation and subsidiaries ("MannKind Corporation") appearing in this Annual Report on Form 10-K of MannKind Corporation for the year ended December 31, 2020.

/s/ Deloitte & Touche LLP

Los Angeles, CA

February 25, 2021

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, 2021

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, 2021

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, 2020, 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, 2021.

/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, 2020, 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, 2021.

/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.