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, 2021

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.)**
1 Casper Street **Danbury, Connecticut**	**06810**
(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, 2021, 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 $1,266,168,274.

As of February 11, 2022, there were 251,798,303 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 2022 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than May 2, 2022 are incorporated by reference into 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, 2021

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Forward-Looking Statements

Statements in this report that are not strictly historical in nature are “forward-looking statements” within the meaning of the federal securities laws made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward-looking statements by terms such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “goal,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would,” and similar expressions intended to identify forward-looking statements, though not all forward-looking statements contain these identifying words. These statements may include, but are not limited to, statements regarding: our ability to successfully market, commercialize and achieve market acceptance for Afrezza or any other product candidates or therapies that we may develop; our ability to manufacture sufficient quantities of Afrezza and obtain insulin supply as needed; our ability to successfully commercialize our Technosphere drug delivery platform; our estimates for future performance; our estimates regarding anticipated operating losses, future revenues, capital requirements and our needs for additional financing; the progress or success of our research, development and clinical programs, including the application for and receipt of regulatory clearances and approvals; our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; and scientific studies and the conclusions we draw from them. These statements are only predictions or conclusions based on current information and expectations and involve a number of risks and uncertainties. The underlying information and expectations are likely to change over time. Actual events or results may differ materially from those projected in the forward-looking statements due to various factors, including, but not limited to, those set forth under the caption “Risk Factors” and elsewhere in this report. In addition, statements like “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements. Except as required by law, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Afrezza®, Technosphere®, BluHale® and MannKind Corporation 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

- Afrezza may only achieve a limited degree of commercial success. 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.
- 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 need to raise additional capital to fund our operations.
- 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 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.
- 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 be able to establish additional 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 successfully commercialize our product candidates.
- If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.
- 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 partner fails to comply with federal and state healthcare laws, including fraud and abuse and health information laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.
- We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

RISKS RELATED TO OUR COMMON STOCK

- We may not be able to generate sufficient cash to service all of our indebtedness and commitments. We may be forced to take other actions to satisfy our obligations 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 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 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, 37.3 million people in the United States had diabetes in 2019. Globally, the International Diabetes Federation has estimated that approximately 537 million adults had diabetes in 2021 and approximately 783 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. Our sales representatives promote Afrezza to endocrinologists and selected primary care physicians located throughout the United States. Our sales efforts are aided by support programs, such as our AfrezzaAssist program that helps patients and physicians navigate through access, reimbursement and training questions, and savings programs, such as our co-pay assistance program for patients with commercial insurance and our cash pay program for patients with no insurance. 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 partner in India, Cipla Ltd. ("Cipla"), is currently conducting a clinical study of Afrezza in order to meet the requirements for a regulatory submission to the Drug Controller General of India.

As part of the approval of Afrezza, the FDA required us to conduct certain additional clinical studies of Afrezza in pediatric patients. In the third quarter of 2021, we initiated a Phase 3 clinical trial to evaluate the safety and efficacy of Afrezza in combination with basal insulin versus multiple daily injections of insulin in children and adolescents aged 4-17 who are living with type 1 or type 2 diabetes. This study, known as the INHALE-1 study, is a 26-week open-label, randomized clinical trial with a 26-week extension period. The primary endpoint is change in HbA1c level after 26 weeks. Secondary endpoints include change in fasting plasma glucose after 26 weeks, and rate of hypoglycemic events. We do not expect to complete the INHALE-1 study until 2023 at the earliest.

When Afrezza was approved, the FDA also required us to conduct a five-year, randomized, controlled trial in 8,000-10,000 patients with type 2 diabetes to assess the long-term safety of Afrezza. In discussions with the FDA during 2021, the agency indicated that this requirement could potentially be satisfied through a retrospective analysis or a prospective registry study rather than a randomized controlled trial. The details of such a modified requirement will be elaborated in further discussions with the FDA that are planned for later in 2022.

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.

Using our formulation and inhaler technology, we advanced an inhaled formulation of treprostinil Technosphere into clinical development in June 2018. In September 2018, we entered into a license and collaboration agreement (the "UT License Agreement") with United Therapeutics Corporation ("United Therapeutics" or "UT"), pursuant to which UT assumed responsibility for global development, regulatory and commercial activities with respect to a product that UT has branded as Tyvaso DPI, while we retained responsibility for manufacturing clinical and commercial supplies. In April 2021, United Therapeutics submitted a new drug application ("NDA") to the FDA seeking approval of Tyvaso DPI for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with

interstitial lung disease (PH-ILD). In October 2021, the FDA provided UT with a complete response letter (CRL) in which it declined to approve the Tyvaso DPI NDA, citing an open inspection issue at a third-party analytical testing facility for the treprostinil drug substance as the single deficiency preventing approval of Tyvaso DPI. The CRL noted, but did not cite as a deficiency, that the FDA had not yet completed its review of a citizen petition submitted to the FDA in July 2021 concerning the safety of an excipient in Tyvaso DPI. In December 2021, UT resubmitted the NDA to the FDA, addressing the single deficiency cited in the CRL. In January 2022, the FDA accepted the resubmitted NDA for review, and designated it as a class 1 resubmission with an expected two-month review period ending in February 2022. In mid-February 2022, the FDA requested additional information from UT concerning the pulmonary safety of Tyvaso DPI related to the citizen petition. UT promptly responded to the FDA's request. The FDA subsequently indicated that the response constitutes a major amendment to the Tyvaso DPI NDA, which extends to May 2022 the FDA's deadline to complete its review of the pending NDA.

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. The lead program from this acquisition (MNKD-101) is an inhaled, nebulized formulation of clofazimine, which could potentially provide several clinical advantages over the current solid oral dosage form of this drug. MNKD-101 is currently being evaluated in an initial clinical study in Australia. The FDA has designated MNKD-101 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 MNKD-101, we are evaluating 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. We have also partnered with several third parties that have proprietary rights to certain compounds in order to evaluate the feasibility of developing dry-powder formulations of such compounds. We may seek to convert certain of these exploratory programs into full development programs funded by the external parties.

To aid in the development of 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. A consumer version of the apparatus, with additional features, is 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 and package the cartridges into blister packs. We utilize a contract packager to assemble the final kits of Afrezza and Tyvaso DPI cartridges along with inhalers and package inserts.

The quality management systems of our Danbury 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 July 2021 when the FDA conducted a pre-approval inspection related to Tyvaso DPI and a GMP inspection related to Afrezza. The FDA made one observation during its most recent inspection, which we corrected and addressed with the FDA following the site visit. We were also inspected by the Agência Nacional de Vigilância Sanitária ("ANVISA") (Brazil National Health Surveillance Agency) in May 2018. 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 Danbury facility has enough capacity to satisfy the current demand for Afrezza and, if approved, Tyvaso DPI. In addition, we are currently expanding production capacity with additional filling lines and other equipment in order to meet the demand for Tyvaso DPI projected by UT over the next several years. The costs of this expansion project are being borne by UT.

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, 2027. As of December 31, 2021, there was $82.8 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 at no cost by 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.

The BluHale device is assembled for us by a contract manufacturer using components that are sourced from multiple vendors.

In general, our suppliers and contract manufacturers are sophisticated and mature organizations, often with multinational operations, that have significant experience with pharmaceutical and medical device manufacturing. Our quality and manufacturing personnel conduct extensive inspections to qualify new vendors and periodic GMP audits of their operations on an ongoing basis. With the expansion of our supply chain into the electronic components that are required for BluHale devices, we have begun to require our vendors to confirm that conflict minerals are not knowingly or intentionally added during the manufacturing process for, or are unnecessary to the functionality or production of, the components that we source from such vendors.

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 640 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 65 applications pending that may provide additional protection for Afrezza if and when they are allowed. Similarly, Tyvaso DPI is protected by approximately 400 issued patents in the United States and elsewhere and an additional 50 pending applications. The longest-lived patent protection for Tyvaso DPI will expire in 2035. Our entire portfolio consists of approximately 1,100 issued patents and approximately 170 patent applications that provide protection for MNKD-101, 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 178 registered trademarks and 60 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 research, clinical development, testing, manufacture, labeling, storage, shipping, approval, recordkeeping, advertising, promotion, sale and distribution of medical devices and new drug and biologic 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, 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, such as 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 the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, "PPACA"), which was enacted in March 2010. In the years since the PPACA was enacted, there have been a number of executive, judicial and congressional challenges to certain aspects of PPACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain provisions of the PPACA have been signed into law. For example, 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". Subsequently, a Texas U.S. District Court Judge ruled in December 2018 that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Ultimately, in June 2021 the Supreme Court dismissed this challenge to the constitutionality of the PPACA, so it remains in effect in its current form. However, 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 presidential executive orders, 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, July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. It is unclear whether these or similar policy initiatives will be implemented in the future. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In addition, Congress is considering additional health reform measures. 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, among other things, 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), certain other healthcare professionals (such as physician assistants and

nurse practitioners), and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and (ii) report annually certain ownership and investment interests held by physicians and their immediate family members.

In 2020, we reported approximately $383,700 in payments to physicians under the Physician Payments Sunshine Act, which consisted of $216,140 in speaking fees, $121,740 in meals, $31,600 in consulting fees and $14,220 in other payments. We also reported approximately $294,190 in research payments to teaching hospitals. Our report for payments to physicians and teaching hospitals for 2021 is due to be submitted to the Centers for Medicare & Medicaid Services ("CMS") by March 31, 2022.

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. 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 personal data, including 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. For example, the California Consumer Privacy Act of 2018 ("CCPA") imposes obligations on covered businesses. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA allows for statutory fines for noncompliance (up to $7,500 per violation). Although the CCPA exempts some data processed in the context of clinical trials, the CCPA may increase compliance costs and potential liability with respect to other personal data we maintain about California residents. In addition, it is anticipated that the California Privacy Rights Act of 2020 ("CPRA"), effective January 1, 2023, will expand the CCPA. Additionally, the CPRA establishes a new California Privacy Protection Agency to implement and enforce the CPRA, which could increase the risk of enforcement. Other states have enacted data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which become effective in 2023. U.S. federal and state consumer protection laws require us to publish statements that accurately and fairly describe how we handle personal data and choices individuals may have about the way we handle their personal data.

Foreign data privacy and security laws impose significant and complex compliance obligations on entities that are subject to those laws. As one example, the European Union's General Data Protection Regulation 2016/679 ("EU GDPR"), contains 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 EU GDPR.

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 requires that our employees promote our products fairly, truthfully, accurately and on-label. Off-label promotion of our products is explicitly prohibited, as are sales activities that would interfere with a healthcare provider's independent medical judgment or the doctor-patient relationship. All sales staff received compliance training upon hire and on an annual basis. We also routinely monitor sales calls. 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 avoid the incidence of unethical marketing practices.

As part of our commitment to patient support and education, our employees and consultants may attend and participate in certain patient events, such as health fairs or local disease awareness and advocacy events. In all cases, interactions with patients and patient groups may only be conducted in settings that are suitable for patient education and separate from the usual place(s) of clinical business of healthcare providers or institutions. In addition, our sponsorship of such events, if any, must be clearly disclosed through prominent signage.

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 manufacture our approved and investigational products in accordance with the applicable cGMPs, QSR and other requirements enforced by the FDA and other regulatory bodies that have oversight over our products. 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.

All of our employees are required to adhere to a standard operating procedure for capturing and reporting adverse events, safety information, and product complaints/adverse incidents involving any drug products marketed by us. These reports, as well as those that are collected by our third-party call center, are evaluated, processed and reported to regulatory authorities in accordance with FDA regulations and guidance on the post-marketing reporting of adverse experiences involving drugs, medical devices and combination products.

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 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 clinical research organizations (CROs) that we engage. We also inspect our CROs prior to, and during, an engagement. 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.

Our policy is to disclose the basic results of all clinical trials that we conduct to test the effectiveness of investigational drugs intended to treat serious or life-threatening diseases or conditions (i.e., phase 2-4 clinical studies). Additionally, we may voluntarily disclose the results of initial safety studies (i.e., phase 1 clinical studies). We strive to disclose these results within one year of study completion or within 30 days of marketing authorization approval. In our disclosure of clinical trial results, our policy is to include all serious adverse events and those non-serious adverse events that have a frequency of at least five percent.

Corruption and Bribery

Our Code of Business Conduct and Ethics reflects the business practices and principles of behavior that we expect of every employee, officer and director. All new employees are trained on the Code of Business Conduct and Ethics and existing employees are required to acknowledge annually that they have refreshed their familiarity with the policies contained within it. Our Code of Business Conduct and Ethics includes clear guidelines on anti-bribery and anti-corruption practices. In addition, we have adopted a separate 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 $36.6 million and $25.9 million as of December 31, 2021 and 2020, respectively.

Employees and Human Capital

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. Specifically, our policy is that no aspect of employment, including hiring and promotional opportunities, will be subject to unlawful discrimination or harassment (including sexual harassment) based on race, creed, color, religion, national origin, ancestry, gender (including pregnancy, breastfeeding or medical conditions related to pregnancy or breastfeeding), age, physical or intellectual disability, sexual orientation, gender identity, gender expression, gender stereotyping, marital status, military or veteran status, citizenship, genetic characteristic or information, or any other characteristic protected by applicable federal, state or local law.

As of December 31, 2021, we had 349 total at-will employees, of which 348 were full-time. Of our full-time employees, 147 were engaged in manufacturing, 41 in research and development, 50 in general and administrative and 110 in selling and marketing. Seventeen of these employees had a Ph.D. degree and/or M.D. degree and were engaged in activities relating to research and development, manufacturing, quality assurance or business development. As of December 31, 2021, our workforce was distributed along genders and ethnic minorities as follows:

Grade Levels	Number	Female (%)	Ethnic minority (%)
Vice President and above	14	21%	14%
Executive Director, Director and Senior Manager	97	44%	28%
Managers and below	238	43%	43%
All employees	**349**	**43%**	**38%**

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 strive to conduct employee surveys approximately every six months.

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 components:

- 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.
- Employee Recognition Program – We provide a company-wide Spot and Peer to Peer Recognition Program to more directly reward performance and behaviors and drive cultural improvement.

The majority of our employees are essential workers involved in the production of medicine for chronic diseases. As such, they cannot work remotely and must perform their job duties in our Connecticut facility according to a 24/7 shift schedule. Other employees have work responsibilities that can be performed somewhat asynchronously and in different locations. For such employees, our general preference is that in-office employees be in the office during core business hours at least four days per week in order to maximize the productivity gains that come from having a collaborative culture and a common workplace; however, we also recognize that such employees can be equally productive working from home some of the time or with a flexible workday that they can structure around significant events outside of the workplace, such as commute times or childcare responsibilities.

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 2021, our total illness and injury incidence rate was 0.3 per 100 employees compared to the 2020 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 2020 industry average of 1.2. 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 1 Casper Street, Danbury, Connecticut 06810, and our general telephone number is (818) 661-5000. 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.	45	Chief Executive Officer
Steven B. Binder	59	Chief Financial Officer
Alejandro Galindo	49	Chief Commercial Officer
Joseph Kocinsky	58	Chief Technology Officer
Stuart A. Tross, Ph.D.	55	Chief People and Workplace Officer
David B. Thomson, Ph.D., J.D.	55	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

Afrezza may only achieve a limited degree of commercial success. 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 commercialization and development of Afrezza, which has been on the market since February 2015. To date, Afrezza sales have been modest by comparison to other mealtime insulins. If we remain on the existing growth curve, we may never generate significant revenues from Afrezza in the United States.

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 may need to 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 medical and sales materials 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, as part of the approval of Afrezza, the FDA required us to conduct certain additional clinical studies of Afrezza. These studies will require significant capital resources, some of which may not be available to us. We have initiated one of these studies, a Phase 3 clinical trial to evaluate the safety and efficacy of Afrezza in 4-17 year-old children and adolescents. We have engaged a clinical research organization to assist us with conducting this study and have budgeted the projected costs of the study in our operating plans. The other required study is a long-term safety study that was originally intended 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 agency’s current interest in the long-term safety of Afrezza and an appropriate study design to address any concerns. To date, we have not commenced a long-term safety study or budgeted any amount for it, but such a study in its original design would be anticipated to require substantial capital resources that we may not be able to obtain.

If we fail to achieve better commercial success with Afrezza in the United States, our prospects for generating significant revenues from this product 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, and package the cartridges into secondary packaging. We also assemble the inhalers from their individual molded parts. These semi-finished goods are then assembled into the final kits for commercial sale by a contract packager.

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. These problems include difficulties with production costs and yields and quality control and assurance. We may experience shortages of qualified personnel, which could impact our ability to meet production schedules. There is also a need to comply with strictly enforced federal, state and foreign regulations, including inspections. Our facility is inspected on a regular basis by the FDA, most recently in July 2021 when the FDA conducted a pre-approval inspection related to Tyvaso DPI and a GMP inspection related to Afrezza. The FDA made one observation during its most recent inspection, which we corrected and addressed with the FDA following the site visit. If the FDA makes any major observations during future inspections, the corrective actions required could be

onerous and time-consuming.

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.

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 cGMP for drug products, and the production of the Afrezza/Tyvaso DPI 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 or Tyvaso DPI. 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.

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. Even if favorable coverage and reimbursement status is attained for Afrezza or our product candidates for which we or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. 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.

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.

We may need to raise additional capital to fund our operations.

As of December 31, 2021, we had cash and cash equivalents of $124.2 million, short-term investments of $79.9 million and long-term investments of $56.6 million, and we had $288.4 million principal amount of outstanding debt. We may need to raise additional capital, whether through the sale of equity or debt securities, additional strategic business collaborations, the establishment of other funding facilities, licensing arrangements, asset sales or other means, in order to support our ongoing activities, including the commercialization of Afrezza and the development of our product candidates. It may be difficult for us to raise additional funds on favorable terms, or at all. The extent of our additional funding requirements will depend on a number of factors, including:

- the degree to which revenue from Afrezza exceeds or does not exceed the minimum revenue covenants under the MidCap credit facility, if applicable;
- the degree to which we are able to generate revenue from Tyvaso DPI and our Technosphere drug delivery platform, including through collaborations;
- the costs of developing and commercializing Afrezza on our own in the United States, including the costs of expanding our commercialization capabilities;
- the demand by any or all of the holders of our debt instruments to require us to repay or repurchase such debt securities if and when required;
- our ability to repay or refinance existing indebtedness, and the extent to which our notes with conversion options or any other convertible debt securities we may issue are converted into or exchanged for shares of our common stock;
- the rate of progress and costs of our clinical studies and research and development activities;
- the costs of procuring raw materials and operating our manufacturing facility;
- our obligation to make lease payments and 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, Tyvaso DPI 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 ongoing 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.

Issuances of additional debt or equity securities or the issuance of common stock upon conversion of outstanding convertible debt securities 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.

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

Our operating results have fluctuated in the past and are likely to do so in future periods. Some of the factors that could cause our operating results to fluctuate from period to period include the factors that will affect our funding requirements described above under “Risk Factors — We may need to raise additional capital to fund our operations.”

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 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.

Our business could be adversely affected by the effects of health pandemics or epidemics in regions where we have business operations, and we could experience significant disruptions in the operations of third-party manufacturers and distributors upon whom we rely. In particular, the ongoing COVID-19 pandemic could materially affect our operations, including 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.

The ongoing COVID-19 pandemic has resulted in a number of restrictions to reduce the spread of the disease, many of which have been eased or lifted in recent months. The emergence of new variants of the SARS-CoV-2 virus raises the possibility that recurring cycles of infection and corresponding restrictions will be imposed in the future, notwithstanding vaccination and other public health efforts. The effects of the restrictions related to the COVID-19 pandemic and our related policies addressing the pandemic, including the evolving nature of such policies, may negatively impact productivity, disrupt our business and delay our development programs, regulatory and commercialization timelines. We may also face challenges or disruptions as employees return back to the workplace, including re-integration challenges by our employees and distractions to management related to such transition. 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 2022, 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 COVID-19 pandemic has the potential to continue to negatively impact the distribution of Afrezza by our partner in Brazil.

Sales and demand for Afrezza have been adversely affected by the COVID-19 pandemic, and we expect this trend to continue for at least the near-term. Although our sales representatives are conducting in-person sales calls to the extent permitted by state and local public health authorities and by the policies of individual healthcare providers that they interact with, they 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 periods 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 ongoing or planned clinical trials of Afrezza or those conducted by our Cipla or our other regional partners 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, 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 be able to establish additional 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, establish and maintain 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.

Other than Tyvaso DPI, which we licensed to UT in September 2018 after we conducted a Phase 1 clinical study, we have sought to develop our product candidates through our internal research programs. All of our product candidates will require additional research and development and, in some cases, significant preclinical, clinical and other testing prior to seeking regulatory approval to market them. Accordingly, these product candidates will not be commercially available for a number of years, if at all. Further research and development on these programs will require significant financial resources. Given our limited financial resources, our need to support the launch preparations of Tyvaso DPI and our ongoing attention on the development and commercialization of Afrezza, we may 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 through 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, 2021, we had an accumulated deficit of $3.1 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 and advance product candidates in our pipeline. In addition, under our Insulin Supply Agreement with Amphastar, we agreed to purchase certain annual minimum quantities of insulin through 2027. As of December 31, 2021, there was $82.8 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, 2021, we had $288.4 million principal amount of outstanding debt, consisting of:

- $230.0 million aggregate principal amount of Senior convertible notes bearing interest at 2.50% payable semi-annually in arrears on March 1 and September 1 of each year, beginning on September 1, 2021 and will mature on March 1, 2026, unless earlier converted, redeemed or repurchased. The Senior convertible notes are convertible at an initial conversion price of approximately $5.21 per share of Common Stock. The conversion rate is subject to adjustment under certain circumstances in accordance with the terms of the Indenture.
- $40.0 million principal amount under the MidCap credit facility, bearing interest at an annual rate equal to one-month LIBOR plus 6.25%, subject to a one-month LIBOR floor of 1.00%, payable in equal monthly installments beginning in September 2023 through maturity in August 2025.
- $18.4 million principal amount of indebtedness under the Mann Group convertible note bearing interest at a fixed rate of 2.50% per annum compounded quarterly and maturing in December 2025, which is convertible into shares of our common stock at the option of 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 pay interest in-kind or in shares.

Under the MidCap credit facility, our interest rate on borrowed amounts is dependent on one-month LIBOR, which is the basic rate of interest used in lending between banks on the London interbank market. LIBOR is widely used as a reference for setting the interest rate on loans globally. In March 2021, the Chief Executive of the United Kingdom Financial Conduct Authority, which regulates LIBOR, announced that the one-month LIBOR will either cease to be provided by any administrator or no longer be representative, effective immediately after June 30, 2023. The United States Federal Reserve has also advised banks to cease entering into new contracts that use LIBOR as a reference rate. 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 not yet been agreed upon. The Alternative Reference Rate Committee, a committee convened by the Federal Reserve that includes major market participants, has identified the Secured Overnight Financing Rate ("SOFR"), a new index calculated by short-term repurchase agreements, backed by Treasury securities, as its preferred alternative rate for LIBOR. We are not able to predict how markets will respond to SOFR or other alternative reference rates as the transition away from the LIBOR benchmarks. Accordingly, the outcome of these reforms is uncertain and any changes in the methods by which LIBOR is determined or regulatory activity related to LIBOR's phase-out could cause LIBOR to perform differently than in the past or cease to exist. The consequences of these developments cannot entirely be predicted, but could result in higher interest rates on our loans under the MidCap credit facility. Furthermore, we cannot predict or quantify the time, effort and cost required to transition to the use of new benchmark rates, including with respect to negotiating and implementing any necessary changes to existing contractual agreements, and implementing changes to our systems and processes. We cannot provide assurance that future

interest rate changes will not have a material negative impact on our business, financial position, or operating results.

Under the MidCap credit facility, we must comply with a minimum cash covenant of $10.0 million at all times prior to the approval by the FDA of Tyvaso DPI and we may be required to comply with additional covenants in the future under certain circumstances. 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.

If our unrestricted cash and short-term investments balance falls below $90.0 million, we will be subject to 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, or repay, our outstanding term loan under the MidCap credit facility 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.

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. 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 successfully 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 product liability claims are brought against us, we may incur significant liabilities and suffer damage to our reputation.

The testing, manufacturing, marketing and sales 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 as well as an errors and omissions policy 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. 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 Biden administration and Congress have proposed various U.S. federal tax law changes, which if enacted could have a material impact on our business, cash flow, financial conditions or results of operations. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax 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, 2021, we had federal and state net operating loss carryforwards of $2.2 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 current law, 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. 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, 2021, 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, 2021. There is a risk that changes in ownership may occur in tax years after December 31, 2021. 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. 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.

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 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. 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 our facility in Connecticut in 2001, a soil and groundwater investigation and remediation was being conducted by a former site operator (a responsible party) under the oversight of the Connecticut Department of Energy & Environmental Protection (formerly the Connecticut Department of Environmental Protection), which investigation and remediation is ongoing. The former site operator and responsible party will make further filings necessary to achieve closure for the environmental investigation and remediation it has conducted at the site, and has agreed to indemnify us for any future costs and expenses we may incur that are directly related to its prior operations at the facility. 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. When we sold a portion of the property upon which our facility is located to the entity that is now our landlord, we became an additional responsible party for any environmental investigation and remediation on that portion of the property, including with respect to investigation or remediation that may be required as a result of our activities since 2001. To date, we have not identified any material environmental investigation or remediation activities that we are required to perform.

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.

We, and third parties acting on our behalf, employ and are increasingly dependent upon information technology systems, infrastructure, applications, websites and other resources. Our business requires collecting, manipulating, analyzing, storing and otherwise processing large amounts of data, including proprietary data, sensitive data, personal data and other confidential information. In addition, we rely on an enterprise software system to operate and manage our business. Our business, including our ability to manufacture drug products and conduct clinical trials, therefore depends on the continuous, effective, reliable and secure operation of our information technology resources and those of third parties acting on our behalf, including computer hardware, software, networks, Internet servers and related infrastructure.

Cyberattacks, malicious internet-based activity, and online and offline fraud are prevalent and continue to increase. These threats are becoming increasingly difficult to detect. These threats come from a variety of sources, including traditional computer "hackers," threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors. We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats. Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems (including our products) or the third-party information technology systems that support us and our services. The COVID-19 pandemic and our remote workforce poses increased risks to our information technology systems and data, as more of our employees work from home, utilizing network connections outside our premises. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities,

as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies.

Any of the previously identified or similar threats could cause a security incident or other interruption. A security incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our products. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standards or reasonable security measures to protect our information technology systems and sensitive information. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We have not always been able in the past and may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. For example, like many companies, we use SolarWinds to help manage our information technology systems. A cyberattack on SolarWinds was discovered in December 2020 and widely exploited by threat actors. Upon learning of this vulnerability, we applied the software patch provided by SolarWinds and remediated the incident. The incident did not appear to have any negative impact on our operations or the sensitive information we may process. In addition, a ransomware attack on Ultimate Kronos Group's ("UKG") Kronos Private Cloud service was discovered in December 2021. We use UKG Pro, a product offered through UKG that is not in the Kronos Private Cloud, for human capital management. UKG is not aware of an impact on UKG Pro and the incident did not appear to have any negative impact on our operations or the sensitive information we may process. Thus, despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our products, deter new customers from using our products, and negatively impact our ability to grow and operate our business. Additionally, our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our cybersecurity insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

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 United Kingdom ("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 for product candidates, as well as the manufacturing and marketing of approved products, 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 as well as the manufacturing and marketing of drug products 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.

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 drug products is 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 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. In addition, interested parties (such as individuals, advocacy groups and competing pharmaceutical companies) can file a citizen petition with the FDA to request policy change or some form of administrative action on the FDA's part, including with respect to an NDA. For example, in July 2021, a third party submitted a citizen petition to the FDA requesting that the FDA refuse to approve Tyvaso DPI, and/or impose additional requirements in order to approve the product. This has prompted the FDA to request additional information concerning Tyvaso DPI and to delay the review deadline for the Tyvaso DPI NDA from February 2022 to May 2022. If successful, a citizen petition can significantly delay, or even prevent, the approval of a drug product.

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 be denied marketing approval or lose any marketing approval that we have already obtained. 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, as amended by the Health Care Education and Reconciliation Act (collectively, the "PPACA") substantially changed the way healthcare is financed by both governmental and private insurers and continues to significantly affect 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 ("AMP") 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 have been executive, judicial and congressional challenges to certain provisions of the PPACA, although the constitutionality of the PPACA appears to now be settled. It is possible that the PPACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges, other litigation, and the healthcare reform measures of the current administration will impact the PPACA.

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. Presidential executive orders, 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.

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 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, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. It is unclear whether these or similar policy initiatives will be implemented in the future. In addition, Congress is considering additional health reform measures. 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 will be 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.

We expect that PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private third-party 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 partner fails to comply with federal and state healthcare laws, including fraud and abuse and health information 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. The number and scope of these laws, regulations and industry standards are changing, subject to differing applications and interpretations, and may be inconsistent between jurisdictions or in conflict with each other, making compliance difficult. The key 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;
- 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), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members.

- Other 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 and other processing of personal data (including 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, or any contractual obligations related to the same, we may be subject to governmental enforcement actions, investigations, litigation (including class action lawsuits) and other penalties, including significant civil, criminal and administrative penalties, damages, fines, imprisonment, disgorgement, defense costs, exclusion from U.S. federal or state healthcare programs, additional reporting requirements and/or oversight (including if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws), bans or restrictions on our processing of personal data, indemnity obligations and the curtailment or restructuring of our operations. Any such event or consequence, including penalties, damages, fines, and curtailment or restructuring of our operations, could materially adversely affect our ability to operate our business, including our ability to run clinical trials, and our financial results and harm our reputation. Although compliance programs can help mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be 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 fraud laws may prove costly.

We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws. For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. In addition, the CCPA imposes obligations on covered businesses. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA allows for statutory fines for noncompliance (up to $7,500 per violation). Although the CCPA exempts some data processed in the context of clinical trials, the CCPA may increase compliance costs and potential liability with respect to other personal data we maintain about California residents. In addition, it is anticipated that the CPRA, effective January 1, 2023, will expand the CCPA. Additionally, the CPRA establishes a new California Privacy Protection Agency to implement and enforce the CPRA, which could increase the risk of enforcement. Other states have enacted data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which become effective in 2023. In addition, data privacy and security laws have been proposed at the federal, state, and local levels in recent years, which could further complicate compliance efforts.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the GDPR, the United Kingdom's GDPR ("UK GDPR"), and Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or "LGPD") (Law No. 13,709/2018) impose strict requirements for processing personal data. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4% of annual global revenue, whichever is greater. Further, individuals may initiate litigation related to processing of their personal data.

Certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws, which could make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the EU or in other foreign jurisdictions). Existing mechanisms that facilitate cross-border personal data transfers may change or be invalidated. The more reliant our business is on the ability to effectuate cross-border data transfers, the more impact we may experience in light of any changes in the legal landscape.

In addition, privacy advocates and industry groups have proposed, and may propose, standards with which we are legally or contractually bound to comply.

Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires significant resources and may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party vendor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to or interruption in our ability to operate our business and proceedings against us by governmental entities or others. If we fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-related claims); additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

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. For example, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's AMP, for single source and innovator multiple source drugs, beginning January 1, 2024. 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 U.S. Department of Health and Human Services and other Congressional, enforcement and administrative bodies have recently increased their focus on pricing requirements for products, including, but not limited to the methodologies used by manufacturers to calculate 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 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 extends 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 or our product candidates 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 or our product candidates infringe any third-party patents, if a plaintiff was to allege infringement of 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 and commitments. We may be forced to take other actions to satisfy our obligations or we may experience a financial failure.

Our ability to make scheduled payments on our lease and debt obligations will depend on our financial and operating performance, which is subject to the commercial success of Afrezza and, if approved, Tyvaso DPI, 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 obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness and lease obligations. 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 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;
- the trades of short sellers;
- 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 Global 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 common stock could negatively affect the market price of our common stock and other securities.

As of February 11, 2022, we had 251,798,303 shares of common stock outstanding. 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 the Senior convertible notes, 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. The Danbury facility contains our principle executive offices. We believe the Danbury 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 a portion of our facility in Danbury, Connecticut and other assets.

On November 8, 2021, we sold a portion of the Danbury facility to an affiliate of Creative Manufacturing Properties (the "Purchaser") for a sales price of $102.3 million and entered into a 20-year lease agreement with the Purchaser, with four renewal options of five years each. See Note 5 – Property and Equipment and Note 13 – Commitments and Contingencies in the consolidated financial statements included in Part II, Item 8 – Financial Statements and Supplementary Data.

As of December 31, 2021, we also 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. See Note 13 – Commitments and Contingencies in the consolidated financial statements included in Part II, Item 8 – Financial Statements and Supplementary Data.

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 $4.06 on February 11, 2022 and there were 105 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 October 2021, MidCap exercised 1,171,614 and 111,853 warrants issued in association with Tranches 1 and 2, respectively, under the MidCap credit facility, as amended, to purchase an aggregate of 1,283,467 shares of the Company's common stock through a cashless exercise that resulted in the net issuance of 964,113 shares. See Note 7 – *Borrowings*.

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. [Reserved]

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 patients with endocrine and orphan lung diseases. Our lead product is Afrezza (insulin human) Inhalation Powder, an ultra rapid-acting inhaled insulin indicated to improve glycemic control in adults with diabetes, which was approved by the FDA in June 2014. We collaborate with a number of third parties to formulate their drugs on our Technosphere drug delivery platform. Since September 2018, we have been collaborating with United Therapeutics to develop an inhaled formulation of treprostinil known as Tyvaso DPI. In April 2021, United Therapeutics submitted an NDA to the FDA seeking approval of Tyvaso DPI for the treatment of PAH and PH-ILD. The NDA was resubmitted in December 2021 following a CRL in October 2021. The FDA is expected to complete its review of the pending NDA for Tyvaso DPI by May 2022.

Our business is subject to significant risks, including but not limited to 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 drug development, 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. 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. The COVID-19 pandemic 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, 2021, we had an accumulated deficit of $3.1 billion and a stockholders' deficit of $209.3 million. We had net loss of $80.9 million and $57.2 million in the years ended December 31, 2021 and 2020, respectively. To date, we have funded our operations through the sale of convertible debt securities and equity, from the receipt of upfront and milestone payments from certain collaborations, from borrowings, from sales of Afrezza and, most recently, from the proceeds of a sale-leaseback of our manufacturing facility in Danbury, CT.

Critical Accounting Policies and Estimates

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 and retail pharmacies in the U.S. (collectively, "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. We recognize revenue on product sales to a retail pharmacy as the product is dispensed to patients. 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 us and our, payers, and other indirect customers relating to the sale of our products.

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 us and our Customers, payers, and other indirect customers relating to the sale of our products. These reserves 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 Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 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 our best estimates of the amount of consideration to which we are 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. Our analysis also contemplates application of the constraint in accordance with the guidance, under which we determined a material reversal of revenue would not occur in a future period for the estimates detailed below as of December 31, 2021 and, therefore, the transaction price was not reduced further during the year ended December 31, 2021. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from our estimates, we 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.

Our reserves for variable consideration are reflected in our gross-to-net adjustments which were 38.8% of gross revenue, or $24.9 million, for the year ended December 31, 2021, compared to 40.6% of gross revenue, or $22.1 million, for the year ended December 31, 2020. If there is a 10% difference between the estimates for accruals and the actual liability in the reserves for variable consideration, the impact to our revenue for commercial product sales would be $0.9 million or a 1% change in the gross-to-net adjustment percentage for the year ended December 31, 2021.

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 commercial manufacturing 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. With respect to our significant collaboration and service agreement with UT that includes a long-term customer supply agreement ("CSA"), we have identified three distinct performance obligations: (1) R&D Services and License; (2) Next-Gen R&D Services; and (3) a material right for manufacturing services ("Manufacturing Services"). Pre-production activities under the CSA, such as facility expansion services and other administrative services, were considered bundled services under the Manufacturing Services performance obligation as required by ASC 606. See Note 8 – *Collaboration, Licensing and Other Arrangements* of the Notes to Consolidated Financial Statements included in Part II, Item 8 — Financial Statements and Supplementary Data.

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.

If there is a 10% difference in the estimates used to determine the transaction price for the CSA entered into in August 2021 with UT, the related allocation of the transaction price between performance obligations, the difference between the estimates for accruals and the actual liability for deferred revenue and revenue recognized for collaborations and services would be $0.2 million for the year ended December 31, 2021.

Stock-Based Compensation — Share-based payments to employees, including grants of nonqualified stock options ("options"), restricted stock units, performance-based awards, 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. We use the Black-Scholes option valuation model to estimate the grant date fair value of employee 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. The grant date fair value and the effect of the market conditions for the Market RSUs was estimated using a Monte Carlo valuation.

The grant date fair value for the Market RSUs was $9.30 per unit for the Market RSUs granted during the year ended December 31, 2021, compared to $3.77 per unit for the Market RSUs granted during the year ended December 31, 2020. If there is a 10% difference in the grant date fair value of the Market RSUs, the impact to our stock-based compensation expense would be $0.4 million for the year ended December 31, 2021.

Results of Operations

Trends and Uncertainties

We continue to experience the impact of the COVID-19 pandemic on our marketing of Afrezza, the accrual rate of our Afrezza pediatrics trial, our Brazil partner's (Biomm) ability to market Afrezza and delays in the start of our clinical study in India. COVID-19 has impacted the supply chain for manufacturing Afrezza and Tyvaso DPI where we have increased safety stock of raw materials to mitigate supply chain risk.

Our manufacturing of Tyvaso DPI may not meet the required demand of our partner, UT. If we fail as an effective manufacturing organization, we may be unable to support commercialization of Tyvaso DPI, if approved.

Years ended December 31, 2021 and 2020

Revenues

The following table provides a comparison of the revenue categories for the years ended December 31, 2021 and 2020 (dollars in thousands):

	Year Ended December 31,			
	2021	**2020**	**$ Change**	**% Change**
Net revenue — commercial product sales:				
Gross revenue from product sales	$ 64,023	$ 54,457	$ 9,566	18%
Wholesaler distribution fees, rebates and chargebacks, product returns and other discounts	(24,855)	(22,133)	$ 2,722	12%
Net revenue — commercial product sales	39,168	32,324	$ 6,844	21%
Revenue — collaborations and services	36,274	32,820	$ 3,454	11%
Total revenues	$ 75,442	$ 65,144	$ 10,298	16%

Gross revenue from the sales of Afrezza increased by $9.6 million, or 18%, for the year ended December 31, 2021 compared to the prior year. The increase primarily reflects higher product demand including a more favorable mix of Afrezza cartridges and price. The gross-to-net adjustment was 38.8% of gross revenue, or $24.9 million, for the year ended December 31, 2021, compared to 40.6% of gross revenue, or $22.1 million, for the prior year. The decrease in the gross-to-net percentage was primarily driven by a decrease in wholesale distribution fees as a result of the termination of our free goods program on December 31, 2020, and a decrease in product returns including an adjustment related to the start of an agreement with a retail pharmacy, partially offset by an increase in co-pay assistance. As a result, net revenue from sales of Afrezza increased by $6.8 million, or 21%, for the year ended December 31, 2021 compared to the prior year.

Net revenue from collaborations and services increased by $3.5 million, or 11%, for the year ended December 31, 2021 compared to the prior year. The increase in collaborations and services revenue was primarily attributed to additional development work associated with our collaboration with UT. In August 2021, we entered into the CSA with UT. Revenue associated with the CSA is deferred as of December 31, 2021. 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, 2021 and 2020 (dollars in thousands):

	Year Ended December 31,			
	2021	**2020**	**$ Change**	**% Change**
Commercial product gross profit:				
Net revenue — commercial product sales	$ 39,168	$ 32,324	$ 6,844	21%
Less cost of goods sold	(16,833)	(15,084)	$ 1,749	12%
Commercial product gross profit (loss):	$ 22,335	$ 17,240	$ 5,095	30%
Gross margin	57%	53%		

Commercial product gross profit for the year ended December 31, 2021 increased by $5.1 million, or 30%, compared to the prior year. Gross margin for the year ended December 31, 2021 increased to 57% from 53% for the prior year. The increase in gross profit and gross margin was attributable to an increase in Afrezza sales, partially offset by an increase in cost of goods sold. Cost of goods sold increased by $1.8 million, or 12%, for the year ended December 31, 2021 compared to the prior year, primarily due to a $2.0 million fee for the amendment of the Insulin Supply Agreement, a $1.5 million increase in inventory write-offs and a $1.0 million increase related to decreased manufacturing activities. The increase in cost of goods sold was partially offset by $2.3 million in reduced manufacturing-related spending, $0.5 million of costs associated with lower cost per unit and the termination of the free goods program in December 31, 2020. On a non-GAAP basis, which excludes the $2.0 million insulin supply amendment fee, gross margin was 62% for the year ended December 31, 2021 compared to 53% for the prior year. See the reconciliation to non-GAAP net loss and Earnings per Common Share (“EPS”) under Non-GAAP Measures below.

Expenses

The following table provides a comparison of the expense categories for the years ended December 31, 2021 and 2020 (dollars in thousands):

	Year Ended December 31,			
	2021	**2020**	**$ Change**	**% Change**
Expenses:				
Cost of goods sold	$ 16,833	$ 15,084	$ 1,749	12%
Cost of revenue — collaborations and services	22,024	9,557	$ 12,467	130%
In-process research and development	—	13,233	$ (13,233)	*
Research and development	12,312	6,248	$ 6,064	97%
Selling	45,528	34,365	$ 11,163	32%
General and administrative	31,889	24,675	$ 7,214	29%
Impairment of assets	106	1,889	$ (1,783)	(94%)
(Gain) loss on foreign currency translation	(6,567)	8,006	$ (14,573)	*
Loss on purchase commitments	339	—	$ 339	*
Total expenses	$ 122,464	$ 113,057	$ 9,407	8%

* Not meaningful

Cost of revenue – collaborations and services increased by $12.5 million, or 130%, for the year ended December 31, 2021 compared to the prior year. The increase was primarily attributable to an increase in manufacturing activities in preparation for supplying commercial product to UT.

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 increased by $6.1 million, or 97%, for the year ended December 31, 2021 compared to the prior year. The increase was mainly attributable to costs incurred for development activities on our product pipeline and the Afrezza pediatrics clinical study (INHALE-1) as well as personnel costs primarily associated with additional headcount.

Selling expenses increased by $11.2 million, or 32%, for the year ended December 31, 2021 compared to the prior year. The increase was primarily attributable to higher promotional expenses, patient support services, and personnel-related expenses driven by increased headcount to support Afrezza growth and our voluntary reduction in compensation expense in the prior year in response to the COVID-19 pandemic.

General and administrative expenses increased by $7.2 million, or 29%, for the year ended December 31, 2021 compared to the prior year. This increase was primarily attributable to increased personnel costs associated with increased headcount and stock-based compensation in addition to our voluntary reduction in compensation expense in the prior year in response to the COVID-19 pandemic. Additional increases consisted of professional fees and business development expenses.

During the year ended December 31, 2021, an impairment of $0.1 million was recognized for the write-off of a contract asset related to a co-promotion collaboration arrangement. 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.

Under the Insulin Supply Agreement with Amphastar, payment obligations are denominated in Euros. We are required to record the foreign currency translation impact of the U.S. dollar to Euro exchange rate associated with the recognized loss on purchase commitments. The foreign currency translation resulted in a gain of $6.6 million for the year ended December 31, 2021 compared to a loss of $8.0 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, 2021 and 2020 (dollars in thousands):

	Year Ended December 31,			
	2021	2020	$ Change	% Change
Interest income	$ 112	$ 167	$ (55)	(33%)
Interest expense on financing liability	(1,373)	—	$ 1,373	*
Interest expense on notes	(15,204)	(9,471)	$ 5,733	61%
Loss on extinguishment of debt	(17,200)	(264)	$ (16,936)	*
Other (expense) income	(239)	23	$ 262	*
Total other expense	$ (33,904)	$ (9,545)	$ 24,359	255%

* Not meaningful

Interest expense on financing liability was $1.3 million for the year ended December 31, 2021 and represented interest incurred on the sale lease-back transaction for our manufacturing facility in Danbury, CT.

Interest expense on notes increased by $5.7 million, or 61%, for the year ended December 31, 2021 compared to the same period in the prior year. The increase was primarily due to interest expense on the Senior convertible notes as well as a $3.7 million milestone obligation that was achieved during the first quarter of 2021, partially offset by a decrease in interest expense on Mann Group promissory notes due to (i) the repayment of $35.1 million of outstanding principal under the Mann Group non-convertible note, (ii) the $10.0 million reduction of principal and interest on the Mann Group convertible note from a conversion to our common stock and (iii) a decrease of the interest rate from 7.00% to 2.50% on the remaining promissory note. See Note 6 — *Borrowings*.

Loss on extinguishment of debt of $17.2 million for the year ended December 31, 2021 consisted of a $22.1 million loss on extinguishment of debt for the amendment to the Mann Group convertible note, which did not result in a change in our financial position, partially offset by a $4.9 million gain on extinguishment of debt as a result of the U.S. Small Business Administration's ("SBA") forgiveness of the Paycheck Protection Program loan (the "PPP loan"). 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. See Note 6 — *Borrowings*.

Net Loss and EPS

The net loss for the year ended December 31, 2021 was $80.9 million, or $0.32 per share, compared to a $57.2 million net loss in the prior year, or $0.26 per share. The increase in net loss of $23.7 million was primarily due to the non-cash loss on extinguishment of the Mann Group convertible note of $22.1 million net of a non-cash gain on extinguishment of the PPP loan of $4.9 million, as well as an increase in SG&A expenses and cost of revenue – collaboration and services, partially offset by an increase in Afrezza net revenues and revenues from collaboration and services, a gain on purchase commitment as well as cost for in-process research and development incurred in the prior year.

Non-GAAP net loss, adjusted to exclude $17.2 million net loss on extinguishment of debt, net, which consisted of the $22.1 million non-cash loss on extinguishment of the Mann Group convertible note partially offset by the $4.9 million gain on extinguishment of the PPP loan, in addition to the Amphastar amendment fee of $2.0 million was $61.7 million or $0.25 per share, for the year ended December 31, 2021 compared to $57.2 million, or $0.26 per share, for the prior year. See the reconciliation to non-GAAP net loss and EPS under Non-GAAP Measures below.

Non-GAAP Measures

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

These non-GAAP financial measures are not meant to be considered in isolation or as a substitute for comparable GAAP measures; should be read in conjunction with our consolidated financial statements prepared in accordance with GAAP; have no standardized meaning prescribed by GAAP; and are not prepared under any comprehensive set of accounting rules or principles. In addition, from time to time in the future there may be other items that we may exclude for purposes of our non-GAAP financial measures; and we may in the future cease to exclude items that we have historically excluded for purposes of our non-GAAP financial measures. Likewise, we may determine to modify the nature of its adjustments to arrive at our non-GAAP financial measures. Because of the non-standardized definitions of non-GAAP financial measures, the non-GAAP financial measures as used by us in this Annual Report on Form 10-K have limits in their usefulness to investors and may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by other companies.

The following tables reconcile our financial measure for net loss and net loss per share as reported in our consolidated statement of operations to a non-GAAP presentation as adjusted for the $22.1 million non-cash loss on extinguishment of the Mann Group convertible note net of the $4.9 million gain on extinguishment of the PPP loan for the year ended December 31, 2021, which did not result in a change in our financial position, as well as the $2.0 million Amphastar amendment fee.

	Year Ended December 31,			
	2021	2020	Change	% Change
GAAP to Non-GAAP Net Loss and EPS				
Net loss	$ (80,926)	$ (57,240)	$ 23,686	41%
Net loss per share - basic and diluted	$ (0.32)	$ (0.26)	$ 0.06	23%
Less non-cash loss on extinguishment of debt, net(1)	17,200	—	$ 17,200	*
Less Amphastar amendment fee(1)	2,000	—	$ 2,000	*
Non-GAAP net loss	$ (61,726)	$ (57,240)	$ 4,486	8%
Non-GAAP net loss per share - basic and diluted	$ (0.25)	$ (0.26)	$ (0.01)	(4%)
Shares used to compute non-GAAP net loss per share — basic and diluted	249,244	222,585	26,659	12%

* Not meaningful

(1) There is no impact for income taxes associated with the non-cash loss on extinguishment of debt, net or the Amphastar amendment fee as a result of our full valuation allowance.

The following table reconciles our gross margin financial measure as reported in Management's Discussion and Analysis of Financial Condition and Results of Operations to a non-GAAP presentation as adjusted for the nonrecurring amendment fee related to an amendment to our Insulin Supply Agreement in May 2021.

	Year Ended December 31,			
	2021	2020	$ Change	% Change
Net revenue — commercial product sales	$ 39,168	$ 32,324	$ 6,844	21%
Less cost of goods sold	(16,833)	(15,084)	$ 1,749	12%
GAAP gross profit — Afrezza	22,335	17,240	$ 5,095	30%
Exclude Amphastar amendment fee	2,000	—	$ 2,000	*
Non-GAAP gross profit — Afrezza	$ 24,335	$ 17,240	$ 7,095	41%
Non-GAAP gross margin	62%	53%		

Liquidity and Capital Resources

Our principal sources of liquidity are our cash, cash equivalents, and investments. Our primary uses of cash include the development of our product pipeline, the manufacturing and marketing of Afrezza, the funding of general and administrative expenses, and interest expense on our financing liability and debt.

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, from borrowings, from sales of Afrezza and the sale lease-back of our manufacturing facility in Danbury, CT.

We believe we will be able to meet our liquidity needs over the next twelve months based on the balance of cash, cash equivalents and investments on hand. We believe we will meet longer-term expected future cash requirements and obligations, through a combination of cash and investments on hand, operating activities including manufacturing revenue and royalties from the production and sale of Tyvaso DPI, if approved, to UT, and available credit from our Midcap credit facility.

The following table presents our material cash requirements associated with contractual commitments for future periods (in thousands):

	2022	2023 - 2024	2025 - 2026	Thereafter	Total
Senior convertible notes[1]	$ 5,750	$ 11,500	$ 238,625	$ —	$ 255,875
MidCap credit facility[2]	2,940	31,161	13,617	—	47,718
Mann Group convertible note[3]	—	—	18,829	—	18,829
Financing liability	6,373	19,801	20,813	199,092	246,079
Insulin purchase agreement	6,171	26,519	39,646	10,494	82,830
Total material cash requirements	$ 21,234	$ 88,981	$ 331,530	$ 209,586	$ 651,331

(1) $230.0 million aggregate principal amount of Senior convertible notes bearing interest at 2.50% payable semi-annually in arrears on March 1 and September 1 of each year, beginning on September 1, 2021 and will mature on March 1, 2026, unless earlier converted, redeemed or repurchased. The Senior convertible notes are convertible at an initial conversion price of approximately $5.21 per share of Common Stock. The conversion rate is subject to adjustment under certain circumstances in accordance with the terms of the Indenture.

(2) $40.0 million principal amount under the MidCap credit facility, bearing interest at an annual rate equal to one-month LIBOR plus 6.25%, subject to a one-month LIBOR floor of 1.00%, payable in equal monthly installments beginning in September 2023 through maturity in August 2025.

(3) $18.4 million principal amount of indebtedness under the Mann Group convertible note bearing interest at a fixed rate of 2.50% per annum compounded quarterly and maturing in December 2025, which is convertible into shares of our common stock at the option of Mann Group at a conversion price of $2.50 per share. Interest was paid-in-kind from August 2019 until the end of 2020, after which we have the option to pay interest in-kind or in shares.

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 Senior convertible notes, the MidCap credit facility or the Mann Group convertible note. The Senior convertible notes and Mann Group convertible note are fully convertible 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 repurchase the Mann Group promissory notes, 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 Original Milestone Purchasers. The Milestone Rights provided the Original Milestone Purchasers certain rights to receive payments of up to $90.0 million upon the occurrence of specified strategic and sales milestones, $65.0 million of which remains payable to Barings upon achievement of such milestones. See Note 12 – *Commitments and Contingencies* and Note 7 – *Borrowings* for further information related to the Milestone Rights.

During the year ended December 31, 2021, we used $61.7 million of cash for our operating activities, which primarily consisted of $65.8 million of selling, general and administrative expenses, $35.5 million of cost of goods sold and cost of revenue, $11.7 million of costs for research and development and $6.5 million of cash paid for interest, partially offset by $47.6 million of revenue.

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 assets 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.

Cash used in investing activities of $151.5 million for the year ended December 31, 2021 was primarily due to the purchase of debt securities of $196.1 million, partially offset by proceeds received from sales of debt securities of $59.1 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 provided by financing activities of $270.3 million for the year ended December 31, 2021 was primarily due to net proceeds from the offering of Senior convertible notes of $222.7 million and net proceeds from the sale-leaseback transaction of $99.1 million, partially offset by the repayment of $35.1 million of Mann Group non-convertible notes and related unpaid accrued interest and the repayment of $10.0 million of principal and $1.0 million prepayment penalty for the MidCap credit facility.

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.

Future Liquidity Needs

We are not currently profitable and have rarely generated positive net cash flow 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 development costs for other product candidates in our pipeline. As of December 31, 2021, we had capital resources of $124.2 million in cash and cash equivalents, $79.9 million in short-term investments and $56.6 million in long-term investments, and total principal amount of outstanding borrowings of $288.4 million.

In March 2021, we issued $230.0 million of Senior convertible notes. In April 2021, we made a $10.0 million principal prepayment against outstanding term loans under the MidCap credit facility and repaid the entire principal amount of $35.1 million outstanding under the Mann Group non-convertible note (together with all accrued and unpaid interest thereon) as further disclosed in Note 7 – Borrowings. As amended, the MidCap credit facility provides a secured term loan facility with an aggregate principal amount of up to $100.0 million, of which $60.0 million remains available for borrowing if the conditions for Tranche 3 are met. In November 2021, we closed a sale-leaseback transaction of our manufacturing facility in Danbury, CT for a sales price of $102.3 million.

We believe our resources will be sufficient to fund our operations for the next twelve months from the date of issuance of our consolidated financial statements included in Item 8 – Financial Statements.

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 2021 and other new accounting standards that have been issued by the FASB but are not effective until after December 31, 2021.

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

Interest Rate Risk

Interest on borrowings under the MidCap credit facility accrues interest at an annual rate equal to the lesser of (i) 8.25% and (ii) the one-month LIBOR (subject to a one-month LIBOR floor of 1.00%) plus 6.25%. Accordingly, our interest expense under the MidCap credit facility is subject to changes in the one-month LIBOR rate. See "Risk Factors--*We have a substantial amount of debt, and we may be unable to make required payments of interest and principal as they become due"* under Item 1A of this report for additional information regarding the risks we face related to the planned phase-out of LIBOR.

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 2.50% and the interest rate under the Senior convertible notes is fixed at 2.50%. 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, 2021 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, 2021, we realized a $6.6 million currency gain, which was included in (gain) 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, 2021 were to have occurred, this change would have resulted in a foreign currency impact to our pre-tax loss of approximately $8.3 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 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 the design and operation of our disclosure controls and procedures as of December 31, 2021.

Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that the design and operation of our disclosure controls and procedures were effective as of December 31, 2021.

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, 2021. 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, 2021, our internal control over financial reporting was effective based on those criteria.

The effectiveness of our internal control over financial reporting has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their attestation report herein, which expresses an unqualified opinion on the effectiveness of our internal control over financial reporting as of December 31, 2021.

Changes in Internal Control over Financial Reporting

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

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of MannKind Corporation

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of MannKind Corporation and subsidiaries (the "Company") as of December 31, 2021, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2021, of the Company and our report dated February 24, 2022, expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Deloitte & Touche LLP

Los Angeles, California
February 24, 2022

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

None.

Item 9C. ***Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.***

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 2022 Annual Meeting of Stockholders (the "Proxy Statement"), to be filed with the SEC on or before May 2, 2022, 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 "Corporate Governance" 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" 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 "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 60:

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 (incorporated by reference to Exhibit 4.3 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on February 25, 2021).
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	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).

Exhibit Number	Description of Document
4.7	Amendment No. 1 to Convertible Promissory Note, dated April 22, 2021, by and between MannKind Corporation and The Mann Group LLC (incorporated by reference to Exhibit 99.2 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on April 26, 2021).
4.8	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).
4.9	Indenture, dated as of March 4, 2021, by and between MannKind Corporation and U.S. Bank National Association, as Trustee (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 March 5, 2021).
4.10	Form of Global Note, representing MannKind Corporation's 2.50% Convertible Senior Notes due 2026 (included as Exhibit A to the Indenture filed as Exhibit 4.15) (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 March 5, 2021).
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 (incorporated by reference to Exhibit 10.4 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on February 25, 2021).
10.5*	Offer Letter, dated August 11, 2003, by and between MannKind and Joseph Kocinsky (incorporated by reference to Exhibit 10.5 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on February 25, 2021).
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).

Exhibit Number	Description of Document
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).
10.21*	MannKind Corporation 2004 Employee Stock Purchase Plan, as amended (incorporated by reference to Exhibit 99.4 to MannKind's registration statement Form S-8 (File No. 333-226648), filed with the SEC on August 7, 2018).
10.22*	MannKind Corporation Market Price Stock Purchase Plan (incorporated by reference to Exhibit 99.1 to MannKind's registration statement Form S-8 (File No. 333-225428), filed with the SEC on June 5, 2018).
10.23***	Supply Agreement, dated as of July 31, 2014, by and between MannKind and Amphastar France Pharmaceuticals S.A.S. (incorporated by reference to Exhibit 10.23 to MannKind's Annual Report on Form 10-K (File No. 000-50865), filed with the SEC on February 25, 2021)
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***	Sixth Amendment to Supply Agreement, dated May 24, 2021, by and between MannKind Corporation and Amphastar Pharmaceuticals, Inc. (incorporated by reference to Exhibit 99.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on May 25, 2021).
10.30	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).
10.31	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).
10.32	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).
10.33**	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).
10.34**	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).
10.35***	Credit and Security Agreement, dated August 6, 2019, by and among MannKind Corporation, MannKind LLC, the lenders party thereto from time to time and MidCap Financial Trust, as agent (incorporated by reference to Exhibit 99.1 to MannKind's Current Report on Form 8-K (File No. 000-50865), filed with the SEC on August 7, 2019).

Exhibit Number	Description of Document
10.36	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).
10.37	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).
10.38	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).
10.39	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).
10.40	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).
10.41	Amendment No. 6 to Credit and Security Agreement, dated March 1, 2021, 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 March 5, 2021).
10.42	Amendment No. 7 to Credit and Security Agreement, dated April 22, 2021, 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 April 26, 2021).
10.43***	Commercial Supply Agreement, dated August 12, 2021, by and between MannKind Corporation and United Therapeutics Corporation (incorporated by reference to Exhibit 10.1 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on November 9, 2021).
10.44***	First Amendment to Commercial Supply Agreement, dated October 16, 2021, by and between MannKind Corporation and United Therapeutics Corporation (incorporated by reference to Exhibit 10.2 to MannKind's Quarterly Report on Form 10-Q (File No. 000-50865), filed with the SEC on November 9, 2021).
10.45***	Purchase and Sale Agreement, dated September 23, 2021, by and between MannKind Corporation and 1 Casper, 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 November 9, 2021).
23.1	Consent of Independent Registered Public Accounting Firm.
31.1	Certification of the Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of the Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of the Chief Executive Officer pursuant to Rules 13a-14(b) and 15d-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).
32.2	Certification of the Chief Financial Officer pursuant to Rules 13a-14(b) and 15d-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).
101	Inline 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 24, 2022

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 24, 2022
/s/ Steven B. Binder Steven B. Binder	Chief Financial Officer *(Principal Financial and Accounting Officer)*	February 24, 2022
/s/ James S. Shannon James S. Shannon, M.D., MRCP (UK)	Chairman of the Board of Directors	February 24, 2022
/s/ Ronald J. Consiglio Ronald J. Consiglio	Director	February 24, 2022
/s/ Michael Friedman Michael Friedman, M.D.	Director	February 24, 2022
/s/ Jennifer Grancio Jennifer Grancio	Director	February 24, 2022
/s/ Anthony C. Hooper Anthony C. Hooper	Director	February 24, 2022
/s/ Sabrina Kay Sabrina Kay	Director	February 24, 2022
/s/ Kent Kresa Kent Kresa	Director	February 24, 2022
/s/ Christine Mundkur Christine Mundkur	Director	February 24, 2022

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, 2021 and 2020, 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, 2021 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, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, in conformity with the accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 24, 2021, expressed an unqualified opinion on the Company's internal control over financial reporting.

Basis for Opinion

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

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

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current-period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Net Revenue – Commercial Product Sales – Government Rebates – Refer to Note 2 and 8 to the financial statements

Critical Audit Matter Description

As more fully disclosed in Note 2 and 8 to the financial statements, the Company recognizes revenue for commercial product sales 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. Government rebates are provided to Medicare and state Medicaid programs. Government rebates involve the use of significant assumptions and judgments to estimate 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. These significant assumptions and judgments include consideration of historical claims experience, payer channel mix, current contract prices, unbilled claims, claim submission time lags and inventory in the distribution channel.

Given the complexity involved in determining the significant assumptions and judgments used in estimating the government 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 rebates included the following, among others:

- We tested the effectiveness of controls over management's processes to account for the variable consideration associated with Government Rebates.
- We evaluated key inputs used in management's analysis of the government rebate estimates.
- We inspected contractual documents associated with the government 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 rebates.
- We performed the following procedures to evaluate the significant assumptions and judgments used by management to estimate government rebates:
- Evaluated the reasonableness of government rebates by comparing the underlying data to historical adjustments.
- Evaluated management's ability to accurately forecast government rebates by comparing management's assumptions of expected government rebates to actuals incurred subsequent to year end.

Revenue — Collaborations and Services – UT Commercial Supply Agreement – Refer to Note 2 and 8 to the financial statements

Critical Audit Matter Description

As discussed in Note 8 to the financial statements, the Company generates collaboration and services revenue from the United Therapeutics ("UT") commercial supply agreement (the "CSA"). The Company is responsible for manufacturing and supplying to United Therapeutics, and United Therapeutics is responsible for purchasing from the Company on a cost-plus basis, Tyvaso DPI and BluHale inhalation profiling devices, as required for commercial distribution and sale by United Therapeutics. Three distinct performance obligations are identified as a result of the CSA: (1) the license, supply of product to be used in clinical development, and continued development and approval support for Tyvaso DPI; (2) development activities for the next generation of Tyvaso DPI Next-Gen R&D Services; and (3) a material right associated with future commercial manufacturing and supply of product ("Manufacturing Services").

The accounting treatment involves several significant subjective management assumptions and estimates including the identification of performance obligations within the contract. Specifically, the significant subjective management judgement is required to determine if the pre-production activities are a separate and discrete performance obligation under the CSA based on the nature of responsibilities of the Company agreed within the contract and ASC 606 requirement in contrast with being bundled with "Manufacturing Services" as assessed under the accounting policy.

Given the complexity of the accounting analysis of the UT CSA, including the significant assumptions and judgments involved in identifying performance obligations under the CSA, auditing the related revenue 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 identification of performance obligations under the CSA included the following, among others:

- We tested the effectiveness of controls over management's determination of the separate and discrete performance obligations under the agreement.
- We inspected contractual documents associated with the CSA to obtain sufficient understanding of the nature of the contract. We evaluated the Company's analysis of the accounting treatment for the CSA for reasonableness and appropriateness in accordance with applicable guidance.
- We used our firm specialist resources to assist in auditing management's conclusions through an accounting consultation, wherein we independently evaluated the reasonableness of the accounting treatment for leasehold buildout reimbursements to assess if it represents a separate performance obligation.

/s/ Deloitte & Touche LLP

Los Angeles, California
February 24, 2022

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

MANNKIND CORPORATION AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2021	2020
	(In thousands except share and per share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 124,184	$ 67,005
Restricted cash	—	158
Short-term investments	79,932	—
Accounts receivable, net	4,994	4,218
Inventory	7,152	4,973
Prepaid expenses and other current assets	3,482	3,122
Total current assets	219,744	79,476
Property and equipment, net	36,612	25,867
Long-term investments	56,619	—
Other assets	8,186	3,265
Total assets	$ 321,161	$ 108,608
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 6,956	$ 5,582
Accrued expenses and other current liabilities	27,419	19,707
Financing liability — current	6,977	—
Paycheck Protection Program loan — current	—	4,061
Deferred revenue — current	827	33,275
Recognized loss on purchase commitments — current	6,170	11,080
Total current liabilities	48,349	73,705
Promissory notes	18,425	63,027
Accrued interest — promissory notes	404	4,150
Financing liability — long term	93,525	—
Long-term Midcap credit facility	38,833	49,335
Senior convertible notes	223,944	—
Recognized loss on purchase commitments — long term	76,659	84,208
Operating lease liability	1,040	1,202
Deferred revenue — long term	19,543	1,662
Milestone rights liability	4,838	5,926
2024 convertible notes	—	5,000
Paycheck Protection Program loan — long term	—	812
Deposits from customer	4,950	—
Total liabilities	530,510	289,027
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, 2021 and 2020	—	—
Common stock, $0.01 par value — 400,000,000 shares authorized, 251,477,562 and 242,117,089 shares issued and outstanding at December 31, 2021 and 2020, respectively	2,515	2,421
Additional paid-in capital	2,918,205	2,866,303
Accumulated other comprehensive loss	—	—
Accumulated deficit	(3,130,069)	(3,049,143)
Total stockholders' deficit	(209,349)	(180,419)
Total liabilities and stockholders' deficit	$ 321,161	$ 108,608

See notes to consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2021	2020
	(In thousands except per share data)	
Revenues:		
Net revenue — commercial product sales	$ 39,168	$ 32,324
Revenue — collaborations and services	36,274	32,820
Total revenues	75,442	65,144
Expenses:		
Cost of goods sold	16,833	15,084
Cost of revenue — collaborations and services	22,024	9,557
In-process research and development	—	13,233
Research and development	12,312	6,248
Selling, general and administrative	77,417	59,040
Impairment of assets	106	1,889
(Gain) loss on foreign currency translation	(6,567)	8,006
Loss on purchase commitments	339	—
Total expenses	122,464	113,057
Loss from operations	(47,022)	(47,913)
Other (expense) income:		
Interest income	112	167
Interest expense on financing liability	(1,373)	—
Interest expense on notes	(15,204)	(9,471)
Loss on extinguishment of debt	(17,200)	(264)
Other (expense) income	(239)	23
Total other expense	(33,904)	(9,545)
Loss before income tax expense	(80,926)	(57,458)
Benefit from income taxes	—	218
Net loss	$ (80,926)	$ (57,240)
Net loss per share — basic and diluted	$ (0.32)	$ (0.26)
Shares used to compute net loss per share — basic and diluted	249,244	222,585

See notes to consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Year Ended December 31,	
	2021	2020
	(In thousands)	
Net loss	$ (80,926)	$ (57,240)
Other comprehensive loss:		
Cumulative translation loss	—	(19)
Comprehensive loss	$ (80,926)	$ (57,259)

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, 2020	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)
Net issuance of common stock associated with stock options and restricted stock units	1,572	16	(514)	—	—	(498)
Issuance of common stock under Employee Stock Purchase Plan	527	5	1,085	—	—	1,090
Stock-based compensation expense	—	—	12,200	—	—	12,200
Issuance of common stock pursuant to conversion of the Mann Group convertible note	3,830	38	9,535	—	—	9,573
Issuance of common stock pursuant to conversion of the Mann Group convertible note interest	170	2	425	—	—	427
Issuance of common stock pursuant to conversion of the 2024 convertible notes	1,667	17	4,983	—	—	5,000
Issuance of common stock pursuant to payoff of the 2024 convertible note interest	27	—	143	—	—	143
Issuance of at-the-market placement	578	6	1,880	—	—	1,886
Issuance costs associated with at-the-market placement	—	—	(38)	—	—	(38)
Premium on Mann Group convertible note	—	—	22,107	—	—	22,107
Issuance of common stock from market price stock purchase	25	—	106	—	—	106
Issuance of common stock pursuant to a warrant conversion	964	10	(10)	—	—	—
Net loss	—	—	—	—	(80,926)	(80,926)
BALANCE, DECEMBER 31, 2021	251,478	$ 2,515	$ 2,918,205	$ -	$ (3,130,069)	$ (209,349)

See notes to consolidated financial statements.

MANNKIND CORPORATION AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2021	2020
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (80,926)	$ (57,240)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on extinguishment of debt, net	17,200	264
Stock-based compensation expense	12,200	6,511
Depreciation, amortization and accretion	4,215	2,149
Interest on milestone right	3,663	—
Write-off of inventory	1,902	496
Interest expense on promissory notes	1,598	5,148
Amortization of financing liability	1,372	—
Amortization of right-of-use assets	1,258	1,177
Asset impairment	106	1,889
(Gain) loss on foreign currency translation	(6,567)	8,006
In-process research and development	—	13,233
Other, net	—	19
Changes in operating assets and liabilities:		
Accounts receivable, net	(776)	(705)
Inventory	(4,081)	(1,314)
Prepaid expenses and other current assets	(360)	(154)
Other assets	(138)	227
Accounts payable	1,374	793
Accrued expenses and other current liabilities	8,814	3,346
Deferred revenue	(14,567)	(5,910)
Recognized loss on purchase commitments	(5,892)	(4,751)
Operating lease liabilities	(2,135)	(1,312)
Accrued interest on Mann Group promissory notes	(4,919)	—
Deposits from customer	4,950	—
Net cash used in operating activities	(61,709)	(28,128)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of held-to-maturity debt securities	(196,131)	—
Proceeds from maturity of debt securities	59,060	—
Purchase of property and equipment	(11,466)	(801)
Purchase of available-for-sale securities	(3,000)	—
Proceeds from sale of treasury bills	—	20,000
Acquisition of in-process research and development, net of cash acquired	—	(3,983)
Net cash (used in) provided by investing activities	(151,537)	15,216
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the Senior convertible notes	230,000	—
Issuance costs associated with Senior convertible notes	(7,268)	—
Proceeds from the sale-leaseback transaction	102,250	—
Issuance costs associated with the sale-leaseback transaction	(3,120)	—
Deposit for the sale-leaseback transaction	(2,000)	—
Principal payments on Mann Group promissory notes	(35,051)	—
Payment of MidCap credit facility	(10,000)	—
Payment of MidCap credit facility prepayment penalty	(1,000)	—
Milestone payment	(5,000)	—
Proceeds from at-the-market-offering	1,886	23,450
Issuance costs associated with at the market offering	(38)	(518)
Payment of employment taxes related to vested restricted stock units and exercise of stock options	(498)	233
Proceeds from market price stock purchase plan	106	215
Issuance of common stock from the exercise of warrants	—	11,600
Proceeds from MidCap credit facility	—	10,000
Proceeds from PPP loan	—	4,873
Net cash provided by financing activities	270,267	49,853
NET INCREASE IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	57,021	36,941
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING OF PERIOD	67,163	30,222
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, END OF PERIOD	$ 124,184	$ 67,163

MANNKIND CORPORATION AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)

	Year Ended	
	2021	2020
	(In thousands)	
SUPPLEMENTAL CASH FLOWS DISCLOSURES:		
Interest paid in cash, net of amounts capitalized	11,268	3,558
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Reclassification of investments from long-term to current	32,654	—
Premium on Mann Group convertible note	22,107	—
Payment on Mann Group convertible note through issuance of common stock	9,575	7,000
Payment of 2024 convertible notes through issuance of common stock	5,000	5,261
Forgiveness of PPP loan	(4,873)	—
Addition of right-of-use-asset	1,425	—
Right-of-use asset modification	278	—
Non-cash construction in progress and property and equipment	1,264	92
Issuance of common stock under Employee Stock Purchase Plan	1,090	684
Payment of Mann Group convertible note interest through issuance of common stock	425	3,000
Payment of interest on 2024 convertible notes through issuance of common stock	143	288
Issuance of common stock for acquisition of in-process research and development	—	9,250
Issuance of warrants associated with the MidCap Credit Facility	—	275
Receivable from at-the-market offering	—	226

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 lead product is Afrezza (insulin human) Inhalation Powder, an ultra rapid-acting inhaled insulin indicated to improve glycemic control in adults with diabetes, which was approved by the U.S. Food and Drug Administration ("FDA") in June 2014. The Company collaborates with a number of third parties to formulate their drugs on the Company's Technosphere drug delivery platform. Since September 2018, the Company has been collaborating with United Therapeutics Corporation ("United Therapeutics" or "UT") to develop an inhaled formulation of treprostinil, known as Tyvaso DPI. In April 2021, United Therapeutics submitted a new drug application ("NDA") to the FDA seeking approval of Tyvaso DPI for the treatment of PAH and PH-ILD. The NDA was resubmitted in December 2021 following a complete response letter in October 2021. The FDA is expected to complete its review of the NDA for Tyvaso DPI by May 2022.

Basis of Presentation — The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP").

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 of other product candidates in the Company's pipeline. As of December 31, 2021, the Company had capital resources of $124.2 million in cash and cash equivalents, $79.9 million in short-term investments, $56.6 million in long-term investments, an accumulated deficit of $3.1 billion and $288.4 million of total principal amount of outstanding borrowings.

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"). The MidCap Credit Facility currently provides a secured term loan facility with a potential aggregate principal amount of up to $100.0 million, of which $40.0 million was outstanding as of December 31, 2021. See Note 7 – *Borrowings*. In March 2021, the Company issued $230.0 million of 2.50% convertible senior notes due 2026 (the "Senior convertible notes") to provide additional operating capital and pay down higher cost debt.

The Company believes its resources will be sufficient to fund its operations for the next twelve months from the date of issuance of these consolidated financial statements.

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 the consolidated statement of operations to disclose a single caption for interest expense on all outstanding notes. Changes were also made to Note 6 – *Accrued Expenses and Other Current Liability* to combine accruals for certain services into the Other line. In addition, changes were made to Note 2 – *Summary of Significant Accounting Policies* and Note 9 – *Fair Value of Financial Instruments* to conform the presentation of certain short-term investments to the current year presentation.

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

2. Summary of Significant Accounting Policies

Financial Statement Estimates — The preparation of financial statements in conformity with 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, including gross-to-net adjustments, stand-alone selling price considerations for recognition of collaboration revenue 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. The Company recognizes revenue on product sales to a retail pharmacy as the product is dispensed to patients.

To determine revenue recognition for arrangements that are within the scope of Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), the Company performs the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to arrangements that meet the definition of a contract under ASC 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 ASC 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, specialty and retail 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 and retail 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 and retail 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. The Company recognizes revenue on product sales to a retail pharmacy as the product is dispensed to patients. 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 ASC 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, 2021 and, therefore, the transaction price was not reduced further during the year ended December 31, 2021. 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, research or other agreements under which the Company licenses certain rights to its product candidates to third parties, or conducts research or provides other 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. With respect to our significant collaboration and service agreement with UT that includes a long-term customer supply agreement ("CSA"), we have identified three distinct performance obligations: (1) R&D Services and License; (2) Next-Gen R&D Services; and (3) a material right for manufacturing services ("Manufacturing Services"). Pre-production activities under the CSA, such as facility expansion services and other administrative services, were considered bundled services under the Manufacturing Services performance obligation as required by ASC 606. See Note 8 – *Collaboration, Licensing and Other Arrangements* of the Notes to Consolidated Financial Statements included in Part II, Item 8 — Financial Statements and Supplementary Data.

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. If the license is considered to be a distinct performance obligation, then the estimated revenue is included in the transaction price for the contract, which is then allocated to each performance obligation based on the respective standalone selling prices. If the revenue for a sales-based or usage-based royalty is promised in exchange for an intellectual property license, the Company recognizes revenue as the latter of the subsequent sale or usage occurs or the performance obligation to which the royalty has been allocated has been satisfied or partially 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 been 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, semi-finished goods 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. Accordingly, the Company concluded that its collaborative agreements must generally be accounted for pursuant to ASC 606.

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. The Company assessed the CSA agreement with UT and determined that a material right existed for the manufacturing services performance obligation. The transaction price is allocated to the material right as well as the remaining performance obligations in accordance with ASC 606. The Company also evaluates grants of additional licensing rights upon option exercises to determine whether such should be accounted for as separate contracts.

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.

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 de minimis amount of accrued interest is included in accrued expenses and other current liabilities. On July 28, 2021, the Company received notification from the U.S. Small Business Administration ("SBA") that the full principal amount of the PPP loan was forgiven. 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 for standard costing, 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. Cost of goods sold excludes the cost of insulin purchased under our supply agreement with Amphastar ("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.

Cost of Revenues – Collaborations and Services — Cost of revenues – collaborations and services includes material, labor costs, manufacturing overhead, and excess capacity costs. These costs, in addition to the write-offs of inventory are recorded as expenses in the period in which they are incurred, rather than as a portion of inventory costs. Cost of revenues – collaborations and services also includes the cost of product development and the allocation of selling expenses related to a co-promotion collaboration agreement.

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, 2021 and 2020, cash equivalents were comprised of money market, corporate bonds and commercial paper accounts with original 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.

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,	
	2021	2020
Cash and cash equivalents	$ 124,184	$ 67,005
Restricted cash	—	158
Total cash, cash equivalents, and restricted cash	$ 124,184	$ 67,163

Held-to-Maturity Investments — The Company's investments generally consist of commercial paper, corporate notes or bonds and U.S. Treasury securities. For the year ended December 31, 2021, the Company held short-term and long-term investments of debt securities, including commercial paper and bonds. The Company assesses whether it has any intention to sell the investment before maturity, whether any declines in fair value are the result of credit losses, as well as whether there were other-than-temporary impairments associated with the available for sale investment. The Company intends to hold its investments until maturity; therefore, these investments are stated at amortized cost. The investments with maturities less than 12 months are included in short-term investments and investments with maturities in excess of twelve months are included in long-term investments in the consolidated balance sheets. The amortization or accretion of the Company's investments is recognized as interest income in the consolidated statements of operations and was approximately $0.5 million for the year ended December 31, 2021. There was no such amortization or accretion for the year ended December 31, 2020. No allowance for credit losses on held-to-maturity securities was required as of December 31, 2021.

The contractual maturities of our held to maturity investments as of December 31, 2021 and 2020 are summarized below (in thousands):

	December 31, 2021		December 31, 2020	
	Amortized Cost Basis	Aggregate Fair Value	Amortized Cost Basis	Aggregate Fair Value
Due in one year or less(1)	$ 103,733	$ 103,669	$ 59,495	$ 59,495
Due after one year through five years	56,619	56,433	—	—
Total	$ 160,352	$ 160,102	$ 59,495	$ 59,495

(1) The investments due in one year or less include cash equivalents of $23.8 million as of December 31, 2021 and $59.5 million as of December 31, 2020.

Available-for-Sale Investment — In June 2021, the Company invested $3.0 million in Thirona Bio, Inc. ("Thirona") and received a $3.0 million convertible promissory note (as amended, the "Thirona convertible note"). Unless earlier converted into conversion shares pursuant to the note purchase agreement, the principal and accrued interest shall be due and payable by Thirona on demand by the Company at any time after the maturity date of December 31, 2023. Interest shall accrue at a rate of 6% per annum. The Thirona convertible note is a general unsecured obligation of Thirona. The Thirona convertible note is classified as an available-for-sale security and is included in other assets in the consolidated balance sheet. Available-for-sale investments are subsequently measured at fair value. Unrealized holding gains and losses are excluded from earnings and reported in other comprehensive income until realized. The Company assesses whether it has any intention to sell the investment, determines fair value of its available-for-sale investments using level 3 inputs as well as assesses whether there were other-than-temporary impairments associated with the available for sale investment. As of December 31, 2021, the Company evaluated the fair value of its investment in Thirona and determined that the fair value approximates the carrying value of $3.0 million and determined that there were no other-than-temporary impairments. In June 2021, the Company and Thirona also entered into a collaboration agreement to develop a compound for the treatment of fibrotic lung diseases. See Note 8 – *Collaboration, Licensing and Other Arrangements* for additional information. Subsequent to December 31, 2021, the Company invested an additional $5.0 million in Thirona and received a $5.0 million convertible promissory note.

Concentration of Credit Risk — Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents and 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 with maturities less than 90 days. Investments generally consist of commercial paper, corporate notes or bonds and U.S. Treasury securities. The cash equivalents and investments are regularly monitored by management.

Accounts Receivable and Allowance for Credit Losses — Accounts receivable are recorded at the invoiced amount and are not interest bearing. Accounts receivable are presented net of an allowance for credit losses 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 credit losses. The allowance for expected credit losses is based primarily on past collections experience relative to the length of time receivables are past due. However, when available evidence reasonably supports an assumption that future economic conditions will differ from current and historical payment collections, an adjustment is reflected in the allowance for expected credit losses. 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,	
	2021	**2020**
Accounts receivable – commercial		
Accounts receivable, gross	$ 7,939	$ 8,090
Wholesaler distribution fees and prompt pay discounts	(1,696)	(1,205)
Reserve for returns	(2,797)	(2,667)
Total accounts receivable – commercial, net	3,446	4,218
Accounts receivable – collaborations and services		
Accounts receivable, gross	2,060	—
Allowance for credit losses	(767)	—
Total accounts receivable – collaborations and services, net	1,293	4,218
Accounts receivable – other	255	—
Total accounts receivable, net	$ 4,994	$ 4,218

As of December 31, 2021 and December 31, 2020, the allowance for credit losses was *de minimis*. As of December 31, 2021 and December 31, 2020, the Company had three wholesale distributors representing approximately 80% and 86% of gross sales and 79% and 90% of accounts receivable, respectively.

As of December 31, 2021, the allowance for accounts receivable – collaborations and services of $0.8 million was related to $0.8 million of accounts receivable for Vertice Pharma, a collaboration partner for the co-promotion of Thyquidity. The Company had one collaboration partner, United Therapeutics, that comprised 100% of the collaboration and services net accounts receivable as of December 31, 2021 and approximately 95% of gross revenue from collaborations and services for the year ended December 31, 2021.

Pre-Launch Inventory — An improvement to the manufacturing process for the Company's primary excipient fumaryl diketopiperazine ("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 during the second quarter of 2020 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 $0.1 million of asset impairments for the year ended December 31, 2021.

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 statements of operations. The liability balance of the recognized loss on insulin purchase commitments as of December 31, 2021 and 2020 was $82.8 million and $95.3 million, respectively. No *new contracts were identified in 2021 that required a new loss on purchase commitment accrual.*

Milestone Rights Liability — In July 2013, in conjunction with the execution of a (now repaid) loan agreement with Deerfield Private Design Fund II, L.P. and Deerfield Private Design International II, L.P. (collectively, "Deerfield"), we issued the Milestone Rights to Deerfield Private Design Fund II, L.P. and Horizon Santé FLML SÀRL, (the "Milestone Purchasers"). In December 2021, the Milestone Rights were purchased by Barings Global Special Situations Credit Fund 4 (Delaware), L.P. and Barings Global Special Situations Credit 4 (LUX) S.ar.l. (together "Barings"). As a result, Barings has assumed the obligations of the Original Milestone Purchasers and is now entitled to all rights under the Milestone Agreement. As of December 31, 2021, $65.0 million remained payable pursuant to the Milestone Agreement upon achievement of sales milestones.

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. Market RSUs are valued using a Monte Carlo valuation model and RSUs with performance conditions are evaluated for 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 addition to internal costs associated 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 August 2020, the FASB issued ASU 2020-06, Issuer's Accounting for Convertible Instruments and Contracts on an Entity's Own Equity, which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. The Company adopted this standard as of January 1, 2021. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

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

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. 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, MNKD-101 (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 MNKD-101 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 MNKD-101. 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 MNKD-101 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,	
	2021	**2020**
Raw materials	$ 2,703	$ 1,393
Work-in-process	2,522	2,484
Finished goods	1,927	1,096
Total inventory	$ 7,152	$ 4,973

Work-in-process and finished goods as of December 31, 2021 and 2020 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, 2021 and 2020, 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.

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, 2021 and 2020. Inventory that was forecasted to become obsolete due to expiration as well as inventory that does not meet acceptable standards is recorded in costs of goods sold in the accompanying consolidated statements of operations. For the year ended December 31, 2021, there was an inventory write-off of $1.9 million as a result of this assessment, including $0.7 million related to the start of an agreement with a retail pharmacy. There was an inventory write-off of $0.5 million for the year ended December 31, 2020.

5. Property and Equipment

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

	Estimated Useful Life (Years)	December 31, 2021		December 31, 2020
Land	—	$ 875		$ 875
Buildings	39-40	17,389		17,389
Building improvements	5-40	38,651		37,543
Machinery and equipment	3-15	55,334		55,054
Furniture, fixtures and office equipment	5-10	2,969		3,004
Computer equipment and software	3	8,163		8,319
Construction in progress	—	10,892	(1)	503
		134,273		122,687
Less accumulated depreciation		(97,661)		(96,820)
Total property and equipment, net		$ 36,612		$ 25,867

(1) Construction in progress includes $4.7 million of equipment under construction for the manufacturing expansion for UT (the "UT Equipment"). The Company acts as agent on behalf of UT for the procurement of the UT Equipment. The Company has received $5.0 million in deposit for this service, which was recognized as deposit from customer in the consolidated balance sheet as of December 31, 2021. See Note 8 – *Collaboration, Licensing and Other Arrangements*.

Depreciation expense related to property and equipment for the years ended December 31, 2021 and 2020 was $2.0 million and $1.8 million, respectively. During the year ended December 31, 2021 and 2020, the Company retired $1.1 million and $0.3 million, respectively of manufacturing equipment, computer hardware and software, lab equipment, and furniture and fixtures, as it was no longer in service. The net book value for the disposed assets was *de minimis*.

On November 8, 2021, the Company sold certain land, building and improvements located in Danbury, CT (the "Property") to an affiliate of Creative Manufacturing Properties (the "Purchaser") for a sales price of $102.3 million, subject to terms and the conditions contained in a purchase and sale agreement. Effective with the closing of this transaction, the Company entered into a 20-year lease agreement with the Purchaser (the "Sale-Leaseback Transaction"). The sale of the Property and subsequent lease did not result in the transfer of control of the Property to the Purchaser; therefore, the Sale-Leaseback Transaction qualified as a failed sale leaseback transaction whereby the lease is accounted for as finance lease and the Property remains as a long-lived asset of the Company and is depreciated at its remaining useful life of 20 years or less. See Note 13 – *Commitments and Contingencies*.

6. Accrued Expenses and Other Current Liabilities

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

	December 31, 2021	December 31, 2020
Salary and related expenses	$ 14,022	$ 11,250
Discounts and allowances for commercial product sales	4,227	3,688
Accrued interest	2,166	519
Deferred lease liability	1,380	1,422
Current portion of milestone rights liability	1,088	1,337
Professional fees	895	533
Retail inventory purchase	875	—
Danbury facility buildout	786	—
Other	1,980	958
Accrued expenses and other current liabilities	$ 27,419	$ 19,707

7. Borrowings

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

	December 31,	
	2021	2020
Senior convertible notes	$ 223,944	$ —
Mann Group promissory notes(1)	18,425	63,027
MidCap credit facility	38,833	49,335
2024 convertible notes	—	5,000
PPP Loan	—	4,873
Total debt — net carrying amount	$ 281,202	$ 122,235

(1) The amendment to the Mann Group convertible note in the second quarter of 2021 resulted in a substantial premium of $22.1 million based on the fair value post modification, which contributed to the loss on extinguishment in the consolidated statement of operations for the year ended December 31, 2021 and was recognized as additional paid-in capital in the consolidated balance sheet as of December 31, 2021. The accounting for the $22.1 million loss on extinguishment did not result in a change in the financial position of the Company.

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

	Amount Due		Terms		
	December 31, 2021	December 31, 2020	Annual Interest Rate	Maturity Date	Conversion Price
Senior convertible notes	$230.0 million	—	2.50%	March 2026	$5.21 per share
MidCap credit facility(1)	$40.0 million	$50.0 million	one-month LIBOR (1% floor) plus 6.25% (1)	August 2025 (1)	N/A
Mann Group convertible note	$18.4 million (plus $0.4 million accrued interest paid-in-kind)	$28.0 million (plus $0.6 million accrued interest paid-in-kind)	2.50% (2)	December 2025 (2)	$2.50 per share
Mann Group non-convertible note(3)	—	$35.1 million (plus $3.6 million accrued interest paid-in-kind)	7.00%	November 2024	N/A
PPP loan(4)	—	$4.9 million	0.98%	April 2022	N/A
2024 convertible notes(5)	—	$5.0 million	5.75%	November 2024	$3.00 per share

(1) In April 2021, the Company prepaid $10.0 million principal balance and amended the MidCap credit facility. The interest rate prior to the amendment was one-month LIBOR (2% floor) plus 6.75% and the maturity date was in August 2024.

(2) In April 2021, the Mann Group convertible note was amended. The interest rate prior to the amendment was 7.00% and the maturity date was in November 2024.

(3) In April 2021, the Company prepaid $35.1 million principal balance as well as accrued unpaid interest.

(4) In July 2021, the Company received full forgiveness from the SBA for the $4.9 million principal balance of the PPP loan and recognized a gain on extinguishment of debt for the full principal balance and a de minimis amount of accrued but unpaid interest.

(5) In February 2021, the $5.0 million principal balance was converted into 1,666,667 shares of the Company's common stock.

The maturities of our borrowings as of December 31, 2021 are as follows (in thousands):

	Amounts
2022	$ —
2023	6,667
2024	20,000
2025	31,758
Thereafter	230,000
Total principal payments	288,425
Unamortized discount	(1,167)
Debt issuance costs	(6,056)
Total debt	$ 281,202

Senior convertible notes – On March 4, 2021, the Company issued $200.0 million aggregate principal amount of Senior convertible notes in a private offering. Pursuant to an option to purchase additional senior convertible notes in the purchase agreement between the Company and the initial purchasers of the Senior convertible notes, the Company issued an additional $30.0 million aggregate principal amount of Senior convertible notes on March 15, 2021. The Senior convertible notes were issued pursuant to an indenture, dated March 4, 2021 (the "Indenture"), between the Company and U.S. Bank National Association, as trustee.

The Senior convertible notes are general unsecured obligations of the Company and will mature on March 1, 2026, unless earlier converted, redeemed or repurchased. The Senior convertible notes will bear cash interest from March 4, 2021 at an annual rate of 2.50% payable semi-annually in arrears on March 1 and September 1 of each year, beginning on September 1, 2021. The Senior convertible notes are convertible at the option of the holders at any time prior to the close of business on the business day immediately preceding December 1, 2025, only under the following circumstances: (1) during any calendar quarter commencing after the calendar quarter ending on June 30, 2021 (and only during such calendar quarter), if the last reported sale price of the Company's common stock, par value $0.01 per share, for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price for the Senior convertible notes on each applicable trading day; (2) during the five business day period after any ten consecutive trading day period in which the trading price (as defined in the Indenture) per $1,000 principal amount of the Senior convertible notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Common Stock and the conversion rate on each such trading day; (3) if the Company calls such Notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date, but only with respect to the Senior convertible notes called (or deemed called) for redemption; or (4) upon the occurrence of specified corporate events as set forth in the Indenture. On or after December 1, 2025 until the close of business on the business day immediately preceding the maturity date, holders may convert all or any portion of their Notes at any time, regardless of the foregoing circumstances. Upon conversion, the Company will pay or deliver, as the case may be, cash, shares of the Common Stock or a combination of cash and shares of Common Stock, at the Company's election, in the manner and subject to the terms and conditions provided in the Indenture.

The initial conversion rate is 191.8281 shares of Common Stock per $1,000 principal amount of Notes (equivalent to an initial conversion price of approximately $5.21 per share of Common Stock). The initial conversion price of the Senior convertible notes represents a premium of approximately 30% to the last reported sale price of the Common Stock on the Nasdaq Global Market on March 1, 2021. The conversion rate for the Senior convertible notes is subject to adjustment under certain circumstances in accordance with the terms of the Indenture, but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date of the Senior convertible notes or if the Company delivers a notice of redemption in respect of the Senior convertible notes, the Company will, in certain circumstances, increase the conversion rate of the Senior convertible notes for a holder who elects to convert its Senior convertible notes in connection with such a corporate event or convert its Notes called for redemption during the related redemption period (as defined in the Indenture), as the case may be.

The Company may not redeem the Senior convertible notes prior to March 6, 2024. The Company may redeem for cash all or any portion of the Senior convertible notes, at its option, on or after March 6, 2024 and prior to the 36th scheduled trading day immediately preceding the maturity date, if the last reported sale price of Common Stock has been at least 130% of the conversion price for the Senior convertible notes then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which the Company provides notice of redemption at a redemption price equal to 100% of the principal amount of the Senior convertible notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. If the Company elects to redeem less than all of the outstanding Senior convertible notes, at least $75.0 million aggregate principal amount of Senior convertible notes must be outstanding and not subject to redemption as of the relevant redemption notice date. No sinking fund is provided for the Senior convertible notes.

If the Company undergoes a fundamental change (as defined in the Indenture), then, subject to certain conditions and except as described in the Indenture, holders may require the Company to repurchase for cash all or any portion of their Notes at a fundamental change repurchase price equal to 100% of the principal amount of the Senior convertible notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

The Indenture includes customary covenants and sets forth certain events of default after which the Senior convertible notes may be declared immediately due and payable.

If certain bankruptcy and insolvency-related events of default involving the Company (and not just any of its significant subsidiaries) occur, 100% of the principal of and accrued and unpaid interest on the Senior convertible notes will automatically become due and payable. If an event of default with respect to the Senior convertible notes, other than certain bankruptcy and insolvency-related events of default involving the Company (and not just any of its significant subsidiaries), occurs and is continuing, the trustee, by notice to the Company, or the holders of at least 25% in principal amount of the outstanding Senior convertible notes by notice to the Company and the trustee, may, and the trustee at the request of such holders shall, declare 100% of the principal of and accrued and unpaid interest, if any, on all the Senior convertible notes to be due and payable. Notwithstanding the foregoing, the Indenture provides that, to the extent the Company so 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 365 days after the occurrence of such an event of default consist exclusively of the right to receive additional interest on the Senior convertible notes as set forth in the Indenture.

The Indenture provides that the Company shall not consolidate with or merge with or into, or sell, convey, transfer or lease all or substantially all of the consolidated properties and assets of the Company and its subsidiaries, taken as a whole, to, another person (other than any such sale, conveyance, transfer or lease to one or more of the Company's direct or indirect wholly owned subsidiaries), unless: (i) the resulting, surviving or transferee person (if not the Company) is a corporation organized and existing under the laws of the United States of America, any State thereof or the District of Columbia, and such corporation (if not the Company) expressly assumes by supplemental indenture all of the Company's obligations under the Senior convertible notes and the Indenture; and (ii) immediately after giving effect to such transaction, no default or event of default has occurred and is continuing under the Indenture.

The Company's net proceeds from the Offering were approximately $222.7 million, after deducting the initial purchasers' discounts and commissions and the estimated Offering expenses payable by the Company. As of December 31, 2021, the unamortized debt issuance cost was $6.1 million.

MidCap credit facility — In August 2019, the Company entered into the MidCap credit facility and 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. In April 2021, $10.0 million was prepaid. Under the terms of the MidCap credit facility, a third advance of $60.0 million ("Tranche 3") will be available to the Company between January 1, 2022 and June 30, 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 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 Tranche 3 such that the third advance was 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 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 statements 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.

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, Inc. 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.

In March 2021 the Company entered into the sixth amendment to the MidCap credit facility to accommodate the issuance of the Senior convertible notes.

On April 22, 2021, the Company entered into the seventh amendment of the MidCap credit facility, pursuant to which the parties agreed to, among other things, (i) increase the amount available under the third advance from $25.0 million to $60.0 million and extend the date through which the third advance is available to June 30, 2022, (ii) amend the conditions to the third advance of $60.0 million being available to draw, including certain milestone conditions associated with Tyvaso DPI, (iii) remove the Company's obligation to issue a warrant to purchase shares of the Company's common stock upon drawing down the third advance, (iv) extend the interest-only period until September 1, 2023 and extend the maturity date until August 1, 2025, (v) amend the financial covenant relating to trailing 12 month minimum Afrezza net revenue, (vi) decrease the minimum cash covenant, (vii) decrease the interest rate on any amounts outstanding, now or in the future, under the MidCap credit facility, (viii) permit the Company to make certain acquisitions, subject to requirements, and (ix) permit the Company to make investments of up to an additional $9.0 million so long as the Company has $90.0 million or more of unrestricted cash and short-term investments following such investment. Concurrent with entering into this amendment, the Company made a $10.0 million principal prepayment against outstanding term loans under the MidCap credit facility and paid a related $1.0 million exit fee in lieu of the unaccrued portion of the original exit fee and prepayment penalties that would otherwise have been due with respect to the partial prepayment.

Tranche 1, Tranche 2 and, if borrowed, Tranche 3, each accrue interest at an annual rate equal to the lesser of (i) 8.25% and (ii) the one-month LIBOR (subject to a one-month LIBOR floor of 1.00%) plus 6.25%. Interest on each term loan advance is due and payable monthly in arrears. Principal on each term loan advance under Tranche 1, Tranche 2 and, if applicable, Tranche 3 is payable in 24 equal monthly installments beginning September 1, 2023, until paid in full on August 1, 2025. The Company has the option to prepay its existing term loans, in whole or in part, subject to early termination fees in an amount equal to 3.00% of principal prepaid if prepayment occurs on or prior to April 22, 2022; 2.00% of principal prepaid if prepayment occurs on or after April 23, 2022 through and including April 22, 2023; and 1.00% of principal prepaid if prepayment occurs on or after April 23, 2023 through the maturity date. Tranche 3 will be subject to a similar scheme of early termination fees measured from the anniversary of the funding date for such tranche, if ever.

The prepayment penalty of $1.0 million related to the payment of $10.0 million was capitalized and will be amortized over the remaining life of the debt. As of December 31, 2021, the unamortized debt discount was $0.4 million and the unamortized prepayment penalty was $0.8 million.

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, unless the Company has $90.0 million or more of unrestricted cash and short-term investments. The Company is also subject to a minimum cash covenant of $10.0 million at all times; however, this covenant will be eliminated in the event that Tyvaso DPI is approved by the FDA. As of December 31, 2021, 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 Tranches 1 and 2 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 Company determined that these warrants met the criteria for equity classification and accounted for such warrants in additional paid-in capital. During the year ended December 31, 2021, the Tranche 1 and Tranche 2 MidCap warrants were exercised in full.

Mann Group promissory notes — In August 2019, the Company 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 issued a non-convertible note to 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") as part of a restructuring of its then existing indebtedness to Mann Group.

The Mann Group promissory notes each accrued 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. On April 22, 2021, the Company and Mann Group entered into an amendment of the Mann Group convertible note, pursuant to which the parties agreed to (i) reduce the interest rate from 7.0% to 2.5% effective on April 22, 2021, and (ii) extend the maturity date from November 3, 2024 to December 31, 2025.

The amendment to the Mann Group convertible note resulted in a debt extinguishment with a substantial premium based on the fair value post extinguishment. The fair value in excess of the face amount of $18.4 million contributed to a loss on extinguishment of $22.1 million in the consolidated statement of operations for year ended December 31, 2021 and resulted in a corresponding debt premium of $22.1 million which was recognized as additional paid-in capital in the consolidated balance sheet as of December 31, 2021. The accounting for the $22.1 million loss on extinguishment did not result in a change in the financial position of the Company. The Company wrote off a *de minimis* amount of debt issuance cost.

The principal and any accrued and unpaid interest under the Mann Group convertible note may be converted, at the option of 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 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, 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. During the year ended December 31, 2021, Mann Group converted $0.4 million of interest and $9.6 million of principal into 4,000,000 shares of common stock.

On April 22, 2021, the Company repaid the entire principal amount of $35.1 million outstanding under the Mann Group non-convertible note, together with all accrued and unpaid interest thereon.

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. On July 28, 2021, the Company received notification from the SBA that the full principal amount of the PPP loan was forgiven. The Company recognized a $4.9 million gain on extinguishment of debt for the forgiveness of the principal amount and accrued but unpaid interest for the year ended December 31, 2021.

Prior to being forgiven, the PPP loan was evidenced by a promissory note dated April 9, 2020 that matured on April 9, 2022 and bore interest at a rate of 0.98% per annum (which was being deferred). The Company used all proceeds from the PPP loan to retain employees, maintain payroll and make lease, interest and utility payments.

2024 convertible notes — In August 2019, the Company issued 5.75% convertible senior subordinated exchange notes due November 2024 (the "2024 convertible notes") pursuant to an indenture, dated as of August 6, 2019, between the Company and U.S. Bank National Association, as trustee (the "2019 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 accrued 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 were 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.

In February 2021, the Company converted the $5.0 million 2024 convertible notes with the issuance of 1,666,667 shares of the Company's common stock.

Amortization of the premium and accretion of debt issuance costs related to all borrowings for the years ended December 31, 2021 and 2020 are as follows (in thousands):

	Year Ended December 31,	
	2021	2020
Amortization of debt discount	377	268
Amortization of debt issuance cost	1,215	101

Milestone Rights — As of December 31, 2021 and 2020, the remaining Milestone Rights liability balance was $5.9 million and $7.3 million, respectively, which was based on initial fair value estimates calculated using the income approach and reduced by milestone achievement payments made. During the first quarter of 2021, the Company achieved the second Afrezza net sales milestone specified by the Milestone Rights. The milestone carrying value of the Milestone Rights liability related to the $5.0 million payment, which was made in the second quarter of 2021, was approximately $1.3 million, which represented the fair value as determined in 2013 (the most recent measurement date).

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

8. Collaboration, Licensing and Other Arrangements

Revenue from collaborations and services for the years ended December 31, 2021 and 2020 are as follows (in thousands):

	Year Ended December 31,	
	2021	2020
UT License Agreement	$ 34,145	$ 32,213
UT CSA Agreement	267	—
Vertice Pharma Co-Promotion Agreement	1,147	—
Receptor CLA	245	250
Cipla License and Distribution Agreement	147	147
Other	323	—
UT Research Agreement	—	210
Total revenue from collaborations and services	$ 36,274	$ 32,820

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

	December 31,	
	2021	2020
Deferred revenue:		
Beginning balance	$ 34,937	$ 40,847
Additions	21,707	1,910
Upfront and milestone payments	—	25,000
Revenue — collaborations and services	(36,274)	(32,820)
Ending balance	$ 20,370	$ 34,937

United Therapeutics License Agreement — In September 2018, the Company and UT entered into an exclusive global license and collaboration agreement (the “UT License Agreement”), pursuant to which 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.

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 (“R&D Services”). 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 expected to complete the activities specified in the initial development plan and to achieve the milestone events by December 31, 2021 for total consideration of approximately $105.8 million, which included an upfront payment, four milestone payments, various pass-through costs and payments for clinical supplies. Revenue was allocated as follows:

Distinct Performance Obligation	Transaction Price	Allocation of Price	Recognition Method	Progress Measure	Recognition Period	
	(in millions)					
R&D Services and License	$ 105.8	100%	Over time	Ratably	Sep 2018 - Dec 2021	(1)

(1) Recognition period represents the estimated period to satisfy the performance obligation.

In May 2021, UT and the Company updated the development plan under the UT License Agreement to provide for additional process-development and stability-testing activities as well as the expansion of the Company's commercial manufacturing capacity. The activities and deliverables under the current development plan resulted in four distinct performance obligations which include: (1) the continued development and approval process for an NDA ("R&D Services"); (2) certain pre-commercial services in preparation for commercial launch of Tyvaso DPI "(Pre-Commercial Services"); (3) development activities for the next generation of Tyvaso DPI ("Next-Gen R&D Services"); and (4) certain design and construction activities in anticipation of expansion of the Company's commercial manufacturing facility ("Facility Expansion Services").

The total consideration for the updated development plan of $50.9 million was allocated to the four distinct performance obligations based on management's assessment of the stand-alone selling price of each performance obligation. Revenue was allocated as follows:

Description	Transaction Price	Allocation of Price(1)	Recognition Method	Progress Measure	Revenue Recognition	
	(in millions)					
Total transaction price	$ 50.9					
Distinct Performance Obligation						
R&D Services and License		$ 18.4	Over time	Ratably	May 2021 - Oct 2021	(2)
Pre-Commercial Services		$ 4.6	Over time	Input	% of completion of costs	(3)
Next-Gen R&D Services		$ 7.2	Over time	Input	% of completion of costs	(3)
Facility Expansion Services(4)		$ 20.7	Point in time		Transfer of control	(5)

(1) Allocation is based on management's assessment of the stand-alone selling price of each performance obligation.

(2) Represents the estimated period when the R&D Services performance obligation will be substantially complete.

(3) Pre-Commercial Services and Next-Gen R&D Services performance obligations will be satisfied over time using the input method based on the costs incurred to date as a percentage of the total estimated costs to fulfill the contract. Incurred cost represents work performed, which corresponds with, and thereby best depicts, the transfer of control to the customer.

(4) The Company also acts as agent for the procurement of equipment for the manufacturing expansion for the UT Equipment. The Company received $5.0 million from UT for the UT Equipment, which was recognized as deposits from customer on the consolidated balance sheet and will be released as the title is transferred to UT.

(5) The Facility Expansion Services performance obligation would be recognized as control of manufactured products is transferred to the customer.

On August 12, 2021, the Company and UT entered into a commercial supply agreement (the "CSA"), pursuant to which the Company is responsible for manufacturing and supplying to UT, and UT is responsible for purchasing from the Company on a cost-plus basis, Tyvaso DPI and BluHale inhalation profiling devices, as required for commercial distribution and sale by UT. In addition, UT is responsible for supplying treprostinil at its expense in quantities necessary to enable the Company to manufacture Tyvaso DPI as required by the CSA. Also pursuant to the CSA, UT will remit a reimbursement of certain pre-production costs incurred by the Company to support the manufacturing and supply of Tyvaso DPI.

The activities and deliverables under the CSA and the current development plan resulted in three distinct performance obligations which include: (1) the license, supply of product to be used in clinical development, and continued development and approval support for Tyvaso DPI ("R&D Services and License"); (2) development activities for the next generation of Tyvaso DPI Next-Gen R&D Services; and (3) a material right associated with future commercial manufacturing and supply of product ("Manufacturing Services").

The total revised anticipated cash flows of $221.5 million from the transaction was allocated to the three distinct performance obligations as follows.

Description	Anticipated Cash Flow	Anticipated Revenue Allocation(1)	Recognition Method	Progress Measure	Revenue Recognition	
	(in millions)					
Total anticipated cash flow	$ 221.5					
Distinct Performance Obligation						
R&D Services and License(2)		$ 6.0	Over time	Ratably	Aug 2021 - Oct 2021	(3)
Next-Gen R&D Services		$ 8.8	Over time	Input	% of completion of costs	(4)
Manufacturing Services		$ 206.7	Point in time		Transfer of control	(5)

(1) Allocation is based on management's assessment of the stand-alone selling price of each performance obligation.

(2) The license for the Company's IP was considered to be interdependent with the development activities to support approval of Tyvaso DPI. A sales-based royalty is promised in exchange for the IP license; therefore, the royalties associated with the license are excluded from the determination of the transaction price and the Company will recognize revenue as the sale of Tyvaso DPI to a patient occurs.

(3) Represents the estimated period when the R&D Services performance obligation will be substantially complete.

(4) The Next-Gen R&D Services performance obligation will be satisfied over time using the input method based on the costs incurred to date as a percentage of the total estimated costs to fulfill the contract. Incurred cost represents work performed, which corresponds with, and thereby best depicts, the transfer of control to the customer.

(5) The Manufacturing Services performance obligation will be recognized as control of manufactured products is transferred to the customer; therefore, no revenue associated with this obligation was recognized during the year ended December 31, 2021. The allocation of transaction price includes a material right related to manufacturing services. The total anticipated cash flow is based on the Company's estimated production and the ultimate cash flows may vary as manufacturing purchase orders are received.

As amended by an amendment dated October 16, 2021, the term of the CSA continues until December 31, 2031 (unless earlier terminated) and is thereafter renewed automatically for additional, successive two-year terms unless (i) United Therapeutics provides notice to the Company at least 24 months in advance of such renewal that United Therapeutics does not wish to renew the CSA or (ii) the Company provides notice to United Therapeutics at least 48 months in advance of such renewal that the Company does not wish to renew the CSA. The Company and United Therapeutics each have normal and customary termination rights, including termination for material breach that is not cured within a specific timeframe or in the event of liquidation, bankruptcy or insolvency of the other party.

The Company accounted for the contract modification as if it were part of the existing contract since the amendment modified the scope and price of the CSA by extending the term and increasing the occupancy rate. The effect of the modification on the transaction price and on the measure of progress is recognized as an adjustment to revenue as of the date of the modification. The modification did not result in a change the activities and deliverables under the CSA.

Description	Anticipated Cash Flow	Anticipated Revenue Allocation(1)	Recognition Method	Progress Measure	Revenue Recognition	
	(in millions)					
Total anticipated cash flow(2)	$ 463.5					
Distinct Performance Obligation						
R&D Services and License(3)		$ —	Over time	Ratably	Aug 2021 - Oct 2021	(4)
Next-Gen R&D Services(5)		$ 4.8	Over time	Input	% of completion of costs	(6)
Manufacturing Services(7)		$ 458.7	Point in time		Transfer of control	(8)

(1) Allocation is based on management's assessment of the stand-alone selling price of each performance obligation.

(2) The total anticipated cash flow includes a transaction price of $64.3 million for the contractual obligations under the CSA for the Manufacturing Services and the Next-Gen R&D Services performance obligations and $399.2 million for future supply of Tyvaso DPI over the remaining term of the CSA.

(3) The license for the Company's IP was considered to be interdependent with the development activities to support approval of Tyvaso DPI. A sales-based royalty is promised in exchange for the IP license; therefore, the royalties associated with the license are excluded from the determination of the transaction price and the Company will recognize revenue as the sale of Tyvaso DPI to a patient occurs.

(4) Represents the period when the revenue for the R&D Services performance obligation was recognized.

(5) The standalone selling price ("SSP") for the Next-Gen R&D Services performance obligation was based on industry ratios as well as the Company's historical R&D projects. The transaction price for the Next-Gen R&D Services was based on fixed consideration which was allocated between performance obligations as discussed in note (2) above.

(6) The Next-Gen R&D Services performance obligation will be satisfied over time using the input method based on the costs incurred to date as a percentage of the total estimated costs to fulfill the contract. Incurred cost represents work performed, which corresponds with, and thereby best depicts, the transfer of control to the customer.

(7) Pre-production activities under the CSA, such as facility expansion services and certain other administrative services, were considered bundled services that are part of the Company's Manufacturing Services performance obligation, given the nature of the Company's contractual responsibilities and ASC 606 requirements.

(8) The Manufacturing Services performance obligation will be recognized as control of manufactured products is transferred to the customer. The modification did not result in a cumulative catch-up adjustment as a result of the revenue being deferred for the performance obligations that were affected by the modification. The allocation of transaction price includes a material right related to manufacturing services in the amount of $144.5 million. The total anticipated cash flow is based on the Company's estimated production and the ultimate cash flows may vary as manufacturing purchase orders are received.

As of December 31, 2021, deferred revenue consisted of $18.6 million, of which $0.6 million was classified as current and $18.0 million was classified as long-term on the consolidated balance sheet.

Vertice Pharma Co-Promotion 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 Pharma is obligated to pay fixed quarterly payments to the Company, as well as variable consideration based on gross profits resulting from all sales of Thyquidity. Vertice Pharma launched Thyquidity in collaboration with the Company in February 2021.

At inception of the agreement, the Company identified a single performance obligation that the Company will satisfy over time. The Company estimates the total transaction price is approximately $6.3 million, consisting of fixed consideration and the unconstrained amount of estimated variable consideration, which is based on gross profit applied to defined revenue benchmarks. The amount of variable consideration is constrained to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur and the payments will be received. At the end of each subsequent reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price 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 in the period of adjustment. The total transaction price will be recognized over a two-year period. the period over which the Company is required to satisfy its performance obligation, using the input method based on the costs incurred to date as a percentage of the total estimated costs to fulfill the contract. Incurred cost represents work performed, which corresponds with, and thereby best depicts, the transfer of control to the customer. In July 2021, the Company and Vertice Pharma entered into an amendment to the Vertice Pharma Co-Promotion Agreement that modifies the terms of payment where 50% of the previously fixed consideration will be subject to certain promotional conditions, resulting in variable consideration.

In September 2021, the Company and Vertice Pharma mutually agreed that the Company would cease promotional activities under the co-promotion agreement effective September 30, 2021, other than certain transitional activities that continued until October 15, 2021. The Company and Vertice Pharma are currently negotiating a final settlement of all obligations related to the termination of the co-promotion agreement.

As of December 31, 2021, the Company fully reserved $0.8 million of revenue from the co-promotion of Thyquidity, which was recognized as allowance for credit losses – collaborations and services, which is included in accounts receivable, net in the consolidated balance sheet. In addition, the Company recognized an impairment on contract assets of $0.1 million related to variable consideration from gross profits which was recognized during the year ended December 31, 2021.

Thirona Collaboration Agreement — In June 2021, the Company and Thirona entered into a collaboration agreement to evaluate the therapeutic potential of Thirona's compound for the treatment of pulmonary fibrosis. If initial studies are promising, the Company can exercise certain rights to seek a full license to the compound for clinical development and commercialization. The parties will perform their respective obligations and provide reasonable support for research, clinical development and regulatory strategy. The collaboration agreement will be accounted for under ASC 808, Collaborative Agreements; however, no consideration will be exchanged between the parties. The Company will expense the costs incurred as research and development in the consolidated statements of operations.

Biomm Supply and Distribution Agreement — In May 2017, the Company and Biomm S.A. ("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 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. During the year ended December 31, 2020, the Company sold $0.2 million of product to Biomm. No shipments of product were made to Biomm during the year ended December 31, 2021.

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 is 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, 2021, the deferred revenue balance was $1.7 million, of which $0.1 million is classified as current and $1.6 million is classified as long term in the consolidated balance sheets.

AMSL Distribution Agreement — In May 2019, the Company entered into an exclusive marketing and distribution agreement with Australasian Medical & Scientific Ltd. ("AMSL") for the commercialization of Afrezza in Australia. Under the terms of this agreement, AMSL is responsible for obtaining regulatory and reimbursement approvals to distribute Afrezza in Australia. On August 1, 2021, Dexcom, Inc. acquired all of the outstanding shares of AMSL. As a result, on November 4, 2021, the Company exercised its right under the marketing and distribution agreement to terminate such agreement.

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. Inputs used in the valuation techniques to derive fair values are classified based on a three-level hierarchy, 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.

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, long- and short-term investments, MidCap credit facility, Mann Group promissory notes, 2024 convertible notes, Senior convertible notes, Milestone Rights liabilities and Financing liability are disclosed below (amounts in millions).

		December 31, 2021		
	Investment Level	Amortized Cost (Carrying Value)	Gross Unrealized Holding Losses	Estimated Fair Value
Commercial bonds and paper	Level 2	$ 115.2	$ 0.2	$ 115.0
Money market funds	Level 1	21.3	—	21.3
U.S. Treasuries	Level 2	23.9	0.1	23.8
Total cash equivalents and investments		$ 160.4	$ 0.3	$ 160.1
Less cash equivalents		(23.8)	—	(23.8)
Total Investments		$ 136.6	$ 0.3	$ 136.3

		December 31, 2020		
	Investment Level	Amortized Cost (Carrying Value)	Gross Unrealized Holding Losses	Estimated Fair Value
Cash equivalents - U.S. Treasuries	Level 2	$ 59.5	$ —	$ 59.5

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, 2021 and 2020, the Company held $124.2 million and $67.0 million, respectively, of cash and cash equivalents. The Company held $0.2 million in restricted cash as of December 31, 2020, which was comprised of money market funds, corporate bonds and commercial paper for the collateralization of a letter of credit and treasury bills. There was no restricted cash as of December 31, 2021.

Held-to-Maturity Investments — Investments consist of highly liquid investments that are intended to facilitate liquidity and capital preservation. As of December 31, 2021, the Company held $79.9 million of short-term investments and $56.6 million of long-term investments. As of December 31, 2020, the Company did not hold any investments.

Available-for-Sale Investment — The Thirona convertible note is classified as an available-for-sale security and is included in other assets in the consolidated balance sheet. Available-for-sale investments are subsequently measured at fair value. Unrealized holding gains and losses are excluded from earnings and reported in other comprehensive income until realized. The Company determines fair value of its

available-for-sale investments using level 3 inputs. As of December 31, 2021, the Company evaluated the fair value of its investment in Thirona and determined that the fair value approximates the carrying value of $3.0 million.

Financial Liabilities — The following tables set forth the fair value of the Company's financial instruments (Level 3 in the fair value hierarchy) (in millions):

	December 31, 2021		
		Fair Value	
	Carrying Amount	Significant Unobservable Inputs (Level 3)	Total Fair Value
Financial liabilities:			
Senior convertible notes(1)	$ 223.9	$ 237.5	$ 237.5
MidCap credit facility(2)	38.8	40.8	40.8
Mann Group convertible notes(3)	18.4	37.8	37.8
Milestone rights(4)	5.9	18.1	18.1

(1) Fair value determined by applying a discounted cash flow analysis to the straight note with a hypothetical yield of 12%, volatility of 90% and a Monte Carlo simulation for the value of the conversion feature. A change in yield of + or – 2% would result in a fair value of $226.6 million and $249.4 million, respectively.

(2) Fair value determined by applying a discounted cash flow analysis with a hypothetical yield of 10%. A change in yield of + or – 2% would result in a fair value of $39.1 million and $42.7 million, respectively.

(3) The April 2021 amendment to the Mann Group convertible note resulted in a substantial premium of $22.1 million based on the fair value post modification which was recognized as additional paid-in capital in the consolidated balance sheet as of December 31, 2021. The accounting for the $22.1 million loss on extinguishment did not result in a change in the financial position of the Company. The fair value assessed as of December 31, 2021 was determined by applying a discounted cash flow analysis with a hypothetical yield of 12% and volatility of 85% to the straight note and a binomial option pricing model for the value of the conversion feature. A change in yield of + or – 2% would result in a fair value of $36.9 million and $38.8 million, respectively.

(4) Fair value determined by applying a Monte Carlo simulation.

	December 31, 2020		
		Fair Value	
	Carrying Value	Significant Unobservable Inputs (Level 3)	Total Fair Value
Financial liabilities:(1)			
MidCap credit facility	$ 49.3	$ 55.4	$ 55.4
Mann Group promissory notes(2)	63.0	78.9	78.9
2024 convertible notes	5.0	7.0	7.0
PPP loan	4.9	4.7	4.7
Milestone Rights	7.3	19.8	19.8

(1) Fair value measurements were based on a discounted cash flow model, except for the Milestone rights for which a Monte Carlo simulation was applied.

(2) Mann Group promissory notes consisted of the following carrying values and fair values:
Mann Group convertible notes carrying value of $28.0 million and fair value of $52.2 million.
Mann Group non-convertible notes carrying value of $35.1 million and fair value of $26.7 million.

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.

Financing Liability — The failed Sale Leaseback Transaction in November 2021 resulted in a financing liability which is included in our consolidated balance sheets as a current financing liability of $7.0 million and a long-term financing liability of $93.5 million. The Company determined the fair value of the financing liability using level 3 inputs. As of December 31, 2021, the Company evaluated the fair value of its financing liability and determined that the fair value approximates the carrying value.

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, 2021 and 2020, 251,477,562 and 242,117,089 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 "CF 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, 2021, the Company sold an aggregate of 578,063 shares of the Company's common stock at an average purchase price of $3.26 per share for an aggregate gross proceeds of approximately $1.9 million pursuant to the Sales Agreement. 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 CF Sales Agreement.

In June 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. In October 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 in June and October 2020 were determined based on the Company's closing stock price on the day preceding the settlement date. See Note 7 – *Borrowings*.

In June 2020, 7,250,000 warrants were exercised at a price of $1.60 per share. The warrants were issued pursuant to an underwriting agreement with Leerink Partners LLC for 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. There are no remaining warrants outstanding under this agreement.

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 1,666,667 shares of the Company's common stock.

In October 2021, MidCap exercised 1,171,614 and 111,853 warrants issued in association with Tranches 1 and 2, respectively, under the MidCap credit facility, as amended, to purchase an aggregate of 1,283,467 shares of the Company's common stock through a cashless exercise that resulted in the net issuance of 964,113 shares. See Note 7 – *Borrowings*.

During the year ended December 31, 2021, the Company received $0.1 million from the market price stock purchase plan ("MPSPP") for 25,000 shares and a *de minimis* amount during the year ended December 31, 2020.

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,	
	2021	2020
EPS — basic and diluted:		
Net loss (numerator)	$ (80,926)	$ (57,240)
Weighted average common shares (denominator)	249,244	222,585
Net loss per share	$ (0.32)	$ (0.26)

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 convertible notes.

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

	Year Ended December 31,	
	2021	2020
Senior convertible notes	44,120,463	—
Common stock options and PNQs	10,655,146	12,264,616
Mann Group convertible notes	7,370,000	11,200,000
Warrants associated with MidCap credit facility	—	1,283,467
2024 convertible notes	—	1,666,667
RSUs and Market RSUs(1)	7,609,025	6,037,542
Employee stock purchase plan	243,375	292,981
Total shares	69,998,009	32,745,273

(1) Market RSUs are included at the maximum share delivery percentage.

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 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, 2021 had a grant date fair value of $9.30 per share and will vest on May 17, 2024 provided that the closing price of the Company's common stock on such vesting date is not less than the closing price on May 17, 2021. The fair value of the Market RSUs was determined using a share price of $4.26, risk-free interest rate of 0.34%, volatility of 88%, 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 May 18, 2021 until May 17, 2024 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, 2021:

	Outstanding Options	Outstanding Restricted Stock Units	Shares Available for Future Issuance
2004 Equity Incentive Plan	206,358	—	—
2013 Equity Incentive Plan	3,639,936	2,600	—
2018 Equity Incentive Plan	6,800,852	7,606,425	5,344,810
2004 Non-Employee Directors' Stock Option Plan	8,000	—	—
Total	10,655,146	7,609,025	5,344,810

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, 2021 and 2020, the Company recorded RSU and option based stock compensation expense of $11.5 million, $6.2 million and employee stock purchase plan compensation of $0.7 million and $0.3 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,	
	2021	2020
Cost of goods sold	$ 407	$ 446
Cost of revenue — collaborations and services	1,708	626
Research and development	614	338
Selling, general and administrative	9,471	5,101
Total	$ 12,200	$ 6,511

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. There were no options issued in the year ended December 31, 2021. The Company calculated the fair value of employee stock options granted during the year ended December 31, 2020 using the following assumptions:

	Year Ended December 31,
	2020
Risk-free interest rate	0.39% — 1.52%
Expected lives	5.67 — 7.0 years
Volatility	93.83% — 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, 2021	12,264,616	$ 3.41	6.45	$ 15,414
Granted	—	—		
Exercised	(586,572)	1.72		
Forfeited	(258,410)	1.59		
Expired	(764,488)	11.57		
Outstanding at December 31, 2021	10,655,146	$ 2.96	5.82	$ 25,458
Exercisable at December 31, 2021	8,009,961	$ 3.40	5.58	$ 18,436

There were no stock options granted in the year ended December 31, 2021. The weighted average grant date fair value of the stock options granted during the year ended December 31, 2020 was $0.97. Total fair value of stock options vested during the years ended December 31, 2021 and 2020 was $2.3 million and $4.5 million, respectively. The total intrinsic value of options exercised during the years ended

December 31, 2021 and 2020 was $1.7 million and $0.5 million, respectively. Intrinsic value is measured using the fair market value at the date of exercise for options exercised or at December 31 for outstanding options, less the applicable exercise price.

Cash received from the exercise of options during the years ended December 31, 2021 and December 31, 2020 was approximately $1.0 million and $0.6 million, respectively.

As of December 31, 2021 and 2020, the Company recognized a $0.1 million and $0.2 million, respectively, of compensation costs related to the performance-based stock options. As of December 31, 2021 and 2020, there was $0.3 million and $0.4 million, respectively 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, 2021	6,037,542	$ 2.20
Granted	3,326,798	5.82
Vested	(1,516,065)	2.22
Forfeited	(239,250)	2.58
Outstanding at December 31, 2021	7,609,025	3.77

Total fair value of restricted stock units vested during the years ended December 31, 2021 and 2020 was $6.7 million and $2.5 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, 2021 and 2020 was $19.3 million and $13.3 million, respectively.

As of December 31, 2021, there was $2.1 million of unrecognized compensation expense related to options and PNQs and $21.1 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 1.32 to 2.59 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 (“IRC”) 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 0.5 million and 0.6 million shares of common stock pursuant to the ESPP for the years ended December 31, 2021 and 2020, respectively. There were approximately 1.1 million shares of common stock available for issuance under the ESPP as of December 31, 2021.

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, 2021, 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.

Contingencies — In July 2013, the Company entered into an agreement with the Original 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, $65.0 million of which remains payable to Barings upon achievement of such milestones (see Note 7 — *Borrowings*). The fair value of the Milestone Rights is recorded in the consolidated balance sheet, including $1.1 million in accrued expenses and other current liabilities and $4.8 million in milestone rights liability.

Sale lease-back — On November 8, 2021, the Company sold the Property to the Purchaser for a sales price of $102.3 million, subject to terms and the conditions contained in a purchase and sale agreement.

Effective with the closing of the Sale-Leaseback Transaction, the Company and the Purchaser entered into a lease agreement (the "Lease"), pursuant to which the Company leased the Property from the Purchaser for an initial term of 20 years, with four renewal options of five years each. The total annual rent under the Lease starts at approximately $9.5 million per year, subject to a 50% rent abatement during the first year of the Lease, and will increase annually by (i) 2.5% in the second through fifth year of the Lease and (ii) 3% in the sixth and each subsequent year of the Lease, including any renewal term. The Company is responsible for payment of operating expenses, property taxes and insurance for the Property. The Purchaser will hold a security deposit of $2.0 million during the Lease term. Pursuant to the terms of the Lease, the Company has four options to repurchase the Property, in 2026, 2031, 2036 and 2041, for the greater of (i) $102.3 million and (ii) the fair market value of the Property.

Effective with the closing of the Sale-Leaseback Transaction, the Company and the Purchaser also entered into a right of first refusal agreement (the "ROFR"), pursuant to which the Company has a right to re-purchase the Property from the Purchaser in accordance with terms and conditions set forth in the ROFR. Specifically, if the Purchaser receives, and is willing to accept, a bona fide purchase offer for the Property from a third-party purchaser, the Company has certain rights of first refusal to purchase the Property on the same material terms as proposed in such bona fide purchase offer.

As of December 31, 2021, the related financing liability was $100.5 million, which was recognized in our consolidated balance sheet as $93.5 million of financing liability — long-term and $7.0 million of financing liability — short-term.

Financing liability information is as follows (in thousands):

	December 31, 2021
Weighted average remaining lease term (in years)	19.8
Weighted average discount rate	9.0%

	December 31, 2021
Interest expense on financing liability	$ 1,373

Financing liability payments as of December 31, 2021 was as follows (in thousands):

	December 31, 2021
2022[1]	$ 6,373
2023	9,778
2024	10,023
2025	10,274
2026	10,539
Thereafter	199,091
Total	246,078
Interest payments	(142,485)
Debt issuance costs	(3,091)
Total financing liability	$ 100,502

(1) 2022 includes the amortization of the rent abatement.

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 May 2021, the Company and Amphastar France Pharmaceuticals S.A.S. (“Amphastar”) amended the Insulin Supply Agreement to extend the term and restructure the annual purchase commitments. In connection with the amendment, the Company agreed to pay $2.0 million of amendment fees, which were recognized in cost of goods sold for the year ended December 31, 2021. The remaining purchase commitments as of December 31, 2021 and March 31, 2021 (pre-amendment) were as follows:

	December 31, 2021	March 31, 2021
2022	€ 5.4 million	€ 7.0 million
2023	€ 8.8 million	€ 8.5 million
2024	€ 14.6 million	€ 10.9 million
2025	€ 15.5 million	€ 14.6 million
2026	€ 19.4 million	€ 15.5 million
2027	€ 9.2 million	€ 19.4 million

Pursuant to the amendment, the term of the Insulin Supply Agreement expires on December 31, 2027, unless terminated earlier, 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.

Vehicle Leases – During the second quarter of 2018, the Company entered into a lease agreement with Enterprise Fleet Management Inc. During 2021, 85 vehicles were retired and all of those vehicles were replaced, resulting in a fleet size of 89 vehicles. The Company received proceeds for the gain on the retired vehicles residual value in the amount of $0.5, which is included as a reduction to our lease expense. The revised monthly payment inclusive of maintenance fees, insurance and taxes is approximately $0.1 million and the additional right of use asset and lease obligation is approximately $1.4 million in the consolidated balance sheets. The lease expense is included in selling, general and administrative expenses in the consolidated statements of operations.

Office Leases — In May 2017, the Company executed an office lease with Russell Ranch Road II LLC for the Company’s corporate offices 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 offices 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.

Lease information is as follows (in thousands):

	December 31, 2021	December 31, 2020
Weighted average remaining lease term (in years)	2.6	1.9
Weighted average discount rate	7.3%	7.5%

	December 31,	
	2021	2020
Operating lease costs	$ 863	$ 1,403
Variable lease costs	515	394
Cash paid	1,867	1,797

Future minimum office and vehicle lease payments as of December 31, 2021 and 2020 were as follows (in thousands):

	December 31,	
	2021	2020
2021	$ —	$ 1,494
2022	1,444	1,239
2023	497	88
2024	409	—
2025	311	—
Total	$ 2,661	$ 2,821

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, 2021, the Company matched each participant's deferral at the rate of 50% of each participant's deferral up to the first 10% of compensation. Participants hired after March 31, 2021 became vested in Company contributions at 100% after two years of service. 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 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 $1.5 million and $0.9 million for the years ended December 31, 2021 and 2020, respectively.

15. Income Taxes

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

	Year Ended December 31,	
	2021	2020
United States	$ (80,926)	$ (57,458)
Foreign	—	—
Loss before provision for income taxes	$ (80,926)	$ (57,458)

At December 31, 2021, the Company has concluded that it is more likely than not that the Company may not realize the benefit of its deferred tax assets due to its history of losses. The 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,	
	2021	2020
Current		
U.S. federal	$ —	$ —
U.S. state	—	—
Non-U.S.	—	(218)
Total current	—	(218)
Deferred		
U.S. federal	(5,170)	(4,377)
U.S. state	(14,461)	(469)
Non-U.S.	—	—
Total deferred	(19,631)	(4,846)
Valuation allowance	19,631	4,846
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, 2021 and 2020, are approximately as follows (in thousands):

	December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	$ 542,800	$ 533,448
Research and development credits	78,804	79,455
Milestone Rights	1,440	1,547
Accrued expenses	2,591	1,436
Loss on purchase commitment	24,845	23,864
Non-qualified stock option expense	5,684	3,766
Capitalized patent costs	7,518	5,273
Other	2,568	2,093
Lease liability	588	559
Interest expense limitation	5,696	2,460
Depreciation	22,983	20,735
Deferred Product Revenue & Costs	404	1,569
Total net deferred tax assets	695,921	676,205
Valuation allowance	(695,094)	(675,463)
Net deferred tax assets	$ 827	$ 742
Deferred tax liabilities:		
Right of use asset	$ (555)	$ (510)
Other prepaids	(272)	(232)
Total deferred tax liabilities	(827)	(742)
Net deferred tax assets	$ —	$ —

The Company’s effective tax rate differs from the statutory federal income tax rate as follows for the years ended December 31, 2021 and 2020:

	Year Ended December 31,	
	2021	2020
Federal tax benefit rate	21.0%	21.0%
Permanent items	-4.4%	-6.1%
Stock based compensation	0.3%	-0.5%
Tax attribute expirations	-5.9%	-6.6%
Foreign withholding tax	0.0%	0.4%
Valuation allowance	-11.2%	-7.8%
Other	0.2%	0.0%
Effective income tax rate	0.0%	0.4%

As of December 31, 2021 and 2020, 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 our deferred tax assets will not be realized. Under this guidance, a valuation allowance must be established for deferred tax assets when it is more likely than not (a probability level of more than 50 percent) that they will not be realized. 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, 2021. Accordingly, a valuation allowance of $695.1 million has been recorded to offset this deferred tax asset. During the years ended December 31, 2021 and 2020, the change in valuation allowance was $19.6 million and $4.8 million, respectively.

As of December 31, 2021, the Company had federal and state net operating loss carryforwards of approximately $2.2 billion and $1.3 billion available, respectively, to reduce future taxable income. $452.7 million of the federal losses do not expire and the remaining federal losses have started expiring, beginning in the current year through various future dates.

Pursuant to IRC Sections 382 and 383, annual use of the Company's federal and California 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 IRC 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, 2021, 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, 2021]. There is a risk that changes in ownership may occur in tax years after December 31, 2021. 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, 2021, the Company had $54.2 million of U.S. federal research and development credits which expire beginning in 2024, and $24.6 million of state research and development credits. The California credits do not expire and $2.0 million of the available $2.2 million New Jersey credits expired at the end of 2021. The Company also had two types of credits in Connecticut of which $19.8 million do not expire and $0.1 million of $1.2 million expired at the end of 2021.

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 tax laws. The Company's tax years since 2016 remain subject to examination by federal, state and foreign tax authorities.

A reconciliation of beginning and ending amounts of unrecognized tax benefits in 2021 and 2020, respectively, was as follows (in thousands):

	Year Ended December 31,	
	2021	2020
Unrecognized Tax Benefit		
Beginning of Year	$ 268,902	$ —
Gross increases for tax positions of prior years	—	268,902
Gross decreases for tax positions of current year	—	—
Settlements	—	—
Lapse of statute of limitations	—	—
End of Year	$ 268,902	$ 268,902

At December 31, 2021 and 2020, the Company has not recognized a liability for unrecognized tax benefits. If any were recognized, it would affect the Company's effective tax rate. The Company does not expect its unrecognized tax benefits to change significantly over the next 12 months. The Company recognizes interest and penalties accrued related to unrecognized tax benefits in income tax expense. During the years ended December 31, 2021 and 2020, the Company did not recognize any interest and/or penalties.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-117811, 333-127876, 333-137332, 333-149049, 333-160225, 333-176409, 333-182457, 333-188790, 333-213366, 333-225428, 333-226648, and 333-242367 on Form S-8 and Registration Statement No. 333-230633 on Form S-3 of our reports dated February 24, 2022, relating to the financial statements of MannKind Corporation and subsidiaries ("MannKind Corporation") and the effectiveness of MannKind Corporation's internal control over financial reporting appearing in this Annual Report on Form 10-K of MannKind Corporation for the year ended December 31, 2021.

/s/ Deloitte & Touche LLP

Los Angeles, CA

February 24, 2022

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 24, 2022

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 24, 2022

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, 2021, 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 24th day of February, 2022.

/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, 2021, 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 24th day of February, 2022.

/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.