MANNKIND CORP
Form 10-K
March 16, 2017
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

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

For the fiscal year ended December 31, 2016

or

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

For the transition period from _____ to _____

Commission file number: 000-50865

MannKind Corporation

(Exact name of registrant as specified in its charter)

Delaware	**13-3607736**
(State or other jurisdiction of	**(I.R.S. Employer**
incorporation or organization)	**Identification No.)**
25134 Rye Canyon Loop Suite 300	
Valencia, California	**91355**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone number, including area code

(661) 775-5300

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

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

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

None

(Title of Class)

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

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

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

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

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

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

Large accelerated filer Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

As of June 30, 2016, the aggregate market value of the voting stock held by non-affiliates of the registrant, computed by reference to the last sale price of such stock as of such date on the NASDAQ Global Market, was approximately $372,097,776.

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

DOCUMENTS INCORPORATED BY REFERENCE

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

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MANNKIND CORPORATION

Annual Report on Form 10-K

For the Fiscal Year Ended December 31, 2016

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

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

PART I

Item 1. *Business*

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

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

Afrezza is a rapid-acting, inhaled insulin used to control high blood sugar in adults with type 1 and type 2 diabetes. The product consists of a dry powder formulation of human insulin delivered from a small and portable inhaler. Administered at the beginning of a meal, Afrezza dissolves rapidly upon inhalation to the lung and delivers insulin quickly to the bloodstream. Peak insulin levels are achieved within 12 to 15 minutes of administration.

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

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

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

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

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

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

- An open-label PK and multiple-dose safety and tolerability dose-titration trial of Afrezza in pediatric patients ages 4 to 17 years with type 1 diabetes followed by a prospective, open-label, randomized, controlled trial comparing the efficacy and safety of prandial Afrezza to prandial subcutaneous insulin as part used in combination with subcutaneous basal insulin in pediatric patients 4 to 17 years old with type 1 or type 2 diabetes; and

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

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

determined by continuous glucose monitoring.

Manufacturing and Supply

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

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

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

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

Currently, the only approved source of insulin for Afrezza is manufactured by Amphastar France Pharmaceuticals S.A.S. (Amphastar). In April 2014, Amphastar acquired a manufacturing facility from N.V. Organon, a subsidiary of Merck & Co., Inc., where we had previously obtained the insulin that we use to make Afrezza. On July 31, 2014, we entered into a supply agreement with Amphastar (the Insulin Supply Agreement), pursuant to which we agreed to purchase certain annual minimum quantities of insulin for calendar years 2015 through 2019 for an aggregate total purchase price of approximately 120.1 million, of which 93.0 million remained unpurchased as of December 31, 2016. On November 9, 2016, we amended the contract with Amphastar to extend the term over which we are required to purchase insulin, by four additional years, without reducing the total amount of insulin we will purchase. Unless earlier terminated, the term of the Insulin Supply Agreement now expires on December 31, 2023 and can be renewed for additional, successive two year terms upon 12 months written notice given prior to the end of the initial term or any additional two year term. We and Amphastar each have normal and customary termination rights, including termination for material breach that is not cured within a specific time frame or in the event of liquidation, bankruptcy or insolvency of the other party. In addition, we may terminate the Insulin Supply Agreement upon two years prior written notice to Amphastar without cause or upon 30 days prior written notice to Amphastar if a controlling regulatory authority withdraws approval for Afrezza, provided, however, in the event of a termination pursuant to either of the latter two scenarios, the provisions of the Insulin Supply Agreement require us to pay the full amount of all unpaid purchase commitments due over the initial term within 60 calendar days of the effective date of such termination.

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

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

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

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

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Technosphere Formulation Technology

Afrezza utilizes our proprietary Technosphere formulation technology; however, the application of this technology is not limited to insulin delivery. We believe it represents a versatile drug delivery platform that may allow the oral inhalation of a wide range of therapeutics. We have successfully prepared Technosphere formulations of anionic and cationic drugs, hydrophobic and hydrophilic drugs, proteins, peptides and small molecules. Technosphere powders are based on our proprietary excipient, FDKP, which is a pH-sensitive organic molecule that self-assembles into small particles under acidic conditions. Certain drugs, such as insulin, can be loaded onto these particles by combining a solution of the drug with a suspension of Technosphere material, which is then dried to powder form. The resulting powder has a consistent and narrow range of particle sizes with good aerodynamic properties that enable efficient delivery deep into the lungs. Technosphere powders dissolve extremely fast after inhalation when the particles contact the moist lung surface with its neutral pH, releasing the drug molecules to diffuse across a thin layer of cells into the arterial circulation, bypassing the liver to provide excellent systemic exposure.

We have also created an innovative line of breath-powered, dry powder inhalers. Our inhalers are easy to use, cost-effective and can be produced in both a reusable (chronic treatment) and a single-use (acute treatment) format. Both the reusable and single use inhaler formats use the same internal air-flow design. Being breath-powered, our inhalers require only the patient s inhalation effort to deliver the powder. To administer the inhalation powder, a patient loads a cartridge into our inhaler and inhales through the mouthpiece. Upon inhalation, the dry powder is lifted out of the cartridge and broken (or de-agglomerated) into small particles. The inhalers are engineered to produce an aggressive airstream to de-agglomerate the powder while keeping the powder moving slowly. This slow-moving powder effectively navigates the patient s airways for delivery into the lung with minimal deposition at the back of the throat. Our inhalers show very little change in performance over a wide range of inhalation efforts and produce high bioavailability. In a handling study, pediatric subjects as young as four years old were readily able to effectively use the inhaler.

To aid in the development of our oral inhalation products, we have created a number of innovative development tools and techniques. For example, our BluHale technology is a novel inhalation profiling tool that uses miniature sensors to assess the drug delivery process at the level of an individual inhaler. This tool provides real-time insight into patient usage, device system performance and pharmacokinetic effects. We can combine this tool with other development tools, such as patient inhalation simulators and anatomically correct airway models, in order to integrate inhaler performance with formulation development right from the beginning of the development program. The result is a powder/inhaler combination product customized to the target patient population from the first clinical study.

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

Our Strategy

The following are the key elements of our strategy:

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

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

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

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

Intellectual Property

Our success will depend in large measure on our ability to continue enforcing our intellectual property rights, effectively maintain our trade secrets and avoid infringing the proprietary rights of third parties. Our policy is to file patent applications on what we deem to be important technological developments that might relate to our product candidates or methods of using our product candidates and to seek intellectual property protection in the United States, Europe, Japan and selected other jurisdictions for all significant inventions. We have obtained, are seeking, and will continue to seek patent protection on the compositions of matter, methods and devices flowing from our research and development efforts.

Our Technosphere drug delivery platform, including Afrezza, enjoys patent protection relating to the particles, their manufacture, and their use for pulmonary delivery of drugs. We have additional patent coverage relating to dry powder formulations and the treatment of diabetes using Afrezza. We have been granted patent coverage for the commercial version of our inhaler and cartridges. We have additional pending patent applications, and expect to file further applications, relating to the drug delivery platform, methods of manufacture, the Afrezza product and its use, and other Technosphere-based products, inhalers and inhaler cartridges. Overall, Afrezza is protected by over 425 issued patents in the United States and selected jurisdictions around the world and we also have over 250 applications pending that may provide additional protection if and when they are allowed. These include composition and inhaler and cartridge patents providing protection for Afrezza with various expiration dates, the longer-lived of which will not expire until 2032. In addition, we have certain method of treatment claims that have terms extending into 2031.

The field of pulmonary drug delivery is crowded and a substantial number of patents have been issued in these fields. In addition, because patent positions can be highly uncertain and frequently involve complex legal and factual questions, the breadth of claims obtained in any application or the enforceability of issued patents cannot be confidently predicted. Further, there can be substantial delays in commercializing pharmaceutical products, which can partially consume the statutory period of exclusivity through patents.

In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued, either in the United States or abroad. Statutory differences in patentable subject matter may limit the protection we can obtain on some of our inventions outside of the United States. For example, methods of treating humans are not patentable in many countries outside of the United States. These and other issues may limit the patent protection we are able to secure internationally. Consequently, we do not know whether any of our pending or future patent applications will result in the issuance of patents or, to the extent patents have been issued or will be issued, whether these patents will be subjected to further proceedings limiting their scope, will provide significant proprietary protection or competitive advantage, or will be circumvented or invalidated. Furthermore, patents already issued to us or our pending applications may become subject to disputes that could be resolved against us. In addition, in certain

countries, including the United States, applications are generally published 18 months after the application s priority date. In any event, because publication of discoveries in scientific or patent literature often trails behind actual discoveries, we cannot be certain that we were the first

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inventor of the subject matter covered by our pending patent applications or that we were the first to file patent applications on such inventions.

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

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

Competition

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

Diabetes Treatments

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

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

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

Rapid-acting (Injected) Insulin

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

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

Inhaled Insulin Delivery Systems

In January 2006, Exubera®, developed by Pfizer in collaboration with Nektar Therapeutics, Inc., was approved for the treatment of adults with type 1 and type 2 diabetes. Exubera® was slow to gain market acceptance and, in October 2007, Pfizer announced that it was discontinuing the product. Pfizer subsequently withdrew the NDA for Exubera from the FDA.

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

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

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

Non-insulin Medications

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

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

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

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

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

Alpha-glucosidase inhibitors, which lower the amount of glucose absorbed from the intestines, thereby reducing the rise in blood glucose that occurs after a meal.

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

Government Regulation and Product Approval

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

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

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

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

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

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

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

In Phase 1, the drug is initially introduced into a small number of individuals and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. Phase 1 clinical trials are often conducted in healthy human volunteers and such cases do not provide evidence of efficacy. In the case of severe or life-threatening diseases, the initial human testing is often conducted in patients rather than healthy volunteers. Because these patients already have the target disease, these studies may provide initial evidence of efficacy that would traditionally be obtained in Phase 2 clinical trials. Consequently, these types of trials are frequently referred to as Phase 1/2 clinical

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

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

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

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

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

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

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

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

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

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jurisdictions may not agree that our product candidates have been shown to be safe and effective. We cannot be certain that any approval of our investigational products will be granted on a timely basis, if at all. For an approved product such as Afrezza, we are subject to continuing regulation by the FDA, including post marketing study commitments or requirements, risk evaluation and mitigation strategies, record-keeping requirements, reporting of adverse experiences with the product, submitting other periodic reports, drug sampling and distribution requirements, notifying the FDA and gaining its approval of certain manufacturing or labeling changes, and complying with certain electronic records and signature requirements. Prior to and following approval, if granted, all manufacturing sites are subject to inspection by the FDA and other national regulatory bodies and must comply with cGMP, QSR and other requirements enforced by the FDA and other national regulatory bodies through their facilities inspection program. Foreign manufacturing establishments must comply with similar regulations. In addition, our drug-manufacturing facilities located in Danbury and the facilities of our insulin supplier, the supplier(s) of FDKP and the supplier(s) of our inhaler and cartridges are subject to federal registration and listing requirements and, if applicable, to state licensing requirements. Failure, including those of our suppliers, to obtain and maintain applicable federal registrations or state licenses, or to meet the inspection criteria of the FDA or the other national regulatory bodies, would disrupt our manufacturing processes and would harm our business. In complying with standards set forth in these regulations, manufacturers must continue to expend time, money and effort in the area of production and quality control to ensure full compliance. Numerous device regulatory requirements apply to the device part of a drug-device combination. These include:

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

Further, the supplier we contract with to manufacture our inhaler and cartridges is subject to QSRs, which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process of medical devices, among other requirements.

Failure to adhere to regulatory requirements at any stage of development, including the preclinical and clinical testing process, the review process, or at any time afterward, including after approval, may result in various adverse consequences. These consequences include action by the FDA or another national regulatory body that has the effect of delaying approval or refusing to approve a product; suspending or withdrawing an approved product from the market; seizing or recalling a product; or imposing criminal penalties against the manufacturer. In addition, later

discovery of previously unknown problems may result in restrictions on a product, its manufacturer, or the NDA holder, or market restrictions through labeling changes or product withdrawal. Also, new government requirements may be established or current government requirements may be changed at any time, which could delay or prevent regulatory approval of our products under development. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

In addition, the FDA imposes a number of complex regulations on entities that advertise and promote drugs, which include, among other requirements, standards for and regulations of direct-to-consumer advertising, off-label promotion, industry sponsored scientific and educational activities, and promotional activities involving the Internet. The FDA has very broad enforcement authority under the FDCA, and failure to comply with these

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regulations can result in penalties, including the issuance of a warning letter requirements for corrective advertising to healthcare providers, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and state and federal civil and criminal investigations and prosecutions.

Products manufactured in the United States and marketed outside the United States are subject to certain FDA regulations, as well as regulation by the country in which the products are to be sold. We also would be subject to foreign regulatory requirements governing clinical trials and drug product sales if products are studied or marketed abroad. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries usually must be obtained prior to the marketing of the product in those countries. The approval process varies from jurisdiction to jurisdiction and the time required may be longer or shorter than that required for FDA approval.

There can be no assurance that the current regulatory framework will not change or that additional regulation will not arise at any stage of our product development or marketing that may affect approval, delay the submission or review of an application or require additional expenditures by us. There can be no assurance that we will be able to obtain necessary regulatory clearances or approvals on a timely basis, if at all, for any of our product candidates under development, and delays in receipt or failure to receive such clearances or approvals, the loss of previously received clearances or approvals, or failure to comply with existing or future regulatory requirements could have a material adverse effect on our business and results of operations.

In addition to the foregoing, we are subject to numerous federal, state and local laws relating to such matters as laboratory practices, the experimental use of animals, the use and disposal of hazardous or potentially hazardous substances, controlled drug substances, privacy of individually identifiable healthcare information, safe working conditions, manufacturing practices, environmental protection and fire hazard control.

Healthcare Regulatory and Pharmaceutical Pricing

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

The United States and some foreign jurisdictions have enacted or are considering a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the U.S. and elsewhere, there is significant interest

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

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

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In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology and Clinical Health Act (HITECH), and their respective implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA s privacy and security standards directly applicable to business associates independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Also, many states have similar healthcare statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, that apply regardless of the payer. Additional state laws require pharmaceutical companies to implement a comprehensive compliance program and/or limit expenditure for, or payments to, individual medical or health professionals.

We may incur significant costs to comply with these laws and regulations now or in the future. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, individual imprisonment, disgorgement, exclusion of products from reimbursement under government programs, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Research and Development Expenses

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

Long-Lived Assets

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

Employees

As of December 31, 2016, we had 153 full-time employees, of which 66 were engaged in manufacturing, 34 in research and development, 30 in general and administrative and 23 in selling and marketing. Fifteen of these employees had a Ph.D. degree and/or M.D. degree and were engaged in activities relating to research and development, manufacturing, quality assurance or business development.

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

Corporate Information

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

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

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

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

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

Scientific Advisors

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

- our research and development programs;
- the design and implementation of our clinical programs;
- our patent and publication strategies;
- market opportunities from a clinical perspective;

new technologies relevant to our research and development programs; and

specific scientific and technical issues relevant to our business.

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Executive Officers of the Registrant

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

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

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

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

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

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

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

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

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

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

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

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

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

RISKS RELATED TO OUR BUSINESS

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

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

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

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

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

the emergence of competing technologies and products and other market developments;

the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights or defending against claims of infringement by others;

the level of our legal and litigation expenses; and

the costs of discontinuing projects and technologies, and/or decommissioning existing facilities, if we undertake any such activities.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders equity. As of December 31, 2016, we had stockholders deficit of $183.6 million. Our ability to achieve and sustain positive cash flow from operations and profitability depends heavily upon successfully commercializing Afrezza, and we cannot be sure when, if ever, we will generate positive cash flow from operations or become profitable.

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

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

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

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

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

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

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

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

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

There can be no assurance that we will be able to comply with the covenants under any of the foregoing agreements, and we cannot predict whether the holders of the 2019 notes or Tranche B notes would demand repayment of the outstanding balance of the 2019 notes or the Tranche B notes as applicable or exercise any other remedies available to such holders if we were unable to comply with these covenants. The covenants and restrictions contained in the foregoing agreements could significantly limit our ability to respond to changes in our business or competitive activities or take advantage of business opportunities that may create value for our stockholders and the holders of our other securities. In addition, our inability to meet or otherwise comply with the covenants under these agreements could have an adverse impact on our financial position and results of operations and could result in an event of default under the terms of our other indebtedness, including our indebtedness under the 2018 notes. In the event of certain

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

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

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

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

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

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

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

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

The rapid rate of scientific discoveries and technological changes could result in Afrezza or one or more of our product candidates becoming obsolete or noncompetitive. Our competitors may develop or introduce new products that render our technology or Afrezza less competitive, uneconomical or obsolete. For example, in January 2017, Novo Nordisk announced that Fiasp®, a faster formulation of insulin aspart, was approved in Europe and Canada. It is currently undergoing regulatory review in the United States. Our future success will depend not only on our ability to develop our product candidates but to improve them and keep pace with emerging industry developments. We cannot assure you that we will be able to do so.

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

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

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

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

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

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

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

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

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manufacturers may not meet relevant regulatory requirements, and if we are unable to obtain any of these materials in sufficient amounts, in a timely manner and at reasonable prices, or if we encounter delays or difficulties in our relationships with manufacturers or suppliers, the production of Afrezza may be delayed. Likewise, if Amphastar ceases to manufacture or is otherwise unable to deliver insulin for Afrezza, we will need to locate an alternative source of supply and the production of Afrezza may be delayed. If any of our suppliers is unwilling or unable to meet its supply obligations and we are unable to secure an alternative supply source in a timely manner and on favorable terms, our business, financial condition, and results of operations may be harmed and the market price of our common stock and other securities may decline.

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

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

Any of these factors could cause us to delay or suspend production, could entail higher costs and may result in our being unable to obtain sufficient quantities for the commercialization of Afrezza at the costs that we currently anticipate. Furthermore, if we or a third-party manufacturer fail to deliver the required commercial quantities of the product or any raw material on a timely basis, and at commercially reasonable prices, sustainable compliance and acceptable quality, and we were unable to promptly find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volume and quality on a timely basis, we would likely be unable to meet demand for Afrezza and we would lose potential revenues.

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

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

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

- approved labeling claims;

effectiveness of efforts by us or any future marketing partner to educate physicians about the benefits and advantages of Afrezza or our other products and to provide adequate support for them, and the perceived advantages and disadvantages of competitive products;

willingness of the healthcare community and patients to adopt new technologies;

ability to manufacture the product in sufficient quantities with acceptable quality and cost;

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perception of patients and the healthcare community, including third-party payors, regarding the safety, efficacy and benefits compared to competing products or therapies;

convenience and ease of administration relative to existing treatment methods;

coverage and pricing and reimbursement relative to other treatment therapeutics and methods; and

marketing and distribution support.

Because of these and other factors, Afrezza and any other product that we develop may not gain market acceptance, which would materially harm our business, financial condition and results of operations.

If third-party payors do not cover Afrezza or any of our product candidates for which we receive regulatory approval, Afrezza or such product candidates might not be prescribed, used or purchased, which would adversely affect our revenues.

Our future revenues and ability to generate positive cash flow from operations may be affected by the continuing efforts of government and other third-party payors to contain or reduce the costs of healthcare through various means. For example, in certain foreign markets the pricing of prescription pharmaceuticals is subject to governmental control. In the United States, there has been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental controls. We cannot be certain what legislative proposals will be adopted or what actions federal, state or private payors for healthcare goods and services may take in response to any drug pricing and reimbursement reform proposals or legislation. Such reforms may limit our ability to generate revenues from sales of Afrezza or other products that we may develop in the future and achieve profitability. Further, to the extent that such reforms have a material adverse effect on the business, financial condition and profitability of any future marketing partner for Afrezza, and companies that are prospective collaborators for our product candidates, our ability to commercialize Afrezza and our product candidates under development may be adversely affected.

In the United States and elsewhere, sales of prescription pharmaceuticals still depend in large part on the availability of coverage and adequate reimbursement to the consumer from third-party payors, such as governmental and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. The market for Afrezza and our product candidates for which we may receive regulatory approval will depend significantly on access to third-party payors drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. In addition, because each third-party payor individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time-consuming and costly process. We may be required to provide scientific and clinical support for the use of any product to each third-party payor separately with no assurance that approval would be obtained. This process could delay the market acceptance of any product and could have a negative effect on our future revenues and operating results. Even if we succeed in bringing more products to market, we cannot be certain that any such products would be considered cost-effective or that coverage and adequate reimbursement to the consumer would be available. Patients will be unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

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

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medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. We may face competition for Afrezza or any of our other product candidates that receives marketing approval from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, there may be importation of foreign products that compete with our own products, which could negatively impact our profitability.

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

Healthcare legislation may make it more difficult to receive revenues.

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

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

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

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

- a licensure framework for follow-on biological products;

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

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

Part D;

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

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

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

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

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investment interests held by physicians and their immediate family members and applicable group purchasing organizations during the preceding calendar year;

a new requirement to annually report drug samples that certain manufacturers and authorized distributors provide to physicians; and

a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

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

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

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

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

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

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

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

the federal Anti-Kickback Statute (as amended by PPACA, which modified the intent requirement of the federal Anti-Kickback Statute so that a person or entity no longer needs to have actual knowledge of the Statute or specific intent to violate it to have committed a violation), which constrains our business activities, including our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities by prohibiting, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

federal civil and criminal false claims laws, including without limitation the civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other federal healthcare programs that are false or fraudulent, and knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government, and under PPACA, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal false claims laws;

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

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

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

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

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

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information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; state laws that require pharmaceutical companies to comply with the industry s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government that otherwise restricts certain payments that may be made to healthcare providers and entities; and state laws that require drug manufacturers to report information related to payments and other transfer of value to physicians and other healthcare providers and entities.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exceptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. To the extent that Afrezza or any of our product candidates that receives marketing approval is ultimately sold in a foreign country, we may be subject to similar foreign laws and regulations. If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, individual imprisonment, disgorgement, exclusion of products from reimbursement under U.S. federal or state healthcare programs, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could materially adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management s attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the United States, we could be subject to additional reimbursement requirements, fines, sanctions and exposure under other laws which could have a material adverse effect on our business, results of operations and financial condition.

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

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

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

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

The testing, manufacturing, marketing and sale of Afrezza and any clinical testing of our product candidates expose us to potential product liability claims. A product liability claim may result in substantial judgments as well as consume significant financial and management resources and result in adverse publicity, decreased demand for a product, injury to our reputation, withdrawal of clinical studies volunteers and loss of revenues. We currently carry worldwide product liability insurance in the amount of $10.0 million. Our insurance coverage may not be adequate to satisfy any liability that may arise, and because insurance coverage in our industry can be very expensive and difficult to obtain, we cannot assure you that we will seek to obtain, or be able to obtain if desired, sufficient additional coverage. If losses from such claims exceed our liability insurance coverage, we may incur substantial liabilities that we may not have the resources to pay. If we are required to pay a product liability claim our business, financial condition and results of operations would be harmed and the market price of our common stock and other securities may decline.

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

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

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

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

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

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If our internal controls over financial reporting are not considered effective, our business, financial condition and market price of our common stock and other securities could be adversely affected.

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to evaluate the effectiveness of our internal controls over financial reporting as of the end of each fiscal year, and to include a management report assessing the effectiveness of our internal controls over financial reporting in our annual report on Form 10-K for that fiscal year. Section 404 also requires our independent registered public accounting firm to attest to, and report on, our internal controls over financial reporting.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system s objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud involving a company have been, or will be, detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and we cannot assure you that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. A material weakness in our internal controls has been identified in the past, and we cannot assure you that we or our independent registered public accounting firm will not identify a material weakness in our internal controls in the future. A material weakness in our internal controls over financial reporting would require management and our independent registered public accounting firm to evaluate our internal controls as ineffective. If our internal controls over financial reporting are not considered effective, we may experience a loss of public confidence, which could have an adverse effect on our business, financial condition and the market price of our common stock and other securities.

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

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

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

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

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

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

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

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

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

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

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

We are increasingly dependent upon information technology systems, infrastructure and data security. Our business requires manipulating, analyzing and storing large amounts of data. In addition, we rely on an enterprise software system to operate and manage our business. Our business therefore depends on the continuous, effective, reliable and secure operation of our computer hardware, software, networks, Internet servers and related infrastructure. The multitude and complexity of our computer systems and the potential value of our data make them inherently vulnerable to service interruption or destruction, malicious intrusion and random attack. Likewise, data privacy or security breaches by employees or others may pose a risk that sensitive data including intellectual property, trade secrets or personal information belonging to us or our customers or other business partners may be exposed to unauthorized persons or to the public. Our systems are also potentially subject to cyber-attacks, which can be highly sophisticated and may be difficult to detect. Such attacks are often carried out by motivated, well-resourced, skilled and persistent actors including nation states, organized crime groups and hacktivists. Cyber-attacks could include the deployment of harmful malware and key loggers, a denial-of-service attack, a malicious website, the use of social engineering and other means to affect the confidentiality, integrity and availability of our information technology systems, infrastructure and data. Our key business partners face similar risks and any security breach of their systems could adversely affect our security status. While we continue to invest in the protection oicly traded technology company during the first quarter of 2004, and other miscellaneous items.

Provision for income taxes: During the three months ended March 31, 2005, December 31, 2004, and March 31, 2004, we recorded an income tax expense of $6.3 million, $6.0 million and $6.0 million, respectively. The expense primarily relates to foreign income taxes. Excluding certain foreign jurisdictions, the future benefit of temporary differences, including operating losses, is not being recognized.

FINANCIAL CONDITION, CAPITAL RESOURCES AND LIQUIDITY

Cash, cash equivalents and short-term investments increased to $865.9 million at March 31, 2005, from $814.6 million at December 31, 2004. As described below, the increase is mainly due to net cash inflows from operating and financing activities and net cash outflows from investing.

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Working capital. Working capital increased by $32.2 million to $1.0 billion at March 31, 2005, from $969.0 million at December 31, 2004. Working capital for the three months ended March 31, 2005 was impacted by the following activities:

- Cash, cash equivalents and short-term investments increased by $51.3 million.

- Other accrued liabilities decreased by $8.5 million primarily due to a decrease of $7.2 million in restructuring reserves mainly for payments for severance and previously exited leases and a consumption tax payment of approximately $7.8 million; offset in part by a $7.8 million increase in interest payable due to the timing of interest payments on our Convertible Notes.

- Accounts payable decreased by $6.6 million primarily due to the timing of invoice receipt and payments.

The increase in working capital was offset, in part, by the following:

- Inventories decreased by $15.5 million to $203.4 million as of March 31, 2005, from $218.9 million as of December 31, 2004. The decline in inventory levels reflects our continued focus on supply chain management.

- Accounts receivable decreased by $12.6 million. The increase is mainly attributable to greater linearity of our revenues in the first quarter of 2005 when compared to the fourth quarter of 2004.

- Income taxes payable increased by $3.9 million due to the timing of tax payments made and the

income tax provision recorded in the first quarter of 2005.

Accrued salaries, wages and benefits increased by $1.6 million primarily due to the timing differences in payment of salaries and benefits.

Cash and cash equivalents generated from operating activities. During the three months ended March 31, 2005, we generated $59.3 million of net cash and cash equivalents from operating activities compared to $10.1 million generated in the same period of 2004. Cash and cash equivalents generated by operating activities for the three months ended March 31, 2005, were the result of the following:

Income (before depreciation and amortization, non-cash restructuring and other items and amortization of non-cash deferred stock compensation). The non-cash items and other non-operating adjustments are quantified in our Consolidated Statements of Cash Flows included in this Current Report on Form 10-Q; and

A net increase from assets and liabilities including changes in working capital components from December 31, 2004, to March 31, 2005, as discussed above.

Cash and cash equivalents used in investing activities. Cash and cash equivalents used in investing activities were $11.2 million for the three months ended March 31, 2005, compared to $9.6 million in the same period in 2004. The investing activities during the three months ended March 31, 2005 were as follows:

Purchases of debt and equity securities available for sale, net of sales and maturities;

Purchases of property, equipment and software;

Proceeds from the sale of property and equipment; and

Receipt of an income tax refund for pre-acquisition tax matters associated with C-Cube Microsystems Inc. (C-Cube Microsystems was acquired by us in May 2001).

We expect capital expenditures to be approximately $60 million in 2005. In recent years we have reduced our level of capital expenditures as a result of our focus on establishing strategic supplier alliances with foundry semiconductor manufacturers, which enables us to have access to advanced manufacturing capacity, and reduces our capital spending requirements.

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Cash and cash equivalents provided by financing activities. Cash and cash equivalents provided by financing activities during the three months ended March 31, 2005, were $1.3 million as compared to $2.4 million in the same period in 2004. The primary financing activity during the three months ended March 31, 2005, was the issuance of common stock under our employee stock option and purchase plans.

We may seek additional equity or debt financing from time to time. We believe that our existing liquid resources and funds generated from operations, combined with funds from such financing and our ability to borrow funds, will be adequate to meet our operating and capital requirements and obligations for the foreseeable future. However, we cannot be certain that additional financing will be available on favorable terms. Moreover, any future equity or convertible debt financing will decrease the percentage of equity ownership of existing stockholders and may result in dilution, depending on the price at which the equity is sold or the debt is converted.

Contractual Obligations

The following table summarizes our contractual obligations at March 31, 2005, and the effect these obligations are expected to have on our liquidity and cash flow in future periods.

	Payments due by period				
Contractual Obligations	**Less than 1 year**	**1 3 years**	**4 5 years**	**After 5 years**	**Total**
			(in millions)		
Convertible Subordinated Notes	$	$ 421.5	$	$ 350.0	$ 771.5
Operating lease obligations	65.6	66.1	38.6	30.7	201.0
Purchase commitments	291.8	7.0	2.3		301.1
Total	$ 357.4	$ 494.6	$ 40.9	$ 380.7	$ 1,273.6

Convertible Subordinated Notes

As of March 31, 2005, we have $422 million of Convertible Subordinated Notes due in November 2006 (2001 Convertible Notes) and $350 million of Convertible Subordinated Notes due in May 2010 (2003 Convertible Notes). All of the Convertible Notes are subordinated to all existing and future senior debt and are convertible at the holder s option, at any time prior to the maturity date of the Convertible Notes, into shares of our common stock. The 2001 and 2003 Convertible Notes have conversion prices of approximately $26.34 per share and $13.42 per share, respectively. The 2001 Convertible Notes are redeemable at our option, in whole or in part, on at least 30 days notice at any time on or after the call date, which is two years before the due date. We cannot elect to redeem the 2003 Convertible Notes prior to maturity. Each holder of the 2001 and 2003 Convertible Notes has the right to cause us to repurchase all of such holder s convertible notes at 100% of their principal amount plus accrued interest upon the occurrence of any fundamental change to us, which includes a transaction or event such as an exchange offer, liquidation, tender offer, consolidation, merger or combination. Interest is payable semiannually.

Fluctuations in our stock price impact the prices of our outstanding convertible securities and the likelihood of the convertible securities being converted into cash or equity. If we are required to redeem any of the Convertible Notes for cash, it may affect our liquidity position. In the event they do not convert to equity, we believe that our current cash position and expected future operating cash flows will be adequate to meet these obligations as they mature.

From time to time, we redeem or repurchase Convertible Notes.

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Operating Lease Obligations

We lease real estate, certain non-manufacturing equipment and software under non-cancelable operating leases.

Purchase Commitments

We maintain certain purchase commitments, primarily for raw materials, with suppliers and for some non-production items. Purchase commitments for inventory materials are generally restricted to a forecasted time-horizon as mutually agreed upon between the parties. This forecast time-horizon can vary among different suppliers.

Critical Accounting Policies

The discussion and analysis of our financial condition and results of operations are based on the consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires estimates and assumptions that affect the reported amounts and disclosures. For a detailed discussion of our critical accounting policies, please see the Critical Accounting Policies contained in Part II, Item 7 of the Management s Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2004.

We monitor the recoverability of goodwill recorded in connection with acquisitions annually, or sooner if events or changes in circumstances indicate that the carrying amount may not be recoverable. Impairment, if any, would be determined in accordance with SFAS No. 142, which uses a fair value model for determining the carrying value of goodwill. We plan to perform our next annual impairment review in the fourth quarter of 2005.

Recent Accounting Pronouncements

The information contained in Item 1 in Note 1 of the Notes under the heading Recent Accounting Pronouncements is hereby incorporated by reference into this Item 2.

FACTORS THAT MAY AFFECT FUTURE OPERATING RESULTS

Keep these risk factors in mind when you read forward-looking statements elsewhere in this Form 10-Q and in the documents incorporated herein by reference. These are statements that relate to our expectations for future events and time periods. Generally, the words, anticipate, expect, intend and similar expressions identify forward-looking statements. Forward-looking statements involve risks and uncertainties, and actual results could differ materially from those anticipated in the forward-looking statements.

We believe that our future operating results will continue to be subject to quarterly variations based upon a wide variety of factors. Our actual results in future periods may be significantly different from any future performance suggested in this report. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. While management believes that the discussion and analysis in this report is adequate for a fair presentation of the information, we recommend that you read this discussion and analysis in conjunction with the Annual Report on Form 10-K. Risks and uncertainties that may affect our results include, among others:

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A general economic weakness may reduce our revenues. The semiconductor industry is cyclical in nature and is characterized by wide fluctuations in product supply and demand. In addition, our results of operations are dependent on the global economy. Any geopolitical factors such as terrorist activities, armed conflict or global health conditions, which adversely affects the global economy, may adversely impact our operating results and financial condition. In addition, goodwill and other long-lived assets could be impacted by a further decline in revenues because impairment is measured based upon estimates of future cash flows. These estimates include assumptions about future conditions within our company and industry.

We operate in highly competitive markets. The Semiconductor and Storage Systems segments in which we conduct business are characterized by rapid technological change, short product cycles and evolving industry standards. We believe our future success depends, in part, on our ability to improve on existing technologies and to develop and implement new ones in order to continue to reduce semiconductor chip size and improve product performance and manufacturing yields. We must also be able to adopt and implement emerging industry standards in a timely manner and to adapt products and processes to technological changes. If we are not able to implement new process technologies successfully or to achieve volume production of new products at acceptable yields, our operating results and financial condition may be adversely impacted.

Our competitors include many large domestic and foreign companies that have substantially greater financial, technical and management resources than we do. Several major diversified electronics companies offer ASIC products and/or other standard products that are competitive with our product lines. Other competitors are specialized, rapidly growing companies that sell products into the same markets that we target. Some of our large customers may develop internal design and production capabilities to manufacture their own products, thereby displacing our products. There is no assurance that the price and performance of our products will be superior relative to the products of our competitors. As a result, we may experience a loss of competitive position that could result in lower prices, fewer customer orders, reduced revenues, reduced gross profit margins and loss of market share.

We are dependent on a limited number of customers. Our concentrated customer base accounts for a substantial portion of our revenues. For the three months ended March 31, 2005, IBM and Seagate represented 13% and 11% of our total consolidated revenues, respectively.

Our operating results and financial condition could be significantly affected if:

- we do not win new product designs from major existing customers;
- major customers reduce or cancel their existing business with us;
- major customers make significant changes in scheduled deliveries; or
- there are declines in the prices of products that we sell to these customers.

Our new products may not achieve market acceptance. We introduce many new products each year. We must continue to develop and introduce new products that compete effectively on the basis of price and performance and that satisfy customer requirements. We continue to emphasize engineering development and acquisition of CoreWare building blocks and integration of our CoreWare libraries into our design capabilities. Our cores and standard products are intended to be based upon industry standard functions, interfaces, and protocols so that they are useful in a wide variety of systems applications. Development of new products and cores often requires long-term forecasting of market trends, development and implementation of new or changing technologies and a substantial capital commitment. We cannot provide assurance that the cores or standard products that we select for investment of our financial and engineering resources will be developed or acquired in a timely manner or will enjoy market acceptance.

The manufacturing facilities we operate are highly complex and require high fixed costs. Our wafer fabrication site is located in Gresham, Oregon. In addition, we own our Storage Systems segment manufacturing facility in Wichita, Kansas. The manufacture and introduction of our products is a

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complicated process. We continually strive to implement the latest process technologies and manufacture products in a clean and tightly controlled environment. We confront challenges in the manufacturing process that require us to:

maintain a competitive manufacturing cost structure;

implement the latest process technologies required to manufacture new products;

exercise stringent quality control measures to ensure high yields;

effectively manage the subcontractors engaged in the wafer fabrication, test and assembly of products; and

update equipment and facilities as required for leading edge production capabilities.

We outsource a substantial portion of wafers manufactured. We have consolidated our internal semiconductor manufacturing in Gresham, Oregon. We have developed outsourcing arrangements for the manufacture of some of our products based on process technology that is unique to the supplier. There is no assurance that the third party manufacturer will be able to produce and deliver wafers that meet our specifications or that our supplier will be able to successfully provide the process technology. If the third party is not able to deliver products and process technology on a timely and reliable basis, our results of operations could be adversely affected.

We have significant capital requirements to maintain and grow our business. We continue to make significant investments in our facilities and capital equipment, and, as a result, our fixed costs for manufacturing remain high. We also seek to obtain access to advanced manufacturing capacities through strategic supplier alliances with wafer foundries. In general, we seek to optimally allocate the manufacture of our products between our facilities and those of our foundry suppliers. Nonetheless, a high level of capital expenditures in our facilities results in relatively high fixed costs. If demand for our products does not absorb the available capacity, the fixed costs and operating expenses related to our production capacity could have a material adverse impact on our operating results and financial condition.

We finance our capital expenditure needs from operating cash flows, bank financing and capital market financing. As of March 31, 2005, we had convertible notes outstanding of approximately $772 million. We may need to seek additional equity or debt financing from time to time and cannot be certain that additional financing will be available on favorable terms. Moreover, any future equity or equity-linked financing may dilute the equity ownership of existing stockholders.

We are exposed to fluctuations in foreign currency exchange rates. We have some exposure to fluctuations in foreign currency exchange rates. We have international subsidiaries and distributors that operate and sell our products globally. We routinely hedge these exposures in an effort to minimize the impact of currency fluctuations. However, we may still be adversely affected by changes in foreign currency exchange rates or declining economic conditions in these countries.

We procure parts and raw materials from limited domestic and foreign sources. We do not maintain an extensive inventory of parts and materials for manufacturing. We purchase a portion of our requirements for parts and raw materials from a limited number of sources, primarily from suppliers in Japan and their U.S. subsidiaries, and we obtain other material inputs on a local basis. There is no assurance that, if we have difficulty in obtaining parts or materials in the future, alternative suppliers will be available, or that these suppliers will provide parts and materials in a timely manner or on favorable terms. As a result, we may be adversely affected by delays in product shipments. If we cannot obtain adequate materials for manufacture of our products or if such materials are not available at reasonable prices, there could be a material adverse impact on our operating results and financial condition.

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We utilize indirect channels of distribution over which we have limited control. Our financial results could be adversely affected if our relationship with resellers or distributors were to deteriorate or if the financial condition of these resellers or distributors were to decline. In addition, as our business grows, we may have an increased reliance on indirect channels of distribution. There can be no assurance that we will be successful in maintaining or expanding these indirect channels of distribution. This could result in the loss of certain sales opportunities. Furthermore, the partial reliance on indirect channels of distribution may reduce our visibility with respect to future business, thereby making it more difficult to accurately forecast orders.

Our operations are affected by cyclical fluctuations. The Semiconductor and Storage Systems segments in which we compete are subject to cyclical fluctuations in demand. The Semiconductor industry has in the past experienced periods of rapid expansion of production capacity followed by periods of significant downturn. Even when the demand for our products remains constant, the availability of additional excess production capacity in the industry creates competitive pressure that can degrade pricing levels, which can reduce revenues. Furthermore, customers who benefit from shorter lead times may defer some purchases to future periods, which could adversely affect revenues in the short term. As a result, we may experience downturns or fluctuations in demand for our products and experience adverse effects on our operating results and financial condition.

We engage in acquisitions and alliances giving rise to economic and technological risks. We are continually exploring strategic acquisitions that build upon our existing library of intellectual property, human capital and engineering talent, and increase our leadership position in the markets where we operate. We did not complete any material acquisitions or alliances in the first quarter of 2005. We completed two acquisitions in 2004. Mergers and acquisitions of high-technology companies bear inherent risks. No assurance can be given that our previous or future acquisitions will be successful and will not materially adversely affect our business, operating results or financial condition. We must manage any growth effectively. Failure to manage growth effectively and to integrate acquisitions could adversely affect our operating results and financial condition.

In addition, we intend to continue to make investments in companies, products and technologies through strategic alliances. Investment activities often involve risks, including the need to acquire timely access to needed capital for investments related to alliances and to invest in companies and technologies that contribute to the growth of our business.

The price of our securities may be subject to wide fluctuations. Our stock has experienced substantial price volatility, particularly as a result of quarterly variations in results, the published expectations of analysts and announcements by our competitors and us. In addition, the stock market has experienced price and volume fluctuations that have affected the market price of many technology companies and that have often been unrelated to the operating performance of such companies. The price of our securities may also be affected by general global, economic and market conditions. While we cannot predict the individual effect that these and other factors may have on the price of our securities, these factors, either individually or in the aggregate, could result in significant variations in price during any given period of time. These fluctuations in our stock price also impact the price of our outstanding convertible securities and the likelihood of the convertible securities being converted into cash or equity. If our stock price is below the conversion price of our convertible bonds on the date of maturity, they may not convert into equity and we may be required to redeem the convertible securities for cash. However, in the event they do not convert to equity, we believe that our current cash position and expected future operating cash flows will be adequate to meet these obligations as they mature.

We may rely on capital and bank markets to provide liquidity. In order to finance strategic acquisitions, capital assets needed in our manufacturing facilities and other general corporate needs, we may rely on capital and bank markets to provide liquidity. Historically, we have been able to access capital and bank markets, but this does not necessarily guarantee that we will be able to access these markets in the future or at terms that are acceptable to us.

The availability of capital in these markets is affected by several factors, including geopolitical risk, the interest rate environment and the condition of the economy as a whole. In addition, our own operating performance, capital structure and expected future performance impact our ability to raise capital. We believe that our current cash, cash equivalents, short-term investments and future cash provided by operations will be sufficient to fund our needs in the foreseeable future. This includes repaying our existing convertible debt when due. However, if our operating performance falls below expectations, we may need additional funds.

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We design and develop highly complex cell-based ASICs. As technology advances to 0.13 micron and smaller geometries, there are increases in the complexity, time and expense associated with the design, development and manufacture of ASICs. We must incur substantial research and development costs to confirm the technical feasibility and commercial viability of any ASIC products that in the end may not be successful. Therefore, we cannot guarantee that any new ASIC products will result in market acceptance.

Our global operations expose us to numerous international business risks. We have substantial business activities in Asia and Europe. Both manufacturing and sales of our products may be adversely impacted by changes in political and economic conditions abroad. A change in the current tax laws, tariff structures, export laws, regulatory requirements or trade policies in either the United States or foreign countries could adversely impact our ability to manufacture or sell our products in foreign markets. Moreover, a significant decrease in sales by our customers to end users in either Asia or Europe could result in a decline in orders.

We subcontract wafer manufacturing, test and assembly functions to independent companies located in Asia. A reduction in the number or capacity of qualified subcontractors or a substantial increase in pricing could cause longer lead times, delays in the delivery of products to customers or increased costs.

The high technology industry in which we operate is prone to intellectual property litigation. Our success is dependent in part on our technology and other proprietary rights, and we believe that there is value in the protection afforded by our patents, copyright rights and trademarks. We have a program whereby we actively protect our intellectual property by acquiring patent and other intellectual property rights. However, the industry is characterized by rapidly changing technology and our future success depends primarily on the technical competence and creative skills of our personnel.

As is typical in the high technology industry, from time to time we have received communications from other parties asserting that certain of our products, processes, technologies or information infringe upon their patent rights, copyrights, trademark rights or other intellectual property rights. We regularly evaluate such assertions. In light of industry practice, we believe, with respect to existing or future claims that any licenses or other rights that may be necessary may generally be obtained on commercially reasonable terms. Nevertheless, there is no assurance that licenses will be obtainable on acceptable terms or that a claim will not result in litigation or other administrative proceedings. Resolution of whether our product or intellectual property has infringed on valid rights held by others could have a material adverse effect on our financial position or results of operations and may require material changes in production processes and products.

See Legal Matters in Note 11 (Legal Matters) of the Notes regarding current patent litigation.

Our manufacturing facilities are subject to disruption. Operations at any of our primary manufacturing facilities may be disrupted for reasons beyond our control, including work stoppages, fire, earthquake, tornado, floods or other natural disasters, which could have a material adverse effect on our financial position or results of operation.

We depend on independent foundry subcontractors to manufacture a portion of our current products, and any failure to secure and maintain sufficient foundry capacity could materially and adversely affect our business. Outside foundry subcontractors, located in Asia, manufacture a portion of our semiconductor devices in current production. Availability of foundry capacity has in the recent past been reduced due to strong demand. In addition, a recurrence of SARS or the occurrence of another public health emergency in Asia could further affect the production capabilities of our manufacturers by resulting in quarantines or closures. If we are unable to secure sufficient capacity at our existing foundries, or in the

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event of a quarantine or closure at any of these foundries, our revenues, cost of revenues and results of operations would be negatively impacted. If any of our foundries experiences a shortage in capacity, or suffers any damage to its facilities due to earthquakes or other natural disasters, experiences power outages, encounters financial difficulties or any other disruption of foundry capacity, we may need to qualify an alternative foundry in a timely manner. Even our current foundries need to have new manufacturing processes qualified if there is a disruption in an existing process. We typically require several months to qualify a new foundry or process before we can begin shipping products from it. If we cannot accomplish this qualification in a timely manner, we may experience a significant interruption in supply of the affected products.

Because we rely on outside foundries with limited capacity, we face several significant risks, including:

a lack of guaranteed wafer supply and potential wafer shortages and higher wafer prices;

limited control over delivery schedules, quality assurance, manufacturing yields and production costs; and

the unavailability of, or potential delays in obtaining access to, key process technologies.

In addition, the manufacture of integrated circuits is a highly complex and technologically demanding process. Although we work closely with our foundries to minimize the likelihood of reduced manufacturing yields, our foundries have from time to time experienced lower than anticipated manufacturing yields. This often occurs during the production of new products or the installation and start-up of new process technologies. Poor yields from our foundries could result in product shortages or delays in product shipments, which could seriously harm our relationships with our customers and materially and adversely affect our results of operations.

The ability of each foundry to provide us with semiconductor devices is limited by its available capacity and existing obligations. Although we have entered into contractual commitments to supply specified levels of products to some of our customers, we do not have a long-term volume purchase agreement or a significant guaranteed level of production capacity with any of our foundries. Foundry capacity may not be available when we need it or at reasonable prices. Availability of foundry capacity has in the recent past been reduced from time to time due to strong demand. We place our orders on the basis of our customers purchase orders or our forecast of customer demand, and the foundries can allocate capacity to the production of other companies products and reduce deliveries to us on short notice. It is possible that foundry customers that are larger and better financed than we are, or that have long-term agreements with our main foundries, may induce our foundries to reallocate capacity to them. This reallocation could impair our ability to secure the supply of components that we need. Although we use a number of independent foundries to manufacture our semiconductor products, most of our components are not manufactured at more than one foundry at any given time, and our products typically are designed to be manufactured in a specific process at only one of these foundries. Accordingly, if one of our foundries is unable to provide us with components as needed, we could experience significant delays in securing sufficient supplies of those components. Also, our third party foundries typically migrate capacity to newer, state-of-the-art manufacturing processes on a regular basis, which may create capacity shortages for our products designed to be manufactured on an older process. We cannot assure you that any of our existing or new foundries will be able to produce integrated circuits with acceptable manufacturing yields, or that our foundries will be able to deliver enough semiconductor devices to us on a timely basis, or at reasonable prices. These and other related factors could impair our ability to meet our customers needs and have a material and adverse effect on our operating results.

Although we may utilize new foundries for other products in the future, in using new foundries we will be subject to all of the risks described in the foregoing paragraphs with respect to our current foundries.

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We depend on third-party subcontractors to assemble, obtain packaging materials for, and test substantially all of our current products. If we lose the services of any of our subcontractors or if these subcontractors are unable to attain sufficient packaging materials, shipments of our products may be disrupted, which could harm our customer relationships and adversely affect our net sales. Third-party subcontractors located in Asia assemble, obtain packaging materials for, and test substantially all of our current products. Because we rely on third-party subcontractors to perform these functions, we cannot directly control our product delivery schedules and quality assurance. This lack of control has in the past resulted, and could in the future result, in product shortages or quality assurance problems that could delay shipments of our products or increase our manufacturing, assembly or testing costs.

If our third-party subcontractors are unable to obtain sufficient packaging materials for our products in a timely manner, we may experience a significant product shortage or delay in product shipments, which could seriously harm our customer relationships and materially and adversely affect our net sales. If any of these subcontractors experiences capacity constraints or financial difficulties, suffers any damage to its facilities, experiences power outages or any other disruption of assembly or testing capacity, we may not be able to obtain alternative assembly and testing services in a timely manner. Due to the amount of time that it usually takes us to qualify assemblers and testers, we could experience significant delays in product shipments if we are required to find alternative assemblers or testers for our components. Any problems that we may encounter with the delivery, quality or cost of our products could damage our customer relationships and materially and adversely affect our results of operations. We are continuing to develop relationships with additional third-party subcontractors to assemble and test our products. However, even if we use these new subcontractors, we will continue to be subject to all of the risks described above.

We are increasingly exposed to various legal, business, political and economic risks associated with our international operations. We currently obtain a substantial portion all of our manufacturing, and all of our assembly and testing services from suppliers located outside the United States. We also frequently ship products to our domestic customers international manufacturing divisions and subcontractors. We also undertake design and development activities in Canada, China, India, Taiwan and the United Kingdom. We intend to continue to expand our international business activities and to open other design and operational centers abroad. The recent war in Iraq and the lingering effects of terrorist attacks in the United States and abroad, the resulting heightened security and the increasing risk of extended international military conflicts may adversely impact our international sales and could make our international operations more expensive. International operations are subject to many other inherent risks, including but not limited to:

- political, social and economic instability;
- exposure to different legal standards, particularly with respect to intellectual property;
- natural disasters and public health emergencies;
- nationalization of business and blocking of cash flows;
- trade and travel restrictions;
- the imposition of governmental controls and restrictions;
- burdens of complying with a variety of foreign laws;
- import and export license requirements and restrictions of the United States and each other country in which we operate;

unexpected changes in regulatory requirements;

foreign technical standards;

changes in tariffs;

difficulties in staffing and managing international operations;

fluctuations in currency exchange rates;

difficulties in collecting receivables from foreign entities or delayed revenue recognition; and

potentially adverse tax consequences.

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Any of the factors described above may have a material adverse effect on our ability to increase or maintain our foreign sales.

Additionally, our operations may be impacted by SARS-related factors, including, but not limited to, disruptions at our third-party manufacturers that are primarily located in Asia, reduced sales in our international retail channels and increased supply chain costs. If SARS recurs or spreads to other areas, or other similar public health emergencies arise, our international sales and operations could be harmed.

We must attract and retain key employees in a highly competitive environment. Our employees are vital to our success and our key management, engineering and other employees are difficult to replace. We do not generally have employment contracts with our key employees. Despite the economic slowdown of the last few years, competition for certain key technical and engineering personnel remains intense. Our continued growth and future operating results will depend upon our ability to attract, hire and retain significant numbers of qualified employees.

Engenio Information Technologies, Inc. represents a significant portion of our business, and an initial public offering, sale or spin-off of the Storage Systems segment, may cause our operating results to suffer and may cause net revenues and income to decline. Engenio Information Technologies, Inc. represents a significant portion of our business, and it is currently reported as a separate segment in our consolidated financial statements. For the three months ended March 31, 2005, the Storage Systems segment represented 24% of our revenues. For the fiscal year ended 2004, the Storage Systems segment represented 27% of our revenues.

If we engage in a transaction that results in Engenio no longer being our subsidiary, the Storage Systems segment s financial results, including its net revenues and net income, will no longer be included in our consolidated financial statements. Consequently, our financial results may be harmed as a result of a spin-off or sale of the storage systems business, which may cause our stock price to decline. Accordingly, our historical consolidated financial results may not necessarily reflect our future financial position, results of operations and cash flows after Engenio ceases to be a subsidiary.

The separation and possible initial public offering, sale or spin-off of Engenio Information Technologies, Inc. from us is a substantial undertaking that may disrupt our ongoing business and may increase expenses, which may affect our results of operations or financial condition. The separation of Engenio, and the possible initial public offering of the subsidiary s common stock to the public and the potential spin-off of the subsidiary to our stockholders continues to require the substantial dedication of management resources. Furthermore, we expect to incur significant expenses in future periods related to the separation. We have not yet made any adjustments to our historical financial information to reflect the significant changes that may occur in our cost structure, funding and operations as a result of the separation. In addition, the efforts required to complete the separation of Engenio from us may disrupt our ongoing business activities, may result in employee distraction and may harm Engenio s and our ability to attract, retain and motivate key employees. If any of the foregoing occurs, our results of operations or financial condition may suffer.

Future changes in financial accounting standards or practices or existing taxation rules or practices may cause adverse unexpected fluctuations and affect our reported results of operations. Financial accounting standards in the United States are constantly under review and may be changed from time to time. We would be required to apply these changes when adopted. Once implemented, these changes could result in material fluctuations in our financial results of operations and/or the way in which such results of operations are reported. Similarly, we are subject to taxation in the United States and a number of foreign jurisdictions. Rates of taxation, definitions of income, exclusions from income, and other tax policies are subject to change over time. Changes in tax laws in a jurisdiction in which we have reporting obligations could have a material impact on our results of operations.

We expect that the adoption of Statement of Financial Accounting Standard (SFAS) No. 123 (Revised 2004), entitled Share-Based Payment, effective for the beginning in the first quarter of 2006, will have a significant impact

on our reported results as described under Recent Accounting

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Pronouncements. Because the factors that will affect compensation expense we incur due to the adoption of SFAS No. 123 (Revised 2004) are unknown, the impact on our operating results at the point of adoption, or in the future, cannot be determined. Changes in these or other rules, or modifications to our current practices, may have a significant adverse effect on our reported operating results or in the way in which we conduct our business in the future.

We face uncertainties related to the effectiveness of internal controls. Public companies in the United States are required to review their internal controls over financial reporting under the Sarbanes-Oxley Act of 2002. It should be noted that any system of controls, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the system are met. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of future events. Because of these and other inherent limitations of control systems, there can be no assurance that any design will achieve its stated goal under all potential future conditions, regardless of how remote.

Internal control deficiencies or weaknesses that are not yet identified could emerge. Over time we may identify and correct deficiencies or weaknesses in our internal controls and, where and when appropriate, report on the identification and correction of these deficiencies or weaknesses. However, the internal control procedures can provide only reasonable, and not absolute, assurance that deficiencies or weaknesses are identified. Deficiencies or weaknesses that are not yet identified could emerge and the identification and corrections of these deficiencies or weaknesses could have a material impact on the results of operations for the Company.

Internal control issues that appear minor now may later become reportable conditions. We are required to publicly report on deficiencies or weaknesses in our internal controls that meet a materiality standard as required by law. While the Company meets its statutory obligations, management may, at a point in time, accurately categorize a deficiency or weakness as immaterial or minor and therefore not be required to publicly report such deficiency or weakness. Such determination, however, does not preclude a change in circumstances such that the deficiency or weakness could, at a later time, become a reportable condition that could have a material impact on our results of operations.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

There have been no significant changes in the market risk disclosures during the three months ended March 31, 2005, as compared to the discussion in Part II, Item 7a of our Annual Report on Form 10-K for the year ended December 31, 2004.

Item 4. Controls and Procedures

Our management evaluated, with the participation of our chief executive officer and our chief financial officer, the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 promulgated under the Securities Exchange Act of 1934 as of March 31, 2005. Based on this evaluation, our chief executive officer and our chief financial officer have concluded that our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

There was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal

control over financial reporting. We are aware that any system of control, however well designed and operated, can only provide reasonable, and not absolute, assurance that the objectives of this system are met, and that maintenance of disclosure controls and procedures is an ongoing process that may change over time.

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PART II OTHER INFORMATION

Item 1. Legal Proceedings

This information is included in Note 11 (Legal Matters) of the Notes to the Unaudited Consolidated Condensed Financial Statements, which information is incorporated herein by reference from Item 1 of Part I hereof.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On July 28, 2000, the Company s Board of Directors authorized a new stock repurchase program in which up to 5 million shares of the Company s common stock may be repurchased in the open market from time to time. There is no expiration date for the plan. No shares were repurchased under this plan during the first three months of 2005. There are 3.5 million shares available for repurchase under this plan as of March 31, 2005.

Item 6. Exhibits

31.1 Certification of the Chief Executive Officer pursuant to Securities Exchange Act Rules 13a-15(e) and 15d-1(e), as adopted pursuant to Section 302 of the Sarbarnes-Oxley Act of 2002.

31.2 Certification of the Chief Financial Officer pursuant to Securities Exchange Act Rules 13a-15(e) and 15d-1(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

32.1 Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *

32.2 Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *

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* Furnished not filed.

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SIGNATURES

Pursuant to the requirements 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.

LSI LOGIC CORPORATION
(Registrant)

Date: May 13, 2005

By /s/ Bryon Look

Bryon Look
Executive Vice President &
Chief Financial Officer

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