AMAG PHARMACEUTICALS INC.
Form 10-K
February 24, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10 K

(Mark One)

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

For the Fiscal Year Ended December 31, 2015

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 001 10865

AMAG Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	04 2742593
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
1100 Winter Street Waltham, Massachusetts	02451
(Address of Principal Executive Offices)	(Zip Code)

(617) 498 3300

(Registrant's Telephone Number, Including Area Code)

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

Title of each class	Name of each exchange on which registered
Common Stock, par value $0.01 per share	NASDAQ Global Select Market
Preferred Share Purchase Rights	

Securities registered pursuant to Section 12(g) of the Act: None

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 the 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 definition of "accelerated filer," "large 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

The aggregate market value of the registrant's voting stock held by non affiliates as of June 30, 2015 was approximately $2.125 billion based on the closing price of $69.06 of the Common Stock of the registrant as reported on the NASDAQ Global Select Market on such date. As of February 12, 2016, there were 34,748,689 shares of the registrant's Common Stock, par value $0.01 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement to be filed in connection with the solicitation of proxies for the Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10 K.

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AMAG PHARMACEUTICALS, INC.

FORM 10 K

FOR THE YEAR ENDED DECEMBER 31, 2015

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PART I

Except for the historical information contained herein, the matters discussed in this Annual Report on Form 10 K may be deemed to be forward looking statements that involve risks and uncertainties. We make such forward looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. In this Annual Report on Form 10 K terminology such as “may,” “will,” “could,” “should,” “would,” “expect,” “anticipate,” “continue,” “believe,” “plan,” “estimate,” “intend” or other similar words and expressions (as well as ot words or expressions referencing future events, conditions or circumstances) are intended to identify forward looking statements.

Examples of forward-looking statements contained in this report include, without limitation, statements regarding the following: our plans to continue to expand the impact of our portfolio by delivering on our growth strategy; plans to bring to market medical therapies and other innovations that provide clear benefits and improve patients’ lives; plans to diversify and grow our portfolio, including our intent to continue to expand and diversify our portfolio through the in-license or purchase of additional pharmaceutical products, services or companies; expectations that results from the Velo pivotal Phase 2b/3a study could be available as early as 2018; expectations and plans as to regulatory and commercial developments and activities, including the pursuit of a broader indication for Feraheme, requirements and initiatives for clinical trials and studies, post-approval commitments for our products and the next generation development programs for Makena; expectations regarding our response to the U.S. Food and Drug Administration ("FDA") on the complete response letter for approval of the single-dose preservative-free Makena and our expectations of the timing of the related commercial launch; expectations regarding the regulatory timelines for the Makena auto-injector, including expectations of the related filing date and launch; the growth of our maternal health portfolio; expectations as to what impact recent regulatory developments will have on our business and competition, including recent changes to the Feraheme product information and label; expectations regarding our intellectual property, including patent protection, and the impact generic and other competition could have on our business; our expectations on the timing of initiation for our new Feraheme trial for adults patients with iron deficiency anemia; the market opportunities for each of our products and services; plans regarding our sales and marketing initiatives, including our contracting and discounting strategy and efforts to increase patient compliance and access; our expectation of costs to be incurred in connection with and revenue sources to fund our future operations; our expectations regarding the contribution of revenues from our products or services to the funding of our on-going operations; expectations regarding the manufacture of all drug substance, drug products and key materials at our third-party manufacturers or suppliers; the strategic fit of the CBR Services into our maternal health portfolio; our expectations regarding customer returns and other revenue-related reserves and accruals; estimates regarding our effective tax rate and our ability to realize our net operating loss carryforwards and other tax attributes; the impact of accounting pronouncements; the effect of product price increases; expected increases in research and development expenses and the timing of our planned research and development projects; expectations regarding our financial results, including revenues, cost of product sales and services, selling, general and administrative expenses, restructuring costs, amortization and other income (expense); our investing activities; estimates and beliefs related to our debt, including our 2023 Senior Notes, Convertible Notes and the 2015 Term Loan Facility; the impact of volume-based and other rebates and incentives; the valuation of certain intangible assets, goodwill, contingent consideration, debt and other assets and liabilities, including our methodology and assumptions regarding fair value measurements; our expectations regarding competitive pressures and the impact on growth on our product revenues; our plans regarding manufacturing; the manner in which we intend or are required to settle the conversion of our

Convertible Notes; and our expectations for our cash, revenue, cash equivalents, investments balances, capital needs and information with respect to any other plans and strategies for our business. Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated or indicated in any forward-looking statements.

Any forward looking statement should be considered in light of the factors discussed in Part I, Item 1A below under "Risk Factors" and elsewhere in this Annual Report on Form 10 K. We caution readers not to place undue reliance on any such forward looking statements, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the U.S. Securities and Exchange Commission, to publicly update or revise any such statements to reflect any change in company expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward looking statements.

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ITEM 1. BUSINESS:

Overview

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We use our business and clinical expertise to develop and commercialize products that provide clear benefits and improve people's lives. We have a diverse portfolio of products and services with a focus on maternal health, anemia management and cancer supportive care, including our product Makena® (hydroxyprogesterone caproate injection), services related to the collection, processing and storage of umbilical cord blood stem cell and cord tissue units operated through Cord Blood Registry® ("CBR"), our product Feraheme® (ferumoxytol) for intravenous ("IV") use and MuGard® Mucoadhesive Oral Wound Rinse. We intend to continue to expand the impact of these and future products and services for patients by delivering on our growth strategy, which includes organic growth, as well as the pursuit of products and companies that align with our existing therapeutic areas or those that could benefit from our proven core competencies. Currently, our primary sources of revenue are from sales of Makena, CBR Services and Feraheme.

Our common stock trades on the NASDAQ Global Select Market ("NASDAQ") under the trading symbol "AMAG."

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Products and Services

The following table summarizes the current uses and, subject to regulatory approval, potential uses of the products and services we own or to which we have rights, their current U.S. status and the nature of our rights. Currently, our therapeutic products are marketed and sold solely in the U.S. and the CBR Services are marketed and sold primarily in the U.S.

Product or Service	Uses/Potential Uses	U.S. Regulatory Status	Nature of Rights to Product or Service
Makena® (hydroxyprogesterone caproate injection) (5 mL multidose vial)	A progestin indicated to reduce the risk of preterm birth in women pregnant with a single baby who have a history of singleton spontaneous preterm birth.	Approved and marketed.	Own worldwide rights.
Makena® (hydroxyprogesterone caproate injection) (1 mL single-dose vial)	A progestin indicated to reduce the risk of preterm birth in women pregnant with a single baby who have a history of singleton spontaneous preterm birth.	Prior approval supplement for Hospira, Inc. (“Hospira”) approved February 2016. Prior approval supplement submitted to the FDA in October 2014 for Coldstream Laboratories, Inc. (“Coldstream”). Working with Coldstream to respond to complete response letter.	Own worldwide rights.
Makena® (hydroxyprogesterone caproate injection) (Auto-injector device)	An auto-injector device for subcutaneous administration of Makena.	Supplemental new drug application (“sNDA”) expected to be filed in the first quarter of 2017.	Own worldwide rights to drug product; exclusively license rights to auto-injector device from Antares Pharma, Inc. (“Antares”).

Feraheme® (ferumoxytol)	IV iron replacement therapeutic agent for the treatment of iron deficiency anemia (“IDA”) in adult patients with chronic kidney disease (“CKD”).	Approved and marketed.	Own worldwide rights.
Feraheme® (ferumoxytol)	IV iron replacement therapeutic agent for the treatment of patients with a history of unsatisfactory oral iron therapy or in whom oral iron cannot be used.	sNDA filed December 2012. Phase 3 clinical trial to be initiated in the first quarter of 2016.	Own worldwide rights.
MuGard® Mucoadhesive Oral Wound Rinse	Management of oral mucositis/stomatitis and all types of oral wounds.	Cleared and marketed.	Exclusively license rights to develop and sell MuGard in the U.S. from Abeona Therapeutics, Inc. (“Abeona”).
Digoxin immune fab	A polyclonal antibody for the treatment of severe preeclampsia in pregnant women.	In clinical development.	Own option to obtain exclusive license from Velo Bio LLC (“Velo”) to U.S. rights upon completion of Phase 2b/3a development.
Cord Blood Registry®	Services related to the collection, processing and storage of umbilical cord blood and cord tissue units.	Privately banked umbilical cord blood stem cells and cord tissue are regulated by the FDA in the U.S. (no prior approval needed). Facilities are inspected by the FDA.	Services are marketed and sold primarily in the U.S. and we have certain commercial agreements in Chili, Mexico and the Dominican Republic.

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Makena

Overview

In November 2014, we acquired Lumara Health Inc. ("Lumara Health"), a privately held pharmaceutical company specializing in women's health, at which time Lumara Health became our wholly-owned subsidiary. Under the terms of the acquisition agreement (the "Lumara Agreement"), we acquired 100% of the equity ownership of Lumara Health, excluding the assets and liabilities of the Women's Health Division and certain other assets and liabilities, which were divested by Lumara Health prior to closing, for $600.0 million in cash consideration, subject to net working capital and other adjustments, and issued approximately 3.2 million shares of our common stock, having a value of approximately $112.0 million at the time of closing, to the holders of common stock of Lumara Health. The Lumara Agreement provides for future contingent payments of up to $350.0 million in cash (or upon mutual agreement between us and the former Lumara Health security holders, future contingent payments may also be made in common stock or some combination thereof) payable by us to the former Lumara Health security holders based upon the achievement of certain sales milestones through calendar year 2019. Additional details regarding the Lumara Agreement can be found in Note C, "Business Combinations," to our consolidated financial statements included in this Annual Report on Form 10 K.

By virtue of the acquisition of Lumara Health, we acquired Makena, the only FDA-approved drug indicated to reduce the risk of preterm birth in women pregnant with a single baby who have a history of singleton spontaneous preterm birth. Makena is an intramuscular injection administered weekly by a healthcare professional at a dose of 250 mg (1 mL) with treatment beginning between 16 weeks and 20 weeks and six days of gestation and continuing until 36 weeks and six days of gestation or delivery, whichever happens first. Makena is a progestin whose active ingredient is hydroxyprogesterone caproate ("HPC"), which is a synthetic chemical structurally related to progesterone. Progestins, such as HPC, and progesterone belong to a class of drugs called progestogens. Progestogens have been studied to reduce preterm birth and have shown varying results depending upon the subjects enrolled. The Society for Maternal Fetal Medicine ("SMFM") Publications Committee published clinical guidelines for the use of progestogens to reduce the risk of preterm birth in the American Journal of Obstetrics and Gynecology in May 2012. The SMFM Clinical Guidelines recommend the use of intramuscular HPC injection, such as Makena, to reduce the risk of recurrent preterm birth for clinically indicated patients.

We sell Makena primarily to specialty pharmacies, specialty distributors, home infusion companies and pharmacies which, in turn, sell Makena to healthcare providers, hospitals, government agencies and integrated delivery systems. In 2015, sales of Makena accounted for approximately 60% of our total net revenues Makena was approved by the FDA in February 2011 and was granted orphan drug exclusivity through February 3, 2018. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, defined, in part, as a patient population of fewer than 200,000. The company that first obtains FDA approval for a designated orphan drug for the specified rare disease or condition receives orphan drug marketing exclusivity for that drug for a period of seven years. This orphan drug exclusivity prevents the FDA from approving another application for the same drug for the same orphan indication during the exclusivity period, except in very limited circumstances. A designated orphan drug may not receive orphan drug exclusivity for an approved indication if that indication is for the treatment of a condition broader than that for which it received orphan designation. In addition, orphan drug exclusivity marketing rights may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Finally, the FDA may approve a subsequent drug that is otherwise the same as a currently approved orphan drug for the same orphan indication during the exclusivity period if the sponsor of the subsequent drug can demonstrate that the drug is clinically superior to the already approved drug. According to the

FDA, clinical superiority may be demonstrated by showing that a drug is more effective in a clinical trial, safer in a substantial portion of the target population, or provides a major contribution to patient care relative to the currently approved drug.

Preterm Birth

Preterm birth is defined as a birth prior to 37 weeks of pregnancy. According to the Centers for Disease Control and Prevention, in 2014, preterm births affected nearly 400,000 babies, or one of every ten infants born in the U.S. Although

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the causes of preterm births are not fully understood, certain women are at a greater risk for preterm birth, including those who have had a previous preterm birth, are pregnant with multiples or have certain uterine or cervical problems. High blood pressure, pregnancy complications (such as placental problems) and certain other health or lifestyle factors may also be contributing factors. Makena is indicated only for women with a history of singleton spontaneous preterm birth who are pregnant with a single baby, which accounts for approximately 140,000 pregnancies annually in the U.S.

Preterm birth can increase the risk of infant death and can also result in serious long term health issues for the child, including respiratory problems, gastrointestinal conditions, cerebral palsy, developmental delays, and vision and hearing impairments. According to a 2007 report by the Institute of Medicine (US) Committee on Understanding Premature Birth and Assuring Healthy Outcome, the annual societal economic cost associated with preterm birth is at least $26.2 billion and includes medical and healthcare costs for the baby, labor and delivery costs for the mother, early intervention and special education services, and costs associated with lost work and pay.

Post Approval Commitments for Makena

Makena was approved under the provisions of the FDA's "Subpart H" Accelerated Approval regulations. The Subpart H regulations allow certain drugs, for serious or life threatening conditions, to be approved on the basis of surrogate endpoints or clinical endpoints other than survival or irreversible morbidity. As a condition of approval under Subpart H, the FDA required that Makena's sponsor perform certain adequate and well controlled post approval clinical studies to verify and describe the clinical benefit of Makena as well as fulfill certain other post approval commitments. We have completed a pharmacokinetic ("PK") study of women taking Makena. In addition, the following clinical studies for Makena are currently ongoing: (a) an efficacy and safety clinical study of Makena and (b) a follow up study of the babies born to mothers from the efficacy and safety clinical study. Given the patient population (i.e., pregnant women who are at high risk for recurrent preterm delivery based on their pregnancy history) and the informed risk of receiving a placebo instead of the active approved drug, the pool of prospective subjects for such clinical trials in the U.S. is small and we have therefore sought enrollment on a global scale. In October 2015, in response to our request to extend our agreed-upon completion dates for two of these studies, the FDA notified us that it approved a two-year extension for the ongoing clinical studies to December 2018 and October 2020.

Next Generation Development Programs

To enhance the product profile of Makena for patients and their healthcare providers, we are pursuing a next generation development program for Makena, including new routes of administration and the use of new delivery technologies, as well as reformulation technologies, some elements of which could provide new intellectual property or data exclusivity beyond February 2018. As part of this program, in July 2015, we filed a prior approval supplement to the original Makena New Drug Application ("NDA") with the FDA seeking approval of Hospira, our current manufacturer of the multidose vial, to be approved to manufacture the single-dose preservative-free formulation of Makena. In February 2016, the prior approval supplement for Hospira was approved. In addition, in October 2014, we filed a prior approval supplement to the original Makena NDA with the FDA seeking approval of a single-dose preservative-free formulation of Makena to be manufactured by Coldstream. In May 2015, we received a complete response letter from the FDA for the Coldstream prior approval supplement requesting additional information related to manufacturing procedures for the single-dose preservative-free formulation and we are currently working with Coldstream to develop the required information requested by the FDA in the complete response letter in order to provide a response to the FDA. In light of the recent approval of the Hospira prior approval supplement, we are planning for a commercial launch of the single-dose preservative-free formulation in the second quarter of 2016.

Makena is currently available in a 5 dose (5 mL) vial.

In addition, we are working to develop an auto-injector device for subcutaneous administration of Makena, including chemistry, manufacturing and controls ("CMC") development with Antares and pilot clinical studies to establish the appropriate subcutaneous dose. We are planning for a single-dose PK bioequivalence study. Based on our current timelines and assumptions, we anticipate filing an sNDA in the first quarter of 2017 with the goal of launching the auto-injector prior to the loss of current exclusivity in February 2018. We also plan to conduct an additional study intended to capture certain clinical measures to support clinical superiority over the existing intramuscular injection, which may provide the basis for new orphan drug exclusivity. We are also in the early stages of developing a longer-acting formulation of Makena with the goal of optimizing the drug release profile.

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CBR Services

Overview

In August 2015, we acquired CBR from CBR Acquisition Holdings Corp. for $700.0 million in cash consideration, subject to estimated working capital, indebtedness and other adjustments. CBR is the largest private newborn stem cell bank in the world that offers pregnant women and their families the ability to preserve their newborns' umbilical cord blood and cord tissue for potential future use (the "CBR Services"). We market and sell the CBR Services directly to consumers, who pay for the services, as third-party insurance and reimbursement are not available. Even though our business is limited to the sale of our services required to collect, process, and store umbilical cord blood stem cells and cord tissue, the FDA regulates them as products. Additional details regarding the acquisition of CBR can be found in Note C, "Business Combinations," to our consolidated financial statements included in this Annual Report on Form 10 K.

The CBR Services include the collection, processing and storage of both umbilical cord blood and cord tissue. As of December 31, 2015, CBR stored approximately 633,000 umbilical cord blood and cord tissue units, which we estimate to represent approximately more than half of all privately stored cord blood and cord tissue units in the U.S.

CBR is the first family newborn stem cell bank to partner with reputable research institutions on FDA-regulated clinical trials exploring the potential regenerative ability of cord blood stem cells to help treat conditions that have no cure today, including acquired hearing loss, autism, cerebral palsy and pediatric stroke. In addition, in an effort to realize the full potential of newborn stem cells, CBR's Newborn Possibilities Program® provides free processing and five years of free storage of cord blood and cord tissue for families with a qualifying medical need, as further discussed below.

In 2005, the Institute of Medicine ("IOM") issued a report to Congress on cord blood banking containing recommendations that healthcare professionals provide all expectant parents with fair and balanced education on cord blood preservation prior to labor and delivery so that families can make an informed choice regarding their options to preserve their newborns' stem cells for potential future family use, donate the cells for public use or research, or dispose of them after birth. The IOM's recommendations have prompted federal legislation as well as regulations in more than 20 states that support educating expectant parents about cord blood. In support of this legislation, CBR collaborates with outside organizations to develop education initiatives to provide quality, relevant information to expectant parents regarding their options for newborn stem cell preservation.

CBR has been accredited by the AABB (formerly known as the American Association of Blood Banks) since 1998 and the company's quality standards have been recognized through International Organization for Standardization (ISO) 9001:2008 certification - the global business standard for quality. In addition, CBR is also certified by CLIA (Clinical Laboratory Improvement Amendments), a federal program to ensure quality laboratory testing.

Cord Blood and Cord Tissue

Cord blood comes from a newborn's umbilical cord and can be collected immediately after birth. It contains hematopoietic stem cells, which have been used in the treatment of over 80 diseases, including various cancers, blood disorders, immune disorders and metabolic disorders. Cord tissue contains mesenchymal stem cells, which are unique and powerful stem cells that are being investigated for their ability to help repair and heal the body in different ways than cord blood stem cells. Although there are not yet any conditions proven to be treatable with cord tissue, these cells have potential for use in regenerative medicine and are currently being evaluated in over 30 clinical trials outside of the U.S. for their potential to treat heart disease, stroke and spinal cord damage, among other conditions. Approximately 77% of the stem cell units released by CBR have been used for experimental regenerative therapies.

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Feraheme for the treatment of IDA in patients with CKD

Overview

Feraheme was approved for marketing by the FDA in June 2009 for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD.

While Feraheme is approved for IDA in all stages of CKD, beginning in 2010, due to changes in the way the federal government reimburses providers for the care of dialysis patients, the utilization of Feraheme shifted to non dialysis patients. The non dialysis CKD IDA market is made up of a range of healthcare providers who administer IV iron, including nephrologists, hematologists and oncologists, both in outpatient and hospital settings and other end users who treat patients with CKD. We anticipate the majority of all Feraheme utilization will continue to be in the non dialysis CKD patient population if and until Feraheme receives a broader label to include non CKD patients. We began selling Feraheme in the U.S. in July 2009 through our commercial organization, including a specialty sales force. We sell Feraheme to authorized wholesalers and specialty distributors, who, in turn, sell Feraheme to healthcare providers who administer Feraheme primarily within nephrology clinics, hematology and oncology centers and hospitals. In 2015, U.S. sales of Feraheme accounted for approximately 21% of our total net revenues.

In December 2014, we entered into an agreement (the "Takeda Termination Agreement") with Takeda Pharmaceutical Company Limited ("Takeda"), which terminated our License, Development and Commercialization Agreement with Takeda (as amended, the "Takeda Agreement"). Under the terms of the Takeda Agreement, Takeda had exclusive rights to develop and commercialize Feraheme as a therapeutic agent in certain agreed-upon territories outside of the U.S. Pursuant to the Takeda Termination Agreement, the termination of the Takeda Agreement was effective on a rolling basis, with final termination pursuant to its terms occurring in June 2015. As a result, we recognized all remaining deferred revenues related to Takeda into revenues in 2015.

In March 2015, following discussions with the FDA, we updated our Feraheme label to include (a) the addition of a boxed warning related to the risks of serious hypersensitivity reactions or anaphylaxis, which risks were previously described only in the Warnings and Precautions section; (b) revisions to the Dosing and Administration section to indicate that Feraheme should only be administered by IV infusion; and (c) modifications to the Warnings and Precautions section to include a statement that patients with a history of multiple drug allergies may have a greater risk of anaphylaxis with parenteral iron products.

On February 5, 2016, we received a Paragraph IV certification notice letter regarding an Abbreviated New Drug Application (an "ANDA") submitted to the FDA by Sandoz Inc. ("Sandoz") requesting approval to engage in commercial

manufacture, use and sale of a generic version of ferumoxytol. A generic version of Feraheme can be marketed only with the approval of the FDA of the respective application for such generic version. The Drug Price Competition and Patent Term Restoration Act of 1984, as amended (the "Hatch Waxman Act") requires an applicant whose subject drug is a drug listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," also known as the "Orange Book," to notify the patent holder of their application and potential infringement of their patent rights. The Paragraph IV certification notice is required to contain a detailed factual and legal statement explaining the basis for the applicant's opinion that the proposed product does not infringe the subject patents, that such patents are invalid, or both. Receipt of the certification notice triggers a 45 day window during which we may bring a patent infringement suit in federal district court against the applicant seeking approval of a product. In its notice letter, Sandoz claims that our ferumoxytol patents are invalid, unenforceable and/or not infringed by Sandoz's manufacture, use, sale or offer for sale of the generic version. We are evaluating the notice letter and intend to vigorously enforce our intellectual property rights relating to ferumoxytol. We plan to initiate a patent infringement suit to defend the patents identified in the notice letter. If we were to commence such a suit, the FDA is generally prohibited from granting approval of an application until the earliest of 30 months from the date the FDA accepted the application for filing, the conclusion of litigation in the generic's favor, or expiration of the patent(s) (though such stay may be shortened or lengthened if either party fails to cooperate in the litigation). If the litigation is resolved in favor of the applicant or the challenged patent expires during the 30 month stay period, the stay is lifted and the FDA may thereafter

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approve the application based on the applicable standards for approval. The ANDA process is discussed in more detail below under the heading “Pharmaceutical Product Approval Process - Abbreviated New Drug Application.”

Chronic kidney disease, anemia, and iron deficiency

CKD is a progressive condition that leads to chronic and permanent loss of kidney function. It contributes to the development of many complications, including anemia, hypertension, fluid and electrolyte imbalances, acid/base abnormalities, bone disease and cardiovascular disease. According to the National Kidney Foundation, 26 million Americans are living with CKD and millions of others are at risk. Anemia, a common condition among CKD patients, is associated with cardiovascular complications, decreased quality of life, hospitalizations, and increased mortality. Anemia develops early during the course of CKD and worsens with advancing kidney disease. Patients with anemia can look pale, feel fatigued, experience shortness of breath, low energy, headaches, palpitations or chest pains, and have a loss of appetite, trouble sleeping and trouble concentrating. Anemia in CKD patients is most often caused by an insufficient production of erythropoietin, a hormone made by the kidneys which tells the body to produce red blood cells, and iron deficiency, due to inadequate iron intake, blood loss or because the body cannot use iron stores. Regardless of the cause of the iron deficiency, iron replacement therapy is essential to increase iron stores and raise hemoglobin levels. Iron is also essential for effective treatment with erythropoiesis stimulating agents (“ESAs”), which are commonly used in anemic patients to stimulate red blood cell production. Based on data contained in a 2009 publication in the Journal of the American Society of Nephrology, we estimate that there are at least 1.6 million adults in the U.S. diagnosed with IDA in stages 3 through 5 CKD, who are patients in the mid to later stages of CKD but not yet on dialysis and could therefore benefit from receiving IV iron.

Currently there are two methods of iron therapy used to treat IDA in CKD patients: oral iron supplements and IV iron. The National Kidney Foundation’s Kidney Disease Outcomes Quality Initiative guidelines recommend either oral or IV iron for peritoneal dialysis patients and non dialysis patients with stages 1 through 5 CKD. Oral iron is currently the first line iron replacement therapy for most physicians. However, oral iron supplements are poorly absorbed by many patients, which may adversely impact their effectiveness, and are associated with certain side effects, such as constipation, diarrhea, and cramping, that may adversely affect patient compliance in using such products. In addition, it can take an extended time for hemoglobin levels to improve following the initiation of oral iron treatment, and even then the targeted hemoglobin levels may not be reached. Conversely, iron given intravenously allows larger amounts of iron to be provided to patients in a shorter time frame while avoiding many of the side effects and treatment compliance issues associated with oral iron, and can result in faster rises in hemoglobin levels. The administration of IV iron has been shown to be effective in treating anemia either when used alone or in combination with an ESA. Current treatment guidelines indicate that treating first with iron alone may delay or reduce the need for ESA therapy. Iron supplementation is widely used in CKD patients to treat iron deficiency, prevent its development in ESA treated patients, raise hemoglobin levels in the presence or absence of ESA treatment, and reduce ESA doses in patients receiving ESA treatment. We believe that IV iron is underutilized in non dialysis CKD patients who are diagnosed with IDA, and thus a significant opportunity remains to grow the market for IV iron in this patient population.

Post Marketing Commitments of Feraheme in CKD

We had initiated a randomized, active controlled pediatric study of Feraheme for the treatment of IDA in pediatric CKD patients to meet our FDA post approval Pediatric Research Equity Act requirement to support pediatric labeling of Feraheme in the U.S. The study covered both dialysis dependent and non dialysis dependent CKD pediatric patients and was intended to assess the safety and efficacy of Feraheme treatment as compared to oral iron in approximately 288 pediatric patients. We have elected to terminate this trial due to difficulty in enrollment and plan to work with the FDA to discuss the path forward regarding this post-approval commitment for Feraheme.

We have recently completed and are currently in the process of analyzing the data from our global multi center randomized clinical trial to evaluate the safety and efficacy of repeat doses of ferumoxytol as compared to iron sucrose for the treatment of IDA in patients with hemodialysis dependent CKD.

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Feraheme for the treatment of IDA in a broad range of patients

Overview

IDA not associated with CKD is widely prevalent in many different patient populations. For many of these patients, treatment with oral iron is unsatisfactory. In the U.S., approximately one million grams of IV iron were administered for the treatment of non dialysis patients with IDA in 2015. We believe that approximately half, or 500,000 grams, of the IV iron administered was for the treatment of non dialysis patients with CKD and the other half was for non CKD patients with IDA due to other causes, including patients with gastrointestinal diseases or disorders, abnormal uterine bleeding, inflammatory diseases, and chemotherapy induced anemia. It is estimated that more than 4.5 million patients in the U.S. have IDA (CKD and non CKD) and we estimate that a small fraction of non-dialysis CKD patients who are diagnosed with IDA are currently being treated with IV iron.

In December 2012, we submitted an sNDA to the FDA seeking approval for Feraheme for the treatment of IDA in adult patients who had failed or could not tolerate oral iron, or in whom oral iron was contraindicated. The sNDA included data from two controlled, multi center Phase 3 clinical trials, including more than 1,400 patients, which evaluated the safety and efficacy of ferumoxytol for the treatment of IDA in this broader patient population. Both studies met the primary efficacy endpoints related to improvements in hemoglobin.

In January 2014, we received a complete response letter from the FDA for the sNDA informing us that our sNDA could not be approved in its present form and stating that we had not provided sufficient information to permit labeling of Feraheme for safe and effective use for the proposed broader indication. The FDA indicated that its decision was based on the cumulative ferumoxytol data, including the global Phase 3 IDA program and global post-marketing safety reports for the currently indicated CKD patient population. The FDA suggested, among other things, that we submit additional clinical trial data in the proposed broad IDA patient population. Following discussions with the FDA, we have recently commenced start-up activities on a new head-to-head Phase 3 clinical trial evaluating Feraheme in adults with IDA, excluding patients on hemodialysis. This new trial is a randomized, double-blind multicenter non-inferiority trial that will evaluate the incidence of moderate to severe hypersensitivity reactions (including anaphylaxis) and moderate to severe hypotension with Feraheme compared to ferric carboxymaltose infusion in adults with IDA. Two thousand patients will be randomized in a 1:1 ratio into one of two treatment groups, those receiving 1.02 grams of Feraheme IV infusion or those receiving 1.5 grams of ferric carboxymaltose IV infusion. We currently expect to initiate the trial in the first quarter of 2016.

MuGard

In June 2013, we entered into a license agreement (the “MuGard License Agreement”) with Abeona (formerly known as PlasmaTech Biopharmaceuticals, Inc. and Access Pharmaceuticals, Inc.), under which we acquired the U.S. commercial rights to MuGard for the management of oral mucositis and stomatitis (the “MuGard Rights”). MuGard was launched in the U.S. by Abeona in 2010 after receiving 510(k) clearance from the FDA and is indicated for the management of oral mucositis/stomatitis (that may be caused by radiotherapy and/or chemotherapy) and all types of oral wounds (mouth sores and injuries), including aphthous ulcers/canker sores and traumatic ulcers, such as those caused by oral surgery or ill fitting dentures or braces.

Oral mucositis is the painful inflammation and ulceration of the mucous membranes of the mouth and a common and often debilitating complication of cancer treatment that may impair oral nutritional intake or result in delays, unplanned breaks or decreases in dose for chemotherapy and/or radiation treatments, leading to sub optimal cancer treatment results. In the U.S., there are approximately 400,000 people per year who experience oral mucositis and approximately 80% of patients with oral mucositis experience severe oral pain. The incidence rate and severity of symptoms depends on the type of anti cancer treatment and patient related risk factors. For example, the incidence of oral mucositis for patients undergoing radiation therapy for the treatment of head and neck cancer could reach up to 100%. The incidence of oral mucositis for stem cell transplant patients undergoing high dose chemotherapy and/or radiation pre conditioning is up to approximately 90%. Patients with other tumor types undergoing chemotherapy or radiation therapy, such as breast, lung or colorectal cancers, also experience very high levels of oral mucositis/stomatitis, ranging from 40% to 80%.

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There are few effective treatments for oral mucositis and the products in this market remain mostly undifferentiated. There are a number of approaches used to treat or manage oral mucositis, including the use of ice chips during chemotherapy treatments, various medicinal mouthwashes, topical anesthetics and analgesics, and oral gel treatments. We sell MuGard through a distribution network of specialty pharmacies and wholesalers, who in turn supply it to hospitals or hematology/oncology clinics. Currently, MuGard is only used by a small percentage of the oral mucositis patients in the U.S., providing us with a significant opportunity to address an unmet medical need and grow the sales of MuGard in the oral mucositis market.

Recent Financings

On August 17, 2015, in connection with the CBR acquisition, we completed a private placement of $500.0 million aggregate principal amount of 7.875% Senior Notes due 2023 (the "2023 Senior Notes") and entered into a credit agreement with a group of lenders and Jefferies Finance LLC, as administrative and collateral agent, that provided us with, among other things, a six-year $350.0 million term loan facility (the "2015 Term Loan Facility"). We borrowed the full $350.0 million available under the 2015 Term Loan Facility on August 17, 2015. We used the net proceeds from the August 2015 Offering, as defined below, the offering of the 2023 Senior Notes and borrowings under the 2015 Term Loan Facility along with existing cash to fund the acquisition of CBR, to repay the remaining $323.0 million outstanding principal amount under our then existing five-year term loan facility (the "2014 Term Loan Facility"), and to pay prepayment premiums, fees and expenses in connection with the foregoing.

On August 5, 2015, we sold approximately 3.6 million shares of our common stock at a public offering price of $63.75 per share (the "August 2015 Offering"), resulting in net proceeds to us of approximately $218.6 million.

In March 2015, we sold approximately 4.6 million shares of our common stock at a public offering price of $44.00 per share, resulting in net proceeds to us of approximately $188.8 million.

Additional details regarding our recent financing activities can be found in Note N, "Stockholders' Equity" and Note R, "Debt" to our consolidated financial statements included in this Annual Report on Form 10-K.

Collaboration, License and Other Strategic Agreements

Velo

In July 2015, we entered into an option agreement with Velo, a privately held life-sciences company that granted us an option to acquire the rights to an orphan drug candidate, digoxin immune fab (“DIF”), a polyclonal antibody in clinical development for the treatment of severe preeclampsia in pregnant women. We made an upfront payment of $10.0 million in the third quarter of 2015 for the option to acquire the global rights to the DIF program (the “DIF Rights”). DIF has been granted both orphan drug and fast-track review designations by the FDA for use in treating severe preeclampsia. Under the option agreement, Velo will complete a dose ranging study and a Phase 2b/3a clinical study. Following the conclusion of the DIF Phase 2b/3a study, we may terminate, or, for additional consideration, exercise or extend, our option to acquire the DIF Rights. If we exercise the option to acquire the DIF Rights, we would be responsible for additional costs in pursuing FDA approval, and would be obligated to pay certain milestone payments and single-digit royalties based on regulatory approval and commercial performance of the product to Velo. If we exercise the option, we will be responsible for payments totaling up to $65.0 million (including the payment of the option exercise price and the regulatory milestone payments) and up to an additional $250.0 million in sales milestone payments based on the achievement of annual sales milestones at targets ranging from $100.0 million to $900.0 million. We anticipate that results from the pivotal Phase 2b/3a study could be available as early as 2018.

Antares

In September 2014, Lumara Health entered into a development and license agreement with Antares (“Antares Agreement”), which in connection with our acquisition of Lumara Health in November of 2014, grants us an exclusive, worldwide, royalty-bearing license, with the right to sublicense, to certain intellectual property rights, including know-

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how, patents and trademarks, to develop, use, sell, offer for sale and import and export an Antares' auto-injection system for use with HPC (the "Product"). In consideration for the license, to support joint meetings and a development strategy with the FDA, and for initial tooling and process validation, Lumara Health paid Antares an up-front payment in October 2014. Under the Antares Agreement, we are responsible for the clinical development and preparation, submission and maintenance of all regulatory applications in each country where we desire to market and sell the Product, including the U.S. We are required to pay royalties to Antares on net sales of Products commencing on Product launch in a particular country until the Product is no longer developed, marketed, sold or offered for sale in such country (the "Antares Royalty Term"). The royalty rates range from high single digit to low double digits and are tiered based on levels of net sales of Products and decrease after the expiration of licensed patents or where there are generic equivalents to the Product being sold in a particular country. Antares is the exclusive supplier of our requirements for the auto-injection system devices for the Products and Antares remains responsible for the manufacture and supply of the devices and assembly of the Product. We are responsible for the supply of the drug to be used in the assembly of the finished Product. The development and license agreement terminates at the end of the Antares Royalty Term, but is subject to early termination by us for convenience, by Antares if we do not submit regulatory filings in the U.S. by a certain date and by either party upon an uncured breach by or bankruptcy of the other party.

Abeona

In June 2013, we entered into the MuGard License Agreement under which Abeona granted us an exclusive, royalty bearing license, with the right to grant sublicenses, to certain intellectual property rights, including know how, patents and trademarks, to use, import, offer for sale, sell, manufacture and commercialize MuGard in the U.S. and its territories (the "U.S. Territory") for the management of oral mucositis/stomatitis (that may be caused by radiotherapy and/or chemotherapy) and all types of oral wounds (mouth sores and injuries), including aphthous ulcers/canker sores and traumatic ulcers, such as those caused by oral surgery or ill fitting dentures or braces.

In consideration for the license, we paid Abeona an upfront license fee of $3.3 million in June 2013. We are required to pay royalties to Abeona on net sales of MuGard until the later of (a) the expiration of the licensed patents or (b) the tenth anniversary of the first commercial sale of MuGard in the U.S. Territory (the "MuGard Royalty Term"). These tiered, double digit royalty rates decrease after the expiration of the licensed patents and are subject to off set against certain of our expenses. After the expiration of the MuGard Royalty Term, the license shall become a fully paid up, royalty free and perpetual license in the U.S. Territory.

Abeona remains responsible for the manufacture of MuGard and we have entered into a quality agreement and a supply agreement under which we purchase MuGard inventory from them. Our inventory purchases are at the price actually paid by Abeona to purchase it from a third party plus a mark up to cover administration, handling and overhead.

Abeona is responsible for maintenance of the licensed patents at its own expense, and we retain the first right to enforce any licensed patent against third-party infringement. The MuGard License Agreement terminates at the end of the MuGard Royalty Term, but is subject to early termination by us for convenience and by either party upon an uncured breach by or bankruptcy of the other party.

Takeda

In December 2014, we entered into the Takeda Termination Agreement, which terminated the Takeda Agreement. Under the terms of the Takeda Agreement, Takeda had exclusive rights to develop and commercialize Feraheme as a therapeutic agent in certain agreed-upon territories outside of the U.S. Pursuant to the Takeda Termination Agreement, the termination of the Takeda Agreement was effective on a rolling basis, whereby the termination was effective for a particular geographic territory (i.e., countries under the regulatory jurisdictions of Health Canada, the European Medicines Agency and SwissMedic) upon the earlier of effectiveness of the transfer to us or a withdrawal of the marketing authorization for such territory, with the final effective termination date to be on the third such effective date. On April 13, 2015, the marketing authorization for ferumoxytol was withdrawn in the EU and Switzerland. On June 25, 2015, the transfer from Takeda to us of the Feraheme marketing authorization in Canada became effective and marked the final termination date of the Takeda Agreement.

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In connection with the final termination of the Takeda Agreement, we recognized into revenues the remaining balances of deferred revenue related to the upfront and milestone payments we received from Takeda during the life of the agreement as well as amounts associated with the terms of the Takeda Termination Agreement. In 2015, we recognized $44.4 million in revenues associated with the amortization of the remaining deferred revenue balance and recorded it in license fee, collaboration and other revenues in our consolidated statement of operations included in this Annual Report on Form 10-K. In addition, we recognized $6.7 million of additional revenues in 2015 related to payments made by Takeda upon the final termination date as required under the terms of the Takeda Termination Agreement.

Manufacturing

Overview

We do not own or operate, and currently do not plan to own or operate, facilities for the manufacture of our commercially distributed products or for any commercial products we may acquire or in-license. We rely solely on third-party contract manufacturers to manufacture our products for our commercial and clinical use and for certain materials required to support the CBR Services. The business model for CBR Services is limited to charging customers for our services related to the collection, processing and storage of umbilical cord blood stem cells and cord tissues. Nevertheless, the FDA considers those services to constitute manufacturing of products, and enforces regulations to ensure that establishments that perform such services do so in accordance with current Good Tissue Practices. Our third party contract manufacturing facilities are subject to current good manufacturing practices ("cGMP") and regulations enforced by the FDA and equivalent foreign regulatory agencies through periodic inspections to confirm such compliance. We target to maintain sufficient inventory levels throughout our supply chain to meet our projected near term demand for all of our drug products in order to minimize risks of supply disruption at points in our single source supply chain. For example, although we do not currently have a manufacturer for the production of Makena drug substance, our supply chain practices have resulted in inventory of Makena drug substance which we believe to be sufficient to meet demand until we can qualify a new drug substance manufacturer. We also rely upon third-party contractors to assist in supporting the CBR Services, including to supply proprietary materials, some of whom are sole source providers. We intend to continue to outsource the manufacture and distribution of our products for the foreseeable future, and we believe this manufacturing strategy will enable us to direct more of our financial resources to the commercialization of our products and services. Under the terms of the MuGard License Agreement, Abeona is responsible for all aspects of manufacturing MuGard. We have entered into a quality agreement and a supply agreement with Abeona under which we purchase MuGard inventory from Abeona.

To support the commercialization of our products and services, we have developed a fully integrated manufacturing support system, including quality assurance, quality control, regulatory affairs and inventory control policies and procedures. These support systems are intended to enable us to maintain high standards of quality for our products and services.

Makena

The Makena drug product for our commercial and clinical use is currently manufactured by Hospira under a Development and Supply Agreement (as amended, the "Hospira Agreement"). The Hospira Agreement requires that we satisfy certain minimum purchase requirements. The term of the Hospira Agreement applies to the manufacture of certain dosage forms (for the single-dose the term expires on December 31, 2016 and for the multidose the term expires on December 31, 2017) and provides for an option to extend the term based on the occurrence, timing and amount of certain forecasts and purchase orders related to other dosage forms.

Lumara Health, as our wholly-owned subsidiary following consummation of the acquisition, is subject to certain continuing obligations under a Consent Decree of Permanent Injunction (the "Consent Decree") covering certain prior manufacturing and distribution practices by Lumara Health's predecessor company, K V Pharmaceutical Company ("K-V Pharmaceutical"), entered into among the FDA, K-V Pharmaceutical and certain former officers and affiliates of K V Pharmaceutical. In particular, Lumara Health is bound by a number of provisions and requirements in the Consent Decree including, but not limited to, inspection of Lumara Health's places of business by the FDA without prior notice,

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and notification of FDA of particular actions and events. If Lumara Health fails to comply with applicable provisions in the Consent Decree, the Federal Food, Drug, and Cosmetic Act (the "FDC Act") or the FDC Act's implementing regulations, the FDA may impose specific sanctions including, but not limited to, the requirement to cease any of Lumara Health's manufacturing operations, the imposition of substantial financial penalties, and the requirement to implement additional corrective actions.

Feraheme

We are party to a Commercial Supply Agreement with Sigma Aldrich, Inc. ("SAFC") pursuant to which SAFC agreed to manufacture and we agreed to purchase from SAFC the active pharmaceutical ingredient ("API") or the drug product intermediate ("DPI") for use in the finished product of ferumoxytol for commercial sale as well as for use in clinical trials (as amended, the "SAFC Agreement"). Subject to certain conditions, the SAFC Agreement provides that we purchase from SAFC certain minimum quantities of API or DPI each year, but we are not obligated to use SAFC as our sole supplier of API or DPI. In addition, the prices for each batch will decline as batches are produced in greater quantities throughout each year of the agreement. The SAFC Agreement has an initial term that ends December 31, 2020, which may be automatically extended thereafter for additional two year periods, unless cancelled by us or SAFC within an agreed upon notice period.

We are party to a Pharmaceutical Manufacturing and Supply Agreement with Patheon, Inc. (formerly DSM Pharmaceuticals, Inc.) ("Patheon") pursuant to which Patheon agreed to manufacture ferumoxytol finished drug product for commercial sale and for use in clinical trials at a fixed price per vial (as amended, the "Patheon Agreement"). The Patheon Agreement will continue in force until December 31, 2020. The Patheon Agreement may be terminated at any time upon mutual written agreement by us and Patheon or at any time by us subject to certain notice requirements and early termination fees. In addition, the Patheon Agreement may be terminated by either us or Patheon in the event of a material breach of the agreement by the other party provided that the breaching party fails to cure such breach within an agreed upon notice period.

Raw Materials

We and our third party product manufacturers currently purchase certain raw and other materials used to manufacture our products from third party suppliers and, at present, do not have long term supply contracts with most of these third parties. We also rely upon third-party contractors to assist in providing the CBR Services, including to supply proprietary materials. Although certain of our raw or other materials are readily available, others may be obtained only from qualified suppliers. The qualification of an alternative source may require repeated testing of the new materials and generate greater expenses to us if materials that we test do not perform in an acceptable manner. In addition, we or our third party manufacturers sometimes obtain raw or other materials from one vendor only, even where multiple sources are available, to maintain quality control and enhance working relationships with suppliers, which could make us susceptible to price inflation by the sole supplier, thereby increasing our production costs. As a result of the high quality standards imposed on our raw or other materials, we or our third party manufacturers may not

be able to obtain such materials of the quality required to manufacture Feraheme or Makena or support the CBR Services from an alternative source on commercially reasonable terms, or in a timely manner, if at all.

Patents, Trademarks and Trade Secrets

We consider the protection of our technology to be material to our business. Because of the substantial length of time and expense associated with bringing new products through development and regulatory approval to the marketplace, we place considerable importance on obtaining patent protection and maintaining trade secret protection for our products. Our success depends, in large part, on our ability to maintain the proprietary nature of our technology and other trade secrets. To do so, we must prosecute and maintain existing patents, obtain new patents and ensure trade secret protection. We must also operate without infringing the proprietary rights of third parties or allowing third parties to infringe our rights.

Our policy is to aggressively protect our competitive technology position by a variety of means, including applying for patents in the U.S. and in appropriate foreign countries. We currently hold a number of U.S. and foreign patents for

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Feraheme, which expire at various times through 2025. One of our U.S. Feraheme patents is subject to a patent term extension under U.S. patent law and FDA regulations and will expire in June 2023. Our foreign patents may also be eligible for extension in accordance with applicable law in certain countries. There are no issued patents covering Makena or the CBR Services. We have a license to two U.S. patents relating to MuGard, that each expire in 2022. We have licenses to issued patents and pending applications that will provide protection for the auto-injector product we are developing. In addition, we have entered into an agreement that gives us an exclusive option to acquire the rights to an orphan drug candidate for the treatment of severe preeclampsia in pregnant women. Under the option agreement, at the conclusion of a Phase 2b/3a clinical trial, we may exercise, extend or terminate the acquisition option, at which time we have the right to purchase all intellectual property of Velo related to the DIF Rights.

We have pending patent applications in the U.S. directed to Makena and Feraheme. Although further patents may be issued on pending applications, we cannot be sure that any such patents will be issued on a timely basis, if at all. In addition, any issued patents may not provide us with competitive advantages or may be challenged by others, and the existing or future patents of third parties may limit our ability to commercialize our products.

We also have numerous U.S. and foreign trademark registrations directed to our corporate and affiliate names, as well as our products, compliance programs and services. These marks help to further distinguish our products and services and enhance our overall intellectual property position.

Competition

The pharmaceutical and cord blood banking industries are intensely competitive and subject to rapid technological change. For Makena, most of our competition comes from pharmacies that compound a non FDA approved version of Makena, which is sold at a much lower list price than Makena. Many of our competitors for Feraheme are large, well known pharmaceutical companies and may benefit from significantly greater financial, sales and marketing capabilities, greater technological or competitive advantages, and other resources. For the CBR Services, competition in the private cord blood and cord tissue banking business is already intense and is likely to increase as the number of competitors continues to grow given the relatively low barriers to entry. Our existing or potential competitors may develop products or services that are more widely accepted than ours and may receive patent protection that dominates, blocks, makes obsolete or adversely affects our product development or business.

Makena

Although Makena is the only FDA approved drug indicated to reduce the risk of preterm birth in women pregnant with a single baby who have a history of singleton spontaneous preterm birth, it competes for market share primarily with compounding pharmacies. HPC is the active ingredient in Makena. Compounding pharmacies have been manufacturing formulations of HPC (which compounded formulations we refer to as “c17P”) for many years and c17P formulations will likely remain available at a lower cost to Makena even though Makena has been granted orphan drug exclusivity until February 2018. In November 2013, the FDA implemented the Drug Quality and Security Act (“DQSA”), which amended the FDC Act with respect to the regulation and monitoring of the manufacturing of compounding drugs. Although the FDA has issued a public statement recommending the use of Makena instead of a compounded drug except when there is a specific medical need (i.e., an allergy) that cannot be met by the approved drug and has stated that when it identifies a pharmacist that compounds regularly or in inordinate amounts of any drug

products that are essentially copies of Makena, it intends to take enforcement action as it deems appropriate, doctors continue to prescribe and compounders continue to manufacture and sell c17P.

Makena is priced at a premium to c17P, which has negatively impacted coverage of Makena by some state Medicaid programs and certain commercial payers. Although we are undertaking efforts to educate physicians and patients about progress made toward expanding coverage of Makena and about the benefits of Makena, certain doctors continue to choose to prescribe non FDA approved purported substitute products made by pharmacy compounders in lieu of prescribing Makena.

Based on market research we have conducted, we believe that approximately 38% of the at risk patient population in the U.S. is treated with c17P. Makena currently has approximately 35% of the market share of the at risk patient population with approximately 27% of the at risk patient population being treated either with other therapies, such as

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vaginal progesterone, that are not approved for women pregnant with a single baby with a prior history of singleton spontaneous preterm birth, or not treated at all.

Additionally, in 1956, the FDA approved the drug Delalutin, which contained the same active ingredient as Makena. Delalutin was approved for conditions other than reducing the risk of preterm birth and was marketed by Bristol-Myers Squibb ("BMS"). BMS stopped marketing and manufacturing Delalutin and it was withdrawn from the market in 1999. In 2010, the FDA determined that Delalutin was not withdrawn from sale for reasons of safety or efficacy. As such, generic drug applications may reference the withdrawn Delalutin NDA. In August 2015, the FDA approved an ANDA for HPC, which was submitted by McGuff Pharmaceuticals, Inc. ("McGuff") in 2009, and which was subsequently transferred to Aspen Global Incorporated ("Aspen") in 2015. The ANDA label approved by the FDA for the McGuff product is for the same patient population and indications as Delalutin (i.e., it is approved only for use in non-pregnant women with indications such as uterine cancer or abnormal uterine bleeding). Aspen has indicated that it intends to make its generic version of Delalutin commercially available in the U.S. in 2016. Although Aspen's generic version of Delalutin is not indicated for pregnant women and is not therapeutically equivalent to Makena, doctors may elect to prescribe this product off-label for Makena's orphan-protected indication, which could have an adverse impact on our business and results of operations. In addition, if such generic Delalutin product is priced at a discount to Makena, commercial or government insurers could prefer or encourage the use of the generic Delalutin product for patients who are indicated for Makena.

In addition, generic Makena competitors could enter the market through approval of ANDAs that use Makena as a reference listed drug, which would allow generic competitors to rely on Makena's safety and efficacy trials instead of conducting their own studies. Because entry into the market can occur upon the expiration of the reference listed drug's exclusivity, we could face such competition in the near term as Makena's orphan drug exclusivity expires in February 2018.

For a detailed discussion regarding the risks and uncertainties related to competition for Makena, please refer to our Risk Factors, "Our ability to successfully commercialize Makena is dependent upon a number of factors, including maintaining the benefits of Makena's orphan drug exclusivity and the length of time before competitors begin selling generic versions of Makena" and "If we are unsuccessful in differentiating Makena from compounded HPC products, sales of Makena, and thus our profitability, could be materially adversely affected."

CBR Services

In the last few years, the cord blood banking industry has seen significant change. For example, in 2013 approximately 2.6% of U.S. parents were privately storing cord blood as compared to 2004 when only 0.2% of parents were privately storing cord blood. Similarly, the storage of umbilical cord tissue has grown substantially from 2008 when it was first offered to the public as a commercial option. CBR was the first major company in the U.S. to offer umbilical cord tissue storage and in 2015, most private U.S. cord blood banks offer this service. In addition, the barriers to entry into the cord blood and cord tissue banking business are relatively low. We therefore face competition from new entrants to the market, which could affect our market share or put downward pressure on the pricing of the CBR Services. Furthermore, new market entrants may not abide by industry guidelines, regulations and standards, including quality, compliance and marketing standards that could allow them to offer and promote similar services at lower prices and/or engage in marketing behaviors that communicate false or misleading information. In addition to having a potential adverse impact on our business, these behaviors of such competitors could create a negative perception of our industry if they violate regulations or pursue questionable business practices.

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In the U.S., CBR is considered the largest private cord blood bank based on the number of cord blood and cord tissue units banked. CBR's three largest U.S. competitors include ViaCord®, a subsidiary of PerkinElmer, Inc., Cryo-Cell International, Inc. ® and StemCyte™. In addition to these three primary competitors, CBR competes with more than 20 other blood banks in the U.S.

For a detailed discussion regarding the risks and uncertainties related to competition for CBR, please refer to our Risk Factor, "Competition in the cord blood and cord tissue banking business is significant and may be increasing. If we are unable to maintain our position as the market leader, our CBR business may decline and our results of operations could suffer."

Feraheme

Although Feraheme is approved in the U.S. for the treatment of IDA in adult patients with CKD, including both dialysis and non dialysis CKD patients, our commercial strategy is entirely focused on growing the utilization of Feraheme in non dialysis dependent adult CKD patients who are diagnosed with IDA. We believe there is a significant opportunity for Feraheme for the treatment of IDA in CKD patients not yet on dialysis. The non dialysis IV iron market is comprised primarily of three sites of care where a substantial number of CKD patients are treated: hospitals, hematology and oncology centers, and nephrology clinics.

Feraheme currently competes primarily with the following IV iron replacement therapies for the treatment of IDA in CKD patients:

- Venofer®, an iron sucrose complex, which is approved for use in hemodialysis, peritoneal dialysis, non dialysis dependent CKD patients and pediatric CKD patients and is marketed in the U.S. by Fresenius Medical Care North America and American Regent Laboratories, Inc. ("American Regent"), a subsidiary of Luitpold Pharmaceuticals, Inc. Venofer® is typically administered as a slow intravenous injection over two to five minutes in doses of 100 to 200 milligrams, thus requiring five to ten physician visits to reach a standard one gram therapeutic course;
- Injectafer®, a ferric carboxymaltose injection, was approved in the U.S. in July 2013 to treat IDA in adult patients who have intolerance to oral iron or have had an unsatisfactory response to oral iron. Injectafer® is also indicated for IDA in adult patients with non dialysis dependent CKD. Injectafer® is marketed in the U.S. by American Regent, the same distributor of Venofer®. The labeled administration of Injectafer® is two slow injections or infusion of 750 milligrams each separated by at least seven days for a total cumulative dose of 1,500 milligrams, or one and a half grams per therapeutic course;
- Ferrlecit®, a sodium ferric gluconate, which is marketed by Sanofi Aventis U.S. LLC, is approved for use only in hemodialysis patients. The recommended dose of Ferrlecit® and the generic version of Ferrlecit® is 125 milligrams administered by intravenous infusion over one hour per dialysis session or undiluted as a slow intravenous injection per dialysis session, thus requiring eight physician visits to reach a standard one gram therapeutic course;
- A generic version of Ferrlecit® marketed by Teva Pharmaceuticals, Inc.; and
-

INFeD®, an iron dextran product marketed by Allergan, Inc. which is approved in the U.S. for the treatment of patients with documented iron deficiency in whom oral iron administration is unsatisfactory or impossible. The recommended dose of INFeD® is a slow push in 100 milligram doses, which would require up to ten physician visits to receive a standard one gram therapeutic course.

As compared to the dosing regimens described above for Feraheme's competitors, Feraheme is currently administered as a 510 milligram infusion followed by a second 510 milligram infusion three to eight days later, thereby making it possible for the patient to receive a full gram of iron in as few as three days. In March 2015, following discussions with the FDA, we updated our Feraheme label to include (a) the addition of a boxed warning related to the risks of serious hypersensitivity reactions or anaphylaxis, which risks were previously described only in the Warnings

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and Precautions section; (b) revisions to the Dosing and Administration section to indicate that Feraheme should only be administered by IV infusion; and (c) modifications to the Warnings and Precautions section to include a statement that patients with a history of multiple drug allergies may have a greater risk of anaphylaxis with parenteral iron products. These or any future changes to the label/package could adversely impact our ability to successfully compete in the IV iron market.

Feraheme may also face competition from generic IV iron replacement therapy products that achieve commercial success. For example, as discussed above, on February 5, 2016, we received a Paragraph IV certification notice letter regarding an ANDA submitted to the FDA by Sandoz requesting approval to engage in commercial manufacture, use and sale of a generic version of ferumoxytol. We are evaluating the notice letter and intend to vigorously enforce our intellectual property rights relating to ferumoxytol. We plan to initiate a patent infringement suit to defend the patents identified in the notice letter. If we were to commence such a suit, the FDA is generally prohibited from granting approval of an application until the earliest of 30 months from the date the FDA accepted the application for filing, the conclusion of litigation in the generic's favor, or expiration of the patent(s). If the litigation is resolved in favor of the applicant or the challenged patent expires during the 30 month stay period, the stay is lifted and the FDA may thereafter approve the application based on the applicable standards for approval.

Further, in 2011, a generic version of Ferrlecit® was launched in the U.S. for the treatment of IDA in adult patients and in pediatric patients ages six years and older undergoing chronic hemodialysis who are receiving supplemental epoetin therapy. Sagent Pharmaceuticals, Inc. has also indicated its intention to introduce a generic iron sucrose in the U.S. in the future.

Companies that manufacture generic products typically invest far fewer resources in research and development than the manufacturers of branded products and can therefore price their products significantly lower than those branded products already on the market. Therefore, competition from generic IV iron products could limit our sales.

Based on sales data provided to us in January 2016 by IMS Health Incorporated ("IMS"), we estimate that the size of the total 2015 U.S. non-dialysis IV iron replacement therapy market was approximately one million grams, which represents an increase of approximately 11% over 2014. Feraheme currently competes in the CKD portion of this market, which we estimate is approximately half of the total market. Based on this IMS data, the following represents the 2015 and 2014 U.S. market share allocation of the total non dialysis IV iron market based on the volume of IV iron administered:

	2015 U.S. Non dialysis IV Iron Market (1,000,000 grams)		2014 U.S. Non dialysis IV Iron Market (900,000 grams)	
Venofer®	40	%	43	%
INFeD®	18	%	20	%
Feraheme	14	%	16	%
Injectafer®	14	%	6	%
Generic sodium ferric gluconate	9	%	10	%
Ferrlecit®	5	%	5	%

The market share data listed in the table above is not necessarily indicative of the market shares in dollars due to the variations in selling prices among the IV iron products.

MuGard

Depending on tumor type, oral mucositis can develop in 35% to 100% of patients undergoing chemotherapy and/or radiation therapy for their treatment/management of cancer. There are currently few effective treatments for the treatment or management of oral mucositis. The market for treating oral mucositis is driven primarily by convenience, price and reimbursement and the products in this market remain mostly undifferentiated. There are a number of approaches used to treat or manage oral mucositis, including the use of ice chips during chemotherapy treatments, various medicinal mouthwashes, topical anesthetics and analgesics, and oral gel treatments. For example, many physicians use what is commonly known as “magic mouthwash”, which may currently be the most commonly prescribed

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medication to manage oral mucositis. Magic mouthwash is a combination of generic ingredients which are typically compounded in a pharmacy and is preferred by many physicians because of the availability of less expensive generic ingredients used to formulate the mouthwash. However, there is no clinical trial data to support the efficacy or safety of magic mouthwash. The efficacy of MuGard has been supported by a randomized, Phase 4 multicenter, double blind, controlled trial against an active agent.

The treatment and management of oral mucositis remains a large unmet need in the U.S. Our current commercial strategy for MuGard includes targeting appropriate Health Care Providers ("HCPs"), raising awareness of oral mucositis among these HCPs, differentiating MuGard from other currently used approaches for treating and managing oral mucositis, and expanding reimbursement coverage for MuGard.

Sales, Marketing and Distribution

Makena

In connection with the November 2014 acquisition of Lumara Health, we retained the Makena field sales force, which was subsequently combined with CBR's field sales force in connection with our August 2015 acquisition of CBR. We currently have approximately 100 sales representatives dedicated exclusively to our maternal health products and services focused on calling on approximately 16,000 obstetricians in the U.S. Makena prescriptions are dispensed via the payer-preferred pharmacy or purchased directly by hospitals, government agencies and integrated delivery systems.

Based on market research we conducted, we estimate that Makena is currently used to treat approximately 35% of the at risk patient population, allowing for significant potential to increase its market share. Our sales and marketing teams use a variety of strategies and focused, multi-channel methods to promote Makena, including dedicating a separate managed care team to focus on health plans, including commercial payers, pharmacy benefit managers, and managed Medicaid plans as well as fee for service Medicaid programs.

In addition, we offer customer support through the Makena Care Connection, which is designed to help the prescriber and patient navigate each individual patient's needs throughout the Makena prescription process. Every woman's maternity insurance benefits are unique in terms of insurance coverage for certain medications, required copays, coinsurance or deductibles, and how medications are dispensed. The Makena Care Connection provides customer support to patients in processing the prescription, including confirming insurance coverage, assisting with prior authorizations (when applicable), and working in collaboration with the payer-preferred pharmacy and home health agency to help ensure timely initiation of therapy.

The Makena Care Connection also screens and enrolls patients in financial assistance programs including our copay assistance program, which helps lower the out-of-pocket cost for commercially insured patients whose plan covers Makena. The copay assistance program applies to copays, coinsurance and deductibles with no upper level income cap. The Makena Care Connection also screens and enrolls patients in our patient assistance program, which provides a full course of therapy at no charge to eligible uninsured patients, with no upper level income cap. To be eligible for these programs, the patient must meet the FDA-approved indication. In compliance with federal regulations, patients insured by a government-funded program are not eligible to participate.

In April 2015, we launched the My Adherence Program, a telephonic 24/7 nursing services program to assist with increasing patient compliance. The program encourages adherence to the weekly Makena injection schedule, helps identify challenges that may interfere with patient compliance in receiving the weekly injection and offers potential solutions, provides educational materials that address important topics during pregnancy, and empowers patients to take an active role in their health. Program participants are paired with a dedicated maternal health nursing specialist to support them throughout their pregnancy. To be eligible for the My Adherence Program, patients must meet the FDA-approved indication.

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CBR Services

In August 2015, we acquired CBR, which performs the CBR Services. In connection with the acquisition, CBR's field sales force was combined with our Makena field sales force. We currently have approximately 100 sales representatives dedicated exclusively to our maternal health products and services focused on calling on approximately 16,000 obstetricians in the U.S.

We directly market CBR Services to pregnant women and their families through social media and digital marketing channels, and believe that we have the potential to reach approximately two million pregnant women each year, representing approximately half of the pregnancies in the U.S. We also utilize the CBR consumer sales team to educate families on their cord blood banking options. This team of inside tele-sales representatives is dedicated to a direct-to-consumer approach based on our digital marketing lead generation and qualification expertise. Additionally, we nurture and develop customer referrals from an existing base of over 350,000 families through our customer service team and digital and social media marketing efforts.

We also offer the Newborn Possibilities Program®, which provides free processing and five years of free storage for cord blood and cord tissue to families with a qualifying medical need. To date, over 6,000 families have been enrolled. Further, the Newborn Possibilities Program has been expanded with the launch of the first registry aimed at collecting family health data on diseases and conditions common among registry participants to help target medical research on those that may be treatable with newborn stem cell therapy. Currently, over 100,000 families are participating in the Family Health Registry™.

Feraheme

We sell Feraheme to authorized wholesalers and specialty distributors who, in turn, sell Feraheme to healthcare providers who administer Feraheme primarily within hospitals, hematology and oncology centers and nephrology clinics. Since many hospitals and hematology, oncology and nephrology practices are members of group purchasing organizations ("GPOs"), which leverage the purchasing power of a group of entities to obtain discounts based on the collective bargaining power of the group, we also routinely enter into pricing agreements with GPOs in these markets so the members of the GPOs have access to Feraheme and to the related discounts or rebates.

Our sales and marketing organization uses a variety of common pharmaceutical marketing strategies and methods to promote Feraheme including sales calls to purchasing entities, such as hospitals, hematology and oncology centers and nephrology practices in addition to individual physicians or other healthcare professionals, medical education symposia, personal and non personal promotional materials, local and national educational programs, scientific meetings and conferences and informational and disease state awareness websites. In addition, we provide customer service and other related programs for Feraheme including physician reimbursement support services, a patient assistance program for uninsured or under insured patients and a customer service call center.

Our commercial strategy currently focuses on the non dialysis dependent CKD market in the U.S. We believe there is a significant opportunity in this market to provide IV iron to non dialysis CKD patients, and our sales team has been working to educate physicians who treat CKD patients on the benefits of IV iron and the advantages of Feraheme in order to identify appropriate CKD patients and expand the IV iron use in physicians' offices, clinics, and hospitals where CKD patients are treated for IDA.

MuGard

Our current commercial strategy for MuGard includes targeting appropriate HCPs, raising awareness of oral mucositis among these HCPs, differentiating MuGard from other currently used approaches for treating and managing oral mucositis and expanding reimbursement coverage for MuGard.

Our sales and marketing teams use a variety of common pharmaceutical marketing strategies and methods to promote MuGard, including sales calls to providing entities, such as hospitals and hematology and oncology centers. In addition, other tactical programs may include personal and non personal promotional materials to individual physicians

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or other healthcare professionals, sponsoring local and national educational programs, participation in scientific meetings and conferences and implementing informational product specific websites.

We market and sell MuGard to wholesalers and specialty pharmacies. Patients primarily receive MuGard through specialty pharmacies, which receive prescriptions from either our MuGard patient reimbursement and support center (the "HUB") or from physicians directly. We utilize the HUB as a centralized patient intake and referral management center to process insurance coverage issues and administer our patient assistance and copayment programs. In order to provide MuGard to patients as soon as possible, we have implemented a robust program that delivers a starter kit to clinicians, including a sample bottle and all pertinent information that the patient or caregiver needs to immediately begin MuGard therapy.

Product Supply Chain

We outsource a number of our product supply chain services for our products to third party logistics providers, including services related to warehousing and inventory management, distribution, chargeback processing, accounts receivable management, sample distribution to our sales force, and customer service call center management.

Major Customers

The following table sets forth customers who represented 10% or more of our total revenues for 2015, 2014, and 2013. Revenues from Takeda include payments related to the Amended Takeda Agreement and the Takeda Termination Agreement.

	Years Ended December 31,					
	2015		2014		2013	
AmerisourceBergen Drug Corporation	25	%	34	%	41	%
Takeda Pharmaceuticals Company Limited	12	%	11	%	11	%
McKesson Corporation	11	%	21	%	24	%
Cardinal Health, Inc.	<10	%	15	%	16	%

In addition, approximately 26%, 26% and 30% of our Feraheme end user demand in 2015, 2014 and 2013, respectively, was generated by members of a single GPO with whom we have contracted.

The loss of any of these customers would have a material adverse effect on our business.

Government Regulation

Overview

Our activities are subject to extensive regulation by numerous governmental authorities in the U.S. The FDC Act and other federal and state statutes and regulations govern, among other things, the research and development, manufacturing, quality control, labeling, recordkeeping, approval, storage, distribution, and advertising and promotion of pharmaceutical products and medical devices. In addition, under the Public Health Service Act and its implementing regulations, we are required to register with the FDA, which governs all aspects of cord blood preservation, including the recovery, screening, testing, processing, storage, labeling, packaging and distribution of cord blood stem cells.

Failure to comply with any of the applicable U.S. requirements may result in a variety of administrative or judicially imposed sanctions including, among other things, the regulatory agency’s refusal to approve pending applications, suspension, variations or withdrawals of approval, clinical holds, warning letters, product recalls, product seizures, total or partial suspension of operations, injunctions, fines, civil penalties, or criminal prosecution.

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Pharmaceutical Product Approval Process

Clinical Development

Before we may market a new drug product, we must obtain FDA approval of a NDA for that product. The FDA may approve an NDA if the safety and efficacy of the drug candidate can be established based on the results of clinical trials.

Clinical testing proceeds in three phases. Phase 1 trials seek to establish initial data about safety, tolerability, and optimal dosing of the drug candidate in humans. The goal of Phase 2 trials is to provide evidence about the desired therapeutic efficacy of the product candidate in limited studies with small numbers of carefully selected subjects. Phase 3 trials generally consist of expanded, large scale, randomized, double blind, multi center studies of the safety and efficacy of the product in the target patient population.

Although we currently have no new unapproved drugs in development and our intention is to expand our portfolio with additional commercial stage specialty products, we would be required to comply with the requirements for drug approval if we develop new or acquire earlier stage products.

Submission and FDA Review of NDAs/sNDAs

Following the successful completion of clinical trials, the sponsor submits the results to the FDA as part of an NDA. The NDA must also include the results of pre clinical tests and studies, information related to the preparation and manufacturing of the drug candidate, analytical methods, and proposed packaging and labeling. Pursuant to the Prescription Drug User Fee Act ("PDUFA"), the FDA has a goal of acting on most original NDAs within six months or ten months of the application filing date, depending on the nature of the drug. For drug candidates intended to treat serious and life threatening conditions, the FDA has a number of programs intended to help expedite testing, review, and approval. For example, under the provisions of the FDA's Subpart H Accelerated Approval regulations, accelerated approval is permitted for a new drug that is intended to treat a serious or life threatening disease or condition and that fills an unmet medical need based on a surrogate endpoint.

If the FDA's evaluations of the NDA and of the sponsor's manufacturing facilities are favorable, the FDA will issue an approval letter, and the sponsor may begin marketing the drug for the approved indications, subject to any post approval requirements described further below. If the FDA determines it cannot approve the NDA in its current form, it will issue a complete response letter indicating that the application will not be approved in its current form. The complete response letter usually describes the specific deficiencies that the FDA identified in the application and may require additional clinical or other data or impose other conditions that must be met in order to obtain approval of the NDA. Addressing the deficiencies noted by the FDA could be impractical, and it is possible that approval may not be obtained or may be costly and may result in significant delays prior to approval.

Where a sponsor wishes to expand the originally approved prescribing information, such as adding a new indication, it must submit and obtain approval of an sNDA. Changes to an indication generally require additional clinical studies, which can be time consuming and require the expenditure of substantial additional resources. Under PDUFA, the target timeframe for the review of an sNDA to add a new clinical indication is ten months from the date of filing. As with an NDA, if the FDA determines that it cannot approve an sNDA in its current form, it will issue a complete response letter as discussed above. See the discussion above under "Feraheme for the treatment of IDA in a broad range of patients" for our ongoing post marketing activities for Feraheme.

Abbreviated New Drug Application

An ANDA is filed when approval is sought to market a generic equivalent of a drug product previously approved under an NDA and listed in the Orange Book. Rather than directly demonstrating the product's safety and efficacy, as is required of an NDA, an ANDA must show that the proposed generic product is the same as the previously approved product in terms of active ingredient(s), strength, dosage form, route of administration and bioavailability. In addition, with certain exceptions, the generic product must have the same labeling as the product to which it refers.

NDA applicants and holders must provide certain information about patents related to the branded drug for listing in the Orange Book. When an ANDA application is submitted, it must contain one of several possible certifications

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regarding each of the patents listed in the Orange Book for the branded product that is the reference listed drug. A certification that a listed patent is invalid or will not be infringed by the sale of the proposed product is called a Paragraph IV Certification.

Adverse Event Reporting

The FDA requires a sponsor to submit reports of certain information on side effects and adverse events ("AEs") associated with its products that occur either during clinical trials or after marketing approval. These requirements include specific and timely notification of certain serious, unexpected and/or frequent AEs, as well as regular periodic reports summarizing adverse drug experiences. Failure to comply with these FDA safety reporting requirements may result in FDA regulatory action that may include civil action or criminal penalties. In addition, as a result of these reports, the FDA could create a Tracked Safety Issue for a product in the FDA's Document Archiving, Reporting and Regulatory Tracking System, place additional limitations on an approved product's use, such as through labeling changes, or, potentially, could require withdrawal or suspension of the product from the market.

FDA Post Approval Requirements

Even if initial approval of an NDA or sNDA is granted, such approval may be subject to post market regulatory requirements, any or all of which may adversely impact a sponsor's ability to effectively market and sell the approved product. The FDA may require the sponsor to conduct Phase 4 clinical trials, also known as post marketing requirements or post marketing commitments, to provide additional information on safety and efficacy. The results of such post marketing studies may be negative and could lead to limitations on the further marketing of a product. Also, under the Pediatric Research Equity Act, the FDA may require pediatric assessment of certain drugs unless waived or deferred due to the fact that necessary studies are impossible or highly impractical to conduct or where the drug is not likely to be used in a substantial number of pediatric patients. In addition, the FDA may require a sponsor to implement a Risk Evaluation Mitigation Strategy ("REMS"), a strategy to manage a known or potential serious risk associated with the product. Failure to comply with REMS requirements may result in civil penalties. Further, if an approved product encounters any safety or efficacy issues, including drug interaction problems, the FDA has broad authority to force the sponsor to take any number of actions, including but not limited to, undertaking post approval clinical studies, implementing labeling changes, adopting a REMS, issuing DHPC letters, or removing the product from the market.

FDA Regulation of our Products and Services

FDA Regulation of Product Marketing and Promotion

The FDA also regulates all advertising and promotional activities for prescription drugs, both prior to and after approval. Approved drug products must be promoted in a manner consistent with their terms and conditions of approval, including the scope of their approved use. The FDA may take enforcement action against a company for promoting unapproved uses of a product, or off label promotion, or for other violations of its advertising and labeling laws and regulations. Failure to comply with these requirements could lead to, among other things, adverse publicity, product seizures, civil or criminal penalties, or regulatory letters, which may include warnings and require corrective advertising or other corrective communications to healthcare professionals.

Under the Subpart H regulations, until the Makena confirmatory post marketing clinical trial is completed, we are subject to a special 30 day promotional material review by the FDA's Office of Promotional Drug Products. This extra requirement means that there is a longer lead time before we are able to introduce new promotional material to the market for Makena and we are subject to increased scrutiny prior to using promotional pieces to ensure fair balance.

FDA Regulation of Manufacturing Facilities

Manufacturing procedures and quality control for approved drugs must conform to cGMP. Domestic manufacturing establishments must follow cGMP at all times, and are subject to periodic inspections by the FDA in order to assess, among other things, cGMP compliance. In addition, prior to approval of an NDA or sNDA, the FDA will perform a pre approval inspection of the sponsor's manufacturing facility, including its equipment, facilities, laboratories and

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processes, to determine the facility's compliance with cGMP and other rules and regulations. Vendors that supply finished products or components to the sponsor that are used to manufacture, package, and label products are subject to similar regulation and periodic inspections. If the FDA identifies deficiencies during an inspection, it may issue a formal notice, which may be followed by a warning letter if observations are not addressed satisfactorily. FDA guidelines specify that a warning letter be issued only for violations of "regulatory significance" for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action. For example, as discussed above, Lumara Health is subject to certain continuing obligations under the Consent Decree, including, but not limited to, inspection of Lumara Health's places of business by the FDA without prior notice, and notification of FDA of particular actions and events. If Lumara Health fails to comply with applicable provisions in the Consent Decree, the FDC Act, or the FDC Act's implementing regulations, the FDA may impose specific sanctions including, but not limited to, the requirement to cease any of Lumara Health's manufacturing operations, the imposition of substantial financial penalties, and the requirement to implement additional corrective actions.

Product approval may be delayed or denied due to cGMP non compliance or other issues at the sponsor's manufacturing facilities or contractor sites or suppliers included in the NDA or sNDA, and the complete resolution of these inspectional findings may be beyond the sponsor's control. If the FDA determines that the sponsor's equipment, facilities, laboratories or processes do not comply with applicable FDA regulations and conditions of product approval, the FDA may seek civil, criminal or administrative sanctions and/or remedies against the sponsor, including suspension of its manufacturing operations.

Orphan Drug Exclusivity

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, defined, in part, as a patient population of fewer than 200,000. The company that first obtains FDA approval for a designated orphan drug for the specified rare disease or condition receives orphan drug marketing exclusivity for that drug for a period of seven years. This orphan drug exclusivity prevents the FDA from approving another application for the same drug for the same orphan indication during the exclusivity period, except in very limited circumstances. A designated orphan drug may not receive orphan drug exclusivity for an approved indication if that indication is for the treatment of a condition broader than that for which it received orphan designation. In addition, orphan drug exclusivity marketing rights may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Finally, the FDA may approve a subsequent drug that is otherwise the same as a currently approved orphan drug for the same orphan indication during the exclusivity period if the sponsor of the subsequent drug can demonstrate that the drug is clinically superior to the already approved drug. According to the FDA, clinical superiority may be demonstrated by showing that a drug is more effective in a clinical trial, safer in a substantial portion of the target population, or provides a major contribution to patient care relative to the currently approved drug.

Drug Quality and Security Act

In November 2013, the DQSA legislation was implemented to amend the FDC Act with respect to the regulation and monitoring of the manufacturing of compounding drugs. Among other provisions of the DQSA, compounding pharmacies may now elect to register as an "outsourcing facility" under FDC Act 503B. Registration as an outsourcing facility requires that drugs be compounded according to cGMP standards; that facilities report adverse events to the FDA; and that facilities be subject to a risk based inspection schedule, among other requirements. Additionally, FDC

Act 503A describes the conditions that must be satisfied for drug products compounded by a licensed pharmacist or licensed physician to be exempt from approval, labeling, and cGMP requirements. To qualify for these exemptions, a compounded drug product must, among other things, be compounded for an identified patient based on a valid prescription or in limited quantities before the receipt of a prescription for such individual patient in certain circumstances. Under both 503A and 503B of the FDC Act, compounding pharmacies may not compound regularly or in inordinate amounts any drug products that are "essentially copies of commercially available drug products."

Fraud and Abuse Regulation

Our general operations, and the research, development, manufacture, sale, and marketing of our products, are subject to extensive federal and state regulation, including but not limited to FDA regulations, the Federal Anti Kickback Statute ("AKS"), the Federal False Claims Act ("FCA"), and the Foreign Corrupt Practices Act ("FCPA"), and their state

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analogues, and similar laws in countries outside of the U.S., laws governing sampling and distribution of products and government price reporting laws.

- The AKS makes it illegal to knowingly and willfully solicit, offer, receive, or pay any remuneration, directly or indirectly, in cash or in kind, in exchange for, or to induce, purchasing, ordering, arranging for, or recommending the purchase or order of any item or service, including the purchase or prescription of a particular drug, that is reimbursed by a federal healthcare program. Liability may be established without proving actual knowledge of the statute or specific intent to violate it. In addition, federal law now provides that the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA, described below. Violations of the AKS carry potentially significant civil and criminal penalties, including imprisonment, fines, and exclusion from participation in federal healthcare programs. Many states have enacted similar anti kickback laws, including in some cases laws that prohibit paying or receiving remuneration to induce a referral or recommendation of an item or service reimbursed by any payer, including private payers.

- The FCA prohibits, among other things, anyone from knowingly presenting, or causing to be presented, claims for reimbursement of drugs or services to third party payers such as Medicare or Medicaid, or other claims for payment of government funds, where those claims are false or fraudulent. The FCA also prohibits knowingly making, using, or causing to be made or used a false record or statement material to an obligation to pay money to the government or knowingly concealing, or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. The FCA permits a private individual acting as a “whistleblower” to bring an action on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. Government enforcement agencies and private whistleblowers have asserted liability under the FCA for, among other things, claims for items or services not provided as claimed or for medically unnecessary items or services, kickbacks, promotion of off label uses, and misreporting of drug prices to federal agencies. Many states have enacted similar false claims laws, including in some cases laws that apply where a claim is submitted to any third party payer, not just government programs.
- The FCPA prohibits companies and their intermediaries from making, or offering or promising to make improper payments to non U.S. officials for the purpose of obtaining or retaining business or otherwise seeking favorable treatment.

Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. Federal and state authorities continue to devote significant attention and resources to enforcement of these laws within the pharmaceutical industry, and private individuals have been active in bringing lawsuits on behalf of the government under the FCA. We have developed and implemented a corporate compliance program based on what we believe are current best practices in the pharmaceutical industry; however, these laws are broad in scope and there may not be regulations, guidance, or court decisions that definitively interpret these laws in the context of particular industry practices. We cannot guarantee that we, our employees, our consultants, or our contractors are or will be in compliance will all federal, state, and foreign regulations. If we or our representatives fail to comply with any of these laws or regulations, a range of fines, penalties, and/or other sanctions could be imposed on us, including, but not limited to, restrictions on how we market and sell our products, significant fines, exclusions from government healthcare programs, including Medicare and Medicaid, litigation, or other sanctions. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could also have an adverse effect on our business, financial condition and results of operations. Such investigations or suits may also result in related shareholder lawsuits, which can also have an adverse effect on our business.

Other U.S. Regulatory Requirements

In recent years, several states have enacted legislation requiring pharmaceutical companies operating within the state to establish marketing and promotional compliance programs or codes of conduct and/or file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities. In addition, as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the “Healthcare Reform Act”) manufacturers of drugs and medical devices are required to publicly report gifts

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and other payments or transfers of value made to U.S. physicians and teaching hospitals. Several states have also adopted laws that prohibit certain marketing related activities, including the provision of gifts, meals or other items to certain healthcare providers. Many of these requirements are new and uncertain, and the likely extent of future enforcement for failure to comply with these requirements is unclear. However, compliance with these laws is difficult, time consuming, and costly, and if we are found not to be in full compliance with these laws, we may face enforcement actions, fines, and other penalties, and we could receive adverse publicity which could have an adverse effect on our business, financial condition, and results of operations.

We are also subject to data protection laws and regulations (i.e., laws and regulations that address privacy and data security). The legislative and regulatory landscape for data protection continues to evolve, and in recent years there has been an increasing focus on privacy and data security issues. In the U.S., numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of health-related and other personal information. Failure to comply with data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. In addition, we may obtain health information from third parties (i.e., healthcare providers who prescribe our products) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act ("HIPAA"). Although we are not directly subject to HIPAA (other than potentially with respect to providing certain employee benefits) we could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA - covered entity in a manner that is not authorized or permitted by HIPAA. We are also subject to laws and regulations covering data privacy and the protection of health-related and other personal information. We obtain patient health information from most healthcare providers who prescribe our products and research institutions we collaborate with, and they are subject to privacy and security requirements that may affect us. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. For example, through April 29, 2033, CBR is required to comply with a Federal Trade Commission ("FTC") Order (the "FTC Order"). The FTC Order requires CBR, among other things, to implement and maintain a comprehensive information security program and conduct a biennial assessment of its information security program. CBR is also required not to make any misrepresentations, expressly or by implication, regarding its privacy practices or its information security program. The costs of compliance with, and other burdens imposed by, these obligations are substantial and may impede our performance and our ability to develop the CBR Services, or lead to significant fines, penalties or liabilities for noncompliance.

Regulation of Cord Blood and Cord Tissue Banking

Human tissues intended for transplantation, including umbilical cord blood stem cells and cord tissue, are subject to comprehensive regulations that address activities associated with human cells, tissues and cellular and tissue-based products ("HCT/Ps"). One set of regulations requires that companies that engage in the recovery, processing, storage, labeling, packaging, or distribution of any HCT/Ps, or the screening or testing of a cell or tissue donor, register with the FDA. This set of regulations also includes the criteria that must be met in order for the HCT/P to be eligible for distribution solely under Section 361 of the Public Health Service Act (the "PHSA"), and the regulations in 21 CFR Part 1271, rather than under the drug or device provisions of the FDC Act or the biological product licensing provisions of the PHSA. Another set of regulations provides criteria that must be met for donors to be eligible to donate HCT/Ps and is referred to as the "Donor Eligibility" rule. A third set of provisions governs the processing and distribution of the tissues and is often referred to as the "Current Good Tissue Practices" rule. The Current Good Tissue Practices rule covers all stages of HCT/P processing, from procurement to distribution of final allografts. Together

these regulations are designed to ensure that sound, high quality practices are followed to reduce the risk of tissue contamination and of communicable disease transmission to recipients.

CBR is registered with the FDA as an HCT/P establishment that screens, packages, processes, stores, labels and distributes umbilical cord blood stem cell and cord tissue by virtue of the services it provides to expectant parents as a private cord blood and cord tissue bank. The FDA periodically inspects such registered establishments to determine compliance with HCT/P requirements. If the FDA determines that we have failed to comply with applicable regulatory

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requirements, or any future regulatory requirements or standards, it can impose or initiate a variety of enforcement actions, including but not limited to, public warning or untitled letters, written recall or destruction orders, written cease manufacturing orders, court-ordered seizures, injunctions, consent decrees, civil penalties, or criminal prosecutions.

Some states impose additional regulation and oversight of cord blood and cord tissue banks and of clinical laboratories operating within their borders and impose regulatory compliance obligations on out-of-state laboratories providing services to their residents, and many states in which we and our business partners operate have licensing requirements that must be complied with.

Medical Device Regulation

Medical devices, such as MuGard, are similarly subject to FDA approval and extensive post approval regulation under the FDC Act. Authorization to commercially distribute a new medical device in the U.S. is generally received in one of two ways. The first, known as premarket notification, or the 510(k) process, requires a sponsor to demonstrate that the new medical device is substantially equivalent to a legally marketed medical device that is not subject to premarket approval. The second, more rigorous process, known as premarket approval, requires a sponsor to independently demonstrate that the new medical device is safe and effective.

Both before and after a device is commercially released, there are ongoing responsibilities under FDA regulations. The FDA reviews design and manufacturing practices, labeling and record keeping, and manufacturers' required reports of adverse experiences and other information to identify potential problems with marketed medical devices, similar to the reviews conducted in connection with drug product discussed above. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, the FDA could require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health, order a recall, repair, replacement, or refund of such devices, detain or seize adulterated or misbranded medical devices, or ban such medical devices. The FDA may also impose operating restrictions, enjoin and/or restrain certain conduct resulting in violations of applicable law pertaining to medical devices and assess civil or criminal penalties against our officers, employees, or us.

MuGard was launched in the U.S. by Abeona in 2010 after receiving 510(k) clearance from the FDA. Under the terms of the MuGard License Agreement, Abeona continues to hold the 510(k). MuGard is categorized as a pre amendments device. This type of device has not been classified per se, but continues to be subject to regulatory review under the 510(k) premarket clearance process.

Pharmaceutical Pricing and Reimbursement

Our ability to successfully commercialize our products is dependent, in significant part, on the availability and extent of reimbursement to end-users from third-party payers for the use of our products, including governmental payers, health maintenance organizations ("HMOs"), managed care organizations, and private health insurers. The federal government provides health insurance for people who are 65 or older, and certain people with disabilities or certain conditions, irrespective of their age through the Medicare program, and administered by the Centers for Medicare and Medicaid Services ("CMS"). Certain prescription drugs, including Makena and Feraheme, are covered under Medicare Part B. Coverage and reimbursement for products and services under Medicare are determined in accordance with the Social Security Act and pursuant to regulations promulgated by CMS, as well as the agency's subregulatory coverage and reimbursement guidance and determinations. Medicaid is a health insurance program for low-income children, families, pregnant women, and people with disabilities that is jointly funded by the federal and state governments, but administered by the states. In general, state Medicaid programs are required to cover drugs and biologicals of manufacturers that have entered into a Medicaid Drug Rebate Agreement, although such products and biologicals may be subject to prior authorization or other utilization controls. CMS also administers the Medicaid program.

We participate in and have certain price reporting obligations to the Medicaid Drug Rebate program, and we have obligations to report Average Sales Price ("ASP") for the Medicare program. Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made

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available to the states for our drugs under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS. These data include the average manufacturer price ("AMP") and, in the case of innovator products such as Makena and Feraheme, the best price for each drug.

Federal law also requires that a company that participates in the Medicaid Drug Rebate program report ASP information to CMS for certain categories of drugs that are paid under Part B of the Medicare program, such as Makena and Feraheme. This ASP information forms the basis for reimbursement for the majority of our current Feraheme business, and to a lesser extent, for our Makena business. Manufacturers calculate ASP based on a statutorily defined formula and interpretations of the statute by CMS as to what should or should not be considered in computing ASP. An ASP for each National Drug Code for a product that is subject to the ASP reporting requirement must be submitted to CMS no later than 30 days after the end of each calendar quarter. CMS uses these submissions to determine payment rates for drugs under Medicare Part B. Changes affecting the calculation of ASP could affect the ASP calculations for our products and the resulting Medicare payment rate, and could negatively impact our results of operations.

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B drug pricing program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low income patients. The 340B ceiling price is calculated using a statutory formula, which is based on AMP and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program. As described below, the Healthcare Reform Act introduced changes to the definition of AMP and the Medicaid rebate formula and made changes to the 340B drug pricing program as well. These changes could affect our 340B ceiling price calculations and negatively impact our results of operations.

The Healthcare Reform Act also expanded the Public Health Service's 340B drug pricing program to include additional types of covered entities: certain free standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the Healthcare Reform Act. For example, the percentage of Feraheme sold to 340B institutions has grown from 11% in 2011 to 20% in 2015. Since these institutions are granted lower prices than those offered to our other customers, any further growth in our 340B business may have a negative impact on our sales price per gram and operating margins. The Healthcare Reform Act exempts "orphan drugs," such as Makena, from the ceiling price requirements for the covered entity types newly added to the program by the Healthcare Reform Act.

The Healthcare Reform Act obligates the Health Resources and Services Administration ("HRSA"), the agency that administers the 340B program, to create regulations and processes to improve the integrity of the 340B drug pricing program and to update the agreement that manufacturers must sign to participate in the 340B drug pricing program to obligate a manufacturer to offer the 340B price to covered entities if the manufacturer makes the drug available to any other purchaser at any price and to report to the government the ceiling prices for its drugs. HRSA recently issued a

proposed regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, as well as proposed omnibus guidance that addresses many aspects of the 340B drug pricing program, including a proposed expansion of manufacturer recordkeeping requirements and 340B ceiling price restatement and refund obligations. HRSA is currently expected to issue additional proposed regulations in 2016. Any final regulations and guidance could affect our obligations under the 340B drug pricing program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B drug pricing program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting. Additionally, in order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we participate in the Department of Veterans Affairs(the “VA”), Federal Supply Schedule (the “FSS”) pricing program. As part of this program, we are obligated to make our products available for procurement on an FSS contract under which we must comply with standard government terms and conditions and charge a price that is no higher than the statutory Federal Ceiling Price (the FCP”) to four federal agencies (VA, U.S. Department of Defense, DoD, Public Health Service, and Coast Guard, the “Big Four”). The FCP is based on the non-federal AMP (the “Non-FAMP”), which we calculate and report to the VA on a quarterly and annual

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basis. Pursuant to applicable law, knowing provision of false information in connection with a Non-FAMP filing can subject a manufacturer to penalties of $100,000 for each item of false information. These obligations also contain extensive disclosure and certification requirements. Under Section 703 of the National Defense Authorization Act for Fiscal Year 2008, we are also required to pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP. Covered products must be listed on a Tricare Retail Pricing Agreement in order for these products to be eligible for DoD formulary inclusion. We have entered into, and list all of our covered drugs on, a Tricare Retail Pricing Agreement with the Defense Health Agency.

Reimbursement by third party payers depends on a number of factors, including the third party's determination that the product is competitively priced, safe and effective, appropriate for the specific patient, and cost effective. Third party payers are increasingly challenging the prices charged for pharmaceutical products, and have instituted and continue to institute cost containment measures to control or significantly influence the purchase of pharmaceutical products. For example, to reduce expenditures associated with pharmaceutical products, many third party payers use cost containment methods, including: (a) formularies, which limit coverage for drugs not included on a predetermined list; (b) variable copayments, which may make a certain drug more expensive for patients as compared with a competing drug; (c) utilization management controls, such as requirements for prior authorization before the payer will cover the drug; and (d) other coverage policies that limit access to certain drugs for certain uses based on the payer specific coverage policy.

In addition, federal and state governments continues to attempt to curb healthcare costs through legislation, including legislation aimed at reducing the pricing and reimbursement of pharmaceutical products. The Healthcare Reform Act includes certain cost containment measures including an increase to the minimum rebates for products covered by Medicaid programs from 15.1% to 23.1% of AMP for most innovator products, and the expansion of the 340B Drug pricing program under the Public Health Service Act. Effective March 2010, the Healthcare Reform Act expanded manufacturer rebate liability under the Medicaid program from fee for service Medicaid utilization to include the utilization of Medicaid managed care organizations as well. In addition, the Healthcare Reform Act and subsequent legislation changed the definition of AMP. Further, federal budgetary concerns could result in the implementation of significant federal spending cuts, including cuts in Medicare and other health related spending in the near term. For example, past legislative enactments resulted in Medicare payments being subject to a two percent reduction, referred to as sequestration, until 2025. Finally, the Healthcare Reform Act required pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee of $3.0 billion in 2016, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. "Orphan drugs" are specifically defined for purposes of the fee. For each indication approved by the FDA for the drug, such indication must have been designated as orphan by the FDA under section 526 of the FDCA, an orphan drug tax credit under section 45C of the Internal Revenue Code must have been claimed with respect to such indication, and such tax credit must not have been disallowed by the Internal Revenue Service. Finally, the FDA must not have approved the drug for any indication other than an orphan indication for which a section 45C orphan drug tax credit was claimed (and not disallowed). Makena was excluded from the branded prescription drug fee in 2015.

On February 1, 2016, CMS, issued a final regulation to implement the changes to the Medicaid Drug Rebate components of the Medicaid Program under the Healthcare Reform Act. This regulation becomes effective on April 1,

2016. We are evaluating the impact of this regulation on our business and operations.

In addition, the heightened focus on the healthcare industry by the federal government could result in the implementation of significant federal spending cuts including cuts in Medicare and other health related spending in the near term. In recent years, some states have also passed legislation to control the prices of drugs as well as begun a move toward managed care to relieve some of their Medicaid cost burden. These and any future changes in government regulation or private third party payers' reimbursement policies may reduce the extent of reimbursement for our products and adversely affect our future operating results. For example, since almost half of Makena patients are Medicaid beneficiaries, the impact of future legislative changes may have a significant impact on Makena sales. Payers also are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price, average manufacturer price and actual acquisition cost. The existing data for reimbursement based on these metrics is relatively

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limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. CMS surveys and publishes retail community pharmacy acquisition cost information in the form of National Average Drug Acquisition Cost ("NADAC") files, which reflect retail community pharmacy invoice costs, and National Average Retail Price ("NARP") files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates. It may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payers to cover our products. Any failure to cover our products appropriately, in addition to legislative and regulatory changes and others that may occur in the future, could impact our ability to maximize revenues in the federal marketplace.

Currently, in physician clinic and hospital settings, Medicare Part B generally reimburses for physician administered drugs at a rate of 104.3% of the drug's ASP. ASP is defined by statute based on sales and price concession data, including rebates and chargebacks, for a defined period of time. As noted above, we submit the required information to CMS on a quarterly basis. In advance of the quarter in which the payment limit for drugs reimbursed under Medicare Part B program will go into effect, CMS calculates and publishes the payment limit. Under this methodology, payment rates change on a quarterly basis, and significant downward fluctuations in ASP, and therefore reimbursement rates, could negatively impact sales of a product. Because the ASP based payment rate is defined by statute, and changes to Medicare payment methodologies require legislative change, it is unclear if and when ASP reimbursement methodology will change for the physician office setting. While the statute requires Medicare Part B payments for most drugs furnished in the physician office setting to be at 104.3% of ASP, the statute does not have a similar requirement for hospital outpatient departments. For that setting, the Medicare payment for many covered Part B drugs also is at 104.3% of ASP, but CMS could change that through regulations, without any intervening legislation. While Medicare is the predominant payer for Feraheme for treatment of patients with CKD, Medicare payment policy, in time, can also influence pricing and reimbursement in the non Medicare markets, as private third party payers and state Medicaid plans frequently adopt Medicare principles in setting reimbursement methodologies. We cannot predict the impact that any changes in reimbursement policies may have on our ability to compete effectively.

For example, in the U.S. hospital inpatient setting, most drugs are not reimbursed separately within the Medicare prospective payment system, based largely on the drug costs, but are bundled as a per discharge reimbursement based on the diagnosis and/or procedure rather than actual costs incurred in patient treatments, thereby increasing the incentive for a hospital to limit or control expenditures. As a result, we do not expect premium priced products, such as Feraheme, to be broadly used in the hospital inpatient setting.

If adequate reimbursement levels are not maintained by government and other third party payers for our products, our ability to sell our products may be limited and/or our ability to establish acceptable pricing levels for our products may be impaired, thereby reducing anticipated revenues and our profitability.

Backlog

We had a $3.7 million and $4.3 million product sales backlog as of December 31, 2015 and 2014, respectively. We expect to recognize the $3.7 million in 2016, net of any applicable rebates or credits. These backlogs were largely due to timing of orders received from our third party logistics providers. Generally, product orders from our customers are fulfilled within a relatively short time of receipt of a customer order.

Employees

As of February 12, 2016, we had 552 employees. We also utilize consultants and independent contractors on a regular basis to assist in the development and commercialization of our products and services. Our success depends to a significant extent on our ability to continue to attract, retain and motivate qualified sales, technical and laboratory operations, managerial, scientific and medical personnel of all levels. Although we believe we have been relatively successful to date in obtaining and retaining such personnel, we may not be successful in the future. During 2015 and 2014, we expanded our leadership team and strengthened our commercial organization. We expect to continue these efforts in 2016 to support the growth of our business.

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None of our employees is represented by a labor union, and we consider our relationship with our employees to be good.

Foreign Operations

We have no foreign operations. Revenues from customers outside of the U.S. amounted to approximately 12%, 12% and 11% of our total revenues for 2015, 2014 and 2013, respectively, and were principally related to collaboration revenues recognized in connection with our former agreement with Takeda, which is headquartered in Japan, and which was terminated in June 2015 following a six-month transition period. We do not currently expect any material future sales outside of the U.S.

Research and Development

We have dedicated a significant portion of our resources over the last several years to our efforts to develop our products and product candidates, particularly Feraheme and beginning in 2015, Makena. We incurred research and development expenses of $42.9 million, $24.2 million, and $20.6 million during 2015, 2014 and 2013, respectively. We expect our research and development expenses to increase in 2016 due to the initiation in the first quarter of 2016 of a new 2,000 patient head-to head Phase 3 clinical trial evaluating Feraheme in adults with IDA, the ongoing clinical trials related to Makena's post-approval commitments, and the Makena next generation development programs.

Segment Reporting

We conduct our operations in one business segment as further described in Note O, "Business Segments," to our consolidated financial statements included in this Annual Report on Form 10 K.

Code of Ethics

Our Board of Directors has adopted a code of ethics that applies to our officers, directors and employees. We have posted the text of our code of ethics on our website at http://www.amagpharma.com in the "Investors" section. We will provide to any person without charge a copy of such code of ethics, upon request in writing to Investor Relations, AMAG Pharmaceuticals, Inc., 1100 Winter Street, Waltham, MA 02451. In addition, should any changes be made to our code of ethics, we intend to disclose within four business days on our website (or in any other medium required by law or the NASDAQ): (a) the date and nature of any amendment to our code of ethics that applies to our principal

executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (b) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver, and the date of the waiver.

Available Information

We are subject to the information and reporting requirements of the Securities Exchange Act of 1934, under which we file periodic reports, proxy and information statements and other information with the U.S. Securities and Exchange Commission (the "SEC"). Copies of these reports may be examined by the public without charge at 100 F. Street N.E., Room 1580, Washington D.C. 20549 or on the Internet at http://www. sec.gov. Copies of all or a portion of such materials can be obtained from the SEC upon payment of prescribed fees. Please call the SEC at 1-800-SEC-0330 for further information. Our internet website address is http://www.amagpharma.com. Through our website, we make available, free of charge, our annual reports on Form 10 K, quarterly reports on Form 10 Q, current reports on Form 8 K, proxy and registration statements, and all of our insider Section 16 reports (and any amendments to such filings), as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. These SEC reports can be accessed through the "Investors" section of our website. The information found on our website is not part of this or any other report we file with, or furnish to, the SEC. Paper copies of our SEC reports are available free of charge upon request in writing to Investor Relations, AMAG Pharmaceuticals, Inc., 1100 Winter Street, Waltham, MA 02451. The content on any website referred to in this Form 10 K is not incorporated by reference into this Form 10 K unless expressly noted.

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ITEM 1A. RISK FACTORS:

The following information sets forth material risks and uncertainties that may affect our business, including our future financial and operational results and could cause our actual results to differ materially from those contained in forward looking statements we have made in this Annual Report on Form 10 K and elsewhere as discussed in the introduction to Part I above. You should carefully consider the risks described below, in addition to the other information in this Annual Report on Form 10 K, before making an investment decision. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present material risks to our business at this time also may impair our business operations.

Risks Related to Our Products and Services

We are primarily dependent on revenues from our principal products and services.

We currently derive substantially all of our revenue from sales of Makena, services related to the collection, processing and storage of umbilical cord blood stem cell and cord tissue units (the "CBR Services") and Feraheme. Although we may introduce additional products or services for commercialization to our portfolio, we may be substantially dependent on sales of our current products and services for many years. Our financial condition will be materially adversely affected, we may have to restructure our current operations, and our business prospects will be limited if we experience any significant negative developments relating to our products or services, including the following:

Actual or perceived safety or efficacy issues;

Restrictions on current or future labels or other regulatory actions;

The introduction or greater acceptance of competing products or services, including generic products, products that may be prescribed off-label (i.e., outside of indications approved by the U.S. Food and Drug Administration (the "FDA")), products made by compounding pharmacies or cryopreservation services offered by other cord blood banks;

Change in consumers' perception of the value of the cryopreservation of cord blood and/or cord tissue;

Constraints on product or service pricing or the impact of price increases;

The success of our commercialization efforts, such as our ability to retain or grow our current customer base, realize the benefit of our current orphan drug exclusivity and successfully implement our next generation development programs; and

Changes in reimbursement policies or adverse regulatory or legislative developments.

If our products face any safety or efficacy issues, including drug interaction problems, under the Federal Food, Drug and Cosmetic Act (the "FDC Act"), the FDA has broad authority to force us to take any number of actions, including, but not limited to the following:

Requiring us to conduct post-approval clinical studies to assess known risks or new signals of serious risks, or to evaluate unexpected serious risks;

Mandating changes to a product’s label;

Requiring us to implement a risk evaluation and mitigation strategy ("REMS") where necessary to assure safe use of the drug; or

Removing an already approved product from the market.

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Further, until our recent acquisition of Cord Blood Registry ("CBR"), we had no experience providing services or maintaining a service-based business model. The success of our expanded enterprise will be dependent on our ability to manage and promote the CBR Services, which is subject to a number of risks and uncertainties, including our ability to maintain compliance with all applicable FDA or accrediting organization regulations, including those regarding cord blood and cord tissue collection, processing and storage services, the application to and implications for CBR's operations of certain laws, regulations and industry guidelines relating to healthcare or stem cell preservation companies, new and evolving regulatory restrictions on cord blood and cord tissue banking, and those other risks described below under Risks Related to CBR.

The commercial success of our products and services depends upon the level of market adoption and continued use by and the support of physicians, hospitals, patients, and/or healthcare payers, including government payers, health maintenance organizations ("HMOs"), consumers, managed care organizations and specialty pharmacies. Our products and services might not be adopted if perceived to be no safer, less safe, no more effective, less effective, no more convenient, less convenient, or less valuable than currently available products or services. In addition, the pricing and/or reimbursement rates and terms of our products may not be viewed as advantageous to potential prescribers, and payers as compared to the pricing and/or reimbursement rates and terms of other available products, including, generic products and in the case of Makena, compounded products. If our products or services do not achieve or maintain an adequate level of market adoption for any reason, our profitability and our future business prospects will be adversely impacted.

Competition in the pharmaceutical and biopharmaceutical industries, including from companies marketing generic products, is intense. In addition, competition in the cord blood stem cell and cord tissue banking processing and storage business is increasing. If we fail to compete effectively, our business and market position will suffer.

The pharmaceutical and cord blood banking industries are intensely competitive and subject to rapid technological change. For Makena, most of our competition comes from pharmacies that compound a non-FDA approved version of Makena, which is sold at a much lower list price than Makena. Many of our competitors for Feraheme are large, well-known pharmaceutical companies and may benefit from significantly greater financial, sales and marketing capabilities, greater technological or competitive advantages, and other resources. For the CBR Services, competition in the private cord blood and cord tissue banking business is already intense and is likely to increase as the number of competitors continues to grow, given the relatively low barriers to entry. Our existing or potential competitors may develop products or services that are more widely accepted than ours and may receive patent protection that dominates, blocks, makes obsolete or adversely affects our product development or business. The introduction by our competitors of alternatives to our products or services that would be, or are perceived to be, more efficacious, safer, less expensive, easier to administer, available for a broader patient population, provide more favorable insurance coverage, reimbursement or terms, or less valuable than currently available products or services could reduce our revenues and the value of our product development and commercialization efforts. For more information on specific competition risks for our products or services, please see Risk Factors "Our ability to successfully commercialize Makena is dependent upon a number of factors, including maintaining the benefits of Makena's orphan drug exclusivity and the length of time before competitors begin selling generic versions of Makena"; "Market acceptance of Feraheme may suffer as a result of the widespread use of competing iron replacement therapy products, including

Injectafer®, and as a result of the approval of generic drug products in the near-term, which would have a material adverse effect on our operations and our profitability"; and "Competition in the umbilical cord blood stem cell and cord tissue banking business is significant and may be increasing. If we are unable to maintain our position as the market leader, our CBR business may decline and our results of operations could suffer."

The success of our products depends on our ability to maintain the proprietary nature of our technology.

We rely on a combination of patents, trademarks and trade secrets in the conduct of our business. The patent positions of pharmaceutical and biopharmaceutical firms are generally uncertain and involve complex legal and factual questions. We may not be successful or timely in obtaining any patents for which we submit applications. The breadth of the claims obtained in our patents may not provide sufficient protection for our technology. The degree of protection afforded by patents for proprietary or licensed technologies or for future discoveries may not be adequate to preserve our ability to protect or commercially exploit those technologies or discoveries. The patents issued to us may provide us with

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little or no competitive advantage. In addition, there is a risk that others will independently develop or duplicate similar technology or products or circumvent the patents issued to us.

One of our U.S. Feraheme patents is subject to a patent term extension under U.S. patent law and FDA regulations and will expire in June 2023. Our other U.S. patents relating to Feraheme expire in 2020. These and any other patents issued to or acquired by us may be contested or invalidated. There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. We may become a party to intellectual property litigation and other proceedings, including interference and reexamination proceedings declared by the United States Patent and Trademark Office. For example, on February 5, 2016, we received a Paragraph IV certification notice letter regarding an Abbreviated New Drug Application (“ANDA”) submitted to the FDA by Sandoz Inc. (“Sandoz”) requesting approval to engage in commercial manufacture, use and sale of a generic version of Feraheme (ferumoxytol), and we could therefor face generic competition in the near term. In its notice letter, Sandoz claims that our ferumoxytol patents are invalid, unenforceable and/or not infringed by Sandoz’s manufacture, use, sale or offer for sale of the generic version. We plan to initiate a patent infringement suit to defend the patents identified in the notice letter within 45 days after our receipt of the notice letter. Once such suit is commenced within this 45-day period, the FDA would be prevented from approving the ANDA until the earlier of 30 months or entry of a district court decision finding the patents invalid or not infringed. Such litigation is often time-consuming and costly, and may result in generic competition if such patents are not upheld or if the generic competitor is found not to infringe such patents. Further, Sandoz’s application could encourage other generic entrants seeking a path to approval of a generic ferumoxytol to file an ANDA. Even if we are successful, such litigation will be expensive and will consume considerable time and other resources, which could materially and adversely impact business. In addition, there are no patents covering Makena and thus the successful commercialization of Makena is significantly reliant on our ability to take advantage of its orphan drug exclusivity, which risks are described in the Risk Factor - Risks Related to Makena -"Our ability to successfully commercialize Makena is dependent upon a number of factors, including maintaining the benefits of Makena's orphan drug exclusivity and the length of time before competitors begin selling generic versions of Makena."

In addition, claims of infringement or violation of the proprietary rights of others may be asserted against us. If we are required to defend against such claims or to protect our own proprietary rights against others, it could result in substantial financial and business costs, including the distraction of our management. An adverse ruling in any litigation or administrative proceeding could result in monetary damages, injunctive relief or otherwise harm our competitive position, including by limiting our marketing and selling activities, increasing the risk for generic competition, limiting our development and commercialization activities or requiring us to obtain licenses to use the relevant technology (which licenses may not be available on commercially reasonable terms, if at all).

We also rely upon unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our corporate licensees, collaborators, contract manufacturers, employees and consultants. These agreements, however, may be breached. We may not have adequate remedies for any such breaches, and our trade secrets might otherwise become known or might be independently discovered by our competitors. In addition, we cannot be certain that others will not independently develop substantially equivalent or superseding proprietary technology, or that an equivalent product or service will not be marketed in competition with our products, thereby substantially reducing the value of our proprietary rights.

We may not be able to further expand our portfolio by entering into additional business development transactions, such as in-licensing arrangements, acquisitions, or collaborations or, if such arrangements are entered into, we may not realize the anticipated benefits and they could disrupt our business, decrease our profitability, result in dilution to our stockholders or cause us to incur significant additional debt or expense.

As part of our business strategy to expand our portfolio, we are seeking to in-license or acquire additional pharmaceutical products or companies that leverage our corporate infrastructure and commercial expertise, such as the recent acquisitions of Lumara Health Inc. ("Lumara Health") and CBR. We have limited experience with respect to these business development activities and there can be no assurance that we will be able to identify or complete any additional transactions in a timely manner, on a cost-effective basis, or at all.

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Further, the valuation methods that we use for any acquired product or business require significant judgment and assumptions. Actual results and performance of the products or businesses that we may acquire, including anticipated synergies and other financial benefits, could differ significantly from our original assumptions, especially during the periods immediately following the closing of the transaction. In addition, acquisitions may cause significant changes to our current organization and operations, may subject us to more rigid or constraining regulations or government oversight and may have negative tax and accounting consequences. These results could have a negative impact on our financial position or results of operations and result in significant charges in future periods.

In addition, proposing, negotiating and implementing collaborations, in-licensing arrangements or acquisition agreements is a lengthy and complex process. Other companies, including those with substantially greater financial, marketing and sales resources, may compete with us for these arrangements, and we may not be able to enter into such arrangements on acceptable terms or at all. Further, any such strategic transactions by us could result in large and immediate write-offs or the incurrence of additional debt and contingent liabilities, each of which may contain restrictive covenants that could adversely impact or limit our ability to grow our business, enter into new agreements, and adversely affect our operating results. Management of a license arrangement, collaboration, or other strategic arrangement and/or integration of an acquired asset or company may also disrupt our ongoing business and require management resources that otherwise would be available for ongoing development of our existing enterprise.

In addition, our cash, cash equivalents and investments may not be sufficient to finance any additional strategic transactions, and we may choose to issue shares of our common or preferred stock as consideration, which would result in dilution to our stockholders. Alternatively, it may be necessary for us to raise additional funds through public or private financings, and such additional funds may not be available on terms that are favorable to us, if at all, and our stockholders may experience significant dilution. For example, our term loan facility, which provided us with $350.0 million to finance a portion our CBR acquisition (the "2015 Term Loan Facility") contains restrictions on our ability to acquire additional pharmaceutical products and companies, to consummate mergers, to enter into exclusive licensing arrangements, to incur or guarantee additional indebtedness, to create liens, to transfer or sell assets, to pay dividends and to engage in businesses other than our current businesses. The 2015 Term Loan Facility will also require us to use a portion of our free cash flow to repay indebtedness under the facility on an annual basis. These provisions, and similar restrictions contained in the indenture governing our 2023 Senior Notes, described below, may limit our ability to pursue attractive business development opportunities. If we are unable to successfully obtain rights to suitable products or if any acquisition or in-license arrangement we make is not successful, our business, financial condition and prospects for growth could suffer.

Further, even if we do acquire additional products or businesses, the integration of the operations of such acquired products or businesses requires significant efforts, including the coordination of information technologies, sales and marketing, operations, manufacturing, safety and pharmacovigilance, medical, finance and business systems and processes. These efforts result in additional expenses and involve significant amounts of management's time. For example, with the acquisition of CBR in August 2015, our business is significantly larger and more complex than it had been prior to the acquisition. Our future success will significantly depend upon our ability to manage our expanded enterprise, including multiple locations, which will pose substantial challenges for management, including challenges related to the management and monitoring of new operations and associated increased costs and

complexity.

In addition, we may have to rely on the other parties with whom we may enter into a future agreement to perform certain regulatory filings, oversee certain functions, such as pharmacovigilance or the manufacture of the product we license from them, and any failure of such party to perform these functions for any reason, including ceasing doing business, could have a material effect on our ability to commercialize the licensed product. For example, as the CBR service-based business model is substantially different from that of our historical business model, which was focused on product sales, we are dependent upon the contributions of the CBR organization, including key CBR personnel and CBR's pre-acquisition relationships, to drive CBR revenues, and we may be unable to continue to retain the commercial organization, including key personnel, or successfully maintain the relationships CBR had in place at the time of the closing of the acquisition. In addition, different skills and training are required for the promotion of a therapeutic product compared to a service business, and our revenues could suffer if this integrated sales force is unable

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to successfully promote a portfolio of products and services, especially since they may have limited experience with promoting both a therapeutic and a service business.

If we cannot successfully integrate businesses or products we may acquire or in-license into our company, we may experience material negative consequences to our business, financial condition or results of operations. We cannot be certain that, following any such acquisitions or in-licenses we will achieve the expected synergies and other benefits that justify the purchase price of such transaction.

We are completely dependent on third parties to manufacture our commercial products and any difficulties, disruptions or delays, or the need to find alternative sources, could adversely affect our profitability and future business prospects.

We do not own or operate, and currently do not plan to own or operate, facilities for the manufacture of our products or for any commercial products we may acquire or in-license. We rely solely on third-party contract manufacturers to manufacture our products for our commercial and clinical use and for certain materials required to support our CBR Services. We may not be able to enter into agreements with second source manufacturers whose facilities and procedures comply with current good manufacturing practices ("cGMP") regulations and other regulatory requirements on a timely basis and with terms that are favorable to us, if at all. For example, Hospira, Inc. (“Hospira”) is our sole source manufacturer of Makena and our Development and Supply Agreement with Hospira could terminate as early as December 31, 2016 in the case of the single-dose formulation and as early as December 31, 2017 for the multidose formulation. We cannot make any guarantees that we will be able to extend the term of this agreement on favorable terms, if at all.

Our ability to have our products manufactured in sufficient quantities and at acceptable costs to meet our commercial demand and clinical development needs is dependent on the uninterrupted and efficient operation of our third-party contract manufacturing facilities. Any difficulties, disruptions or delays in the manufacturing process could result in product defects or shipment delays, suspension of manufacturing or sale of the product, recall or withdrawal of product previously shipped for commercial or clinical purposes, inventory write-offs or the inability to meet commercial demand in a timely and cost-effective manner. Furthermore, our current third-party product manufacturers do not manufacture for us exclusively and may exhaust some or all of their resources meeting the demand of other customers. In addition, securing additional third-party contract manufacturers will require significant time for transitioning the necessary manufacturing processes, gaining regulatory approval, and for having the appropriate oversight and may increase the risk of certain problems, including cost overruns, process reproducibility, stability issues, the inability to deliver required quantities of product that conform to specifications in a timely manner, or the inability to manufacture our products or the propriety materials for our services in accordance with cGMP.

Further, we and our third-party product manufacturers currently purchase certain raw and other materials used to manufacture our products from third-party suppliers and, at present, do not have long-term supply contracts with most of these third parties. These third-party suppliers may cease to produce the raw or other materials used in Feraheme

and Makena or otherwise fail to supply these materials to us or our third-party manufacturers or fail to supply sufficient quantities of these materials to us or our third-party manufacturers in a timely manner for a number of reasons, including but not limited to the following:

- Adverse financial developments at or affecting the supplier;
- Unexpected demand for or shortage of raw or other materials;
- Regulatory requirements or action;
- An inability to provide timely scheduling and/or sufficient capacity;
- Manufacturing difficulties;
- Changes to the specifications of the raw materials such that they no longer meet our standards;

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Lack of sufficient quantities or profit on the production of raw materials to interest suppliers;

Labor disputes or shortages; or

Import or export problems.

Any other interruption in our third-party supply chain could adversely affect our ability to satisfy commercial demand and our clinical development needs for our products. For example, although we believe we have sufficient Makena drug substance in inventory to meet demand until we can qualify a new drug substance manufacturer, we do not currently have a manufacturer for the production of Makena drug substance. The qualification of an alternative source may require repeated testing of the new materials and generate greater expenses to us if materials that we test do not perform in an acceptable manner. In addition, we or our third-party manufacturers sometimes obtain raw or other materials from one vendor only, even where multiple sources are available, to maintain quality control and enhance working relationships with suppliers, which could make us susceptible to price inflation by the sole supplier, thereby increasing our production costs. As a result of the high-quality standards imposed on our raw or other materials, we or our third-party manufacturers may not be able to obtain such materials of the quality required to manufacture Feraheme or Makena from an alternative source on commercially reasonable terms, or in a timely manner, if at all.

We also rely upon third-party contractors to assist in supporting the CBR Services, including to supply proprietary materials, some of which are sole source providers who we believe may have financial difficulty and be unable to fulfill their contractual obligations to us. Although we believe we have sufficient contingency plans in place, if current suppliers need to be changed or are disrupted, especially our sole source providers, we could face operational delays and lost revenue, as well as the need to reconfigure machinery and/or systems, which could be costly.

If, because of the factors discussed above, we are unable to have our products manufactured on a timely or sufficient basis, or if our supply chain attendant to the CBR Services is disrupted, we may not be able to meet commercial demand or our clinical development needs for our products, may not be able to manufacture Makena or Feraheme in a cost-effective manner or may be unable to adequately provide the CBR Services. As a result, we may lose sales, fail to generate increased revenues or suffer regulatory setbacks, any of which could have an adverse impact on our profitability and future business prospects.

We rely on third parties in the conduct of our business, including our clinical trials and product distribution, and if they fail to fulfill their obligations, our commercialization and development plans may be adversely affected.

We rely on and intend to continue to rely on third parties, including clinical research organizations ("CROs"), healthcare providers, third-party logistics providers, packaging, storage and labeling providers, wholesale distributors and certain other important vendors and consultants in the conduct of our business. For example, third-parties who perform tests on behalf of CBR are responsible for performing such testing in compliance with the FDA regulations that govern those functions. CBR is dependent upon the actions of these third parties with whom CBR contracts. If these third parties fail to comply with applicable requirements, the CBR Services will be negatively affected and at risk of FDA enforcement action, and our business could be negatively affected.

In addition, we have contracted and plan to continue to contract with certain third parties to provide certain services, including site selection, enrollment, monitoring, data management and other services, in connection with the conduct of our clinical trials and the preparation and filing of our regulatory applications. Although we depend heavily on these parties, we do not control them and, therefore, we cannot ensure that these third parties will adequately and timely perform all of their obligations to us. If our third-party service providers cannot adequately fulfill their obligations to us in a timely and satisfactory manner, if the quality and accuracy of our clinical trial data or our regulatory submissions are compromised due to poor quality or failure to adhere to our protocols or regulatory requirements, or if such third parties otherwise fail to adequately discharge their responsibilities or meet deadlines, our current and future development plans and regulatory submissions, or our commercialization efforts in current indications and with the CBR Services, may be delayed, terminated, limited or subject us to additional expense or regulatory action, which would adversely impact our ability to generate revenues.

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Further, in most cases, we do not currently have back-up suppliers or service providers to perform these tasks. If any of these third parties experience significant difficulties in their respective processes, fail to maintain compliance with applicable legal or regulatory requirements, fail to meet expected deadlines or otherwise do not carry out their contractual duties to us, or encounter physical or natural damages at their facilities, our ability to deliver our products to meet commercial demand could be significantly impaired. The loss of any of our third-party providers, especially if compounded by a delay or inability to secure an alternate distribution source for end-users in a timely manner, could cause the distribution of our products to be delayed or interrupted, which would have an adverse effect on our business, financial condition and results of operations.

Additionally, we have limited experience independently commercializing multiple pharmaceutical products and services, including managing and maintaining a supply chain and distribution network for multiple products and the CBR Services, and we are placing substantial reliance on third parties to perform this expanded network of supply chain and distribution services for us. Any failure on our part to effectively execute on our portfolio-wide commercial plans or to effectively manage our supply chain and distribution networks would have an adverse impact on our business.

We depend, to a significant degree, on the availability and extent of reimbursement from third-party payers for the use of our products, and a reduction in the availability or extent of reimbursement could adversely affect our revenues and results of operations.

Our ability to successfully commercialize our products is dependent, in significant part, on the availability and extent of reimbursement to end-users from third-party payers for the use of our products, including governmental payers, HMOs, managed care organizations and private health insurers. Reimbursement by third-party payers depends on a number of factors, including the third-party's determination that the product is competitively priced, safe and effective, appropriate for the specific patient, and cost-effective. Third-party payers are increasingly challenging the prices charged for pharmaceutical products and have instituted and continue to institute cost containment measures to control or significantly influence the purchase of pharmaceutical products, such as through the use of prior authorizations and step therapy. Certain specialty pharmaceuticals, pharmaceutical companies and pricing strategies have been the subject of increased scrutiny and criticism by politicians and the media, which could also increase pricing pressure throughout the industry or lead to new legislation that may limit our pricing flexibility. If these third-party payers do not provide coverage and reimbursement for our products or provide an insufficient level of coverage and reimbursement, physicians and other healthcare providers may choose to use alternative products, which would have an adverse effect on our ability to generate revenues.

In addition, the U.S. government continues to propose and pass legislation designed to reduce the cost of healthcare for patients. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "Healthcare Reform Act") includes certain cost containment measures including an increase to the minimum rebates for products covered by Medicaid programs, the extension of such rebates to drugs dispensed to Medicaid beneficiaries enrolled in Medicaid managed care organizations and the

expansion of the 340B Drug pricing Program under the Public Health Services Act. In addition, federal budgetary concerns could result in the implementation of significant federal spending cuts, including cuts in Medicare and other health related spending in the near-term. The magnitude of the impact of these laws on our business is uncertain. Further, in recent years, some states have also passed legislation to control the prices of drugs as well as begun a move toward managed care to relieve some of their Medicaid cost burden. Given that almost half of Makena patients are Medicaid beneficiaries, the impact of future legislative changes may have a significant and adverse impact on Makena sales. Further, while Medicare is the predominant payer for Feraheme, Medicare payment policy, in time, can also influence pricing and reimbursement in the non-Medicare markets, as private third-party payers and state Medicaid plans frequently adopt Medicare principles in setting reimbursement methodologies. These and any future changes in government regulation or private third-party payers' reimbursement policies may reduce the extent of reimbursement for our products and adversely affect our future operating results.

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Risks Related to Makena

Our ability to successfully commercialize Makena is dependent upon a number of factors, including maintaining the benefits of Makena's orphan drug exclusivity and the length of time before competitors begin selling generic versions of Makena.

Makena has been granted orphan drug exclusivity in the U.S. until February 3, 2018 for reducing the risk of preterm birth in women pregnant with a single baby who have a history of singleton spontaneous preterm birth. Our ability to successfully commercialize Makena is dependent upon maintaining Makena's orphan drug exclusivity. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, defined, in part, as a patient population of fewer than 200,000. The company that first obtains FDA approval for a designated orphan drug for the specified rare disease or condition receives orphan drug marketing exclusivity for that drug for a period of seven years. This orphan drug exclusivity prevents the FDA from approving another application for the same drug for the same orphan indication during the exclusivity period, except in very limited circumstances. A designated orphan drug may not receive orphan drug exclusivity for an approved indication if that indication is for the treatment of a condition broader than that for which it received orphan designation. In addition, Makena's orphan drug exclusivity may be lost if the FDA determines that our request for orphan designation was materially defective or if we are unable to assure sufficient quantity of Makena to meet the needs of patients. Furthermore, the FDA may approve a subsequent drug that is otherwise the same as Makena for the same orphan indication during the orphan drug exclusivity period if the sponsor of the subsequent drug can demonstrate that the drug is clinically superior to Makena. Clinical superiority may be demonstrated by showing that a drug is more effective in a clinical trial, safer in a substantial portion of the target population, or provides a major contribution to patient care relative to the currently approved drug.

Additionally, in 1956, the FDA approved the drug Delalutin, which contained the same active ingredient as Makena. Delalutin was approved for conditions other than reducing the risk of preterm birth and was marketed by Bristol-Myers Squibb ("BMS"). BMS stopped marketing and manufacturing Delalutin and it was withdrawn from the market in 1999. In 2010, the FDA determined that Delalutin was not withdrawn from sale for reasons of safety or efficacy. As such, generic drug applications may reference the withdrawn Delalutin New Drug Application ("NDA"). In August 2015, the FDA approved an ANDA for hydroxyprogesterone caproate ("HPC"), which was submitted by McGuff Pharmaceuticals, Inc. ("McGuff") in 2009, and which was subsequently transferred to Aspen Global Incorporated ("Aspen") in 2015. The ANDA label approved by the FDA for the McGuff product is for the same patient population and indications as Delalutin (i.e., it is approved only for use in non-pregnant women with indications such as uterine cancer or abnormal uterine bleeding). Aspen has indicated that it intends to make its generic version of Delalutin commercially available in the U.S. in 2016. Although Aspen's generic version of Delalutin is not indicated for pregnant women and is not therapeutically equivalent to Makena, doctors may elect to prescribe this product off-label for Makena's orphan-protected indication, which could have an adverse impact on our business and results of operations. In addition, if such generic Delalutin product is priced at a discount to Makena, commercial or government insurers could prefer or encourage the use of the generic Delalutin product for patients who are indicated for Makena.

Moreover, if one or more ANDA applicants were to receive approval to sell a generic or follow-on version of Makena for the orphan indication, those generic products could potentially be approved as early as February 3, 2018 (the date on which Makena's orphan exclusivity ends) and we would become subject to increased competition at that time.

Further, our ability to successfully commercialize Makena depends on a number of additional factors, including but not limited to the following:

- The possibility that the benefit of the remaining exclusivity period resulting from the designation of Makena as an orphan drug may not be realized as a result of on-label or off-label use by physicians of current or future FDA-approved drugs in the market where Makena competes;

- The level of enforcement by the FDA to ensure that compounded copies of commercially available FDA-approved products manufactured by compounding pharmacies, including compounded copies of Makena that may be in violation of the federal Drug Quality and Security Act (“DQSA”) and other relevant provisions of the FDC Act, are not produced and dispensed to patients;

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- The size of the pool of patients who meet the FDA-approved indication for Makena;

- The actual or perceived safety and efficacy of Makena;

- Our ability to increase patient compliance in line with the current label;

- Our ability to gain or maintain insurance coverage for Makena for patients through both commercial insurance companies and government programs such as Medicaid, and that such insurance coverage does not create difficulties for physicians or patients to gain access to Makena, such as through prior authorizations to non-preferred status on hospital or insurance formularies; and

- Our ability to successfully leverage our commercial organization and distribution networks in marketing, selling and supplying Makena.

Failure to achieve any or all of these commercial objectives could have an adverse material effect on the growth of Makena and our ability to achieve our revenue forecasts, which could impact our financial condition or results of operations.

We may not be successful in developing, gaining regulatory approval for and commercializing any products from Makena’s next generation development programs, which could have a negative impact on our business.

We are seeking to expand Makena's drug delivery technologies and formulations as part of our multi-pronged next generation development programs to deliver new and improved versions of Makena. The next generation development programs for Makena is an important strategy for our business, especially in light of the expiration of Makena's orphan drug exclusivity in February 2018, and the possibility that generic versions of Makena could enter the market following such loss of exclusivity.

For example, we are working to develop an auto-injector device for subcutaneous administration of Makena (the “auto-injector”), which could possibly provide Makena with additional exclusivity through the combination of potential additional orphan drug exclusivity and patent protection on the new dosing, route of administration and auto-injector. Although our current timelines anticipate a launch of the auto-injector prior to the loss of current exclusivity in February 2018, this is only an estimate and we can make no assurances that the development work necessary to obtain approval, including the results of planned bioequivalence clinical studies, will yield the anticipated results, or that the FDA will approve the auto-injector on the expected timelines or at all. Further, we can make no assurances that clinical data or other information that we generate or submit will be adequate for the FDA to grant new orphan drug exclusivity for the auto-injector. The degree of protection afforded by any intellectual property that we may in-license

or develop may not enable us to protect or commercially exploit the auto-injector technology, providing us with little or no competitive advantage. In addition, there is a risk that others may circumvent any patents licensed or issued to us relating to the auto-injector, including any intellectual property covering the injector device, or that another company may develop a product that circumvents any new orphan drug exclusivity.

We are relying on third-party manufacturers to aid in the design of the injector device as part of the auto-injector, and we may encounter difficulties finalizing a safe and effective subcutaneous delivery system design. Further, we are currently in discussions with third-party manufacturers to secure commercial supply of certain components and for assembly of the auto-injector. We may not be able to reach agreement on acceptable terms or encounter difficulties including problems involving scale-up, yields, quality control and assurance, product reliability, and manufacturing costs, any of which could result in significant delays in production.

As another example, we are in the early stages of developing a longer-acting formulation of Makena, that could potentially be eligible for orphan drug exclusivity. Because this is a new formulation of Makena, our path to gaining regulatory approval will require us to perform additional formulation work as well as pre-clinical and clinical studies attempting to demonstrate clinical safety and efficacy of the new formulation, rather than gaining approval by demonstrating bioequivalence with the current form of Makena. Furthermore, in order to be eligible for orphan

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exclusivity, we would likely need to demonstrate that this new formulation of Makena is clinically superior to the current form of Makena. Thus, pursuing the new formulation will require significant resources, financial and otherwise, over a considerable period of time. Despite our efforts, we may not be successful in developing the longer-acting formulation, including because the data obtained from any pre-clinical and clinical trials that we undertake may not generate anticipated results, may not demonstrate appropriate safety and efficacy, may be subject to varying interpretations and may not be deemed adequate by the FDA. Unexpected or unfavorable pre-clinical or clinical data can delay, limit or prevent regulatory approval. Failure to demonstrate clinical superiority to the current version of Makena will likely preclude the new formulation of Makena from being eligible for orphan drug exclusivity.

Even if we succeed in gaining FDA approval for an auto-injector or the new formulation for Makena, we will likely be competing against generics of the current formulation of Makena after February 2018. These generics could be less expensive than our potential new and improved version of Makena. As a result of the lower cost for the generics or a lack of perceived benefit of our new formulation of Makena, physicians may choose to prescribe the generic, which could cause sales of Makena to decline. In addition, insurance companies and government payors, such as state Medicaid agencies, who currently provide coverage for Makena may make it more difficult for physicians to prescribe our new version of Makena by charging higher copays, implementing prior authorizations, or not reimbursing for our new version at all. Furthermore, other companies are or may be working on developing additional formulations or routes of administration for products that reduce or prevent preterm birth. For example, an oral HPC is currently in development and its developer has stated that it intends to discuss a Phase 3 development plan with the FDA. If such products are approved, they could be, or be perceived to be, more efficacious, safer, less expensive, easier to administer, available for a broader patient population, or provide more favorable insurance coverage or reimbursement, and could reduce our revenues and the value of our product development efforts.

In addition, in February 2016, the FDA approved our prior approval supplement to the original Makena NDA, which we filed with the FDA in July 2015 seeking approval of a single-dose (1 mL) preservative-free formulation of Makena to be manufactured by Hospira, our current manufacturer of the multidose vial. We are also pursuing approval of our October 2014 prior approval supplement for Coldstream Laboratories, Inc. (“Coldstream”) to be approved to manufacture the single-dose preservative-free formulation. In May 2015, we received a complete response letter from the FDA for the Coldstream prior approval supplement requesting additional information related to manufacturing procedures for the single-dose preservative-free formulation at Coldstream and we are currently working with Coldstream to develop the required information requested by the FDA in the complete response letter in order to provide a response to the FDA. In light of the recent approval of the Hospira prior approval supplement, we are planning for a commercial launch of the single-dose preservative-free formulation in the second quarter of 2016. We can make no assurance that our commercialization plans for the single-dose preservative-free forrmulation of Makena will commence on the expected timeline, or at all, or that Coldstream will also be approved for its manufacture. Further, although we anticipate the single-dose preservative-free forrmulation of Makena will increase market acceptance of Makena, it will not extend our current exclusivity period or grant new exclusivity or provide new patent protection.

We have limited experience in the development of an auto-injector and alternative formulations for Makena and in developing and implementing next generation development programs. If we are not successful in implementing Makena’s next generation development programs, or if such activities cannot be completed on anticipated timelines,

our business will suffer.

If we are unsuccessful in differentiating Makena from compounded HPC products, sales of Makena, and thus our profitability, could be materially adversely affected.

Formulations of HPC have been available from compounding pharmacies for many years (which compounded formulations of HPC we refer to as "c17P") and will likely remain available even though Makena has been granted orphan drug exclusivity until February 3, 2018, and we have no prior experience with facing such competition. In March 2011, the FDA communicated to Lumara Health and also separately issued a press release that, in order to ensure continued access for patients, the FDA intended to refrain from taking enforcement action with respect to compounding pharmacies producing c17P in response to individual prescriptions for individual patients. The FDA's statement had an adverse effect on Lumara Health's ability to realize the benefit of orphan drug exclusivity and its ability to grow sales of Makena following the launch of the product in March 2011. The failure by the FDA to take enforcement action against

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compounding pharmacies resulted in substantial sales of compounded copies of Makena and the effective loss of the value of marketing exclusivity for the affected period of time. In June 2012, the FDA recommended using an FDA-approved drug product, such as Makena, instead of a compounded drug except when there is a specific medical need (i.e., an allergy) that cannot be met by the approved drug. In July 2014, the FDA issued another public statement affirming the position it took in its June 2012 statement recommending use of Makena except when there is a specific need for a compounded drug. The FDA also stated that when it identifies a pharmacist that compounds regularly or in inordinate amounts of any drug products that are essentially copies of Makena, the FDA intends to take enforcement action as it deems appropriate. Despite recent negative publicity regarding compounding pharmacies, including the 2012 meningitis outbreak involving compounded drugs, the November 2013 enactment of the DQSA and recent enforcement actions against compounders violating the FDC Act, Makena may continue to face competition from c17P, especially in light of the long-standing availability of such compounded products, their lower price and the criticism Lumara Health received in the past in connection with the pricing of Makena. Further, if any safety or efficacy concerns arise with respect to the c17P products, it may negatively impact sales of Makena if healthcare providers and patients do not distinguish between the compounded product and Makena.

The commercial success and growth prospects for Makena will be dependent upon perceptions related to pricing and access.

The initial list pricing of Makena was criticized in numerous news articles and internet postings following the FDA's February 2011 approval of Makena for reducing the risk of recurrent preterm birth in certain at-risk women. The list price of Makena was subsequently reduced in March 2011, and had not been increased until January 2016, at which time we increased the price in line with the rate of inflation over the past five years. Makena is priced at a premium to c17P, which has negatively impacted coverage of Makena by some state Medicaid programs and certain commercial payers. Although we are undertaking efforts to educate physicians and patients about progress made toward expanding coverage of Makena and about the benefits of Makena, certain doctors continue to prescribe non-FDA approved compounded formulations of HPC. In addition, efforts to appropriately respond to future concerns about pricing and access raised by the media, professional societies, advocacy groups, policymakers or regulatory agencies regarding patient access to Makena, are costly and may not be successful, especially in light of the increasing scrutiny on specialty pharmaceuticals by politicians and the media. If we are unable to increase the prescribing of Makena by physicians and strengthen relationships with professional societies, advocacy groups, policymakers and regulatory agencies, some of whom have been or are critical of Lumara Health, our sales of Makena may suffer, which would have a materially adverse impact on revenues and our results of operations.

The FDA has required post-marketing studies to verify and describe the clinical benefit of Makena, and the FDA may limit further marketing of the product based on the results of these post-marketing studies, failure to complete these trials in a timely manner or evidence of safety risks or lack of efficacy.

Makena was approved by the FDA in February 2011 under the provisions of the FDA's "Subpart H" Accelerated Approval regulations. As a condition of approval under Subpart H, the FDA required that Makena's sponsor perform certain adequate and well-controlled post-marketing clinical studies to verify and describe the clinical benefits of Makena as well as fulfill certain other post-approval commitments. Given the patient population (i.e., women pregnant

and at an increased high risk for recurrent preterm delivery based on their pregnancy history) and the informed risk of receiving a placebo instead of the active approved drug, the pool of prospective subjects for such clinical trials in the U.S. is small, and we have therefore sought enrollment on a global scale. These factors make the enrollment process slow, difficult, time-consuming and costly. If the required post-marketing studies fail to verify the clinical benefits of the drug, if a sufficient number of participants cannot be enrolled, or if we fail to perform the required post-marketing studies with due diligence, the FDA has the authority to withdraw approval of the drug following a hearing conducted under the FDA's regulations, which would have a materially adverse impact on our business. We cannot be certain of the results of the confirmatory clinical studies or what action the FDA may take if the results of those studies are not as expected based on clinical data that FDA has already reviewed or if such studies are not completed in a timely manner.

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Risks Related to CBR

The potential for cord blood stem cell and cord tissue science and its recognition in regenerative medicine may not continue to grow.

The growth of the CBR Services is partially dependent upon the potential for cord blood stem cell and cord tissue science and upon increasing its recognition, adoption and utility among the medical community for a broader set of applications than is currently established and potentially FDA's approval of those new uses. Although cord blood is utilized for certain homologous uses in the child from whom the cord blood was recovered or in first- or second-degree relatives, if clinical research is unable to demonstrate the utility of cord blood stem cells and cord tissue for use in treating diseases or injuries in a broader set of applications or if the FDA does not permit the clinical use of cord blood stem cells and cord tissue processed and stored using CBR's methods for those applications, then healthcare professionals may discount its potential utility among patients, or may not have access at all to cord blood stem cells and cord tissue for such expanded uses. The perception of the future value and uses of cord blood stem cells and cord tissue stored with CBR is a key driver of CBR's business and therefore any significant changes to this perception could have an adverse impact on sales of CBR Services.

If our cord blood and cord tissue processing and storage facility in Tucson, Arizona is damaged or destroyed, the CBR Services will be materially disrupted and impaired.

Currently, all of our customers' cord blood and cord tissue samples are stored in one facility in Tucson, Arizona. Our business would suffer, and we would lose credibility with and the trust of physicians, healthcare providers and consumers, if there were any material disruption in our ability to maintain continued and fully operating storage systems, or any loss or deterioration of cord blood and cord tissue stored in our storage systems, including in the event of any damage or interruption from fire, earthquake, flood, break-ins, tornadoes and similar events.

Competition in the cord blood and cord tissue banking business is significant and may be increasing. If we are unable to maintain our position as the market leader, our CBR business may decline and our results of operations could suffer.

The barriers to entry into the cord blood and cord tissue banking business are relatively low. We therefore face competition from new entrants to the market, which could affect our market share or put downward pressure on the pricing of the CBR Services. Furthermore, new market entrants may not abide by industry guidelines, regulations and standards, including quality, compliance and marketing standards that could allow them to offer and promote similar services at lower prices and/or engage in marketing behaviors that communicate false or misleading information. In addition to having a potential adverse impact on our business, these behaviors of such competitors could create a negative perception of our industry if they violate or operate outside of regulations and/or pursue other questionable

business practices.

Further, we may face competition from market entrants outside of the cord blood and cord tissue banking business. For example, stem cell science generally is a relatively nascent field and is subject to potential new technological and/or medical and therapeutic developments, which could render stem cell usage for established applications obsolete and could limit the future value of stem cells for our customers resulting in an adverse impact on our growth. Moreover, stem cell research continues to be an area of ethical and social controversy, and has suffered criticism that the benefits of private cord blood and cord tissue banking have been overstated. Any negative public opinion about stem cell therapy or the benefits of private cord blood and cord tissue banking could damage the perception and reputation of our industry, the CBR Services and our overall business, both among the medical community and the public generally, which could cause our stock price to suffer and result in a materially adverse impact on our revenues and results of operations.

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CBR is subject to data security and privacy obligations. With the addition of the CBR Services to our portfolio, our existing data security and privacy obligations have expanded and the failure to comply with these obligations could adversely affect our financial condition and operating results.

CBR is subject to data security and privacy obligations. Through April 29, 2033, CBR is required to comply with a Federal Trade Commission ("FTC") Order (the "FTC Order"). The FTC Order requires CBR, among other things, to implement and maintain a comprehensive information security program and conduct a biennial assessment of its information security program. CBR is also required not to make any misrepresentations, expressly or by implication, regarding its privacy practices or its information security program. The costs of compliance with, and other burdens imposed by, these obligations are substantial and may impede our performance and our ability to develop the CBR Services, or lead to significant fines, penalties or liabilities for noncompliance. The integration of CBR into our operations may also be impacted by the FTC Order. These limitations on our efforts to integrate CBR may impede our ability to operate and deploy our systems in the most efficient and cost effective manner.

The regulatory landscape for cord blood and cord tissue banking is complex and evolving, and we could become subject to a more complicated and rigorous regulatory scheme, which could expose us to more severe FDA enforcement action or other regulatory implications, which could materially harm our business.

Human tissues intended for transplantation, including cord blood stem cells and cord tissue, are subject to comprehensive regulations that address activities associated with human cells, tissues and cellular and tissue-based products ("HCT/Ps"). One set of regulations requires that companies that engage in the recovery, processing, storage, labeling, packaging, or distribution of any HCT/Ps, or the screening or testing of a cell or tissue donor, register with the FDA. This set of regulations also includes the criteria that must be met in order for the HCT/P to be eligible for distribution solely under Section 361 of the Public Health Service Act (the "PHSA"), and the regulations in 21 CFR Part 1271, rather than under the drug or device provisions of the FDC Act or the biological product licensing provisions of the PHSA. Another set of regulations provides criteria that must be met for donors to be eligible to donate HCT/Ps and is referred to as the "Donor Eligibility" rule. A third set of provisions governs the processing and distribution of the tissues and is often referred to as the "Current Good Tissue Practices" rule. The Current Good Tissue Practices rule covers all stages of HCT/P processing, from procurement to distribution of final allografts. Together these regulations are designed to ensure that sound, high quality practices are followed to reduce the risk of tissue contamination and of communicable disease transmission to recipients.

CBR is registered with the FDA as an HCT/P establishment that screens, packages, processes, stores, labels and distributes umbilical cord blood stem cell and cord tissue by virtue of the services it provides to expectant parents as a private cord blood and cord tissue bank. The FDA periodically inspects such registered establishments to determine compliance with HCT/P requirements. Violations of applicable regulations noted by the FDA during facility inspections could adversely affect the continued operation and marketing of the CBR Services.

In addition, the FDA could conclude that CBR cord blood stem cells and cord tissue do not meet the criteria for distribution solely under Section 361 of the PHSA, and therefore, CBR's banked HCT/Ps would require the submission and approval or clearance of a marketing application in order for us to continue to process and distribute any cord blood stem cells or cord tissue. Such an action by the FDA could cause negative publicity, decreased or discontinued sales of CBR's banking services for cord blood stem cells and cord tissue, and significant expense in obtaining required marketing approval or clearance, if we are able to obtain such approval or clearance at all, and in conforming our marketing approach to the FDA's expectations.

Some states impose additional regulation and oversight of cord blood and cord tissue banks and of clinical laboratories operating within their borders and impose regulatory compliance obligations on out-of-state laboratories providing services to their residents, and many states in which we and our business partners operate have licensing requirements that must be complied with.

Further, in the future, the FDA or state governments may promulgate new regulatory requirements and standards for HCT/Ps. We may not be able to comply with any such future regulatory requirements or product standards. If the FDA or any state regulators determine that we have failed to comply with applicable regulatory requirements or any future

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regulatory requirements or standards, it can impose or initiate a variety of enforcement actions, including but not limited to, public warning or untitled letters, written recall or destruction orders, written cease manufacturing orders, court-ordered seizures, injunctions, consent decrees, civil penalties, or criminal prosecutions. Regulatory or other developments could result in unexpected increases in expenses, which will be difficult to pass on to current CBR customers, some of whom have agreed to a set price for a period of future storage services, and potential CBR customers who may be unwilling to pay for the CBR Services if prices were to increase significantly. We can make no assurances that our business partners, or members of our collection center network, will be able to obtain or maintain any necessary licenses required to conduct our business under the current or future regulatory regime, which could in turn negatively impact our business and ability to comply with regulations. If any of these events were to occur, our business could be materially and adversely affected.

Our post-closing recourse from the CBR seller is limited under the CBR Agreement.

We may face legal, regulatory, and compliance scrutiny or increased expenses as a result of CBR's pre-acquisition business practices, including if CBR were alleged to have violated any privacy, data security, or other healthcare compliance laws, or failed to comply with all applicable FDA laws and requirements, regardless of whether such allegations have merit. Our recourse for such risks is limited, as the CBR seller's obligation to indemnify us is limited to breaches of specified representations and warranties and covenants included in the CBR Agreement and certain claims related to the reimbursement of engagement and retainer fees. The maximum liability of the CBR seller for indemnification claims is capped at $20.0 million and the indemnification obligations expire in the first quarter of 2016. If any issues arise, we may not be entitled to sufficient, or any, indemnification or recourse from the CBR Seller, which could have a materially adverse impact on our business and results of operations.

Risks Related to Feraheme

The market for Feraheme is limited because Feraheme is only indicated for the treatment of IDA in adult patients with CKD. Significant safety or drug interaction problems, or the evaluation or reevaluation of existing or future data by the FDA or other regulators, could have an adverse impact on Feraheme in this indication, which would adversely impact our future business prospects.

The market for Feraheme is limited because Feraheme is only indicated for the treatment of iron deficiency anemia ("IDA") in adult patients with chronic kidney disease ("CKD"). Although we intend to continue to dedicate significant resources to the commercialization of Feraheme, it may never receive approval for a broader indication and we may not be successful in our efforts to continue to successfully commercialize Feraheme in its current market, which would have a materially adverse effect on our results of operations and future business prospects.

Sales in the current indication may be limited or may decrease if label changes require us to provide additional warnings and/or restrictions related to Feraheme's current or future indications or impose further limitations or changes to the method of administering the drug, thereby giving rise to increased competitive pressures if Feraheme is viewed as less safe than other IV iron products. Significant safety or drug interaction problems with respect to Feraheme, including an increase in the severity or frequency of known adverse events or the discovery of previously unknown adverse events, or the evaluation or reevaluation of data, including pharmacovigilance data by the FDA, could result in lawsuits and increased regulatory scrutiny or a variety of adverse regulatory actions, including changes to the product label, the implementation of a REMS or any other enforcement actions. For example, in March 2015, following discussions with the FDA, we updated our Feraheme label to include (a) the addition of a boxed warning related to the risks of serious hypersensitivity reactions or anaphylaxis, which risks were previously described only in the Warnings and Precautions section; (b) revisions to the Dosing and Administration section to indicate that Feraheme should only be administered by IV infusion (replacing injection); and (c) modifications to the Warnings and Precautions section to include a statement that patients with a history of multiple drug allergies may have a greater risk of anaphylaxis with parenteral iron products. Our sales have already been negatively impacted by the label changes and these or any future changes to the label/ package could adversely impact our ability to successfully compete in the IV iron market and could have an adverse impact on potential sales of Feraheme and our future business prospects.

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Moreover, new safety or drug interaction issues may arise as Feraheme is used over longer periods of time by a wider group of patients, some of whom may be taking other medicines or have additional underlying health problems, which may require us to, among other things, provide additional warnings and/or restrictions on the label/package insert, notify healthcare providers of new safety information, narrow our approved indications, change the rate of administration, alter or terminate current or future trials for additional uses of Feraheme, or even remove Feraheme from the market, any of which could have a significant adverse impact on potential sales of Feraheme or require us to expend significant additional funds.

We may never receive regulatory approval to market and sell Feraheme to the broader IDA patient population.

In January 2014, we received a complete response letter from the FDA informing us that our supplemental new drug application ("sNDA") for the broad IDA indication could not be approved in its present form. In the letter, the FDA stated that we had not provided sufficient information to permit labeling of Feraheme for safe and effective use for the proposed indication. The FDA indicated that its decision was based on the cumulative ferumoxytol data, including the global Phase 3 IDA program and global post-marketing safety reports for the currently indicated CKD patient population. The FDA suggested, among other things, that we submit additional clinical trial data in the proposed broad IDA patient population. Following discussions with the FDA, we have recently commenced start-up activities on a new head-to-head Phase 3 clinical trial evaluating Feraheme in adults with IDA, excluding patients on hemodialysis. This new trial is a randomized, double-blind multicenter non-inferiority trial that will evaluate the incidence of moderate to severe hypersensitivity reactions (including anaphylaxis) and moderate to severe hypotension with Feraheme compared to ferric carboxymaltose infusion in adults with IDA. We currently expect to initiate the trial in the first quarter of 2016. We will have to demonstrate, through the submission of clinical study reports and data sets from one or more controlled clinical trials, that the benefit of Feraheme use in the proposed population would warrant the risks associated with Feraheme, including the potential for adverse events, including anaphylaxis, cardiovascular events, and death. Although we plan to initiate this new clinical trial, which will be expensive and time-consuming, the FDA has substantial discretion in the approval process and may decide that the results of any such additional trials and the information we submit seeking approval in the broader patient population or other information reviewed, such as post-marketing safety data, including reports of serious anaphylaxis, cardiovascular events, and death, or any information we provide in response to FDA requests, are insufficient for approval or that Feraheme is not effective or safe for the proposed broader indication, or in any of the individual subpopulations of IDA patients.

If we do not obtain approval to market and sell Feraheme for the treatment of IDA in a broad range of patients, or if we experience additional significant delays or setbacks in obtaining approval, or if we receive approval with significant restrictions, or are required to incur significant costs as post-marketing commitments, our cash position, our ability to increase revenues, our ability to leverage our portfolio, our profitability, and the future prospects of our business could be materially adversely affected.

Efforts to pursue a broader indication could also have a negative impact on the commercialization of Feraheme in its current indication if information submitted for purposes of the broader indication and any reevaluation of existing data, such as reports of serious anaphylaxis, cardiovascular events, and death, results in requirements to provide

additional warnings and/or restrictions on our Feraheme label/package insert, change the rate of administration of Feraheme, notify healthcare providers of changes to the label/package insert, narrow the current indication, alter or terminate current or future trials for Feraheme or incur significant costs related to post-marketing requirements/commitments. Such adverse developments could put us at a disadvantage to our competitors and cause healthcare providers to choose to treat all of their IDA patients with competing IV irons based on the actual or perceived safety and efficacy of Feraheme in light of such activities.

Generic competitors are seeking approval of generic versions of Feraheme and the market entry of any such generic would limit Feraheme sales which would have an adverse impact on our business and results of operation.

On February 5, 2016, we received a Paragraph IV certification notice letter regarding an ANDA submitted to the FDA by Sandoz requesting approval to engage in commercial manufacture, use and sale of a generic version of Feraheme (ferumoxytol), and we could therefor face generic competition in the near term. As noted above, in its notice letter, Sandoz claims that our ferumoxytol patents are invalid, unenforceable and/or not infringed by Sandoz's

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manufacture, use, sale or offer for sale of the generic version. We plan to initiate a patent infringement suit to defend the patents identified in the notice letter within 45 days after our receipt of the notice letter. Such litigation is often time-consuming and costly, and may result in generic competition if such patents are not upheld or if the generic competitor is found not to infringe such patents. Further, Sandoz's application could encourage other generic entrants seeking a path to approval of a generic ferumoxytol to file an ANDA. Even if we are successful, such litigation will be expensive and will consume considerable time and other resources, which could materially and adversely impact business.

The Drug Price Competition and Patent Term Restoration Act of 1984, as amended (the "Hatch Waxman Act") permits the FDA to approve ANDAs for generic versions of brand name drugs like Feraheme. The ANDA process permits competitor companies to obtain marketing approval for a drug product with the same active ingredient, dosage form, strength, route of administration, and labeling as the approved brand name drug, but without having to conduct and submit clinical studies to establish the safety and efficacy of the proposed generic product. In place of such clinical studies, an ANDA applicant needs to submit data demonstrating that its product is bioequivalent to the brand name product, usually based on pharmacokinetic studies. The Hatch-Waxman Act requires an applicant for a drug product that relies, in whole or in part, on the FDA's prior approval of Feraheme, to notify us of its application, a Paragraph IV certification notice, if the applicant is seeking to market its product prior to the expiration of the patents that claim Feraheme. A bona fide Paragraph IV certification notice may not be given under the Hatch-Waxman Act until after the generic company receives from the FDA an acknowledgement letter stating that its ANDA is sufficiently complete to permit a substantive review.

If an ANDA filer, such as Sandoz, is ultimately successful in patent litigation against us, meets the requirements for a generic version of Feraheme to the satisfaction of the FDA under its ANDA (after the litigation-related 30-month stay period expires), and is able to supply the product in significant commercial quantities, the generic company could introduce a generic version of Feraheme. Such a market entry would likely limit our Feraheme sales, which would have an adverse impact on our business and results of operations.

Market acceptance of Feraheme may suffer as a result of the widespread use of competing iron replacement therapy products, including Injectafer®, which would have a material adverse effect on our operations and our profitability.

Market acceptance of Feraheme may suffer as a result of competing iron replacement therapy products, in part because most of these products have been on the market longer and are currently widely used by physicians, and because certain of these products are approved for the treatment of IDA in a broader group of patients. For example, in July 2013, Injectafer® was approved by the FDA for the treatment of IDA in adult patients who have an unsatisfactory response to oral iron or who have intolerance to oral iron, which is a broader indication than our current Feraheme indication. Injectafer® is approved in the U.S. with a recommended dose of two slow injections or infusions of 750 milligrams each separated by at least seven days apart for a total of 1,500 milligrams. Given the 2015 changes to the Feraheme label, which provide, among other changes, that Feraheme be administered to patients by infusion over at least 15 minutes (replacing injection), Feraheme has lost a competitive advantage to Injectafer® and other IV irons. Further, we may not be able to offer discounts, incentives or rebates to new or existing customers on terms as appealing as Injectafer® or other IV irons. Even if we eventually obtain labeling of Feraheme in a broader population,

Injectafer® will have already been available for a considerable period of time. During this period, physicians may continue to increase their use of Injectafer®, new physicians may begin to use Injectafer®, and physicians will gain increased familiarity with the product, making it more difficult for us to cause these physicians to use Feraheme in the future. In addition, manufacturers of Injectafer® may enter into commercial contracts with key customers or group purchasing organizations ("GPOs") during this period, which could prevent or make it more difficult for Feraheme to retain its existing customers, gain sales to new customers and gain market share in its existing indication with customers or GPOs, and may make entry into the non-CKD market difficult if we were to receive approval for the broader patient population in the future. If we are not able to differentiate Feraheme from other marketed IV iron products, including Injectafer®, or convince physicians and other customers of Feraheme's safe and effective use, our ability to maintain a premium price, generate revenues and maintain profitability, and our long-term business prospects could be adversely affected.

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Feraheme's ability to maintain its current market share, or gain wider market acceptance in the future, depends on a number of other factors, including but not limited to the following:

- Our ability to demonstrate to healthcare providers, particularly hematologists, oncologists, hospitals, nephrologists, and others who may purchase or prescribe Feraheme, the clinical efficacy and safety of Feraheme as an alternative to currently marketed IV iron products which treat IDA in adult CKD patients;

- Our ability to convince physicians and other healthcare providers to use IV iron, and Feraheme in particular, rather than oral iron, which is the current treatment of choice of most physicians for treating IDA in adult CKD patients;

- The actual or perceived safety and efficacy profile of Feraheme as compared to alternative iron replacement therapeutic agents;

- The relative price and level of reimbursement for Feraheme from payers, including government payers, such as Medicare and Medicaid, and private payers as compared to the price and level of reimbursement for alternative IV iron products;

- The actual or perceived convenience and ease of administration of Feraheme as compared to alternative iron replacement therapeutic agents, including iron administered orally, in light of recent or potential changes to the methods of Feraheme administration;

- Our ability to execute on our contracting strategy and offer competitive discounts, rebates and other incentives, which can result in increasing the rebates we are required to pay under the Medicaid Drug Rebate program and the discounts we are required to offer under the 340B drug pricing program;

- Current and future limitations on the approved indications and patient populations for Feraheme;

- The introduction of generic versions of ferumoxytol, which may occur in the near-term given the ANDA submitted to the FDA by Sandoz requesting approval to engage in commercial manufacture, use and sale of a generic version of ferumoxytol; and

- The effectiveness of our commercial organization and distribution networks in marketing, selling and supplying Feraheme.

The key component of our commercialization strategy for Feraheme is to market and sell Feraheme for use in non-dialysis adult CKD patients. The current non-dialysis CKD market is comprised primarily of three sites of care where a substantial number of CKD patients are treated: hospitals, hematology and oncology centers, and nephrology clinics. Competition in these practices is intense and competitors such as Injectafer® are gaining market share, particularly in hematology practices. IV iron therapeutic products are not currently widely used by certain physicians who treat non-dialysis CKD patients, particularly nephrologists, due to safety concerns and the inconvenience and often impracticability of administering infusion IV iron therapeutic products in their offices. It is often difficult to change physicians' existing treatment paradigms even when supportive clinical data are available. In addition, our ability to effectively market and sell Feraheme in the hospital market depends in part upon our ability to achieve acceptance of Feraheme onto hospital formularies. Since many hospitals and hematology, oncology and nephrology practices are members of GPOs, which leverage the purchasing power of a group of entities to obtain discounts based on the collective bargaining power of the group, our ability to attract customers in these sites of care also depends in part on our ability to effectively promote Feraheme to and enter into pricing agreements with GPOs. The GPOs can also offer opportunities for competitors to Feraheme that provide the ability to quickly gain market share by offering a more attractive price or contracts and incentives that encourage the members of the GPO to use or switch to the competing product. If we are not successful in capturing a significant share of the non-dialysis CKD market or if we are not successful in securing and maintaining formulary coverage for Feraheme, or if we cannot maintain strong relationships and offer competitive contracts to key customers and GPOs, our profitability as well as our long-term business prospects could be adversely affected.

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We derive a substantial amount of our Feraheme revenue from a limited number of customers and the loss of one or more of these customers, a change in their fee structure, or a decline in revenue from one or more of these customers could have an adverse impact on our results of operations and financial condition.

We sell Feraheme primarily to wholesalers and specialty distributors and therefore a significant portion of our revenues is generated by a small number of customers and most of these customers are not under long-term contracts with us. The loss of any of our customers, including if a customer views Feraheme as having a higher risk profile as compared to other IV iron products, especially in light of our recent label changes, could have a materially adverse impact on our results of operations. In addition, in 2015 three customers accounted for greater than 90% of our total Feraheme net revenues and accounts receivable balance. We pay these wholesalers and specialty distributors a fee for the services that they provide to us. Because our business is concentrated with such a small number of wholesalers and specialty distributors, we could be forced to accept increases in their fees in order to maintain the current distribution networks through which Feraheme is sold. Any increase in fees could have a negative impact on our current and future sales of Feraheme and could have a negative impact on the reimbursement rate an individual physician, hospital or clinic would realize upon using Feraheme.

In addition, a significant portion of our Feraheme sales are generated through a small number of contracts with GPOs. For example, approximately 26% of our Feraheme end-user demand during the year ended December 31, 2015 was generated by members of a single GPO with whom we have contracted. As a result of the significant percentage of our end-user demand being generated by a single GPO, we may be at a disadvantage in future contract or price negotiations with such GPO and that GPO may be able to influence the demand for Feraheme from its members in a particular quarter through communications they make to their customers. In addition, competitors of Feraheme may be able to quickly gain market share if they are able to offer GPOs a more attractive price or contracts and incentives that encourage the members of the GPO to use or switch to the competing product, especially if such competing drug can be administered to a broader patient population. The loss of some or all of this demand to a competitor, a material reduction in sales volume, or a significant adverse change in our relationship with any of our key wholesalers, distributors or GPOs could have a material adverse effect on our revenue and results of operations.

Regulatory Risks

There have been, and we expect there will continue to be, a number of federal and state legislative initiatives implemented to reform the U.S. healthcare system in ways that could adversely impact our business and our ability to sell our products and services profitably.

We expect that the Healthcare Reform Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase our product sales. These changes might impact existing government healthcare programs and may result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

Changes that may affect our business include, but are not limited to, those governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under the health insurance exchanges, expansion of the 340B drug pricing program, and fraud and abuse enforcement. For example, beginning April 1, 2013, Medicare payments for all items and services under Part A and B, including drugs and biologicals, and most payments to plans under Medicare Part D were reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011 ("BCA") as amended by the American Taxpayer Relief Act of 2012. The BCA requires sequestration for most federal programs, excluding Medicaid, Social Security, and certain other programs. The BCA caps the cuts to Medicare payments for items and services at 2% and subsequent legislation extended the 2% reduction, on average, to 2025. In addition, various healthcare reform proposals have emerged at the state level in the U.S.

On February 1, 2016, CMS issued a final regulation to implement the changes to the Medicaid Drug Rebate Program under the Health Reform Act. This regulation becomes effective on April 1, 2016. We are evaluating the impact of this regulation on our business and operations.

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While we are continuing to evaluate this legislation and its potential impact on our business, we cannot predict the impact that newly enacted laws or any future legislation or regulation will have on us. We expect that there will continue to be a number of U.S. federal and state proposals to implement governmental pricing controls and limit the growth of healthcare costs. These efforts could adversely affect our business by, among other things, limiting the prices that can be charged for our products or services, or the amount of reimbursement rates and terms available from governmental agencies or third-party payers, limiting the profitability of our products and services, increasing our rebate liability or limiting the commercial opportunities for our products and services, including acceptance by healthcare payers.

If our products and services are marketed or distributed in a manner that violates federal, state or foreign healthcare fraud and abuse laws, marketing disclosure laws or other federal, state or foreign laws and regulations, we may be subject to civil or criminal penalties.

In addition to FDA and related regulatory requirements, our general operations, and the research, development, manufacture, sale and marketing of our products and services, are subject to extensive additional federal, state and foreign healthcare regulation, including the Federal Anti Kickback Statute and the Federal False Claims Act (“FCA”) (and their state analogues), as discussed above in Item 1. Business under the heading "Government Regulation - Fraud and Abuse Regulation." If we fail to comply with any federal, state or foreign laws or regulations governing our industry, we could be subject to a range of regulatory actions that could adversely affect our ability to commercialize our products and services, harm or prevent sales of our products and services, or substantially increase the costs and expenses of commercializing and marketing our products and services, all of which could have a material adverse effect on our business, financial condition and results of operations.

Our activities relating to the sale and marketing of our products and services may be subject to scrutiny under these laws, and private individuals have been active in bringing lawsuits on behalf of the government under the FCA and similar regulations in other countries. In addition, incentives exist under applicable U.S. law that encourages employees and physicians to report violations of rules governing promotional activities for pharmaceutical products. These incentives could lead to so-called whistleblower lawsuits as part of which such persons seek to collect a portion of moneys allegedly overbilled to government agencies as a result of, for example, promotion of pharmaceutical products beyond labeled claims. For example, federal enforcement agencies recently have showed interest in pharmaceutical companies’ product and patient assistance programs, including manufacturer reimbursement support services and relationships with specialty pharmacies. Some of these investigations have resulted in government enforcement authorities intervening in related whistleblower lawsuits and obtaining significant civil and criminal settlements. Such lawsuits, whether with or without merit, are typically time-consuming and costly to defend. Such suits may also result in related shareholder lawsuits, which are also costly to defend.

Further, the FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. For drug products like Makena that are approved by the FDA under the FDA's accelerated approval regulations, unless otherwise informed by the FDA, the sponsor must submit promotional materials at least 30 days prior to the intended time of initial dissemination of the promotional materials, which delays

and may negatively impact our commercial team's ability to implement changes to Makena's marketing materials, thereby negatively impacting revenues. Moreover, under Subpart H, the FDA may also withdraw approval of Makena if, among other things, the promotional materials are false or misleading, or other evidence demonstrates that Makena is not shown to be safe or effective under its conditions of use.

In recent years, several states have enacted legislation requiring pharmaceutical companies to establish marketing and promotional compliance programs or codes of conduct and/or to file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Several states have also adopted laws that prohibit certain marketing-related activities, including the provision of gifts, meals or other items to certain healthcare providers. In addition, as part of the Healthcare Reform Act, substantial new provisions affecting compliance have been enacted, which may require us to modify our business practices with healthcare providers and potentially incur additional costs. One such requirement is for manufacturers of drugs to publicly report gifts and other payments or transfers of value made to physicians and teaching hospitals.

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We have developed and implemented a corporate compliance program based on what we believe are current best practices in the pharmaceutical industry; however, these laws are broad in scope and there may not be regulations, guidance or court decisions that definitively interpret these laws in the context of particular industry practices. We cannot guarantee that we, our employees, our consultants or our contractors are or will be in compliance with all federal, state and foreign regulations. If we or our representatives fail to comply with any of these laws or regulations, a range of fines, penalties and/or other sanctions could be imposed on us, including, but not limited to, restrictions on how we market and sell our products, significant fines, exclusions from government healthcare programs, including Medicare and Medicaid, litigation, or other sanctions. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could also have an adverse effect on our business, financial condition and results of operations. Such investigations or suits may also result in related shareholder lawsuits, which can also have an adverse effect on our business.

Further, with our recent acquisition of CBR, we will be subject to additional and complex regulations with regard to the CBR Services, as detailed above under the Risk Factors – Risks Related to CBR – "CBR is subject to data security and privacy obligations. With the addition of the CBR Services to our portfolio, our existing data security and privacy obligations have expanded and the failure to comply with these obligations could adversely affect our financial condition and operating results" and "The regulatory landscape for cord blood and cord tissue banking is complex and evolving. This landscape coupled with our inexperience with the CBR Services could subject us to FDA enforcement action or other regulatory implications, which could materially harm our business."

If we fail to comply with our reporting and payment obligations under governmental pricing programs, we could be required to reimburse government programs for underpayments and could pay penalties, sanctions and fines which could have a material adverse effect on our business, financial condition and results of operations.

As a condition of reimbursement by various federal and state healthcare programs, we are required to calculate and report certain pricing information to federal and state healthcare agencies. Please see our discussion above under the heading, "Pharmaceutical Pricing and Reimbursement" in Item 1. Business for more information regarding our price reporting obligations under the Medicaid Drug Rebate Program, Medicare Part B, and the Department of Veterans Affairs Federal Supply Schedule (the "FSS") program.

Price reporting and payment obligations are highly complex and vary among products and programs. The calculations are often subject to interpretation by us, governmental or regulatory agencies and the courts. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction.

If we have to restate our calculation of government price reports, we may be forced to refund certain monies back to payers to comply with federal pricing agreements. Such a restatement of our government price reports would also adversely impact our reported financial results of operations in the period of such restatement. As a result, our price

reporting calculations remain subject to the risk of errors and our methodologies for calculating these prices could be challenged under the FCA or other laws. In addition, the Healthcare Reform Act modified the rules related to certain price reports, among other things. Presently, uncertainty exists as many of the specific determinations necessary to implement this new legislation have yet to be decided and communicated to industry participants. This uncertainty in the interpretation of the legislation increases the chances of an error in price reporting, which could in turn lead to a legal challenge, restatement or investigation. On February 1, 2016, CMS issued a final regulation to implement the changes to the Medicaid Drug Rebate Program under the Health Reform Act. This regulation becomes effective on April 1, 2016. We are evaluating the impact of this regulation on our business and operations.

If we become subject to investigations, restatements, or other inquiries concerning our compliance with price reporting laws and regulations, we could be required to pay or be subject to additional reimbursements, penalties, sanctions or fines, which could have a material adverse effect on our business, financial condition and results of operations.

Our processes for estimating amounts due under these governmental pricing programs involve subjective decisions and estimates. Often, state Medicaid programs may be slow to invoice pharmaceutical companies for these rebates

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resulting in a significant lag between the time a sale is recorded and the time the rebate is paid. This results in us having to carry a significant liability on our consolidated balance sheets for the estimate of rebate claims expected for Medicaid patients. For example, almost half of Makena sales are reimbursed through state Medicaid programs and are subject to the statutory Medicaid rebate, and in some cases, supplemental rebates offered by us. If actual claims are higher than current estimates, our financial position and results of operations could be adversely affected.

We are liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B drug pricing program refunds, if we are found to have knowingly submitted any false price information related to the Medicaid Drug Rebate Program to CMS to the government, we may be liable for civil monetary penalties in the amount of $100,000 per item of false information. If we are found to have made a misrepresentation in the reporting of our average sales price, the Medicare statute provides for civil monetary penalties of up to $10,000 for each misrepresentation for each day in which the misrepresentation was applied. Our failure to submit the required price data to CMS on a timely basis could result in a civil monetary penalty of $10,000 per day for each day the information is late beyond the due date. Such failure could also be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, federal payments may not be available under government programs, including Medicaid or Medicare Part B, for our covered outpatient drugs.

Additionally, if we overcharge the government in connection with the FSS contract or Tricare Retail Pharmacy Program, whether due to a misstated FCP or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the FCA and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects

We are subject to ongoing regulatory obligations and oversight of our products and services, and any failure by us to maintain compliance with applicable regulations may result in several adverse consequences including the suspension of the manufacturing, marketing and sale of our respective products and services, the incurrence of significant additional expense and other limitations on our ability to commercialize our respective products and services.

We are subject to ongoing regulatory requirements and review, including by periodic audits pertaining to the development, manufacture, labeling, packaging, adverse event reporting, distribution, storage, marketing, promotion, record keeping and export of our respective products and for their preservation and, storage and other activities associated with the CBR Services. Failure to comply with such regulatory requirements or the later discovery of previously unknown problems with our products or services, or our third-party contract manufacturing facilities or processes by which we manufacture our products or supply our services may result in restrictions on our ability to manufacture, market, distribute or sell our products or services, including potential withdrawal of our products from the market. Any such restrictions could result in a decrease in sales, damage to our reputation or the initiation of lawsuits against us and/or our third-party contract manufacturers. We may also be subject to additional sanctions, including but not limited to the following:

Warning letters, public warnings and untitled letters;

Court-ordered seizures or injunctions;

Civil or criminal penalties, or criminal prosecutions;

Variation, suspension or withdrawal of regulatory approvals for our products or services;

Changes to the package insert of our products, such as additional warnings regarding potential side effects or potential limitations on the current dosage and administration;

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Requirements to communicate with physicians and other customers about concerns related to actual or potential safety, efficacy, or other issues involving our products and services;

Implementation of risk mitigation programs and post-marketing obligations;

Restrictions on our continued manufacturing, marketing, distribution or sale of our products, or the ability to continue to market our services;

Temporary or permanent closing of the facilities of our third-party contract manufacturers;

Interruption of clinical trials;

For HCT/Ps, including umbilical cord blood stem cells and cord tissue, recalls, destruction orders, or cease manufacturing orders; and

Refusal by regulators to consider or approve applications for additional indications.

Any of the above sanctions could have a material adverse impact on our revenues and profitability or the value of our brand, and cause us to incur significant additional expenses.

Additionally, Lumara Health, as our wholly-owned subsidiary following consummation of the acquisition, is subject to certain continuing obligations under a Consent Decree of Permanent Injunction (“Consent Decree”) between the FDA, Lumara Health’s predecessor company, K-V Pharmaceutical Company (“K-V Pharmaceutical”), and certain former officers and affiliates of K-V Pharmaceutical. In particular, Lumara Health is bound by a number of provisions and requirements in the Consent Decree including, but not limited to, inspection of Lumara Health's places of business by the FDA without prior notice, and notification of FDA of particular actions and events. If Lumara Health fails to comply with applicable provisions in the Consent Decree, the FDC Act, or the FDC Act’s implementing regulations, the FDA may impose specific sanctions including, but not limited to, the requirement to cease any of Lumara Health's manufacturing operations, the imposition of substantial financial penalties and the requirement to implement additional corrective actions.

Regulators could determine that our clinical trials and/or our manufacturing processes, and/or our storage or those of our third parties, were not properly designed or are not properly operated, which could cause significant costs or setbacks for our commercialization activities.

We are obligated to conduct, and are in the process of conducting, certain post-approval clinical trials, including in pursuit of the broader IDA indication for Feraheme, and we may be required to conduct additional clinical trials, including if we pursue approval of additional indications, new formulations or methods of administration for our products, seek commercialization in other jurisdictions, or in support of our current indications. The FDA could determine that our clinical trials and/or our manufacturing processes were not properly designed, did not include enough patients or appropriate administration, were not conducted in accordance with applicable laws and regulations, or were otherwise not properly managed. In addition, according to current good clinical practices regulations ("cGCP") we are responsible for conducting, recording and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA may conduct inspections of clinical investigator sites which are involved in our clinical development programs to ensure their compliance with cGCP regulations. If the FDA determines that we, our CROs or our study sites fail to comply with applicable cGCP regulations, the FDA may deem the clinical data generated in our clinical trials to be unreliable and may disqualify certain data generated from those sites or require us to perform additional clinical trials. Our clinical trials and manufacturing processes are subject to similar risks and uncertainties outside of the U.S. Any such deficiency in the design, implementation or oversight of our clinical development programs or post-approval clinical studies could cause us to incur significant additional costs, experience delays or prevent us from commercializing Makena and Feraheme in their current indications, or obtaining marketing approval for additional indications, including the approval for use of Feraheme for the broad IDA indication.

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In addition, the Current Good Tissue Practices rule governs the processing and distribution of cord blood stem cells and cord tissue and covers all stages of HCT/P processing, from procurement to distribution of final allografts. CBR is registered with the FDA as an HCT/P establishment that screens, packages, processes, stores, labels and distributes umbilical cord blood stem cells and cord tissue by virtue of the services it provides to expectant parents as a private cord blood and cord tissue bank. The FDA periodically inspects such registered establishments to determine compliance with HCT/P requirements. Violations of applicable regulations noted by the FDA during facility inspections could adversely affect the continued operation and marketing of the CBR Services.

Further, our third-party contract manufacturing facilities are subject to cGMP regulations enforced by the FDA and equivalent foreign regulations and regulatory agencies through periodic inspections to confirm such compliance. Contract manufacturers must continually expend time, money and effort in production, record-keeping and quality assurance and control to ensure that these manufacturing facilities meet applicable regulatory requirements. Failure to maintain ongoing compliance with cGMP or similar foreign regulations and other applicable manufacturing requirements of various U.S. or foreign regulatory agencies could result in, among other things, the issuance of warning letters, fines, the withdrawal or recall of our products from the marketplace, total or partial suspension of product production, the loss of inventory, suspension of the review of our current or future sNDAs or equivalent foreign filings, enforcement actions, injunctions or criminal prosecution and suspension of manufacturing authorizations. A government-mandated recall or a voluntary recall could divert managerial and financial resources, could be difficult and costly to correct, could result in the suspension of sales of our products and could have a severe adverse impact on our profitability and the future prospects of our business. If any regulatory agency inspects any of these manufacturing facilities and determines that they are not in compliance with cGMP or similar regulations or our contract manufacturers otherwise determine that they are not in compliance with these regulations, as applicable, such contract manufacturers could experience an inability to manufacture sufficient quantities of product to meet demand or incur unanticipated compliance expenditures.

We have also established certain testing and release specifications with the FDA. This release testing must be performed in order to allow finished product to be used for commercial sale. If a finished product does not meet these release specifications or if the release testing is variable, we may not be able to supply product to meet our projected demand. We monitor annual batches of our finished product for ongoing stability after it has been released for commercial sale. If a particular batch of finished drug product exhibits variations in its stability or begins to generate test results that demonstrate an adverse trend against our specifications, we may need to conduct an investigation into the test results, quarantine the product to prevent further use, destroy existing inventory no longer acceptable for commercial sale, or recall the batch or batches. If we are unable to develop, validate, transfer or gain regulatory approval for the new release test, our ability to supply product will be adversely affected. Such setbacks could have an adverse impact on our revenues, our profitability and the future prospects of our business.

Our failure to comply with data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We are subject to data protection laws and regulations (i.e., laws and regulations that address privacy and data security). The legislative and regulatory landscape for data protection continues to evolve, and in recent years there has been an increasing focus on privacy and data security issues. In the US, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of health-related and other personal information. Failure to comply with data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. In addition, we may obtain health information from third parties (i.e., healthcare providers who prescribe our products) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act ("HIPAA"). Although we are not directly subject to HIPAA (other than potentially with respect to providing certain employee benefits) we could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

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Risks Related to Our Business Generally

With our Lumara Health and CBR acquisitions, we have significantly expanded the size of our organization and we may experience difficulties in managing this or future expansion.

With the Lumara Health and CBR acquisitions, we more than doubled the size of our employee-base. Management, personnel, systems and facilities that we currently have in place may not be adequate to support this recent growth and the addition of a service-based business to our portfolio, and we may not be able to retain or recruit qualified personnel in the future in this competitive environment to adequately support our expanded organization. To manage any future growth effectively, we may be required to continue to manage and expand the sales and marketing efforts for our existing products and services while continuing to identify and acquire attractive additions to our portfolio, enhance our operational, financial and management controls, reporting systems and procedures, benefit plan maintenance, and establish and increase our access to commercial supplies of our products and call points for our services, which will be challenging and for which we might not be successful, especially given our newly-expanded organization. We will be required to expand and maintain our facilities and equipment and manage our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors, collaborators, distributors and other third parties and we will have to manage multiple geographic locations across the U.S., which we have no experience doing. In addition, management may have to divert a disproportionate amount of its attention away from day-to-day activities and towards managing these growth activities, which could be disruptive to our business. Our future financial performance and our ability to execute on our business plan will depend, in part, on our ability to effectively manage our recent and any future growth. If we experience difficulties or are unsuccessful in managing our expansion, our results of operations and business prospects will be negatively impacted.

Our level of indebtedness and the terms of the 2015 Term Loan Facility, 2023 Senior Notes and Convertible Notes could adversely affect our operations and limit our ability to plan for or respond to changes in our business or acquire additional products for our portfolio. If we are unable to comply with restrictions in the 2015 Term Loan Facility, or cannot repay or refinance the 2023 Senior Notes or Convertible Notes, the repayment of our indebtedness could be accelerated.

In order to consummate the CBR acquisition, we incurred a substantial amount of additional debt, which could adversely affect our business. As of December 31, 2015, we had $1.0 billion of total debt outstanding. In August 2015, we entered into the 2015 Term Loan Facility, with a floating annual interest rate (currently 4.75%), and issued $500.0 million in aggregate principal Senior Notes due 2023 bearing interest at 7.875% annually (the “2023 Senior Notes”) to help fund our acquisition of CBR and potential expansion and diversification of our portfolio through the in-license or purchase of additional pharmaceutical products or companies, among other things. We also incurred indebtedness in February 2014 in the amount of $200.0 million in aggregate principal convertible notes due February 15, 2019 bearing interest at 2.5% annually (the “Convertible Notes”). Our high level of indebtedness could adversely affect our business in the following ways, among other things:

make it more difficult for us to satisfy our financial obligations under our current debt obligations, or other indebtedness, as well as our contractual and commercial commitments, and could increase the risk that we may default on our debt obligations;

prevent us from raising the funds necessary to repurchase 2023 Senior Notes tendered to us if there is a change of control, which would constitute a default under the indenture governing the 2023 Senior Notes, the Convertible Notes and the 2015 Term Loan Facility;

require us to use a substantial portion of our cash flow from operations to pay interest and principal on our current debt obligations or other indebtedness, which would reduce the funds available for working capital, capital expenditures and other general corporate purposes;

limit our ability to obtain additional financing for working capital, capital expenditures, acquisitions and other investments or general corporate purposes, which may limit the ability to execute our business strategy;

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heighten our vulnerability to downturns in our business, our industry or in the general economy, and restrict us from exploiting business opportunities or making acquisitions;

place us at a competitive disadvantage compared to those of our competitors that may have proportionately less debt;

limit management's discretion in operating our business;

limit our flexibility in planning for, or reacting to, changes in our business, the industry in which we operate or the general economy; and

result in higher interest expense if interest rates increase and we have outstanding floating rate borrowings such as our 2015 Term Loan Facility.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the 2015 Term Loan Facility, the 2023 Senior Notes and the Convertible Notes ("our current debt obligations"), depends on our future performance, which is subject to economic, financial, competitive and other factors that may be beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and support our growth strategies. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations, including under our current debt obligations. In addition, if for any reason we are unable to meet our debt service and repayment obligations, we would be in default under the terms of the agreements governing our indebtedness, which would allow our creditors at that time to declare all outstanding indebtedness to be due and payable. This would likely in turn trigger cross-acceleration or cross-default rights between our applicable debt agreements. Under these circumstances, our lenders could compel us to apply all of our available cash to repay our indebtedness or they could prevent us from making payments on our current debt obligations.

The 2015 Term Loan Facility requires us to make certain payments of principal and interest over time and contains a number of other restrictive covenants. The 2015 Term Loan Facility also contains covenants and terms limiting our ability to enter into new acquisitions, licenses, mergers, foreign investments, to take on new debt and sell assets, and requiring us to pay penalties in the event we want to prepay the 2015 Term Loan Facility early. The maturity date of the 2015 Term Loan Facility could also be accelerated in certain circumstances, including in the event of an uncured event of default as outlined in the 2015 Term Loan Facility. The 2015 Term Loan Facility has a floating interest rate based on the prevailing London Interbank Offered Rate rate, making interest payments subject to adjustment depending on the interest rate environment. These and other terms in the 2015 Term Loan Facility have to be

monitored closely for compliance and could restrict our ability to grow our business or enter into transactions that we believe will be beneficial to our business.

Also, upon the occurrence of specific types of change of control events, we will be required to offer to repurchase all of the outstanding 2023 Senior Notes at a price equal to 101% of the aggregate principal amount of the 2023 Senior Notes repurchased, plus accrued and unpaid interest up to, but not including, the date of repurchase. In addition, in connection with certain asset sales, we may be required to offer to repurchase a portion of the 2023 Senior Notes at a price equal to 100% of the principal amount, plus accrued and unpaid interest and additional interest up to, but not including, the date of repurchase. We may not have sufficient funds available to repurchase all of the 2023 Senior Notes tendered pursuant to any such offer and any other debt that would become payable upon a change of control or in connection with such an asset sale offer. The 2015 Term Loan Facility also limits our ability to repurchase the 2023 Senior Notes. Our failure to repurchase the 2023 Senior Notes upon the occurrence of specific types of change of control events would be a default under the indenture governing the 2023 Senior Notes, which would in turn trigger a default under our 2015 Term Loan Facility, the indenture governing the Convertible Notes and may trigger a default under any future credit facility and the terms of our other indebtedness outstanding at such time.

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Further, holders of the Convertible Notes have the right to require us to repurchase their notes upon the occurrence of a fundamental change at a repurchase price equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest. Upon conversion of the Convertible Notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we will be required to make cash payments in respect of the notes being converted. We may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of Convertible Notes surrendered therefor or at the time Convertible Notes are being converted. Our failure to repurchase Convertible Notes at a time when the repurchase is required by the indenture or to pay any cash payable on future conversions of the Convertible Notes would constitute an event of default. Moreover, if our stock price increases, the parties with whom we entered into warrant transactions in connection with the pricing of the Convertible Notes (the "Warrants") could exercise such warrants, thereby causing substantial dilution to our stockholders. The Convertible Notes are, the Warrants may be, and any additional equity or equity-linked financings or alternative strategic arrangements would be, dilutive to our stockholders.

Our 2015 Term Loan Facility and the indenture governing the 2023 Senior Notes impose operating and financial restrictions on us and our subsidiaries that may prevent us from pursuing certain business opportunities and restrict our ability to operate our business.

The terms of our current debt instruments or any additional debt financing could greatly restrict our ability to raise additional capital and may provide rights and preferences to the investors in any such financing which are senior to those of, and not available to, current stockholders, impose restrictions on our day-to-day operations or place limitations on our ability to enter into combination transactions with other entities. Our inability to raise additional capital on terms and within a timeframe acceptable to us when needed could force us to dramatically reduce our expenses and delay, scale back or eliminate certain of our activities and operations, including our commercialization and development activities, any of which would have a material adverse effect on our business, financial condition and future business prospects.

Our 2015 Term Loan Facility and the indenture governing the 2023 Senior Notes contain covenants that restrict our and our restricted subsidiaries' ability to take various actions, such as:

- paying dividends, redeeming subordinated indebtedness or making other restricted payments, including certain investments;
- incurring or guaranteeing additional indebtedness or issuing preferred stock;
- creating or incurring liens;

consummating a merger;

consolidation or sale of all or substantially all of our or our subsidiaries' assets;

entering into transactions with affiliates;

transferring or selling assets;

engaging in businesses other than our current businesses and reasonably related extensions thereof;

designating subsidiaries as unrestricted subsidiaries; and

allowing to exist certain restrictions on the ability of restricted subsidiaries to pay dividends or make other payments to us.

We cannot make any assurances that our future operating results will be sufficient to ensure compliance with the covenants in these arrangements or to remedy any such default. In the event of an acceleration of this indebtedness, we may not have or be able to obtain sufficient funds to make any accelerated payments. Any of the factors discussed above could materially and adversely affect our business, financial condition and results of operations. In addition, if we incur additional indebtedness, the risks related to our business and our ability to service or repay our indebtedness would increase.

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Our variable rate indebtedness subjects us to interest rate risk, which could cause our debt service obligations to increase significantly.

Borrowings under our 2015 Term Loan Facility, and other indebtedness we incur in the future may, bear interest at variable rates exposing us to interest rate risk. If interest rates increase, our debt service obligations on the variable rate indebtedness would increase even though the amount borrowed remained the same, and our net income and cash available for servicing our indebtedness would decrease.

We may need additional capital to achieve our business objectives and to service our debt obligations, including the 2015 Term Loan Facility, our Convertible Notes, our 2023 Senior Notes and contingent payments that may become due under the Lumara Agreement, which could cause significant dilution to our stockholders.

We may require additional funds or need to establish additional alternative strategic arrangements to execute a business development transaction. We may at any time seek funding through additional arrangements with collaborators through public or private equity or debt financings, subject to the covenants in the documents governing our debt obligations. We may not be able to obtain financing or to secure alternative strategic arrangements on acceptable terms or within an acceptable timeframe, if at all, which would limit our ability to execute on our strategic plan. Moreover, the condition of the credit markets can be unpredictable and we may experience a reduction in value or loss of liquidity with respect to our investments, which would put further strain on our cash resources. For example, as of December 31, 2015, our 2023 Senior Notes are trading at 87.5 (a discount to par) from the time they were issued in August 2015. The yields on debt of comparable credit quality have risen significantly since the time we issued the 2023 Senior Notes implying that our cost of capital could be higher in the future.

Our current level of cash on hand may limit our ability to take advantage of attractive business development opportunities and execute on our strategic plan. In addition, our cash on hand may not be sufficient to service the principal and interest payments under our current debt obligations or any cash milestone payments to the former Lumara Health security holders upon the achievement of sales milestones. Our ability to make these required payments could be adversely affected if we do not achieve expected revenue and cash flow forecasts or if we are unable to find other sources of cash in the future and we may need to offer the former Lumara Health security holders shares of our common stock or issue shares of our common stock to raise cash resulting in dilution to our stockholders.

Our long-term capital requirements will depend on many other factors, including, but not limited to the commercial success of our products and efforts we make in connection with commercialization and development, our ability to realize synergies and opportunities in connection with our acquisitions and portfolio expansion, the outcome of and costs associated with any material litigation or patent challenges to which we are or may become a party, the timing and magnitude of costs associated with qualifying additional manufacturing capacities and alternative suppliers, and

our ability to raise additional capital on terms and within a timeframe acceptable to us, if necessary.

Our ability to use net operating loss carryforwards and tax credit carryforwards is dependent on generating future taxable income and may be limited, including as a result of future transactions involving our common stock.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended (the “Code”), a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses and certain other tax assets to offset future taxable income. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders increases by more than 50 percentage points over such stockholders' lowest percentage ownership during the testing period, which is generally three years. An ownership change could limit our ability to utilize our net operating loss and tax credit carryforwards for taxable years including or following such "ownership change" by allowing us to utilize only a portion of the net operating losses and tax credits that would otherwise be available but for such ownership change. Limitations imposed on the ability to use net operating losses and tax credits to offset future taxable income or the failure to generate sufficient taxable income could require us to pay more U.S. federal income taxes than we have estimated and could cause such net operating losses and tax credits to expire unused, in each case reducing or eliminating the benefit of such net operating losses and tax credits and potentially adversely affecting our financial position, including our after-tax net income. Similar rules and limitations may apply for state income tax purposes.

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In September 2014, we adopted an amendment to our shareholder rights plan to help preserve our tax assets by deterring certain stockholders from increasing their percentage ownership in our stock; however, such amendment is merely a deterrent that does not actually prevent Section 382 ownership limitations and there can be no assurance that we will not undergo an ownership change. Even minor accumulations by certain of our stockholders could result in triggering an ownership change under Section 382. If such an ownership change were to occur, we expect that our net operating losses could become limited; however, the amount of the limitation would depend on a number of factors including our market value at the time of the ownership change. For a discussion of the amendment to our shareholder rights plan, see the discussion in Note N, "Stockholders' Equity," to our consolidated financial statements included in this Annual Report on Form 10-K.

In addition, we have recorded deferred tax assets based on our assessment that we will be able to realize the benefits of our net operating losses and other favorable tax attributes. Realization of deferred tax assets involve significant judgments and estimates which are subject to change and ultimately depends on generating sufficient taxable income of the appropriate character during the appropriate periods. Changes in circumstances may affect the likelihood of such realization, which in turn may trigger a write-down of our deferred tax assets, the amount of which would depend on a number of factors. A write-down would reduce our reported net income, which may adversely impact our financial condition or results of operations or cash flows. In addition, we are potentially subject to ongoing and periodic tax examinations and audits in various jurisdictions, including with respect to the amount of our net operating losses and any limitation thereon. An adjustment to such net operating loss carryforwards, including an adjustment from a taxing authority, could result in higher tax costs, penalties and interest, thereby adversely impacting our financial condition, results of operations or cash flows.

An adverse determination in any current or future lawsuits in which we are a defendant could have a material adverse effect on us.

The administration of our products to, or the use of our products by, humans may expose us to liability claims, whether or not our products are actually at fault for causing any harm or injury. As Feraheme is used over longer periods of time by a wider group of patients taking numerous other medicines or by patients with additional underlying health problems, the likelihood of adverse drug reactions or unintended side effects, including death, may increase. While these adverse events are rare, all IV irons, including Feraheme, can cause patients to experience serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and/or fatal. Makena is a prescription hormone medicine (progestin) used to lower the risk of preterm birth in women who are pregnant and who have previously delivered preterm in the past. It is not known if Makena is safe and effective in women who have other risk factors for preterm birth. In one clinical study, certain complications or events associated with pregnancy occurred more often in women who received Makena. These included miscarriage (pregnancy loss before 20 weeks of pregnancy), hospital admission for preterm labor, preeclampsia, gestational hypertension and gestational diabetes. In addition, other hormones administered during pregnancy have in the past been shown to cross the placenta and have negative effects on the offspring. Although we maintain product liability insurance coverage for claims arising from the use of our products in clinical trials and commercial use, coverage is expensive, and we may not be able to maintain sufficient insurance at a reasonable cost, if at all. Product liability claims, whether or not they have merit, could also decrease demand for our products, subject us to product recalls or

harm our reputation, cause us to incur substantial costs, and divert management's time and attention.

We may also be the target of claims asserting violations of securities and fraud and abuse laws and derivative actions or other litigation. Any such litigation could result in substantial costs and divert our management's attention and resources, which could cause serious harm to our business, operating results and financial condition. Further, we may not be successful in defending ourselves in the litigation and, as a result, our business could be materially harmed. These lawsuits may result in large judgments or settlements against us, any of which could have a negative effect on our financial condition and business if in excess of our insurance coverage. Though we maintain liability insurance, if any costs or expenses associated with litigation exceed our insurance coverage, we may be forced to bear some or all of these costs and expenses directly, which could be substantial.

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Our success depends on our ability to attract and retain key employees, and any failure to do so may be disruptive to our operations.

We are a pharmaceutical company focused on marketing commercial products and services and we plan to expand our portfolio, including through the addition of commercial-stage products or services through acquisitions and in-licensing; thus, the range of skills of our executive officers needs to be broad and deep. If we are not able to hire and retain talent to drive commercialization and expansion of our portfolio, we will be unlikely to maintain profitability. Because of the specialized nature of our business, including the recent introductions of a service-based business model, our success depends to a significant extent on our ability to continue to attract, retain and motivate qualified sales, technical operations, managerial, scientific, regulatory compliance and medical personnel of all levels. The loss of key personnel or our inability to hire and retain personnel who have such sales, technical operations, managerial, scientific, regulatory compliance and medical backgrounds could materially adversely affect our business (including research and development efforts).

Our operating results will likely fluctuate, including as a result of wholesaler, distributor and customer buying patterns, so you should not rely on the results of any single quarter to predict how we will perform over time.

Our future operating results will likely vary from quarter to quarter depending on a number of factors, including the factors described in these Risk Factors, many of which we cannot control, as well as the timing and magnitude of:

Product revenues;

The loss of a key customer or GPO;

Costs and liabilities incurred in connection with business development activities or business development transactions into which we may enter;

Costs associated with the commercialization of our products and services;

Makena milestone payments we may be required to pay to the former shareholders of Lumara Health pursuant to the Lumara Agreement;

Tax payments and of principal and interest payments in connection with our debt obligations, including the 2015 Term Loan Facility, the 2023 Notes and our Convertible Notes;

Costs associated with the manufacture of our products and collection, processing and storage services, including costs of raw and other materials and costs associated with maintaining commercial inventory and qualifying additional manufacturing capacities and alternative suppliers;

The recognition of deferred tax assets during periods in which we generate taxable income and our ability to preserve our net operating loss carryforwards and other tax assets;

Costs associated with our ongoing and planned clinical studies of Feraheme, including costs associated with pursuing a broader indication of Feraheme;

Costs associated with the ongoing and planned clinical studies of Makena in connection with current or future post-approval commitments, and our pursuit of our multi-pronged next generation development programs for Makena;

Any changes to the mix of our business;

Costs associated with manufacturing batch failures or inventory write-offs due to out-of-specification release testing or ongoing stability testing that results in a batch no longer meeting specifications;

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Changes in accounting estimates related to reserves on revenue, returns, contingent consideration, impairment of long-lived or intangible assets or other accruals or changes in the timing and availability of government or customer discounts, rebates and incentives; and

The implementation of new or revised accounting or tax rules or policies.

Our results of operations, including, in particular, product revenues, may also vary from period to period due to the buying patterns of our wholesalers, distributors, pharmacies, clinics or hospitals and specialty pharmacies. Further, our contracts with GPOs often require certain performance from the members of the GPOs on an individual account level or group level such as growth over prior periods or certain market share attainment goals in order to qualify for discounts off the list price of our products, and a GPO may be able to influence the demand for our products from its members in a particular quarter through communications they make to their members. In the event wholesalers, distributors, pharmacies, clinics or hospitals with whom we do business determine to limit their purchases of our products, our product revenues could be adversely affected. Also, in the event wholesalers, distributors, pharmacies, clinics or hospitals purchase increased quantities of our products to take advantage of volume discounts or similar benefits, our quarterly results will fluctuate as re-orders become less frequent, and our overall net pricing may decrease as a result of such discounts and similar benefits. In addition, these contracts are often cancellable at any time by our customers, often without notice, and are non-exclusive agreements within the Feraheme or Makena markets. While these contracts are intended to support the use of our products, our competitors could offer better pricing, incentives, higher rebates or exclusive relationships. Because Feraheme is not indicated for the broad IDA population, the incentives in our contracts for a particular site of care are capped based on our estimate of their patients covered by our current CKD label. Because some of our competitors' products have the broad IDA label, they may provide additional incentives for all of a customer's IV iron usage, essentially becoming an exclusive provider to that particular customer.

Our contracting strategy can also have an impact on the timing of certain purchases causing product revenues to vary from quarter to quarter. For example, in advance of an anticipated or rumored price increase, including following the publication of our quarterly ASP, which affects the rate at which Feraheme is reimbursed, or a reduction in expected rebates or discounts for one of our products, customers may order our products in larger than normal quantities, which could cause sales to be lower in subsequent quarters than they would have been otherwise. Further, any changes in purchasing patterns or inventory levels, changes to our contracting strategy, increases in product returns, delays in purchasing products or delays in payment for products by one of our distributors or GPOs could also have a negative impact on our revenue and results of operations.

As a result of these and other factors, our quarterly operating results could fluctuate, and this fluctuation could cause the market price of our common stock to decline. Results from one quarter should not be used as an indication of future performance.

If the estimates we make, or the assumptions on which we rely, in preparing our consolidated financial statements and/or our projected guidance prove inaccurate, our actual results may vary from those reflected in our projections and accruals.

Our consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires management to make certain estimates and assumptions that affect the reported amounts of our assets, liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities. On an ongoing basis, our management evaluates our critical and other significant estimates and assumptions, including among others those associated with revenue recognition related to product and services sales; product sales allowances and accruals; investments; inventory; acquisition date fair value and subsequent fair value estimates used to assess impairment of long-lived assets, including goodwill, in-process research and development and other intangible assets; contingent consideration; debt obligations; certain accrued liabilities, including clinical trial accruals and restructuring liabilities; income taxes and equity-based compensation expense. We base our estimates on market data, our observance of trends in our industry, and various other assumptions that we believe to be reasonable under the circumstances. If actual results differ from these estimates, there could be a material adverse effect on our financial results and the performance of our stock.

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Further, in January 2016, we issued financial guidance, including expected 2016 total revenues and Makena, CBR and Feraheme net sales, which is likewise based on estimates and the judgment of management. If, for any reason, we are unable to realize our projected 2016 revenue, we may not realize our publicly announced financial guidance. If we fail to realize, or if we change or update any element of, our publicly disclosed financial guidance or other expectations about our business, our stock price could decline in value.

As part of our revenue recognition policy, our estimates of product returns, rebates and chargebacks, fees and other discounts require subjective and complex judgments due to the need to make estimates about matters that are inherently uncertain. Any significant differences between our actual results and our estimates could materially affect our financial position and results of operations.

In addition, to determine the required quantities of Feraheme, Makena, and the materials that support the CBR Services and their related manufacturing schedules, we also need to make significant judgments and estimates based on inventory levels, current market trends, anticipated sales, forecasts and other factors. Because of the inherent nature of estimates, there could be significant differences between our estimates and the actual amount of product need. For example, the level of our access to wholesaler and distributor inventory levels and sales data, which varies based on the wholesaler, distributor, clinic or hospital, affects our ability to accurately estimate certain reserves included in our financial statements. Any difference between our estimates and the actual amount of product or services demand could result in unmet demand or excess inventory, each of which would adversely impact our financial results and results of operations.

Our stock price has been and may continue to be volatile, and your investment in our stock could decline in value or fluctuate significantly, including as a result of analysts' activities.

The market price of our common stock has been, and may continue to be, volatile, and your investment in our stock could decline in value or fluctuate significantly. Our stock price has ranged between $20.48 and $77.73 in the fifty-two week period through February 12, 2016. The stock market has from time to time experienced extreme price and volume fluctuations, particularly in the biotechnology and pharmaceuticals sectors, which have often been unrelated to the operating performance of particular companies. Various factors and events, including the factors and events described in these Risk Factors, many of which are beyond our control, may have a significant impact on the market price of our common stock. Our stock price could also be subject to fluctuations as a result of general market conditions, shareholder activism and attempts to disrupt our strategy by activist investors, sales of large blocks of our common stock, the impact of our stock repurchase program or the dilutive effect of our Convertible Notes, other equity or equity-linked financings, or alternative strategic arrangements.

In addition, the trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us and our business. We do not control these or any other analysts. Furthermore, there are many large, well-established, publicly traded companies active in our industry and market, which may mean that it is less likely that we will receive widespread analyst coverage. In addition, our future operating results are subject to

substantial uncertainty, and our stock price could decline significantly if we fail to meet or exceed analysts' forecasts and expectations. If any of the analysts who cover us downgrade our stock, lower their price target or issue commentary or observations about us or our stock that are perceived by the market as negative, our stock price would likely decline rapidly. In addition, if these analysts cease coverage of our company, we could lose visibility in the market, which in turn could also cause our stock price to decline.

If we identify a material weakness in our internal controls over financial reporting, our ability to meet our reporting obligations and the trading price of our stock could be negatively affected.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Accordingly, a material weakness increases the risk that the financial information we report contains material errors.

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We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. In addition, we are required under the Sarbanes-Oxley Act of 2002 to report annually on our internal control over financial reporting. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. If we, or our independent registered public accounting firm, determine that our internal controls over our financial reporting are not effective, or we discover areas that need improvement in the future, or we experience high turnover of our personnel in our financial reporting functions, these shortcomings could have an adverse effect on our business and financial results, and the price of our common stock could be negatively affected.

If we cannot conclude that we have effective internal control over our financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified opinion regarding the effectiveness of our internal control over financial reporting, investors could lose confidence in the reliability of our financial statements, which could lead to a decline in our stock price. Failure to comply with reporting requirements could subject us to sanctions and/or investigations by the U.S. Securities and Exchange Commission, NASDAQ or other regulatory authorities.

Our shareholder rights plan, certain provisions in our charter and by-laws, certain provisions of our Convertible Notes, certain contractual relationships and certain Delaware law provisions could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove the current members of our Board.

We have a shareholder rights plan, the provisions of which are intended to protect our net operating loss and tax credit carryforwards. Although the plan was put in place to protect these assets, its provisions could function to deter a hostile takeover by making any proposed hostile acquisition of us more expensive and less desirable to a potential acquirer by enabling our stockholders (other than the potential hostile acquiror) to purchase significant amounts of additional shares of our common stock at dilutive prices. The rights issued pursuant to our shareholder rights plan, as amended in September 2014, become exercisable generally upon the earlier of 10 days after a person or group acquires 4.99% or more of our outstanding common stock or 10 business days after the announcement by a person or group of an intention to acquire 4.99% of our outstanding common stock via tender offer or similar transaction. The shareholder rights plan could delay or discourage transactions involving an actual or potential change in control of us or our management, including transactions in which stockholders might otherwise receive a premium for their shares over then-current prices.

In addition, certain provisions in our certificate of incorporation and our by-laws may discourage, delay or prevent a change of control or takeover attempt of our company by a third-party as well as substantially impede the ability of our stockholders to benefit from a change of control or effect a change in management and our Board. These provisions include:

- the ability of our Board to increase or decrease the size of the Board without stockholder approval;

advance notice requirements for the nomination of candidates for election to our Board and for proposals to be brought before our annual meeting of stockholders;

the authority of our Board to designate the terms of and issue new series of preferred stock without stockholder approval;

non-cumulative voting for directors; and

limitations on the ability of our stockholders to call special meetings of stockholders.

As a Delaware corporation, we are subject to the provisions of Section 203 of the Delaware General Corporation Law ("Section 203"), which prevents us from engaging in any business combination with any "interested stockholder," which is defined generally as a person that acquires 15% or more of a corporation's outstanding voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business

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combination is approved in the manner prescribed in Section 203. These provisions could have the effect of delaying or preventing a change of control, whether or not it is desired by, or beneficial to, our stockholders.

In addition to the above factors, an acquisition of our company could be made more difficult by employment agreements we have in place with our executive officers, as well as a company-wide change of control policy, which provide for severance benefits as well as the full acceleration of vesting of any outstanding options or restricted stock units in the event of a change of control and subsequent termination of employment. Further, our Third Amended and Restated 2007 Equity Incentive Plan generally permits our Board to provide for the acceleration of vesting of options granted under that plan in the event of certain transactions that result in a change of control.

Furthermore, holders of the Convertible Notes have the right to require us to repurchase their notes at a price equal to 100% of the principal amount thereof and the conversion rate for the Convertible Notes may be increased as described in the indenture, in each case, upon the occurrence of certain change of control transactions. Additionally, upon certain change of control transactions, the offsetting convertible bond hedge and warrant transactions that we entered into at the time we issued the Convertible Notes may be exercised and/or terminated early. Upon any such exercise and/or early termination, the proceeds we receive upon the exercise of the convertible bond hedge transactions may prove to be significantly lower than the amounts we would be required to pay upon termination of the warrant transactions. These features of the Convertible Notes and the convertible bond hedge and warrants, including the financial implications of any renegotiation of the above-mentioned provisions, could have the effect of preventing a change of control, whether or not it is desired by, or beneficial to, our stockholders, or may result in the acquisition of us being on terms less favorable to our stockholders than it would otherwise be.

Significant disruptions of information technology systems or security breaches could adversely affect our business.

We are increasingly dependent upon information technology systems, infrastructure, and data to operate our business. In the ordinary course of business, we collect, store, and transmit large amounts of confidential information (including but not limited to intellectual property, proprietary business information, and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party vendors who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of third-party vendors with whom we contract, and the large amounts of confidential information stored on those systems, make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third-party vendors, and/or business partners, or from cyber-attacks by malicious third parties. Cyber-attacks are increasing in their frequency, sophistication, and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, denial-of-service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information. Significant disruptions of our information technology systems or security breaches could adversely affect our business operations and/or result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including but not limited to trade secrets or other intellectual property, proprietary business information, and personal information), and could result in financial, legal, business, and reputational harm to us. For example, any such event

that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our patients or employees, could harm our reputation, require us to comply with federal and/or state breach notification laws and foreign law equivalents, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. Security breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures to protect our information technology systems and infrastructure, there can be no assurance that such measures will prevent service interruptions or security breaches that could adversely affect our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS:

None.

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ITEM 2. PROPERTIES:

In connection with the August 2015 acquisition of CBR, we own an 80,000 square foot facility located at 6550 S Bay Colony Drive #160, Tucson, Arizona, which stores all of our customers' cord blood and cord tissue samples.

In June 2013, we entered into a lease agreement with BP Bay Colony LLC (the "Landlord") for the lease of certain real property located at 1100 Winter Street, Waltham, Massachusetts for use as our principal executive offices. Beginning in September 2013, the initial term of the lease is five years and two months with one five year extension term at our option. During 2015, we entered into several amendments to the original lease to add additional space and to extend the term of the original lease to June 2021. In addition to base rent, we are also required to pay a proportionate share of the Landlord's operating costs.

In connection with November 2014 acquisition of Lumara Health, we assumed the lease of certain real property located at 16640 Chesterfield Grove Road, Chesterfield, Missouri (the "St. Louis Premises"). We terminated the lease in May 2015.

In connection with the August 2015 acquisition of CBR, we assumed the lease of certain real property located at 1200 Bayhill Drive, San Bruno, California. The lease expires in September 2017 and provides for a 3% annual increase in rent.

See Note P, "Commitments and Contingencies" to our consolidated financial statements included in this Annual Report on Form 10 K for additional information.

ITEM 3. LEGAL PROCEEDINGS

We accrue a liability for legal contingencies when we believe that it is both probable that a liability has been incurred and that we can reasonably estimate the amount of the loss. We review these accruals and adjust them to reflect ongoing negotiations, settlements, rulings, advice of legal counsel and other relevant information. To the extent new information is obtained and our views on the probable outcomes of claims, suits, assessments, investigations or legal proceedings change, changes in our accrued liabilities would be recorded in the period in which such determination is made. For certain matters referenced below, the liability is not probable or the amount cannot be reasonably estimated and, therefore, accruals have not been made. In addition, in accordance with the relevant authoritative guidance, for any matters in which the likelihood of material loss is at least reasonably possible, we will provide disclosure of the

possible loss or range of loss. If a reasonable estimate cannot be made, however, we will provide disclosure to that effect. See Note P, “Commitments and Contingencies” to our consolidated financial statements included in this Annual Report on Form 10 K for a description of our legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

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PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES:

Market Information

Our common stock trades on the NASDAQ Global Select Market ("NASDAQ") under the trading symbol "AMAG." On February 12, 2016, the closing price of our common stock, as reported on the NASDAQ, was $21.40 per share. The following table sets forth, for the periods indicated, the high and low sale prices per share for our common stock as reported on the NASDAQ.

	High	Low
Year Ended December 31, 2015		
First quarter	$ 59.29	$ 38.25
Second quarter	$ 74.21	$ 50.32
Third quarter	$ 77.73	$ 37.73
Fourth quarter	$ 42.95	$ 25.26
Year Ended December 31, 2014		
First quarter	$ 24.93	$ 18.52
Second quarter	$ 20.88	$ 16.49
Third quarter	$ 33.57	$ 17.79
Fourth quarter	$ 44.81	$ 29.76

Stockholders

On February 12, 2016, we had approximately 80 stockholders of record of our common stock, and we believe that the number of beneficial holders of our common stock was approximately 17,000 based on responses from brokers to a search conducted by Broadridge Financial Solutions, Inc. on our behalf.

Dividends

We have never declared or paid a cash dividend on our common stock. We currently anticipate that we will retain all of our earnings for use in the development of our business and do not anticipate paying any cash dividends in the foreseeable future.

Repurchases of Equity Securities

The following table provides certain information with respect to our purchases of shares of our stock during the fourth quarter of 2015.

Period	Total Number of Shares Purchased(1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
October 1, 2015 through October 31, 2015	—	$ —	—	—
November 1, 2015 through November 30, 2015	2,362	29.30	—	—
December 1, 2015 through December 31, 2015	7,999	29.03	—	—
Total	10,361	$ 29.09	—	—

(1) Consists of the surrender of shares of our common stock withheld by us to satisfy the minimum tax withholding obligations in connection with the vesting of restricted stock units held by our employees.

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In January 2016, we announced a repurchase program to repurchase up to $60.0 million in shares of our common stock. The repurchase program does not have an expiration date and may be suspended for periods or discontinued at any time.

Securities Authorized for Issuance Under Equity Compensation Plans

See Part III, Item 12 for information regarding securities authorized for issuance under our equity compensation plans. Such information is incorporated by reference to our definitive proxy statement pursuant to Regulation 14A, which we intend to file with the U.S. Securities and Exchange Commission (the "SEC") not later than 120 days after the close of our year ended December 31, 2015.

Five Year Comparative Stock Performance

The following graph compares the yearly percentage change in the cumulative total stockholder return on our common stock with the cumulative total return on the NASDAQ Global Market Composite Index and NASDAQ Biotechnology Index over the past five years. This year we added to our comparison table the NASDAQ Global Select Market Index as that is the market our stock currently trades on and we therefore believe that the companies comprising that index more closely reflect the business characteristics of our company. We will not include the NASDAQ Global Market Composite Index in next year's performance graph. The comparisons assume $100 was invested on December 31, 2010 in our common stock, in the NASDAQ Global Market, the NASDAQ Biotechnology Index and the NASDAQ Global Select Market, and assumes reinvestment of dividends, if any.

	12/31/2010	12/31/2011	12/31/2012	12/31/2013	12/31/2014	12/31/2015
AMAG Pharmaceuticals, Inc.	100.00	104.48	81.27	134.14	235.47	166.80
NASDAQ Global Market Composite Index	100.00	86.69	100.14	167.09	177.14	177.11
NASDAQ Biotechnology Index	100.00	112.09	148.78	247.01	331.99	371.06
NASDAQ Global Select Market Index	100.00	98.72	114.45	157.93	179.57	190.54

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The stock price performance shown in this performance graph is not necessarily indicative of future price performance. Information used in the graph was obtained from Zach's Investment Research, Inc., a source we believe is reliable.

The material in this section captioned Five Year Comparative and Stock Performance is being furnished and shall not be deemed "filed" with the SEC for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall the material in this section be deemed to be incorporated by reference in any registration statement or other document filed with the SEC under the Securities Act of 1933, except to the extent we specifically and expressly incorporate it by reference into such filing.

ITEM 6. SELECTED FINANCIAL DATA:

The following table sets forth selected financial data as of and for the years ended December 31, 2015, 2014, 2013, 2012 and 2011. The selected financial data set forth below has been derived from our audited financial statements. This information should be read in conjunction with the financial statements and the related notes thereto included in Part II, Item 8 of this Annual Report on Form 10 K and Management's Discussion and Analysis of Financial Condition and Results of Operations included in Part II, Item 7 of this Annual Report on Form 10 K.

	Years Ended December 31,				
	2015 (1)	2014 (2)	2013	2012	2011
	(in thousands, except per share data)				
Statement of Operations Data					
Revenues:					
U.S. product sales, net	$ 341,816	$ 109,998	$ 71,692	$ 58,903	$ 52,928
Service revenues, net	24,132	—	—	—	—
License fee, collaboration and other revenues (3)	52,328	14,386	9,164	26,475	8,321
Total revenues	418,276	124,384	80,856	85,378	61,249
Costs and expenses:					
Cost of product sales (4)	78,509	20,306	11,960	14,220	10,531
Cost of services	9,992	—	—	—	—
Research and development expenses	42,878	24,160	20,564	33,296	58,140
Selling, general and administrative expenses	160,309	72,254	59,167	53,071	68,863
Acquisition-related costs	11,232	9,478	782	—	—
Restructuring expenses	4,136	2,023	—	2,215	3,508
Total costs and expenses	307,056	128,221	92,473	102,802	141,042
Operating income (loss)	111,220	(3,837)	(11,617)	(17,424)	(79,793)
Other income (expense):					
Interest expense (5)	(53,251)	(14,697)	—	—	—
Loss on debt extinguishment (5)	(10,449)	—	—	—	—
Interest and dividend income, net	1,512	975	1,051	1,286	1,747
Other income (expense) (5)	(9,188)	217	964	(1,466)	(193)
Total other income (expense)	(71,376)	(13,505)	2,015	(180)	1,554
Net income (loss) before income taxes	39,844	(17,342)	(9,602)	(17,604)	(78,239)
Income tax expense (benefit) (6)	7,065	(153,159)	—	(854)	(1,170)
Net income (loss)	$ 32,779	$ 135,817	$ (9,602)	$ (16,750)	$ (77,069)
Net income (loss) per share:					

Basic	$ 1.04	$ 6.06	$ (0.44)	$ (0.78)	$ (3.64)
Diluted	$ 0.93	$ 5.45	$ (0.44)	$ (0.78)	$ (3.64)
Weighted average shares outstanding used to compute net income (loss) per share:					
Basic	31,471	22,416	21,703	21,392	21,189
Diluted	35,308	25,225	21,703	21,392	21,189

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	December 31, 2015	2014	2013	2012	2011
	(in thousands)				
Balance Sheet Data					
Cash, cash equivalents and investments	$ 466,331	$ 144,186	$ 213,789	$ 227,043	$ 229,704
Working capital (current assets less current liabilities)	$ 360,753	$ 107,548	$ 211,284	$ 221,423	$ 201,037
Total assets	$ 2,487,432	$ 1,388,933	$ 265,459	$ 258,137	$ 267,224
Long-term liabilities	$ 1,309,247	$ 762,492	$ 59,930	$ 52,383	$ 47,634
Stockholders' equity	$ 932,264	$ 459,953	$ 172,408	$ 172,797	$ 180,596

(1) Includes the results of operations of CBR during the post acquisition period from August 17, 2015 through December 31, 2015. See Note C, "Business Combinations," to our consolidated financial statements included in this Annual Report on Form 10 K for additional information.

(2) Includes the results of operations of Lumara Health during the post acquisition period from November 12, 2014 through December 31, 2014. See Note C, "Business Combinations," to our consolidated financial statements included in this Annual Report on Form 10 K for additional information.

(3) In 2015, we recognized $44.4 million in revenues associated with the amortization of the remaining deferred revenue balance as a result of terminating the Takeda Agreement and $6.7 million of additional revenues related to payments made by Takeda upon the final termination date under the terms of the Takeda Termination Agreement.

(4) Cost of product sales in 2015 and 2014 includes approximately $63.3 million and $6.1 million of non cash expense related to the amortization of the step up of Lumara Health's inventories and intangible assets to fair value at the acquisition date. See Note C, "Business Combinations," and Note H, "Goodwill and Intangible Assets, Net," to our consolidated financial statements included in this Annual Report on Form 10 K for additional information.

(5) Includes interest expense associated with our current debt obligations, including the 2023 Senior Notes and the 2015 Term Loan Facility entered into in August 2015, the 2014 Term Loan Facility entered into in November 2014 and repaid in August 2015, and the Convertible Notes entered into in February 2014. In addition, a $10.4 million loss on debt extinguishment is included in 2015 as the result of the early repayment of the 2014 Term Loan Facility. 2015 also includes $9.2 million of other expense associated with the financing of the CBR acquisition.

(6) The $153.2 million income tax benefit in 2014 reflects a $132.9 million decrease in our valuation allowance due to taxable temporary differences available as a source of income to realize the benefit of certain of our pre existing deferred tax assets as a result of the acquisition of Lumara Health. See Note J, "Income Taxes," to our consolidated financial statements included in this Annual Report on Form 10 K for additional information.

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ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS:

AMAG's Portfolio of Products and Services

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We use our business and clinical expertise to develop and commercialize products that provide clear benefits and improve people's lives. We have a diverse portfolio of products and services with a focus on maternal health, anemia management and cancer supportive care, including our product Makena® (hydroxyprogesterone caproate injection), which we acquired in November 2014, services related to the collection, processing and storage of umbilical cord blood stem cell and cord tissue units operated through Cord Blood Registry® ("CBR"), which we acquired in August 2015, our product Feraheme® (ferumoxytol) and MuGard® Mucoadhesive Oral Wound Rinse. We intend to continue to expand the impact of these and future products and services for patients by delivering on our growth strategy, which includes organic growth, as well as the pursuit of products and companies that align with our existing therapeutic areas or those that could benefit from our proven core competencies. Currently, our primary sources of revenue are from sales of Makena, CBR Services and Feraheme.

On August 17, 2015, we acquired CBR from CBR Acquisition Holdings Corp. for $700.0 million in cash consideration, subject to estimated working capital, indebtedness and other adjustments. CBR is the largest private newborn stem cell bank in the world that offers pregnant women and their families the ability to preserve their newborns' umbilical cord blood and cord tissue for potential future use (the "CBR Services"), which we market and sell directly to consumers. As of December 31, 2015, CBR stored approximately 633,000 umbilical cord blood and cord tissue units. Additional details regarding the acquisition of CBR can be found in Note C, "Business Combinations," to our consolidated financial statements included in this Annual Report on Form 10 K.

On July 22, 2015, we entered into an option agreement with Velo Bio, LLC ("Velo"), a privately held life-sciences company that granted us an option to acquire the rights to an orphan drug candidate, digoxin immune fab ("DIF"), a polyclonal antibody in clinical development for the treatment of severe preeclampsia in pregnant women. We made an upfront payment of $10.0 million in the third quarter of 2015 for the option to acquire the global rights to the DIF program (the "DIF Rights"), which was recorded in research and development expenses in our consolidated statements of operations. DIF has been granted both orphan drug and fast-track review designations by the U.S. Food and Drug Administration ("FDA") for use in treating severe preeclampsia. Under the option agreement, Velo will complete a dose ranging study and a Phase 2b/3a clinical study. Following the conclusion of the DIF Phase 2b/3a study, we may terminate, or, for additional consideration, exercise or extend, our option to acquire the DIF Rights. If we exercise the option to acquire the DIF Rights, we would be responsible for additional costs in pursuing FDA approval, and would be obligated to pay certain milestone payments and single-digit royalties based on regulatory approval and commercial performance of the product to Velo. If we exercise the option, we will be responsible for payments totaling up to $65.0 million (including the payment of the option exercise price and the regulatory milestone payments) and up to an additional $250.0 million in sales milestone payments based on the achievement of annual sales milestones at targets ranging from $100.0 million to $900.0 million. We anticipate that results from the pivotal Phase 2b/3a study could be available as early as 2018.

In November 2014, we acquired Lumara Health Inc. (“Lumara Health”) at which time Lumara Health became our wholly-owned subsidiary. Under the terms of the acquisition agreement (the “Lumara Agreement”), we acquired 100% of the equity ownership of Lumara Health, excluding the assets and liabilities of the Women’s Health Division and certain other assets and liabilities, which were divested by Lumara Health prior to closing, for $600.0 million in cash consideration, subject to net working capital and other adjustments, and issued approximately 3.2 million shares of our common stock, having a value of approximately $112.0 million at the time of closing, to the holders of common stock of Lumara Health. The Lumara Agreement provides for future contingent payments of up to $350.0 million in cash (or upon mutual agreement between us and the former Lumara Health security holders, future contingent payments may also be made in common stock or some combination thereof) payable by us to the former Lumara Health security holders based upon the achievement of certain sales milestones through calendar year 2019. By virtue of the acquisition of Lumara Health, we acquired Makena, a progestin indicated to reduce the risk of preterm birth in women pregnant with a single baby who have a history of singleton spontaneous preterm birth. Makena was approved by the FDA in February 2011 and was granted orphan drug exclusivity through February 3, 2018. We sell Makena primarily to

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specialty pharmacies, specialty distributors, home infusion companies and pharmacies which, in turn, sell Makena to healthcare providers, hospitals, government agencies and integrated delivery systems. In 2015, sales of Makena accounted for approximately 60% of our total net revenues. Additional details regarding the Lumara Agreement can be found in Note C, “Business Combinations,” to our consolidated financial statements included in this Annual Report on Form 10 K.

Feraheme was approved for marketing in the U.S. in June 2009 by the FDA for use as an IV iron replacement therapy for the treatment of iron deficiency anemia (“IDA”) in adult patients with chronic kidney disease (“CKD”). We began selling Feraheme in July 2009 through our commercial organization, including a specialty sales force. We sell Feraheme to authorized wholesalers and specialty distributors, who, in turn, sell Feraheme to healthcare providers who administer Feraheme primarily within hospitals, hematology and oncology centers, and nephrology clinics. In 2015, U.S. sales of Feraheme accounted for approximately 21% of our total net revenues.

In June 2013, we entered into a license agreement with Abeona Therapeutics, Inc. (“Abeona”) (formerly known as PlasmaTech Biopharmaceuticals, Inc. and Access Pharmaceuticals, Inc.), under which we acquired the U.S. commercial rights to MuGard for the management of oral mucositis and stomatitis (the “MuGard Rights”). Additional details regarding the acquisition of the MuGard Rights can be found in Note C, “Business Combinations,” to our consolidated financial statements included in this Annual Report on Form 10 K.

Makena Developments

In February 2016, the FDA approved our prior approval supplement to the original Makena New Drug Application (“NDA”) filed with the FDA in July 2015 seeking approval of a single-dose (1 mL) preservative-free formulation of Makena to be manufactured by Hospira, Inc. (“Hospira”), our current manufacturer of the multidose vial. We are also pursuing approval of our October 2014 prior approval supplement for Coldstream Laboratories, Inc. (“Coldstream”) to be approved to manufacture the single-dose preservative-free formulation. In May 2015, we received a complete response letter from the FDA for the Coldstream prior approval supplement requesting additional information related to manufacturing procedures for the single-dose preservative-free formulation at Coldstream and we are currently working with Coldstream to develop the required information requested by the FDA in the complete response letter in order to provide a response to the FDA. In light of the recent approval of the Hospira prior approval supplement, we are planning for a commercial launch of the single-dose preservative-free formulation in the second quarter of 2016.

We have continued to advance our multi-pronged next generation development programs for Makena (which we previously referred to as our lifecycle management program) seeking to enhance the product profile for patients and their healthcare providers. We are working to develop an auto-injector device for subcutaneous administration of Makena, including chemistry, manufacturing and controls (“CMC”) development with Antares Pharma, Inc. (“Antares”) and pilot clinical studies to establish the appropriate subcutaneous dose. We are planning for a single-dose pharmacokinetics (“PK”) bioequivalence study to capture certain clinical measures to support clinical superiority of the

auto-injector compared to the existing intramuscular injection. We are also in the early stages of developing a longer-acting formulation of Makena, including conducting formulation work and pre-clinical studies to optimize the drug release profile.

Makena was approved under the provisions of the FDA's "Subpart H" Accelerated Approval regulations. As a condition of approval under Subpart H, the FDA required that Makena's sponsor perform certain adequate and well-controlled post-approval clinical studies to verify and describe the clinical benefit of Makena as well as fulfill certain other post-approval commitments. We have completed a PK trial of women taking Makena and are currently conducting two other studies to fulfill these obligations. In October 2015, in response to our request to extend our agreed-upon completion dates for two of these studies, the FDA notified us that it approved a two-year extension for those two studies to December 2018 and October 2020.

Feraheme Developments

In March 2015, following discussions with the FDA, we updated our Feraheme label to include (a) the addition of a boxed warning related to the risks of serious hypersensitivity reactions or anaphylaxis, which risks were previously

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described only in the Warnings and Precautions section; (b) revisions to the Dosing and Administration section to indicate that Feraheme should only be administered by IV infusion; and (c) modifications to the Warnings and Precautions section to include a statement that patients with a history of multiple drug allergies may have a greater risk of anaphylaxis with parenteral iron products.

In December 2014, we entered into an agreement (the "Takeda Termination Agreement"), which terminated our License, Development and Commercialization Agreement (as amended, the "Takeda Agreement") with Takeda Pharmaceutical Company Limited ("Takeda") . Under the terms of the Takeda Agreement, Takeda had exclusive rights to develop and commercialize Feraheme as a therapeutic agent in certain agreed-upon territories outside of the U.S. Pursuant to the Takeda Termination Agreement, the termination of the Takeda Agreement was effective on a rolling basis, with final termination pursuant to its terms occurring in June 2015. As a result, we recognized all remaining deferred revenues related to Takeda into revenues in 2015.

In December 2012, we submitted a supplemental new drug application ("sNDA") to the FDA seeking approval for Feraheme for the treatment of IDA in adult patients who had failed or could not tolerate oral iron or in whom oral iron was contraindicated. In January 2014, we received a complete response letter from the FDA for the sNDA informing us that our sNDA could not be approved in its present form and stating that we had not provided sufficient information to permit labeling of Feraheme for safe and effective use for the proposed broader indication. The FDA indicated that its decision was based on the cumulative ferumoxytol data, including the global Phase 3 IDA program and global post-marketing safety reports for the currently indicated CKD patient population. The FDA suggested, among other things, that we submit additional clinical trial data in the proposed broad IDA patient population. Following discussions with the FDA, we have recently commenced start-up activities on a new head-to-head Phase 3 clinical trial evaluating Feraheme in adults with IDA, excluding patients on hemodialysis. This new trial is a randomized, double-blind multicenter non-inferiority trial that will evaluate the incidence of moderate to severe hypersensitivity reactions (including anaphylaxis) and moderate to severe hypotension with Feraheme compared to ferric carboxymaltose infusion in adults with IDA. Two thousand patients will be randomized in a 1:1 ratio into one of two treatment groups, those receiving 1.02 grams of Feraheme IV infusion or those receiving 1.5 grams of ferric carboxymaltose IV infusion. We currently expect to initiate the trial in the first quarter of 2016.

Recent Financings

On August 17, 2015, in connection with the CBR acquisition, we completed a private placement of $500.0 million aggregate principal amount of 7.875% Senior Notes due 2023 (the "2023 Senior Notes") and entered into a credit agreement with a group of lenders and Jefferies Finance LLC, as administrative and collateral agent, that provided us with, among other things, a six-year $350.0 million term loan facility (the "2015 Term Loan Facility"). We borrowed the full $350.0 million available under the 2015 Term Loan Facility on August 17, 2015. We used the net proceeds from the August 2015 Offering, as defined below, the offering of the 2023 Senior Notes and borrowings under the 2015 Term Loan Facility along with existing cash to fund the acquisition of CBR, to repay the remaining $323.0 million outstanding principal amount under our then existing five-year term loan facility (the "2014 Term Loan Facility"), and to pay prepayment premiums, fees and expenses in connection with the foregoing.

On August 5, 2015, we sold approximately 3.6 million shares of our common stock at a public offering price of $63.75 per share (the “August 2015 Offering”), resulting in net proceeds to us of approximately $218.6 million.

In March 2015, we sold approximately 4.6 million shares of our common stock at a public offering price of $44.00 per share, resulting in net proceeds to us of approximately $188.8 million.

Additional details regarding our recent financing activities can be found in Note N, “Stockholders’ Equity” and Note R, “Debt” to our consolidated financial statements included in this Annual Report on Form 10-K.

Our common stock trades on the NASDAQ Global Select Market under the trading symbol “AMAG.”

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Critical Accounting Policies

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires management to make certain estimates and assumptions that affect the reported amount of assets, liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities. Actual results could differ materially from those estimates. Management employs the following critical accounting policies affecting our most significant estimates and assumptions: revenue recognition and related sales allowances and accruals; business combinations, including goodwill, intangible assets and acquisition related contingent consideration; valuation of investments; equity based compensation; and income taxes.

1.Revenue Recognition and Related Sales Allowances and Accruals

Our primary sources of revenue during the reporting periods were: (i) product revenues from Makena and Feraheme; (ii) service revenues associated with the CBR Services; and (iii) license fees, collaboration and other revenues, which primarily included milestone payments received from our collaboration agreements, royalties received from our license agreements, and international product revenues of Feraheme derived from our collaboration agreement with Takeda. Revenue is recognized when the following criteria are met:

· Persuasive evidence of an arrangement exists;

· Delivery of product has occurred or services have been rendered;

· The sales price charged is fixed or determinable; and

· Collection is reasonably assured.

Product Revenue

We recognize product revenues net of certain allowances and accruals in our consolidated statements of operations at the time of sale. Our contractual adjustments include provisions for returns, pricing and prompt payment discounts, as well as wholesaler distribution fees, and volume-based and other commercial rebates. Governmental rebates relate to our reimbursement arrangements with state Medicaid programs. In addition, we also monitor our distribution channel to determine whether additional allowances or accruals are required based on inventory in our sales channel. Calculating these gross to net sales adjustments involves estimates and judgments based primarily on actual product

sales data, forecasted customer buying patterns, and market research data related to utilization rates by various end-users. If we determine in future periods that our actual experience is not indicative of our expectations, if our actual experience changes, or if other factors affect our estimates, we may be required to adjust our allowances and accruals estimates, which would affect our net product sales in the period of the adjustment and could be significant.

Classification of Product Sales Allowances and Accruals

Product sales allowances and accruals are primarily comprised of both direct and indirect fees, discounts and rebates and provisions for estimated product returns. Direct fees, discounts and rebates are contractual fees and price adjustments payable to wholesalers, specialty distributors and other customers that purchase products directly from us. Indirect fees, discounts and rebates are contractual price adjustments payable to healthcare providers and organizations, such as certain physicians, clinics, hospitals, group purchasing organizations (“GPOs”), and dialysis organizations that typically do not purchase products directly from us but rather from wholesalers and specialty distributors. In accordance with guidance related to accounting for fees and consideration given by a vendor to a customer, including a reseller of a vendor’s products, these fees, discounts and rebates are presumed to be a reduction of the selling price. Product sales allowances and accruals are based on definitive contractual agreements or legal requirements (such as Medicaid laws and regulations) related to the purchase and/or utilization of the product by these entities and are recorded in the same period that the related revenue is recognized. We estimate product sales allowances and accruals using either historical, actual and/or other data, including estimated patient usage, applicable contractual rebate rates, contract performance by the

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benefit providers, other current contractual and statutory requirements, historical market data based upon experience of our products and other products similar to them, specific known market events and trends such as competitive pricing and new product introductions, current and forecasted customer buying patterns and inventory levels, and the shelf life of our products. As part of this evaluation, we also review changes to federal and other legislation, changes to rebate contracts, changes in the level of discounts, and changes in product sales trends. Although allowances and accruals are recorded at the time of product sale, certain rebates are typically paid out, on average, up to three months or longer after the sale.

Allowances against receivable balances primarily relate to prompt payment discounts, provider chargebacks and certain government agency rebates and are recorded at the time of sale, resulting in a reduction in product sales revenue and the reporting of product sales receivables net of allowances. Accruals related to Medicaid and provider volume rebates, wholesaler and distributor fees, GPO fees, other discounts to healthcare providers and product returns are recorded at the time of sale, resulting in a reduction in product sales and the recording of an increase in accrued expenses.

Discounts

We typically offer a 2% prompt payment discount to our customers as an incentive to remit payment in accordance with the stated terms of the invoice, generally thirty days. Because we anticipate that those customers who are offered this discount will take advantage of the discount, we accrue 100% of the prompt payment discount at the time of sale, based on the gross amount of each invoice. We adjust the accrual quarterly to reflect actual experience.

Chargebacks

Chargeback reserves represent our estimated obligations resulting from the difference between the prices at which we sell our products to wholesalers and the sales price ultimately paid to wholesalers under fixed price contracts by third-party payers, including governmental agencies. We determine our chargeback estimates based on actual product sales data and forecasted customer buying patterns. Actual chargeback amounts are determined at the time of resale to the qualified healthcare provider, and we generally issue credits for such amounts within several weeks of receiving notification from the wholesaler. Estimated chargeback amounts are recorded at the time of sale, and we adjust the allowance quarterly to reflect actual experience.

Distributor/Wholesaler and Group Purchasing Organization Fees

Fees under our arrangements with distributors and wholesalers are usually based upon units of product purchased during the prior month or quarter and are usually paid by us within several weeks of our receipt of an invoice from the wholesaler or distributor, as the case may be. Fees under our arrangements with GPOs are usually based upon member purchases during the prior quarter and are generally billed by the GPO within 30 days after period end. Current accounting standards related to consideration given by a vendor to a customer, including a reseller of a vendor's products, specify that cash consideration given by a vendor to a customer is presumed to be a reduction of the selling price of the vendor's products or services and therefore should be characterized as a reduction of product sales. Consideration should be characterized as a cost incurred if we receive, or will receive, an identifiable benefit (goods or services) in exchange for the consideration and we can reasonably estimate the fair value of the benefit received. Because the fees we pay to wholesalers do not meet the foregoing conditions to be characterized as a cost, we have characterized these fees as a reduction of product sales and have included them in government and other rebates in the table below. We generally pay such amounts within several weeks of our receipt of an invoice from the distributor, wholesaler or GPO. Accordingly, we accrue the estimated fee due at the time of sale, based on the contracted price invoiced to the customer. We adjust the accrual quarterly to reflect actual experience.

Product Returns

Consistent with industry practice, we generally offer our wholesalers, specialty distributors and other customers a limited right to return our products based on the product's expiration date. Currently the expiration dates for Feraheme and Makena are five and three years, respectively. We estimate product returns based on the historical return patterns and

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known or expected changes in the marketplace. We track actual returns by individual production lots. Returns on lots eligible for credits under our returned goods policy are monitored and compared with historical return trends and rates.

We expect that wholesalers and healthcare providers will not stock significant inventory due to the cost of the product, the expense to store our products, and/or that our products are readily available for distribution. We record an estimate of returns at the time of sale. If necessary, our estimated rate of returns may be adjusted for actual return experience as it becomes available and for known or expected changes in the marketplace. During 2014, we reduced our reserve for Feraheme product returns by approximately $1.8 million, primarily as a result of a lower than expected rate of product returns. We did not significantly adjust our reserve for product returns during 2015 or 2013. To date, returns of Feraheme have been relatively limited; however, returns experience may change over time. As we continue to gain more historical experience with actual returns and continue to gain additional experience with return rates for Makena, we may be required to make a future adjustment to our product returns estimate, which would result in a corresponding change to our net product sales in the period of adjustment and could be significant.

Government and Other Rebates

Government and other rebate reserves relate to our reimbursement arrangements with state Medicaid programs, and contractual or performance rebate agreements with certain classes of trade. We determine our estimates for Medicaid rebates, if applicable, based on actual product sales data and our historical product claims experience. In estimating these reserves, we provide for a Medicaid rebate associated with both those expected instances where Medicaid will act as the primary insurer as well as in those instances where we expect Medicaid will act as the secondary insurer. For rebates associated with reaching defined performance goals, we determine our estimates using actual product sales data and forecasted customer buying and utilization patterns. Rebate amounts generally are invoiced quarterly and are paid in arrears, and we expect to pay such amounts within several weeks of notification by the Medicaid or provider entity. Estimated government and other rebates are recorded at the time of sale and, with the exception of Medicaid as discussed below, we adjust the accrual quarterly to reflect actual experience.

During 2013, we revised our estimated Feraheme Medicaid reserve rate based on actual product-specific rebate claims received since the 2009 launch of Feraheme, our expectations of state level activities, and estimated rebate claims not yet submitted, which resulted in a reduction of our then estimated Medicaid rebate reserve related to prior period Feraheme sales of $0.6 million. These changes in estimates were reflected as an increase in our net product sales for 2013 and resulted in a reduction to our gross to net percentages in 2013. We did not make any significant adjustments to our Medicaid reserve in 2015 or 2014. We regularly assess our Medicaid reserve balance and the rate at which we accrue for claims against product sales. If we determine in future periods that our actual rebate experience is not indicative of expected claims, if actual claims experience changes, or if other factors affect estimated claims rates, we may be required to adjust our current Medicaid accumulated reserve estimate, which would affect net product sales in the period of the adjustment and could be significant.

Healthcare Reform Legislation

The Health Care and Education Reconciliation Act of 2010 (the "Healthcare Reform Act") was enacted in the U.S. in March 2010 and includes certain cost containment measures including an increase to the minimum rebates for products covered by Medicaid programs and the extension of such rebates to drugs dispensed to Medicaid beneficiaries enrolled in Medicaid managed care organizations as well as the expansion of the 340B Drug pricing program under the Public Health Service Act. This legislation contains provisions that can affect the operational results of companies in the pharmaceutical industry and healthcare related industries, including us, by imposing on them additional costs.

The Healthcare Reform Act also requires pharmaceutical manufacturers to pay a prorated share of the overall Branded Drug Fee, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the legislation. The amount of our annual share of the Branded Drug Fee for each of the 2015, 2014 and 2013 annual periods was approximately $0.1 million and these payments were non deductible for income tax purposes. We have included these amounts in selling, general and administrative expense in our consolidated statements of operations. The amount of this annual payment could increase in future years due to both higher eligible Feraheme sales and the increasing amount of the overall fee assessed across manufacturers, but any such increases are not expected to be

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material to our results of operations or financial condition. The Healthcare Reform Act exempts “orphan drugs” such as Makena from 340B ceiling price requirements for the covered entity types newly added to the program by the Healthcare Reform Act.

In addition, the number of 340B institutions, which provide drugs at reduced rates, was expanded by the Healthcare Reform Act to include additional hospitals. As a result, the volume of Feraheme business sold to 340B eligible entities has increased since the implementation of the Healthcare Reform Act. Feraheme sold to 340B eligible entities comprised approximately 20% and 17% of our total Feraheme sales in grams for 2015 and 2014, respectively. Because these institutions are eligible for federal pricing discounts, the revenue realized per unit of Feraheme sold to 340B institutions is lower than from some of our other customers.

Further, under the sequestration required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012, Medicare payments for all items and services under Parts A and B incurred on or after April 1, 2013 have been reduced by up to 2%. Therefore, after adjustment for deductible and co insurance, the reimbursement rate for physician administered drugs, including Feraheme, under Medicare Part B has been reduced from average selling price (“ASP”) plus 6% to ASP plus 4.3%. Beginning in April 2013, we amended certain of our Feraheme customer contracts to try to partially address the impact of sequestration on our customers and their patients. These amendments have led to increased discounts and rebates in 2015 as compared to 2014.

We were not materially impacted by healthcare reform legislation during 2015, 2014 and 2013. Presently, we have not identified any provisions that could materially impact our business but we continue to monitor ongoing legislative developments and we are assessing what impact recent healthcare reform legislation will have on our business following the consummation of our recent acquisitions.

Multiple Element Arrangements

We evaluate revenue from arrangements that have multiple elements to determine whether the components of the arrangement represent separate units of accounting as defined in the accounting guidance related to revenue arrangements with multiple deliverables. Under current accounting guidance, which governs any agreements that contain multiple elements that are either entered into or materially modified subsequent to January 1, 2011, companies are required to establish the selling price of its products and services based on a separate revenue recognition process using management’s best estimate of the selling price when there is no vendor-specific objective evidence or third-party evidence to determine the selling price of that item. If a delivered element is not considered to have standalone value, all elements of the arrangement are recognized as revenue as a single unit of accounting over the period of performance for the last such undelivered item or services. Significant management judgment is required in determining what elements constitute deliverables and what deliverables or combination of deliverables should be considered units of accounting.

When multiple deliverables are combined and accounted for as a single unit of accounting, we base our revenue recognition pattern on the last to be delivered element. Revenue is recognized using either a proportional performance or straight-line method, depending on whether we can reasonably estimate the level of effort required to complete our performance obligations under an arrangement and whether such performance obligations are provided on a best-efforts basis. To the extent we cannot reasonably estimate our performance obligations, we recognize revenue on a straight-line basis over the period we expect to complete our performance obligations. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which we are expected to complete our performance obligations under an arrangement. We may have to revise our estimates based on changes in the expected level of effort or the period we expect to complete our performance obligations.

For multiple element arrangements, we allocate revenue to all deliverables based on their relative selling prices. We determine the selling price to be used for allocating revenue to deliverables as follows: (i) vendor specific objective evidence; (ii) third-party evidence of selling price and (iii) the best estimate of the selling price. Vendor specific objective evidence generally exists only when we sell the deliverable separately and it is the price actually charged by us for that deliverable. Any discounts given to the customer are allocated by applying the relative selling price method.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in our

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consolidated balance sheets. Deferred revenue associated with our service revenues includes (i) amounts collected in advance of unit processing and (ii) amounts associated with unearned storage fees collected at the beginning of the storage contract term, net of allocated discounts. Amounts not expected to be recognized within the next year are classified as long-term deferred revenues.

Service Revenue

We have identified two deliverables contained in the revenue arrangements for the CBR Services, which include: (i) enrollment, including the provision of a collection kit and cord blood and cord tissue unit processing, which are delivered at the beginning of the relationship (the “processing services”), with revenue for this deliverable recognized after the collection and successful processing of the cord blood and cord tissue; and (ii) the storage of newborn cord blood and cord tissue units (the “storage services”), for either an annual fee or a prepayment of 18 years or the lifetime of the newborn donor (“lifetime option”), with revenue for this deliverable recognized ratably over the applicable storage period. For the lifetime option, storage fees are not charged during the lifetime of the newborn donor. However, if the newborn donor dies and his/her legal guardian chooses to continue to store the newborn stem cells and/or cord tissue, the number of remaining years of storage covered by the lifetime option without additional charge is calculated by taking the average of male and female life expectancies based on lifetime actuarial tables published by the Social Security Administration in effect at the time of the newborn’s birth and subtracting the age at death. As there are other vendors who provide processing services and storage services at separately stated list prices, the processing services and storage services, including the first year storage, each have standalone value to the customer, and therefore represent separate deliverables. The selling price for the processing services are estimated based on the best estimate of selling price because we do not have vendor specific objective evidence or third-party evidence of selling price for these elements. The selling price for the storage services is determined based on vendor specific objective evidence as we have standalone renewals to support the selling price.

License Fee, Collaboration and Other Revenues

The terms of product development and commercialization agreements entered into between us and our collaborative licensees may include non-refundable license fees, payments based on the achievement of certain milestones and performance goals, reimbursement of certain out-of-pocket costs, including research and development expenses, payment for manufacturing services, and royalties on product sales. We recognize license fee and research and development revenue under collaborative arrangements over the term of the applicable agreements using a proportional performance model, if practical. Otherwise, we recognize such revenue on a straight-line basis. Under this model, revenue is generally recognized in an amount equal to the lesser of the amount due under the agreements or an amount based on the proportional performance to date. In cases where project costs or other performance metrics are not estimable but there is an established contract period, revenues are recognized on a straight-line basis over the term of the relevant agreement. In cases where we are reimbursed for certain research and development costs associated with our collaboration agreements and where we are acting as the principal in carrying out these services, any reimbursement payments are recorded in license fee, collaboration and other revenues in our consolidated statement of operations to match the costs that we incur during the period in which we perform those services. Nonrefundable payments and fees are recorded as deferred revenue upon receipt and may require deferral of revenue

recognition to future periods.

Our collaboration agreements may entitle us to additional payments upon the achievement of performance-based milestones. If a milestone involves substantive effort on our part and its achievement is not considered probable at the inception of the collaboration, we recognize the milestone consideration as revenue in the period in which the milestone is achieved only if it meets the following additional criteria:

· The milestone consideration received is commensurate with either the level of effort required to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from our performance to achieve the milestone;

· The milestone is related solely to our past performance; and

· The milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement.

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There is significant judgment involved in determining whether a milestone meets all of these criteria. For milestones that do not meet the above criteria and are therefore not considered substantive milestones, we recognize that portion of the milestone payment equal to the percentage of the performance period completed at the time the milestone is achieved and the above conditions are met. The remaining portion of the milestone will be recognized over the remaining performance period using a proportional performance or straight-line method.

2.Business Combinations

We account for acquired businesses using the acquisition method of accounting, under which the total purchase price of an acquisition is allocated to the net tangible and identifiable intangible assets acquired and liabilities assumed based on their estimated fair values as of the acquisition date. Acquisition related costs are expensed as incurred. Any excess of the consideration transferred over the estimated fair values of the identifiable net assets acquired is recorded as goodwill.

The purchase price allocations are initially prepared on a preliminary basis and are subject to change as additional information becomes available concerning the fair value and tax basis of the assets acquired and liabilities assumed. Any adjustments to the purchase price allocations are made as soon as practicable but no later than one year from the acquisition date.

Acquired inventory is recorded at its fair value, which generally requires a step up adjustment to recognize the inventory at its expected net realizable value. The inventory step up is recorded to cost of product sales in our consolidated statements of operations when related inventory is sold, and we record step-up costs associated with clinical trial material as research and development expense.

Goodwill and Intangible Assets

Goodwill is not amortized, but is reviewed for impairment annually as of October 31 or more frequently if indicators of impairment are present. We determine whether goodwill may be impaired by comparing the carrying value of our single reporting unit, including goodwill, to the fair value of the reporting unit. If the fair value is less than the carrying amount, a more detailed analysis is performed to determine whether goodwill is impaired. The impairment loss, if any, is measured as the excess of the carrying value of the goodwill over the implied fair value of the goodwill and is recorded in our consolidated statements of operations.

Finite lived intangible assets are amortized to their estimated residual values using an economic consumption method over their estimated useful lives and reviewed for impairment if certain events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. When such facts and circumstances exist, management compares the projected undiscounted future cash flows associated with the asset over its estimated useful life against the carrying amount. The impairment loss, if any, is measured as the excess of the carrying amount of the asset over its fair value.

Acquired in-process research and development ("IPR&D") represents the fair value assigned to research and development assets that we acquire and have not been completed at the acquisition date. The fair value of IPR&D acquired in a business combination is capitalized on our consolidated balance sheets at the acquisition date fair value and is determined by estimating the costs to develop the technology into commercially viable products, estimating the resulting revenue from the projects, and discounting the projected net cash flows to present value. IPR&D is not amortized, but rather is reviewed for impairment on an annual basis or more frequently if indicators of impairment are present, until the project is completed or abandoned. If we determine that IPR&D becomes impaired or is abandoned, the carrying value is written down to its fair value with the related impairment charge recognized in our consolidated statement of operations in the period in which the impairment occurs. Upon successful completion of each project and launch of the product, we will make a separate determination of the estimated useful life of the IPR&D intangible asset and the related amortization will be recorded as an expense prospectively over its estimated useful life.

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The projected discounted cash flow models used to estimate our IPR&D reflect significant assumptions regarding the estimates a market participant would make in order to evaluate a drug development asset, including the following:

· Probability of successfully completing clinical trials and obtaining regulatory approval;

· Market size, market growth projections, and market share;

· Estimates regarding the timing of and the expected costs to advance our clinical programs to commercialization;

· Estimates of future cash flows from potential product sales; and

· A discount rate.

Additionally, we have other indefinite-lived intangible assets which we acquired through our business combinations. These assets are reviewed for impairment on an annual basis or more frequently if indicators of impairment are present. If we determine that the asset becomes impaired, the carrying value is written down to its fair value with the related impairment charge recognized in our consolidated statements of operations in the period in which the impairment occurs.

Acquisition related Contingent Consideration

Contingent consideration arising from a business combination is included as part of the purchase price and is recognized at its estimated fair value as of the acquisition date. Subsequent to the acquisition date, we measure contingent consideration arrangements at fair value for each period until the contingency is resolved. These changes in fair value are recognized in our selling, general and administrative expenses in our consolidated statements of operations. Changes in fair values reflect new information about the likelihood of the payment of the contingent consideration and the passage of time.

3.Valuation of investments

We account for and classify our investments as either “available for sale,” “trading,” or “held to maturity,” in accordance w the accounting guidance related to the accounting and classification of certain investments in debt and equity

securities. The determination of the appropriate classification by us is based primarily on management's intent to sell the investment at the time of purchase. As of December 31, 2015 and 2014, all of our investments were classified as available for sale securities.

Available for sale securities are those securities which we view as available for use in current operations, if needed. We generally classify our available for sale securities as short term investments, even though the stated maturity date may be one year or more beyond the current balance sheet date. Available for sale investments are stated at fair value with their unrealized gains and losses included in accumulated other comprehensive loss within the consolidated statements of stockholders' equity until such gains and losses are realized in other income (expense) within the consolidated statements of operations or until an unrealized loss is considered other than temporary.

We recognize other than temporary impairments of our debt securities when there is a decline in fair value below the amortized cost basis and if (a) we have the intent to sell the security or (b) it is more likely than not that we will be required to sell the security prior to recovery of its amortized cost basis. If either of these conditions is met, we recognize the difference between the amortized cost of the security and its fair value at the impairment measurement date in our consolidated statements of operations. If neither of these conditions is met, we must perform additional analyses to evaluate whether the unrealized loss is associated with the creditworthiness of the issuer of the security rather than other factors, such as interest rates or market factors. If we determine from this analysis that we do not expect to receive cash flows sufficient to recover the entire amortized cost of the security, a credit loss exists, the impairment is considered other than temporary and is recognized in our consolidated statements of operations.

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4.Equity Based Compensation

Equity based compensation cost is generally measured at the estimated grant date fair value and recorded to expense over the requisite service period, which is generally the vesting period. Because equity based compensation expense is based on awards ultimately expected to vest, we must make certain judgments about whether employees, officers, directors, consultants and advisors will complete the requisite service period, and reduce the compensation expense being recognized for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures are estimated based upon historical experience and adjusted for unusual events such as corporate restructurings, which can result in higher than expected turnover and forfeitures. If factors change and we employ different assumptions in future periods, the compensation expense that we record in the future may differ significantly from what we have recorded in the current period.

We estimate the fair value of equity based compensation involving stock options based on the Black Scholes option pricing model. This model requires the input of several factors such as the expected option term, the expected risk free interest rate over the expected option term, the expected volatility of our stock price over the expected option term, and the expected dividend yield over the expected option term and are subject to various assumptions. The fair value of awards calculated using the Black Scholes option pricing model is generally amortized on a straight line basis over the requisite service period, and is recognized based on the proportionate amount of the requisite service period that has been rendered during each reporting period.

We estimate the fair value of our restricted stock units (“RSUs”) whose vesting is contingent upon market conditions using the Monte Carlo simulation model. The fair value of RSUs where vesting is contingent upon market conditions is amortized based upon the estimated derived service period. The fair value of RSUs granted to our employees and directors is determined based upon the quoted closing market price per share on the date of grant, adjusted for estimated forfeitures.

We believe our valuation methodologies are appropriate for estimating the fair value of the equity awards we grant to our employees and directors. Our equity award valuations are estimates and may not be reflective of actual future results or amounts ultimately realized by recipients of these grants. These amounts are subject to future quarterly adjustments based upon a variety of factors, which include, but are not limited to, changes in estimated forfeiture rates and the issuance of new equity based awards.

5.Income Taxes

We use the asset and liability method of accounting for deferred income taxes. Under this method, deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. A deferred tax

asset is established for the expected future benefit of net operating loss ("NOL") and credit carryforwards. Deferred tax assets and liabilities are measured using enacted rates in effect for the year in which those temporary differences are expected to be recovered or settled. A valuation allowance against net deferred tax assets is required if, based on available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. Significant judgments, estimates and assumptions regarding future events, such as the amount, timing and character of income, deductions and tax credits, are required in the determination of our provision for income taxes and whether valuation allowances are required against deferred tax assets. In evaluating our ability to recover our deferred tax assets, we consider all available evidence, both positive and negative, including the existence of taxable temporary differences, our past operating results, the existence of cumulative income in the most recent fiscal years, changes in the business in which we operate and our forecast of future taxable income. In determining future taxable income, we are responsible for assumptions utilized including the amount of state and federal operating income, the reversal of temporary differences and the implementation of feasible and prudent tax planning strategies. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates that we are using to manage the underlying businesses. As of December 31, 2015, we maintained a valuation allowance on our state NOL carryforwards acquired from Lumara Health as we do not anticipate that Lumara Health will have future taxable income in the states in which the NOLs were generated. Additionally, we have federal capital loss carryforwards that can only be utilized to the extent

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that we generate future capital gains. Since we do not anticipate that we will have future capital gains, we have maintained a valuation allowance against the federal capital loss carryfowards.

We account for uncertain tax positions using a "more likely than not" threshold for recognizing and resolving uncertain tax positions. The evaluation of uncertain tax positions is based on factors that include, but are not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity, and changes in facts or circumstances related to a tax position. We evaluate uncertain tax positions on a quarterly basis and adjust the level of the liability to reflect any subsequent changes in the relevant facts surrounding the uncertain positions. Any changes to these estimates, based on the actual results obtained and/or a change in assumptions, could impact our income tax provision in future periods. Interest and penalty charges, if any, related to unrecognized tax benefits would be classified as a provision for income tax in our consolidated statement of operations.

Impact of Recently Issued and Proposed Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board or other standard setting bodies that are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption. For further discussion on recent accounting pronouncements, please see Note V, "Recently Issued and Pronounced Accounting Pronouncements," to our consolidated financial statements included in this Annual Report on Form 10 K for additional information.

Results of Operations - 2015 as compared to 2014

Revenues

Total revenues for 2015 and 2014 consisted of the following (in thousands):

	Years Ended December 31,		2015 to 2014		
	2015	2014	$ Change	% Change	
U.S. product sales, net					
Makena	$ 251,615	$ 22,513	$ 229,102	>100	%
Feraheme	88,452	86,282	2,170	3	%
MuGard	1,749	1,203	546	45	%
Total	341,816	109,998	231,818	>100	%
Service revenues, net	24,132	—	24,132	N/A	
License fee, collaboration and other revenues	52,328	14,386	37,942	>100	%
Total revenues	$ 418,276	$ 124,384	$ 293,892	>100	%

Our total revenues in 2015 increased by $293.9 million as compared to 2014, primarily as the result of a $229.1 million increase in Makena net product sales and $24.1 million of 2015 CBR service revenue following our November 2014 and August 2015 acquisitions of Lumara Health and CBR, respectively. In addition, we recognized $44.4 million in deferred revenues during 2015, a $36.2 million increase from 2014, in connection with the December 2014 Takeda Termination Agreement.

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The following table sets forth customers who represented 10% or more of our total revenues for 2015 and 2014:

	Years Ended December 31,			
	2015		2014	
AmerisourceBergen Drug Corporation	25	%	34	%
Takeda Pharmaceuticals Company Limited	12	%	11	%
McKesson Corporation	11	%	21	%
Cardinal Health, Inc.	<10	%	15	%

Product Sales

Our product sales were offset by provisions for allowances and accruals as follows (in thousands):

	Years Ended December 31,								
	2015	Percent of gross U.S. product sales		2014	Percent of gross U.S. product sales		2015 to 2014 $ Change	% Change	
Gross U.S. product sales	$ 561,255			$ 190,512			$ 370,743	>100	%
Less provision for product sales allowances and accruals:									
Contractual adjustments	161,665	29	%	73,262	38	%			
Governmental rebates	57,774	10	%	7,252	4	%			
Total	219,439	39	%	80,514	42	%			
Net U.S. product sales	$ 341,816			$ 109,998			$ 231,818	>100	%

Gross U.S. product sales increased by $370.7 million during 2015 as compared to 2014 primarily due to increases of $353.9 million and $15.9 million of Makena and Feraheme gross sales in 2015 as compared to 2014, respectively. The $353.9 million increase in gross Makena sales in 2015 was due to increased volume since we acquired Makena in November 2014. Of the $15.9 million increase in gross U.S. Feraheme sales, $21.8 million was due to price increases, partially offset by a decrease of $5.9 million due to decreased units sold. This total increase in gross product sales was partially offset by $138.9 million of additional allowances and accruals in 2015. As a result, total net product sales increased by $231.8 million, or greater than 100%, during 2015 as compared to 2014.

We expect gross product sales to increase in 2016 based on increased units sold and projected price increases to our products.

Product Sales Allowances and Accruals

The increase in Makena contractual adjustments reflects the inclusion of a full year of Makena as part of our product portfolio in 2015. Total Feraheme contractual adjustments for 2015 were $79.2 million, or 47% of total gross U.S. Feraheme product sales, as compared to $65.4 million, or 43%, in 2014. The increase in total contractual adjustments as a percentage of total gross U.S. Feraheme product sales was related primarily to a change in our customer mix.

The increase in Makena governmental rebates reflects the inclusion of a full year in 2015. Total Feraheme governmental rebates were $0.7 million in 2015 as compared to $0.8 million in 2014.

During 2014, we reduced our reserve for Feraheme product returns by approximately $1.8 million, primarily as the result of a lower than expected rate of product returns. As a result, the product returns provision applied to gross product sales for 2014 was a credit of $1.2 million, resulting in an increase to product sales. There were no significant adjustments to our reserve for product returns in 2015.

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An analysis of the amount of our product reserves for 2015 and 2014 is as follows (in thousands):

	Contractual Adjustments	Governmental Rebates	Total
Balance at January 1, 2014	$ 7,059	$ 487	$ 7,546
Product reserves resulting from the Lumara Health acquisition	16,888	28,405	45,293
Current provisions relating to sales in current year	67,952	786	68,738
Adjustments relating to sales in prior years	(1,429)	—	(1,429)
Payments/returns relating to sales in current year	(58,464)	(401)	(58,865)
Payments/returns relating to sales in prior years	(5,598)	(175)	(5,773)
Balance at December 31, 2014	$ 26,408	$ 29,102	$ 55,510
Measurement period adjustments - Lumara Health acquisition	(2,619)	(4,034)	(6,653)
Current provisions relating to sales in current year	156,234	58,011	214,245
Adjustments relating to sales in prior years	172	(237)	(65)
Payments/returns relating to sales in current year	(131,214)	(33,073)	(164,287)
Payments/returns relating to sales in prior years	(18,804)	(24,002)	(42,806)
Balance at December 31, 2015	$ 30,177	$ 25,767	$ 55,944

During 2015 and 2014, we implemented gross price increases for Feraheme, some portion of which were discounted back to customers under volume or market share based contracts. When portions of price increases are discounted back to customers, it can widen the gross to net adjustment percentage while still resulting in a greater net price per gram.

In 2016, we expect contractual adjustments and governmental rebates to continue to increase as a percentage of gross product sales due to our contracting and discounting strategy, the mix of our business to different customers and increasing competitive pressure on our products.

Service Revenues

The $24.1 million in service revenues was due to the addition of the CBR Services in August 2015.

License Fee, Collaboration and Other Revenues

License fee, collaboration and other revenues for 2015 and 2014 consisted of the following (in thousands):

	Years Ended December 31,		2015 to 2014		
	2015	2014	$ Change	% Change	
Deferred license fee revenues recognized from Takeda	$ 44,376	$ 8,217	$ 36,159	>100	%
Other revenues	7,952	5,169	2,783	54	%
Deferred revenues recognized from 3SBio termination	—	1,000	(1,000)	(100)	%
Total license fee, collaboration and other revenues	$ 52,328	$ 14,386	$ 37,942	>100	%

Our license fee, collaboration and other revenues in 2015 increased by $37.9 million as compared to 2014 primarily as the result of the recognition of the $44.4 million balance of deferred revenue in connection with the effective termination of the Takeda Agreement in 2015. In addition, other revenues increased by $2.8 million primarily due to $6.7 million of revenues recognized in 2015 related to payments made by Takeda as required under the terms of the Takeda Termination Agreement as compared to $3.0 million recognized in 2014 related to the Takeda Termination Agreement, and which was recorded in other products sales and royalties in our 2014 consolidated statement of operations.

We expect that our license fee, collaboration and other revenues, if any, will be immaterial in 2016 due to the termination of the Amended Takeda Agreement.

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Costs and Expenses

Cost of Product Sales

Cost of product sales for 2015 and 2014 were as follows (in thousands):

	Years Ended December 31,		2015 to 2014	
	2015	2014	$ Change	% Change
Cost of product sales	$ 78,509	$ 20,306	$ 58,203	>100 %
Percentage of net product sales	23 %	18 %		

Our cost of product sales are primarily comprised of manufacturing costs, costs of managing our contract manufacturers, and costs for quality assurance and quality control associated with our U.S. product sales, and the amortization of product-related intangible assets and inventory step up in connection with the November 2014 acquisition of Lumara Health. The $58.2 million increase in our cost of product sales for 2015 as compared to 2014 was attributable to the following factors:

- $57.2 million increase related to $46.9 million of amortization of the Makena product intangible asset and $10.3 million of amortization of the Makena inventory step up;
- $2.0 million increase in costs related to Makena for a full year of sales in 2015 as compared to a partial year in 2014;
- $1.0 million increase in internal departmental costs, including salaries, benefits, and additional equity compensation; and
- $2.8 million decrease in costs related to sales of Feraheme to Takeda, including the accelerated recognition of product costs in 2014 previously deferred as a result of the Takeda Termination Agreement.

We expect our cost of product sales as a percentage of net product sales to decrease slightly in 2016 as compared to 2015 primarily due to lower gross margins from CBR.

Cost of Services

	Years Ended December 31,		2015 to 2014	
	2015	2014	$ Change	% Change
Cost of services	$ 9,992	$ —	$ 9,992	N/A
Percentage of service revenues	41 %	—		

The $10.0 million in cost of services was due to the addition of the CBR Services in August 2015. Cost of services includes the transportation of the umbilical cord blood stem cells and cord tissue from the hospital and direct material plus labor costs for processing, cryogenic storage and collection kit materials. We expect our cost of services to increase in 2016 due to the recognition of a full year of CBR Services in 2016.

Research and Development Expenses

Research and development expenses include external expenses, such as costs of clinical trials, contract research and development expenses, certain manufacturing research and development costs, regulatory filing fees, consulting and professional fees and expenses, and internal expenses, such as compensation of employees engaged in research and development activities, the manufacture of product needed to support research and development efforts, related costs of facilities, and other general costs related to research and development. Where possible, we track our external costs by major project. To the extent that external costs are not attributable to a specific project or activity, they are included in

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other external costs. Prior to the initial regulatory approval of our products or development of new manufacturing processes, costs associated with manufacturing process development and the manufacture of drug product are recorded as research and development expenses, unless we believe regulatory approval and subsequent commercialization of the product candidate is probable and we expect the future economic benefit from sales of the product to be realized, at which point we capitalize the costs as inventory.

Research and development expenses for 2015 and 2014 consisted of the following (in thousands):

	Years Ended December 31,		2015 to 2014		
	2015	2014	$ Change	% Change	
External research and development expenses					
Makena-related costs	$ 10,820	$ 1,703	$ 9,117	>100	%
Feraheme-related costs	6,279	10,588	(4,309)	(41)	%
Velo option	10,000	—	10,000	N/A	
Other external costs	1,799	980	819	84	%
Total	28,898	13,271	15,627	>100	%
Internal research and development expenses	13,980	10,889	3,091	28	%
Total research and development expenses	$ 42,878	$ 24,160	$ 18,718	77	%

Total research and development expenses incurred in 2015 increased by $18.7 million, or 77%, as compared to 2014. The increase was primarily due to a $10.0 million upfront payment made to Velo in July 2015 for an option to acquire the rights to an orphan drug candidate in clinical development for the treatment of severe preeclampsia in pregnant women. In addition, the increase reflects new costs related to Makena clinical trials and related development costs.

We expect our research and development expenses to increase in 2016 as compared to 2015 due to the initiation in the first quarter of 2016 of a new 2,000 patient head-to head Phase 3 clinical trial evaluating Feraheme in adults with IDA, the ongoing clinical trials related to Makena's post-approval commitments and the Makena next generation development programs.

Research and Development Activities

We track our external costs on a major project basis, in most cases through the later of the completion of the last trial in the project or the last submission of a regulatory filing to the FDA. We do not track our internal costs by project since our research and development personnel work on a number of projects concurrently and much of these costs benefit multiple projects or our operations in general. The following major research and development projects were ongoing as of December 31, 2015:

- Makena: This project currently includes studies conducted as part of the post-approval commitments under the provisions of the FDA's "Subpart H" Accelerated Approval regulations as well as certain research and development expenses associated with our next generation development programs, including: (a) an ongoing efficacy and safety clinical study of Makena; (b) an ongoing follow-up study of the children born to mothers from the efficacy and safety clinical study; (c) a completed PK trial of women taking Makena; and (d) studies associated with our next generation development programs, including an auto-injector device and a longer-acting formulation of Makena.

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Feraheme to treat IDA in CKD patients: This project currently includes the following: (a) a completed clinical study evaluating Feraheme treatment as compared to treatment to another IV iron; (b) a pediatric program as part of our post-approval Pediatric Research Equity Act requirement to support pediatric CKD labeling of Feraheme. We have elected to terminate this trial due to difficulty in enrollment and plan to work with the FDA to discuss the path forward regarding this post-approval commitment for Feraheme; and (c) a completed global multi-center randomized clinical trial to determine the safety and efficacy of repeat doses of Feraheme as compared to iron sucrose for the treatment of IDA in patients with hemodialysis dependent CKD ("FACT"). This study has recently been completed and we are in the process of analyzing the data.

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- Feraheme to treat IDA regardless of the underlying cause: This project currently includes a randomized, double-blind multicenter non-inferiority trial that will evaluate the incidence of moderate to severe hypersensitivity reactions (including anaphylaxis) and moderate to severe hypotension with Feraheme compared to ferric carboxymaltose infusion in adults with IDA, currently expected to be initiated in the first quarter of 2016.

From November 12, 2014 (the date of the Lumara Health acquisition) through December 31, 2015, we have incurred aggregate external research and development expenses of approximately $8.3 million related to our current program for Makena, described above. We currently estimate that the total remaining external costs associated with this development project will be in the range of approximately $25.0 million to $30.0 million over the next several years. Given the current early stage of our development of the longer-acting formulation of Makena, we are unable to estimate with any certainty the future costs we will incur for such formulation and have therefore not included an estimate in the expected range above.

Through December 31, 2015, we have incurred aggregate external research and development expenses of approximately $41.4 million related to our current program for the development of Feraheme to treat IDA in CKD patients, described above. We currently estimate that the total remaining external costs associated with this development project will be less than $5.0 million.

We incurred approximately $57.8 million of aggregate external research and development expenses related to our program for the development of Feraheme to treat IDA regardless of the underlying cause up to the submission of our sNDA in 2013. In January 2014, we received a complete response letter from the FDA for the sNDA informing us that our sNDA could not be approved in its present form and stating that we had not provided sufficient information to permit labeling of Feraheme for safe and effective use for the proposed broader indication. In the third quarter of 2015, based on feedback received from the FDA on a proposed clinical trial to address certain deficiencies noted by the FDA in our complete response letter, as described above, we commenced start up activities related to this program, including a head-to-head Phase 3 clinical trial, described above. We currently estimate that the total remaining external costs associated with this development project will be in the range of approximately $30.0 million to $35.0 million through the end of 2017.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses include costs related to our commercial personnel, including our specialty sales force, medical education professionals, pharmacovigilance, and safety monitoring and commercial support personnel, costs related to our administrative personnel, including our legal, finance, business development and executive personnel, external and facilities costs required to support the marketing and sale of our products and services, and other costs associated with our corporate activities.

Selling, general and administrative expenses for 2015 and 2014 consisted of the following (in thousands):

	Years Ended December 31,		2015 to 2014		
	2015	2014	$ Change	% Change	
Compensation, payroll taxes and benefits	$ 62,122	$ 31,261	$ 30,861	99	%
Professional, consulting and other outside services	78,981	34,767	44,214	>100	%
Fair value of contingent consideration liability	4,271	(681)	4,952	<(100)	%
Amortization expense related to customer relationship intangible	1,061	—	1,061	N/A	
Equity-based compensation expense	13,874	6,907	6,967	>100	%
Total selling, general and administrative expenses	$ 160,309	$ 72,254	$ 88,055	>100	%

Total selling, general and administrative expenses incurred in 2015 increased by $88.1 million, or greater than 100%, as compared to 2014 for the following reasons:

· $30.9 million increase in compensation, payroll taxes and benefits primarily due to increased costs associated with additional personnel in connection with the November 2014 Lumara Health and August 2015 CBR acquisitions;

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- $27.0 million increase in sales and marketing consulting, professional fees, and other expenses primarily due to costs related to Makena marketing activities since the November 2014 acquisition and CBR activities since the August 2015 acquisition;
- $17.2 million increase in general and administrative consulting, professional fees and other expenses primarily due to increased costs associated with consulting, finance, legal, and other infrastructure activities in support of our product portfolio expansion as well as costs associated with Lumara Health and CBR after the November 2014 and August 2015 acquisitions, respectively;
- $7.0 million increase in equity based compensation expense due primarily to the expense associated with equity awards to new and existing employees, including additional employees from the Lumara Health and CBR acquisitions as well as one time charges associated with the departure of certain of our executive officers during 2015; and
- $5.0 million increase to the contingent consideration liability due to a $6.7 million increase to the Lumara Health related contingent consideration, partially offset by a $1.7 million reduction of the MuGard related contingent consideration primarily resulting from a 2015 revision of our total projected MuGard sales.

We expect that total selling, general and administrative expenses will increase in 2016 as compared to 2015 as a result of the increased headcount following the August 2015 acquisition of CBR.

Acquisition related costs

We incurred approximately $11.2 million and $9.5 million of acquisition related costs in 2015 and 2014, respectively, related to our acquisitions of CBR and Lumara Health, which primarily represented financial advisory fees, legal fees, due diligence and other costs and expenses.

Restructuring Expenses

In connection with the August 2015 CBR acquisition and the November 2014 Lumara Health acquisition, we initiated restructuring programs, which included severance benefits related to former CBR and Lumara Health employees. As a result of these restructurings, we recorded charges of approximately $4.1 million and $2.0 million in 2015 and 2014, respectively. We expect to pay substantially all of the restructuring costs by the end of 2016.

Other Income (Expense)

Other income (expense) for 2015 and 2014 consisted of the following (in thousands):

	Years Ended December 31,		2015 to 2014		
	2015	2014	$ Change	% Change	
Interest expense	$ (53,251)	$ (14,697)	(38,554)	>100	%
Loss on debt extinguishment	(10,449)	—	(10,449)	N/A	
Interest and dividend income, net	1,512	975	537	55	%
Other income (expense)	(9,188)	217	(9,405)	<(100)	%
Total other income (expense)	$ (71,376)	$ (13,505)	$ (57,871)	>100	%

Other income (expense) for 2015 decreased by $57.9 million as compared to 2014 primarily as the result of the following:

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An additional $38.6 million in interest expense in 2015, which was primarily comprised of the amortization of debt discount, contractual interest expense and amortization of debt issuance costs in connection with our current debt obligations as compared to 2014;

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- $10.4 million loss on debt extinguishment as the result of the early repayment in 2015 of the remaining $323.0 million outstanding principal amount of the 2014 Term Loan Facility; and
- $9.4 million of other expense, which included a $6.8 million bridge loan commitment fee paid in the third quarter of 2015 as part of the planned financing for the CBR acquisition, but which was not utilized to fund the acquisition, and $2.4 million in fees and expenses in 2015 from the 2014 Term Loan Facility that were expensed in accordance with accounting guidance for the modification of debt arrangements.

We expect our net other income (expense) to remain constant in 2016 as compared to 2015 as a result of the increase in interest expense due to our 2015 debt financings, partially offset by the non-recurring charges in 2015 related to the loss on debt extinguishment and other expenses associated with the debt financings for the CBR acquisition.

Income Tax Expense (Benefit)

We recognized a $7.1 million income tax expense and a $153.2 million income tax benefit for 2015 and 2014, respectively. The $7.1 million tax expense in 2015 reflected the impact of a valuation allowance release related to certain deferred tax assets, partially offset by non-deductible transaction costs associated with the acquisition of CBR and non-deductible contingent consideration expense associated with Lumara Health. The $153.2 million income tax benefit in 2014 reflected a $132.9 million decrease in our valuation allowance due to taxable temporary differences available as a source of income to realize the benefit of certain of our pre existing deferred tax assets as a result of the acquisition of Lumara Health.

Results of Operations - 2014 as compared to 2013

Revenues

Total revenues for 2014 and 2013 consisted of the following (in thousands):

	Years Ended December 31,		2014 to 2013		
	2014	2013	$ Change	% Change	
U.S. product sales, net	$ 109,998	$ 71,692	$ 38,306	53	%
License fee, collaboration and other revenues	14,386	9,164	5,222	57	%
Total revenues	$ 124,384	$ 80,856	$ 43,528	54	%

Our total revenues in 2014 increased by $43.5 million, or 54%, as compared to 2013, primarily as the result of $22.5 million of Makena net product sales following our November 2014 acquisition of Lumara Health, as discussed above, and a $14.9 million increase in U.S. Feraheme net product sales. In addition, included in our net product sales for 2014 and 2013 was a $1.8 million reduction in our reserves for Feraheme product returns and a $0.6 million reduction of our estimated Medicaid rebate reserve related to prior Feraheme sales, respectively.

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The following table sets forth customers who represented 10% or more of our total revenues for 2014 and 2013:

	Years Ended December 31,			
	2014		2013	
AmerisourceBergen Drug Corporation	34	%	41	%
McKesson Corporation	21	%	24	%
Cardinal Health, Inc.	15	%	16	%
Takeda Pharmaceuticals Company Limited	11	%	11	%

Product Sales

Our product sales for the 2014 and 2013 were offset by provisions for allowances and accruals as follows (in thousands):

	Years Ended December 31,								
	2014	Percent of gross U.S. product sales		2013	Percent of gross U.S. product sales		2014 to 2013 $ Change	2014 to 2013 % Change	
Gross U.S. product sales	$ 190,512			$ 120,195			$ 70,317	59	%
Less provision for product sales allowances and accruals:									
Contractual adjustments	73,262	38	%	48,433	40	%			
Governmental rebates	7,252	4	%	70	0	%			
Total	80,514	42	%	48,503	40	%			
Net U.S. product sales	$ 109,998			$ 71,692			$ 38,306	53	%

Gross U.S. product sales increased by $70.3 million during 2014 as compared to 2013 primarily due to increases of $35.7 million and $32.7 million of Makena and Feraheme gross sales in 2014, respectively, as compared to 2013. The $35.7 million increase in gross Makena sales in 2014 was due to increased volume as a result of the addition of Makena to our product portfolio in November 2014. Of the $32.7 million increase in gross U.S. Feraheme sales, $17.4 million was due to price increases and $15.3 million was due to increased units sold. This total increase in gross product sales was partially offset by $32.0 million of additional allowances and accruals in 2014. As a result, total net product sales increased by $38.3 million, or 53%, during 2014 as compared to 2013.

Product Sales Allowances and Accruals

Total Feraheme contractual adjustments for 2014 were $65.4 million, or 43% of total gross U.S. Feraheme product sales, as compared to $48.3 million, or 40%, in 2013. The increase in total contractual adjustments as a percentage of total gross U.S. Feraheme product sales was related primarily to a change in our customer mix, increased sales to clinics and hospitals that had volume or market share contracts with us during 2014 as compared to 2013, and changes in the structure of our performance based rebate programs.

During 2014, we reduced our reserve for Feraheme product returns by approximately $1.8 million, primarily as the result of a lower than expected rate of product returns. As a result, the product returns provision applied to gross product sales for 2014 was a credit of $1.2 million, resulting in an increase to product sales. There were no significant adjustments to our reserve for product returns in 2013.

During 2013, we reduced our estimated Medicaid rebate reserve related to prior Feraheme sales by approximately $0.6 million based on actual product specific rebate claims received since the July 2009 launch of Feraheme, our expectations of state level activity, and estimated rebate claims not yet submitted. The $0.6 million Medicaid rebate reserves adjustment resulted in an increase to product sales during that period.

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An analysis of the amount of Makena product reserves for 2014 and the amount and change in Feraheme product reserves for 2014 and 2013 is as follows (in thousands):

	Contractual Adjustments	Governmental Rebates	Total
Balance at January 1, 2013	$ 4,262	$ 956	$ 5,218
Current provisions relating to sales in current year	48,434	638	49,072
Adjustments relating to sales in prior years	—	(568)	(568)
Payments/returns relating to sales in current year	(42,623)	(197)	(42,820)
Payments/returns relating to sales in prior years	(3,014)	(342)	(3,356)
Balance at December 31, 2013	$ 7,059	$ 487	$ 7,546
Product reserves resulting from the Lumara Health acquisition	16,888	28,405	45,293
Current provisions relating to sales in current year	67,952	786	68,738
Adjustments relating to sales in prior years	(1,429)	—	(1,429)
Payments/returns relating to sales in current year	(58,464)	(401)	(58,865)
Payments/returns relating to sales in prior years	(5,598)	(175)	(5,773)
Balance at December 31, 2014	$ 26,408	$ 29,102	$ 55,510

License Fee, Collaboration and Other Revenues

License fee, collaboration and other revenues for the 2014 and 2013 consisted of the following (in thousands):

	Years Ended December 31,		2014 to 2013		
	2014	2013	$ Change	% Change	
Deferred license fee revenues recognized from Takeda	$ 8,217	$ 7,896	$ 321	4	%
Other revenues	5,169	1,268	3,901	>100	%
Deferred license fee revenues recognized from 3SBio termination	1,000	—	1,000	N/A	
Total license fee, collaboration and other revenues	$ 14,386	$ 9,164	$ 5,222	57	%

Our license fee, collaboration and other revenues in 2014 increased by $5.2 million as compared to 2013 primarily as the result of $4.5 million of previously deferred revenue and the reimbursement of certain out-of-pocket development costs recognized in connection with the Takeda Termination Agreement. In addition, during 2014 we recognized $1.0 million of previously deferred revenue from our former partnership with 3SBio, Inc. (“3SBio”) as the result of the termination of our license agreement in January 2014. We have no further obligations under the agreement with 3SBio.

Costs and Expenses

Cost of Product Sales

Cost of product sales for 2014 and 2013 were as follows (in thousands):

	Years Ended December 31,		2014 to 2013	
	2014	2013	$ Change	% Change
Cost of product sales	$ 20,306	$ 11,960	$ 8,346	70 %
Percentage of net product sales	18 %	17 %		

The $8.3 million increase in our cost of product sales for 2014 as compared to 2013 was attributable to the following factors:

· $6.1 million increase related to the amortization of the Lumara Health intangible asset and Makena inventory step up;

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- $2.6 million increase in costs related to sales of Feraheme to Takeda, including the accelerated recognition of product costs previously deferred as a result of the Takeda Termination Agreement; and
- $2.2 million decrease due to a lower average cost per vial of Feraheme sold, partially offset by a $1.7 million increase due to a higher volume of Feraheme vials sold in 2014.

Research and Development Expenses

Research and development expenses for 2014 and 2013 consisted of the following (in thousands):

	Years Ended December 31,		2014 to 2013		
	2014	2013	$ Change	% Change	
External research and development expenses					
Feraheme-related costs	$ 10,588	$ 6,970	$ 3,618	52	%
Makena-related costs	1,703	—	1,703	N/A	
Other external costs	980	2,026	(1,046)	(52)	%
Total	13,271	8,996	4,275	48	%
Internal research and development expenses	10,889	11,568	(679)	(6)	%
Total research and development expenses	$ 24,160	$ 20,564	$ 3,596	17	%

Total research and development expenses incurred in 2014 increased by $3.6 million, or 17%, as compared to 2013. The increase was primarily due to a $4.3 million increase in external research and development costs pertaining to our CKD related trials during 2014 as well as new costs related to Makena clinical trials and related manufacturing costs. This increase was partially offset by reduced internal research and development costs of $0.7 million.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for 2014 and 2013 consisted of the following (in thousands):

	Years Ended December 31,		2014 to 2013		
	2014	2013	$ Change	% Change	
Compensation, payroll taxes and benefits	$ 31,261	$ 22,819	$ 8,442	37	%
Professional, consulting and other outside services	34,767	29,540	5,227	18	%
Fair value of contingent consideration liability	(681)	1,074	(1,755)	<(100)	%
Equity-based compensation expense	6,907	5,734	1,173	20	%
Total selling, general and administrative expenses	$ 72,254	$ 59,167	$ 13,087	22	%

Total selling, general and administrative expenses incurred in 2014 increased by $13.1 million, or 22%, as compared to 2013 for the following reasons:

- $8.4 million increase in compensation, payroll taxes and benefits primarily due to increased costs associated with additional personnel in our commercial functions, including the Lumara Health sales force acquired in connection with the November 2014 acquisition of Lumara Health, and increased costs associated with certain of our general and administrative functions, including the addition of Lumara Health employees;
- $3.3 million increase in sales and marketing consulting, professional fees, and other expenses primarily due to costs related to Makena marketing activities since the November 2014 acquisition, and increased consulting costs related to the commercialization of MuGard;
- $1.9 increase in general and administrative consulting, professional fees and other expenses primarily due to increased costs associated with business development, consulting and other legal related activities in support of

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our product portfolio expansion as well as costs associated with Lumara Health after the November 2014 acquisition. These increased costs were offset by a number of non recurring costs in 2013, including $1.9 million of accelerated depreciation expense recognized related to our prior corporate headquarters, $0.6 million of costs related to the closure of our Cambridge, Massachusetts manufacturing facility and $0.6 million of costs associated with the relocation of our corporate headquarters;

- $1.8 million decrease to the contingent consideration liability due to a $3.4 million reduction of the MuGard related contingent consideration primarily resulting from a 2014 revision of our total projected MuGard sales, partially offset by a $1.6 million increase to the Lumara Health related contingent consideration; and
- $1.2 million increase in equity based compensation expense due primarily to one time charges associated with the departure of our former Senior Vice President of Business Development and Chief Business Officer in June 2014 as well as the expense associated with equity awards to new and existing employees.

Acquisition related costs

We incurred approximately $9.5 million of acquisition related costs in 2014 related to our acquisition of Lumara Health, which primarily represented financial advisory fees, legal fees, due diligence and other costs and expenses. During 2013, in connection with the acquisition of the MuGard Rights we incurred approximately $0.8 million of expenses primarily related to professional and legal fees.

Restructuring Expenses

In connection with the November 2014 Lumara Health acquisition, we initiated a restructuring program in the fourth quarter of 2014, which included severance benefits primarily related to former Lumara Health employees. As a result of the restructuring, we recorded charges of approximately $2.0 million in 2014.

Other Income (Expense)

Other income (expense) for 2014 and 2013 consisted of the following (in thousands):

	Years Ended December 31,		2014 to 2013		
	2014	2013	$ Change	% Change	
Interest expense	$ (14,697)	$ —	$ (14,697)	N/A	
Interest and dividend income, net	975	1,051	(76)	(7)	%
Other income (expense)	217	964	(747)	(77)	%
Total other income (expense)	$ (13,505)	$ 2,015	$ (15,520)	<(100)	%

Other income (expense) for 2014 decreased by $15.5 million as compared to 2013 primarily as the result of the recognition of $14.7 million of interest expense, which was comprised of the amortization of debt discount, contractual interest expense and amortization of debt issuance costs in connection with the issuance of the $200.0 million of 2.5% convertible senior notes due February 15, 2019 (the “Convertible Notes”) and our $340.0 million 2014 Term Loan Facility. In addition, the decrease in other income (expense) reflects 2013 non recurring gains of $0.5 million in connection with the sale of Combidex®, a legacy product of ours, and $0.4 million in connection with the sale of fixed assets related to our previously owned Cambridge, Massachusetts manufacturing facility.

Income Tax Benefit

The $153.2 million income tax benefit for 2014 reflects a $132.9 million decrease in our valuation allowance due to taxable temporary differences available as a source of income to realize the benefit of certain of our pre existing deferred tax assets as a result of the acquisition of Lumara Health. We did not recognize any federal or state income tax benefit for 2013 as we were subject to a full valuation allowance.

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Liquidity and Capital Resources

General

We currently finance our operations primarily from the sale of our products and services and cash generated from our investing and financing activities. We expect to continue to incur significant expenses as we continue to market, sell and contract for the manufacture of Makena and Feraheme, as we market and sell the CBR Services and MuGard, as we pursue next generation development programs for Makena, and as we further develop and seek regulatory approval for Feraheme for the treatment of IDA in a broad range of patients in the U.S. For a detailed discussion regarding the risks and uncertainties related to our liquidity and capital resources, please refer to our Risk Factors in Part I, Item 1A of this Annual Report on Form 10 K.

Cash, cash equivalents, investments and certain financial obligations as of December 31, 2015 and 2014 consisted of the following (in thousands):

	2015	2014	$ Change	% Change	
Cash and cash equivalents	$ 228,705	$ 119,296	$ 109,409	92	%
Investments	237,626	24,890	212,736	>100	%
Total	$ 466,331	$ 144,186	$ 322,145	>100	%
Outstanding principal on 2023 Senior Notes	$ 500,000	$ —	$ 500,000	N/A	
Outstanding principal on Convertible Notes	200,000	200,000	—	—	%
Outstanding principal on 2015 Term Loan Facility	345,625	—	345,625	N/A	
Outstanding principal on 2014 Term Loan Facility	—	340,000	(340,000)	(100)	%
Total	$ 1,045,625	$ 540,000	$ 505,625	94	%

We place our cash in instruments that meet high credit quality and diversification standards, as specified in our investment policy. Our investment policy also limits the amount of our credit exposure to any one issue or issuer, excluding U.S. government entities and money market funds, and seeks to manage these assets to achieve our goals of preserving principal, maintaining adequate liquidity at all times, and maximizing returns.

The $322.1 million increase in cash, cash equivalents and investments as of December 31, 2015, as compared to December 31, 2014, was primarily due to net proceeds of $188.8 million received in the first quarter of 2015 following the sale of approximately 4.6 million shares of our common stock in an underwritten public offering, net proceeds of $218.6 million received in the third quarter of 2015 following the sale of approximately 3.6 million shares of our common stock in an underwritten public offering, $824.7 million net proceeds from our August 2015 debt financings and cash flow from product sales, partially offset by $682.4 million of net cash used to acquire CBR, $327.5 million repayment of the 2014 Term Loan Facility and expenditures to fund our operations. The $505.6 million increase in our debt obligations as of December 31, 2015, as compared to December 31, 2014, was due to the issuance of the 2023 Senior Notes and entry into the 2015 Term Loan Facility, as discussed in more detail below, partially offset by the repayment of our 2014 Term Loan Facility.

We expect that our cash, cash equivalents and investments balances, in the aggregate, may increase as the result of increased net sales for 2016, which assumes our continued investment in the development and commercialization of our products and services. We believe that our cash, cash equivalents and investments as of December 31, 2015, and the cash we currently expect to receive from sales of our products and services, and earnings on our investments, will be sufficient to service our debt obligations and satisfy our cash flow needs for the foreseeable future, including a potential $100.0 million milestone payment expected to be paid in 2016 to the former Lumara Health security holders based on the achievement of a net sales milestone of Makena.

Borrowings and Other Liabilities

In August 2015, in connection with the CBR acquisition, we completed a private placement of the 2023 Senior Notes and entered into the 2015 Term Loan Facility. The 2023 Senior Notes, which are senior unsecured obligations of

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the Company, will mature on September 1, 2023 and will bear interest at a rate of 7.875% per year, with interest payable semi-annually on September 1 and March 1 of each year, beginning on March 1, 2016. We borrowed the full $350.0 million available under the 2015 Term Loan Facility in August 2015. The 2015 Term Loan Facility imposes restrictive covenants on us and obligates us to make certain payments of principal and interest over time. In addition, the 2015 Term Loan Facility includes an annual mandatory prepayment of the debt in an amount equal to 50% of our excess cash flow (as defined in the 2015 Term Loan Facility) as measured on an annual basis, beginning with the fiscal year ending December 31, 2016. On or after December 31, 2016, the applicable excess cash flow percentage shall be reduced based on the total net leverage ratio as of the last day of the period. For additional information, see Note R, “Debt,” to our consolidated financial statements included in this Annual Report on Form 10 K.

In November 2014, we partially financed the $600.0 million cash portion of the Lumara Health acquisition through $327.5 million of net proceeds from borrowings under the 2014 Term Loan Facility. On August 17, 2015, we repaid the remaining $323.0 million outstanding principal amount and recognized a $10.4 million loss on debt extinguishment as a result of the early repayment.

In addition, in February 2014, we issued $200.0 million aggregate principal amount of Convertible Notes, as discussed in more detail in Note R, “Debt,” to our consolidated financial statements included in this Annual Report on Form 10 K. The Convertible Notes are senior unsecured obligations and bear interest at a rate of 2.5% per year, payable semi-annually in arrears on February 15 and August 15 of each year. The Convertible Notes will mature on February 15, 2019, unless repurchased or converted earlier. The Convertible Notes will be convertible into cash, shares of our common stock, or a combination thereof, at our election (subject to certain limitations in the 2015 Term Loan Facility), at a conversion rate of approximately 36.9079 shares of common stock per $1,000 principal amount of the Convertible Notes, which corresponds to a conversion price of approximately $27.09 per share of our common stock. The conversion rate is subject to adjustment from time to time. Based on the last reported sale price of our common stock during the last 30 trading days of 2015, the Convertible Notes are not convertible as of December 31, 2015.

For details on the business development activities that these financings supported, see Note C, “Business Combinations,” to our consolidated financial statements included in this Annual Report on Form 10 K.

Share Repurchase Program

In January 2016, we announced that our Board had authorized a program to repurchase up to $60.0 million in shares of our common stock. The repurchase program does not have an expiration date and may be suspended for periods or discontinued at any time. Under the program, we may purchase our stock from time to time at the discretion of management in the open market or in privately negotiated transactions. The number of shares repurchased and the timing of the purchases will depend on a number of factors, including share price, trading volume and general market conditions, along with working capital requirements, general business conditions and other factors. We may also from time to time establish a trading plan under Rule 10b5-1 of the Securities and Exchange Act of 1934 to facilitate

purchases of our shares under this program.

Cash Flow Activity for the Year Ended December 31, 2015

Cash flows from operating activities

Net cash provided by operating activities in 2015 was $96.0 million as compared to $11.4 million in 2014. The increase in cash provided by operating activities was primarily due to increased product sales from the addition of Makena and CBR to our product portfolio. We expect to generate cash from operations as we continue to grow our business, partially offset by increased expenditures to support our growth.

During 2015, our $96.0 million of cash provided by operations was attributable to our net operating income of approximately $32.8 million, adjusted for the following:

· Non cash operating items resulting in a net increase of $116.8 million, including deferred income taxes, equity based compensation expense, a write down of inventory, amortization of debt discount and debt issuance

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costs, amortization of premium/discount on purchased securities, change in fair value of contingent consideration, depreciation and amortization, loss on debt extinguishment and other non cash items;

- $34.0 million of cash used in operating activities due to net increases in receivables and inventories, partially offset by decreases in prepaid and other current assets;
- $9.2 million of cash provided by operating activities due to decreases in other long term assets;
- $7.9 million of cash provided by operating activities due to increases in accounts payable and accrued expenses;
- $24.2 million of cash used in operating activities due to decreases in deferred revenues and other long term liabilities; and
- $12.5 million repayment of original issue discount related to the 2014 Term Loan Facility.

Cash flows from investing activities

Net cash used in investing activities in 2015 was $899.0 million as compared to $432.9 million in 2014. Cash used in investing activities increased in 2015 primarily due to $682.4 million of net cash used to fund the acquisition of CBR and $424.8 million of cash used to purchase investments with the proceeds we received from our March 2015 and August 2015 public equity offerings, partially offset by $209.0 of proceeds from the sales and maturities of our investments.

Cash flows from financing activities

Net cash provided by financing activities in 2015 and 2014 was $912.5 million and $513.8 million, respectively. Cash provided by financing activities increased during 2015 as compared to 2014 primarily due to the $407.5 million in net proceeds from the aggregate issuance of common stock from our March 2015 and August 2015 public offerings, $824.7 million received from the proceeds of new debt offerings, partially offset by the repayment of the 2014 Term Loan Facility.

Cash Flow Activity for the Year Ended December 31, 2014

Cash flows from operating activities

During 2014, our $11.4 million of cash provided by operations was attributable principally to our net operating income of approximately $135.8 million, adjusted for the following:

- Non cash operating items resulting in a net decrease of $128.2 million, including deferred income taxes, equity based compensation expense, a write down of inventory, amortization of debt discount and debt issuance costs, amortization of premium/discount on purchased securities, change in fair value of contingent consideration, depreciation and amortization, and other non cash items;
- $0.3 million of cash provided by operating activities due to increases in accounts receivable, inventories and prepaid and other current assets;
- $10.7 million of cash provided by operating activities due to increases in accounts payable and accrued expenses;
- $9.2 million of cash used in operating activities due to decreases in deferred revenues and other long term liabilities; and

· $2.0 million of cash provided by operating activities due to decreases in other long term assets.

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Our net income of $135.8 million was primarily the result of the recognition of a $153.2 million income tax benefit resulting from our merger with Lumara Health, partially offset by our costs to operate our business.

Cash flows from investing activities

Cash used in investing activities in 2014 was $432.9 million and was primarily attributable to the $595.6 million net cash used to fund the acquisition of Lumara Health, partially offset by proceeds from the sales and maturities of our investments, including the liquidation of $170.4 million to partially fund the acquisition of Lumara Health as well as a $2.9 million change in restricted cash following the return of escrowed funds related to a 2013 business development transaction that we did not complete.

Cash flows from financing activities

Cash provided by financing activities in 2014 was $513.8 million and was primarily attributable to the $327.5 million proceeds from the Term Loan Facility, which were used to partially fund the acquisition of Lumara Health and $178.1 million in net proceeds received from the issuance of the Convertible Notes in February 2014. In addition, we received $8.5 million in proceeds from the exercise of stock options.

Cash Flow Activity for the Year Ended December 31, 2013

Cash flows from operating activities

During 2013 our use of $6.8 million of cash in operations was attributable principally to our net loss of approximately $9.6 million, adjusted for the following:

- Non-cash operating items resulting in a net increase of $16.1 million including equity-based compensation expense, depreciation and amortization, amortization of premium/discount on purchased securities, change in fair value of contingent consideration, gains on the sale of assets, a write-down of inventory, and other non-cash items;

- An aggregate decrease in deferred revenues and other long-term liabilities of $6.9 million;

- An aggregate decrease of $5.7 million in accounts payable and accrued expenses;

- An aggregate decrease of $1.3 million in accounts receivable, prepaid assets and inventories; and

- An increase of $2.0 million in other long-term assets.

Our net loss of $9.6 million was primarily the result of compensation to employees, commercialization expenses, including marketing and promotion costs, research and development costs, including costs associated with our clinical trials, and general and administrative costs, partially offset by net product sales and collaboration revenues.

Cash flows from investing activities

Cash used in investing activities in 2013 was $13.9 million and was primarily attributable to the purchases of investments, partially offset by proceeds from the sales and maturities of our investments. In addition, we used $3.4 million of available cash and cash equivalents to purchase the MuGard Rights and related inventory, $2.9 million was held in an escrow account related to a business development transaction that we did not complete, and approximately $1.6 million to purchase leasehold improvements and furniture and fixtures for our new corporate headquarters. We also received $2.5 million from the sale of our Cambridge, Massachusetts manufacturing facility and related fixtures and equipment and $0.5 million from the sale of Combidex®, a molecular imaging agent which we were not actively pursuing development.

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Cash flows from financing activities

Cash provided by financing activities in 2013 was $1.4 million and was primarily attributable to the proceeds from the exercise of stock options.

Contractual Obligations

Our long term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business. These include commitments related to our facility leases, purchases of inventory and other purchases related to our products, debt obligations (including interest payments), and other purchase obligations. Future lease obligations and purchase commitments, as of December 31, 2015, are as follows (in thousands):

	Payment due by period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Facility lease obligations	$ 13,768	$ 2,967	$ 5,048	$ 4,588	$ 1,165
Purchase commitments	7,889	2,629	5,260	—	—
2023 Senior Notes	816,531	40,906	78,750	78,750	618,125
2015 Term Loan Facility	425,465	33,606	64,717	61,392	265,750
2.5% Convertible Notes	215,833	5,000	10,000	200,833	—
Total	$ 1,479,486	$ 85,108	$ 163,775	$ 345,563	$ 885,040

Facility Lease Obligations

In June 2013, we entered into a lease agreement with BP Bay Colony LLC (the “Landlord”) for the lease of certain real property located at 1100 Winter Street, Waltham, Massachusetts (the “Waltham Premises”) for use as our principal executive offices. Beginning in September 2013, the initial term of the lease is five years and two months with one five year extension term at our option. During 2015, we entered into several amendments to the original lease to add additional space and to extend the term of the original lease to June 2021. In addition to base rent, we are also required to pay a proportionate share of the Landlord’s operating costs.

The Landlord agreed to pay for certain agreed-upon improvements to the Waltham Premises and we agreed to pay for any increased costs due to changes by us to the agreed-upon plans. We record all tenant improvements paid by us as leasehold improvements and amortize these improvements over the shorter of the estimated useful life of the improvement or the remaining life of the initial lease term. Amortization of leasehold improvements is included in depreciation expense.

In addition, in connection with our facility lease for the Waltham Premises, in June 2013 we delivered to the Landlord a security deposit of $0.4 million in the form of an irrevocable letter of credit. This security deposit was increased to $0.6 million in 2015. The cash securing this letter of credit is classified on our balance sheet as of December 31, 2015 and 2014 as a long-term asset and is restricted in its use.

In connection with November 2014 acquisition of Lumara Health, we assumed the lease of certain real property located at 16640 Chesterfield Grove Road, Chesterfield, Missouri. We terminated the lease in May 2015.

In connection with the August 2015 acquisition of CBR, we assumed the lease of certain real property located at 1200 Bayhill Drive, San Bruno, California. The lease expires in September 2017 and provides for a 3% annual increase in rent.

Facility-related rent expense, net of deferred rent amortization, for all the leased properties was $1.5 million, $0.8 million and $1.5 million for 2015, 2014, and 2013, respectively.

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Purchase Commitments

In connection with our acquisition of CBR, we have certain minimum purchase commitments associated with an agreement entered into by CBR prior to our acquisition. This agreement expires in December 2018, with the remaining amount of minimum purchase commitments totaling $7.9 million as of December 31, 2015.

Contingent Consideration Related to Business Combinations

In connection with our acquisition of Lumara Health in November 2014, we agreed to pay up to an additional $350.0 million based on the achievement of certain sales milestones. Due to the contingent nature of these milestone payments, we cannot predict the amount or timing of such payments with certainty. See Note C, “Business Combinations,” to our consolidated financial statements included in this Annual Report on Form 10 K for more information on the Lumara Health acquisition and related milestone payments.

As of December 31, 2015, the contingent consideration related to the Lumara Health and MuGard acquisitions are our only finanicial liabilities measured and recorded using Level 3 inputs in accordance with accounting guidance for fair value measurements, and represent 100% of the total liabilities measured at fair value. See Note E, “Fair Value Measurements” to our consolidated financial statements included in this Annual Report on Form 10 K for more information.

Contingent Regulatory and Commercial Milestone Payments

In connection with the option agreement entered into with Velo, if we exercise the option to acquire the DIF rights, we will be responsible for payments totaling up to $65.0 million (including the payment of the option exercise price and the regulatory milestone payments) and up to an additional $250.0 million in sales milestone payments based on the achievement of annual sales milestones at targets ranging from $100.0 million to $900.0 million. We anticipate that results from the pivotal Phase 2b/3a clinical study could be available as early as 2018, and as such no contingencies related to this agreement have been recorded in our consolidated financial statements as of December 31, 2015.

In connection with the development and license agreement entered into with Antares (the “Antares Agreement”), we are required to pay royalties to Antares on net sales of the auto-inection system commencing on the product’s launch in a particular country until the product is no longer developed, marketed, sold or offered for sale in such country. The royalty rates range from high single digit to low double digits and are tiered based on levels of net sales of the product and decrease after the expiration of licensed patents or where there are generic equivalents to the product being sold in a particular country.

Other Funding Commitments

As of December 31, 2015, we had several ongoing clinical studies in various clinical trial stages. Our most significant clinical trial expenditures were to clinical research organizations ("CROs"). The contracts with CROs are generally cancellable, with notice, at our option. We have recorded accrued expenses in our consolidated balance sheet of approximately $1.6 million representing expenses incurred with these organizations as of December 31, 2015, net of any amounts prepaid to these CROs.

Severance Arrangements

We have entered into employment agreements or other arrangements with most of our executive officers and certain other employees, which provide for the continuation of salary and certain benefits and, in certain instances, the acceleration of the vesting of certain equity awards to such individuals in the event that the individual is terminated other than for cause, as defined in the applicable employment agreements or arrangements.

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Indemnification Obligations

In the course of operating our business, we have entered into a number of indemnification arrangements under which we may be required to make payments to or on behalf of certain third parties including our directors, officers, and certain employees as well as certain other third parties with whom we enter into agreements. For further discussion of how this may affect our business, see Note P, “Commitments and Contingencies,” to our consolidated financial statements included in this Annual Report on Form 10 K.

Legal Proceedings

For detailed information on our legal proceedings, see Note P, “Commitments and Contingencies,” to our consolidated financial statements included in this Annual Report on Form 10 K.

Off Balance Sheet Arrangements

As of December 31, 2015, we did not have any off balance sheet arrangements as defined in Regulation S K, Item 303(a)(4)(ii).

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK:

Interest Rate Risk

As of December 31, 2015 and 2014, our investments equaled $237.6 million and $24.9 million, respectively, and were invested in corporate debt securities, commercial paper and municipal securities. Our investments meet high credit quality and diversification standards, as specified in our investment policy. Our investment policy also limits the amount of our credit exposure to any one issue or issuer, excluding U.S. government entities, and seeks to manage these assets to achieve our goals of preserving principal, maintaining adequate liquidity at all times, and maximizing returns. These investments are subject to interest rate risk. The modeling technique used measures the change in fair values arising from an immediate hypothetical shift in market interest rates and assumes that ending fair values include principal plus accrued interest. If market interest rates for comparable investments were to increase immediately and uniformly by 50 basis points, or one half of a percentage point, from levels as of December 31, 2015 and 2014, this would have resulted in a hypothetical decline in fair value of our investments of approximately $1.1 million and $0.1 million, respectively, and if market interest rates for comparable investments were to decrease immediately and uniformly by 50 basis points, or one half of a percentage point, from levels as of December 31, 2015 and 2014, this would have resulted in a hypothetical increase in fair value of our investments of approximately $1.1 million and $0.1 million, respectively. These amounts are determined by considering the impact of the hypothetical interest rate movements on our available for sale investment portfolios. This analysis does not consider the effect of credit risk as a result of the changes in overall economic activity that could exist in such an environment.

The 2015 Term Loan Facility bears interest, at our option, at the London Interbank Offered Rate (“LIBOR”) plus a margin of 3.75% or the prime rate plus a margin of 2.75%. The LIBOR is subject to a 1.00% floor and the prime rate is subject to a 2.00% floor. As of December 31, 2015, the stated interest rate, based on the LIBOR, was 4.75%, and the effective interest rate was 5.65%. An increase in the LIBOR of 50 basis points above the 1.00% LIBOR floor would increase our interest expense by $1.7 million per year.

Equity Price Risk

Convertible Notes

On February 14, 2014, we issued $200.0 million aggregate principal amount of Convertible Notes. The Convertible Notes are senior unsecured obligations and bear interest at a rate of 2.5% per year, payable semi annually in arrears on February 15 and August 15 of each year. The Convertible Notes will mature on February 15, 2019, unless repurchased or converted earlier. The Convertible Notes will be convertible into cash, shares of our common stock, or a combination thereof, at our election (subject to certain limitations in the 2015 Term Loan Facility), at a conversion rate of

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approximately 36.9079 shares of common stock per $1,000 principal amount of the Convertible Notes, which corresponds to a conversion price of approximately $27.09 per share of our common stock and represents a conversion premium of approximately 35% based on the last reported sale price of our common stock of $20.07 on February 11, 2014, the date the notes offering was priced. As of December 31, 2015, the fair value of the Convertible Notes was $246.0 million. Our Convertible Notes include conversion and settlement provisions that are based on the price of our common stock at conversion or at maturity of the notes. The amount of cash we may be required to pay is determined by the price of our common stock. The fair values of our Convertible Notes are dependent on the price and volatility of our common stock and will generally increase or decrease as the market price of our common stock changes.

Convertible Bond Hedge and Warrant Transactions

In order to reduce the potential dilution to our common stock and/or offset cash payments due upon conversion of the Convertible Notes, in February 2014 we entered into convertible bond hedge transactions covering approximately 7.4 million shares of our common stock underlying the $200.0 million aggregate principal amount of the Convertible Notes. The convertible bond hedges have an exercise price of approximately $27.09 per share, subject to adjustment upon certain events, and are exercisable when and if the Convertible Notes are converted. If upon conversion of the Convertible Notes, the price of our common stock is above the exercise price of the convertible bond hedges, each of JPMorgan Chase Bank, National Association, London Branch, Morgan Stanley & Co. International plc and Royal Bank of Canada will deliver shares of our common stock and/or cash with an aggregate value approximately equal to the difference between the price of our common stock at the conversion date and the exercise price, multiplied by the number of shares of our common stock related to the convertible bond hedges being exercised.

In February 2014, we also entered into separate warrant transactions relating to, in the aggregate, approximately 7.4 million shares of our common stock underlying the $200.0 million aggregate principal amount of the Convertible Notes. The initial exercise price of the warrants is $34.12 per share, subject to adjustment upon certain events, which is 70% above the last reported sale price of our common stock of $20.07 on February 11, 2014. The warrants would separately have a dilutive effect to the extent that the market value per share of our common stock, as measured under the terms of the warrants, exceeds the applicable exercise price of the warrants.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA:

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MANAGEMENT'S ANNUAL REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Management is responsible for establishing and maintaining adequate internal controls over financial reporting, as such term is defined in Rule 13a 15(f) under the Securities and Exchange Act of 1934, as amended. Our internal control over financial reporting is a process designed under the supervision of our principal executive officer and principal financial officer to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with U.S. generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, including our principal executive officer and principal financial officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2015 based on the framework in Internal Control -Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in 2013. Our assessment did not include evaluating the effectiveness of internal control over financial reporting of recently acquired CBR Acquisition Holdings Corp. or CBR Acquisition Holdings Corp.'s subsidiaries, the consolidated results of which are included in our fiscal year 2015 and 2014 consolidated financial statements and constituted 2% of total assets as of December 31, 2015 and 6% of total revenue for the year then ended. Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2015.

The effectiveness of our internal control over financial reporting as of December 31, 2015, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included herein.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of AMAG Pharmaceuticals, Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows present fairly, in all material respects, the financial position of AMAG Pharmaceuticals, Inc. and its subsidiaries at December 31, 2015, and 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control -Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As discussed in Note J to the consolidated financial statements, the Company changed the manner in which it classifies deferred taxes in 2015 due to the adoption of Accounting Standards Update 2015-17, Balance Sheet Classification of Deferred Taxes.

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

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

As described in Management's Annual Report on Internal Control over Financial Reporting, management has excluded CBR Acquisition Holdings Corp. from its assessment of internal control over financial reporting as of December 31, 2015 because it was acquired by the Company in a purchase business combination during 2015. We have also excluded CBR Acquisition Holdings Corp. from our audit of internal control over financial reporting. CBR Acquisition Holdings Corp. is a wholly-owned subsidiary whose total assets and total revenues represent 2% and 6%, respectively, of the related consolidated financial statement amounts as of and for the year ended December 31, 2015.

Boston, Massachusetts

February 24, 2016

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AMAG PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)

	As of December 31,	
	2015	2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 228,705	$ 119,296
Investments	237,626	24,890
Accounts receivable, net	85,678	38,172
Inventories	40,645	40,610
Receivable from collaboration	428	4,518
Deferred tax assets	—	32,094
Prepaid and other current assets	13,592	14,456
Total current assets	606,674	274,036
Property, plant and equipment, net	28,725	1,519
Goodwill	639,188	205,824
Intangible assets, net	1,196,771	887,908
Restricted cash	2,593	2,397
Other long-term assets	13,481	17,249
Total assets	$ 2,487,432	$ 1,388,933
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,906	$ 7,301
Accrued expenses	106,363	80,093
Current portion of long-term debt	17,500	34,000
Current portion of acquisition-related contingent consideration	96,967	718
Deferred revenues	20,185	44,376
Total current liabilities	245,921	166,488
Long-term liabilities:		
Long-term debt, net	811,250	293,905
Convertible 2.5% notes, net	174,390	167,441
Acquisition-related contingent consideration	125,592	217,984
Deferred tax liabilities	189,145	77,619
Deferred revenues	5,093	—
Other long-term liabilities	3,777	5,543
Total liabilities	1,555,168	928,980
Commitments and contingencies		
Stockholders' equity:		

Preferred stock, par value $0.01 per share, 2,000,000 shares authorized; none issued	—	—
Common stock, par value $0.01 per share, 117,500,000 shares authorized at December 31, 2015 and 58,750,000 authorized at December 31, 2014; 34,733,117 and 25,599,550 shares issued and outstanding at December 31, 2015 and 2014, respectively	347	256
Additional paid-in capital	1,233,786	793,757
Accumulated other comprehensive loss	(4,205)	(3,617)
Accumulated deficit	(297,664)	(330,443)
Total stockholders' equity	932,264	459,953
Total liabilities and stockholders' equity	$ 2,487,432	$ 1,388,933

The accompanying notes are an integral part of these consolidated financial statements.

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AMAG PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(IN THOUSANDS, EXCEPT PER SHARE DATA)

	Years Ended December 31,		
	2015	2014	2013
Revenues:			
U.S. product sales, net	$ 341,816	$ 109,998	$ 71,692
Service revenues, net	24,132	—	—
License fee, collaboration and other revenues	52,328	14,386	9,164
Total revenues	418,276	124,384	80,856
Costs and expenses:			
Cost of product sales	78,509	20,306	11,960
Cost of services	9,992	—	—
Research and development expenses	42,878	24,160	20,564
Selling, general and administrative expenses	160,309	72,254	59,167
Acquisition-related costs	11,232	9,478	782
Restructuring expenses	4,136	2,023	—
Total costs and expenses	307,056	128,221	92,473
Operating income (loss)	111,220	(3,837)	(11,617)
Other income (expense):			
Interest expense	(53,251)	(14,697)	—
Loss on debt extinguishment	(10,449)	—	—
Interest and dividend income, net	1,512	975	1,051
Other income (expense)	(9,188)	217	964
Total other income (expense)	(71,376)	(13,505)	2,015
Net income (loss) before income taxes	39,844	(17,342)	(9,602)
Income tax expense (benefit)	7,065	(153,159)	—
Net income (loss)	$ 32,779	$ 135,817	$ (9,602)
Net income (loss) per share:			
Basic	$ 1.04	$ 6.06	$ (0.44)
Diluted	$ 0.93	$ 5.45	$ (0.44)
Weighted average shares outstanding used to compute net income (loss) per share:			
Basic	31,471	22,416	21,703
Diluted	35,308	25,225	21,703

The accompanying notes are an integral part of these consolidated financial statements.

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AMAG PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(IN THOUSANDS)

	Years Ended December 31,		
	2015	2014	2013
Net income (loss)	$ 32,779	$ 135,817	$ (9,602)
Other comprehensive income (loss):			
Unrealized (losses) gains on securities:			
Holding losses arising during period, net of tax	(4)	(191)	(268)
Reclassification adjustment for (losses) gains included in net income (loss), net of tax	(584)	65	24
Net unrealized losses on securities	(588)	(126)	(244)
Total comprehensive income (loss)	$ 32,191	$ 135,691	$ (9,846)

The accompanying notes are an integral part of these consolidated financial statements.

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AMAG PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(IN THOUSANDS)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2012	21,507	$ 215	$ 632,487	$ (3,247)	$ (456,658)	$ 172,797
Net shares issued in connection with the exercise of stock options and restricted stock units	252	3	1,274	—	—	1,277
Shares issued in connection with employee stock purchase plan	14	—	176	—	—	176
Non-cash equity-based compensation	—	—	8,004	—	—	8,004
Unrealized losses on securities	—	—	—	(244)	—	(244)
Net loss	—	—	—	—	(9,602)	(9,602)
Balance at December 31, 2013	21,773	218	641,941	(3,491)	(466,260)	172,408
Equity component of Convertible Notes, net of issuance costs	—	—	36,907	—	—	36,907
Purchase of convertible bond hedges, net of tax	—	—	(39,760)	—	—	(39,760)
Sale of warrants	—	—	25,620	—	—	25,620
Net shares issued in connection with the acquisition of Lumara Health	3,210	32	111,932	—	—	111,964
Net shares issued in connection with the exercise of stock options and vesting of restricted stock units	617	6	8,492	—	—	8,498
Non-cash equity-based compensation	—	—	8,625	—	—	8,625
	—	—	—	(126)	—	(126)

Unrealized losses on securities						
Net income	—	—	—	—	135,817	135,817
Balance at December 31, 2014	25,600	256	793,757	(3,617)	(330,443)	459,953
Shares issued in connection with financings, net of issuance costs of $24.7 million	8,196	82	407,395	—	—	407,477
Net shares issued in connection with the exercise of stock options and vesting of restricted stock units	937	9	15,397	—	—	15,406
Non-cash equity-based compensation	—	—	17,237	—	—	17,237
Unrealized losses on securities, net of tax	—	—	—	(588)	—	(588)
Net income	—	—	—	—	32,779	32,779
Balance at December 31, 2015	34,733	$ 347	$ 1,233,786	$ (4,205)	$ (297,664)	$ 932,264

The accompanying notes are an integral part of these consolidated financial statements.

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AMAG PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(IN THOUSANDS)

	Years Ended December 31,		
	2015	2014	2013
Cash flows from operating activities:			
Net income (loss)	$ 32,779	$ 135,817	$ (9,602)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	69,103	6,984	3,085
Amortization of premium/discount on purchased securities	2,152	2,080	2,758
Write-down of inventory to net realizable value	1,235	1,309	2,175
Gain (loss) on disposal of property and equipment	—	(103)	(924)
Non-cash equity-based compensation expense	17,237	8,625	8,004
Non-cash loss on debt extinguishment	6,426	—	—
Amortization of debt discount and debt issuance costs	11,379	6,870	—
Gains on investments, net	(14)	(114)	(40)
Change in fair value of contingent consideration	4,271	(681)	1,074
Deferred income taxes	5,007	(153,159)	—
Changes in operating assets and liabilities:			
Accounts receivable, net	(36,913)	3,588	(432)
Inventories	(5,237)	(1,360)	(1,040)
Receivable from collaboration	4,090	(4,239)	(15)
Prepaid and other current assets	4,034	2,331	2,817
Other long-term assets	9,209	1,964	(1,964)
Accounts payable and accrued expenses	7,876	10,694	(5,730)
Deferred revenues	(22,197)	(8,384)	(6,694)
Other long-term liabilities	(1,965)	(808)	(246)
Repayment of term loan attributable to original issue discount	(12,491)	—	—
Net cash provided by (used in) operating activities	95,981	11,414	(6,774)
Cash flows from investing activities:			
Acquisition of Lumara Health, net of acquired cash	562	(595,602)	—
Acquisition of CBR, net	(682,356)	—	—
Proceeds from sales or maturities of investments	208,966	223,568	106,030
Purchase of investments	(424,759)	(63,747)	(115,046)
Acquisition of MuGard Rights and inventory	—	—	(3,434)
Change in restricted cash	(195)	2,883	(2,823)
Capital expenditures, net of proceeds from sale of assets	(1,259)	(44)	1,338
Net cash (used in) investing activities	(899,041)	(432,942)	(13,935)
Cash flows from financing activities:			
	407,477	—	—

Proceeds from the issuance of common stock, net of underwriting discount and other expenses			
Long-term debt principal payments	(327,509)	—	—
Proceeds from issuance of convertible 2.5% notes	—	200,000	—
Proceeds from 2015 term loan	344,750	—	—
Proceeds from long-term debt	490,000	327,509	—
Payment of debt issuance costs	(10,004)	(7,760)	—
Proceeds from issuance of warrants	—	25,620	—
Purchase of convertible bond hedges	—	(39,760)	—
Payment of contingent consideration	(456)	(270)	(51)
Payment to former CBR shareholders	(7,195)	—	—
Proceeds from the exercise of stock options	15,406	8,499	1,277
Proceeds from the issuance of common stock under ESPP	—	—	176
Net cash provided by financing activities	912,469	513,838	1,402
Net increase (decrease) in cash and cash equivalents	109,409	92,310	(19,307)
Cash and cash equivalents at beginning of the year	119,296	26,986	46,293
Cash and cash equivalents at end of the year	$ 228,705	$ 119,296	$ 26,986
Supplemental data of cash flow information:			
Cash paid for taxes	$ 2,373	$ —	$ —
Cash paid for interest	$ 28,014	$ 2,500	$ —
Non-cash investing activities:			
Fair value of acquisition-related contingent consideration	$ —	$ 205,000	$ 13,700
Fair value of common stock issued in connection with the Lumara Health acquisition	$ —	$ 111,964	$ —

The accompanying notes are an integral part of these consolidated financial statements.

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AMAG PHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

A. DESCRIPTION OF BUSINESS

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We use our business and clinical expertise to develop and commercialize products that provide clear benefits and improve people's lives. We have a diverse portfolio of products and services with a focus on maternal health, anemia management and cancer supportive care, including our product Makena® (hydroxyprogesterone caproate injection), which we acquired in November 2014, services related to the collection, processing and storage of umbilical cord blood stem cell and cord tissue units (the "CBR Services") operated through Cord Blood Registry® ("CBR"), which we acquired in August 2015, our product Feraheme® (ferumoxytol) for intravenous ("IV") use and MuGard® Mucoadhesive Oral Wound Rinse.

We are subject to risks common to companies in the pharmaceutical industry including, but not limited to (as such risks pertain to our business) our dependence on the success of our product portfolio and maintaining commercialization of our products and services, including Makena, the CBR Services and Feraheme; intense competition, including from generic products; maintaining and defending the proprietary nature of our technology; our dependence upon third-party manufacturers; our reliance on other third parties in our business, including to conduct our clinical trials and undertake our product distribution; our reliance on and the extent of reimbursement from third parties for the use of our products, including Makena's high Medicaid reimbursement concentration; the impact of Makena's loss of orphan drug exclusivity in February 2018; competition from compounded pharmacies; our ability to implement Makena's next generation development programs (which we previously referred to as the lifecycle management program); perceptions related to pricing and access for Makena; the potential for cord blood stem cell and cord tissue science and its recognition in regenerative medicine; if our storage facility in Tucson, Arizona is damaged or destroyed; post-approval commitments for Makena; limitations on Feraheme sales given its narrow chronic kidney disease indication and the potential impact on sales of any actual or perceived safety problems; our ability to receive regulatory approval for Feraheme in the broader iron deficiency anemia indication and Feraheme's ability to compete in such market even if regulatory approval is received; our customer concentration, especially with regard to Feraheme; uncertainties regarding federal and state legislative initiatives; potential inability to obtain raw or other materials; our potential inadvertent failure to comply with federal, state or foreign healthcare fraud and abuse laws, marketing disclosure laws or other federal, state or foreign laws and regulations; uncertainties regarding reporting and payment obligations under government pricing programs and our level of indebtedness, our access to sufficient capital, the availability of net operating loss carryforwards and other tax assets, employee retention, our ability to be profitable in the future, the potential fluctuation of our operating results, potential differences between actual future results and the estimates or assumptions used by us in preparation of our consolidated financial statements, the volatility of our stock price, potential litigation, including securities and product liability suits and the impact of market overhang on our stock price.

Throughout this Annual Report on Form 10-K, AMAG Pharmaceuticals, Inc. and our consolidated subsidiaries are collectively referred to as "the Company," "AMAG," "we," "us," or "our."

B. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the U.S. ("GAAP") and include the accounts of our wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. Our results of operations for 2015 include the results

of CBR, subsequent to August 17, 2015, the date of acquisition. See Note C, “Business Combinations,” for additional information.

Use of Estimates and Assumptions

The preparation of consolidated financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and the

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related disclosure of contingent assets and liabilities. The most significant estimates and assumptions are used to determine amounts and values of, but are not limited to: revenue recognition related to product and services sales; product sales allowances and accruals; investments; inventory; acquisition date fair value and subsequent fair value estimates used to assess impairment of long-lived assets, including goodwill, in-process research and development ("IPR&D") and other intangible assets; contingent consideration; debt obligations; certain accrued liabilities, including clinical trial accruals and restructuring liabilities; income taxes and equity-based compensation expense. Actual results could differ materially from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents consist principally of cash held in commercial bank accounts, money market funds and U.S. Treasury securities having an original maturity of less than three months at the date of acquisition. We consider all highly liquid investments with a maturity of three months or less as of the acquisition date to be cash equivalents. At December 31, 2015 and December 31, 2014, substantially all of our cash and cash equivalents were held in either commercial bank accounts or money market funds.

Investments

We account for and classify our investments as either "available-for-sale," "trading," or "held-to-maturity," in accordance with the accounting guidance related to the accounting and classification of certain investments in debt and equity securities. The determination of the appropriate classification by us is based primarily on management's intent to sell the investment at the time of purchase. As of December 31, 2015 and 2014, all of our investments were classified as available for sale securities.

Available for sale securities are those securities which we view as available for use in current operations, if needed. We generally classify our available for sale securities as short term investments, even though the stated maturity date may be one year or more beyond the current balance sheet date. Available for sale investments are stated at fair value with their unrealized gains and losses included in accumulated other comprehensive loss within the consolidated statements of stockholders' equity, until such gains and losses are realized in other income (expense) within the consolidated statements of operations or until an unrealized loss is considered other than temporary.

We recognize other than temporary impairments of our debt securities when there is a decline in fair value below the amortized cost basis and if (a) we have the intent to sell the security or (b) it is more likely than not that we will be required to sell the security prior to recovery of its amortized cost basis. If either of these conditions is met, we recognize the difference between the amortized cost of the security and its fair value at the impairment measurement date in our consolidated statements of operations. If neither of these conditions is met, we must perform additional analyses to evaluate whether the unrealized loss is associated with the creditworthiness of the issuer of the security

rather than other factors, such as interest rates or market factors. If we determine from this analysis that we do not expect to receive cash flows sufficient to recover the entire amortized cost of the security, a credit loss exists, the impairment is considered other-than-temporary and is recognized in our consolidated statements of operations.

Fair Value Measurements

Under current accounting standards, fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

Current accounting guidance establishes a hierarchy used to categorize how fair value is measured and is based on three levels of inputs, of which the first two are considered observable and the third unobservable, as follows:

Level 1 - Quoted prices in active markets for identical assets or liabilities.

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Level 2 - Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

We hold certain assets and liabilities that are required to be measured at fair value on a recurring basis, including our cash equivalents, investments, and acquisition-related contingent consideration.

Inventory

Inventory is stated at the lower of cost or market (net realizable value), with approximate cost being determined on a first-in, first-out basis. Prior to initial approval from the FDA or other regulatory agencies, we expense costs relating to the production of inventory in the period incurred, unless we believe regulatory approval and subsequent commercialization of the product candidate is probable and we expect the future economic benefit from sales of the product to be realized, at which point we capitalize the costs as inventory. We assess the costs capitalized prior to regulatory approval each quarter for indicators of impairment, such as a reduced likelihood of approval. We expense costs associated with clinical trial material as research and development expense.

On a quarterly basis, we analyze our inventory levels to determine whether we have any obsolete, expired, or excess inventory. If any inventory is expected to expire prior to being sold, has a cost basis in excess of its net realizable value, is in excess of expected sales requirements as determined by internal sales forecasts, or fails to meet commercial sale specifications, the inventory is written-down through a charge to cost of product sales. The determination of whether inventory costs will be realizable requires estimates by management of future expected inventory requirements, based on sales forecasts. Once packaged, Makena currently has a shelf-life of three years and Feraheme has a shelf-life of five years. As a result of comparison to internal sales forecasts, we expect to fully realize the carrying value of our current Makena and Feraheme finished goods inventory. If actual market conditions are less favorable than those projected by management, inventory write-downs may be required. Charges for inventory write-downs are not reversed if it is later determined that the product is saleable.

Restricted Cash

As of December 31, 2015 and 2014, we classified $2.6 million and $2.4 million as restricted cash, respectively, which included $2.0 million held in a restricted fund previously established by Lumara Health Inc. (“Lumara Health”) in

connection with its Chapter 11 plan of reorganization to pay potential claims against its former directors and officers. In addition, the restricted cash balances included a $0.6 million and a $0.4 million security deposit delivered to the landlord of our Waltham, Massachusetts headquarters in the form of an irrevocable letter of credit as of December 31, 2015 and 2014, respectively.

Concentrations and Significant Customer Information

Financial instruments which potentially subject us to concentrations of credit risk consist principally of cash and cash equivalents, investments, and accounts receivable. As of December 31, 2015, our cash, cash equivalents and investments amounted to approximately $466.3 million. We currently hold our excess cash primarily in institutional money market funds, corporate debt securities and commercial paper. As of December 31, 2015, approximately $73.7 million of our total $228.7 million cash and cash equivalents balance was invested in institutional money market funds, of which $40.7 million was invested in a single fund.

Our operations are located entirely within the U.S. We focus on developing, manufacturing, and commercializing Makena and Feraheme, commercializing MuGard, and marketing and selling the CBR Services. We perform ongoing

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credit evaluations of our product sales customers and generally do not require collateral. The following table sets forth customers or partners who represented 10% or more of our total revenues for 2015, 2014 and 2013:

	Years Ended December 31,					
	2015		2014		2013	
AmerisourceBergen Drug Corporation	25	%	34	%	41	%
Takeda Pharmaceuticals Company Limited	12	%	11	%	11	%
McKesson Corporation	11	%	21	%	24	%
Cardinal Health, Inc.	<10	%	15	%	16	%

In addition, approximately 26%, 26% and 30% of our Feraheme end-user demand in 2015, 2014 and 2013, respectively, was generated by members of a single group purchasing organization ("GPO") with whom we have contracted. Revenues from outside of the U.S. amounted to approximately 12%, 12% and 11% of our total revenues for 2015, 2014 and 2013, respectively, and were principally related to deferred Feraheme revenue recognized in connection with the termination of our license, development and commercialization agreement (the "Takeda Agreement") with Takeda Pharmaceutical Company Limited ("Takeda"), which is headquartered in Japan.

Our net accounts receivable were $85.7 million and $38.2 million as of December 31, 2015 and 2014, respectively, and primarily represented amounts due for products sold directly to wholesalers, distributors and specialty pharmacies and amounts due for CBR Services sold directly to consumers.

As part of our credit management policy, we perform ongoing credit evaluations of our product sales customers, and we have not required collateral from any customer. We have not experienced significant bad debts and have not established an allowance for doubtful accounts on our product sales at either December 31, 2015 or 2014. We maintain an allowance for doubtful accounts for estimated losses inherent in our CBR service revenues portfolio. In establishing the allowance, we consider historical losses adjusted to take into account current market conditions and customers' financial conditions, the amount of receivables in dispute, and the current receivables aging and current payment patterns. Account balances are charged off against the allowance after all collection means have been exhausted and the potential for recovery is considered remote. If the financial condition of any of our significant product sales customers was to deteriorate and result in an impairment of its ability to make payments owed to us, an allowance for doubtful accounts may be required which could have a material effect on earnings in the period of any such adjustment.

Customers which represented greater than 10% of our accounts receivable balances as of December 31, 2015 and 2014 were as follows:

	December 31,			
	2015		2014	
AmerisourceBergen Drug Corporation	43	%	45	%
McKesson Corporation	<10	%	12	%

We are currently dependent on a single supplier for Feraheme drug substance (produced in two separate facilities) and finished drug product and a single supply chain for Makena finished drug product. In addition, we rely on single sources for certain materials required to support the CBR Services. We would be exposed to a significant loss of revenue from the sale of our products and services if our suppliers and/or manufacturers cannot fulfill demand for any reason.

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Property, Plant and Equipment

Property, plant and equipment are recorded at cost and depreciated when placed into service using the straight-line method based on their estimated useful lives as follows:

	Useful Life
Buildings and improvements	15 - 40 Years
Computer equipment and software	5 Years
Furniture and fixtures	5 Years
Leasehold improvements	Lesser of Lease or Asset Life
Laboratory and production equipment	5 Years
Land improvements	10 Years

Costs for capital assets not yet placed in service are capitalized on our balance sheets and will be depreciated in accordance with the above guidelines once placed into service. Costs for maintenance and repairs are expensed as incurred. Upon sale or other disposition of property, plant and equipment, the cost and related depreciation are removed from the accounts and any resulting gain or loss is charged to our consolidated statements of operations. Long-lived assets to be held and used are evaluated for impairment whenever events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their estimated fair values. Assets classified as held for sale are no longer subject to depreciation and are recorded at the lower of carrying value or estimated net realizable value.

Business Combinations

We account for acquired businesses using the acquisition method of accounting, which requires that assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date. Acquisition-related costs are expensed as incurred. Any excess of the consideration transferred over the estimated fair values of the identifiable net assets acquired is recorded as goodwill.

Acquisition-Related Contingent Consideration

Contingent consideration arising from a business combination is included as part of the purchase price and is recognized at its estimated fair value as of the acquisition date. Subsequent to the acquisition date, we measure contingent consideration arrangements at fair value for each period until the contingency is resolved. These changes in fair value are recognized in selling, general and administrative expenses in our consolidated statements of operations. Changes in fair values reflect new information about the likelihood of the payment of the contingent consideration and the passage of time.

Goodwill and Intangible Assets

Goodwill is not amortized, but is reviewed for impairment annually as of October 31, or more frequently if indicators of impairment are present. We determine whether goodwill may be impaired by comparing the carrying value of our single reporting unit, including goodwill, to the fair value of the reporting unit. If the fair value is less than the carrying amount, a more detailed analysis is performed to determine whether goodwill is impaired. The impairment loss, if any, is measured as the excess of the carrying value of the goodwill over the fair value of the goodwill and is recorded in our consolidated statements of operations.

Finite-lived intangible assets are amortized to their estimated residual values over their estimated useful lives and reviewed for impairment if certain events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. When such facts and circumstances exist, management compares the projected undiscounted future cash flows associated with the asset over its estimated useful life against the carrying amount. The impairment loss, if any, is measured as the excess of the carrying amount of the asset over its fair value.

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Acquired IPR&D represents the fair value assigned to research and development assets that we acquire and have not been completed at the acquisition date. The fair value of IPR&D acquired in a business combination is capitalized on our consolidated balance sheet at the acquisition-date fair value and is determined by estimating the costs to develop the technology into commercially viable products, estimating the resulting revenue from the projects, and discounting the projected net cash flows to present value. IPR&D is not amortized, but rather is reviewed for impairment on an annual basis or more frequently if indicators of impairment are present, until the project is completed or abandoned. If we determine that IPR&D becomes impaired or is abandoned, the carrying value is written down to its fair value with the related impairment charge recognized in our consolidated statement of operations in the period in which the impairment occurs. Upon successful completion of each project and launch of the product, we will make a separate determination of the estimated useful life of the IPR&D intangible asset and the related amortization will be recorded as an expense prospectively over its estimated useful life.

Additionally, we have other indefinite-lived intangible assets which we acquired through our business combinations. These assets are reviewed for impairment on an annual basis or more frequently if indicators of impairment are present. If we determine that the asset becomes impaired, the carrying value is written down to its fair value with the related impairment charge recognized in our consolidated statements of operations in the period in which the impairment occurs.

Patents

We expense all patent-related costs in selling, general and administrative expenses as incurred.

Revenue Recognition and Related Sales Allowances and Accruals

Our primary sources of revenue during the reporting periods were: (i) product revenues from Makena and Feraheme; (ii) service revenues associated with the CBR Services; and (iii) license fees, collaboration and other revenues, which primarily included milestone payments received from our collaboration agreements, royalties received from our license agreements, and international product revenues of Feraheme derived from our collaboration agreement with Takeda. Revenue is recognized when the following criteria are met:

· Persuasive evidence of an arrangement exists;

· Delivery of product has occurred or services have been rendered;

· The sales price charged is fixed or determinable; and

· Collection is reasonably assured.

Product Revenue

We recognize product revenues net of certain allowances and accruals in our consolidated statements of operations at the time of sale. Our contractual adjustments include provisions for returns, pricing and prompt payment discounts, as well as wholesaler distribution fees, and volume-based and other commercial rebates. Governmental rebates relate to our reimbursement arrangements with state Medicaid programs. In addition, we also monitor our distribution channel to determine whether additional allowances or accruals are required based on inventory in our sales channel. Calculating these gross to net sales adjustments involves estimates and judgments based primarily on actual product sales data, forecasted customer buying patterns, and market research data related to utilization rates by various end-users. If we determine in future periods that our actual experience is not indicative of our expectations, if our actual experience changes, or if other factors affect our estimates, we may be required to adjust our allowances and accruals estimates, which would affect our net product sales in the period of the adjustment and could be significant.

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Our product revenues were offset by provisions for allowances and accruals as follows (in thousands):

	Years Ended December 31,		
	2015	2014	2013
Gross U.S. product sales	$ 561,255	$ 190,512	$ 120,195
Provision for U.S. product sales allowances and accruals:			
Contractual adjustments	161,665	73,262	48,433
Governmental rebates	57,774	7,252	70
Total provision for U.S. product sales allowances and accruals	219,439	80,514	48,503
U.S. product sales, net	$ 341,816	$ 109,998	$ 71,692

Classification of Product Sales Allowances and Accruals

Product sales allowances and accruals are primarily comprised of both direct and indirect fees, discounts and rebates and provisions for estimated product returns. Direct fees, discounts and rebates are contractual fees and price adjustments payable to wholesalers, specialty distributors and other customers that purchase products directly from us. Indirect fees, discounts and rebates are contractual price adjustments payable to healthcare providers and organizations, such as certain physicians, clinics, hospitals, GPOs, and dialysis organizations that typically do not purchase products directly from us but rather from wholesalers and specialty distributors. In accordance with guidance related to accounting for fees and consideration given by a vendor to a customer, including a reseller of a vendor’s products, these fees, discounts and rebates are presumed to be a reduction of the selling price. Product sales allowances and accruals are based on definitive contractual agreements or legal requirements (such as Medicaid laws and regulations) related to the purchase and/or utilization of the product by these entities and are recorded in the same period that the related revenue is recognized. We estimate product sales allowances and accruals using either historical, actual and/or other data, including estimated patient usage, applicable contractual rebate rates, contract performance by the benefit providers, other current contractual and statutory requirements, historical market data based upon experience of our products and other products similar to them, specific known market events and trends such as competitive pricing and new product introductions, current and forecasted customer buying patterns and inventory levels, and the shelf life of our products. As part of this evaluation, we also review changes to federal and other legislation, changes to rebate contracts, changes in the level of discounts, and changes in product sales trends. Although allowances and accruals are recorded at the time of product sale, certain rebates are typically paid out, on average, up to three months or longer after the sale.

Allowances against receivable balances primarily relate to prompt payment discounts, provider chargebacks and certain government agency rebates and are recorded at the time of sale, resulting in a reduction in product sales revenue and the reporting of product sales receivables net of allowances. Accruals related to Medicaid and provider volume rebates, wholesaler and distributor fees, GPO fees, other discounts to healthcare providers and product returns are recorded at the time of sale, resulting in a reduction in product sales and the recording of an increase in accrued expenses.

Discounts

We typically offer a 2% prompt payment discount to our customers as an incentive to remit payment in accordance with the stated terms of the invoice, generally thirty days. Because we anticipate that those customers who are offered this discount will take advantage of the discount, we accrue 100% of the prompt payment discount at the time of sale, based on the gross amount of each invoice. We adjust the accrual quarterly to reflect actual experience.

Chargebacks

Chargeback reserves represent our estimated obligations resulting from the difference between the prices at which we sell our products to wholesalers and the sales price ultimately paid to wholesalers under fixed price contracts by third-party payers, including governmental agencies. We determine our chargeback estimates based on actual product sales data and forecasted customer buying patterns. Actual chargeback amounts are determined at the time of resale to the qualified healthcare provider, and we generally issue credits for such amounts within several weeks of receiving notification from the wholesaler. Estimated chargeback amounts are recorded at the time of sale, and we adjust the allowance quarterly to reflect actual experience.

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Distributor/Wholesaler and Group Purchasing Organization Fees

Fees under our arrangements with distributors and wholesalers are usually based upon units of product purchased during the prior month or quarter and are usually paid by us within several weeks of our receipt of an invoice from the wholesaler or distributor, as the case may be. Fees under our arrangements with GPOs are usually based upon member purchases during the prior quarter and are generally billed by the GPO within 30 days after period end. Current accounting standards related to consideration given by a vendor to a customer, including a reseller of a vendor's products, specify that cash consideration given by a vendor to a customer is presumed to be a reduction of the selling price of the vendor's products or services and therefore should be characterized as a reduction of product sales. Consideration should be characterized as a cost incurred if we receive, or will receive, an identifiable benefit (goods or services) in exchange for the consideration and we can reasonably estimate the fair value of the benefit received. Because the fees we pay to wholesalers do not meet the foregoing conditions to be characterized as a cost, we have characterized these fees as a reduction of product sales and have included them in government and other rebates in the table above. We generally pay such amounts within several weeks of our receipt of an invoice from the distributor, wholesaler or GPO. Accordingly, we accrue the estimated fee due at the time of sale, based on the contracted price invoiced to the customer. We adjust the accrual quarterly to reflect actual experience.

Product Returns

Consistent with industry practice, we generally offer our wholesalers, specialty distributors and other customers a limited right to return our products based on the product's expiration date. Currently the expiration dates for Feraheme and Makena are five years and three years, respectively. We estimate product returns based on the historical return patterns and known or expected changes in the marketplace. We track actual returns by individual production lots. Returns on lots eligible for credits under our returned goods policy are monitored and compared with historical return trends and rates.

We expect that wholesalers and healthcare providers will not stock significant inventory due to the cost of the product, the expense to store our products, and/or that our products are readily available for distribution. We record an estimate of returns at the time of sale. If necessary, our estimated rate of returns may be adjusted for actual return experience as it becomes available and for known or expected changes in the marketplace. During 2014, we reduced our reserve for Feraheme product returns by approximately $1.8 million, primarily as a result of a lower than expected rate of product returns. We did not significantly adjust our reserve for product returns during 2015 or 2013. The reduction of our reserve had an impact of increasing our 2014 net income by $0.08 and $0.07 per basic and diluted share, respectively. To date, our product returns of Feraheme have been relatively limited; however, returns experience may change over time. As we continue to gain more historical experience with actual returns and continue to gain additional experience with return rates for Makena, we may be required to make a future adjustment to our product returns estimate, which would result in a corresponding change to our net product sales in the period of adjustment and could be significant.

Government and Other Rebates

Government and other rebate reserves relate to our reimbursement arrangements with state Medicaid programs, and contractual or performance rebate agreements with certain classes of trade. We determine our estimates for Medicaid rebates, if applicable, based on actual product sales data and our historical product claims experience. In estimating these reserves, we provide for a Medicaid rebate associated with both those expected instances where Medicaid will act as the primary insurer as well as in those instances where we expect Medicaid will act as the secondary insurer. For rebates associated with reaching defined performance goals, we determine our estimates using actual product sales data and forecasted customer buying and utilization patterns. Rebate amounts generally are invoiced quarterly and are paid in arrears, and we expect to pay such amounts within several weeks of notification by the Medicaid or provider entity. Estimated government and other rebates are recorded at the time of sale and, with the exception of Medicaid as discussed below, we adjust the accrual quarterly to reflect actual experience.

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During 2013, we revised our estimated Feraheme Medicaid reserve rate based on actual product-specific rebate claims received since the 2009 launch of Feraheme, our expectations of state level activities, and estimated rebate claims not yet submitted, which resulted in a reduction of our then estimated Medicaid rebate reserve related to prior period Feraheme sales of $0.6 million. These changes in estimates were reflected as an increase in our net product sales for 2013 and resulted in a reduction to our gross to net percentages in 2013. The reduction of our estimated Medicaid rebate reserve had an impact of $0.03 per basic and diluted share in 2013. We did not significantly adjust our Medicaid rebate reserve during 2015 and 2014. We regularly assess our Medicaid reserve balance and the rate at which we accrue for claims against product sales. If we determine in future periods that our actual rebate experience is not indicative of expected claims, if actual claims experience changes, or if other factors affect estimated claims rates, we may be required to adjust our current Medicaid accumulated reserve estimate, which would affect net product sales in the period of the adjustment and could be significant.

Multiple Element Arrangements

We evaluate revenue from arrangements that have multiple elements to determine whether the components of the arrangement represent separate units of accounting as defined in the accounting guidance related to revenue arrangements with multiple deliverables. Under current accounting guidance, which governs any agreements that contain multiple elements that are either entered into or materially modified subsequent to January 1, 2011, companies are required to establish the selling price of its products and services based on a separate revenue recognition process using management’s best estimate of the selling price when there is no vendor-specific objective evidence or third-party evidence to determine the selling price of that item. If a delivered element is not considered to have standalone value, all elements of the arrangement are recognized as revenue as a single unit of accounting over the period of performance for the last such undelivered item or services. Significant management judgment is required in determining what elements constitute deliverables and what deliverables or combination of deliverables should be considered units of accounting.

When multiple deliverables are combined and accounted for as a single unit of accounting, we base our revenue recognition pattern on the last to be delivered element. Revenue is recognized using either a proportional performance or straight-line method, depending on whether we can reasonably estimate the level of effort required to complete our performance obligations under an arrangement and whether such performance obligations are provided on a best-efforts basis. To the extent we cannot reasonably estimate our performance obligations, we recognize revenue on a straight-line basis over the period we expect to complete our performance obligations. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which we are expected to complete our performance obligations under an arrangement. We may have to revise our estimates based on changes in the expected level of effort or the period we expect to complete our performance obligations.

For multiple element arrangements, we allocate revenue to all deliverables based on their relative selling prices. We determine the selling price to be used for allocating revenue to deliverables as follows: (i) vendor specific objective evidence; (ii) third-party evidence of selling price and (iii) the best estimate of the selling price. Vendor specific objective evidence generally exists only when we sell the deliverable separately and it is the price actually charged by us for that deliverable. Any discounts given to the customer are allocated by applying the relative selling price

method.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in our consolidated balance sheets. Deferred revenue associated with our service revenues includes (i) amounts collected in advance of unit processing and (ii) amounts associated with unearned storage fees collected at the beginning of the storage contract term, net of allocated discounts. Amounts not expected to be recognized within the next year are classified as long-term deferred revenues.

Service Revenue

We have identified two deliverables contained in the revenue arrangements for the CBR Services, which include: (i) enrollment, including the provision of a collection kit and cord blood and cord tissue unit processing, which are delivered at the beginning of the relationship (the “processing services”), with revenue for this deliverable recognized after the collection and successful processing of the cord blood and cord tissue; and (ii) the storage of newborn cord blood and cord tissue units (the “storage services”), for either an annual fee or a prepayment of 18 years or the lifetime of the

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newborn donor ("lifetime option"), with revenue for this deliverable recognized ratably over the applicable storage period. For the lifetime option, storage fees are not charged during the lifetime of the newborn donor. However, if the newborn donor dies and his/her legal guardian chooses to continue to store the newborn stem cells and/or cord tissue, the number of remaining years of storage covered by the lifetime option without additional charge is calculated by taking the average of male and female life expectancies based on lifetime actuarial tables published by the Social Security Administration in effect at the time of the newborn's birth and subtracting the age at death. As there are other vendors who provide processing services and storage services at separately stated list prices, the processing services and storage services, including the first year storage, each have standalone value to the customer, and therefore represent separate deliverables. The selling price for the processing services are estimated based on the best estimate of selling price because we do not have vendor specific objective evidence or third-party evidence of selling price for these elements. The selling price for the storage services is determined based on vendor specific objective evidence as we have standalone renewals to support the selling price.

License Fee, Collaboration and Other Revenues

The terms of product development and commercialization agreements entered into between us and our collaborative licensees may include non-refundable license fees, payments based on the achievement of certain milestones and performance goals, reimbursement of certain out-of-pocket costs, including research and development expenses, payment for manufacturing services, and royalties on product sales. We recognize license fee and research and development revenue under collaborative arrangements over the term of the applicable agreements using a proportional performance model, if practical. Otherwise, we recognize such revenue on a straight-line basis. Under this model, revenue is generally recognized in an amount equal to the lesser of the amount due under the agreements or an amount based on the proportional performance to date. In cases where project costs or other performance metrics are not estimable but there is an established contract period, revenues are recognized on a straight-line basis over the term of the relevant agreement. In cases where we are reimbursed for certain research and development costs associated with our collaboration agreements and where we are acting as the principal in carrying out these services, any reimbursement payments are recorded in license fee, collaboration and other revenues in our consolidated statement of operations to match the costs that we incur during the period in which we perform those services. Nonrefundable payments and fees are recorded as deferred revenue upon receipt and may require deferral of revenue recognition to future periods.

Our collaboration agreements may entitle us to additional payments upon the achievement of performance-based milestones. If a milestone involves substantive effort on our part and its achievement is not considered probable at the inception of the collaboration, we recognize the milestone consideration as revenue in the period in which the milestone is achieved only if it meets the following additional criteria:

- The milestone consideration received is commensurate with either the level of effort required to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from our performance to achieve the milestone;

· The milestone is related solely to our past performance; and

· The milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement.

There is significant judgment involved in determining whether a milestone meets all of these criteria. For milestones that do not meet the above criteria and are therefore not considered substantive milestones, we recognize that portion of the milestone payment equal to the percentage of the performance period completed at the time the milestone is achieved and the above conditions are met. The remaining portion of the milestone will be recognized over the remaining performance period using a proportional performance or straight-line method.

Research and Development Expenses

Research and development expenses include external expenses, such as costs of clinical trials, contract research and development expenses, certain manufacturing research and development costs, regulatory filing fees, consulting and professional fees and expenses, and internal expenses, such as compensation of employees engaged in research and

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development activities, the manufacture of product needed to support research and development efforts, related costs of facilities, and other general costs related to research and development. Manufacturing costs are generally expensed as incurred until a product has received the necessary initial regulatory approval.

Advertising Costs

Advertising costs are expensed as incurred and included in selling, general and administrative expenses in our consolidated statements of operations. Advertising costs, including promotional expenses, costs related to trade shows and CBR print media advertising space were $8.0 million, $2.1 million and $1.9 million for the years ended December 31, 2015, 2014 and 2013, respectively.

Shipping and Handling Costs

We bill customers of our CBR Services a fee for the shipping of the collection kits to CBR.

Equity-Based Compensation

Equity-based compensation cost is generally measured at the estimated grant date fair value and recorded to expense over the requisite service period, which is generally the vesting period. Because equity-based compensation expense is based on awards ultimately expected to vest, we must make certain judgments about whether employees, officers, directors, consultants and advisors will complete the requisite service period, and reduce the compensation expense being recognized for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures are estimated based upon historical experience and adjusted for unusual events such as corporate restructurings, which can result in higher than expected turnover and forfeitures. If factors change and we employ different assumptions in future periods, the compensation expense that we record in the future may differ significantly from what we have recorded in the current period.

We estimate the fair value of equity-based compensation involving stock options based on the Black-Scholes option pricing model. This model requires the input of several factors such as the expected option term, the expected risk-free interest rate over the expected option term, the expected volatility of our stock price over the expected option term, and the expected dividend yield over the expected option term and are subject to various assumptions. The fair value of awards calculated using the Black-Scholes option pricing model is generally amortized on a straight-line basis over the requisite service period, and is recognized based on the proportionate amount of the requisite service period that has been rendered during each reporting period.

We estimate the fair value of our restricted stock units ("RSUs") whose vesting is contingent upon market conditions using the Monte-Carlo simulation model. The fair value of RSUs where vesting is contingent upon market conditions is amortized based upon the estimated derived service period. The fair value of RSUs granted to our employees and directors is determined based upon the quoted closing market price per share on the date of grant, adjusted for estimated forfeitures.

We believe our valuation methodologies are appropriate for estimating the fair value of the equity awards we grant to our employees and directors. Our equity award valuations are estimates and may not be reflective of actual future results or amounts ultimately realized by recipients of these grants. These amounts are subject to future quarterly adjustments based upon a variety of factors, which include, but are not limited to, changes in estimated forfeiture rates and the issuance of new equity-based awards.

Income Taxes

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using future enacted rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of our deferred tax assets will not be realized.

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We account for uncertain tax positions using a "more-likely-than-not" threshold for recognizing and resolving uncertain tax positions. The evaluation of uncertain tax positions is based on factors that include, but are not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity, and changes in facts or circumstances related to a tax position. We evaluate uncertain tax positions on a quarterly basis and adjust the level of the liability to reflect any subsequent changes in the relevant facts surrounding the uncertain positions. Any changes to these estimates, based on the actual results obtained and/or a change in assumptions, could impact our income tax provision in future periods. Interest and penalty charges, if any, related to unrecognized tax benefits would be classified as a provision for income tax in our consolidated statement of operations.

Comprehensive Income (Loss)

Our comprehensive income (loss) consists of net income (loss) and other comprehensive income (loss). Other comprehensive income (loss) includes changes in equity that are excluded from net income (loss), which for all periods presented in these consolidated financial statements related to unrealized holding gains and losses on available-for-sale investments, net of tax.

Basic and Diluted Net Income (Loss) per Share

We compute basic net income (loss) per share by dividing net income (loss) by the weighted average number of common shares outstanding during the relevant period. Diluted net income (loss) per common share has been computed by dividing net income (loss) by the diluted number of common shares outstanding during the period. Except where the result would be antidilutive to net income (loss), diluted net income (loss) per common share would be computed assuming the impact of the conversion of the $200.0 million of 2.5% convertible senior notes due February 15, 2019 (the "Convertible Notes"), the exercise of outstanding stock options, the vesting of RSUs, and the exercise of warrants.

We have a choice to settle the conversion obligation under the Convertible Notes in cash, shares or any combination of the two. Pursuant to certain covenants in our six-year $350.0 million term loan facility (the "2015 Term Loan Facility"), which we entered into in 2015 to partially fund the acquisition of CBR, we may be restricted from settling the conversion obligation in whole or in part with cash unless certain conditions in the 2015 Term Loan Facility are satisfied. Since the November 2014 acquisition of Lumara Health, we utilized the if converted method to reflect the impact of the conversion of the Convertible Notes. This method assumes the conversion of the Convertible Notes into shares of our common stock and reflects the elimination of the interest expense related to the Convertible Notes. Prior to the acquisition of Lumara Health in November 2014, we intended to settle the principal value of the Convertible Notes in cash and the excess conversion premium in shares. We utilized the treasury stock method to reflect the dilutive effect of the conversion premium in 2014, as if it were a freestanding written call option on our shares prior to the November 2014 acquisition of Lumara Health. The impact of the conversion premium has been considered in the calculation of diluted net income per share for 2014 by applying the closing price of our common stock on December

31, 2014 to calculate the number of shares issuable under the conversion premium.

The dilutive effect of the warrants, stock options and RSUs has been calculated using the treasury stock method.

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The components of basic and diluted net income (loss) per share for 2015, 2014 and 2013 were as follows (in thousands, except per share data):

	Years Ended December 31,		
	2015	2014	2013
Net income (loss) - basic	$ 32,779	$ 135,817	$ (9,602)
Dilutive effect of convertible 2.5% notes	—	1,654	—
Net income (loss) - diluted	$ 32,779	$ 137,471	$ (9,602)
Weighted average common shares outstanding	31,471	22,416	21,703
Effect of dilutive securities:			
Warrants	2,466	—	—
Stock options and RSUs	1,371	520	—
Convertible 2.5% notes	—	2,289	—
Shares used in calculating dilutive net income (loss) per share	35,308	25,225	21,703
Net income (loss) per share:			
Basic	$ 1.04	$ 6.06	$ (0.44)
Diluted	$ 0.93	$ 5.45	$ (0.44)

The following table sets forth the potential common shares issuable upon the exercise of outstanding options, the vesting of RSUs, the exercise of warrants (prior to consideration of the treasury stock method), and the conversion of the 2.5% Convertible Notes, which were excluded from our computation of diluted net income (loss) per share because their inclusion would have been anti-dilutive (in thousands):

	Years Ended December 31,		
	2015	2014	2013
Options to purchase shares of common stock	1,619	2,708	2,820
Shares of common stock issuable upon the vesting of RSUs	167	322	465
Warrants	—	7,382	—
Convertible 2.5% notes	7,382	—	—
Total	9,168	10,412	3,285

In connection with the issuance of the Convertible Notes, in February 2014, we entered into convertible bond hedges. The convertible bond hedges are not included for purposes of calculating the number of diluted shares outstanding, as their effect would be anti dilutive. The convertible bond hedges are generally expected, but not guaranteed, to reduce the potential dilution and/or offset the cash payments we are required to make upon conversion of the Convertible Notes. During 2015, the average common stock price was above the exercise price of the warrants and during 2014, the average common stock price was below the exercise price of the warrants.

Reclassifications

Certain amounts in prior periods have been reclassified in order to conform to the current period presentation. In 2015, we reclassified certain immaterial revenue amounts in 2014 and 2013 within the consolidated statements of operations to more accurately reflect the underlying revenue type.

C. BUSINESS COMBINATIONS

As part of our strategy to expand our portfolio, in August 2015, we acquired CBR and in November 2014, we acquired Lumara Health and its product Makena. In addition, in June 2013, we entered into a license agreement (the "MuGard License Agreement") with Abeona Therapeutics, Inc. ("Abeona") (formerly known as PlasmaTech Biopharmaceuticals, Inc. and Access Pharmaceuticals, Inc.) pursuant to which we acquired the U.S. commercial rights to MuGard for the management of oral mucositis and stomatitis (the "MuGard Rights").

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CBR Acquisition

On August 17, 2015 (the "CBR Acquisition Date"), we acquired CBR from CBR Acquisition Holdings Corp. for $700.0 million in cash consideration, subject to estimated working capital, indebtedness and other adjustments. We believe CBR is a strong strategic fit for our growing business and offers a unique opportunity to reach a broader population of expectant mothers who may benefit from our product offerings in the maternal health space, including Makena.

We accounted for the acquisition of CBR as a business combination using the acquisition method of accounting. Under the acquisition method of accounting, the total purchase price of an acquisition is allocated to the net tangible and identifiable intangible assets acquired and liabilities assumed based on their estimated fair values as of the date of acquisition. We have made a preliminary allocation of the purchase price to the net tangible and intangible assets acquired and liabilities assumed, based on available information and various assumptions we believe are reasonable, with the remaining purchase price recorded as goodwill.

The following table summarizes the components of the total purchase price paid for CBR, as adjusted for the final net working capital, indebtedness and other adjustments (in thousands):

	Total Acquisition Date Fair Value
Cash consideration	$ 700,000
Estimated working capital, indebtedness and other adjustments	(17,837)
Purchase price paid at closing	682,163
Cash paid on finalization of the net working capital, indebtedness and other adjustments	193
Total purchase price	$ 682,356

The following table summarizes the preliminary fair values assigned to the CBR assets acquired and liabilities assumed by us along with the resulting goodwill at the CBR Acquisition Date (in thousands):

	Total Acquisition Date Fair Value
Accounts receivable	$ 8,660
Inventories	3,825
Prepaid and other current assets	8,360
Restricted cash - short-term	30,752
Property, plant and equipment	29,401
Customer relationships	297,000
Trade name and trademarks	65,000
Favorable lease asset	358

Deferred income tax assets		5,155
Other long-term assets		198
Accounts payable		(2,853)
Accrued expenses		(13,798)
Deferred revenues - short-term		(3,100)
Payable to former CBR shareholders		(37,947)
Deferred income tax liabilities		(149,530)
Other long-term liabilities		(200)
Total estimated identifiable net assets	$	241,281
Goodwill		441,075
Total	$	682,356

Measurement period adjustments recorded in the fourth quarter of 2015, which are reflected in the table above, consisted primarily of reductions to accounts receivable, inventories, prepaid and other current assets and property, plant

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and equipment totaling $1.9 million and increases to accrued expenses and long-term liabilities totaling $0.5 million, which resulted in an increase to goodwill of $1.8 million, net of $0.6 million of deferred taxes. These measurement period adjustments have been reflected as current period adjustments in the fourth quarter of 2015 in accordance with the guidance in Accounting Standards Update ("ASU") 2015-16, Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments ("ASU 2015-16"), which we early adopted in the third quarter of 2015. Any remaining adjustments to the preliminary fair value of these acquired assets and liabilities assumed will be made as soon as practicable but not later than one year from the CBR Acquisition Date.

The gross contractual amount of accounts receivable at the CBR Acquisition Date of $11.7 million was adjusted to its fair value of $8.7 million. The fair value amounts for CBR's customer relationships, trade names and trademarks were determined based on assumptions that market participants would use in pricing an asset, based on the most advantageous market for the assets (i.e., its highest and best use). We determined the fair value of the customer relationships, using an income approach, which is a valuation technique that provides an estimate of the fair value of an asset based on market participant expectations of the cash flows an asset would generate over its remaining life. Some of the more significant assumptions used in the income approach from the perspective of a market participant include the estimated net cash flows for each year for the identifiable intangible asset, the discount rate that measures the risk inherent in each cash flow stream, as well as other factors. The fair value of the trade names and trademarks was determined using the relief from royalty method, which is also an income approach. We believe the fair values assigned to the CBR customer relationships, and the trade names and trademarks are based upon reasonable estimates and assumptions given available facts and circumstances as of the CBR Acquisition Date. If these assets are not successful, sales and profitability may be adversely affected in future periods, and as a result, the value of the assets may become impaired.

The customer relationships will be amortized to selling, general and administrative expenses based on an economic consumption model over an expected useful life of approximately 20 years. The trade names and trademark intangible asset is deemed to be an indefinite-lived asset, which is not amortized but will be subject to periodic assessments of impairment.

Based on the fair value adjustments primarily related to deferred revenue and identifiable intangible assets acquired, we recorded a net deferred tax liability of $144.3 million in our consolidated balance sheet as of December 31, 2015 using a combined federal and state statutory income tax rate of 37%. The net deferred tax liability represents the $149.5 million of deferred tax liabilities recorded in acquisition accounting, primarily related to the fair value adjustments to CBR's deferred revenue and identifiable intangible assets, offset by $5.2 million of deferred tax assets acquired from CBR. These tax estimates are preliminary and subject to change based on, among other things, any adjustments to management's determination of the fair values of the tangible and identifiable intangible assets acquired and liabilities assumed by jurisdiction, the deductibility of acquisition-related costs and other costs recorded by CBR prior to the acquisition, and management's assessment of the combined company's ability to utilize the future benefits from acquired and legacy deferred tax assets.

We incurred approximately $11.2 million of acquisition-related costs in 2015 related to the CBR acquisition. These costs primarily represented financial advisory fees, legal fees, due diligence and other costs and expenses.

In connection with the CBR acquisition, we incurred a $6.8 million bridge loan commitment fee, which was included in other income (expense) in our 2015 condensed consolidated statement of operations and paid in the third quarter of 2015.

During the post-acquisition period in 2015, CBR generated approximately $24.1 million of revenue. Separate disclosure of CBR's earnings for the post-acquisition period in 2015 is not practicable due to the integration of CBR's operations into our business upon acquisition.

Lumara Health Acquisition

On November 12, 2014 (the "Lumara Health Acquisition Date"), we acquired Lumara Health at which time Lumara Health became our wholly-owned subsidiary. By virtue of the acquisition, we acquired Lumara Health's existing commercial product, Makena. Under the terms of the acquisition agreement, we acquired 100% of the equity ownership

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of Lumara Health, excluding the assets and liabilities of the Women's Health Division and certain other assets and liabilities, which were divested by Lumara Health prior to closing, for $600.0 million in cash, subject to certain net working capital and other adjustments, and issued approximately 3.2 million shares of our common stock, having a value of approximately $112.0 million at the time of closing, to the holders of common stock of Lumara Health. The acquisition of Lumara Health provided a strategic commercial entry into the maternal health business. The addition of Lumara Health's rapidly growing Makena product, the only FDA-approved therapy to reduce the risk of preterm birth in certain at-risk women, added a complementary commercial platform to our portfolio and transformed us into a multi-product specialty pharmaceutical company.

We agreed to pay additional merger consideration, up to a maximum of $350.0 million, based upon the achievement of certain net sales milestones of Makena for the period from December 1, 2014 through December 31, 2019 as follows:

- A one-time payment of $100.0 million payable upon achievement of $300.0 million in aggregate net sales in any consecutive 12-month period, commencing in the month following the Lumara Health Acquisition Date ("the First Milestone"); plus

- A one-time payment of $100.0 million payable upon achievement of $400.0 million in aggregate net sales in any consecutive 12-month period commencing in the month following the last month in the First Milestone period (the "Second Milestone"); if the Third Milestone payment (described below) has been or is required to be made prior to achieving the Second Milestone, the Second Milestone payment shall be reduced from $100.0 million to $50.0 million; plus
- A one-time payment of $50.0 million payable if aggregate net sales equal or exceed $700.0 million in any consecutive 24 calendar month period (which may include the First Milestone period) (the "Third Milestone"); however, no Third Milestone payment will be made if the Second Milestone payment has been or is required to be made in the full amount of $100.0 million; plus
- A one-time payment of $100.0 million payable upon achievement of $500.0 million in aggregate net sales in any consecutive 12 month period commencing in the month following the last month in the Second Milestone period (the "Fourth Milestone"); plus
- A one-time payment of $50.0 million payable upon achievement of $200.0 million in aggregate net sales in each of the five (5) consecutive calendar years from and including the 2015 calendar year to the 2019 calendar year (the "Fifth Milestone").

In the event that the conditions to more than one contingent payment are met in any calendar year, any portion of the total amount of contingent payment due in such calendar year in excess of $100.0 million shall be deferred until the next calendar year in which less than $100.0 million in contingent payments is due. This contingent consideration is recorded as a liability and measured at fair value based upon significant unobservable inputs.

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The following table summarizes the components of the total purchase price paid for Lumara Health, as adjusted for the final net working capital and other adjustments (in thousands):

	Total Acquisition Date Fair Value
Cash consideration	$ 600,000
Fair value of AMAG common stock issued	111,964
Fair value of contingent milestone payments	205,000
Estimated working capital and other adjustments	821
Purchase price paid at closing	917,785
Less:	
Cash received on finalization of the net working capital and other adjustments	(562)
Cash acquired from Lumara Health	(5,219)
Total purchase price	$ 912,004

At the closing, $35.0 million of the cash consideration was contributed to a separate escrow fund (the “Indemnification Escrow”) to secure the former Lumara Health security holders’ obligations to indemnify us for certain matters, including breaches of representations and warranties, covenants included in the Lumara Agreement, payments made by us to dissenting stockholders, specified tax claims, excess parachute claims, and certain claims related to the Women’s Health Division of Lumara Health, which was divested by Lumara Health prior to the closing. The portion of the Indemnification Escrow that has not been reduced by any claims by us and is not subject to any unresolved claims will be released to the former Lumara Health security holders at the earlier of (a) March 15, 2016 or (b) five days after the date on which our audited financial statements for our fiscal year ending December 31, 2015 are filed with the Securities and Exchange Commission.

The fair value of the 3.2 million shares of AMAG common stock was determined based on the closing price of our common stock on the NASDAQ Global Select Market (“NASDAQ”) of $34.88 per share on November 11, 2014, the closing price immediately prior to the closing of the transaction.

The fair value of the contingent milestone payments was determined based on our probability-adjusted discounted cash flows estimated to be realized from the net sales of Makena from December 1, 2014 through December 31, 2019. The cash flows were discounted at a rate of 5%, which we believe is reasonable given the level of certainty of the pay-out.

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The following table summarizes the fair values assigned to assets acquired and liabilities assumed by us along with the resulting goodwill at the Lumara Health Acquisition Date, as adjusted for certain measurement period adjustments for Lumara Health recorded during 2015 (in thousands):

	Total Acquisition Date Fair Value
Accounts receivable	$ 36,852
Inventories	30,300
Prepaid and other current assets	3,322
Deferred income tax assets	102,355
Property and equipment	60
Makena Base Technology	797,100
IPR&D	79,100
Restricted cash - long term	1,997
Other long-term assets	3,412
Accounts payable	(3,807)
Accrued expenses	(36,561)
Deferred income tax liabilities	(295,676)
Other long-term liabilities	(4,563)
Total estimated identifiable net assets	$ 713,891
Goodwill	198,113
Total	$ 912,004

During 2015, we finalized the fair values assigned to the assets acquired and liabilities assumed by us at the Lumara Health Acquisition Date. The measurement period adjustments recorded in 2015 consisted primarily of a $7.2 million reduction to our Makena revenue reserves and a $5.4 million reduction related to net deferred tax liabilities, partially offset by a $4.5 million increase in the purchase price associated with the final settlement of net working capital with the former stockholders. These measurement period adjustments have been reflected as current period adjustments during 2015 in accordance with the guidance in ASU 2015-16.

The gross contractual amount of accounts receivable at the Lumara Health Acquisition Date was $40.5 million. The $30.3 million fair value of inventories included a fair value step-up adjustment of $26.1 million, which will be amortized and recognized as cost of product sales in our consolidated statements of operations as the related inventories are sold. We recognized $11.6 million and $1.3 million of the fair value adjustment as cost of product sales during the years ended December 31, 2015 and December 31, 2014, respectively. An additional $1.2 million of the fair value adjustment was recognized as research and development expense during the year ended December 31, 2015. The remaining $12.0 million is estimated to be recognized as follows: $4.8 million in 2016, $4.0 million in 2017 and $3.2 million in 2018.

The fair value amounts for the Makena base technology (“Makena Base Technology”) and IPR&D were determined based on assumptions that market participants would use in pricing an asset, based on the most advantageous market for the assets (i.e., its highest and best use). We determined the fair value of the Makena Base Technology and the IPR&D using the income approach. Some of the more significant assumptions used in the income approach for these assets include the estimated net cash flows for each year for each project or product, the discount rate that measures the risk inherent in each future cash flow stream, the assessment of each asset’s life cycle, competitive trends

impacting the asset and each cash flow stream as well as other factors, including the major risks and uncertainties associated with the timely and successful completion of the IPR&D projects, such as legal and regulatory risk.

The fair value of the acquired IPR&D asset represents the value assigned to acquired research and development projects that, as of the Lumara Health Acquisition Date, had not established technological feasibility and had no alternative future use, including certain programs associated with the Makena next generation development programs to extend the brand franchise beyond the February 2018 exclusivity date, such as new routes of administration, the use of new delivery technologies, as well as reformulation technologies. We believe the fair values assigned to the Makena Base Technology and IPR&D assets are based upon reasonable estimates and assumptions given available facts and circumstances as of the Lumara Health Acquisition Date. If these assets are not successful or successfully developed, sales and profitability may be adversely affected in future periods, and as a result, the value of the assets may become impaired.

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Both AMAG and Lumara Health had deferred tax assets for which full valuation allowances were provided in the pre-acquisition financial statements. However, we considered certain of the deferred tax liabilities recorded in acquisition accounting as sources of income to support realization of Lumara Health's deferred tax assets. We recorded a net deferred tax liability of $193.3 million in our consolidated balance sheet in acquisition accounting using a combined federal and state statutory income tax rate of 38.8%. The net deferred tax liability represents the $295.7 million of deferred tax liabilities recorded in acquisition accounting (primarily related to the fair value adjustments to Lumara Health's inventories and identifiable intangible assets) offset by $102.4 million of deferred tax assets acquired from Lumara Health which we have determined, are 'more likely than not' to be realized. See Note J, "Income Taxes," for additional information.

We incurred approximately $9.5 million of acquisition-related costs in 2014 related to the acquisition of Lumara Health. These costs primarily represented financial advisory fees, legal fees, due diligence and other costs and expenses.

During the post-acquisition period in fiscal 2014, Lumara Health generated $22.5 million of revenue from sales of Makena. Separate disclosure of Lumara Health's earnings for the post-acquisition period in fiscal 2014 is not practicable due to the integration of Lumara Health's operations into our business upon acquisition.

Unaudited Pro Forma Supplemental Information

The following supplemental unaudited pro forma information presents our revenue and net income (loss) on a pro forma combined basis, including CBR and Lumara Health, assuming that the CBR acquisition occurred on January 1, 2014 and that the Lumara Health acquisition occurred on January 1, 2013. For purposes of preparing the following pro forma information, certain items recorded during 2015, such as the $11.2 million of acquisition-related costs, the $10.4 million loss on debt extinguishment, and $9.2 million of other one-time fees and expenses incurred in connection with the CBR acquisition financing, are excluded from 2015 and reflected in 2014. In addition, certain items recorded in 2014, such as the $153.2 million tax benefit and the $9.5 million of acquisition-related costs incurred in connection with the acquisition of Lumara Health, are excluded from 2014 and reflected in 2013. Further, the pro forma combined net income (loss) in fiscal 2013 does not give effect to the elimination of approximately $385.9 million of non-recurring reorganization gains, net of losses and expenses, realized in connection with Lumara Health's exit from bankruptcy in September 2013 as such amounts are not directly related to the acquisition of Lumara Health. The pro forma amounts do not include any expected cost savings or restructuring actions which may be achievable or may occur subsequent to the acquisition of Lumara Health or CBR, or the impact of any non-recurring activity. The following table presents the unaudited pro forma consolidated results (in thousands):

	Years Ended December 31,		
	2015	2014	2013
Pro forma combined revenues	$ 490,451	$ 364,447	$ 179,561
Pro forma combined net income (loss)	$ 28,217	$ (57,739)	$ 463,522

The pro forma adjustments reflected in the pro forma combined net income (loss) in the above table primarily represent adjustments to historical amortization of intangible assets, to historical depreciation of property, plant and equipment, and reductions to historical CBR revenues due to fair value purchase accounting adjustments to intangible assets, property, plant and equipment and deferred revenue. In addition, the pro forma combined net income (loss) includes increased interest expense due to the increase in term loan borrowings and the issuance of $500.0 million aggregate principal amount of 7.875% Senior Notes due 2023 (the “2023 Senior Notes”) in connection with the CBR acquisition. Income taxes for all periods were adjusted accordingly. This pro forma financial information is not necessarily indicative of our consolidated operating results that would have been reported had the transactions been completed as described herein, nor is such information necessarily indicative of our consolidated results for any future period.

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Goodwill

In connection with the CBR acquisition, we recognized $441.1 million of goodwill, primarily due to the synergies expected from combining our operations with CBR and to deferred tax liabilities recorded on the fair value adjustments, primarily those relating to intangible assets and deferred revenue. In connection with the Lumara Health acquisition, we recognized $198.1 million of goodwill, primarily due to the net deferred tax liabilities recorded on the fair value adjustments to Lumara Health's inventories and identifiable intangible asset. The $639.2 million of goodwill resulting from the CBR and Lumara Health acquisitions is not deductible for income tax purposes.

MuGard License Agreement

In June 2013, we entered into the MuGard License Agreement with Abeona, under which we obtained an exclusive, royalty bearing license, with the right to grant sublicenses, to certain intellectual property rights, including know how, patents and trademarks, to use, import, offer for sale, sell, manufacture and commercialize MuGard in the U.S. and its territories (the "U.S. Territory").

In consideration for the license, we paid Abeona an upfront payment of $3.3 million on June 6, 2013 (the "MuGard License Date"). We are required to pay royalties to Abeona on future net sales of MuGard until the later of (a) the expiration of the licensed patents or (b) the tenth anniversary of the first commercial sale of MuGard under the MuGard License Agreement in the U.S. Territory ("the "MuGard Royalty Term"). These tiered, double-digit royalty rates decrease for any part of the MuGard Royalty Term occurring after the expiration of the licensed patents and are subject to off-set against certain of our expenses. After the expiration of the MuGard Royalty Term, the license shall become a fully paid-up, royalty-free and perpetual license in the U.S. Territory.

We did not assume any pre-existing liabilities related to the MuGard business, contingent or otherwise, arising prior to the MuGard License Date. We accounted for the acquisition of the MuGard Rights as a business combination under the acquisition method of accounting since we acquired the U.S. commercial rights for MuGard and inventory, and obtained access to certain related regulatory assets and product supply, employees and other assets, including certain patent and trademark rights, contracts, and related books and records, held by Abeona, which are exclusively related to MuGard. In addition, during the term of the MuGard License Agreement, we will have control over sales, distribution and marketing of MuGard in the U.S. as Abeona has assigned to us all of its right, title and interest in MuGard-related internet and social media outlets and other sales, marketing and promotional materials currently owned or controlled by Abeona. Abeona will no longer commercialize, market, promote, sell or make public communications relating to MuGard in the U.S Territory, except as may be agreed to by us. Abeona has also agreed to not, directly or indirectly, research, develop, market, sell or commercialize any medical devices that directly compete with MuGard for the treatment of any diseases or conditions of the oropharyngeal cavity in the U.S. Territory.

The following table summarizes the total consideration for the MuGard Rights (in thousands):

	Total Acquisition

	Date Fair Value
Cash	$ 3,434
Acquisition-related contingent consideration	13,700
Total consideration	$ 17,134

During 2013, we completed the valuation for the acquisition of the MuGard Rights and determined the fair value of the contingent consideration and the intangible asset as of the MuGard License Date to be $13.7 million and $16.9 million, respectively. The acquisition date fair value of the contingent consideration was determined based on various market factors, including an analysis of estimated sales and using a discount rate of approximately 15%.

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The following table summarizes the fair values of the assets acquired related to the business combination as of the MuGard License Date (in thousands):

	Total Acquisition Date Fair Value
MuGard intangible asset	$ 16,893
Inventory	241
Total identifiable assets acquired	$ 17,134

We incurred approximately $0.8 million of acquisition-related costs in 2013, which were primarily related to professional and legal fees.

Pro forma results of operations would not be materially different as a result of the acquisition of the MuGard Rights and therefore are not presented.

D. INVESTMENTS

As of December 31, 2015 and 2014, our investments equaled $237.6 million and $24.9 million, respectively, and consisted of securities classified as available-for-sale in accordance with accounting standards which provide guidance related to accounting and classification of certain investments in debt and equity securities.

The following is a summary of our investments as of December 31, 2015 and 2014 (in thousands):

	December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities				
Due in one year or less	$ 27,964	$ —	$ (38)	$ 27,926
Due in one to three years	173,652	3	(904)	172,751
Commercial paper				
Due in one year or less	34,452	2	(5)	34,449
Municipal securities				
Due in one year or less	2,500	—	—	2,500
Total investments	$ 238,568	$ 5	$ (947)	$ 237,626

	December 31, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities				
Due in one year or less	$ 11,656	$ 3	$ (4)	$ 11,655
Due in one to three years	13,258	10	(33)	13,235
Total investments	$ 24,914	$ 13	$ (37)	$ 24,890

Impairments and Unrealized Gains and Losses on Investments

We did not recognize any other-than-temporary impairment losses in our consolidated statements of operations related to our securities during 2015, 2014 or 2013. We considered various factors, including the length of time that each security was in an unrealized loss position and our ability and intent to hold these securities until the recovery of their amortized cost basis occurs. As of December 31, 2015, none of our investments has been in an unrealized loss position for more than one year. Future events may occur, or additional information may become available, which may cause us to identify credit losses where we do not expect to receive cash flows sufficient to recover the entire amortized cost basis

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of a security and may necessitate the recording of future realized losses on securities in our portfolio. Significant losses in the estimated fair values of our investments could have a material adverse effect on our earnings in future periods.

E. FAIR VALUE MEASUREMENTS

The following tables represent the fair value hierarchy as of December 31, 2015 and 2014, for those assets and liabilities that we measure at fair value on a recurring basis (in thousands):

	Fair Value Measurements at December 31, 2015 Using:			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds	$ 73,676	$ 73,676	$ —	$ —
Corporate debt securities	200,677	—	200,677	—
Commercial paper	34,449	—	34,449	—
Municipal securities	2,500	—	2,500	—
Total Assets	$ 311,302	$ 73,676	$ 237,626	$ —
Liabilities:				
Contingent consideration - Lumara Health	$ 214,895	$ —	$ —	$ 214,895
Contingent consideration - MuGard	7,664	—	—	7,664
Total Liabilities	$ 222,559	$ —	$ —	$ 222,559

	Fair Value Measurements at December 31, 2014 Using:			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds	$ 77,254	$ 77,254	$ —	$ —
Corporate debt securities	24,890	—	24,890	—
Total Assets	$ 102,144	$ 77,254	$ 24,890	$ —
Liabilities:				
Contingent consideration - Lumara Health	$ 206,600	$ —	$ —	$ 206,600
Contingent consideration - MuGard	12,102	—	—	12,102

Total Liabilities	$ 218,702	$ —	$ —	$ 218,702

Investments

Our money market funds are classified as Level 1 assets under the fair value hierarchy as these assets have been valued using quoted market prices in active markets and do not have any restrictions on redemption. Our investments are classified as Level 2 assets under the fair value hierarchy as these assets were primarily determined from independent pricing services, which normally derive security prices from recently reported trades for identical or similar securities, making adjustments based upon other significant observable market transactions. At the end of each reporting period, we perform quantitative and qualitative analyses of prices received from third parties to determine whether prices are reasonable estimates of fair value. After completing our analyses, we did not adjust or override any fair value measurements provided by our pricing services as of December 31, 2015 or 2014. In addition, there were no transfers or reclassifications of any securities between Level 1 and Level 2 during 2015 or 2014.

Contingent consideration

We accounted for the acquisitions of each of Lumara Health, CBR and the MuGard Rights as business combinations

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under the acquisition method of accounting. Additional details regarding our acquisitions and license agreements can be found in Note C, “Business Combinations.” There were no contingent consideration obligations related to the CBR acquisition. The fair value measurements of contingent consideration obligations and the related intangible assets arising from business combinations are classified as Level 3 assets under the fair value hierarchy as these assets have been valued using unobservable inputs. These inputs include: (a) the estimated amount and timing of projected cash flows; (b) the probability of the achievement of the factors on which the contingency is based; and (c) the risk adjusted discount rate used to present value the probability weighted cash flows. Significant increases or decreases in any of those inputs in isolation could result in a significantly lower or higher fair value measurement.

The following table presents a reconciliation of contingent consideration obligations related to the acquisition of Lumara Health and the MuGard Rights (in thousands):

Balance as of January 1, 2014	$ 14,550
Payments made	(270)
Adjustments to fair value of contingent consideration	(681)
Acquisition date fair value of Lumara Health contingent consideration	205,000
Other adjustments	103
Balance as of December 31, 2014	$ 218,702
Payments made	(456)
Adjustments to fair value of contingent consideration	4,271
Other adjustments	42
Balance as of December 31, 2015	$ 222,559

The $4.3 million increase in adjustments to the fair value of the contingent consideration liability in 2015 were due primarily to a $8.3 million increase to the Makena contingent consideration related to the time value of money, partially offset by a $4.0 million reduction to the MuGard contingent consideration due to changes in estimated amounts and timing of cash flows related to the royalties we expect to pay to Abeona under the MuGard License Agreement as a result of an update to the total forecasted net sales for MuGard. During 2014, we also revised our forecast of total projected net sales for MuGard and reassessed the fair value of the contingent consideration liability related to the MuGard Rights. As a result, we reduced our contingent consideration liability by $2.3 million for year ended December 31, 2014. This reduction was partially offset by a $1.6 million increase to the Makena contingent consideration liability related to the time value of money. These adjustments were included in selling, general and administrative expenses in our consolidated statements of operations. We have classified $96.4 million of the Makena contingent consideration and $0.6 million of the MuGard contingent consideration as short-term liabilities in our consolidated balance sheet as of December 31, 2015.

The fair value of the contingent milestone payments payable by us to the former stockholders of Lumara Health was determined based on our probability-adjusted discounted cash flows estimated to be realized from the net sales of Makena from December 1, 2014 through December 31, 2019. The cash flows were discounted at a rate of 5%, which

we believe is reasonable given the estimated likelihood of the pay-out. As of December 31, 2015, the total undiscounted milestone payment amounts we could pay in connection with the Lumara Health acquisition is $350.0 million over the period from December 1, 2014 to December 31, 2019.

The fair value of the contingent royalty payments payable by us to Abeona was determined based on various market factors, including an analysis of estimated sales using a discount rate of approximately 12%. As of December 31, 2015, we estimate that the undiscounted royalty amounts we could pay under the MuGard License Agreement, based on current projections, may range from $9.0 million to $13.0 million over a ten year period beginning on June 6, 2013, the acquisition date, which is our best estimate of the period over which we expect the majority of the asset's cash flows to be derived.

We believe the estimated fair values of Lumara Health and the MuGard Rights are based on reasonable assumptions, however, our actual results may vary significantly from the estimated results.

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Debt

We estimate the fair value of our debt obligations by using quoted market prices obtained from third-party pricing services, which is classified as a Level 2 input. As of December 31, 2015, the estimated fair value of our 2023 Senior Notes was $437.5 million. As of December 31, 2015 and 2014, the estimated fair value of our 2.5% Convertible Notes was approximately $246.0 million and $332.0 million, respectively, which differed from their carrying values. In addition, the estimated fair value of our 2015 and 2014 term loan facilities was $337.8 million and $342.0 million, which differed from their carry values. See Note R, "Debt" for additional information on our debt obligations.

F. INVENTORIES

Our major classes of inventories were as follows as of December 31, 2015 and 2014 (in thousands):

	December 31,	
	2015	2014
Raw materials	$ 19,673	$ 14,188
Work in process	1,985	5,965
Finished goods	18,987	20,457
Inventories included in current assets	40,645	40,610
Included in other long-term assets:		
Raw materials	—	7,798
Total inventories	$ 40,645	$ 48,408

Total inventories as of December 31, 2015 decreased by $7.8 million as compared to 2014 primarily due to inventory sold to customers, partially offset by the inclusion of CBR inventory acquired in connection with the August 2015 acquisition of CBR, which consists of cord blood and cord tissue collection kits, and processing bags. Additionally, during 2015 we expensed $3.6 million of Makena inventory and $1.0 million of Feraheme commercial inventory, respectively, which may not be saleable and which was recorded in cost of product sales in our consolidated statements of operations. The $3.6 million of expensed Makena inventory included a fair value adjustment of $3.3 million. During 2014, we expensed $0.7 million of Feraheme commercial inventory, which we determined would be solely used in development activities at our third-party suppliers and which we recorded in research and development expenses in our consolidated statements of operations.

As of December 31, 2015, we believed that FDA approval and subsequent commercialization of the single-dose preservative-free formulation of Makena was probable and therefore capitalized approximately $3.8 million of

inventory related to the single-dose preservative-free formulation of Makena, which included a fair value adjustment of $1.5 million. In February 2016, we received FDA approval for the single-dose formulation of Makena for inventory produced at Hospira, Inc. and we expect to begin commercialization of it in the second quarter of 2016.

In the fourth quarter of 2014, we recorded the acquired Makena inventory at fair value of $30.3 million, which required a $26.1 million step-up adjustment to recognize the inventory at its expected net realizable value. We are amortizing and recognizing the step-up adjustment as cost of product sales in our consolidated statements of operations as the related inventories are sold and we record step-up costs associated with clinical trial material as research and development expense.

See Note C, "Business Combinations," for additional information.

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G. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following as of December 31, 2015 and 2014 (in thousands):

	December 31,	
	2015	2014
Land	$ 700	$ —
Land improvements	300	—
Building and improvements	9,500	—
Computer equipment and software	13,193	894
Furniture and fixtures	1,725	680
Leasehold improvements	1,717	430
Laboratory and production equipment	5,683	493
Construction in progress	786	—
	33,604	2,497
Less: accumulated depreciation	(4,879)	(978)
Property, plant and equipment, net	$ 28,725	$ 1,519

During 2015, we acquired land and a building in Tucson, Arizona as well as other fixed assets in connection with the CBR acquisition.

During 2015, 2014 and 2013 we incurred $3.9 million, $0.5 million and $3.0 million of depreciation expense, respectively. The $3.0 million of depreciation expense in 2013 included $1.9 million of accelerated depreciation expense related to fixed assets at our prior office facility that was sold.

H. GOODWILL AND INTANGIBLE ASSETS, NET

Goodwill

Our goodwill balance consisted of the following (in thousands):

Balance at January 1, 2014	$ —
Goodwill acquired through Lumara Health acquisition	205,824
Balance as of December 31, 2014	205,824
Goodwill acquired through CBR acquisition	441,075
Measurement period adjustments related to Lumara Health acquisition	(7,711)
Balance as of December 31, 2015	$ 639,188

The measurement period adjustments related to the Lumara Health acquisition were comprised primarily of a $7.2 million reduction associated with adjustments to our Makena revenue reserves and a $5.4 million reduction related to net deferred tax liabilities, partially offset by a $4.5 million increase associated with the final settlement of net working capital with the former stockholders of Lumara Health. These current period adjustments have been recorded in accordance with the guidance in ASU 2015-16, which we early adopted in 2015. As of December 31, 2015, we had no accumulated impairment losses related to goodwill. See Note C, “Business Combinations,” for additional information.

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Intangible Assets

As of December 31, 2015 and 2014, our identifiable intangible assets consisted of the following (in thousands):

	December 31, 2015