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, 2016

or

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

For the transition period from to

Commission file number 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, 2016 was approximately $813.4 million based on the closing price of $23.92 of the Common Stock of the registrant as reported on the NASDAQ Global Select Market on such date. As of February 13, 2017, there were 34,339,448 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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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 other 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; expected timing of the Feraheme sNDA filing in mid-2017; expected timing of a Rekynda NDA in early 2018; anticipated FDA review timeline of the Makena auto-injector sNDA filing; anticipated Feraheme utilization in the non-dialysis CKD patient population; significant growth opportunities for Feraheme in the IV iron market; our plans to raise awareness and education of FSD; our expected investment in FSD label expansion for Intrarosa; expansion of our sales force in mid-2017, maintenance of our current Makena and CBR sales forces and the commercialization impact of our sales forces; the timing and amounts of Palatin and Endoceutics milestone and royalty payments; 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 Velo will begin its Phase 2b/3a study in the first quarter of 2017; 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; the growth of our maternal health portfolio; expectations as to what impact recent regulatory developments will have on our business and competition, including changes to the Feraheme product information and label; expectations regarding our intellectual property, including patent protection, and the impact generics and other competition could have on our business; 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; the expected timing and occurrence of consummation of the Endoceutics License Agreement; our expectation of costs to be incurred in connection with 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 substances, drug products and key materials at our third-party manufacturers or suppliers; the availability of raw materials; the strategic fit of Palatin and Rekynda in our product 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; expectations relating to the Endoceutics License Agreement; 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 of our product revenues; 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.

ITEM 1. BUSINESS:

Overview

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a biopharmaceutical company focused on developing and delivering important therapeutics, conducting clinical research in areas of unmet need and creating education and support programs for the patients and families we serve. Our currently marketed products support the health of patients in the areas of women's health, anemia management and cancer supportive care, including Makena® (hydroxyprogesterone caproate injection), Feraheme® (ferumoxytol) for Intravenous ("IV") use and MuGard® Mucoadhesive Oral Wound Rinse. Through services related to the preservation of umbilical cord blood stem cell and cord tissue units (the "CBR Services") operated through Cord Blood Registry® ("CBR"), we also help families to preserve newborn stem cells, which are used today in transplant medicine for certain cancers and blood, immune and metabolic disorders, and which we believe have the potential to play a valuable role in the ongoing development of regenerative medicine. In addition, on February 2, 2017, we closed a license agreement in which we received the rights to research, develop and commercialize Rekynda™ (bremelanotide), which is being developed for the treatment of hypoactive sexual desire disorder ("HSDD") in pre-menopausal women. On February 13, 2017, we signed a license agreement in which we will acquire the rights to market Intrarosa™ (prasterone) in the U.S. for the treatment of moderate-to-severe dyspareunia, a common symptom of vulvar and vaginal atrophy ("VVA"), due to menopause.

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 product sales of *Makena* and *Feraheme* and service revenue from the CBR Services.

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

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 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	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.	Approved and marketed.	Own worldwide rights.
Makena® (hydroxyprogesterone caproate injection) (Auto-injector device)	An auto-injector device for subcutaneous administration of *Makena* (the "Makena auto-injector").	Supplemental new drug application ("sNDA") expected to be filed in the second quarter of 2017.	Own worldwide rights to drug product; exclusively license rights to auto-injector device from Antares Pharma, Inc. ("Antares").
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.
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. Complete response letter received January 2014. Phase 3 clinical trial ongoing and sNDA expected to be filed in mid-2017.	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").
Rekynda™ (bremelanotide) (Auto-injector device)	An investigational product designed for on-demand treatment of HSDD in pre-menopausal women.	New Drug Application ("NDA") expected to be filed in early 2018.	Exclusively license rights to research, develop and sell *Rekynda* in North America from Palatin Technologies, Inc. ("Palatin").
Digoxin immune fab ("DIF")	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.

Makena

Overview

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. We acquired the rights to *Makena* in connection with our acquisition of Lumara Health Inc. ("Lumara Health") in November 2014. Additional details regarding our acquisition of Lumara Health can be found in Note C, "*Business Combinations*," to our consolidated financial statements included in this Annual Report on Form 10-K.

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 (the "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, and which were affirmed in 2014. The SMFM Clinical Guidelines recommend the use of an intramuscular HPC injection, such as *Makena*, to reduce the risk of recurrent preterm birth for clinically indicated patients. Further, in January 2017, the SMFM stated that vaginal progesterone should not be considered a substitute for hydroxyprogesterone caproate in women with a history of spontaneous preterm birth.

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 2016, sales of *Makena* accounted for approximately 63% of our total net revenues. *Makena* was approved by the FDA in February 2011 and was granted orphan drug exclusivity through February 3, 2018.

Preterm Birth

Preterm birth is defined as a birth prior to 37 weeks of pregnancy. According to the National Center for Health Statistics Report, in 2015, preterm births affected nearly 400,000 babies, or one of every ten infants born in the U.S. Although 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 response to our request to extend our agreed-upon completion dates for the ongoing clinical studies, the FDA approved a two-year extension to December 2018 and October 2020.

Next Generation Development Programs

We continue to advance our next generation development program for *Makena*, seeking to enhance the product profile for patients and their healthcare providers. As part of this program, in February 2016 the FDA approved a single-dose preservative-free formulation of *Makena* manufactured by the Pfizer CentreOne group of Pfizer, Inc., ("Pfizer") (formerly Hospira, Inc.), who also manufactures our multidose vial of *Makena*. We began promoting the single-dose preservative-free formulation of *Makena* to physicians in the second quarter of 2016. In July 2016, we received approval of our prior approval supplement for Piramal Pharma Solutions (formerly Coldstream Laboratories, Inc.) to also manufacture the single-dose preservative-free formulation of *Makena*.

We are developing an auto-injector device for subcutaneous administration of *Makena* (the "*Makena* auto-injector"), including chemistry, manufacturing and controls ("CMC") development with Antares. During 2016, we met with the FDA to discuss our proposed development and regulatory strategy, focusing on our plans to conduct a definitive PK study designed to demonstrate comparable bioavailability of the subcutaneous *Makena* auto-injector to the current intramuscular ("IM") injection form of *Makena*. We believe that demonstrating bioequivalence for area under the curve is the most relevant PK parameter for *Makena*. In October 2016, we initiated an open label parallel study which enrolled approximately 120 healthy post-menopausal women in a 1:1 randomization. In February 2017, we announced topline results from this definitive PK study. *Makena* administered subcutaneously demonstrated bioequivalence to the IM injection on area under the curve ("AUC") ($AUC_{0\text{-to-inf}}$ 2,386 ng/mL compared to 2,086 ng/mL) with the 90% confidence interval for the ratio of AUC (105.17 to 124.39) falling within the 80% to 125% range, which the FDA uses to define bioequivalence. The mean maximum or peak plasma concentration ("Cmax") for *Makena* administered subcutaneously was slightly higher than for the IM (7.3 ng/mL compared to 6.3 ng/mL) with the 90% confidence interval for the ratio of Cmax (96.6% to 138.7%) falling outside of the bioequivalence range of 80% to 125%. No serious adverse events were reported and the drug was generally well tolerated, although there was a higher reporting rate of injection site related adverse events (e.g. transient burning/stinging sensation), in the subcutaneous injection arm of the study. Similar observations were also reported in the subcutaneous arm of our open label, parallel comparative pain study (also initiated in October 2016), which we recently elected to discontinue. We will not be requesting orphan exclusivity as part of the sNDA filing and, therefore, anticipate a six-month FDA review timeline. There are multiple device and drug-device combination patents and patent applications in-licensed from Antares which relate to the subcutaneous *Makena* auto-injector and we intend to request Orange Book listing of eligible Antares drug-device patents. We expect to file an sNDA for approval of the *Makena* auto-injector in the second quarter of 2017.

CBR Services

Overview

CBR is the largest private newborn stem cell bank in the world and 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 acquired CBR from CBR Acquisition Holdings in August 2015. Additional details regarding our 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.

We market and sell the CBR Services directly to consumers, who pay for the services directly, 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.

The CBR Services include the collection, processing and storage of both umbilical cord blood and cord tissue. As of December 31, 2016, CBR stored approximately 665,000 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. In 2016, revenue from the CBR Services accounted for approximately 19% of our total net revenues.

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 and cerebral palsy. 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 comprehensive report to Congress on cord blood banking. The report contained clear recommendations that healthcare professionals should provide all expectant parents with fair and balanced education on cord blood preservation prior to labor and delivery, thereby enabling families to make an informed decision regarding their options: preserve their newborns' stem cells for potential future family use, donate the cells for public use or

research, or dispose of the cord blood. The IOM report has helped guide health policy at the state level and to date, 29 states have passed some form of cord blood education legislation, the majority of which follow the IOM recommendations. Several other states are in various stages of developing similar legislation to help inform healthcare providers and expectant parents of all medically appropriate options for preserving cord blood stem cells In support of this legislation, CBR collaborates with outside organizations to develop education initiatives to provide quality, relevant information to expectant parents, and medical professionals, including courses where continuing medical education credits can be earned, regarding new parents' 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. We believe that maintaining these accreditations, while not a requirement for preserving stem cells, are an important indicator of the quality of our services and the CBR brand.

Cord Blood and Cord Tissue

Cord blood comes from a newborn's umbilical cord and can only 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 blood also contains a variety of other types of stem cells and monocytes that are being investigated for a variety of other therapeutic applications. Cord tissue contains mesenchymal stem cells, which are unique 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 79% of the stem cell units released by CBR have been used for experimental regenerative therapies.

***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 hematologists and oncologists and nephrologists, both in outpatient and hospital settings and other end-users who treat IDA 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 hospitals, hematology and oncology centers and nephrology clinics. In 2016, sales of *Feraheme* accounted for approximately 18% of our total net revenues.

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 ANDA applicant whose proposed drug is a generic version of a previously-approved drug listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," also known as the "Orange Book," to certify to any patents listed in the Orange Book for the previously-approved drug and, in the case of a Paragraph IV certification, to notify the owner of the approved application and the relevant patent-holder. 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 unenforceable, or both. If a patent infringement suit is filed within 45 days of receipt of the Paragraph IV notice, a so-called 30-month stay is triggered that generally prevents the FDA from approving the ANDA until the expiration of the 30-month stay period, conclusion of the litigation in the generic applicant's favor, or expiration of the patent, whichever is earlier. 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. In March 2016, we initiated a patent infringement suit alleging that Sandoz' ANDA filing itself constituted an act of infringement and that if it is approved, the manufacture, use, offer for sale, sale or importation of Sandoz' ferumoxytol products would infringe our patents. By the filing of this complaint, we believe a 30-month stay was triggered and that the FDA is prohibited from granting approval of Sandoz' application until the earliest of 30 months from the date of receipt of the notice of certification by the patent owner, 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 months stay period, the stay is lifted and the FDA may thereafter approve the application based on the applicable standards for approval. On May 2, 2016, Sandoz filed a response to our patent infringement suit and the trial is scheduled for March 12, 2018. Any future unfavorable outcome in this matter could negatively affect the magnitude and timing of future *Feraheme* revenues. We intend to vigorously enforce our intellectual property rights relating to ferumoxytol. 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 of 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 of 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 IV 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. During 2015, we terminated this trial due to difficulty in enrollment. In December 2016, we met with the FDA to develop a plan forward in order to satisfy this post-approval commitment for *Feraheme* and recently proposed a protocol to the FDA for a new pediatric study.

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

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., over one million grams of IV iron were administered for the treatment of non-dialysis patients with IDA in 2016. 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 these non-dialysis patients who are diagnosed with IDA regardless of the underlying cause are currently being treated with IV iron.

In December 2016, in order to support an sNDA 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, we completed enrollment in 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 (the "*Feraheme* comparator trial"). Approximately 2,000 patients were 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. As background, in December 2012, we submitted an sNDA to the FDA seeking approval for this broader label, which 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 suggested, among other things, that we submit additional clinical trial data in the proposed broad IDA patient population and, following discussions with the FDA, we determined to undertake the *Feraheme* comparator trial in pursuit of the broader indication. We currently expect to file an sNDA for this broader indication in mid-2017.

MuGard

MuGard 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 certain ulcers/canker sores and traumatic ulcers, such as those caused by oral surgery or ill-fitting dentures or braces. We acquired the U.S. commercial rights to *MuGard* under a license agreement with Abeona in June 2013. (the "MuGard Rights") *MuGard* was launched in the U.S. by Abeona in 2010 after receiving 510(k) clearance from the FDA. Additional details regarding the acquisition of the MuGard Rights can be found in Note Q, "*Collaboration, License and Other Strategic Agreements*," to our consolidated financial statements included in this Annual Report on Form 10-K.

Based on interactions with government payors during 2016, we determined that broader reimbursement coverage for *MuGard* by was unlikely and we assessed the MuGard Rights for potential impairment. From this assessment, we concluded that based on the lack of broad reimbursement and insurance coverage for *MuGard* and the resulting decrease in expected revenues and cash flows, the projected undiscounted cash flows were less than the book value, indicating impairment of this intangible asset. As a result of an analysis of the fair value of the net MuGard Rights intangible asset as compared to its recorded book value, we recognized an impairment charge for the full $15.7 million net intangible asset in 2016.

Rekynda

Overview

On January 8, 2017, we entered into a license agreement (the "Palatin License Agreement") with Palatin Technologies, Inc. ("Palatin") under which we acquired (a) an exclusive license in all countries of North America (the "Rekynda Territory"), with the right to grant sub-licenses, to research, develop and commercialize *Rekynda* and any other products containing bremelanotide (collectively, the "Rekynda Products"), an investigational product designed to be an on-demand treatment for HSDD in pre-menopausal women, (b) a worldwide non-exclusive license, with the right to grant sub-licenses, to manufacture the Rekynda Products, and (c) a non-exclusive license in all countries outside the Rekynda Territory, with the right to grant sub-licenses, to research, develop and manufacture (but not commercialize) the Rekynda Products. Following the satisfaction of the conditions to closing under the Palatin License Agreement, the transaction closed on February 2, 2017. Additional details regarding the Palatin License Agreement can be found below under the heading "*Collaboration, License and Other Strategic Agreements-Palatin*."

Rekynda, bremelanotide, is a melanocortin-4 receptor agonist designed to activate pathways in the brain that are involved in the body's normal sexual responses, which is currently being developed for the treatment of HSDD in pre-menopausal women. *Rekynda* is designed to be an on-demand therapy given prior to anticipated sexual activity and is self-administrated by the patient in the thigh or abdomen via a single-use subcutaneous auto-injector. Two recently completed Phase 3 *Rekynda* studies conducted by Palatin for the treatment of HSDD in pre-menopausal women met the pre-specified co-primary efficacy endpoints of median improvement in desire and decrease in distress associated with low sexual desire as measured using validated patient-reported outcome instruments. Both trials consisted of double-blind placebo-controlled, randomized parallel group studies comparing a subcutaneous dose of 1.75 mg *Rekynda* versus placebo, in each case, delivered via an auto-injector. The co-primary endpoints for these trials were evaluated using Question One and Two of the Female Sexual Function Index: Desire Domain ("FSFI-D") and Female Sexual Distress Scale-Desires/Arousal/Orgasm ("FSDS-DAO") Item 13 scores. For women taking *Rekynda* compared to placebo, the change in FSFI-D was measured using the median change and showed statistically significant improvement in measures of desire in both Phase 3 studies, with one study demonstrating a median change of 0.60 vs. 0.00 and p=0.0002, and the other study demonstrating a median change of 0.60 vs. 0.00 and p<0.0001. These studies also demonstrated statistically significant mean changes in FSFI-D for women taking *Rekynda* compared to placebo of 0.54 vs. 0.24 and 0.63 vs. 0.21. The FSDS-DAO Item 13 scores were also measured using the median change and showed statistically significant decreases in measures of distress related to low sexual desire in both Phase 3 studies for women taking *Rekynda* compared to placebo, with one study demonstrating a median change of -1.0 vs. 0.0 and p<0.0001, and the other study demonstrating a median change of -1.0 vs. 0.0 and p=0.0057. These studies also demonstrated statistically significant mean changes in FSDS-DAO Item 13 scores for women taking *Rekynda* compared to placebo of -0.74 vs. -0.35 and -0.71 vs. -0.41. The change in the number of satisfying sexual events, a key secondary endpoint, was not significantly different from placebo in either clinical trial. Each trial consisted of over 600 patients randomized in a 1:1 ratio to either the treatment arm or placebo, each with a 24 week evaluation period. The most frequent adverse events were nausea, flushing and headache, which were generally mild-to-moderate in severity. Approximately 18% of patients discontinued participation in the *Rekynda* arm due to adverse events in both studies. Women in the trials had the option, after completion of the randomized trial, to continue in an ongoing open-label safety extension study for an additional 52 weeks, which is intended to gather additional data on the safety of long-term and repeated use of *Rekynda*. Nearly 80% of patients who completed the randomized portion of the study elected to remain in the ongoing open-label portion of the study. All of the patients in the extension study are receiving *Rekynda*. Palatin is continuing to oversee the conduct of the extension study, which we expect to be completed in the second half of 2017. We currently expect to submit an NDA in early 2018 following completion of multiple Phase 1 drug interaction and safety pharmacology studies, including an abuse-liability study and drug-to-drug interaction studies with anti-hypertensive and anti-arrhythmic therapies, as well as certain chemistry, manufacturing and controls activities, including drug product process validation studies by Palatin. Palatin will continue to conduct the remaining studies through clinical research organizations, and we will oversee such development work to support our filing an NDA for *Rekynda* for the treatment of HSDD.

The Phase 3 *Rekynda* studies were predicated on the results of a Phase 2b clinical study of bremelanotide conducted by Palatin. The Phase 2b clinical study was a multicenter, placebo-controlled, randomized, parallel group, dose-finding trial testing three dose levels, 0.75 mg, 1.25 mg and 1.75 mg, of subcutaneously administered bremelanotide against placebo in pre-menopausal women diagnosed with HSDD, female sexual arousal disorder or both. Palatin reported that the 1.75 mg dose demonstrated clinically meaningful and statistically significant results for all predefined endpoints and was well-tolerated.

Female Sexual Dysfunction and Hypoactive Sexual Desire Disorder

Female sexual dysfunction ("FSD") is defined as persistent or recurring problems during one or more of the stages of a woman's sexual response, which, as a result, causes distress. HSDD is the most common type of FSD and is characterized by a decreased sexual desire with significant personal distress or interpersonal difficulties as a result of the lack of desire. Studies suggest that approximately 15 million women in the U.S. are affected by HSDD and approximately 5.8 million of these women are pre-menopausal and have a primary diagnosis of HSDD. Despite one FDA-approved HSDD therapy on the market today for pre-menopausal women, we believe that patient awareness and understanding of the condition is extremely low, and that few women currently seek treatment. HSDD may go undiagnosed due to various factors such as embarrassment or stigma, lack of awareness of low sexual desire as a medical condition or attribution to other external factors, such as stress or fatigue. Recent market research commissioned by Palatin indicates that 95% of pre-menopausal women suffering from HSDD are unaware that it is a treatable medical condition. As a result, assuming FDA approval of our NDA, we expect that the initial focus of our *Rekynda* commercialization efforts will be raising awareness and education about the disease for both healthcare professionals and patients with this disorder.

Intrarosa

Overview

On February 13, 2017, we entered into a license agreement (the "Endoceutics License Agreement") with Endoceutics, Inc. ("Endoceutics") pursuant to which Endoceutics has agreed to grant to us rights to *Intrarosa*, an FDA-approved product for the treatment of moderate-to-severe dyspareunia (pain during sexual intercourse), a symptom of VVA due to menopause. The Endoceutics License Agreement grants us the right to develop and commercialize pharmaceutical products containing dehydroepiandrosterone ("DHEA"), including *Intrarosa*, at dosage strengths of 13 mg or less per dose and formulated for intravaginal delivery, excluding any dosage strengths over 13 mg per dose and combinations with other active pharmaceutical ingredients, in the U.S. for the treatment of VVA and FSD. The closing of the transactions contemplated by the Endoceutics License Agreement is subject to clearance under the Hart-Scott-Rodino Act and other customary closing conditions. At closing, we and Endoceutics will also enter into an exclusive commercial supply agreement, under which Endoceutics will supply *Intrarosa* to us.

In addition to commercializing *Intrarosa* for VVA, we have also committed to co-fund a Phase 3 clinical program, which would be conducted by Endoceutics to support regulatory approval of *Intrarosa* for the treatment of certain types of FSD in post-menopausal women. We and Endoceutics have agreed to share the direct costs related to such studies with our investment not to exceed $20.0 million. In addition, we have also committed to a minimum marketing spend in 2017 for *Intrarosa*. Additional details regarding the Endoceutics License Agreement can be found below under the heading "*Collaboration, License and Other Strategic Agreements-Pending Endoceutics License Agreement*."

Intrarosa is the only FDA-approved, vaginally administered, daily non-estrogen steroid, which is prescribed for the treatment of moderate-to-severe dyspareunia. *Intrarosa* contains prasterone, also known as DHEA. DHEA is an inactive endogenous precursor of hormones, which is converted locally into androgens and estrogens to help restore the vaginal tissue as indicated by improvements in the percentage of superficial cells, parabasal cells, and pH. The mechanism of action is not fully established. The effectiveness of *Intrarosa* on moderate-to-severe dyspareunia was examined in two primary 12-week placebo-controlled efficacy trials. All women in both studies were assessed for improvement from baseline to week 12 for four co-primary efficacy endpoints: most bothersome moderate-to-severe symptom of dyspareunia, the percentage of vaginal superficial cells, the percentage of parabasal cells, and vaginal pH. All primary endpoints were statistically significant. Women taking *Intrarosa* experienced a significant reduction in moderate-to-severe dyspareunia, as well as statistically significant improvements in the percentage of vaginal superficial cells, parabasal cells and vaginal pH.

A 52-week long-term safety study of 422 post-menopausal women showed no evidence of endometrial hyperplasia, a potential precursor to endometrial cancer that is associated with the use of unopposed estrogen. Vaginal discharge and atypical pap smears were the most common adverse reactions and were were reported as a treatment-emergent adverse reaction in at least 2% of women taking *Intrarosa*. *Intrarosa* is contraindicated in women with undiagnosed abnormal uterine bleeding. In clinical trials, the most common adverse reactions were vaginal discharge and abnormal pap smear. The label for *Intrarosa* contains a precaution that it has not been studied in women with a history of breast cancer.

Vulvar and Vaginal Atrophy

In the U.S., there are an estimated 64 million post-menopausal women, with approximately half, or 32 million, of those women suffering from symptoms VVA, which we estimate is an approximately $1.0 billion-a-year market. Of the 32 million women who suffer from symptoms of VVA, there are an estimated 44% to 78% who report symptoms of dyspareunia, a common symptom of VVA.

As a non-estrogen-based product, *Intrarosa* is not subject to the labeling restrictions associated with the results of the Women's Health Initiative (WHI), led to class labeling for all estrogen containing products, including a boxed safety warning of the increased risk of certain types of cancer, cardiovascular disease, and probable dementia associated with the use of exogenous estrogen. *Intrarosa* is not subject to the boxed warning and dosing restrictions of all other currently approved prescription products to treat VVA.

We plan to invest in a new sales force of approximately 150 sales representatives dedicated to support the *Intrarosa* launch, which we anticipate to take place in mid-2017. This new sales force will also allow for additional flexibility as our portfolio evolves, including opportunities for *Intrarosa* label expansion, preparing for the potential launch of *Rekynda* and for future products acquired in the women's health space over time.

Collaboration, License and Other Strategic Agreements

Palatin

Under the terms of the Palatin License Agreement, which closed on February 2, 2017, we paid Palatin $60.0 million as a one-time upfront payment. We will also reimburse Palatin up to an aggregate amount of $25.0 million for all reasonable, documented, out-of-pocket expenses incurred by Palatin in connection with the development and regulatory activities necessary to submit an NDA for *Rekynda* for the treatment of HSDD, which we expect to incur in 2017. In addition, the Palatin License Agreement provides for future contingent payments of (a) up to $80.0 million upon achievement of certain regulatory milestones, including FDA approval, and (b) up to $300.0 million of aggregate sales milestone payments upon the achievement of certain annual net sales milestones over the course of the license. The first sales milestone of $25.0 million will be triggered when *Rekynda* annual net sales exceed $250.0 million. We are also obligated to pay Palatin tiered royalties on annual net sales of the Rekynda Products, on a product-by-product basis, in the Rekynda Territory ranging from the high-single digits to the low double-digits. The royalties will expire on a product-by-product and country-by-country basis upon the latest to occur of (a) the earliest date on which there are no valid claims of Palatin patent rights covering such Rekynda Product in such country, (b) the expiration of the regulatory exclusivity period for such Rekynda Product in such country and (c) 10 years following the first commercial sale of such Rekynda Product in such country. These royalties are subject to reduction in the event that: (i) we must license additional third party intellectual property in order to develop, manufacture or commercialize a Rekynda Product or (ii) generic competition occurs with respect to a Rekynda Product in a given country, subject to an aggregate cap on such deductions of royalties otherwise payable to Palatin. After the expiration of the applicable royalties for any Rekynda Product in a given country, the license for such Rekynda Product in such country would become a fully paid-up, royalty-free, perpetual and irrevocable license.

The Palatin License Agreement expires on the date of expiration of all royalty obligations due thereunder unless earlier terminated in accordance with the agreement. In addition, we have the right to terminate the Palatin License Agreement without cause, in its entirety or on a product-by-product and country-by-country basis upon at least 180 days' prior written notice to Palatin. Either party may terminate the Palatin License Agreement for cause if the other party materially breaches or defaults in the performance of its obligations, and, if curable, such material breach remains uncured for 90 days.

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, 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, which we expect to begin in the first quarter of 2017. 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 to Velo certain milestone payments and single-digit royalties based on regulatory approval and commercial sales of the product. 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.

Antares

Through our acquisition of Lumara Health, we are party to a development and license agreement with Antares (the "Antares Agreement"), which grants us an exclusive, worldwide, royalty-bearing license, with the right to sublicense, to certain intellectual property rights, including know-how, patents and trademarks, to develop, use, sell, offer for sale and import and export the *Makena* auto-injector, an Antares' auto-injection system for use with HPC. 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 *Makena* auto-injector, including the U.S. We are required to pay royalties to Antares on net sales of the *Makena* auto-injector commencing on the launch of the *Makena* auto-injector in a particular country until the *Makena* auto-injector is no longer 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 the *Makena* auto-injector and decrease after the expiration of licensed patents or where there are generic equivalents to the *Makena* auto-injector being sold in a particular

country. Antares is the exclusive supplier of our requirements for the auto-injection system devices for the *Makena* auto-injector and Antares remains responsible for the manufacture and supply of the devices and assembly of the *Makena* auto-injector. We are responsible for the supply of the drug in pre-filled syringes to be used in the assembly of the finished auto-injector 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 a license agreement (the "MuGard License Agreement") with 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 "MuGard 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 certain 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 MuGard 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 MuGard 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.

Pending Endoceutics License Agreement

Under the terms of the Endoceutics License Agreement, which we entered into with Endoceutics on February 13, 2017, Endoceutics has agreed to grant to us rights to *Intrarosa*, an FDA-approved product for the treatment of moderate-to-severe dyspareunia. The Endoceutics License Agreement grants us the right to develop and commercialize pharmaceutical products containing DHEA, including *Intrarosa*, at dosage strengths of 13 mg or less per dose and formulated for intravaginal delivery, excluding any dosage strengths over 13 mg per dose and combinations with other active pharmaceutical ingredients, in the U.S. for the treatment of VVA and FSD. The closing of the transactions contemplated by the Endoceutics License Agreement (the "Effective Date") is subject to clearance under the Hart-Scott-Rodino Act and other customary closing conditions.

Subject to the terms of the Endoceutics License Agreement, Endoceutics has agreed to conduct clinical studies for the use of *Intrarosa* in FSD to support an application for regulatory approval for *Intrarosa* for the treatment of FSD in the U.S. We and Endoceutics have agreed to share the direct costs related to such studies based upon a negotiated allocation with us funding up to $20.0 million. We may, with Endoceutics' consent (not to be unreasonably withheld, conditioned or delayed), conduct any other studies of *Intrarosa* for the treatment of VVA and FSD anywhere in the world for the purpose of obtaining or maintaining regulatory approval of or commercializing *Intrarosa* for the treatment of VVA or FSD in the U.S. All data generated in connection with the above described studies would be owned by Endoceutics and licensed to us pursuant to the Endoceutics License Agreement.

We will have the exclusive right to commercialize *Intrarosa* for the treatment of VVA or FSD in the U.S., subject to the terms of the Endoceutics License Agreement, including having final decision making authority with respect to commercial strategy, pricing and reimbursement and other commercialization matters. We have agreed to use commercially reasonable efforts to market, promote and otherwise commercialize *Intrarosa* for the treatment of VVA or FSD in the U.S., including a commitment to a minimum marketing spend for *Intrarosa* in 2017. Endoceutics has the right to directly conduct, itself or through its affiliates or subcontractors, additional commercialization activities for *Intrarosa* for the treatment of VVA or FSD in the U.S., which scope of activities will be agreed to by the parties acting reasonably and in good faith, and has the right to

conduct activities related generally to the field of intracrinology, in each case, subject to our right to withhold approval in certain instances.

Upon Closing, we will make an upfront payment of $50.0 million and, subject to certain conditions, will issue 600,000 shares of unregistered common stock, to Endoceutics, 300,000 of which will be subject to a 180-day lock-up provision, and the other 300,000 of which will be subject to a one-year lock-up provision. We have also agreed to make a payment to Endoceutics of up to $10.0 million upon the delivery of launch quantities of *Intrarosa* and a payment of $10.0 million on the first anniversary of the closing. In addition, we have also agreed to pay tiered royalties to Endoceutics equal to a percentage of net sales of *Intrarosa* in the U.S. ranging from mid-teens (for calendar year net sales up to $150.0 million) to mid twenty percent (for any calendar year net sales that exceed $1 billion) (such royalty rate to be dependent on the aggregate annual net sales of *Intrarosa*) for the commercial life of *Intrarosa*, with deductions (a) after the later of (i) the expiration date of the last to expire of a licensed patent containing a valid patent claim or (ii) ten years after the first commercial sale of *Intrarosa* for the treatment of VVA or FSD in the U.S., (b) for generic competition and (c) for third party payments. Endoceutics is also eligible to receive certain sales milestone payments, including a first sales milestone payment of $15.0 million, which would be triggered when *Intrarosa* annual net U.S. sales exceed $150.0 million, and a second milestone payment of $30.0 million, which would be triggered when annual net U.S. sales exceed $300.0 million. If annual net U.S. sales exceed $500.0 million, there are additional sales milestone payments totaling up to $850.0 million, which would be triggered at various increasing sales thresholds.

In connection with the Endoceutics License Agreement, we and Endoceutics have agreed to enter into an exclusive commercial supply agreement on or about the Effective Date, pursuant to which Endoceutics, itself or through affiliates or contract manufacturers, would agree to manufacture and supply *Intrarosa* to us (the "Supply Agreement") and would be our exclusive supplier of *Intrarosa* in the U.S., subject to certain rights for us to manufacture and supply *Intrarosa* in the event of a cessation notice or supply failure (as such terms are defined in the Supply Agreement). Under the Supply Agreement, Endoceutics would maintain at all times a second source supplier for the manufacture of DHEA and the drug product and identify and validate and transfer manufacturing intellectual property to the second source supplier within two years of the Effective Date. The Supply Agreement will remain in effect until the termination of the Endoceutics License Agreement, unless terminated earlier by either party for an uncured material breach or insolvency of the other party, or by us if we exercise our rights to manufacture and supply *Intrarosa* following a cessation notice or supply failure.

Under the Endoceutics License Agreement, except as permitted under the Endoceutics License Agreement or the Supply Agreement, and except for any compounds or products affecting the melanocortin receptor pathway, including without limitation, bremelanotide (collectively, "Excluded Product"), we will not be permitted to research, develop, manufacture, or commercialize (i) DHEA for delivery by any route of administration anywhere in world, (ii) any compound (including DHEA) or product for use in VVA anywhere in the world, or (iii) commencing on the date of an approval of *Intrarosa* for the treatment of FSD in the U.S. and continuing for the remainder of the term of the Endoceutics License Agreement, any compound (including DHEA) for use in FSD (each, a "Competing Product"). Any compound or product for use in FSD that would be a Competing Product in the United States but that (i) does not contain DHEA and (ii) was acquired or licensed or for which the research, development, manufacture or commercialization of such compound or product is initiated by us or our affiliates, in each case, prior to the date of an approval of *Intrarosa* for the treatment of FSD in the U.S., will be an Excluded Product and will not be subject to the exclusivity obligations under the Endoceutics License Agreement in the treatment of FSD, subject to certain restrictions in the Endoceutics License Agreement. These noncompete restrictions are subject to certain exclusions relating to the acquisition of competing programs.

The Endoceutics License Agreement expires on the date of expiration of all royalty obligations due thereunder unless earlier terminated in accordance with the Endoceutics License Agreement. The Endoceutics License Agreement may be terminated by either Party if the Effective Date has not occurred within 180 days following the execution date or such date as the parties may mutually agree. The Endoceutics License Agreement may be terminated by either Party for material breach that is either uncured after a 90-day notice period, or if such breach cannot be cured within such 90-day period, if the breaching party does not commence appropriate and material actions to cure such breach within the notice period and continue to diligently cure such breach for a period not to exceed 90 days, in either case, subject to tolling or determination of the arbitrators, if dispute resolution procedures are initiated within 30 days' of the termination notice. We have the ability to elect not to terminate the Endoceutics License Agreement in the case of a material breach, in which case future milestone and royalty payments owed to Endoceutics would be reduced by a negotiated percentage or by an amount determined by arbitration. Either party may terminate under certain situations relating to the bankruptcy or insolvency of the other party. We may terminate the Endoceutics License Agreement for a valid business reason upon 365 days prior written notice to Endoceutics; or upon 60 days written notice in the event we reasonably determine in good faith, after due inquiry and after discussions with Endoceutics, that we cannot reasonably continue to develop or commercialize any Product as a result of a safety issue regarding the use of *Intrarosa*. We may also terminate the Endoceutics License Agreement upon 180 days' notice if there is a change of control of

AMAG and the acquiring entity (alone or with its affiliates) is engaged in a competing program (as defined in the Licensed Agreement) in the U.S. or in at least three countries within the European Union.

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, product candidates or for any commercial products or product candidates we may acquire or in-license. We rely solely on third-party contract manufacturers and our licensors (who, in turn, may also rely 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, and those of our licensors, are subject to current good manufacturing practices ("cGMP") and regulations enforced by the FDA through periodic inspections to confirm such compliance. We target to maintain, where possible, second source suppliers and/or 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 and development of our products and services.

To support the commercialization and development 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 Pfizer under a Development and Supply Agreement (as amended and restated, the "Pfizer Agreement"). The Pfizer Agreement requires that we satisfy certain minimum purchase requirements but we are not obligated to use Pfizer as our sole supplier of drug product. The Pfizer Agreement expires on December 31, 2022, which term may be automatically extended thereafter for additional 18 month periods, unless cancelled by us or Pfizer within an agreed-upon notice period.

Antares is the exclusive supplier of our requirements for the auto-injection system devices for the *Makena* auto-injector and Antares remains responsible for the manufacture and supply of the devices and assembly of the *Makena* auto-injector. We are responsible for the supply of the drug in pre-filled syringes to be used in the assembly of the finished auto-injector product. The Antares 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.

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") 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 exclusively all of our API from SAFC. 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. ("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.

MuGard

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.

Rekynda

Rekynda is a synthetic peptide and while the production process involves well-established technology, there are few manufacturers capable of scaling up to commercial quantities under cGMP at acceptable costs. Under the Palatin License Agreement, we assumed a long-term commercial supply agreement for fill, finish, and packaging services for *Rekynda.* We are currently negotiating other manufacturing and supply agreements for the drug substance and auto-injector sub-assemblies and may not be able to enter into such agreements on acceptable terms, if at all.

Raw Materials

We, our licensors and our respective 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 or our licensors if materials that we test do not perform in an acceptable manner. In addition, we, our licensors or our respective 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, our licensors or our respective 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, and the ability of our licensors, collaborators and other business partners 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. patents for *Feraheme*, which expire at various times through 2023. 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. There are no issued patents covering *Makena* or the CBR Services. We have a license to two U.S. patents relating to *MuGard*, which expire in 2022. We have licenses to issued patents and pending applications that will provide protection for the *Makena* auto-injector 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.

Under the Palatin License Agreement, we have exclusive rights to a number of issued and pending U.S. and foreign patents related to bremelanotide that are owned by Palatin. Certain of Palatin's U.S. patents include claims directed to the bremelanotide drug composition and methods of use thereof with terms expiring in 2020, and another patent includes claims covering methods of treating FSD using subcutaneous administration of compositions that include bremelanotide with a term expiring in 2033, any one of which may be subject to patent term extension for a maximum period of up to five years but no longer than 14 years after regulatory approval as compensation for patent term lost during drug development and the FDA regulatory review process, pursuant to the Hatch-Waxman Act. Whether we, together with Palatin, will be able to obtain patent term extensions under the Hatch-Waxman Act and the length of any such extension cannot be determined until a product covered by such patents receives FDA approval. In addition, the claims of issued patents covering *Rekynda* may not provide meaningful protection and further, third parties may challenge the validity or scope of any such issued patents.

Under the terms of the Endoceutics License Agreement, we received rights to Endoceutics' three U.S. patents related to *Intrarosa*, including drug-product patent claims with a term which expires in 2031 and two additional patents, including method of use claims and pharmaceutical dosage form claims with terms which expire in 2028.

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. We also expect to face competition for *Rekynda*, including from an FDA-approved product for treatment of HSDD. 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 estimate that the following represents the 2016 and 2015 U.S. market share allocation of the *Makena* at-risk patient population (as calculated by shipments to physicians), including patients treated with *Makena,* patients treated with c17P, and the patient population being treated either with other therapies, such as 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.

	2016	2015
Makena	42%	30%
c17P	28%	40%
Other therapies or untreated	30%	30%

Prior to the February 2016 approval of the single-dose preservative-free formulation of *Makena*, many healthcare providers who preferred a single-dose or preservative-free option were utilizing non-FDA-approved compounded versions of hydroxyprogesterone caproate. The launch of the single-dose formulation allowed us to capture market share from these compounders, increase the number of compounders in our distributor network and partner with organizations formerly using compounded product.

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). In June 2016, ANI Pharmaceuticals, Inc. ("ANI"), Aspen's exclusive distributor, launched HPC in 5 mL vials in the U.S. 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 when *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 past ten 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 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 in 2010 and in 2016, most private U.S. cord blood banks offer this service. The barriers to entry into the cord blood and cord tissue banking business are relatively low. We 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. New entrants may also 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. Though the barriers to entry are low, we believe that establishing a high-quality brand and nationwide reputation like CBR's, and growing a bank to a size where long-term stability of operations is not a primary concern for customers, gives CBR an advantage in the market.

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 largest U.S. competitor is ViaCord®, a subsidiary of PerkinElmer, Inc. Two other banks, Cryo-Cell International, Inc.® and StemCyte™, are significantly smaller than either CBR or ViaCord®, but maintain a national footprint. In addition to these three competitors, CBR competes with more than 20 other blood banks in the U.S., most of whom have regional focuses. CBR differentiates itself from almost all of its competitors through its size and financial stability, its investments in research and its commercial reach.

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

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 1.50grams, 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 and, in an effort to strengthen the warnings and precautions section of the label and mitigate the risk of serious hypersensitivity reactions, including anaphylaxis, 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 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 any 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.

In addition to the currently marketed products described above, *Feraheme* may also compete with Auryxia™ (ferric citrate), an oral treatment, which is in development to treat IDA in adults with non-dialysis CKD. In January 2017, Keryx Biopharmaceuticals, Inc. announced that it has submitted an sNDA for Auryxia™ to the FDA. Further, Akebia Therapeutics, Inc. is developing Vadadustat, an oral HIF stabilizer, to treat anemia related to CKD and has recently commenced a Phase 3 trial.

Feraheme may also face future competition from generic IV iron replacement therapy products. For example, as discussed above, in February 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. In March 2016, we initiated a patent infringement suit alleging that Sandoz' ANDA filing itself constituted an act of infringement and that if it is approved, the manufacture, use, offer for sale, sale or importation of Sandoz' ferumoxytol products would infringe our patents. By the filing of this complaint, the FDA is prohibited from granting approval of Sandoz' application until the earliest of 30 months from the date of receipt of the notice of certification by the patent owner, 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 months stay period, the stay is lifted and the FDA may thereafter approve the application based on the applicable standards for approval. In May 2016, Sandoz filed a response to our patent infringement suit and the trial is scheduled for March 12, 2018.

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.

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 2017 by IMS Health Incorporated ("IMS"), we estimate that the size of the total 2016 U.S. non-dialysis IV iron replacement therapy market was approximately 1.1 million grams, which represents an increase of approximately 11% over 2015. *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 2016 and 2015 U.S. market share allocation of the total non-dialysis IV iron market based on the volume of IV iron administered:

	2016 U.S. Non-dialysis IV Iron Market (1,114,000 grams)	**2015 U.S. Non-dialysis IV Iron Market (1,000,000 grams)**
Venofer®	38%	40%
Injectafer®	21%	14%
INFeD®	15%	18%
Feraheme	13%	14%
Generic sodium ferric gluconate	9%	9%
Ferrlecit®	4%	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

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 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.

Rekynda

If *Rekynda* is approved for marketing by the FDA and if we are successful in launching and commercializing it, we expect *Rekynda* will face competition. Addyi® (flibanserin) was approved by the FDA for commercial use in the U.S. in August 2015 for the treatment of HSDD in pre-menopausal women and is marketed by Valeant Pharmaceuticals International, Inc. ("Valeant"). Addyi® is only available through a risk evaluation and mitigation strategy ("REMS") program because of an increased risk of severe hypotension and syncope due to the interaction between Addyi® and alcohol. In addition, Addyi® was approved with a boxed warning to highlight the risks of severe hypotension and syncope in patients who drink alcohol during treatment with Addyi®, in patients who use Addyi® with moderate or strong CYP3A4 inhibitors, or in patients who have liver impairment.

We are not aware of any company actively developing another melanocortin receptor agonist drug for the treatment of HSDD. However, we are aware of several other drugs at various stages of development, most of which are taken on a chronic, typically once-daily, basis. Lorexys™, an oral, non-hormonal, fixed-dose combination of two antidepressants, bupropion and trazodone, is being developed by S1 Biopharma, Inc. ("S1 Biopharma"). S1 Biopharma intends to seek approval of Lorexys™ utilizing a 505(b)(2) strategy, which may allow S1 Biopharma an accelerated regulatory pathway as well as decreased development costs. Emotional Brain BV is developing two different oral fixed-dose, on-demand combination drugs, one a combination of sildenafil and testosterone and the other a combination of testosterone and buspirone hydrochloride, and has conducted Phase 2 studies. Libigel®, a testosterone gel being developed by ANI, completed two Phase 3 efficacy trials for treatment of FSD in surgically post-menopausal women but ANI reported that it did not show a statistically significant difference from placebo in those trials. Intrinsa, a transdermal testosterone patch, successfully completed a Phase 3 clinical program, but was not approved in the U.S. based on potential long-term use safety risks of cancer and cardiovascular adverse events. There may be other companies developing new drugs for FSD indications, some of which may be in clinical trials in the U.S. or elsewhere. In addition, other companies may sell their products off-label for indications other than HSDD.

Sales, Marketing and Distribution

Makena

We currently have sales representatives dedicated exclusively to *Makena* and the CBR Services, who are focused on calling on approximately 16,000 obstetricians and maternal fetal medicine specialists 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 42% 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. Maternity insurance benefits vary 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.

Our My Adherence Program, a telephonic 24/7 nursing services program to assist with increasing patient compliance, 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.

During 2016, we entered into an agreement with a leading provider of home nursing services (which had previously utilized compounded hydroxyprogesterone caproate) pursuant to which the provider performs at-home administration of *Makena* and, in connection with a recent amendment, also co-promotes *Makena* to certain healthcare providers.

CBR Services

In addition to calling on physicians, we directly market CBR Services to pregnant women and their families through various digital marketing channels, including social media, email and web properties, 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. The CBR consumer sales team educates expectant parents on their cord blood banking options and the benefits of preserving their newborn's stem cells. This team of inside sales representatives uses both telephone and online chat to interact with consumers and is central to CBR's direct-to-consumer approach that is coordinated with our digital marketing lead generation and qualification expertise and with detailing efforts by our women's health field force. Additionally, we nurture and develop customer referrals from an existing base of over 385,000 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 7,500 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 150,000 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 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 this segment of patients is under-diagnosed and under-treated and there is a significant opportunity in this market to provide IV iron to non-dialysis CKD patients. Our sales team has been working to educate HCPs who manage 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 commercial team uses a variety of common pharmaceutical marketing strategies and methods to promote *MuGard,* including sales calls to providing entities, such as hematology and oncology centers and hospitals. In addition, other tactical programs may include personal and non-personal promotional materials to individual physicians 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 program. In order to make *MuGard* available to patients as soon as possible, we provide 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 2016, 2015, and 2014. Revenues from Takeda Pharmaceutical Company Limited ("Takeda"), our former partner for the commercialization of *Feraheme* outside of the U.S., included payments under the license, development and commercialization agreement with Takeda and in connection with its subsequent 2015 termination.

	Years Ended December 31,		
	2016	2015	2014
AmerisourceBergen Drug Corporation	22%	25%	34%
McKesson Corporation	11%	11%	21%
Takeda Pharmaceuticals Company Limited	—%	12%	11%
Cardinal Health, Inc.	<10%	<10%	15%

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.

Pharmaceutical Product Approval Process

Clinical Development

Before we may market a new drug product, we must obtain FDA approval of an 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 pre-clinical and clinical studies.

Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as *in vitro* and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including good laboratory practice regulations. Clinical testing typically proceeds in three phases, which may overlap or be combined. Phase 1 trials seek to collect initial data about safety, tolerability, and optimal dosing of the drug candidate in healthy human subjects or, less commonly, in patients with the target disease or condition. The goal of Phase 2 trials is to provide preliminary evidence about the desired therapeutic efficacy of the product candidate in limited studies with small numbers of carefully selected subjects with the target disease or condition. 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 and are used as the primary basis for regulatory approval.

Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination at www.clinicaltrials.gov.

Submission and FDA Review of NDAs and 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 agreements reached during reauthorization of 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 submission or filing date, depending on the nature of the drug. For drug candidates intended to treat serious or life-threatening diseases and 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 based on a surrogate endpoint for a new drug that is intended to treat a serious or life-threatening disease or condition and that provides a meaningful therapeutic benefit over existing treatments.

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 the sponsor could withdraw its application or 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 six or ten months from the receipt date, depending on whether or not the sNDA has priority review. 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 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, unenforceable, or will not be infringed by the sale of the proposed product is called a Paragraph IV Certification. See the discussion above under *"Feraheme for the treatment of IDA in patients with CKD - Overview*" for a Paragraph IV certification notice letter regarding an ANDA submitted to the FDA by Sandoz.

Adverse Event Reporting

The FDA requires a sponsor to submit reports of certain information on side effects and adverse events 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 adverse events, 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. In addition, FDA could require post-market studies or impose distribution and use restrictions and other requirements via a REMS based upon new safety information obtained through adverse event reporting (discussed further below).

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, including safety labeling changes. 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 REMS, which may include distribution or use restrictions 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 Dear Health Care Provider 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 ("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 often perform a pre-approval inspection of the sponsor's manufacturing facility, including its equipment, facilities, laboratories and 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.

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 enacted to amend the FDC Act with respect to the regulation and monitoring of the manufacturing of compounded 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 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 government 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 a false or fraudulent claim or having possession, custody, or control of property or money used, or to be used, by the federal government and knowingly delivering or causing to be delivered, less than all of that money or property. 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

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 "Affordable Care Act") manufacturers of drugs and medical devices are required to publicly report gifts 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 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 clearance or 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 (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, which is 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 biologics of manufacturers that have entered into a Medicaid Drug Rebate Agreement, although such drugs and biologics may be subject to prior authorization or other utilization controls. CMS also administers the Medicaid program through regulatory and policy guidance to the states.

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 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 Affordable Care Act introduced changes to the definition of AMP and the Medicaid rebate formula and made changes to the 340B drug pricing program as well.

The Affordable Care 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 Affordable Care Act. For example, the percentage of *Feraheme* sold to 340B institutions has grown from 11% in 2011 to 20% in 2016. 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 Affordable Care Act exempts "orphan drugs," such as *Makena*, from the ceiling price requirements for the covered entity types newly added to the program by the Affordable Care Act.

The Affordable Care 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. In January 2017, HRSA issued a final rule regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities. We do not believe this rule will have a material impact on our business or results of operations. 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 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.

Reimbursement by private 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 limits on the number of prescriptions that will be paid over a set time period; 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 continue to attempt to curb healthcare costs through legislation, including legislation aimed at reducing the pricing and reimbursement of pharmaceutical products. The Affordable Care 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 Affordable Care 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 Affordable Care 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 Affordable Care 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 and 2016. On December 13, 2016, President Obama signed into law the 21st Century Cures Act which, among other things, expands the scope of health care economic information that manufacturers may use to promote drugs to payers, formulary committees and similar entities.

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 approximately half of *Makena* patients are Medicaid beneficiaries in 2016, 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, actual acquisition cost and value-based programs that may require cost effectiveness data and analyses, along with expanded packaging of products and services in alternative payment models. The existing data for reimbursement based on these metrics is relatively 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 and payment levels. 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.

We believe reimbursement for HSDD will be similar to approved products treating erectile dysfunction. If this is the case, we expect that commercial payors with a tiered formulary will place *Rekynda* into a Tier 3, which normally requires a higher co-pay or deductible than Tier 1 or 2 category drugs. As a result, patients would be unlikely to receive full reimbursement by third-party commercial payers and may not receive any reimbursement from governmental healthcare programs.

Additionally, a key focus of the recent presidential election was “repeal and replacement” of the Affordable Care Act. The extent, timing and details of the changes are not known, but the federally funded health care landscape could face significant changes during the current presidential administration, including in the near-term, and could impact state and local healthcare programs, including Medicaid and Medicare through reductions in payment levels for drugs.

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 $7.1 million and $3.7 million product sales backlog as of December 31, 2016 and 2015, respectively. We expect to recognize the $7.1 million in the first quarter of 2017, 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 13, 2017, we had 545 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 2016 and 2015, we expanded our leadership team and strengthened our commercial organization. We expect to continue these efforts in 2017 to support the growth of our business.

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. We did not have material revenues from customers outside of the U.S. in 2016. Revenues from customers outside of the U.S. amounted to approximately 12% of our total revenues for both 2015 and 2014 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, including both *Feraheme* and *Makena*. We incurred research and development expenses of $66.1 million, $42.9 million, and $24.2 million during 2016, 2015 and 2014, respectively. We expect our research and development expenses to increase in 2017 as compared to 2016 mostly due to additional expenses associated with research and development related to our commercial products, up to $25.0 million in clinical development and regulatory costs associated with our obligations under the Rekynda License Agreement and related anticipated increase in expenses in our regulatory and clinical functions, and a $60.0 million upfront payment made to Palatin in February 2017.

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.

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 continue to 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.

Further, prior to our 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. Similarly, we have minimal experience with development-stage, investigational products such as Rekynda™ (bremelanotide), and the successful development and commercialization of *Reykynda* is dependent upon our ability to oversee the successful and timely completion of clinical development programs and to obtain regulatory approval for *Rekynda* in North America, as well as our ability to raise awareness and understanding of hypoactive sexual desire disorder ("HSDD"), a type of female sexual dysfunction ("FSD"), and the potential benefits of *Rekynda* in treating HSDD.

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. We also expect to face competition for *Rekynda*, including from an FDA-approved product for treatment of HSDD, flibanserin, which is sold under the trade name Addyi®, and started marketing in October 2015. 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, capable of providing 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*"; "*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*"; "*Competing products and technologies, minimal third party reimbursement opportunities and an uncertain market may limit Rekynda revenues even if Rekynda is approved by the FDA for commercialization*" and "*Intrarosa will face substantial competition and is expected to have minimal third party reimbursement opportunities which may limit its market potential*."

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 issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned or licensed patents may be challenged in the courts or patent offices in the U.S. or abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technologies and products, or limit the duration of the patent protection of our technology and products. As a result, our owned and licensed patent portfolio may not provide us with

sufficient rights to exclude others from developing and commercializing products similar or identical to ours. As a result, the patents issued or licensed to us may provide us with little or no competitive advantage.

In addition, claims of infringement or violation of the proprietary rights of others may be asserted against us or intellectual property rights might be subject to liens or other encumbrances. 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 put one or more of our patents at risk of being invalidated or interpreted narrowly, 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).

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 (the "USPTO"). 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 therefore 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. In March 2016, we initiated a patent infringement suit alleging that Sandoz' ANDA filing itself constituted an act of infringement and that if it is approved, the manufacture, use, offer for sale, sale or importation of Sandoz' ferumoxytol products would infringe our patents. By the filing of the complaint, the FDA is prohibited from granting approval of Sandoz' application until the earliest of 30 months from the date of receipt of the notice of certification by the patent owner, the conclusion of litigation in the generic's favor, or expiration of the patent(s). 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.

There are no issued 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 Maken*a."

On January 8, 2017, we entered into a license agreement (the "Palatin License Agreement") with Palatin Technologies ("Palatin") under which we acquired the North American rights to develop and market *Rekynda*. Under the Palatin License Agreement, we have rights to a number of issued and pending U.S. and foreign patents related to bremelanotide that are owned by Palatin. Certain of Palatin's U.S. patents include claims directed to the bremelanotide drug composition and methods of use thereof with terms expiring in 2020, and another patent includes claims covering methods of treating FSD using subcutaneous administration of compositions that include bremelanotide, with a term expiring in 2033, any one of which may be subject to patent term extension pursuant to the Hatch-Waxman Act. In addition, on February 13, 2017, we entered into a license agreement (the "Endoceutics License Agreement") with Endoceutics, Inc. ("Endoceutics") under which we will acquire the U.S. rights to develop and market *Intrarosa*. Under the terms of the Endoceutics License Agreement, at closing we will receive the rights to Endoceutics' three U.S. patents related to *Intrarosa*, including drug-product patent claims with a term which expires in 2031 and two additional patents, including method of use claims and pharmaceutical dosage form claims with terms which expire in 2028. Although none of the issued patents under the Rekynda License Agreement and the Endoceutics License Agreement are currently subject to a patent reexamination or review or infringement proceeding, we cannot guarantee that they will not be subject to reexamination or review by the USPTO or an infringement suit in the future. If any present or future patents relied on for the development or commercialization of *Rekynda* or *Intrarosa* are narrowed, invalidated or held unenforceable, this could have an adverse effect on our business and financial results. In addition, we believe that each of the patents licensed under the Rekynda License Agreement and the Endoceutics License Agreement was rightfully issued and the respective portfolios give us sufficient freedom to operate; however, if a third-party claims that the development, manufacture or commercialization of *Rekynda* or *Intrarosa* infringes its patents, our business and financial results could be harmed.

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 with the Rekynda License Agreement and Endoceutics License Agreement. There are limited opportunities available that align with our business strategy 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.

Further, the valuation methods that we use for any acquired or licensed product or business require significant judgment and assumptions. Actual results and performance of the products or businesses that we may acquire, including anticipated synergies, economies of scale and other financial benefits, could differ significantly from our original assumptions, especially during the periods immediately following the closing of the transaction. For example, if the timing of FDA approval of *Rekynda*, the market for *Rekynda* or the cost of goods is different from what we predicted in our model, the anticipated financial benefits of *Rekynda* could vary from the financial model. 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, complex, time-consuming and expensive 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 or license 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. Similarly, with the Rekynda License, we are adding a development stage product to our portfolio and will therefore

need to enhance our research and development expertise for product candidates. Our expanded portfolio may necessitate an expanded commercial team, which will take a considerable amount of time and effort to hire and train. Our future success will significantly depend upon our ability to manage our expanded enterprise, including multiple locations and various-staged products, 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, under the Rekynda License, we will rely on Palatin, and we may have to rely on the other parties with whom we may enter into future agreements, to perform or oversee certain functions, such as pharmacovigilance, research and development, regulatory 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 product. Furthermore, we are dependent upon the contributions of Palatin for the development and regulatory activities necessary to submit an NDA for *Rekynda* for the treatment of HSDD and Palatin has limited experience and relies on third parties for conducting a substantial portion of such development and regulatory activities.

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. For example, different skills and training are required for the promotion of various therapeutic products, especially as compared to a service business, such as CBR. Our revenues and profitability could suffer if we do not successfully expand our sales and commercial expertise into new areas, such as HSDD with respect to *Rekynda*, or if our integrated sales force focusing on both the CBR Services and *Makena* is unable to successfully promote a portfolio of products and services, especially since they may have limited experience with promoting both therapeutics and a service business. 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, delays or unexpected costs, 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 or product candidates we may acquire or in-license. We rely solely on third-party contract manufacturers and our licensors (who, in turn, may also rely 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 or our licensors may not be able to enter into agreements with manufacturers or 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, *Rekynda* is a synthetic peptide and while the production process involves well-established technology, there are few manufacturers capable of scaling up to commercial quantities under cGMP at acceptable costs. Further, we do not have commercial supply agreements to manufacture the drug substance and auto-injector sub-assemblies for *Rekynda* and may not be able to enter into such agreements on acceptable terms, including the cost of goods.

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 manufacturers' and licensors' manufacturing facilities. Any difficulties, disruptions or delays in the manufacturing process could result in product defects or shipment delays, suspension of manufacturing of, sale of or clinical development for the product, recall or withdrawal of product previously shipped for commercial or clinical purposes, inventory write-offs or the inability to meet commercial or clinical demand in a timely and cost-effective manner. Furthermore, our current third-party product manufacturers and licensors do not manufacture for us exclusively and may exhaust some or all of their resources meeting the demand of other parties. In addition, securing additional third-party contract manufacturers will require significant time for validating 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, our licensors and our respective third-party product manufacturers currently purchase certain raw and other materials used to manufacture our products from third-party suppliers. At present, we 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 our products or otherwise fail to supply these materials to us, our licensors or our respective third-party manufacturers, or fail to supply sufficient quantities of these materials to us, our licensors or our respective 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;
- 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 or a licensor's 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, our licensors or our respective 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, our licensors or our respective third-party manufacturers may not be able to obtain such materials of the quality required to manufacture our products 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 our products 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 projected revenues or suffer regulatory setbacks, any of which could have an adverse impact on our profitability and future business prospects.

We must work effectively and collaboratively with our licensors to develop, market and/or sell certain products in our portfolio.

We have limited experience commercializing licensed products, and the addition of *Rekynda* to our product portfolio means that our future revenues are more dependent upon our ability to work effectively and collaboratively with our licensors to develop, market and/or sell the licensed products in our portfolio, including to obtain or maintain regulatory approval. Our arrangements with licensors will be critical to successfully bringing our licensed products to market and successfully commercializing them. We rely on our licensors in various respects, including to undertake research and development programs and conduct clinical trials for our licensed products, manage or assist with the regulatory filings and approval process and maintenance and/or to assist with our commercialization efforts. We do not control our licensors, some of whom may be inexperienced, have a limited operating history, face financial and business hardships (including solvency issues), have limited operations or financial or other resources or have limited or no experience with commercialization activities; therefore, we cannot ensure that these third parties will adequately and timely perform all of their obligations to us. For example, under the Palatin License Agreement, Palatin is responsible for all remaining development and manufacturing work to support the NDA submission for *Rekynda*. If they fail to complete the remaining studies successfully, or at all, it could delay, adversely affect or prevent the FDA approval of *Rekynda*. We cannot guarantee the satisfactory performance of any of our licensors and if any of

our licensors breach or terminate their agreements with us, we may not be able to successfully commercialize the licensed product which could materially and adversely affect our business, financial condition, cash flows and results of operations.

Further, even if contractual safeguards are in place in our licensing arrangements, our licensors may use their own or other technology to develop an alternative product and withdraw their support of the licensed product, or to compete with the licensed product. Our licensing arrangements could also limit our activities, including our ability to compete with our licensors in certain geographic or therapeutic areas. Disputes may arise between us and a licensor and may involve the ownership of technology developed under a license or other issues arising out of collaborative agreements. Such disputes could delay the related program or result in expensive arbitration or litigation, which may not be resolved in our favor.

If we fail to comply with our obligations under our license agreements, we could lose rights to the licensed products.

Our license agreements impose various milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations, Palatin, Endoceutics, if closed, or Abeona Therapeutics, Inc. may have the right to terminate the license agreement, in which event we would not be able to continue developing or commercializing the licensed products. Termination of the license agreement or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms, and, if we lose rights to the licensed products it could materially and adversely affect our business.

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 licensors, 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, we, and in the case of *Rekynda*, Palatin, have contracted with, and plan to continue to contract with, certain CROs to provide clinical trial services for the Phase 3 clinical trial evaluating *Feraheme* in adults with IDA, the definitive PK study for the *Makena* auto-injector and the remaining drug interaction and other ancillary studies to support the submission of an NDA for *Rekynda* for the treatment of HSDD, 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. In addition, 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.

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 or our licensors 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.

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 our licensors, 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 third-party provider, 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 and collaborating with partners to commercialize multiple licensed products, including managing and maintaining a supply chain and distribution network for multiple products and the CBR Services, and we are placing substantial reliance on licensors and other 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 "Affordable Care 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 and the new presidential administration could result in the implementation of significant federal spending cuts or regulatory changes, including cuts in Medicare and other health related spending in the near-term or changes to the Affordable Care Act. The magnitude of the impact of these laws and developments 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 approximately 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.

Additionally, a key focus of the recent presidential election was "repeal and replacement" of the Affordable Care Act. The extent, timing and details of the changes are not known, but the federally funded health care landscape could face significant changes during the current presidential administration, including in the near-term, and could impact state and local healthcare programs, including Medicaid and Medicare, which could also have a negative impact on our future operating results. For more information on specific reimbursement risks related to *Rekynda* and *Intrarosa*, please see Risk Factors "*Competing products and technologies, minimal third party reimbursement opportunities and an uncertain market may limit Rekynda revenues even if Rekynda is approved by the FDA for commercialization*" and "*Intrarosa will face substantial competition and is expected to have minimal third party reimbursement opportunities which may limit its market potential.*"

Risks Related to *Makena*

We may not be successful in developing, gaining regulatory approval for and commercializing any products from Makena's next-generation development program, 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 program to deliver new and improved versions of *Makena*. The next-generation development program 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.

In October 2016 we initiated a definitive pharmacokinetic ("PK") study to demonstrate bioequivalence of a subcutaneous auto-injector product for *Makena* (the "*Makena* auto-injector") to the current intramuscular injection form of *Makena*. In accordance with FDA guidance, we utilize the term 'bioequivalence' in the context of a supplemental new drug application ("sNDA") to mean "relative bioavailability," and not the strict bioequivalence that is typically required for generic ANDA submissions. We expect to submit an sNDA for the *Makena* auto-injector in the second quarter of 2017. We can make no assurances that the FDA will determine that the study demonstrated adequate comparability on any or all PK parameters to

permit approval without clinical data. For example, *Makena* administered subcutaneously demonstrated bioequivalence to the IM injection on area under the curve ("AUC") with the 90% confidence interval for the ratio of AUC (105.17 to 124.39) falling within the 80% to 125% range, which the FDA uses to define bioequivalence. However, the mean maximum or peak plasma concentration ("Cmax") for *Makena* administered subcutaneously was higher than for the IM with the 90% confidence interval for the ratio of Cmax (96.6% to 138.7%) falling outside of the bioequivalence range of 80% to 125%. We can make no assurances that the FDA will accept our rationale that these potential differences have no clinical impact on safety or efficacy, and the FDA may request that we conduct one or more additional clinical studies in order to gain approval.

No serious adverse events were reported in the PK study and the drug was generally well tolerated, although there was a higher reporting rate of injection site related adverse events (e.g. transient burning/stinging sensation), in the subcutaneous injection arm of the study. In October 2016, we also initiated a comparative pain study intended to capture certain measures to support clinical superiority of the subcutaneous *Makena* auto-injector over the existing intramuscular injection to support an intended submission for new orphan drug exclusivity as part of our sNDA for the *Makena* auto-injector. Similar observations reported in the PK study were also reported in the subcutaneous arm of the pain study, and we therefore elected to discontinue the pain study. Based on the adverse event information, the FDA may request additional studies or not approve the sNDA for the *Makena* auto-injector.

We will not be seeking orphan exclusivity as part of the sNDA filing for the *Makena* auto-injector. Based on our current timelines and assumptions, we anticipate submitting an sNDA for the *Makena* auto-injector in the second quarter of 2017 and expect the review period to be six months. If we experience any delays in this expected timeline, our ability to receive approval for the *Makena* auto-injector before the expiration of *Makena's* orphan drug exclusivity period in February 2018 may be delayed, which could permit generics to enter the market prior to commercialization of the *Makena* auto-injector and could have an adverse impact on our *Makena* sales.

Further, we are currently in discussions with third-party manufacturers to secure commercial supply of certain components. 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.

Even if we succeed in gaining FDA approval of the *Makena* auto-injector, 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 version of *Makena*. As a result of the lower cost for the generics and/or a lack of perceived benefit of the *Makena* auto-injector, such as lack of improvement in safety or efficacy, or perceptions about the pain associated with the *Makena* auto-injector, 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 hydroxyprogesterone caproate product 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.

We have limited experience in the development of an auto-injector for *Makena* and in developing and implementing next-generation development programs. If we are not successful in implementing *Makena*'s next-generation development programs, if the subcutaneous *Makena* auto-injector is not approved before the expiration of *Makena*'s orphan drug exclusivity in February 2018 or at all, our business may suffer.

Our ability to continue 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 and our ability to differentiate *Makena* from other treatment options even after competitors enter the market once our orphan drug exclusivity expires. 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 before February 2018 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). In June 2016, ANI Pharmaceuticals, Inc. ("ANI"), Aspen's exclusive distributor, launched HPC in 5 mL vials in the U.S. 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, the generic Delalutin product is priced at a discount to *Makena*, and as a result, 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;
- 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.

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") at lower prices 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 lower priced and less regulated competition. 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.

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, value, adoption and utility among the medical community for its currently approved uses and a broader set of applications than 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 lowers the perceived value of cord blood stem cell and cord tissue collection, 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. In addition, professional medical organizations periodically recommend certain practices that may negatively impact our business. For example, in January 2017,

the American College of Obstetrics and Gynecology ("ACOG") issued a new opinion on delayed cord clamping ("DCC"), a practice which has been shown to be beneficial to preterm babies but that may also reduce the volume of cord blood available for cord blood preservation. In its opinion, ACOG noted that healthcare providers should counsel their patients that the benefits of DCC may outweigh cord blood banking. As DCC can significantly decrease the volume of cord blood stems cells collected, families may choose not to bank their newborn's cord blood stem cells. 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, such as from generational behavior and attitudes, 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.

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 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.

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 and, in an effort to strengthen the warnings and precautions section of the label and mitigate the risk of serious hypersensitivity reactions, including anaphylaxis, 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 any 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 and could have an adverse impact on potential sales of *Feraheme* and our future business prospects.

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, in 2016 we commenced and completed enrollment in 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. Approximately 2,000 patients were 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 expect to file an sNDA for this broader indication in mid-2017. 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. The FDA has substantial discretion in the approval process and may decide that the results of this trial 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.

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 with claims directed to *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 acknowledgment letter stating that its ANDA is sufficiently complete to permit a substantive review.

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 therefore 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 manufacture, use, sale or offer for sale of the generic version. In March 2016, we initiated a patent infringement suit alleging that Sandoz' ANDA filing itself constituted an act of infringement and that if it is approved, the manufacture, use, offer for sale, sale or importation of Sandoz' ferumoxytol products would infringe our patents. 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.

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, 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.

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.

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 2016 three customers accounted for greater than 95% 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 20% of our *Feraheme* end-user demand during the year ended December 31, 2016 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.

Risks Related to *Rekynda*

Rekynda is not approved for sale by the FDA and we cannot guarantee that Rekynda will receive regulatory approval on a timely basis, or at all, or that such approval, if obtained, will not contain restrictions that the FDA may impose on the use or distribution of Rekynda.

In January 2017, we entered into the Palatin License Agreement under which we acquired an exclusive license from Palatin to research, develop and commercialize *Rekynda* in North America. Palatin recently completed two Phase 3 clinical trials to treat HSDD in pre-menopausal women. The trials consisted of double-blind placebo-controlled, randomized parallel group studies comparing a subcutaneous dose of 1.75 mg *Rekynda* versus placebo, in each case, delivered via an auto-injector. In both clinical trials, *Rekynda* met the pre-specified co-primary efficacy endpoints of median improvement in desire and decrease in distress associated with low sexual desire as measured using validated patient-reported outcome instruments; however, the change in the number of satisfying sexual events, a key secondary endpoint, was not significantly different from placebo in either clinical trial. The most frequent adverse events were nausea, flushing and headache, which were generally mild-to-moderate in severity. Approximately 18% of patients discontinued participation in the *Rekynda* arm due to adverse events in both studies. Palatin is conducting Phase 1 drug interaction and safety pharmacology studies, including an abuse-liability study and drug-drug interaction studies with anti-hypertensive and anti-arrhythmic therapies, as well as certain chemistry, manufacturing and controls activities, including drug product process validation studies to support the filing of an NDA for *Rekynda* for the treatment of HSDD. We currently expect to submit the *Rekynda* NDA in early 2018, subject to the successful and timely completion of the ongoing studies.

Despite the successful completion of the Phase 3 clinical trials, the approval of *Rekynda* for commercial sale in the U.S. could be delayed or denied for a number of reasons, including:

- The FDA may determine that *Rekynda* does not demonstrate safety and efficacy in accordance with regulatory agency standards based on the results of the Phase 3 trial, including the co-primary and secondary endpoints and safety results;
- The FDA may determine that the magnitude of efficacy demonstrated in the *Rekynda* studies does not amount to a clinically meaningful benefit to pre-menopausal women with HSDD and thus that the product cannot be approved despite statically significant efficacy results;
- The FDA could analyze and/or interpret data from pre-clinical testing and clinical trials in different ways than we or Palatin interpret it, such as the calculation of effect size in our Phase 3 studies or the sufficiency of data to determine the timing of onset and the dosing of the product;
- The initiation, conduct or results of the remaining drug interaction, safety pharmacology and other ancillary studies may be delayed or unsuccessful;

- The auto-injector device, supplied by an unaffiliated third party, that we plan to use to administer *Rekynda* may not be adequate or may not be approved by the FDA;
- Palatin's ability to establish, and obtain FDA approval for, a commercially viable manufacturing process for *Rekynda*;
- Adverse medical events reported during the trials, including increases in blood pressure noted in prior clinical trials, could lead to requirements to conduct additional studies;
- The failure of clinical investigational sites and the records kept at such sites, including the clinical trial data, to be in compliance with the FDA's GCP, including the failure to pass FDA inspections of clinical trial sites; and
- The FDA may change their approval policies or adopt new regulations.

Any delay in obtaining regulatory approval for *Rekynda* could adversely affect our ability to successfully commercialize such product. In addition, share prices have declined significantly in certain instances where companies have failed to obtain FDA approval of a product or where the timing of FDA approval is delayed. If the remaining drug interaction, safety pharmacology or other ancillary studies or the FDA's response to any application for approval are delayed or not favorable for *Rekynda*, our share price could decline significantly. In such circumstances, Palatin's share price could also decline and Palatin may be unable to perform its obligations under the Rekynda License.

Even if regulatory approval to market *Rekynda* is granted by the FDA, the approval may impose limitations on the indicated use for which the drug product may be marketed and additional post-approval requirements with which we and Palatin would need to comply in order to maintain *Rekynda's* approval. For example, demonstration of clinically important drug-drug interactions in the ongoing studies, may reduce the population for which *Rekynda* may be approved. In addition, unexpected adverse findings in the safety pharmacology studies may cause FDA to impose restrictions on the distribution of *Rekynda*, which may limit its commercial potential. Similarly, commercialization efforts for the drug product are still ongoing, and based on the results of those efforts, including stability studies, the FDA approval may require that the product be kept refrigerated in the supply chain prior to being dispensed to the patient, in order to lengthen the shelf life, which could affect the cost of goods, or the market acceptance of the product. Our business could be seriously harmed if we and/or Palatin do not complete any post-approval requirements and the FDA, as a result, requires us to change sections of the labeling.

Even if Rekynda receives regulatory approval, it may never achieve market acceptance, in which case our business, financial condition and results of operation will be materially adversely affected.

Regulatory approval for the marketing and sale of *Rekynda* does not assure the product's commercial success. If approved, *Rekynda* will compete with other products that may be manufactured and marketed by major pharmaceutical and other biotechnology companies. If *Rekynda* does not achieve adequate market acceptance, our business, financial condition and results of operations will be materially adversely affected. The degree of market acceptance and commercial success of *Rekynda* will depend on a number of factors, including:

- Perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of *Rekynda*;
- The initiation, conduct or results of safety pharmacology studies and whether the FDA imposes any restrictions on the distribution of *Rekynda*:
- Our ability to increase awareness of HSDD and treatment options, and to engage with and educate health care providers and potential consumers about HSDD and the benefits of *Rekynda*;
- Cost-effectiveness relative to competing products and technologies;
- Availability of reimbursement from third-party payers;
- Advantages over alternative treatment therapies, including the tolerability of any side effects and self-administration by auto-injector;
- Our ability to maintain a commercially viable manufacturing process that is compliant with cGMP;

- Palatin and our ability to enforce Palatin's intellectual property rights in and to *Rekynda* to prohibit a third-party from marketing a generic product and our ability to avoid third-party patent interference or intellectual property infringement claims;

- Our ability to hire and maintain an expanded sales force and experienced commercialization personnel to compete in the market; and

- An increase in the occurrence or severity of the most common adverse events (nausea, headaches and flushing) or the occurrence of additional adverse events causing patients to discontinue treatment.

Competing products and technologies, minimal third party reimbursement opportunities and an uncertain market may limit Rekynda revenues even if Rekynda is approved by the FDA for commercialization.

Flibanserin, a daily-use oral drug sold by Valeant Pharmaceuticals, Inc. under the trade name Addyi®, has been approved by the FDA to treat HSDD in pre-menopausal women and began being marketed in October 2015. We are aware of several other drugs for the treatment of HSDD and FSD in both pre-menopausal and post-menopausal patients under development, including certain drugs being developed by S1 BioPharma, Inc, Emotional Brain BV and ANI Pharmaceuticals, Inc., some of which incorporate testosterone, antidepressants or PDE-5 inhibitors. If our competitors obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, our competitors may establish a market position and could have competitive advantages over *Rekynda* and have a material adverse effect on our business, financial condition and results of operations.

The actual market size and market dynamics for HSDD, particularly in pre-menopausal women, are unknown. While we believe that *Rekynda*, as an on-demand drug to treat HSDD, will have competitive advantages compared to chronic or daily use hormones and other drugs, we may not be able to realize this perceived advantage in the market, in part because *Rekynda* is administered by subcutaneous auto-injection. While the single-use, disposable auto-injector format is designed to maximize market acceptability, apprehension associated with an injectable drug may impact *Rekynda's* ability to achieve significant market acceptance, especially if an oral therapy is available as an alternative.

There is also significant uncertainty concerning the extent and scope of third-party reimbursement for products treating HSDD. Payers frequently employ a tiered system in reimbursing end-users for pharmaceutical products, with tier designation affecting copay or deductible amounts. Because Addyi® is the only FDA-approved therapy to treat HSDD, there is little precedent on which to base expectations as to third-party reimbursement opportunities. We believe reimbursement for HSDD will be similar to approved products treating erectile dysfunction. If this is the case, we expect that commercial payors with a tiered formulary will place *Rekynda* into a Tier 3 drug, which normally requires a higher co-pay or deductible than Tier 1 or 2 category drugs. As a result, patients would be unlikely to receive full reimbursement by third-party commercial payers and may not receive any reimbursement from governmental healthcare programs. Therefore, patients may be subject to substantial copays or deductible requirements. Less than full reimbursement by governmental and other third-party payers may adversely affect the market acceptance of *Rekynda*. If *Rekynda* does not achieve adequate market acceptance, if approved, at an acceptable price point, our business, financial condition and results of operations may be materially adversely affected.

Further, the market for HSDD may be particularly vulnerable to unfavorable economic conditions. Because we expect *Rekynda* to have significant copay or deductible requirements and to be only partially reimbursed by third-party payers, demand for *Rekynda* may be tied to discretionary spending levels of the targeted patient population. Thus, any downturn in the economy could result in weakened demand for *Rekynda*.

Risks Related to the Pending Intrarosa License

We have undertaken efforts to expand our product portfolio with our pending license arrangement with Endoceutics. If we are unable to successfully commercialize Intrarosa pursuant to the pending Endoceutics License Agreement, if consummated, our business and results of operations will suffer.

On February 13, 2017, we entered into a license agreement (the "Endoceutics License Agreement") with Endoceutics, Inc. ("Endoceutics") pursuant to which Endoceutics has agreed to grant to us rights to Intrarosa™ (prasterone), an FDA-approved product for the treatment of moderate-to-severe dyspareunia (pain during sexual intercourse). Upon closing of the Endoceutics License Agreement, our women's health portfolio will be significantly larger and more complex than it is today. We have limited experience with licensed products and with commercializing a drug in the field of vulvar and vaginal atrophy ("VVA"), and were not granted any rights to physical assets and did not hire any employees from Endoceutics as part of the transaction. If the Endoceutics License Agreement closes, our future success will significantly depend upon our ability to expand our

commercial team, including hiring and training a new sales team to market *Intrarosa*, and to leverage our relationships in the obstetrics and gynecology community. These activities will require our management team to spend considerable time and effort in hiring and monitoring new sales force members, and there can be no guarantee that we will be able to identify and hire a sufficient number of qualified individuals to successfully commercialize *Intrarosa*. Our management team could face further challenges in effectively and collaboratively working with Endoceutics in accordance with the terms of the Endoceutics License Agreement. In order to support our growing portfolio, we will need to achieve revenues from sales of and other financial goals for *Intrarosa* consistent with our business expectations, which may prove more difficult than currently expected. Any failure to achieve expectations could affect our profitability.

Further, we will be dependent upon the contributions of Endoceutics following the closing of the transaction, including exclusively providing us with all commercial supply and conducting certain clinical and commercialization activities. Endoceutics is a small company organized outside of the U.S. with limited operations and resources with a history in vulvar and vaginal atrophy. Endoceutics has limited experience manufacturing a product at commercial scale, which imposes significant and complex regulatory and compliance obligations, and Endoceutics may face challenges and difficulties in satisfying such obligations. Furthermore, given that Endoceutics' assets, including the intellectual property licensed to us, are subject to a security interest held by a third-party lender, our rights and remedies under the license agreement may be impaired or inadequate. Accordingly, if Endoceutics fails to perform its obligations in an acceptable manner, or at all, or otherwise breaches the Endoceutics License Agreement or its loan documents, commercialization of *Intrarosa* could suffer and/or our business, financial condition and results of operations may be materially adversely affected.

The Endoceutics License Agreement has not been consummated and we can make no guarantee that the transaction will close on the anticipated timeline, or at all.

The consummation of the Endoceutics License Agreement is subject to a number of closing conditions, including some that are out of our control, including the expiration of the applicable waiting period under the Hart-Scott-Rodino Act, and we can make no assurances that the transaction will close in a timely manner or at all. In the event that the Endoceutics License Agreement is not consummated, we will have spent considerable time and resources and incurred substantial costs, such as legal, accounting and advisory fees, which must be paid even if the transaction is not consummated. If the license is not consummated, our reputation in our industry and in the investment community could be damaged and, as a result, the market price of our common stock could decline.

Even if the Endoceutics License Agreement is consummated, we may be unsuccessful in driving awareness of dyspareunia and the potential benefits of Intrarosa.

The market for VVA therapies is uncertain, and the number of women suffering from the condition is unclear, in part because of a reluctance to discuss vaginal or sexual symptoms with healthcare providers. Despite significant marketing and educational efforts by industry participants intended to spread awareness of the condition and its treatment, studies suggest that women often do not recognize VVA and are often not aware of treatment options. Although we plan to undertake informational and educational programs to help spread awareness of VVA and the benefits of *Intrarosa* for the conditions indicated, such undertakings may not be successful, will be costly and could disrupt management's and other personnel's efforts in other, more profitable, endeavors. *Intrarosa* is indicated to treat only a portion of this unknown VVA market (those women suffering from moderate-to-severe dyspareunia), and although moderate-to-severe dyspareunia is believed to be a common symptom of VVA, this subset of the VVA market is subject to the same and likely heightened uncertainties and obstacles as the overall VVA market. If we have over-estimated the market opportunity for *Intrarosa*, or if we are unable to successfully spread awareness and educate the community about VVA generally, and moderate-to-severe dyspareunia in particular, then our business and results of operations could be materially and adversely affected.

Intrarosa will face substantial competition and is expected to have minimal third party reimbursement opportunities which may limit its market potential.

There are a number of large pharmaceutical companies that currently market and sell products or are pursuing the development of products for the treatment of VVA and dyspareunia. For example, Premarin Vaginal Cream® and Estrace® Cream are vaginal creams marketed by Pfizer, Inc. and Allergan Inc., respectively, for the treatment of VVA. Vagifem® is a suppository marketed by Novo Nordisk A/S for the treatment of VVA and Yuvafem, a generic of Vagifem, is marketed by Amneal Pharmaceuticals LLC. In addition, Osphena® is an oral therapy marketed by Shionogi & Co. Ltd. for the treatment of dyspareunia and Estring is a vaginal ring marketed by Pfizer for the treatment of dyspareunia. TherapeuticsMD, Inc. is also developing Yuvvexy™, a vaginal soft gel for the treatment of dyspareunia and has a PDUFA date in May 2017. Many of the companies against which we will compete have significantly greater financial resources and expertise in marketing products

than we do. In addition, there are numerous over the counter remedies that are marketed for dyspareunia, and over the counter products that contain prasterone.

The actual market size and market dynamics for dyspareunia is uncertain. While we believe that *Intrarosa*, as a FDA approved, non-estrogen containing drug to treat moderate-to-severe dyspareunia, will have competitive advantages compared to estrogen-containing therapies, we may not be able to realize this perceived advantage in the market. Our commercial opportunity could be reduced or eliminated if physicians or patients perceive that other products are more effective, convenient or safe than *Intrarosa*, or if they are less expensive than *Intrarosa*.

In addition, our ability to compete may be affected by the extent and scope of third-party reimbursement for products treating dyspareunia. While some of the products that *Intrarosa* will compete with receive reimbursement from governmental healthcare programs, we expect that *Intrarosa* will be classified as a Tier 3 drug, and as a result patients are unlikely to receive full reimbursement by third-party commercial payers and may not receive any reimbursement from governmental healthcare programs. As a result, patients may be subject to substantial copays or deductible requirements. Less than full reimbursement by governmental and other third-party payers may adversely affect the market acceptance of *Intrarosa* and put it at a competitive disadvantage to some of the competing products, including generic versions, which are often priced lower than brand products. If *Intrarosa* does not achieve adequate market acceptance at an acceptable price point, our business, financial condition and results of operations may be materially adversely affected.

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 Affordable Care Act, as currently enacted or as it may be amended in the future, the 21st Century Cures Act, 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 biologics, 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.

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.

Our partners, including our licensors, are subject to similar requirements and thus the attendant risks and uncertainties. If our partners, including our licensors, suffer material and adverse effects from such risks and uncertainties, our rights and benefits for our licensed products could be negatively impacted, which could have a material and adverse impact on our revenues.

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 under the heading "*Government Regulation - Fraud and Abuse Regulation*." If we or our partners, such as licensors, 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 Affordable Care 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.

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 partners, our consultants or our contractors are or will be in compliance with all federal, state and foreign regulations. If we, our partners, 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, we are 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.*"

Our partners, including our licensors, are subject to similar requirements and obligations as well as the attendant risks and uncertainties. If our partners, including our licensors, suffer material and adverse effects from such risks and uncertainties, our

rights and benefits for our licensed products could be negatively impacted, which could have a material and adverse impact on our revenues.

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 Affordable Care 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.

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 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.

Our partners, including our licensors, are subject to similar requirements and thus the attendant risks and uncertainties. If our partners, including our licensors, suffer material and adverse effects from such risks and uncertainties, our rights and

benefits for our licensed products could be negatively impacted, which could have a material and adverse impact on our revenues.

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;
- 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.

Further, our partners, including our licensors, are subject to similar requirements and obligations as well as the attendant risks and uncertainties. If our partners, including our licensors, suffer material and adverse effects from such risks and uncertainties, our rights and benefits for our licensed products could be negatively impacted, which could have a material and adverse impact on our revenues.

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. Similarly, our licensors will be conducting certain clinical trials to gain approval in various indications for product candidates. The FDA could determine that our clinical trials, or those of our licensors, and/or our or their 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 and/or our licensors 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 clinical development programs for our proprietary or licensed products to ensure their compliance with cGCP regulations. If the FDA determines that we, our licensors, our respective CROs or our respective study sites fail to comply with applicable cGCP regulations, the FDA may deem the clinical data generated in such clinical trials to be unreliable and may disqualify certain data generated from those sites or require us and/or our licensors to perform additional clinical trials. 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 clinical development programs or post-approval clinical studies could cause us to incur significant additional costs, experience delays or prevent us from commercializing our approved products in their current indications, or obtaining marketing approval for additional indications or for product candidates, including the approval for the use of *Feraheme* for the broad IDA indication or *Rekynda* for the treatment of HSDD in pre-menopausal women.

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 and those of our licensors 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, failure to approve product candidates for commercialization, total or partial suspension of product production, the loss of inventory, suspension of the review of our or our licensors' 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 and our licensors 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 or our licensors 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 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 (*e.g.*, 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.

Risks Related to Our Business Generally

With our Lumara Health and CBR acquisitions, and with the Rekynda License, we have significantly expanded the size of our product portfolio and our overall 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 and with the Rekynda License Agreement we have considerably expanded our product portfolio by obtaining certain commercialization rights to *Rekynda*. Management, personnel, systems and facilities that we currently have in place may not be adequate to support this recent growth (especially given that the Rekynda License Agreement did not include the acquisition of or rights to any infrastructure or personnel of our licensors) 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 and diversified portfolio. To manage this and any future growth effectively, we will 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, develop our oversight and collaboration efforts for our licensed products, including development-staged products, 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 limited 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.

Further, as we continue to add acquired and licensed products to our portfolio, we may face legal, regulatory, and compliance scrutiny or increased expenses as a result of the target's or licensor's pre-acquisition or pre-license business practices, including if such targets or licensors 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 may be limited depending upon the remedies we are able to negotiate in the relevant transaction agreements. If any issues arise, we may not be entitled to sufficient, or any, indemnification or recourse from the licensor or the acquired company, which could have a materially adverse impact on our business and results of operations.

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, 2016, we had approximately $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 the further 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;
- 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, 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.

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 therefore 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;
- Consolidating or selling 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.

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.

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. For example, if equity or debt investors perceive that our debt levels are too high relative to our profit, our stock price could be negatively affected and/or our ability to raise new equity or debt capital could be limited.

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.

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. Similarly, as *Rekynda*, if approved is introduced to the market, more serious adverse reactions than those reported during clinical trials could arise. 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.

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 continue to expand our portfolio, including through the addition of commercial or development-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 and development-stage licensed product, 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;
- Milestone payments we may be required to pay pursuant to contractual obligations, including the Lumara Health Agreement and the Rekynda License 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*;
- Costs associated with our obligations under the Rekynda License Agreement;
- 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;
- 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.

Further, in January 2017, we issued financial guidance, including expected 2017 total revenues and *Makena*, CBR and *Feraheme* and *MuGard* net sales, which is likewise based on estimates and the judgment of management. If, for any reason, we are unable to realize our projected 2017 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. For example, we intend to update our 2017 guidance to account for additional expenses related to the recently announced licensing transaction with Endoceutics.

As part of our revenue recognition policy, our estimates of product returns, rebates and chargebacks, accounts receivable, 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 $17.92 and $36.83 in the fifty-two week period through February 13, 2017. 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.

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 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.

ITEM 2. PROPERTIES:

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.

We lease certain real property located at 1200 Bayhill Drive, San Bruno, California. The lease expires in September 2017.

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, 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.

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 13, 2017, the closing price of our common stock, as reported on the NASDAQ, was $22.70 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, 2016		
First quarter	$ 29.65	$ 20.22
Second quarter	$ 28.98	$ 17.92
Third quarter	$ 29.59	$ 22.01
Fourth quarter	$ 36.83	$ 22.81
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

Stockholders

On February 13, 2017, 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 11,000 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 three months ended December 31, 2016.

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 (2)	Maximum Number of Shares (or approximate dollar value) That May Yet Be Purchased Under the Plans or Programs (2)
October 1, 2016 through October 31, 2016	—	$ —	—	1,556,420
November 1, 2016 through November 30, 2016	4,026	30.89	—	1,204,819
December 1, 2016 through December 31, 2016	6,084	33.87	—	1,149,425
Total	10,110	$ 32.68	—	

(1) Represents 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.

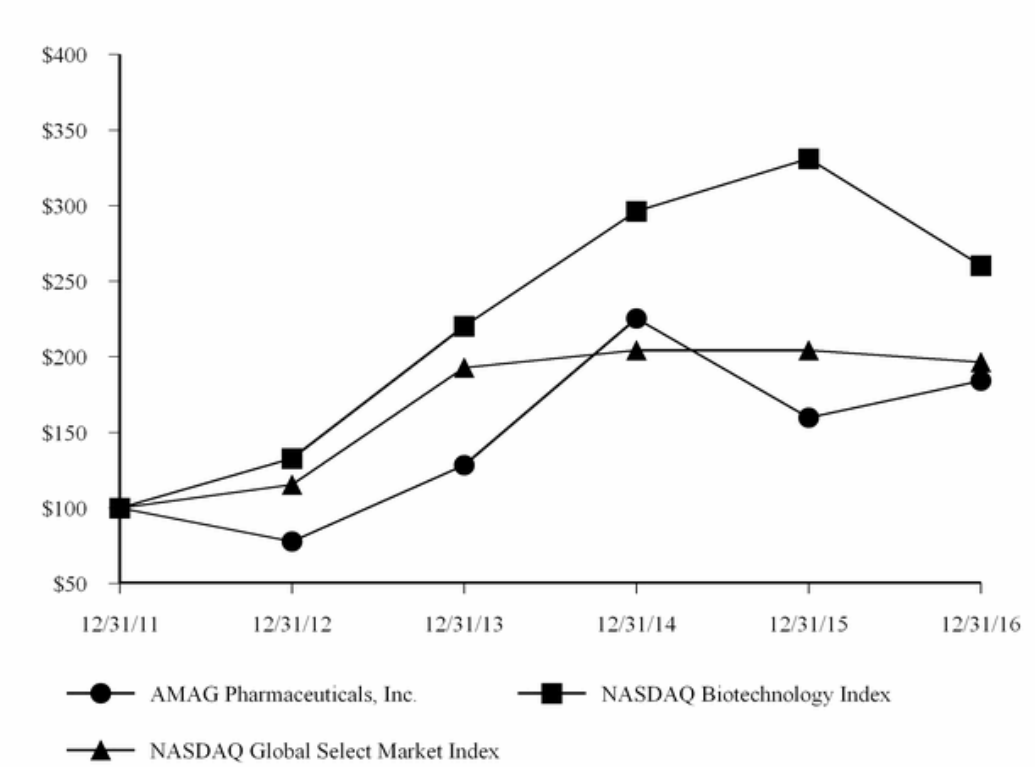
(2) We did not repurchase any of our common stock during the fourth quarter of 2016. We have repurchased and retired $20.0 million of our common stock under our share repurchase program to date. These shares were purchased pursuant to a repurchase program authorized by our board of directors that was announced in January 2016 to repurchase up to $60.0 million of our common stock, of which $40.0 million remains outstanding as of December 31, 2016. 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, 2016.

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 Biotechnology Index and the NASDAQ Global Select Market Index over the past five years. The comparisons assume $100 was invested on December 31, 2011 in our common stock, the NASDAQ Biotechnology Index and the NASDAQ Global Select Market Index, and assumes reinvestment of dividends, if any.



	12/31/2011	12/31/2012	12/31/2013	12/31/2014	12/31/2015	12/31/2016
AMAG Pharmaceuticals, Inc.	100.00	77.79	128.40	225.38	159.65	184.03
NASDAQ Biotechnology Index	100.00	132.74	220.37	296.19	331.05	260.37
NASDAQ Global Select Market Index	100.00	115.52	192.75	204.34	204.31	196.43

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 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, 2016, 2015, 2014, 2013 and 2012. 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,				
	2016	2015 (1)	2014 (2)	2013	2012
	(in thousands, except per share data)				
Statements of Operations Data					
Revenues:					
U.S. product sales, net	$ 432,170	$ 341,816	$ 109,998	$ 71,692	$ 58,903
Service revenues, net	99,604	24,132	—	—	—
License fee, collaboration and other revenues (3)	317	52,328	14,386	9,164	26,475
Total revenues	532,091	418,276	124,384	80,856	85,378
Costs and expenses:					
Cost of product sales (excluding impairment) (4)	96,314	78,509	20,306	11,960	14,220
Cost of services	20,575	9,992	—	—	—
Research and development expenses	66,084	42,878	24,160	20,564	33,296
Selling, general and administrative expenses (5)	249,870	160,309	72,254	59,167	53,071
Impairment of intangible assets (6)	19,663	—	—	—	—
Acquisition-related costs	—	11,232	9,478	782	—
Restructuring expenses	715	4,136	2,023	—	2,215
Total costs and expenses	453,221	307,056	128,221	92,473	102,802
Operating income (loss)	78,870	111,220	(3,837)	(11,617)	(17,424)
Other income (expense):					
Interest expense (7)	(73,153)	(53,251)	(14,697)	—	—
Loss on debt extinguishment (7)	—	(10,449)	—	—	—
Interest and dividend income, net	3,149	1,512	975	1,051	1,286
Other income (expense) (7)	189	(9,188)	217	964	(1,466)
Total other income (expense)	(69,815)	(71,376)	(13,505)	2,015	(180)
Net income (loss) before income taxes	9,055	39,844	(17,342)	(9,602)	(17,604)
Income tax expense (benefit) (8)	11,538	7,065	(153,159)	—	(854)
Net income (loss)	$ (2,483)	$ 32,779	$ 135,817	$ (9,602)	$ (16,750)
Net income (loss) per share:					
Basic	$ (0.07)	$ 1.04	$ 6.06	$ (0.44)	$ (0.78)
Diluted	$ (0.07)	$ 0.93	$ 5.45	$ (0.44)	$ (0.78)
Weighted average shares outstanding used to compute net income (loss) per share:					
Basic	34,346	31,471	22,416	21,703	21,392
Diluted	34,346	35,308	25,225	21,703	21,392

	December 31,				
	2016	2015	2014	2013	2012
Balance Sheet Data					
Cash, cash equivalents and investments	$ 579,086	$ 466,331	$ 144,186	$ 213,789	$ 227,043
Working capital (current assets less current liabilities)	$ 405,681	$ 360,753	$ 107,548	$ 211,284	$ 221,423
Total assets	$ 2,478,426	$ 2,476,210	$ 1,388,933	$ 265,459	$ 258,137
Long-term liabilities	$ 1,231,160	$ 1,298,025	$ 762,492	$ 59,930	$ 52,383
Stockholders' equity	$ 934,389	$ 932,264	$ 459,953	$ 172,408	$ 172,797

(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 the termination of a license, development and commercialization agreement (the "Takeda Termination Agreement") with Takeda Pharmaceutical Company Limited ("Takeda") 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 2016, 2015 and 2014 included approximately $77.8 million, $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, respectively. 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) Reflects a full year recognition of CBR Services selling, general and administrative expenses in 2016 compared to a partial period in 2015 following our August 2015 acquisition of CBR as well as an increase in the *Makena*-related contingent consideration based on the expected timing of the milestone payments.

(6) In 2016, we recognized a $15.7 million impairment charge related to the impairment of the remaining net intangible asset for the MuGard Rights, impairment of the remaining $0.2 million, net, CBR-favorable lease intangible asset and a $3.7 million impairment charge related to the CBR trade names and trademarks intangible asset.

(7) 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.

(8) 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.

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

Overview

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a biopharmaceutical company focused on developing and delivering important therapeutics, conducting clinical research in areas of unmet need and creating education and support programs for the patients and families we serve. Our currently marketed products support the health of patients in the areas of women's health, anemia management and cancer supportive care, including Makena® (hydroxyprogesterone caproate injection), Feraheme® (ferumoxytol) for Intravenous ("IV") use and MuGard® Mucoadhesive Oral Wound Rinse. Through services related to the preservation of umbilical cord blood stem cell and cord tissue units (the "CBR Services") operated through Cord Blood Registry® ("CBR"), we also help families to preserve newborn stem cells, which are used today in transplant medicine for certain cancers and blood, immune and metabolic disorders, and which we believe have the potential to play a valuable role in the ongoing development of regenerative medicine. In addition, on February 2, 2017, we closed a license agreement in which we received the rights to research, develop and commercialize Rekynda™ (bremelanotide), which is being developed for the treatment of hypoactive sexual desire disorder ("HSDD") in pre-menopausal women. On February 13, 2017, we signed a license agreement in which we will acquire the rights to market Intrarosa™ in the U.S. for the treatment of moderate-to-severe dyspareunia, a common symptom of vulvar and vaginal atrophy ("VVA"), due to menopause.

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 product sales of *Makena* and *Feraheme* and service revenue from the CBR Services.

AMAG's Portfolio of Products and Services

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. We acquired the rights to *Makena* in connection with our acquisition of Lumara Health Inc. ("Lumara Health") in November 2014. *Makena* was approved by the FDA in February 2011 and granted orphan drug exclusivity through February 3, 2018. 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 2016, sales of *Makena* accounted for approximately 63% of our total net revenues. Additional details regarding the Lumara Health acquisition can be found in Note C, "*Business Combinations,*" to our consolidated financial statements included in this Annual Report on Form 10-K.

CBR is the largest private newborn stem cell bank in the world and offers pregnant women and their families the ability to preserve their newborns' umbilical cord blood and cord tissue for potential future use. We acquired CBR from CBR Acquisition Holdings in August 2015. We market and sell the CBR Services directly to consumers, who pay for the services directly, 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. In 2016, revenues from CBR Services accounted for approximately 19% of our total net revenues. Additional details regarding the CBR acquisition 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 2016, sales of *Feraheme* accounted for approximately 18% of our total net revenues.

On January 8, 2017, we entered into a license agreement (the "Palatin License Agreement") with Palatin Technologies, Inc. ("Palatin") under which we acquired the North American rights to develop and commercialize *Rekynda*, an investigational product designed to be an on-demand treatment for pre-menopausal women with HSDD, which is the most common type of female sexual dysfunction ("FSD"). Following the satisfaction of the conditions to closing under the Palatin License Agreement, the transaction closed on February 2, 2017. Palatin recently completed two Phase 3 studies to treat HSDD in pre-menopausal women and an extension study is currently ongoing. Palatin is continuing to oversee the conduct of the extension study, which we expect to be completed in the second half of 2017. We currently expect to submit an NDA in early 2018

following completion of multiple Phase 1 drug interaction and safety pharmacology studies, including an abuse-liability study and drug-to-drug interaction studies with anti-hypertensive and anti-arrhythmic therapies, as well as certain chemistry, manufacturing and controls activities, including drug product process validation studies by Palatin. Additional details regarding the Palatin License Agreement can be found in Note W, "*Subsequent Events*," to our consolidated financial statements included in this Annual Report on Form 10-K.

In July 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 (the "DIF 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. Under the option agreement, Velo will complete a Phase 2b/3a clinical study, which we expect to begin in the first quarter of 2017. 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. Additional details regarding the Velo agreement can be found in Note Q, "*Collaboration, License and Other Strategic Agreements,*" to our consolidated financial statements included in this Annual Report on Form 10-K.

In June 2013, we entered into a license agreement with Abeona Therapeutics, Inc., under which we acquired the U.S. commercial rights to MuGard® Mucoadhesive Oral Wound Rinse 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 Q, *"Collaboration, License and Other Strategic Arrangements,"* to our consolidated financial statements included in this Annual Report on Form 10-K.

Makena Developments

We continue to advance our next generation development program for *Makena*, seeking to enhance the product profile for patients and their healthcare providers. As part of this program, in February 2016 the FDA approved a single-dose preservative-free formulation of *Makena* manufactured by the Pfizer CentreOne group of Pfizer, Inc., ("Pfizer") (formerly Hospira, Inc.), who also manufactures our multidose vial of *Makena*. We began promoting the single-dose preservative-free formulation of *Makena* to physicians in the second quarter of 2016. In July 2016, we received approval of our prior approval supplement for Piramal Pharma Solutions (formerly Coldstream Laboratories, Inc.) to also manufacture the single-dose preservative-free formulation of *Makena*.

We are developing an auto-injector device for subcutaneous administration of *Makena* (the "*Makena* auto-injector"), including chemistry, manufacturing and controls ("CMC") development with Antares. During 2016, we met with the FDA to discuss our proposed development and regulatory strategy, focusing on our plans to conduct a definitive PK study designed to demonstrate comparable bioavailability of the subcutaneous *Makena* auto-injector to the current intramuscular ("IM") injection form of *Makena.* We believe that demonstrating bioequivalence for area under the curve is the most relevant PK parameter for *Makena*. In October 2016, we initiated an open label parallel study which enrolled approximately 120 healthy post-menopausal women in a 1:1 randomization. In February 2017, we announced topline results from this definitive PK study. *Makena* administered subcutaneously demonstrated bioequivalence to the IM injection on area under the curve ("AUC") ($AUC_{0\text{-to-inf}}$ 2,386 ng/mL compared to 2,086 ng/mL) with the 90% confidence interval for the ratio of AUC (105.17 to 124.39) falling within the 80% to 125% range, which the FDA uses to define bioequivalence. The mean maximum or peak plasma concentration ("Cmax") for *Makena* administered subcutaneously was slightly higher than for the IM (7.3 ng/mL compared to 6.3 ng/mL) with the 90% confidence interval for the ratio of Cmax (96.6% to 138.7%) falling outside of the bioequivalence range of 80% to 125%. No serious adverse events were reported and the drug was generally well tolerated, although there was a higher reporting rate of injection site related adverse events (e.g. transient burning/stinging sensation), in the subcutaneous injection arm of the study. Similar observations were also reported in the subcutaneous arm of our open label, parallel comparative pain study (also initiated in October 2016), which we recently elected to discontinue. We will not be requesting orphan exclusivity as part of the sNDA filing and, therefore, anticipate a six-month FDA review timeline. There are multiple device and drug-device combination patents and patent applications in-licensed from Antares which relate to the subcutaneous *Makena* auto-injector and we intend to request Orange Book listing of eligible Antares drug-device patents. We expect to file an sNDA for approval of the *Makena* auto-injector in the second quarter of 2017.

Feraheme Developments

In pursuit of a broader indication for *Feraheme* to include the treatment of IDA in adult patients who had failed or could not tolerate oral iron or in whom oral iron was contraindicated, we are conducting 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 December 2016, we completed enrollment in 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. Approximately two thousand patients were 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 file an sNDA for this broader indication in mid-2017.

MuGard Developments

Based on interactions with government payors during 2016, we determined that broader reimbursement coverage for *MuGard* was unlikely and we assessed the MuGard Rights for potential impairment. From this assessment, we concluded that based on the lack of broad reimbursement and insurance coverage for *MuGard* and the resulting decrease in expected revenues and cash flows, the projected undiscounted cash flows were less than the book value, indicating impairment of this intangible asset. As a result of an analysis of the fair value of the net MuGard Rights intangible asset as compared to its recorded book value, we recognized an impairment charge for the full $15.7 million net intangible asset in the second quarter of 2016.

Other Licensing Transactions

Intrarosa

On February 13, 2017, we entered into a license agreement (the "Endoceutics License Agreement") with Endoceutics, Inc. ("Endoceutics") pursuant to which Endoceutics has agreed to grant to us rights to *Intrarosa*, an FDA-approved product for the treatment of moderate-to-severe dyspareunia (pain during sexual intercourse), a symptom of VVA due to menopause. The Endoceutics License Agreement grants us the right to develop and commercialize pharmaceutical products containing dehydroepiandrosterone ("DHEA"), including *Intrarosa*, at dosage strengths of 13 mg or less per dose and formulated for intravaginal delivery, excluding any dosage strengths over 13 mg per dose and combinations with other active pharmaceutical ingredients, in the U.S. for the treatment of VVA and FSD. The closing of the transactions contemplated by the Endoceutics License Agreement is subject to clearance under the Hart-Scott-Rodino Act and other customary closing conditions.

Intrarosa is the only FDA-approved, vaginally administered, daily non-estrogen steroid, which is prescribed for the treatment of moderate-to-severe dyspareunia. *Intrarosa* contains prasterone, also known as DHEA. DHEA is an inactive endogenous precursor of hormones, which is converted locally into androgens and estrogens to help restore the vaginal tissue as indicated by improvements in the percentage of superficial cells, parabasal cells, and pH. The mechanism of action is not fully established. The effectiveness of *Intrarosa* on moderate-to-severe dyspareunia was examined in two primary 12-week placebo-controlled efficacy trials. All women in both studies were assessed for improvement from baseline to week 12 for four co-primary efficacy endpoints: most bothersome moderate-to-severe symptom of dyspareunia, the percentage of vaginal superficial cells, the percentage of parabasal cells, and vaginal pH. All primary endpoints were statistically significant. *Intrarosa* was studied in two pivotal 12-week placebo-controlled Phase 3 efficacy trials. All primary endpoints were statistically significant. Women taking *Intrarosa* experienced a significant reduction in moderate-to-severedyspareunia, as well as statistically significant improvements in the percentage of vaginal superficial cells, parabasal cells, as well as vaginal pH. Additional details regarding the Endoceutics License Agreement can be found in Note W, "*Subsequent Events*," 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."

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 revenue recognized under our collaboration agreements, royalties received from our license agreements, and

international product revenues of *Feraheme* derived from our collaboration agreement with Takeda Pharmaceutical Company Limited ("Takeda"), which was terminated in 2015. 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 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 contractual adjustments or governmental 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 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. We did not significantly adjust our reserve for product returns during 2016 or 2015. 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. 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.

Governmental Rebates

Governmental rebate reserves relate to our reimbursement arrangements with state Medicaid programs. 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. 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 governmental rebates are recorded at the time of sale. During 2016, we revised our estimated Medicaid reserve based on actual claims received since the 2011 launch of *Makena*, our expectations of state level utilization, and estimated rebate claims not yet submitted. This revision resulted in a $6.1 million reduction of our estimated Medicaid rebate reserve related to prior period *Makena* sales. During 2015, we reduced our *Makena*-related Medicaid and chargeback reserves, which were initially recorded at the time of the Lumara Health acquisition, by $4.0 million and $1.9 million, respectively. These measurement period adjustments were recorded to goodwill during 2015. We did not significantly adjust our Medicaid rebate reserve during 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 "Affordable Care 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 Affordable Care 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 2016, 2015, and 2014 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 material to our results of operations or financial condition. The Affordable Care Act exempts "orphan drugs" such as *Makena* from 340B ceiling price requirements for the covered entity types newly added to the program by the Affordable Care Act.

In addition, the number of 340B institutions, which provide drugs at reduced rates, was expanded by the Affordable Care 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 Affordable Care Act. *Feraheme* sold to 340B eligible entities comprised approximately 20%, 20% and 17% of our total *Feraheme* sales in grams for 2016, 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%.

We were not materially impacted by healthcare reform legislation during 2016, 2015 and 2014. 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. Additionally, a key focus of the recent presidential election was "repeal and replacement" of the Affordable Care Act. The extent, timing and details of the changes are not known, but the federally funded health care landscape could face significant changes during the current presidential administration, including in the near-term, and could impact state and local healthcare programs, including Medicaid and Medicare.

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 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 annually during the lifetime of the newborn donor. However, revenue is recognized based on the average of male and female life expectancies using lifetime actuarial tables published by the Social Security Administration in effect at the time of the newborn's birth. 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.

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.

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 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 ability and intent to sell the investment at the time of purchase. As of December 31, 2016 and 2015, 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.

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, 2016, 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 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 - 2016 as compared to 2015

Revenues

Total revenues for 2016 and 2015 consisted of the following (in thousands except for percentages):

	Years Ended December 31,		2016 to 2015	
	2016	2015	$ Change	% Change
U.S. product sales, net				
Makena	$ 334,050	$ 251,615	$ 82,435	33 %
Feraheme	97,058	88,452	8,606	10 %
MuGard	1,062	1,749	(687)	(39)%
Total	432,170	341,816	90,354	26 %
Service revenues, net	99,604	24,132	75,472	>100 %
License fee, collaboration and other revenues	317	52,328	(52,011)	(99)%
Total Revenues	$ 532,091	$ 418,276	$ 113,815	27 %

Our total revenues for 2016 increased by $113.8 million as compared to the same period in 2015, primarily as the result of a $82.4 million increase in our net *Makena* sales and a $75.5 million increase of CBR Services revenue due to the full period recognition of CBR Services revenue in 2016 compared to a partial period in 2015 following our August 2015 acquisition of CBR. This increase in revenues was partially offset by a $52.0 million decrease in license fee, collaboration and other revenues during 2016 as compared to 2015. Under the terms of the 2014 termination of a license, development and commercialization agreement (as amended, the "Takeda Agreement") with Takeda related to the commercialization of *Feraheme* outside of the U.S., in 2015 we recognized revenues of $6.7 million for payments made by Takeda as well as $44.4 million of previously deferred revenues associated with the amortization of the then-remaining deferred revenue balance under the Takeda Agreement.

The following table sets forth customers who represented 10% or more of our total revenues for 2016 and 2015:

	Years Ended December 31,	
	2016	2015
AmerisourceBergen Drug Corporation	22%	25%
McKesson Corporation	11%	11%
Takeda Pharmaceuticals Company Limited	—%	12%

Product Sales

Total gross U.S. product sales were offset by product sales allowances and accruals for 2016 and 2015 as follows (in thousands except for percentages):

	Years Ended December 31,				2016 to 2015	
	2016	Percent of gross U.S. product sales	2015	Percent of gross U.S. product sales	$ Change	% Change
Gross U.S. product sales	$ 748,839		$ 561,255		$ 187,584	33%
Provision for U.S. product sales allowances and accruals:						
Contractual adjustments	229,686	31%	161,665	29%		
Governmental rebates	86,983	12%	57,774	10%		
Total provision for U.S. product sales allowances and accruals	316,669	42%	219,439	39%		
U.S. product sales, net	$ 432,170		$ 341,816		$ 90,354	26%

We expect gross product sales to increase in 2017 primarily based on increased units sold of our products.

Gross U.S. product sales increased by $187.6 million, or approximately 33%, during 2016 as compared to 2015 primarily due to increases of $156.6 million and $32.4 million of *Makena* and *Feraheme* gross sales for 2016 as compared to 2015. Of the $156.6 million increase in gross *Makena* sales in 2016, $135.3 million was due to increased volume of *Makena* and $21.3 million was due to price increases. Of the $32.4 million increase in gross *Feraheme* sales, $20.9 million was due to price increases and $11.5 million was due to increased volume sold. This total increase in gross product sales was partially offset by $97.2 million of additional allowances and accruals in 2016 as compared to the same period in 2015.

Net U.S. product sales increased by $90.4 million, or approximately 26%, during 2016 as compared to 2015 primarily due to a $82.4 million increase in net *Makena* sales and a $8.6 million increase in net *Feraheme* sales. We anticipate that sales of *Makena* will continue to increase in 2017 as compared to 2016 as we continue to gain market share from compounded product due to the availability of the single-dose, preservative-free formulation of *Makena*, which was approved in February 2016. We anticipate that we will also continue to gain market share through broader reimbursement of *Makena*, improved patient compliance and continued educational programs for patients and physicians regarding treatment with *Makena*. We anticipate that sales of *Feraheme* will increase in 2017 as compared to 2016 due to our expectation of continued growth of the IV iron market.

Product Sales Allowances and Accruals

We recognize U.S. product sales net of certain allowances and accruals in our consolidated statement 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, rebates to hospitals that qualify for 340B pricing, and volume-based and other commercial rebates. Governmental rebates relate to our reimbursement arrangements with state Medicaid programs. The increases in contractual adjustments and governmental rebates as a percentage of gross U.S. product sales primarily relate to the growth in sales to state Medicaid agencies.

During 2016, we revised our estimated Medicaid reserve based on actual claims received since the 2011 launch of *Makena*, our expectations of state level utilization, and estimated rebate claims not yet submitted. This revision resulted in a $6.1 million reduction of our estimated Medicaid rebate reserve related to prior period *Makena* sales. During 2015, we reduced our *Makena*-related Medicaid and chargeback reserves, which were initially recorded at the time of the Lumara Health acquisition, by $4.0 million and $1.9 million, respectively. These measurement period adjustments were recorded to goodwill during 2015. We may revise our estimated revenue reserves related to *Makena* as we continue to obtain additional experience or as our customer mix changes. 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.

An analysis of the amount of our product reserves for 2016 and 2015, is as follows (in thousands):

	Contractual Adjustments	Governmental Rebates	Total
Balance at January 1, 2015	$ 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
Current provisions relating to sales in current year	224,894	93,035	317,929
Adjustments relating to sales in prior years	(2,348)	(6,052)	(8,400)
Payments/returns relating to sales in current year	(181,150)	(41,636)	(222,786)
Payments/returns relating to sales in prior years	(23,973)	(19,715)	(43,688)
Balance at December 31, 2016	$ 47,600	$ 51,399	$ 98,999

During 2016 and 2015, 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 2017, 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 $75.5 million increase in service revenues recorded in 2016 as compared to 2015 was due to the full period recognition of CBR Services revenue in 2016 compared to a partial period in 2015 following our August 2015 acquisition of CBR. We expect service revenues to increase in 2017 due to continued efforts to increase new enrollments of cord blood and cord tissue units in our storage facility and recurring revenue from our growing base of stored units.

License Fee, Collaboration and Other Revenues

Our license fee, collaboration and other revenues in 2016 decreased by $52.0 million as compared to 2015 primarily as the result of the 2015 recognition of the $44.4 million balance of deferred revenue and $6.7 million of revenues recognized in 2015 in connection with the 2015 termination of the Takeda Agreement.

We expect that our license fee, collaboration and other revenues, if any, will be immaterial in 2017.

Costs and Expenses

Cost of Product Sales

Cost of product sales for 2016 and 2015 were as follows (in thousands except for percentages):

	Years Ended December 31,		2016 to 2015	
	2016	2015	$ Change	% Change
Cost of product sales	$ 96,314	$ 78,509	$ 17,805	23%
Percentage of net product sales	22%	23%		

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, the amortization of product-related intangible assets and the inventory step-up in connection with the November 2014 acquisition of Lumara Health. Cost of

product sales excludes the impairment of intangible assets described separately below under "*Impairments of Intangible Assets*." The $17.8 million increase in our cost of product sales for 2016 as compared to 2015 was primarily attributable to a $20.0 million net increase in amortization of the *Makena* and *MuGard* product intangible assets and a $5.8 million increase in production costs and overhead, partially offset by $4.4 million decrease of inventory write-offs and $3.5 million decrease in inventory step-up.

We expect our cost of product sales as a percentage of net product sales excluding any impact from the amortization of the *Makena* intangible asset and the amortization of inventory step-up of *Makena* inventory to continue to increase slightly in 2017 as compared to 2016 primarily due to increased sales of the single-dose preservative-free formulation of *Makena,* which we began promoting to physicians in the second quarter of 2016, compared to sales of the multidose vial of *Makena*.

Cost of Services

Cost of services for 2016 and 2015 were as follows (in thousands except for percentages):

	Years Ended December 31,		2016 to 2015	
	2016	2015	$ Change	% Change
Cost of services	$ 20,575	$ 9,992	$ 10,583	>100 %
Percentage of service revenues	21%	41%		

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. The $10.6 million increase in cost of services recorded in 2016 as compared to 2015 was due to the full period recognition of CBR Services revenue in 2016 compared to a partial period in 2015 following our August 2015 acquisition of CBR. The decrease in the cost of services as a percentage of service revenues reflects a higher purchase accounting adjustment to the CBR deferred revenue balance in 2015 as compared to 2016.

We expect our cost of services as a percentage of service revenues to remain relatively constant in future periods as the deferred revenues adjustment associated with the CBR Services revenues becomes more consistent on an annual basis going forward.

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 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 2016 and 2015 consisted of the following (in thousands except for percentages):

	Years Ended December 31,		2016 to 2015	
	2016	2015	$ Change	% Change
External research and development expenses				
Makena-related costs	$ 19,113	$ 10,820	$ 8,293	77 %
Feraheme-related costs	28,067	6,279	$ 21,788	>100 %
Velo option	—	10,000	$ (10,000)	(100)%
Other external costs	3,252	1,799	$ 1,453	81 %
Total	50,432	28,898	21,534	75 %
Internal research and development expenses	15,652	13,980	1,672	12 %
Total research and development expenses	$ 66,084	$ 42,878	$ 23,206	54 %

Total research and development expenses incurred in 2016 increased by $23.2 million, or 54%, as compared to 2015. The $21.8 million increase in *Feraheme*-related costs was primarily attributed to new costs related to our Phase 3 clinical trial evaluating *Feraheme* in adults with IDA, which was initiated and completed enrollment in 2016. The increase of *Makena*-related costs of $8.3 million was primarily attributed to $5.1 million in increased costs related to our *Makena* next-generation development program. The increase in total research and development expenses was partially offset by a $10.0 million 2015 upfront payment related to the Velo option.

We expect our research and development expenses to increase in 2017 as compared to 2016 mostly due to additional expenses associated with research and development primarily related to our newly licensed products, including up to $25.0 million in clinical development and regulatory costs associated with our obligations under the Rekynda License Agreement, $60.0 million upfront payment made to Palatin in February 2017, our share of the clinical development costs associated with the potential clinical studies for the use of *Intrarosa* in FSD and increased internal costs to support our regulatory filings and clinical 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, 2016:

- **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 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; and (c) a completed PK trial of women taking *Makena*. In addition, this project includes studies conducted as part of our *Makena* auto-injector development program, including a completion of the definitive PK study;

- **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 and (b) 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 project also includes a pediatric program as part of our post-approval Pediatric Research Equity Act requirement to support pediatric CKD labeling of *Feraheme,* which we suspended in 2015 due to difficulty in enrollment. In December 2016, we met with the FDA to develop a plan forward in order to satisfy this post-approval commitment for *Feraheme* and recently proposed a protocol to the FDA for a new pediatric study; and

- **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, which was initiated in the first quarter of 2016. We currently expect to file an sNDA for this broader indication in mid-2017.

From November 12, 2014 (the date of the Lumara Health acquisition) through December 31, 2016, we have incurred aggregate external research and development expenses of approximately $26.4 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 $12.8 million to $18.3 million over the next several years.

Through December 31, 2016, we have incurred aggregate external research and development expenses of approximately $41.8 million related to our current program for the development of *Feraheme* to treat IDA in CKD patients, described above. We do not anticipate additional external costs associated with this project.

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, after 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. We began enrolling patients in a head-to-head Phase 3 clinical trial, as described above, in the first quarter of 2016 and have spent approximately $27.6 million since the first quarter of 2016. We currently estimate that the total remaining external costs associated with this development project will be in the range of approximately $6.0 million to $8.0 million through the second quarter of 2017, the expected time of our sNDA submission to the FDA.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses include costs related to our commercial personnel, including our specialty sales forces, 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 2016 and 2015 consisted of the following (in thousands except for percentages):

	Years Ended December 31,		2016 to 2015	
	2016	2015	$ Change	% Change
Compensation, payroll taxes and benefits	$ 78,295	$ 62,122	$ 16,173	26%
Professional, consulting and other outside services	114,813	78,981	35,832	45%
Fair value of contingent consideration liability	25,683	4,271	21,412	>100%
Amortization expense related to customer relationship intangible	12,529	1,061	11,468	>100%
Equity-based compensation expense	18,550	13,874	4,676	34%
Total selling, general and administrative expenses	$ 249,870	$ 160,309	$ 89,561	56%

Total selling, general and administrative expenses incurred in 2016 increased by $89.6 million, or approximately 56%, as compared to the same period in 2015 for the following reasons:

- $16.2 million increase in compensation, payroll taxes and benefits primarily due to increased headcount resulting from the August 2015 CBR acquisition;
- $25.0 million increase in sales and marketing, consulting, professional fees, and other expenses due to costs related to CBR marketing activities and revenue driven spend related to *Makena*;
- $10.8 million increase in general and administrative, consulting, professional fees and other expenses primarily due to increased costs associated with the CBR acquisition;
- $21.4 million increase to the contingent consideration liability due to a $22.8 million increase in the *Makena*-related contingent consideration based on the expected timing of the milestone payments;
- $11.5 million increase in amortization expense related to the CBR customer relationship intangible due to the full period recognition of CBR amortization expense in 2016 compared to a partial period in 2015 following our August 2015 acquisition of CBR; and
- $4.7 million increase in equity-based compensation expense due primarily to an increase in the number of equity awards to new and existing employees, including additional employees from the CBR acquisition.

We expect that total selling, general and administrative expenses will increase substantially in 2017 as compared to 2016 due to significant increased costs associated with the license of *Rekynda* and *Intrarosa,* including the anticipated expansion of our sales force and certain marketing commitments to support the commercialization of *Intrarosa*.

Impairment of Intangible Assets

During the year ended December 31, 2016, we recognized an impairment loss on our intangible assets of $19.7 million, due to a $15.7 million impairment charge related to the impairment of the remaining net intangible asset for the MuGard Rights based on the lack of broad reimbursement and insurance coverage for *MuGard* and the impairment of the remaining $0.2 million, net, CBR-favorable lease intangible asset due the subleasing of a portion of our CBR office space in San Bruno, California at a rate below the market rate used to determine the favorable lease intangible asset. In addition, as part of our annual impairment test, we recorded an impairment charge of $3.7 million in the fourth quarter of 2016 related to the impairment of a portion of the CBR trade names and trademarks indefinite-lived intangible asset based on the revised long-term revenue forecast for CBR. As part of our ongoing assessment of potential impairment indicators related to our finite-lived and indefinite-lived intangible assets, we will closely monitor the performance of our product portfolio and our intangible assets. If our ongoing assessments reveal indications of impairment, we may determine that an impairment charge is necessary and such charge could be material.

Acquisition-related Costs

Acquisition-related costs of $11.2 million incurred in 2015 included costs for financial advising, legal fees, due diligence, and other costs and expenses related to our August 2015 acquisition of CBR. We did not incur any acquisition-related costs in 2016.

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. We recorded charges of approximately $0.7 million and $4.1 million in 2016 and 2015, respectively. We expect to pay the remaining restructuring costs by the end of the first quarter of 2017.

Other Income (Expense)

Other income (expense) for 2016 and 2015 consisted of the following (in thousands except for percentages):

	Years Ended December 31,		2016 to 2015	
	2016	2015	$ Change	% Change
Interest expense	$ (73,153)	$ (53,251)	$ (19,902)	37 %
Loss on debt extinguishment	—	(10,449)	10,449	(100)%
Interest and dividend income, net	3,149	1,512	1,637	>100 %
Other income (expense)	189	(9,188)	9,377	<(100)%
Total other income (expense)	$ (69,815)	$ (71,376)	$ 1,561	(2)%

Other expense for 2016 decreased by $1.6 million as compared to 2015 primarily as the result of the following:

- $10.4 million loss on debt extinguishment in 2015 as the result of the early repayment of the remaining $323.0 million outstanding principal amount of our then existing five-year term loan facility (the “2014 Term Loan Facility”); and
- $9.4 million decrease of other expenses as compared to 2015, including a payment of a $6.8 million bridge loan commitment fee and $2.4 million in fees and expenses paid in 2015 as part of the early repayment of the 2014 Term Loan Facility.

These decreases described above were partially offset by an additional $19.9 million in interest expense in 2016, which was primarily comprised of the amortization of debt discount, contractual interest expense and amortization of debt issuance costs due to the full period recognition in 2016 of the debt obligations incurred in the third quarter of 2015, compared to a partial period in in 2015.

We expect our net other income (expense) to remain relatively constant in 2017 as compared to 2016.

Income Tax Expense

The following table summarizes our effective tax rate and income tax expense for 2016 and 2015 (in thousands except for percentages):

	Years Ended December 31,	
	2016	2015
Effective tax rate	127%	18%
Income tax expense	$ 11,538	$ 7,065

For 2016, we recognized income tax expense of $11.5 million, representing an effective tax rate of 127%. The difference between the expected statutory federal tax rate of 35% and the 127% effective tax rate for 2016 was primarily attributable to the impact of contingent consideration associated with Lumara Health, equity-based compensation expenses and other permanent items, including meals and entertainment expense, officers compensation and *Makena*-related expenses, offset by the benefit of the federal research and development and orphan drug tax credits generated during the year. For 2015, we recognized an income tax expense of $7.1 million, representing an effective tax rate of 18%. The difference between the expected statutory federal tax rate of 35% and the 18% effective tax rate for 2015 was attributable to the impact of a valuation allowance release related to certain deferred tax assets and the impact of state income taxes, partially offset by non-deductible transaction costs associated with the acquisition of CBR and non-deductible contingent consideration expense associated with Lumara Health.

Expectations Related to the Endoceutics License

In addition to the trends and expectations noted above, we expect that the Endoceutics License Agreement will close during the first half of 2017. Pursuant to the terms of the agreement, we will make an up-front payment of $50.0 million, and (subject to certain customary conditions) will issue 600,000 shares of unregistered common stock, to Endoceutics. We also agreed to make a payment to Endoceutics of up to $10.0 million upon the delivery of *Intrarosa* launch quantities and a payment of $10.0 million on the first anniversary of the closing date. Payment of the consideration using cash on hand will lower our cash balance. We agreed to co-fund additional studies in FSD and our commitment is limited to $20.0 million. In addition, we have also committed to a minimum marketing spend in 2017 for *Intrarosa* and expect to incur significant increased costs associated with the anticipated expansion of our sales force and certain marketing commitments to support the commercialization of *Intrarosa*. These obligations, as well as additional expenses that we expect to incur in 2017, including the expansion of our sales force, will lower our cash balance and our expected profitability in 2017. Further, the transaction, including issuing the consideration shares, will dilute earnings in the near term.

Results of Operations - 2015 as compared to 2014

Revenues

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

	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, under the terms of the 2014 termination of the Takeda Agreement, in 2015 we recognized revenues of $6.7 million for payments made by Takeda as well as $44.4 million of

previously deferred revenues associated with the amortization of the then-remaining deferred revenue balance under the Takeda Agreement.

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

Total gross U.S. product sales were offset by product sales allowances and accruals for 2015 as compared to 2014 as follows (in thousands except for percentages):

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

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. During 2015, we reduced our *Makena*-related Medicaid and chargeback reserves, which were initially recorded at the time of the Lumara Health acquisition, by $4.0 million and $1.9 million, respectively. These measurement period adjustments were recorded to goodwill during 2015. Total *Feraheme* governmental rebates were $0.7 million in 2015 as compared to $0.8 million in 2014. We did not significantly adjust our Medicaid rebate reserve during 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.

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.

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 except for percentages):

	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 termination agreement with Takeda as compared to $3.0 million recognized in 2014 related to the termination agreement with Takeda, and which was recorded in other products sales and royalties in our 2014 consolidated statement of operations.

Costs and Expenses

Cost of Product Sales

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

	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%		

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 termination agreement with Takeda.

Cost of Services

Cost of services for 2015 and 2014 were as follows (in thousands except for percentages):

	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.

Research and Development Expenses

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

	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.

Selling, General and Administrative Expenses

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

	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;
- $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.

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.

Other Income (Expense)

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

	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 expense for 2015 increased by $57.9 million as compared to 2014 primarily as the result of the following:

- 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;
- $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 increase 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.

Income Tax Expense (Benefit)

The following table summarizes our effective tax rate and income tax expense (benefit) for 2015 and 2014 (in thousands except for percentages):

	Years Ended December 31,	
	2015	2014
Effective tax rate	18%	(883)%
Income tax expense (benefit)	$ 7,065	$ (153,159)

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.

Liquidity and Capital Resources

General

We currently finance our operations primarily from the cash generated from our operating activities, including sales of our products and services. We expect to continue to incur significant expenses as we continue to market, sell and contract for the manufacture of *Makena* and *Feraheme,* market and sell the CBR Services, pursue the next-generation development program for *Makena,* further develop and seek U.S. regulatory approval for *Feraheme* for the treatment of IDA in a broad range of patients and for *Rekynda* for the treatment of hypoactive sexual desire disorder. 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, 2016 and 2015 consisted of the following (in thousands except for percentages):

	December 31,			
	2016	2015	$ Change	% Change
Cash and cash equivalents	$ 274,305	$ 228,705	$ 45,600	20 %
Investments	304,781	237,626	67,155	28 %
Total	$ 579,086	$ 466,331	$ 112,755	24 %
Outstanding principal on 2023 Senior Notes	$ 500,000	$ 500,000	$ —	— %
Outstanding principal on Convertible Notes	199,998	200,000	(2)	— %
Outstanding principal on 2015 Term Loan Facility	328,125	345,625	(17,500)	(5)%
Total	$ 1,028,123	$ 1,045,625	$ (17,502)	(2)%

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 $112.8 million increase in cash, cash equivalents and investments as of December 31, 2016, as compared to December 31, 2015, was primarily due to cash flow from product and service sales, partially offset by expenditures to fund our operations, service our debt, including principal and interest payments, a $100.0 million milestone paid in 2016 to the former Lumara Health security holders based on our achievement of a $300.0 million annual net *Makena* sales milestone, and $20.0 million of cash used to repurchase our common stock during 2016.

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. In addition, in August 2015, we sold approximately 3.6 million shares of our common stock at a public offering price of $63.75 per share, resulting in net proceeds to us of approximately $218.6 million.

We expect that our cash, cash equivalents and investments balances will be positively impacted by operating profits in 2017, which may be offset by the milestone payments and other commitments that we will make in connection with the Palatin and Endoceutics license agreements. Our expectation takes into consideration our commitments under these license agreements and assumes our continued investment in the development and commercialization of our products and services, including: the $60.0 million upfront license payment to Palatin in February 2017, a $50.0 million upfront payment to be made to Endoceutics upon the close of the transaction, $10.0 million to be paid to Endoceutics for commercial supply of *Intrarosa* in preparation for its 2017 launch, as well as clinical development and regulatory costs associated with our obligations under the Rekynda License Agreement and the related anticipated increase in expenses in our regulatory and clinical functions, significant costs associated with the anticipated expansion of our sales force and certain marketing commitments to support the commercialization of *Intrarosa* and a $100.0 million milestone payment expected to be paid in the second half of 2017 to the former Lumara Health security holders based on the achievement of a net sales milestone of *Makena*. We believe that our cash, cash equivalents and investments as of December 31, 2016, and the cash we currently expect to receive from sales of our products and services, and earnings on our investments, will be sufficient to satisfy our cash flow needs for the foreseeable future.

Borrowings and Other Liabilities

In August 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, including Jefferies Finance LLC, who acted 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"). The 2023 Senior Notes, which are senior unsecured obligations, 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 (which began in March 2016). We borrowed the full $350.0 million available under the 2015 Term Loan Facility in August 2015. 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. As a result, as of December 31, 2016, $3.7 million was estimated and reclassified from long-term debt to current portion of long-term debt in our consolidated balance sheet as the first excess payment is expected to be made in April 2017. 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 February 2014, we issued $200.0 million aggregate principal amount of 2.5% convertible senior notes due February 15, 2019 (the "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 2016, the Convertible Notes were not convertible as of December 31, 2016.

Share Repurchase Program

In January 2016, we announced that our board of directors 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. During 2016, we repurchased and retired 831,744 shares of common stock under this repurchase program for $20.0 million, at an average purchase price of $24.05 per share.

Cash Flow Activity for the Year Ended December 31, 2016

Cash flows from operating activities

Net cash provided by operating activities for 2016 was $246.2 million as compared to $96.0 million in 2015. The increase in net cash provided by operating activities was primarily due to the following:

- Non-cash operating items resulting in a net increase of $191.0 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, loss on debt extinguishment and other non-cash items;

- Change in accounts receivable of $27.0 million, a net increase in CBR deferred revenues of $46.7 million, partially offset by a decrease in net income of approximately $35.3 million.

We expect to generate cash from operations as we continue to grow our business, partially offset by increased expenditures to support our growth.

Cash flows from investing activities

Net cash used in investing activities in 2016 was $72.7 million as compared to $899.0 million in 2015. Cash used in investing activities decreased during 2016 as compared to 2015 primarily due to a net decrease in the purchase and sales of our investments and the $682.4 million of net cash used in 2015 to fund the CBR acquisition.

Cash flows from financing activities

Net cash used in financing activities in 2016 was $127.9 million as compared to net cash provided by financing activities of $912.5 million in 2015. The 2016 financing activities primarily related to $92.1 million in contingent consideration payments related to the acquisition of Lumara Health, $20.0 million of cash to repurchase shares of our common stock under our share repurchase program, and $17.5 million related to mandatory debt principal payments. In 2015, the primary sources of cash from financing activities were $407.5 million in net proceeds from the aggregate issuance of common stock from our March 2015 and August 2015 public offerings, $834.8 million received from the proceeds of new debt offerings in 2015.

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.

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 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 million 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.

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.

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, 2016, 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	$ 10,801	$ 2,925	$ 6,711	$ 1,165	$ —
Purchase commitments	5,260	2,630	2,630	—	—
2.5% Convertible Notes	210,831	5,000	205,831	—	—
2015 Term Loan Facility	391,096	36,310	62,706	292,080	—
2023 Senior Notes	775,625	39,375	78,750	78,750	578,750
Total	$ 1,393,613	$ 86,240	$ 356,628	$ 371,995	$ 578,750

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, 2016 and 2015 as a long-term asset and is restricted in its use.

We lease certain real property located at 1200 Bayhill Drive, San Bruno, California. The lease expires in September 2017.

Facility-related rent expense, net of deferred rent amortization, for all the leased properties was $2.8 million, $1.5 million, and $0.8 million for 2016, 2015 and 2014, respectively.

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 $5.3 million as of December 31, 2016.

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. During 2016, we paid $100.0 million of these milestone payments. We expect to pay the next $100.0 million milestone payment in 2017. 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, 2016, the contingent consideration related to the Lumara Health and *MuGard* acquisitions are our only financial 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 expect that Velo will begin its Phase 2b/3a clinical study in the first quarter of 2017, and as such no contingencies related to this agreement have been recorded in our consolidated financial statements as of December 31, 2016.

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-injection system commencing on the launch of the *Makena* auto-injector in a particular country until the *Makena* auto-injector is no longer 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 *Makena* auto-injector and decrease after the expiration of licensed patents or where there are generic equivalents to the *Makena* auto-injector being sold in a particular country.

Other Funding Commitments

As of December 31, 2016, 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 $10.6 million representing expenses incurred with these organizations as of December 31, 2016, 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.

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, 2016, 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, 2016 and 2015, our investments equaled $304.8 million and $237.6 million, respectively, and were invested in corporate debt securities, U.S. treasury and government agency securities, commercial paper, certificates of deposit 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, 2016 and 2015, this would have resulted in a hypothetical decline in fair value of our investments of approximately $1.4 million and $1.1 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, 2016 and 2015, this would have resulted in a hypothetical increase in fair value of our investments of approximately $1.4 million and $1.1 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, 2016, 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 $1.6 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 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, 2016, the fair value of the Convertible Notes was $282.1 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.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA:

Index To Consolidated Financial Statements

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) and 15d-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, 2016 based on the framework in *Internal Control -Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in 2013. Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2016.

The effectiveness of our internal control over financial reporting as of December 31, 2016, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included herein.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders 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, 2016 and December 31, 2015, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2016 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, 2016, 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 V to the consolidated financial statements, the Company changed the manner in which it accounts for debt issuances costs in 2016.

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.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
February 17, 2017

AMAG PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)

	As of December 31,	
	2016	2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 274,305	$ 228,705
Investments	304,781	237,626
Accounts receivable, net	92,375	85,678
Inventories	37,258	40,645
Receivable from collaboration	—	428
Prepaid and other current assets	9,839	13,592
Total current assets	718,558	606,674
Property, plant and equipment, net	24,460	28,725
Goodwill	639,484	639,188
Intangible assets, net	1,092,178	1,196,771
Restricted cash	2,593	2,593
Other long-term assets	1,153	2,259
Total assets	$ 2,478,426	$ 2,476,210
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,684	$ 4,906
Accrued expenses	156,008	106,363
Current portion of long-term debt	21,166	17,500
Current portion of acquisition-related contingent consideration	97,068	96,967
Deferred revenues	34,951	20,185
Total current liabilities	312,877	245,921
Long-term liabilities:		
Long-term debt, net	785,992	803,669
Convertible 2.5% notes, net	179,363	170,749
Acquisition-related contingent consideration	50,927	125,592
Deferred tax liabilities	197,066	189,145
Deferred revenues	14,850	5,093
Other long-term liabilities	2,962	3,777
Total liabilities	1,544,037	1,543,946
Commitments and contingencies (Note P)		
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; 34,336,147 and 34,733,117 shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively	343	347
Additional paid-in capital	1,238,031	1,233,786
Accumulated other comprehensive loss	(3,838)	(4,205)
Accumulated deficit	(300,147)	(297,664)
Total stockholders' equity	934,389	932,264
Total liabilities and stockholders' equity	$ 2,478,426	$ 2,476,210

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

AMAG PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT PER SHARE DATA)

	Years Ended December 31,		
	2016	2015	2014
Revenues:			
U.S. product sales, net	$ 432,170	$ 341,816	$ 109,998
Service revenues, net	99,604	24,132	—
License fee, collaboration and other revenues	317	52,328	14,386
Total revenues	532,091	418,276	124,384
Costs and expenses:			
Cost of product sales (excluding impairment)	96,314	78,509	20,306
Cost of services	20,575	9,992	—
Research and development expenses	66,084	42,878	24,160
Selling, general and administrative expenses	249,870	160,309	72,254
Impairment of intangible assets	19,663	—	—
Acquisition-related costs	—	11,232	9,478
Restructuring expenses	715	4,136	2,023
Total costs and expenses	453,221	307,056	128,221
Operating income (loss)	78,870	111,220	(3,837)
Other income (expense):			
Interest expense	(73,153)	(53,251)	(14,697)
Loss on debt extinguishment	—	(10,449)	—
Interest and dividend income	3,149	1,512	975
Other income (expense)	189	(9,188)	217
Total other income (expense)	(69,815)	(71,376)	(13,505)
Income (loss) before income taxes	9,055	39,844	(17,342)
Income tax expense (benefit)	11,538	7,065	(153,159)
Net income (loss)	$ (2,483)	$ 32,779	$ 135,817
Net income (loss) per share:			
Basic	$ (0.07)	$ 1.04	$ 6.06
Diluted	$ (0.07)	$ 0.93	$ 5.45
Weighted average shares outstanding used to compute net income (loss) per share:			
Basic	34,346	31,471	22,416
Diluted	34,346	35,308	25,225

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

AMAG PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(IN THOUSANDS)

	Years Ended December 31,		
	2016	2015	2014
Net income (loss)	$ (2,483)	$ 32,779	$ 135,817
Other comprehensive income (loss):			
Unrealized gains (losses) on securities:			
Holding gains (losses) arising during period, net of tax	261	(4)	(191)
Reclassification adjustment for gains (losses) included in net income (loss), net of tax	106	(584)	65
Net unrealized gains (losses) on securities	367	(588)	(126)
Total comprehensive income (loss)	$ (2,116)	$ 32,191	$ 135,691

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

AMAG PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(IN THOUSANDS, EXCEPT SHARES)

	Common Stock					
	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2013	21,772,571	$ 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	3,209,971	32	111,932	—	—	111,964
Net shares issued in connection with the exercise of stock options and vesting of restricted stock units	617,008	6	8,492	—	—	8,498
Non-cash equity-based compensation	—	—	8,625	—	—	8,625
Unrealized losses on securities, net of tax	—	—	—	(126)	—	(126)
Net income	—	—	—	—	135,817	135,817
Balance at December 31, 2014	25,599,550	256	793,757	(3,617)	(330,443)	459,953
Shares issued in connection with financings, net of issuance costs of $24.7 million	8,196,362	82	407,395	—	—	407,477
Net shares issued in connection with the exercise of stock options and vesting of restricted stock units	937,205	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	34,733,117	347	1,233,786	(4,205)	(297,664)	932,264
Net shares issued in connection with the exercise of stock options and vesting of restricted stock units	355,450	3	227	—	—	230
Repurchase of common stock pursuant to the 2016 Share Repurchase Program	(831,744)	(8)	(19,992)	—	—	(20,000)
Issuance of common stock under employee stock purchase plan	79,324	1	1,467	—	—	1,468
Non-cash equity-based compensation	—	—	22,543	—	—	22,543
Unrealized gains on securities, net of tax	—	—	—	367	—	367
Net loss	—	—	—	—	(2,483)	(2,483)
Balance at December 31, 2016	34,336,147	$ 343	$ 1,238,031	$ (3,838)	$ (300,147)	$ 934,389

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,		
	2016	2015	2014
Cash flows from operating activities:			
Net income (loss)	$ (2,483)	$ 32,779	$ 135,817
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization	99,886	69,103	6,984
Impairment of intangible assets	19,663	—	—
Provision for bad debt expense	3,209	—	—
Amortization of premium/discount on purchased securities	624	2,152	2,080
Write-down of inventory to net realizable value	—	1,235	1,309
Gain (loss) on disposal of property and equipment	—	—	(103)
Non-cash equity-based compensation expense	22,543	17,237	8,625
Non-cash loss on debt extinguishment	—	6,426	—
Amortization of debt discount and debt issuance costs	12,105	11,379	6,870
Gains on investments, net	38	(14)	(114)
Change in fair value of contingent consideration	25,683	4,271	(681)
Deferred income taxes	7,279	5,007	(153,159)
Changes in operating assets and liabilities:			
Accounts receivable, net	(9,906)	(36,913)	3,588
Inventories	(2,355)	(5,237)	(1,360)
Receivable from collaboration	428	4,090	(4,239)
Prepaid and other current assets	4,095	4,034	2,331
Accounts payable and accrued expenses	49,037	7,876	10,694
Deferred revenues	24,522	(22,197)	(8,384)
Payment of contingent consideration in excess of acquisition date fair value	(8,116)	—	—
Repayment of term loan attributable to original issue discount	—	(12,491)	—
Other assets and liabilities	(30)	7,244	1,156
Net cash provided by operating activities	246,222	95,981	11,414
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	127,479	208,966	223,568
Purchase of investments	(194,723)	(424,759)	(63,747)
Change in restricted cash	—	(195)	2,883
Capital expenditures	(5,460)	(1,259)	(44)
Net cash used in investing activities	(72,704)	(899,041)	(432,942)
Cash flows from financing activities:			
Proceeds from the issuance of common stock, net of underwriting discount and other expenses	—	407,477	—
Long-term debt principal payments	(17,502)	(327,509)	—
Proceeds from long-term debt	—	834,750	527,509
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	(92,130)	(456)	(270)
Payment to former CBR shareholders	—	(7,195)	—
Payments for repurchases of common stock	(20,000)	—	—
Proceeds from the exercise of stock options	1,468	15,406	8,499
Proceeds from the issuance of common stock under ESPP	2,417	—	—
Payments of employee tax withholding related to equity-based compensation	(2,171)	—	—
Net cash (used in) provided by financing activities	(127,918)	912,469	513,838
Net increase in cash and cash equivalents	45,600	109,409	92,310
Cash and cash equivalents at beginning of the year	228,705	119,296	26,986
Cash and cash equivalents at end of the year	$ 274,305	$ 228,705	$ 119,296
Supplemental data of cash flow information:			

Cash paid for taxes	$ 5,309	$ 2,373	$ —
Cash paid for interest	$ 62,381	$ 28,014	$ 2,500
Non-cash investing activities:			
Fair value of acquisition-related contingent consideration	$ —	$ —	$ 205,000
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.

AMAG PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

A. DESCRIPTION OF BUSINESS

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a biopharmaceutical company focused on developing and delivering important therapeutics, conducting clinical research in areas of unmet need and creating education and support programs for the patients and families we serve. Our currently marketed products support the health of patients in the areas of women's health, anemia management and cancer supportive care, including Makena® (hydroxyprogesterone caproate injection), Feraheme® (ferumoxytol) for intravenous ("IV") use and MuGard® Mucoadhesive Oral Wound Rinse. Through services related to the preservation of umbilical cord blood stem cell and cord tissue units (the "CBR Services") operated through Cord Blood Registry® ("CBR"), we also help families to preserve newborn stem cells, which are used today in transplant medicine for certain cancers and blood, immune and metabolic disorders, and which we believe have the potential to play a valuable role in the ongoing development of regenerative medicine.

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 ability to expand our product portfolio through business development transactions; 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, including regulatory approvals for such programs; our ability to differentiate *Makena* from compounded HPC products; 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; competition in the cord blood and tissue banking business; compliance with cord blood and tissue regulations and laws; 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; competition from generic versions of *Feraheme* and iron replacement therapy products*;* our customer concentration, especially with regard to *Feraheme*; our ability to obtain approval for the sale of Rekynda™ (bremelanotide) by the FDA, our restrictions that may be imposed by the FDA; our ability to commercialize *Rekynda*; uncertainty regarding the market and competitors or *Rekynda* and Intrarosa™ (prasterone); our ability to commercialize *Intrarosa*, including the ability to drive awareness of dyspareunia; our ability to consummate the *Intrarosa* licensing transaction; uncertainties regarding federal and state legislative initiatives; potential inability to obtain raw or other materials; our potential 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 and potential civil or criminal penalties as a result thereof; our ability to managing our expanded product portfolio and operations; uncertainties regarding reporting and payment obligations under government pricing programs and our level of indebtedness; our ability to repay our indebtedness, including upon a change of our variable rate indebtedness; restrictions on our business related to our 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; current or potential litigation, including securities and product liability suits; provisions in our charter, by-laws and certain contracts that discourage an acquisition of our Company; the impact of disruptions to our information technology systems 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. Our results of operations for 2015 include the results of CBR, subsequent to August 17, 2015, the date of acquisition and for 2014 include the results of Lumara Health Inc. ("Lumara Health") and its product *Makena* subsequent to the November 12, 2014 acquisition date. See

Note C, "*Business Combinations*," for additional information. All intercompany balances and transactions have been eliminated in consolidation.

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 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 sales and services revenue; product sales allowances and accruals; allowance for doubtful accounts; 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, 2016 and 2015, 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 ability and intent to sell the investment at the time of purchase. As of December 31, 2016 and 2015, 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 income (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.

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, 2016 and 2015, we classified $2.6 million of our cash as restricted cash, which included $2.0 million held in a restricted fund previously established by Lumara in connection with its Chapter 11 plan of reorganization to pay potential claims against its former directors and officers. In addition, the restricted cash balance as of December 31, 2016 and 2015 included a $0.6 million security deposit delivered to the landlord of our Waltham, Massachusetts headquarters in the form of an irrevocable letter of credit.

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. We currently hold our excess cash primarily in institutional money market funds, corporate debt securities, U.S. treasury and government agency securities, commercial paper and certificates of deposit. As of December 31, 2016, we did not have a material concentration in any single investment.

Our operations are located entirely within the U.S. We focus primarily on developing, manufacturing, and commercializing *Makena* and *Feraheme* and marketing and selling the CBR Services, who pay for the services directly. We perform ongoing 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 2016, 2015 and 2014:

	Years Ended December 31,		
	2016	2015	2014
AmerisourceBergen Drug Corporation	22%	25%	34%
McKesson Corporation	11%	11%	21%
Cardinal Health, Inc.	<10%	<10%	15%
Takeda Pharmaceuticals Company Limited	—%	12%	11%

In addition, approximately 12% of our total revenues for 2015 were principally related to deferred *Feraheme* collaboration 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, and which revenues were thus generated from outside the U.S. Substantially all of the revenues generated during 2016 were generated within the U.S.

Our net accounts receivable primarily represented amounts due for products sold directly to wholesalers, distributors, and specialty pharmacies and amounts due for CBR Services sold to consumers who pay for the services directly. Accounts receivable for our products and services are recorded net of reserves for estimated chargeback obligations, prompt payment discounts and any allowance for doubtful accounts.

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, 2016 or 2015. 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 balance as of December 31, 2016 and 2015 were as follows:

	December 31,	
	2016	2015
McKesson Corporation	32%	<10%
AmerisourceBergen Drug Corporation	13%	43%

We are currently dependent on a single supplier for *Feraheme* drug substance (produced in two separate facilities) and 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 could not fulfill demand for any reason.

Property, Plant and Equipment, Net

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.

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: (a) product revenues from *Makena* and *Feraheme*; (b) service revenues associated with the CBR Services; and (c) license fees, collaboration and other revenues, which primarily included revenue recognized under collaboration agreements, royalties received from our license agreements, and international product revenues of *Feraheme* derived from our collaboration agreement with Takeda, which was terminated in 2015. 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, rebates to hospitals that qualify for 340B pricing 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.

Our U.S. product sales, which primarily represented revenues from *Makena* and *Feraheme* for 2016, 2015 and 2014 were offset by provisions for allowances and accruals as follows (in thousands):

	Years Ended December 31,		
	2016	2015	2014
Gross U.S. product sales	$ 748,839	$ 561,255	$ 190,512
Provision for U.S. product sales allowances and accruals:			
Contractual adjustments	229,686	161,665	73,262
Governmental rebates	86,983	57,774	7,252
Total provision for U.S. product sales allowances and accruals	316,669	219,439	80,514
U.S. product sales, net	$ 432,170	$ 341,816	$ 109,998

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 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 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 contractual adjustments or governmental 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. 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. We did not significantly adjust our reserve for product returns during 2016 or 2015. To date, our product returns of *Feraheme* and *Makena* have been relatively limited; however, returns experience may change over time. We may be required to make future adjustments 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.

Governmental Rebates

Governmental rebate reserves relate to our reimbursement arrangements with state Medicaid programs. 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. 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 governmental rebates are recorded at the time of sale. During 2016, we revised our estimated Medicaid reserve based on actual claims received since the 2011 launch of *Makena*, our expectations of state level utilization, and estimated rebate claims not yet submitted. This revision resulted in a $6.1 million reduction of our estimated Medicaid rebate reserve related to prior period *Makena* sales. During 2015, we reduced our *Makena*-related Medicaid and chargeback reserves, which were initially recorded at the time of the Lumara Health acquisition, by $4.0 million and $1.9 million, respectively. These measurement period adjustments were recorded to goodwill during 2015. We did not significantly adjust our Medicaid rebate reserve during 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, 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: (a) vendor specific objective evidence; (b) third-party evidence of selling price and (c) 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 CBR service revenues includes (a) amounts collected in advance of unit processing and (b) 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

Our service revenues for the CBR Services include the following two deliverables: (a) 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 (b) 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 (the "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, revenue is recognized based on the average of male and female life expectancies using lifetime actuarial tables published by the Social Security Administration in effect at the time of the newborn's birth. 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 is 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 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 $16.4 million, $8.0 million and $2.1 million for the years ended December 31, 2016, 2015 and 2014, respectively.

Shipping and Handling Costs

We bill customers of our CBR Services a fee for the shipping of the collection kits to CBR. Shipping and handling revenues are reported in services revenues, with the associated costs in reported in costs of services.

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.

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 restricted stock units ("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. We utilize 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 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.

The components of basic and diluted net income (loss) per share for 2016, 2015 and 2014 were as follows (in thousands, except per share data):

	Years Ended December 31,		
	2016	2015	2014
Net income (loss) - basic	$ (2,483)	$ 32,779	$ 135,817
Dilutive effect of convertible 2.5% notes	—	—	1,654
Net income (loss) - diluted	$ (2,483)	$ 32,779	$ 137,471
Weighted average common shares outstanding	34,346	31,471	22,416
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	34,346	35,308	25,225
Net income (loss) per share:			
Basic	$ (0.07)	$ 1.04	$ 6.06
Diluted	$ (0.07)	$ 0.93	$ 5.45

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 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,		
	2016	2015	2014
Options to purchase shares of common stock	2,590	1,619	2,708
Shares of common stock issuable upon the vesting of RSUs	613	167	322
Warrants	7,382	—	7,382
Convertible 2.5% notes	7,382	7,382	—
Total	17,967	9,168	10,412

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 2016 and 2014, the average common stock price was below the exercise price of the warrants and during 2015, the average common stock price was above the exercise price of the warrants.

Reclassifications

Certain amounts in the prior period have been reclassified in order to conform to the current period presentation. In accordance with Accounting Standards Update ("ASU") No. 2015-3, *Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*, which we adopted in the first quarter of 2016, we reclassified total debt issuance costs related to our outstanding debt obligations from other long-term assets to the carrying amount of our debt, as a direct deduction, in our consolidated balance sheets as of December 31, 2015. See Note V , "*Recently Issued and Proposed Accounting Pronouncements*" for additional information.

C. BUSINESS COMBINATIONS

As part of our strategy to expand our product and service portfolio, in August 2015, we acquired CBR and the CBR Services and in November 2014, we acquired Lumara Health and its product *Makena*.

CBR Acquisition

On August 17, 2015 (the "CBR Acquisition Date"), we acquired CBR 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 CBR acquisition 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 allocated the purchase price to the net tangible and intangible assets acquired and liabilities assumed, based on available information and various assumptions we believed were 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 fair values assigned to the CBR assets acquired and liabilities assumed by us along with the resulting goodwill at the CBR Acquisition Date, as adjusted for certain measurement period adjustments recorded since the CBR Acquisition Date (in thousands):

	Total Acquisition Date Fair Value
Accounts receivable	$ 8,660
Inventories	3,825
Prepaid and other current assets	8,480
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	5,062
Other long-term assets	496
Accounts payable	(2,853)
Accrued expenses	(13,770)
Deferred revenues - short-term	(3,100)
Payable to former CBR shareholders	(37,947)
Deferred income tax liabilities	(149,873)
Other long-term liabilities	(506)
Total estimated identifiable net assets	$ 240,985
Goodwill	441,371
Total	$ 682,356

During 2016, we recorded measurement period adjustments related to the filing of pre-acquisition federal and state income tax returns and the finalization of other tax-related matters. These measurement period adjustments resulted in a net increase to goodwill of $0.3 million and were reflected as current period adjustments during the second quarter of 2016 in accordance with the guidance in ASU 2015-16, *Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments* ("ASU 2015-16"). Measurement period adjustments recorded in the fourth quarter of 2015 consisted primarily of reductions to accounts receivable, inventories, prepaid and other current assets and property, plant 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.

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 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 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 trade names and trademark intangible asset is deemed to be an indefinite-lived asset, which is not amortized but is subject to periodic assessments for impairment. See Note H, "*Goodwill and Intangible Assets*" for additional information.

Based on the fair value adjustments primarily related to deferred revenue and identifiable intangible assets acquired, we recorded a net deferred tax liability of $144.8 million in acquisition accounting using a combined federal and state statutory income tax rate of 37.0%. The net deferred tax liability represents the $149.9 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, partially offset by $5.1 million of deferred tax assets acquired from CBR.

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 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.

During the third quarter of 2016, we finalized the fair values assigned to the assets acquired and liabilities assumed by us at the CBR Acquisition Date.

Lumara Health Acquisition

On November 12, 2014, (the "Lumara Health Acquisition Date"), we acquired Lumara Health and its existing commercial product, *Makena,* 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 *Makena*, 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. We paid the former Lumara Health security holders $100.0 million in the fourth quarter of 2016 based on our achievement of the First Milestone during the third quarter of 2016.

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 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 Health acquisition 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. As of December 31, 2016, the funds held in escrow have been fully distributed to the former Lumara Health security holders.

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.

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

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 were 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 $4.9 million, $11.6 million and $1.3 million of the fair value adjustment as cost of product sales during the years ended December 31, 2016, 2015 and 2014, respectively. An additional $0.9 million and $1.2 million of the fair value adjustment was recognized as research and development expense during the year ended December 31, 2016 and 2015, respectively. The remaining $6.2 million is estimated to be recognized as follows: $2.1 million in 2017 and $4.1 million in 2018.

The fair value amounts for the *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 program 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.

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.

During 2015, we finalized the fair values assigned to the assets acquired and liabilities assumed by us at the Lumara Health Acquisition Date.

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 as having occurred in 2013. 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
Pro forma combined revenues	490,451	364,447
Pro forma combined net income (loss)	28,217	(57,739)

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.

Goodwill

In connection with the CBR acquisition, we recognized $441.4 million of goodwill, primarily due to the synergies expected from combining our operations with CBR and to deferred tax liabilities related to fair value adjustments of 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 $639.5 million of goodwill resulting from the CBR and Lumara Health acquisitions is not deductible for income tax purposes.

D. INVESTMENTS

As of December 31, 2016 and 2015, our investments 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, 2016 and 2015 (in thousands):

	December 31, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities				
Due in one year or less	$ 106,430	$ 3	$ (69)	$ 106,364
Due in one to three years	139,742	32	(281)	139,493
U.S. treasury and government agency securities				
Due in one year or less	1,021	—	—	1,021
Due in one to three years	11,395	—	(52)	11,343
Commercial paper				
Due in one year or less	40,560	—	—	40,560
Certificates of deposit				
Due in one year or less	6,000	—	—	6,000
Total investments	$ 305,148	$ 35	$ (402)	$ 304,781

	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

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 2016, 2015 and 2014. 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, 2016, 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 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, 2016 and 2015, for those assets and liabilities that we measure at fair value on a recurring basis (in thousands):

	Fair Value Measurements at December 31, 2016 Using:			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 9,951	$ 9,951	$ —	$ —
Corporate debt securities	245,857	—	245,857	—
U.S. treasury and government agency securities	12,364	—	12,364	—
Commercial paper	40,560	—	40,560	—
Certificates of deposit	6,000	—	6,000	—
Total Assets	$ 314,732	$ 9,951	$ 304,781	$ —
Liabilities:				
Contingent consideration - Lumara Health	$ 145,974	$ —	$ —	$ 145,974
Contingent consideration - MuGard	2,021	—	—	2,021
Total Liabilities	$ 147,995	$ —	$ —	$ 147,995

	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:				
Cash equivalents	$ 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

Investments

Our cash equivalents 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, 2016 or 2015. In addition, there were no transfers or reclassifications of any securities between Level 1 and Level 2 during 2016 or 2015.

Contingent consideration

We record contingent consideration related to the Lumara Health acquisition, as discussed in greater detail in Note C, "*Business Combinations*," and related to our June 2013 license agreement for MuGard® Mucoadhesive Oral Wound Rinse (the "MuGard License Agreement") with Abeona Therapeutics, Inc. ("Abeona"), under which we acquired the U.S. commercial rights for the management of oral mucositis and stomatitis (the "MuGard Rights"). 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, 2015	$	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
Payments made		(100,246)
Adjustments to fair value of contingent consideration		25,682
Balance as of December 31, 2016	$	147,995

The $25.7 million of adjustments to the fair value of the contingent consideration liability in 2016 were due to a $31.1 million increase to the *Makena* contingent consideration and a $5.4 million decrease to the *MuGard* contingent consideration. During the second quarter of 2016, we 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 *MuGard*-related contingent consideration liability by $5.6 million during the second quarter of 2016. These adjustments were included in selling, general and administrative expenses in our consolidated statements of operations. We have classified $96.8 million of the *Makena* contingent consideration and $0.3 million of the *MuGard* contingent consideration as short-term liabilities in our consolidated balance sheet as of December 31, 2016.

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 5.0%, which we believe is reasonable given the estimated likelihood of the pay-out. As of December 31, 2016, the total undiscounted milestone payment amounts we could pay in connection with the Lumara Health acquisition was $250.0 million through December 31, 2019.

The fair value of the contingent royalty payments payable by us to Abeona under the MuGard License Agreement was determined based on various market factors, including an analysis of estimated sales using a discount rate of approximately 11% as of December 31, 2016. In addition, as of December 31, 2016, we estimated that the undiscounted royalty amounts we could pay under the MuGard License Agreement, based on current projections, may range from $2.0 million to $6.0 million over the remainder of the ten year period, which commenced 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.

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, 2016, the estimated fair value of our 2023 Senior Notes, Convertible Notes and 2015 Term Loan Facility (each as defined below) was $500.0 million, $282.1 million and $336.0 million, respectively, which differed from their carrying 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, 2016 and 2015 (in thousands):

	December 31,	
	2016	2015
Raw materials	$ 14,382	$ 19,673
Work in process	3,924	1,985
Finished goods	18,952	18,987
Total inventories	$ 37,258	$ 40,645

Total inventories as of December 31, 2016 decreased by $3.4 million as compared to 2015 primarily due to inventory sold to customers, offset by new manufacturing activities during the year.

G. PROPERTY, PLANT AND EQUIPMENT, NET

Property, plant and equipment, net consisted of the following as of December 31, 2016 and 2015 (in thousands):

	December 31,	
	2016	2015
Land	$ 700	$ 700
Land improvements	300	300
Building and improvements	9,500	9,500
Computer equipment and software	13,866	13,193
Furniture and fixtures	2,401	1,725
Leasehold improvements	3,718	1,717
Laboratory and production equipment	6,449	5,683
Construction in progress	1,619	786
	38,553	33,604
Less: accumulated depreciation	(14,093)	(4,879)
Property, plant and equipment, net	$ 24,460	$ 28,725

During 2016, 2015 and 2014, depreciation expense was $9.2 million, $3.9 million and $0.5 million, respectively.

H. GOODWILL AND INTANGIBLE ASSETS, NET

Goodwill

Our goodwill balance consisted of the following (in thousands):

Balance at January 1, 2015	$ 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
Measurement period adjustments related to CBR acquisition	296
Balance as of December 31, 2016	$ 639,484

Our $639.5 million goodwill balance consisted of $198.1 million of goodwill acquired through the November 2014 Lumara Health acquisition and $441.4 million acquired through the August 2015 CBR acquisition. During 2016, the CBR goodwill increased by $0.3 million related to measurement period net tax adjustments. These measurement period adjustments have been reflected as current period adjustments in accordance with ASU 2015-16. As of December 31, 2016, we had no accumulated impairment losses related to goodwill.

Intangible Assets

As of December 31, 2016 and 2015, our identifiable intangible assets consisted of the following (in thousands):

	December 31, 2016				December 31, 2015		
	Cost	Accumulated Amortization	Impairments	Net	Cost	Accumulated Amortization	Net
Amortizable intangible assets:							
Makena base technology	$ 797,100	$ 128,732	$ —	$ 668,368	$ 797,100	$ 56,540	$ 740,560
CBR customer relationships	297,000	13,590	—	283,410	297,000	1,061	295,939
CBR Favorable lease	358	119	239	—	358	63	295
MuGard Rights	16,893	1,169	15,724	—	16,893	1,016	15,877
	1,111,351	143,610	15,963	951,778	1,111,351	58,680	1,052,671
Indefinite-lived intangible assets:							
Makena IPR&D	79,100	—	—	79,100	79,100	—	79,100
CBR trade names and trademarks	65,000	—	3,700	61,300	65,000	—	65,000
Total intangible assets	$ 1,255,451	$ 143,610	$ 19,663	$ 1,092,178	$ 1,255,451	$ 58,680	$ 1,196,771

As of December 31, 2016, the weighted average remaining amortization period for our finite-lived intangible assets was approximately 8.5 years.

The *Makena* base technology and IPR&D intangible assets were acquired in November 2014 in connection with our acquisition of Lumara Health. Amortization of the *Makena* base technology asset is being recognized using an economic consumption model over 20 years from the acquisition date, which we believe is an appropriate amortization period due to the estimated economic lives of the product rights and related intangibles.

The CBR intangible assets (the CBR customer relationships, favorable lease and trade names and trademarks) were acquired in August 2015 in connection with our acquisition of CBR. Amortization of the CBR customer relationships is being recognized using an estimated useful life of 20 years from the acquisition date, which we believe is an appropriate amortization period due to the estimated economic lives of the CBR intangible assets. The favorable lease was being amortized on a straight-line basis over the remaining term of the lease. On May 4, 2016, we entered into a sublease arrangement for a portion of our CBR office space in San Bruno, California with a sublessee at a rate lower than the market rate used to determine the favorable lease intangible asset. We reevaluated the favorable lease asset based on the negotiated sublease rate, resulting in an impairment charge for the full $0.2 million net intangible asset in 2016. In addition, as part of our annual impairment test, we recorded an impairment charge of $3.7 million in the fourth quarter of 2016 related to the impairment of a portion of the CBR trade names and trademarks indefinite-lived intangible asset based on a revised long-term revenue forecast for CBR.

The MuGard Rights were acquired from Abeona in June 2013. Amortization of the MuGard Rights was being recognized using an economic consumption model over ten years from the acquisition date, which represented our best estimate of the period over which we expected the majority of the asset's cash flows to be derived. Based on interactions with government payors during 2016, we determined that broader reimbursement coverage for *MuGard* by was unlikely and we assessed the MuGard Rights for potential impairment. From this assessment, we concluded that based on the lack of broad reimbursement and insurance coverage for *MuGard* and the resulting decrease in expected revenues and cash flows, the projected undiscounted cash flows were less than the book value, indicating impairment of this intangible asset. As a result of an analysis of the fair value of the net MuGard Rights intangible asset as compared to its recorded book value, we recognized an impairment charge for the full $15.7 million net intangible asset in the second quarter of 2016.

See Note C, "*Business Combinations*," and Note Q, "*Collaboration, License and Other Strategic Agreements*," for additional information on our intangible assets.

Total amortization expense for 2016, 2015 and 2014, was $84.9 million, $53.5 million and $5.1 million, respectively. Amortization expense for the *Makena* base technology and the MuGard Rights is recorded in cost of product sales in our consolidated statements of operations. Amortization expense for the CBR related intangibles is recorded in selling, general and administrative expenses in our consolidated statements of operations. We expect amortization expense related to our finite-lived intangible assets to be as follows (in thousands):

Period	Estimated Amortization Expense
Year Ending December 31, 2017	$ 119,900
Year Ending December 31, 2018	81,433
Year Ending December 31, 2019	48,283
Year Ending December 31, 2020	46,845
Year Ending December 31, 2021	46,767
Thereafter	608,550
Total	$ 951,778

I. CURRENT AND LONG-TERM LIABILITIES

Accrued Expenses

Accrued expenses consisted of the following as of December 31, 2016 and 2015 (in thousands):

	December 31,	
	2016	2015
Commercial rebates, fees and returns	$ 89,466	$ 45,161
Professional, license, and other fees and expenses	34,962	27,070
Interest expense	16,683	18,411
Salaries, bonuses, and other compensation	14,823	12,838
Restructuring expense	74	2,883
Total accrued expenses	$ 156,008	$ 106,363

Deferred Revenues

Our deferred revenue balances as of December 31, 2016 and 2015 were related to our CBR Services revenues and included: (a) amounts collected in advance of unit processing and (b) amounts associated with unearned storage fees collected at the beginning of the storage contract term, net of allocated discounts.

Other Long-Term Liabilities

Other long-term liabilities at December 31, 2016 and 2015 consisted of deferred rent related to the lease of our principal executive offices in Waltham, Massachusetts. In addition, other long-term liabilities include future payments to be made to certain states in compliance with a 2011 Lumara Health Settlement Agreement with the Department of Justice, which resolved certain claims under the qui tam provisions of the False Claims Act.

J. INCOME TAXES

For the years ended December 31, 2016, 2015, and 2014, all of our profit or loss before income taxes was from U.S. operations. The income tax expense (benefit) consisted of the following (in thousands):

	Years Ended December 31,		
	2016	2015	2014
Current:			
Federal	$ —	$ —	$ —
State	4,259	2,058	—
Total current	$ 4,259	$ 2,058	$ —
Deferred:			
Federal	$ 9,815	$ 9,819	$ (142,884)
State	(2,536)	(4,812)	(10,275)
Total deferred	$ 7,279	$ 5,007	$ (153,159)
Total income tax expense (benefit)	$ 11,538	$ 7,065	$ (153,159)

The reconciliation of the statutory U.S. federal income tax rate to our effective income tax rate was as follows:

	Years Ended December 31,		
	2016	2015	2014
Statutory U.S. federal tax rate	35.0 %	35.0 %	(34.0)%
State taxes, net of federal benefit	6.4	0.1	(7.9)
Equity-based compensation expense	34.0	0.4	10.6
Contingent consideration	69.9	4.7	3.1
Transaction costs	—	3.9	9.7
Other permanent items, net	21.2	3.2	3.2
Tax credits	(32.3)	(1.7)	(3.0)
Write-down of acquired state net operating losses	114.2	—	—
Valuation allowance	(115.2)	(28.0)	(864.9)
Other, net	(5.8)	0.1	—
Effective tax rate	127.4 %	17.7 %	(883.2)%

For the year ended December 31, 2016, we recognized an income tax expense of $11.5 million, representing an effective tax rate of 127.4%. The difference between the expected statutory federal tax rate of 35.0% and the effective tax rate of 127.4% for the year ended December 31, 2016, was primarily attributable to the impact of contingent consideration associated with Lumara Health, equity-based compensation expenses and other permanent items, including meals and entertainment expense, officers compensation and *Makena*-related expenses, offset by the benefit of the federal research and development and orphan drug tax credits generated during the year. The effective tax rate for the year-ended December 31, 2016 reflected the significance of these permanent differences in relation to the pre-tax income for the year-ended December 31, 2016. As a result of state tax planning during 2016, we analyzed the acquired state net operating losses ("NOLs") and determined that a significant portion were not utilizable and should be written down. This write-down was offset with a decrease in the valuation allowance as we had previously determined that it was more likely than not that these NOLs would not be utilized.

For the year ended December 31, 2015, we recognized income tax expense of $7.1 million representing an effective tax rate of 17.7%. The difference between the expected statutory federal tax rate of 35.0% and the 17.7% effective tax rate for 2015 was primarily attributable to 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.

We released a portion of our valuation allowance for the year ended December 31, 2014, due to taxable temporary differences available as a source of income as a result of the Lumara Health acquisition. As of December 31, 2014, we maintained a partial valuation allowance as we benefited only those deferred tax assets to the extent that existing taxable temporary differences could be used as a source of future income to realize the benefits of those deferred tax assets. During the

year ended December 31, 2015, we achieved a positive income position, and also acquired additional taxable temporary differences available as a source of income as a result of the CBR acquisition. Based primarily on this evidence, we concluded that as of December 31, 2015, the majority of our deferred tax assets are more likely than not to be realized.

For the year ended December 31, 2014, we recognized an income tax benefit of $153.2 million representing an effective tax rate of (883.2)%. The difference between the statutory tax rate and the effective tax rate was attributable to a non-recurring benefit of $153.2 million for the release of a portion of the valuation allowance due to taxable temporary differences available as a source of income to realize the benefit of certain pre-existing AMAG deferred tax assets as a result of the Lumara Health acquisition. Excluding the impact of this item, our overall tax provision and effective tax rate would have been zero. Other factors resulting in a difference between the statutory tax rate and the effective tax rate included certain non-deductible stock compensation expenses, non-deductible transaction costs and contingent consideration associated with the acquisition of Lumara Health, and other non-deductible expenses for tax purposes.

See Note C, "*Business Combinations*," for more information on the Lumara Health and CBR acquisitions.

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 the deferred tax assets will not be realized. As of December 31, 2015, we elected to early adopt new guidance issued by the FASB in November 2015 (ASU 2015-17), which simplifies the presentation of deferred income taxes by eliminating the need for entities to separate deferred income tax liabilities and assets into current and noncurrent amounts in a classified statement of financial position. The components of our deferred tax assets and liabilities were as follows (in thousands):

	December 31,	
	2016	2015
Assets		
Net operating loss carryforwards	$ 116,275	$ 172,944
Tax credit carryforwards	9,415	6,262
Deferred revenue	1,811	626
Equity-based compensation expense	8,045	5,464
Capitalized research & development	18,284	25,216
Reserves	8,018	8,900
Contingent consideration	4,140	1,258
Other	9,769	9,636
Liabilities		
Property, plant and equipment depreciation	(2,145)	(2,844)
Intangible assets and inventory	(367,667)	(400,357)
Debt instruments	(1,040)	(1,213)
Other	(542)	(3,178)
	(195,637)	(177,286)
Valuation allowance	(1,429)	(11,859)
Net deferred tax liabilities	$ (197,066)	$ (189,145)

The valuation allowance decreased by approximately $10.4 million for the year ended December 31, 2016, which was primarily attributable to the write-down of the acquired Lumara Health state NOLs. As a result of state tax planning during 2016, we analyzed the acquired state NOLs and determined that a significant portion were not utilizable and should be written down. We have considered several sources of taxable income in making our valuation allowance assessment, including taxable income in carryback years, future reversals of existing taxable temporary differences, tax planning strategies and forecasted future income. At December 31, 2016, the remaining valuation allowance related primarily to our federal capital loss carryforward and our state NOL carryforwards acquired from Lumara Health.

At December 31, 2016, we had federal and state NOL carryforwards of approximately $377.6 million and $122.0 million, respectively, of which $281.1 million and $19.6 million federal and state NOL carryforwards, were acquired as part of the Lumara Health transaction, respectively. Also included in the state NOL carryforwards at December 31, 2016 were $20.1

million of state NOL carryforwards which were acquired as part of the CBR transaction. The state NOL carryforwards acquired from Lumara Health are subject to a full valuation allowance as it is not more likely than not that they will be realized. We also had federal capital loss carryforwards of $1.5 million to offset future capital gains. At December 31, 2016, $58.3 million and $33.2 million of federal and state NOLs, respectively, related to excess equity-based compensation tax deductions, the benefits for which will be recorded to additional paid-in capital when recognized through a reduction of cash taxes paid. The federal and state NOLs expire at various dates through 2036. The capital loss carryforwards will expire through 2021. We have federal tax credits of approximately $8.6 million to offset future tax liabilities of which $1.5 million were acquired as part of the Lumara Health transaction. We have state tax credits of $1.2 million to offset future tax liabilities. These federal and state tax credits will expire periodically through 2036 if not utilized.

Utilization of our NOLs and research and development ("R&D") credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future in accordance with Section 382 of the Internal Revenue Code of 1986 ("Section 382") as well as similar state provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and taxes, respectively. In general, an ownership change as defined by Section 382 results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. Since our formation, we have raised capital through the issuance of capital stock on several occasions. These financings, combined with the purchasing shareholders' subsequent disposition of those shares, could result in a change of control, as defined by Section 382. We conducted an analysis under Section 382 to determine if historical changes in ownership through December 31, 2016 would limit or otherwise restrict our ability to utilize these NOL and R&D credit carryforwards. As a result of this analysis, we do not believe there are any significant limitations on our ability to utilize these carryforwards. The NOL's and tax credits acquired from Lumara health are subject to restrictions under Section 382. These restricted NOL's and credits may be utilized subject to an annual limitation. While we identified two ownership changes associated with the attributes acquired as part of the Lumara Health transaction and determined these attributes are subject to an annual limitation, we do not expect the limitations to result in expiration of these attributes prior to utilization. However, future changes in ownership after December 31, 2016 could affect the limitation in future years and any limitation may result in expiration of a portion of the NOL or R&D credit carryforwards before utilization.

Unrecognized tax benefits represent uncertain tax positions for which reserves have been established. As of December 31, 2016, we had $13.3 million of unrecognized tax benefits, of which $13.0 million would impact the effective tax rate, if recognized. As of December 31, 2015 we had $12.7 million of unrecognized tax benefits, of which $12.4 million would impact the effective tax rate, if recognized. We had no uncertain tax benefits recorded as of December 31, 2014.

A reconciliation of our changes in uncertain tax positions is as follows (in thousands):

	Years Ended December 31,		
	2016	2015	2014
Uncertain tax benefits at the beginning of the year	$ 12,695	$ —	$ —
Additions based on tax positions related to the current year	300	12,695	—
Additions for tax positions from prior years	379	—	—
Subtractions for tax positions from prior years	(44)	—	—
Uncertain tax benefits at the end of the year	$ 13,330	$ 12,695	$ —

During the year ended December 31, 2016, our unrecognized tax benefits increased by $0.6 million due primarily to tax reserves established on R&D tax credits.

During the year ended December 31, 2015, we completed studies of our historical R&D tax credits and other tax attributes, including those acquired in connection with the Lumara Health transaction. The increase in our unrecognized tax benefits is attributable to the results of these studies, which identified uncertain tax benefits of $12.7 million related to federal and state R&D credits and NOL carryforwards. These amounts were recorded as a reduction to our deferred tax assets as of December 31, 2015. A valuation allowance was recorded against these attributes at December 31, 2014, therefore there was no impact to income tax expense as a result of recording the unrecognized tax benefits during the year ended December 31, 2015.

We have recorded minimal interest or penalties on unrecognized benefits since inception. We recognize both accrued interest and penalties related to unrecognized benefits in income tax expense. We do not expect our uncertain tax benefits to change significantly in the next 12 months.

The statute of limitations for assessment by the Internal Revenue Service (the "IRS") and most state tax authorities is

closed for tax years prior to December 31, 2013, although carryforward attributes that were generated prior to tax year 2013 may still be adjusted upon examination by the IRS or state tax authorities if they either have been or will be used in a future period. We file income tax returns in the U.S. federal and various state jurisdictions. There are currently no federal or state audits in progress.

K. ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)

The table below presents information about the effects of net income (loss) of significant amounts reclassified out of accumulated other comprehensive income (loss), net of tax, associated with unrealized gains (losses) on securities during 2016 and 2015 (in thousands):

	December 31,	
	2016	2015
Beginning balance	$ (4,205)	$ (3,617)
Other comprehensive income (loss) before reclassifications	261	(4)
Reclassification adjustment for gains (losses) included in net income (loss)	106	(584)
Ending balance	$ (3,838)	$ (4,205)

L. EQUITY-BASED COMPENSATION

We currently maintain four equity compensation plans, namely our Third Amended and Restated 2007 Equity Incentive Plan, as amended (the "2007 Plan"), our Amended and Restated 2000 Stock Plan (the "2000 Plan"), the Lumara Health Inc. Amended and Restated 2013 Incentive Compensation Plan (the "Lumara Health 2013 Plan") and our 2015 Employee Stock Purchase Plan ("2015 ESPP"). All outstanding stock options granted under each of our equity compensation plans other than our 2015 ESPP (discussed below) have an exercise price equal to the closing price of a share of our common stock on the grant date.

Our 2007 Plan was originally approved by our stockholders in November 2007, and succeeded our 2000 Plan, under which no further grants may be made. Any shares that remained available for issuance under the 2000 Plan as of the date of adoption of the 2007 Plan are included in the number of shares that may be issued under the 2007 Plan. Any shares subject to outstanding awards granted under the 2000 Plan that expire or terminate for any reason prior to exercise will be added to the total number of shares of our stock available for issuance under the 2007 Plan. The total number of shares available for issuance under the 2007 Plan is 6,995,325. As of December 31, 2016, there were 1,786,672 shares remaining available for issuance under the 2007 Plan, which excludes shares subject to outstanding awards under the 2000 Plan. All outstanding options under the 2007 Plan have either a seven or ten-year term and all outstanding options under the 2000 Plan have a ten-year term.

In November 2014, we assumed the Lumara Health 2013 Plan in connection with the acquisition of Lumara Health. The total number of shares issuable pursuant to awards under this plan as of the effective date of the acquisition and after taking into account any adjustments as a result of the acquisition, was 200,000 shares. As of December 31, 2016, there were 9,710 shares remaining available for issuance under the Lumara Health 2013 Plan, which are available for grants to certain employees, officers, directors, consultants, and advisors of AMAG and our subsidiaries who are newly-hired or who previously performed services for Lumara Health. All outstanding options under the Lumara Health 2013 Plan have a ten-year term.

The 2007 Plan and the Lumara Health 2013 Plan provides for the grant of stock options, RSUs, restricted stock, stock, stock appreciation rights and other equity interests in our company. We generally issue common stock from previously authorized but unissued shares to satisfy option exercises and restricted stock awards. The terms and conditions of each award are determined by our Board of Directors (the "Board") or the Compensation Committee of our Board. The terms and conditions of each award assumed in the acquisition of Lumara Health were previously determined by Lumara Health prior to being assumed in connection with the acquisition, subject to applicable adjustments made in connection with such acquisition.

In May 2015, our stockholders approved our 2015 ESPP, which authorizes the issuance of up to 200,000 shares of our common stock to eligible employees. The terms of the 2015 ESPP permit eligible employees to purchase shares (subject to certain plan and tax limitations) in semi-annual offerings through payroll deductions of up to an annual maximum of 10% of the employee's "compensation" as defined in the 2015 ESPP. Shares are purchased at a price equal to 85% of the fair market value of our common stock on either the first or last business day of the offering period, whichever is lower. Plan periods consist of six-month periods typically commencing June 1 and ending November 30 and commencing December 1 and ending May 31. As of December 31, 2016, 79,324 shares have been issued under our 2015 ESPP.

During 2016, we also granted equity through inducement grants outside of these plans to certain employees to induce them to accept employment with us (collectively, "Inducement Grants"). The options were granted at an exercise price equal to the fair market value of a share of our common stock on the respective grant dates and will be exercisable in four equal annual installments beginning on the first anniversary of the respective grant dates. The RSU grants will vest in three equal annual installments beginning on the first anniversary of the respective grant dates. The foregoing grants were made pursuant to inducement grants outside of our stockholder approved equity plans as permitted under the NASDAQ Stock Market listing rules. We assessed the terms of these awards and determined there was no possibility that we would have to settle these awards in cash and therefore, equity accounting was applied.

Stock Options

The following table summarizes stock option activity during 2016:

	2007 Equity Plan	2000 Equity Plan	2013 Lumara Equity Plan	Inducement Grants	Total
Outstanding at December 31, 2015	1,963,162	14,040	96,000	830,975	2,904,177
Granted	581,648	—	92,400	110,000	784,048
Exercised	(134,455)	—	—	(21,250)	(155,705)
Expired or terminated	(251,533)	(8,840)	(54,219)	(104,750)	(419,342)
Outstanding at December 31, 2016	2,158,822	5,200	134,181	814,975	3,113,178

Restricted Stock Units

The following table summarizes RSU activity during 2016:

	2007 Equity Plan	2000 Equity Plan	2013 Lumara Equity Plan	Inducement Grants	Total
Outstanding at December 31, 2015	446,330	—	52,350	155,675	654,355
Granted	659,618	—	1,500	64,500	725,618
Vested	(209,599)	—	(16,749)	(74,219)	(300,567)
Expired or terminated	(122,545)	—	(9,407)	(10,500)	(142,452)
Outstanding at December 31, 2016	773,804	—	27,694	135,456	936,954

Equity-based compensation expense

Equity-based compensation expense for 2016, 2015 and 2014 consisted of the following (in thousands):

	Years Ended December 31,		
	2016	2015	2014
Cost of product sales and services	$ 520	$ 371	$ 122
Research and development	3,476	2,992	1,596
Selling, general and administrative	18,547	13,874	6,907
Total equity-based compensation expense	$ 22,543	$ 17,237	$ 8,625
Income tax effect	(6,232)	(4,885)	—
After-tax effect of equity-based compensation expense	$ 16,311	$ 12,352	$ 8,625

We reduce the compensation expense being recognized to account for estimated forfeitures, which we estimate based primarily on historical experience, adjusted for unusual events such as corporate restructurings, which may result in higher than expected turnover and forfeitures. Under current accounting guidance, forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

As a result of our historical net losses, there was no income tax effect on our equity-based compensation expense for 2014.

We have not recognized any excess tax benefits from equity-based compensation in additional paid-in capital because the excess tax benefits have not yet reduced cash taxes paid. Accordingly, there was no impact recorded in cash flows from financing activities or cash flows from operating activities as reported in the accompanying consolidated statements of cash flows.

The following table summarizes the weighted average assumptions we utilized for purposes of valuing grants of options to our employees and non-employee directors:

	Years Ended December 31,					
	2016		2015		2014	
	Employees	Non-Employee Directors	Employees	Non-Employee Directors	Employees	Non-Employee Directors
Risk free interest rate (%)	1.32	1.10	1.55	1.24	1.56	1.28
Expected volatility (%)	49	54	47	46	47	46
Expected option term (years)	5.00	3.00	5.00	4.00	5.00	4.00
Dividend yield	none	none	none	none	none	none

Risk free interest rates utilized are based upon published U.S. Treasury yields at the date of the grant for the expected option term. During 2016, 2015 and 2014, we estimated our expected stock price volatility by using the historical volatility of our own common stock price over the prior period equivalent to our expected option term, in order to better reflect expected future volatility. To compute the expected option term, we analyze historical exercise experience as well as expected stock option exercise patterns.

The following table summarizes details regarding stock options granted under our equity incentive plans for the year ended December 31, 2016:

	December 31, 2016			
	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value ($ in thousands)
Outstanding at beginning of year	2,904,177	$ 34.97	—	$ —
Granted	784,048	24.59	—	—
Exercised	(155,705)	17.99	—	—
Expired and/or forfeited	(419,342)	44.10	—	—
Outstanding at end of year	3,113,178	$ 31.97	7.4	$ 28,113
Outstanding at end of year - vested and unvested expected to vest	2,915,930	$ 31.53	7.4	$ 27,038
Exercisable at end of year	1,536,405	$ 27.92	6.3	$ 17,928

The weighted average grant date fair value of stock options granted during 2016, 2015 and 2014 was $10.63, $23.57 and $10.63, respectively. A total of 822,775 stock options vested during 2016. The aggregate intrinsic value of options exercised during 2016, 2015 and 2014, excluding purchases made pursuant to our employee stock purchase plans, measured as of the exercise date, was approximately $1.5 million, $31.2 million and $5.9 million, respectively. The intrinsic value of a stock option is the amount by which the fair market value of the underlying stock on a specific date exceeds the exercise price of the common stock option.

The following table summarizes details regarding RSUs granted under our equity incentive plans for the year ended December 31, 2016:

	December 31, 2016	
	Restricted Stock Units	Weighted Average Grant Date Fair Value
Outstanding at beginning of year	654,355	$ 36.90
Granted	725,618	22.28
Vested	(300,567)	30.38
Forfeited	(142,452)	26.66
Outstanding at end of year	936,954	$ 28.78
Outstanding at end of year and expected to vest	781,165	$ 28.79

The weighted average grant date fair value of RSUs granted during 2016, 2015 and 2014 was $22.28, $52.71 and $22.88, respectively. The total fair value of RSUs that vested during 2016, 2015 and 2014 was $9.1 million, $3.5 million and $2.7 million, respectively.

At December 31, 2016, the amount of unrecorded equity-based compensation expense for both option and RSU awards, net of forfeitures, attributable to future periods was approximately $37.7 million. Of this amount, $21.1 million was associated with stock options and is expected to be amortized on a straight-line basis to expense over a weighted average period of approximately 2.5 years, and $16.6 million was associated with RSUs and is expected to be amortized on a straight-line basis to expense over a weighted average period of approximately 1.8 years. Such amounts will be amortized primarily to research and development or selling, general and administrative expense. These future estimates are subject to change based upon a variety of future events, which include, but are not limited to, changes in estimated forfeiture rates, employee turnover, and the issuance of new stock options and other equity-based awards.

M. EMPLOYEE SAVINGS PLAN

We provide a 401(k) Plan to our employees by which they may defer compensation for income tax purposes under Section 401(k) of the Internal Revenue Code. Each employee may elect to defer a percentage of his or her salary up to a specified maximum. Our 401(k) Plan provides, among other things, for a company contribution of 3% of each employee's combined salary and certain other compensation for the plan year. Salary deferred by employees and contributions by us to the 401(k) Plan are not taxable to employees until withdrawn from the 401(k) Plan and contributions are deductible by us when made. The amount of our company contribution for the 401(k) Plan was $1.9 million, $1.8 million and $0.8 million for 2016, 2015 and 2014, respectively.

N. STOCKHOLDERS' EQUITY

Preferred Stock

Our certificate of incorporation authorizes our Board to issue preferred stock from time to time in one or more series. The rights, preferences, restrictions, qualifications and limitations of such stock are determined by our Board. In September 2009, our Board adopted a shareholder rights plan (the "Rights Agreement").

On February 11, 2014, in connection with the pricing of the Convertible Notes, we and American Stock Transfer & Trust Company, LLC (the "Rights Agent") entered into an amendment (the "Convertible Notes Amendment") to the Rights Agreement. The Convertible Notes Amendment, among other things, provides that, notwithstanding anything in the Rights Agreement to the contrary, each of JPMorgan Chase Bank, National Association, London Branch, Morgan Stanley & Co. International plc and Royal Bank of Canada (together the "Call Spread Counterparties") shall be deemed not to beneficially own any common shares underlying, or synthetically owned pursuant to, any warrant held by such Call Spread Counterparty, any common shares held by such Call Spread Counterparty (or any affiliate thereof) to hedge its exposure with respect to the convertible bond hedges and warrants, any common shares underlying, or synthetically owned pursuant to, any Derivative Securities (as such term is defined in the Rights Agreement), including the Convertible Notes, held, or entered into, by such Call Spread Counterparty (or any affiliate thereof) to hedge its exposure with respect to the convertible bond hedges and warrants or any Convertible Notes held by such Call Spread Counterparty (or any affiliate thereof) in its capacity as underwriter in the notes offering.

On September 26, 2014, we adopted another amendment to our Rights Agreement (which was approved by our stockholders at our 2015 annual meeting of stockholders) to help preserve our substantial tax assets associated with NOLs and other tax benefits by deterring certain stockholders from increasing their percentage ownership in our stock (the "NOL Amendment"). The NOL Amendment shortened the expiration date of the Rights Agreement from September 17, 2019 to March 31, 2017, decreased the exercise price of the rights from $250.00 to $80.00 in connection therewith, and made changes to the definition of "beneficial ownership," as used in the Rights Agreement, as amended, to make it consistent with how ownership is defined under Section 382 of the Internal Revenue Code of 1986, as amended. The original Rights Agreement provided for a dividend distribution of one preferred share purchase right (a "Right") for each outstanding share of our common stock, which dividend was paid on September 17, 2009. Rights will separate from the common stock and will become exercisable upon the earlier of (a) the close of business on the 10th calendar day following the first public announcement that a person or group of affiliated or associated persons has acquired beneficial ownership of 4.99% or more (which percentage had been 20% before the NOL Amendment) of the outstanding shares of common stock, other than as a result of repurchases of stock by us or certain inadvertent actions by a stockholder or (b) the close of business on the 10th business day (or such later day as the Board may determine) following the commencement of a tender offer or exchange offer that could result, upon its consummation, in a person or group becoming the beneficial owner of 4.99% or more (which percentage had been 20% before the NOL Amendment) of the outstanding shares of common stock (the earlier of such dates being herein referred to as the "Distribution Date").

The NOL Amendment provides that the Rights are not exercisable until the Distribution Date and will expire at the earliest of: (a) March 31, 2017; (b) the time at which the Rights are redeemed or exchanged; (c) the effective date of the repeal of Section 382 or any successor statute if the Board determines that the NOL Rights Plan is no longer necessary or desirable for the preservation of our tax benefits; (d) the first day of our taxable year to which the Board determines that no tax benefits may be carried forward; or (e) September 26, 2015 if stockholder approval of the NOL Amendment had not been obtained by or on such date.

There can be no assurance that the NOL Amendment will result in us being able to preserve all or any of the substantial tax assets associated with NOLs and other tax benefits.

Common Stock Transactions

In August 2015, we sold approximately 3.6 million shares of our common stock at a public offering price of $63.75 per share, 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.

At our 2015 Annual Meeting, our stockholders approved a proposal to amend our Certificate of Incorporation, as amended and restated and then currently in effect, to increase the number of authorized shares of our common stock from 58,750,000 shares to 117,500,000 shares (which amendment was subsequently filed with the Secretary of State of the State of Delaware).

Share Repurchase Program

In January 2016, we announced that our board of directors 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. During 2016, we repurchased and retired 831,744 shares of common stock under this repurchase program for $20.0 million, at an average purchase price of $24.05 per share.

O. BUSINESS SEGMENTS

We have determined that we conduct our operations in one business segment: the manufacture, development and commercialization of products and services for use in treating various conditions, with a focus on women's health, anemia management and cancer supportive care. Long-lived assets consist entirely of property, plant and equipment and are located in the U.S. for all periods presented.

P. COMMITMENTS AND CONTINGENCIES

Commitments

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, and other purchase obligations.

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, 2016 and 2015 as a long-term asset and is restricted in its use.

We lease certain real property located at 1200 Bayhill Drive, San Bruno, California. The lease expires in September 2017.

Facility-related rent expense, net of deferred rent amortization, for all the leased properties was $2.8 million, $1.5 million and $0.8 million for 2016, 2015 and 2014, respectively.

Future minimum payments under our non-cancelable facility-related leases as of December 31, 2016 are as follows (in thousands):

Period	Future Minimum Lease Payments
Year Ending December 31, 2017	$ 2,925
Year Ending December 31, 2018	2,123
Year Ending December 31, 2019	2,258
Year Ending December 31, 2020	2,330
Year Ending December 31, 2021	1,165
Total	$ 10,801

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 $5.3 million as of December 31, 2016.

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, of which $100.0 million was paid in 2016, 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*," for more information on the Lumara Health acquisition and related milestone payments.

Contingent Regulatory and Commercial Milestone Payments

In July 2015, we entered into an option agreement with Velo Bio, LLC, a privately-held life-sciences company ("Velo") that granted us an option to acquire the global rights (the "DIF Rights") to an orphan drug candidate, digoxin immune fab ("DIF"), a poly clonal antibody in clinical development for the treatment of severe preeclampsia in pregnant woman. 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. See Note Q, "*Collaboration, License and Other Strategic Agreements*," for more information on the Velo option. We anticipate Velo will begin its Phase 2b/3a clinical study in the first quarter of 2017, and as such no contingencies related to this agreement have been recorded in our consolidated financial statements as of December 31, 2016.

In connection with a development and license agreement (the "Antares Agreement") with Antares Pharma, Inc. ("Antares"), we are required to pay royalties to Antares on net sales of the auto-injection system for use with hydroxyprogesterone caproate (the "*Makena* auto-injector") commencing on the launch of the *Makena* auto-injector in a particular country until the *Makena* auto-injector is no longer 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 the *Makena* auto-injector and decrease after the expiration of licensed patents or where there are generic equivalents to the *Makena* auto-injector being sold in a particular country. We expect to file an sNDA for approval of the *Makena* auto-injector in the second quarter of 2017.

Other Funding Commitments

As of December 31, 2016, 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 $10.6 million representing expenses incurred with these organizations as of December 31, 2016, 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.

Indemnification Obligations

As permitted under Delaware law, pursuant to our certificate of incorporation, by-laws and agreements with all of our current directors, executive officers, and certain of our employees, we are obligated to indemnify such individuals for certain events or occurrences while the officer, director or employee is, or was, serving at our request in such capacity. The maximum potential amount of future payments we could be required to make under these indemnification obligations is not capped. Our director and officer insurance policy limits our initial exposure to $1.5 million and our policy provides significant coverage. As a result, we believe the estimated fair value of these indemnification obligations is likely to be immaterial.

We are also a party to a number of other agreements entered into in the ordinary course of business, which contain typical provisions and which obligate us to indemnify the other parties to such agreements upon the occurrence of certain events. Such indemnification obligations are usually in effect from the date of execution of the applicable agreement for a period equal to the applicable statute of limitations. Our aggregate maximum potential future liability under such indemnification provisions is uncertain. Except for expenses we incurred related to the Silverstrand class action lawsuit, which was settled in 2015, we have not incurred any expenses as a result of such indemnification provisions. Accordingly, we have determined that the estimated aggregate fair value of our potential liabilities under such indemnification provisions is not significant, and we have not recorded any liability related to such indemnification.

Contingencies

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. We expense legal costs as they are incurred.

Sandoz Patent Infringement Lawsuit

On February 5, 2016, we received a Paragraph IV certification notice letter regarding an Abbreviated New Drug Application 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 ANDA applicant whose proposed drug is a generic version of a previously-approved drug listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," also known as the "Orange Book," to certify to any patents listed in the Orange Book for the previously-approved drug and, in the case of a Paragraph IV certification, to notify the owner of the approved application and the relevant patent-holder. 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 unenforceable, or both. If a patent infringement suit is filed within 45 days of receipt of the Paragraph IV notice, a so-called 30-month stay is triggered that generally prevents the FDA from approving the ANDA until the expiration of the 30-month stay period, conclusion of the litigation in the generic applicant's favor, or expiration of the patent, whichever is earlier. 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. In March 2016, we initiated a patent infringement suit alleging that Sandoz' ANDA filing itself constituted an act of infringement and that if it is approved, the manufacture, use, offer for sale, sale or importation of Sandoz' ferumoxytol products would infringe our patents. By the filing of this complaint, we believe 30 month stay was triggered and that the FDA is prohibited from granting approval of Sandoz' application until the earliest of 30 months from the date of receipt of the notice of certification by the patent owner, 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 months stay period, the stay is lifted and the FDA may thereafter approve the application based on the applicable standards for approval. On May 2, 2016, Sandoz filed a response to our patent infringement suit and the trial is scheduled for March 12, 2018. Any future unfavorable outcome in this matter could negatively affect the magnitude and timing of future *Feraheme* revenues. We intend to vigorously enforce our intellectual property rights relating to ferumoxytol.

Other

On July 20, 2015, the Federal Trade Commission (the "FTC") notified us that it is conducting an investigation into whether Lumara Health or its predecessor engaged in unfair methods of competition with respect to *Makena* or any hydroxyprogesterone caproate product. We have fully cooperated with the FTC and provided a thorough response to the FTC in August 2015 and are awaiting their review of our response. The FTC noted in its letter that the existence of the investigation does not indicate that the FTC has concluded that Lumara Health or its predecessor has violated the law and we believe that our contracts and practices comply with relevant law and policy, including the federal Drug Quality and Security Act (the "DQSA"), which was enacted in November 2013, and public statements from and enforcement actions by the FDA regarding its implementation of the DQSA. We have provided the FTC with a response that provides a brief overview of the DQSA for context, which we believe will be helpful, including: (a) how the statute outlined that large-scale compounding of products that are copies or near-copies of FDA-approved drugs (like *Makena*) is not in the interests of public safety; (b) our belief that the DQSA has had a significant impact on the compounding of hydroxyprogesterone caproate; and (c) how our contracts with former compounders allow those compounders to continue to serve physicians and patients with respect to supplying medically necessary alternative/altered forms of hydroxyprogesterone caproate.

On or about April 6, 2016, we received Notice of a Lawsuit and Request to Waive Service of a Summons in a case entitled Plumbers' Local Union No. 690 Health Plan v. Actavis Group et. al. ("Plumbers' Union"), which was filed in the Court of Common Pleas of Philadelphia County, First Judicial District of Pennsylvania and, after removal to federal court, is now

pending in the United States District Court for the Eastern District of Pennsylvania (Civ. Action No. 16-65-AB). Thereafter, we were also made aware of a related complaint entitled Delaware Valley Health Care Coalition v. Actavis Group et. al. ("Delaware Valley"), which was filed with the Court of Common Pleas of Philadelphia County, First Judicial District of Pennsylvania District Court of Pennsylvania (Case ID: 160200806). The complaints name K-V Pharmaceutical Company ("KV") (Lumara Health's predecessor company), certain of its successor entities, subsidiaries and affiliate entities (the "Subsidiaries"), along with a number of other pharmaceutical companies. We acquired Lumara Health in November 2014, a year after KV emerged from bankruptcy protection, at which time it, along with its then existing subsidiaries, became our wholly-owned subsidiary. We have not been served with process or waived service of summons in either case. The actions are being brought alleging unfair and deceptive trade practices with regard to certain pricing practices that allegedly resulted in certain payers overpaying for certain of KV's generic products. On July 21, 2016, the Plaintiff in the Plumbers' Union case dismissed KV with prejudice to refiling and on October 6, 2016, all claims against the Subsidiaries were dismissed without prejudice. We are in discussions with Plaintiff's counsel to similarly dismiss all claims in the Delaware Valley case. Because the Delaware Valley case is in the earliest stages and we have not been served with process in this case, we are currently unable to predict the outcome or reasonably estimate the range of potential loss associated with this matter, if any.

We may periodically become subject to other legal proceedings and claims arising in connection with ongoing business activities, including claims or disputes related to patents that have been issued or that are pending in the field of research on which we are focused. Other than the above actions, we are not aware of any material claims against us as of December 31, 2016.

Q. COLLABORATION, LICENSE AND OTHER STRATEGIC AGREEMENTS

Our commercial strategy includes expanding our portfolio through the in-license or acquisition of additional pharmaceutical products or companies, including revenue-generating commercial products and late-state development assets. As of December 31, 2016, we were a party to the following collaborations:

Velo

Under our option agreement with Velo, we made an upfront payment of $10.0 million in the third quarter of 2015 for the option to acquire 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 Phase 2b/3a clinical study, which we expect to begin in the first quarter of 2017. 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 to Velo certain milestone payments and single-digit royalties based on regulatory approval and commercial sales of the product. 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 have determined that Velo is a variable interest entity ("VIE") as it does not have enough equity to finance its activities without additional financial support. As we do not have the power to direct the activities of the VIE that most significantly affect its economic performance, which we have determined to be the Phase 2b/3a clinical study, we are not the primary beneficiary of and do not consolidate the VIE.

Antares

In September 2014, Lumara Health entered into the Antares Agreement with Antares, 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-how, patents and trademarks, to develop, use, sell, offer for sale and import and export the *Makena* auto-injector. 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 *Makena* auto-injector, including the U.S. We are required to pay royalties to Antares on net sales of the *Makena* auto-injector for the life of 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 the *Makena* auto-injector and decrease after the expiration of licensed patents or where there are generic equivalents to the *Makena* auto-injector being sold in a particular country. Antares is the exclusive supplier of the device components of the *Makena* auto-injector and Antares remains responsible for the manufacture and supply of the device components and assembly of the *Makena* auto-injector. We are responsible for the supply of the drug to be used in the assembly of the finished auto-injector 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 "MuGard 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 certain 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 MuGard 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 MuGard 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.

R. DEBT

Our outstanding debt obligations as of December 31, 2016 and December 31, 2015 consisted of the following (in thousands):

	December 31,	
	2016	2015
2023 Senior Notes	$ 489,612	$ 488,481
2015 Term Loan Facility	317,546	332,688
2.5% Convertible Notes	179,363	170,749
Total long-term debt	986,521	991,918
Less: current maturities	21,166	17,500
Long-term debt, net of current maturities	$ 965,355	$ 974,418

2023 Senior Notes

On August 17, 2015, in connection with the CBR acquisition, we completed a private placement of $500 million aggregate principal amount of 7.875% Senior Notes due 2023 (the "2023 Senior Notes"). The 2023 Senior Notes were issued pursuant to an Indenture, dated as of August 17, 2015 (the "Indenture"), by and among us, certain of our subsidiaries acting as guarantors of the 2023 Senior Notes and Wilmington Trust, National Association, as trustee. The Indenture contains certain customary negative covenants, which are subject to a number of limitations and exceptions. Certain of the covenants will be suspended during any period in which the 2023 Senior Notes receive investment grade ratings.

The 2023 Senior Notes, which are senior unsecured obligations of the Company, will mature on September 1, 2023 and bear interest at a rate of 7.875% per year, with interest payable semi-annually on September 1 and March 1 of each year (which began in March 2016). We may redeem some or all of the 2023 Senior Notes at any time, or from time to time, on or after September 1, 2018 at the redemption prices listed in the Indenture, plus accrued and unpaid interest to, but not including, the date of redemption. In addition, prior to September 1, 2018, we may redeem up to 35% of the aggregate principal amount of the 2023 Senior Notes utilizing the net cash proceeds from certain equity offerings, at a redemption price of 107.875% of the principal amount thereof, plus accrued and unpaid interest to, but not including, the date of redemption; provided that at least 65% of the aggregate amount of the 2023 Senior Notes originally issued under the Indenture remain outstanding after such redemption. We may also redeem all or some of the 2023 Senior Notes at any time, or from time to time, prior to September 1, 2018, at a price equal to 100% of the principal amount of the 2023 Senior Notes to be redeemed, plus a "make-whole" premium plus accrued and unpaid interest, if any, to the date of redemption. Upon the occurrence of a "change of control," as defined in the Indenture, we are required to offer to repurchase the 2023 Senior Notes at 101% of the aggregate principal amount thereof, plus any accrued and unpaid interest to, but not including, the repurchase date. The Indenture contains customary events of default, which allow either the trustee or the holders of not less than 25% in aggregate principal amount of the then-outstanding 2023 Senior Notes to accelerate, or in certain cases, which automatically cause the acceleration of, the amounts due under the 2023 Senior Notes.

At December 31, 2016, the principal amount of the outstanding borrowings was $500.0 million and the carrying value of the outstanding borrowings, net of issuance costs and other lender fees and expenses, was $489.6 million.

2015 Term Loan Facility

On August 17, 2015, to fund a portion of the purchase price of CBR, we entered into a credit agreement with a group of lenders, including Jefferies Finance LLC as administrative and collateral agent, that provided us with, among other things, a six-year $350.0 million term loan facility. We borrowed the full $350.0 million available under the 2015 Term Loan Facility on August 17, 2015. The credit agreement also allows for the incurrence of incremental loans in an amount up to $225.0 million. The unamortized original issue costs and other lender fees and expenses, including a prepayment penalty, included $6.8 million of the unamortized original issue costs and other lender fees and expenses from our then existing five-year term loan facility as a result of accounting guidance for the modification of debt arrangements.

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, 2016, the stated interest rate, based on the LIBOR, was 4.75%, and the effective interest rate was 5.65%.

We must repay the 2015 Term Loan Facility in installments of $4.4 million per quarter due on the last day of each quarter beginning with the quarter ended December 31, 2015. The 2015 Term Loan Facility matures on August 17, 2021.

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 year ending December 31, 2016. As a result, as of December 31, 2016, $3.7 million was estimated and reclassified from long-term debt to current portion of long-term debt in our consolidated balance sheet as the first excess payment is expected to be made in April 2017. 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. Excess cash flow is generally defined as our adjusted Earnings Before Interest, Taxes, Depreciation and Amortization ("EBITDA") less debt service costs, unfinanced capital expenditures, unfinanced acquisition expenditures, contingent consideration paid, and current income taxes as well as other adjustments specified in the credit agreement.

The 2015 Term Loan Facility has a lien on substantially all of our assets, including a pledge of 100% of the equity interests in our domestic subsidiaries and a pledge of 65% of the voting equity interests and 100% of the non-voting equity interests in our direct foreign subsidiaries. The 2015 Term Loan Facility contains customary events of default and affirmative and negative covenants for transactions of this type. All obligations under the 2015 Term Loan Facility are unconditionally guaranteed by

substantially all of our direct and indirect domestic subsidiaries, with certain exceptions. These guarantees are secured by substantially all of the present and future property and assets of such subsidiaries, with certain exclusions.

At December 31, 2016, the principal amount of the outstanding borrowings was $328.1 million and the carrying value of the outstanding borrowings, net of issuance costs and other lender fees and expenses, was $317.5 million.

2.5% Convertible Notes

On February 14, 2014, we issued $200.0 million aggregate principal amount of the Convertible Notes. We received net proceeds of $193.3 million from the sale of the Convertible Notes, after deducting fees and expenses of $6.7 million. We used $14.1 million of the net proceeds from the sale of the Convertible Notes to pay the cost of the convertible bond hedges, as described below (after such cost was partially offset by the proceeds to us from the sale of warrants in the warrant transactions described below).

The Convertible Notes are governed by the terms of an indenture between us, as issuer, and Wilmington Trust, National Association, as the trustee. 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 earlier repurchased or converted. Upon conversion of the Convertible Notes, at a holder's election, such 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 an initial conversion price of approximately $27.09 per share of our common stock.

The conversion rate is subject to adjustment from time to time upon the occurrence of certain events, including, but not limited to, the issuance of stock dividends and payment of cash dividends. At any time prior to the close of business on the business day immediately preceding May 15, 2018, holders may convert their Convertible Notes at their option only under the following circumstances:

1) during any calendar quarter (and only during such calendar quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day;

2) during the five business day period after any five consecutive trading day period (the "measurement period") in which the trading price per $1,000 principal amount of the Convertible Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; or

3) upon the occurrence of specified corporate event.

On or after May 15, 2018 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert all or any portion of their Convertible Notes, in multiples of $1,000 principal amount, at the option of the holder regardless of the foregoing circumstances. Based on the last reported sale price of our common stock during the last 30 trading days of 2016, the Convertible Notes were not convertible as of December 31, 2016.

In accordance with accounting guidance for debt with conversion and other options, we separately account for the liability and equity components of the Convertible Notes by allocating the proceeds between the liability component and the embedded conversion option ("equity component") due to our ability to settle the Convertible Notes in cash, common stock or a combination of cash and common stock, at our option (subject to certain limitations in the 2015 Term Loan Facility). The carrying amount of the liability component was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The allocation was performed in a manner that reflected our non-convertible debt borrowing rate for similar debt. The equity component of the Convertible Notes was recognized as a debt discount and represents the difference between the proceeds from the issuance of the Convertible Notes and the fair value of the liability of the Convertible Notes on their respective dates of issuance. The excess of the principal amount of the liability component over its carrying amount ("debt discount") is amortized to interest expense using the effective interest method over five years. The equity component is not remeasured as long as it continues to meet the conditions for equity classification.

Our outstanding Convertible Note balances as of December 31, 2016 consisted of the following (in thousands):

	December 31, 2016
Liability component:	
Principal	$ 199,998
Less: debt discount and issuance costs, net	(20,635)
Net carrying amount	$ 179,363

In connection with the issuance of the Convertible Notes, we incurred approximately $6.7 million of debt issuance costs, which primarily consisted of underwriting, legal and other professional fees, and allocated these costs to the liability and equity components based on the allocation of the proceeds. Of the total $6.7 million of debt issuance costs, $1.3 million was allocated to the equity component and recorded as a reduction to additional paid-in capital and $5.4 million was allocated to the liability component and is now recorded as a reduction of the Convertible Notes in our consolidated balance sheets. The portion allocated to the liability component is amortized to interest expense using the effective interest method over five years.

We determined the expected life of the debt was equal to the five-year term on the Convertible Notes. The effective interest rate on the liability component was 7.23% for the period from the date of issuance through December 31, 2016. As of December 31, 2016, the "if-converted value" did not exceed the remaining principal amount of the Convertible Notes.

The following table sets forth total interest expense recognized related to the Convertible Notes during 2016, 2015 and 2014 (in thousands):

	Years Ended December 31,		
	2016	2015	2014
Contractual interest expense	$ 5,000	$ 5,000	$ 4,375
Amortization of debt issuance costs	1,072	985	800
Amortization of debt discount	7,544	6,927	5,629
Total interest expense	$ 13,616	$ 12,912	$ 10,804

As of December 31, 2016, the principal amount of the Convertible Notes was $200.0 million and the carrying value of the Convertible Notes was $179.4 million.

Convertible Bond Hedge and Warrant Transactions

In connection with the pricing of the Convertible Notes and 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 with the call spread counterparties. 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, the call spread counterparties 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. The convertible bond hedges are separate transactions entered into by us and are not part of the terms of the Convertible Notes or the warrants, discussed below. Holders of the Convertible Notes will not have any rights with respect to the convertible bond hedges. We paid $39.8 million for these convertible bond hedges and recorded this amount as a reduction to additional paid-in capital, net of tax, in 2014.

In February 2014, we also entered into separate warrant transactions with each of the call spread counterparties 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. The warrants were issued to the call spread counterparties pursuant to the exemption from registration set forth in Section 4(a)(2) of the Securities Act of 1933, as amended. We received $25.6 million for these warrants and recorded this amount to additional paid-in capital in 2014.

Aside from the initial payment of $39.8 million to the call spread counterparties for the convertible bond hedges, which was partially offset by the receipt of $25.6 million for the warrants, we are not required to make any cash payments to the call spread counterparties under the convertible bond hedges and will not receive any proceeds if the warrants are exercised.

Future Payments

Future annual principal payments on our long-term debt as of December 31, 2016 were as follows (in thousands):

Period	Future Annual Principal Payments
Year Ending December 31, 2017	$ 21,166
Year Ending December 31, 2018	17,500
Year Ending December 31, 2019	217,498
Year Ending December 31, 2020	17,500
Year Ending December 31, 2021	254,459
Thereafter	500,000
Total	$ 1,028,123

S. RESTRUCTURING

In connection with the CBR and Lumara Health acquisitions, we initiated restructuring programs in the third quarter of 2015 and the fourth quarter of 2014, respectively, which included severance benefit expenses primarily related to certain former CBR and Lumara Health employees. As a result of these restructurings, we recorded $0.7 million charges in 2016 as compared to $4.1 million in 2015. We expect to pay the remaining restructuring costs by the end of the first quarter of 2017.

The following table outlines the components of our restructuring expenses which were included in current liabilities for 2016 and 2015 (in thousands):

	Years Ended December 31,	
	2016	2015
Accrued restructuring, beginning of period	$ 2,883	$ 1,953
Employee severance, benefits and related costs	715	3,874
Payments	(3,524)	(2,944)
Accrued restructuring, end of period	$ 74	$ 2,883

T. CONSOLIDATED QUARTERLY FINANCIAL DATA - UNAUDITED

The following tables provide unaudited consolidated quarterly financial data for 2016 and 2015 (in thousands, except per share data):

	March 31, 2016	June 30, 2016	September 30, 2016	December 31, 2016
Total revenues	$ 109,300	$ 127,419	$ 143,782	$ 151,591
Gross profit (a)	85,474	84,563	113,092	116,349
Operating expenses	78,026	66,486	74,332	101,764
Net income (loss)	$ (7,527)	$ (596)	$ 16,196	$ (10,557)
Net income (loss) per share - basic	$ (0.22)	$ (0.02)	$ 0.47	$ (0.31)
Net income (loss) per share - diluted	$ (0.22)	$ (0.02)	$ 0.43	$ (0.31)

	March 31, 2015	June 30, 2015	September 30, 2015	December 31, 2015
Total revenues (b)	$ 89,505	$ 123,884	$ 96,152	$ 108,735
Gross profit (b)	68,479	104,205	73,803	83,288
Operating expenses (b)	39,671	43,081	75,188	60,615
Net income (loss) (c)	$ 12,904	$ 33,258	$ (20,584)	$ 7,201
Net income (loss) per share - basic	$ 0.47	$ 1.09	$ (0.62)	$ 0.21
Net income (loss) per share - diluted	$ 0.39	$ 0.82	$ (0.62)	$ 0.20

The sum of quarterly income (loss) per share totals differ from annual income (loss) per share totals due to rounding.

(a) Gross profit for the second quarter of 2016 includes the impairment charge of $15.7 million relating to the MuGard Rights intangible asset.

(b) In August 2015, we acquired CBR and recorded $24.1 million and $10.0 million in CBR service revenue and cost of services, respectively, in 2015 and additional operating costs incurred as a result of the acquisition.

(c) In August 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, which we recorded in other income (expense) in our 2015 consolidated statements of operations.

U. VALUATION AND QUALIFYING ACCOUNTS (IN THOUSANDS)

	Balance at Beginning of Period	Additions (a)	Deductions Charged to Reserves	Balance at End of Period
Year ended December 31, 2016:				
Allowance for doubtful accounts (a)	$ 900	$ 3,209	$ (948)	$ 3,161
Accounts receivable allowances (b)	$ 10,783	$ 122,792	$ (124,042)	$ 9,533
Rebates, fees and returns reserves	$ 45,162	$ 186,941	$ (142,637)	$ 89,466
Valuation allowance for deferred tax assets (c)	$ 11,859	$ 632	$ (11,062)	$ 1,429
Year ended December 31, 2015:				
Allowance for doubtful accounts (a)	$ —	$ 900	$ —	$ 900
Accounts receivable allowances (b)	$ 11,618	$ 93,887	$ (94,722)	$ 10,783
Rebates, fees and returns reserves	$ 43,892	$ 120,293	$ (119,023)	$ 45,162
Valuation allowance for deferred tax assets (c)	$ 33,557	$ —	$ (21,698)	$ 11,859
Year ended December 31, 2014:				
Accounts receivable allowances (b)	$ 2,728	$ 60,054	$ (51,164)	$ 11,618
Rebates, fees and returns reserves	$ 4,819	$ 52,548	$ (13,475)	$ 43,892
Valuation allowance for deferred tax assets (c)	$ 166,416	$ 20,299	$ (153,158)	$ 33,557

(a) Additions to allowance for doubtful accounts are recorded in selling, general and administrative expenses. Additions to rebates, fees and returns reserves are recorded as a reduction of revenues.

(b) These accounts receivable allowances represent discounts and other chargebacks related to the provision for our product sales.

(c) The valuation allowance for deferred tax assets includes purchase accounting adjustments and other activity related to our acquisition of Lumara Health.

V. RECENTLY ISSUED AND PROPOSED ACCOUNTING PRONOUNCEMENTS

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that are adopted by us as of the specified effective date.

In January 2017, the FASB issued ASU 2017-04, *Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment* ("ASU 2017-04"). This new standard eliminates Step 2 from the goodwill impairment test. ASU 2017-04 requires an entity to perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value. ASU 2017-04 still allows the option to perform a qualitative assessment for a reporting unit to determine if the quantitative impairment test is necessary. ASU 2017-04 is effective for any annual or interim goodwill impairment tests in the fiscal years beginning after December 15, 2019 and must be applied prospectively. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. We have adopted ASU 2017-01 as of January 1, 2017, with prospective application for our interim or annual goodwill impairment tests.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business* ("ASU 2017-01"). This new standard clarifies the definition of a business and provides a screen to determine when an integrated set of assets and activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. ASU 2017-01 will be effective for us on January 1, 2018. However, we have adopted ASU 2017-01 as of January 1, 2017, with prospective application to any business development transaction. Depending upon individual facts and circumstances of future transactions, this guidance will likely result in more transactions being accounted for as asset acquisitions rather than business combinations.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"). This new standard clarifies certain aspects of the statement of cash flows, including the classification of debt prepayment or debt extinguishment costs or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance policies, distributions received from equity method investees and beneficial interests in securitization transactions. This new standard also clarifies that an entity should determine each separately identifiable source of use within the cash receipts and payments on the basis of the nature of the underlying cash flows. In situations in which cash receipts and payments have aspects of more than one class of cash flows and cannot be separated by source or use, the appropriate classification should depend on the activity that is likely to be the predominant source or use of cash flows for the item. ASU 2016-15 will be effective for us on January 1, 2018. We are currently evaluating the impact of our adoption of ASU 2016-15 in our consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). The new standard requires entities to measure all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions and reasonable and supportable forecasts. ASU 2016-13 will be effective for us for fiscal years beginning on or after January 1, 2020, including interim periods within those annual reporting periods and early adoption is permitted. We are currently evaluating the impact of our adoption of ASU 2016-13 in our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09"). The new standard involves several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. ASU 2016-09 will be effective for us on January 1, 2017. We are currently evaluating the impact of our adoption of ASU 2016-09 in our consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). This new standard requires entities to recognize on its balance sheet assets and liabilities associated with the rights and obligations created by leases with terms greater than twelve months. This new standard is effective for annual reporting periods beginning after December 15, 2018, and interim periods within those annual periods and early adoption is permitted. We are currently evaluating the impact of ASU 2016-02 in our consolidated financial statements and we currently expect that most of our operating lease commitments will be subject to the new standard and recognized as operating lease liabilities and right-of-use assets upon our adoption of ASU 2016-02.

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities* ("ASU 2016-01"). This new standard amends certain aspects of accounting and disclosure requirements of financial instruments, including the requirement that equity investments with readily determinable fair values be measured at fair value with changes in fair value recognized in our results of operations. This new standard does not apply to investments accounted for under the equity method of accounting or those that result in consolidation of the investee. Equity investments that do not have readily determinable fair values may be measured at fair value or at cost minus impairment adjusted for changes in observable prices. A financial liability that is measured at fair value in accordance with the fair value option is required to be presented separately in other comprehensive income for the portion of the total change in the fair value resulting from change in the instrument-specific credit risk. In addition, a valuation allowance should be evaluated on deferred tax assets related to available-for-sale debt securities in combination with other deferred tax assets. ASU 2016-01 will be effective for us on January 1, 2018. The adoption of ASU 2016-01 is not expected to have a material impact on our financial position or results of operations.

In September 2015, the FASB issued ASU No. 2015-16, *Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments* ("ASU 2015-16"). ASU 2015-16 requires that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined and sets forth new disclosure requirements related to the adjustments. We adopted ASU 2015-16 as of January 1, 2016. See Note C, "*Business Combinations*" for additional information.

In July 2015, the FASB issued ASU No. 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory* ("ASU 2015-11"). The new standard applies only to inventory for which cost is determined by methods other than last-in, first-out and the retail inventory method, which includes inventory that is measured using first-in, first-out or average cost. Inventory within the scope of ASU 2015-11 is required to be measured at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. ASU 2015-11 will be effective for us on January 1, 2017. The adoption of ASU 2015-11 is not expected to have a material impact on our results of operations, cash flows or financial position.

In April 2015, the FASB issued ASU No. 2015-03, *Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs* ("ASU 2015-03"). The amendments in ASU 2015-03 require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. In August 2015, the FASB issued ASU No. 2015-15, *Interest - Imputation of Interest (Subtopic 835-30): Presentation and Subsequent Measurement of Debt Issuance Costs Associated with Line-of-Credit Arrangements* ("ASU 2015-15"), which allows presentation of debt issuance costs related to line-of-credit arrangements as either in accordance with the amendments in ASU 2015-03, or as an asset with subsequent amortization of the debt issuance costs ratably over the term of the arrangement. We adopted this guidance retrospectively in the first quarter of 2016. As a result, we presented $11.2 million of unamortized debt issuance costs as of December 31, 2015 as direct deductions from the carrying amounts of the related debt liabilities. We previously included the $11.2 million of unamortized debt issuance costs in "other long-term assets" in our condensed consolidated balance sheet as of December 31, 2015.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements - Going Concern: Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern ("*ASU 2014-15"). ASU 2014-15 is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures, if required. ASU 2014-15 will be effective for annual reporting periods ending after December 15, 2016, which will be our fiscal year ending December 31, 2016, and to annual and interim periods thereafter. We adopted ASU 2014-15 as of December 31, 2016 in our consolidated financial statements and related disclosures, which did not have a material impact on our results of operations, cash flows or financial position.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers, as a new Topic, Accounting Standards Codification Topic 606* ("ASU 2014-09"). The new revenue recognition standard provides a five-step analysis of transactions to determine when and how revenue is recognized. The core principle is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customer Topic 606s, Principal versus Agent Considerations*, which clarifies the implementation guidance

on principal versus agent considerations. In April 2016, the FASB issued ASU 2016-10, *Revenue from Contracts with Customers Topic 606, Identifying Performance Obligations and Licensing*, which clarifies certain aspects of identifying performance obligations and licensing implementation guidance. In May 2016, the FASB issued ASU 2016-12, *Revenue from Contracts with Customers Topic 606, Narrow-Scope Improvements and Practical Expedients*, related to disclosures of remaining performance obligations, as well as other amendments to guidance on collectibility, non-cash consideration and the presentation of sales and other similar taxes collected from customers. In December 2016, the FASB issued ASU No. 2016-20, T*echnical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers*, which amends certain narrow aspects of the guidance issued in ASU 2014-09 including guidance related to the disclosure of remaining performance obligations and prior-period performance obligations, as well as other amendments to the guidance on loan guarantee fees, contract costs, refund liabilities, advertising costs and the clarification of certain examples. We are currently evaluating the method of adoption and the potential impact that Topic 606 may have on our financial position and results of operations. These ASUs are effective for entities for interim and annual reporting periods beginning after December 15, 2017, including interim periods within that year, which for us is the period beginning January 1, 2018. Early adoption is permitted any time after the original effective date. Entities have the choice to apply these ASUs either retrospectively to each reporting period presented or by recognizing the cumulative effect of applying these standards at the date of initial application and not adjusting comparative information. We have not yet selected a transition method and are currently evaluating the impact of this standard in our consolidated financial statements.

W. SUBSEQUENT EVENTS

Palatin License Agreement

On January 8, 2017, we entered into a license agreement (the "Palatin License Agreement") with Palatin Technologies, Inc. ("Palatin") under which we acquired (a) an exclusive license in all countries of North America (the "Rekynda Territory"), with the right to grant sub-licenses, to research, develop and commercialize *Rekynda* and any other products containing bremelanotide (collectively, the "Rekynda Products"), an investigational product designed to be an on-demand treatment for hypoactive sexual desire disorder in pre-menopausal women, (b) a worldwide non-exclusive license, with the right to grant sub-licenses, to manufacture the Rekynda Products, and (c) a non-exclusive license in all countries outside the Rekynda Territory, with the right to grant sub-licenses, to research, develop and manufacture (but not commercialize) the Rekynda Products. Following the satisfaction of the conditions to closing under the Palatin License Agreement, the transaction closed on February 2, 2017.

Under the terms of the Palatin License Agreement, in February 2017 we paid Palatin $60.0 million as a one-time upfront payment and will reimburse Palatin up to an aggregate amount of $25.0 million for all reasonable, documented, out-of-pocket expenses incurred by Palatin in connection with the development and regulatory activities necessary to submit a new drug application in the U.S. for *Rekynda* for the treatment of hypoactive sexual desire disorder ("HSDD") in pre-menopausal women.

In addition, the Palatin License Agreement provides for future contingent payments of (a) up to $80.0 million upon achievement of certain regulatory milestones, including FDA approval and (b) up to $300.0 million of aggregate sales milestone payments upon the achievement of certain annual net sales milestones over the course of the license. The first sales milestone of $25.0 million will be triggered when *Rekynda* annual net sales exceed $250.0 million. We are also obligated to pay Palatin tiered royalties on annual net sales of the Rekynda Products, on a product-by-product basis, in the Rekynda Territory ranging from the high-single digits to the low double-digits. The royalties will expire on a product-by-product and country-by-country basis upon the latest to occur of (a) the earliest date on which there are no valid claims of Palatin patent rights covering such Rekynda Product in such country, (b) the expiration of the regulatory exclusivity period for such Rekynda Product in such country and (c) 10 years following the first commercial sale of such Rekynda Product in such country. These royalties are subject to reduction in the event that: (i) we must license additional third party intellectual property in order to develop, manufacture or commercialize a Rekynda Product or (ii) generic competition occurs with respect to a Rekynda Product in a given country, subject to an aggregate cap on such deductions of royalties otherwise payable to Palatin. After the expiration of the applicable royalties for any Rekynda Product in a given country, the license for such Rekynda Product in such country would become a fully paid-up, royalty-free, perpetual and irrevocable license.

Pending Endoceutics License Agreement

On February 13, 2017, we entered into a license agreement (the "Endoceutics License Agreement") with Endoceutics, Inc. ("Endoceutics") pursuant to which Endoceutics has agreed to grant to us rights to *Intrarosa*, an FDA-approved product for the treatment of moderate-to-severe dyspareunia (pain during sexual intercourse), a symptom of VVA due to menopause. The Endoceutics License Agreement grants us the right to develop and commercialize pharmaceutical products containing

dehydroepiandrosterone ("DHEA"), including *Intrarosa*, at dosage strengths of 13 mg or less per dose and formulated for intravaginal delivery, excluding any dosage strengths over 13 mg per dose and combinations with other active pharmaceutical ingredients, in the U.S. for the treatment of vulvar and vaginal atrophy ("VVA") and female sexual dysfunction ("FSD"). The closing of the transactions contemplated by the Endoceutics License Agreement (the "Effective Date") is subject to clearance under the Hart-Scott-Rodino Act and other customary closing conditions.

Subject to the terms of the Endoceutics License Agreement, Endoceutics has agreed to conduct clinical studies for the use of *Intrarosa* in FSD to support an application for regulatory approval for *Intrarosa* for the treatment of FSD in the U.S. We and Endoceutics have agreed to share the direct costs related to such studies based upon a negotiated allocation with us funding up to $20.0 million. We may, with Endoceutics' consent (not to be unreasonably withheld, conditioned or delayed), conduct any other studies of *Intrarosa* for the treatment of VVA and FSD anywhere in the world for the purpose of obtaining or maintaining regulatory approval of or commercializing *Intrarosa* for the treatment of VVA or FSD in the U.S. All data generated in connection with the above described studies would be owned by Endoceutics and licensed to us pursuant to the Endoceutics License Agreement.

We will have the exclusive right to commercialize *Intrarosa* for the treatment of VVA or FSD in the U.S., subject to the terms of the Endoceutics License Agreement, including having final decision making authority with respect to commercial strategy, pricing and reimbursement and other commercialization matters. We have agreed to use commercially reasonable efforts to market, promote and otherwise commercialize *Intrarosa* for the treatment of VVA or FSD in the U.S., including a commitment to a minimum marketing spend for *Intrarosa* in 2017. Endoceutics has the right to directly conduct, itself or through its affiliates or subcontractors, additional commercialization activities for *Intrarosa* for the treatment of VVA or FSD in the U.S., which scope of activities will be agreed to by the parties acting reasonably and in good faith, and has the right to conduct activities related generally to the field of intracinology, in each case, subject to our right to withhold approval in certain instances.

Upon Closing, we will make an upfront payment of $50.0 million and, subject to certain conditions, will issue 600,000 shares of unregistered common stock, to Endoceutics, 300,000 of which will be subject to a 180-day lock-up provision, and the other 300,000 of which will be subject to a one-year lock-up provision. We have also agreed to make a payment to Endoceutics of up to $10.0 million upon the delivery of launch quantities of *Intrarosa* and a payment of $10.0 million on the first anniversary of the closing. In addition, we have also agreed to pay tiered royalties to Endoceutics equal to a percentage of net sales of *Intrarosa* in the U.S. ranging from mid-teens (for calendar year net sales up to $150.0 million) to mid twenty percent (for any calendar year net sales that exceed $1 billion) (such royalty rate to be dependent on the aggregate annual net sales of *Intrarosa*) for the commercial life of *Intrarosa*, with deductions (a) after the later of (i) the expiration date of the last to expire of a licensed patent containing a valid patent claim or (ii) ten years after the first commercial sale of *Intrarosa* for the treatment of VVA or FSD in the U.S., (b) for generic competition and (c) for third party payments. Endoceutics is also eligible to receive certain sales milestone payments, including a first sales milestone payment of $15.0 million, which would be triggered when *Intrarosa* annual net U.S. sales exceed $150.0 million, and a second milestone payment of $30.0 million, which would be triggered when annual net U.S. sales exceed $300.0 million. If annual net U.S. sales exceed $500.0 million, there are additional sales milestone payments totaling up to $850.0 million, which would be triggered at various increasing sales thresholds.

In connection with the Endoceutics License Agreement, we and Endoceutics have agreed to enter into an exclusive commercial supply agreement on or about the Effective Date, pursuant to which Endoceutics, itself or through affiliates or contract manufacturers, would agree to manufacture and supply *Intrarosa* to us (the "Supply Agreement") and would be our exclusive supplier of *Intrarosa* in the U.S., subject to certain rights for us to manufacture and supply *Intrarosa* in the event of a cessation notice or supply failure (as such terms are defined in the Supply Agreement). Under the Supply Agreement, Endoceutics would maintain at all times a second source supplier for the manufacture of DHEA and the drug product and identify and validate and transfer manufacturing intellectual property to the second source supplier within two years of the Effective Date. The Supply Agreement will remain in effect until the termination of the Endoceutics License Agreement, unless terminated earlier by either party for an uncured material breach or insolvency of the other party, or by us if we exercise our rights to manufacture and supply *Intrarosa* following a cessation notice or supply failure.

Under the Endoceutics License Agreement, except as permitted under the Endoceutics License Agreement or the Supply Agreement, and except for any compounds or products affecting the melanocortin receptor pathway, including without limitation, bremelanotide (collectively, "Excluded Product"), we will not be permitted to research, develop, manufacture, or commercialize (i) DHEA for delivery by any route of administration anywhere in world, (ii) any compound (including DHEA) or product for use in VVA anywhere in the world, or (iii) commencing on the date of an approval of *Intrarosa* for the treatment of FSD in the U.S. and continuing for the remainder of the term of the Endoceutics License Agreement, any compound (including DHEA) for use in FSD (each, a "Competing Product"). Any compound or product for use in FSD that would be a Competing Product in the United States but that (i) does not contain DHEA and (ii) was acquired or licensed or for which the

research, development, manufacture or commercialization of such compound or product is initiated by us or our affiliates, in each case, prior to the date of an approval of *Intrarosa* for the treatment of FSD in the U.S., will be an Excluded Product and will not be subject to the exclusivity obligations under the Endoceutics License Agreement in the treatment of FSD, subject to certain restrictions in the Endoceutics License Agreement. These noncompete restrictions are subject to certain exclusions relating to the acquisition of competing programs.

The Endoceutics License Agreement expires on the date of expiration of all royalty obligations due thereunder unless earlier terminated in accordance with the Endoceutics License Agreement. The Endoceutics License Agreement may be terminated by either Party if the Effective Date has not occurred within 180 days following the execution date or such date as the parties may mutually agree. The Endoceutics License Agreement may be terminated by either Party for material breach that is either uncured after a 90-day notice period, or if such breach cannot be cured within such 90-day period, if the breaching party does not commence appropriate and material actions to cure such breach within the notice period and continue to diligently cure such breach for a period not to exceed 90 days, in either case, subject to tolling or determination of the arbitrators, if dispute resolution procedures are initiated within 30 days of the termination notice. We have the ability to elect not to terminate the Endoceutics License Agreement in the case of a material breach, in which case future milestone and royalty payments owed to Endoceutics would be reduced by a negotiated percentage or by an amount determined by arbitration. Either party may terminate under certain situations relating to the bankruptcy or insolvency of the other party. We may terminate the Endoceutics License Agreement for a valid business reason upon 365 days prior written notice to Endoceutics; or upon 60 days written notice in the event we reasonably determine in good faith, after due inquiry and after discussions with Endoceutics, that we cannot reasonably continue to develop or commercialize any Product as a result of a safety issue regarding the use of *Intrarosa*. We may also terminate the Endoceutics License Agreement upon 180 days notice if there is a change of control of AMAG and the acquiring entity (alone or with its affiliates) is engaged in a competing program (as defined in the Licensed Agreement) in the U.S. or in at least three countries within the European Union.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE:

None.

ITEM 9A. CONTROLS AND PROCEDURES:

Managements' Evaluation of our Disclosure Controls and Procedures

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our "disclosure controls and procedures" (as defined in the Exchange Act Rule 13a-15(e), or Rule 15d-15(e)), with the participation of our management, have each concluded that, as of December 31, 2016, the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures were designed and were effective to provide reasonable assurance that information we are required to disclose in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. It should be noted that any system of controls is designed to provide reasonable, but not absolute, assurances that the system will achieve its stated goals under all reasonably foreseeable circumstances.

Management's Annual Report on Internal Control Over Financial Reporting

Management's Report on Internal Control over Financial Reporting is contained in Part II, Item 8 "Financial Statements and Supplementary Data" of this Annual Report on Form 10-K for the year ended December 31, 2016 and is incorporated herein by reference.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) that occurred during the three months ended December 31, 2016 that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION:

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE:

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which we plan to file with the Securities and Exchange Commission (the "SEC") not later than 120 days after the close of our year ended December 31, 2016.

ITEM 11. EXECUTIVE COMPENSATION:

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which we plan to file with the SEC not later than 120 days after the close of our year ended December 31, 2016.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS:

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which we plan to file with the SEC not later than 120 days after the close of our year ended December 31, 2016.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE:

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which we plan to file with the SEC not later than 120 days after the close of our year ended December 31, 2016.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES:

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which we plan to file with the SEC not later than 120 days after the close of our year ended December 31, 2016.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES:

Exhibit Number	Description
2.1	Agreement and Plan of Merger, dated as of September 28, 2014, by and among Lumara Health Inc., AMAG Pharmaceuticals, Inc., Snowbird, Inc., and Lunar Representative, LLC as the Stockholders' Representative (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed September 29, 2014, File No. 001-10865)
2.2	Stock Purchase Agreement, dated as of June 29, 2015, by and among CBR Holdco, LLC, CBR Acquisition Holdings Corp. and AMAG Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed June 29, 2015, File No. 001-10865)
3.1, 4.1	Certificate of Incorporation of AMAG Pharmaceuticals, Inc., as restated (incorporated herein by reference to Exhibits 3.1 and 4.1to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, File No. 001-10865)
3.2,4.2	Certificate of Amendment to Restated Certificate of Incorporation of AMAG Pharmaceuticals, Inc. as filed on May 21, 2015 with the Delaware Secretary of State (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed May 28, 2015, File No. 001-10865)
3.3, 4.3	Amended and Restated By-Laws of AMAG Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed December 17, 2015, File No. 001-10865)
3.4, 4.4	Certificate of Designation of Series A Junior Participating Preferred Stock (incorporated herein by reference to Exhibits 3.1 and 4.1 to the Company's Current Report on Form 8-K filed September 4, 2009, File No. 0-14732)
4.6	Specimen certificate representing AMAG Pharmaceuticals, Inc.'s Common Stock (incorporated herein by reference to Exhibit 4.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2009, File No. 001-10865)
4.7	Rights Agreement, dated as of September 4, 2009 by and between AMAG Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, LLC (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed September 4, 2009, File No. 0-14732)
4.8	Amendment to Rights Agreement, dated as of May 10, 2012, by and between AMAG Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, LLC (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed May 10, 2012, File No. 001-10865)
4.9	Amendment to Rights Agreement, dated as of February 11, 2014, by and between AMAG Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, LLC (incorporated herein by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
4.10	NOL Amendment to Rights Agreement, dated as of September 26, 2014, by and between AMAG Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, LLC (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed September 29, 2014, File No. 001-10865)
4.11	Form of Rights Certificate (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed September 4, 2009, File No. 0-14732)
4.12	Base Indenture, dated as of February 14, 2014, by and between AMAG Pharmaceuticals, Inc. and Wilmington Trust, National Association (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
4.13	First Supplemental Indenture, dated as of February 14, 2014, by and between AMAG Pharmaceuticals, Inc. and Wilmington Trust, National Association (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
4.14	Form of 2.50% Convertible Senior Note due 2019 (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
4.16	Indenture, dated as of August 17, 2015, by and among AMAG Pharmaceuticals, Inc., the Guarantors party thereto and Wilmington Trust, National Association, as trustee (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed August 17, 2015, File No. 001-10865)
4.17	Form of 7.875% Senior Note due 2023 (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed August 17, 2015, File No. 001-10865)
10.1*	Representative Form of Indemnification Agreement (incorporated herein by reference to Exhibit 10.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2009, File No. 001-10865)

10.2*	AMAG Pharmaceuticals, Inc.'s Non-Employee Director Compensation Policy (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, File No. 001-10865)
10.3*	AMAG Pharmaceuticals, Inc.'s Amended and Restated 2000 Stock Plan (incorporated herein by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A filed December 14, 2005, File No. 0-14732)
10.4*	AMAG Pharmaceuticals, Inc.'s Third Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A filed April 19, 2013, File No. 001-10865)
10.5*	First Amendment to the AMAG Pharmaceuticals, Inc. Third Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Appendix B to the Company's Definitive Proxy Statement on Schedule 14A filed April 16, 2015, File No. 001-10865)
10.6*	Second Amendment to the AMAG Pharmaceuticals, Inc. Third Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A filed April 15, 2016, File No. 001-10865)
10.7*	AMAG Pharmaceuticals, Inc. 2015 Employee Stock Purchase Plan (incorporated herein by reference to Appendix C to the Company's Definitive Proxy Statement on Schedule 14A filed April 16, 2015, File No. 001-10865)
10.8*	Lumara Health Inc. Amended and Restated 2013 Incentive Compensation Plan (incorporated herein by reference to Exhibit 10.6 to the Company's Annual Report on Form 10-K for the year ended December 31, 2014, File No. 001-10865)
10.9*	Form of Incentive Stock Option Agreement for AMAG Pharmaceuticals, Inc. Employees under AMAG Pharmaceuticals, Inc.'s Third Amended and Restated 2007 Equity Incentive Plan and the Lumara Health Inc. Amended and Restated 2013 Incentive Compensation Plan (incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, File No. 001-10865)
10.10*	Form of Non-Qualified Stock Option Agreement for AMAG Pharmaceuticals, Inc. Employees under AMAG Pharmaceuticals, Inc.'s Third Amended and Restated 2017 Equity Incentive Plan and the Lumara Health Inc. Amended and Restated 2013 Incentive Compensation Plan (incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, File No. 001-10865)
10.11*	Form of Restricted Stock Unit Agreement for AMAG Pharmaceuticals, Inc. Employees under AMAG Pharmaceuticals, Inc.'s Third Amended and Restated 2007 Equity Incentive Plan and the Lumara Health Inc. Amended and Restated 2013 Incentive Compensation Plan (incorporated herein by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015, File No. 001-10865)
10.12*	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors under AMAG Pharmaceuticals, Inc.'s Third Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.10 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, File No. 001-10865)
10.13*	Form of Restricted Stock Unit Agreement for Non-Employee Directors under AMAG Pharmaceuticals, Inc.'s Third Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, File No. 001-10865)
10.14*	Non-Plan Restricted Stock Unit Agreement, by and between AMAG Pharmaceuticals, Inc. and William K. Heiden (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed May 10, 2012, File No. 001-10865)
10.15*	Non-Plan Stock Option Agreement, by and between AMAG Pharmaceuticals, Inc. and William K. Heiden (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed May 10, 2012, File No. 001-10865)
10.16*	Form of Non-Qualified Stock Option Agreement - Non-Plan Inducement Grant (incorporated herein by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-8 filed August 7, 2013, File No. 333-190435)
10.17*	Form of Restricted Stock Unit Agreement - Non-Plan Inducement Grant (incorporated herein by reference to Exhibit 10.18 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015, File No. 001-10865)
10.18*	Form of Employment Agreement between AMAG Pharmaceuticals, Inc. and each of its executive officers (other than William K. Heiden) (incorporated herein by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015, File No. 001-10865)

10.19*	Employment Agreement dated as of February 7, 2014 between AMAG Pharmaceuticals, Inc. and William K. Heiden (incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2014, File No. 001-10865)
10.20	Lease Agreement, dated as of May 22, 2008, by and between AMAG Pharmaceuticals, Inc. and Mortimer B. Zuckerman and Edward H. Linde, trustees of 92 Hayden Avenue Trust under Declaration of Trust dated August 18, 1983. This Lease Agreement was assigned in June 2013. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 29, 2008, File No. 0-14732)
10.21	Assignment and Assumption of Lease, dated as of June 10, 2013, by and among AMAG Pharmaceuticals, Inc., Mortimer B. Zuckerman and Edward H. Linde, trustees of 92 Hayden Avenue Trust under Declaration of Trust dated August 18, 1983 and Shire Human Genetic Therapies, Inc. (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed June 13, 2013, File No. 001-10865)
10.22	Lease Agreement, dated as of June 10, 2013, by and between AMAG Pharmaceuticals, Inc. and BP BAY COLONY LLC (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 13, 2013, File No. 001-10865)
10.23	First Amendment to Lease Agreement, dated June 10, 2013, by and between AMAG Pharmaceuticals, Inc. and BP BAY COLONY LLC, dated March 24, 2015 (incorporated herein by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, File No. 001-10865)
10.24	Second Amendment to Lease Agreement, dated June 10, 2013, by and between AMAG Pharmaceuticals, Inc. and BP BAY COLONY LLC, dated December 4, 2015 (incorporated herein by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015, File No. 001-10865)
10.25	Third Amendment to Lease Agreement, dated June 10, 2013, by and between AMAG Pharmaceuticals, Inc. and BP BAY COLONY LLC, dated December 7, 2015 (incorporated herein by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015, File No. 001-10865)
10.26	License Agreement between AMAG Pharmaceuticals, Inc. and Abeona Therapeutics, Inc. (formerly known as PlasmaTech Biopharmaceuticals, Inc. and Access Pharmaceuticals, Inc.) dated as of June 6, 2013 (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, File No. 001-10865) (confidential treatment previously granted)
10.27	Commercial Supply Agreement, dated effective as of August 29, 2012, by and between AMAG Pharmaceuticals, Inc. and Sigma-Aldrich, Inc. (incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012, File No. 001-10865) (confidential treatment previously granted)
10.28	Amendment No.1 to Commercial Supply Agreement, dated October 3, 2013, by and between AMAG Pharmaceuticals, Inc. and Sigma-Aldrich, Inc. (incorporated herein by reference to Exhibit 10.54 to the Company's Annual Report on Form 10-K for the year ended December 31, 2013, File No. 001-10865) (confidential treatment previously granted)
10.29	Amendment No. 2 to Commercial Supply Agreement, dated April 28, 2015, by and between AMAG Pharmaceuticals, Inc. and Sigma-Aldrich, Inc. (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, File No. 001-10865) (confidential treatment previously granted)
10.30	Amendment No. 3 to Commercial Supply Agreement, dated October 19, 2015, by and between the Company and Sigma-Aldrich, Inc. (incorporated herein by reference to Exhibit 10.36 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015, File No. 001-10865) (confidential treatment previously granted)
10.31	Pharmaceutical Manufacturing and Supply Agreement, dated effective as of January 8, 2010, by and between AMAG Pharmaceuticals, Inc. and Patheon Manufacturing Services LLC (as assignee from DSM Pharmaceuticals, Inc.) (incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012, File No. 001-10865) (confidential treatment previously granted)
10.32	Amendment No. 1 to Pharmaceutical Manufacturing and Supply Agreement, dated July 5, 2014, by and between AMAG Pharmaceuticals, Inc. and Patheon Manufacturing Services LLC (as assignee from DSM Pharmaceuticals, Inc.) (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, File No. 001-10865)
10.33	Amendment No. 2 to Pharmaceutical Manufacturing and Supply Agreement, dated June 19, 2015, by and between AMAG Pharmaceuticals, Inc. and Patheon Manufacturing Services LLC (as assignee from DPI Newco LLC as assignee from DSM Pharmaceuticals, Inc.) (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, File No. 001-10865) (confidential treatment previously granted)

10.34+	Amended and Restated Technical Transfer and Supply Agreement, dated as of December 19, 2016, by and between AMAG Pharmaceuticals, Inc. and the Pfizer CentreOne Group of Pfizer, Inc. (Certain confidential information contained in this exhibit was omitted by means of redacting a portion of the text and replacing it with [***]. This exhibit has been filed separately with the SEC without any redactions pursuant to a Confidential Treatment Request under Rule 24b-2 of the Securities and Exchange Act of 1934, as amended)
10.35	Development and License Agreement, dated September 30, 2014, by and between Lumara Health Inc and Antares Pharma, Inc. (incorporated herein by reference to Exhibit 10.42 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015, File No. 001-10865) (confidential treatment previously granted)
10.36	License Agreement, dated January 8, 2017, by and between AMAG Pharmaceuticals, Inc. and Palatin Technologies, Inc., (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed February 3, 2017, File No. 001-10865) (Certain confidential information contained in this exhibit was omitted by means of redacting a portion of the text and replacing it with [***]. This exhibit has been filed separately with the SEC without any redactions pursuant to a Confidential Treatment Request under Rule 24b-2 of the Securities and Exchange Act of 1934, as amended)
10.37	Termination Agreement, dated December 29, 2014, by and between AMAG Pharmaceuticals, Inc. and Takeda Pharmaceutical Company Limited (incorporated herein by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011, File No. 001-10865) (confidential treatment previously granted)
10.38	Underwriting Agreement, dated as of February 11, 2014, among AMAG Pharmaceuticals, Inc. and J.P. Morgan Securities LLC, on its own behalf and as representative of the several underwriters named in Schedule 1 thereto (incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.39	Base Call Option Transaction Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association, London Branch (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.40	Base Call Option Transaction Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and Royal Bank of Canada (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.41	Base Call Option Transaction Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and Morgan Stanley & Co. International plc (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.42	Base Warrants Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association, London Branch (incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.43	Amendment to Warrant Transaction, dated as of February 23, 2015, by and between AMAG Pharmaceuticals, Inc. and J.P. Morgan Securities LLC, as agent (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, File No. 001-10865)
10.44	Base Warrants Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and Royal Bank of Canada (incorporated herein by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.45	Base Warrants Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and Morgan Stanley & Co. International plc (incorporated herein by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.46	Additional Call Option Transaction Confirmation, dated as of February 13, 2014, between AMAG Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association, London Branch (incorporated herein by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.47	Additional Call Option Transaction Confirmation, dated as of February 13, 2014, between AMAG Pharmaceuticals, Inc. and Royal Bank of Canada (incorporated herein by reference to Exhibit 10.8 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.48	Additional Call Option Transaction Confirmation, dated as of February 13, 2014, between AMAG Pharmaceuticals, Inc. and Morgan Stanley & Co. International plc (incorporated herein by reference to Exhibit 10.9 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)

10.49	Additional Warrants Confirmation, dated as of February 13, 2014, between AMAG Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association, London Branch (incorporated herein by reference to Exhibit 10.10 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.50	Additional Warrants Confirmation, dated as of February 13, 2014, between AMAG Pharmaceuticals, Inc. and Royal Bank of Canada (incorporated herein by reference to Exhibit 10.11 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.51	Additional Warrants Confirmation, dated as of February 13, 2014, between AMAG Pharmaceuticals, Inc. and Morgan Stanley & Co. International plc (incorporated herein by reference to Exhibit 10.12 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.52	Credit Agreement, dated as of November 12, 2014, by and among AMAG Pharmaceuticals, Inc., the financial institutions and agents listed therein, and Jefferies Finance LLC (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed November 12, 2014, File No. 001-10865)
10.53	First Amendment to Credit Agreement, dated March 31, 2015, by and among AMAG Pharmaceuticals, Inc., the Lenders named therein, and Jefferies Finance LLC, as administrative agent (incorporated herein by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, File No. 001-10865)
10.54	Credit Agreement, dated as of August 17, 2015, by and among AMAG Pharmaceuticals, Inc., the financial institutions and agents listed therein, and Jefferies Finance LLC (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 17, 2015, File No. 001-10865)
10.55	Underwriting Agreement, dated as of July 30, 2015, among AMAG Pharmaceuticals, Inc., Jefferies LLC and Barclays Capital Inc., as representatives of the underwriters named therein (incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed July 31, 2015, File No. 001-10865)
10.56	Underwriting Agreement, dated as of February 25, 2015, among AMAG Pharmaceuticals, Inc., J.P. Morgan Securities LLC and Deutsche Bank Securities Inc., as representatives of the underwriters named therein (incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed February 26, 2015, File No. 001-10865)
21.1+	Subsidiaries of AMAG Pharmaceuticals, Inc.
23.1+	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm
24.1	Power of Attorney (included on the signature page(s) hereto)
31.1+	Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2+	Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS+	XBRL Instance Document
101.SCH+	XBRL Taxonomy Extension Schema Document
101.CAL+	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB+	XBRL Taxonomy Extension Label Linkbase Document
101.PRE+	XBRL Taxonomy Extension Presentation Linkbase Document

+	Exhibits marked with a plus sign ("+") are filed herewith.
++	Exhibits marked with a double plus sign ("++") are furnished herewith.
*	Exhibits marked with a single asterisk reference management contracts, compensatory plans or arrangements, filed in response to Item 15(a)(3) of the instructions to Form 10-K.

The other exhibits listed have previously been filed with the SEC and are incorporated herein by reference, as indicated.

Exhibits. We hereby file or furnish as exhibits, as the case may be, to this Form 10-K those exhibits listed in Part IV, Item 15(a)(3) above.

Financial Statement Schedules. No financial statement schedules have been submitted because they are not required, not applicable, or because the information required is included in the financial statements or the notes thereto.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AMAG PHARMACEUTICALS, INC.

By: /s/ William K. Heiden
William K. Heiden
Chief Executive Officer

Date: February 17, 2017

We, the undersigned officers and directors of AMAG Pharmaceuticals, Inc., hereby severally constitute and appoint William K. Heiden and Edward Myles, and each of them singly, our true and lawful attorneys, with full power to them and each of them singly, to sign for us in our names in the capacities indicated below, all amendments to this report, and generally to do all things in our names and on our behalf in such capacities to enable AMAG Pharmaceuticals, Inc. to comply with the provisions of the Securities Exchange Act of 1934, as amended, and all requirements of the Securities and Exchange Commission.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ William K. Heiden William K. Heiden	Chief Executive Officer (Principal Executive Officer) and Director	February 17, 2017
/s/ Edward Myles Edward Myles	Senior Vice President of Finance, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	February 17, 2017
/s/ Barbara Deptula Barbara Deptula	Director	February 17, 2017
/s/ John Fallon, M.D. John Fallon, M.D.	Director	February 17, 2017
/s/ Brian P. Kelley Brian P. Kelley	Director	February 17, 2017
/s/ Robert J. Perez Robert J. Perez	Director	February 17, 2017
/s/ Lesley Russell, MB. Ch.B., MRCP Lesley Russell, MB. Ch.B., MRCP	Director	February 17, 2017
/s/ Gino Santini Gino Santini	Director	February 17, 2017
/s/ Davey S. Scoon Davey S. Scoon	Director	February 17, 2017
/s/ James Sulat James Sulat	Director	February 17, 2017

Exhibit Number	Description
2.1	Agreement and Plan of Merger, dated as of September 28, 2014, by and among Lumara Health Inc., AMAG Pharmaceuticals, Inc., Snowbird, Inc., and Lunar Representative, LLC as the Stockholders' Representative (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed September 29, 2014, File No. 001-10865)
2.2	Stock Purchase Agreement, dated as of June 29, 2015, by and among CBR Holdco, LLC, CBR Acquisition Holdings Corp. and AMAG Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed June 29, 2015, File No. 001-10865)
3.1, 4.1	Certificate of Incorporation of AMAG Pharmaceuticals, Inc., as restated (incorporated herein by reference to Exhibits 3.1 and 4.1to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, File No. 001-10865)
3.2,4.2	Certificate of Amendment to Restated Certificate of Incorporation of AMAG Pharmaceuticals, Inc. as filed on May 21, 2015 with the Delaware Secretary of State (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed May 28, 2015, File No. 001-10865)
3.3, 4.3	Amended and Restated By-Laws of AMAG Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed December 17, 2015, File No. 001-10865)
3.4, 4.4	Certificate of Designation of Series A Junior Participating Preferred Stock (incorporated herein by reference to Exhibits 3.1 and 4.1 to the Company's Current Report on Form 8-K filed September 4, 2009, File No. 0-14732)
4.6	Specimen certificate representing AMAG Pharmaceuticals, Inc.'s Common Stock (incorporated herein by reference to Exhibit 4.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2009, File No. 001-10865)
4.7	Rights Agreement, dated as of September 4, 2009 by and between AMAG Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, LLC (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed September 4, 2009, File No. 0-14732)
4.8	Amendment to Rights Agreement, dated as of May 10, 2012, by and between AMAG Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, LLC (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed May 10, 2012, File No. 001-10865)
4.9	Amendment to Rights Agreement, dated as of February 11, 2014, by and between AMAG Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, LLC (incorporated herein by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
4.10	NOL Amendment to Rights Agreement, dated as of September 26, 2014, by and between AMAG Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, LLC (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed September 29, 2014, File No. 001-10865)
4.11	Form of Rights Certificate (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed September 4, 2009, File No. 0-14732)
4.12	Base Indenture, dated as of February 14, 2014, by and between AMAG Pharmaceuticals, Inc. and Wilmington Trust, National Association (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
4.13	First Supplemental Indenture, dated as of February 14, 2014, by and between AMAG Pharmaceuticals, Inc. and Wilmington Trust, National Association (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
4.14	Form of 2.50% Convertible Senior Note due 2019 (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
4.16	Indenture, dated as of August 17, 2015, by and among AMAG Pharmaceuticals, Inc., the Guarantors party thereto and Wilmington Trust, National Association, as trustee (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed August 17, 2015, File No. 001-10865)
4.17	Form of 7.875% Senior Note due 2023 (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed August 17, 2015, File No. 001-10865)
10.1*	Representative Form of Indemnification Agreement (incorporated herein by reference to Exhibit 10.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2009, File No. 001-10865)

10.2*	AMAG Pharmaceuticals, Inc.'s Non-Employee Director Compensation Policy (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, File No. 001-10865)
10.3*	AMAG Pharmaceuticals, Inc.'s Amended and Restated 2000 Stock Plan (incorporated herein by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A filed December 14, 2005, File No. 0-14732)
10.4*	AMAG Pharmaceuticals, Inc.'s Third Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A filed April 19, 2013, File No. 001-10865)
10.5*	First Amendment to the AMAG Pharmaceuticals, Inc. Third Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Appendix B to the Company's Definitive Proxy Statement on Schedule 14A filed April 16, 2015, File No. 001-10865)
10.6*	Second Amendment to the AMAG Pharmaceuticals, Inc. Third Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A filed April 15, 2016, File No. 001-10865)
10.7*	AMAG Pharmaceuticals, Inc. 2015 Employee Stock Purchase Plan (incorporated herein by reference to Appendix C to the Company's Definitive Proxy Statement on Schedule 14A filed April 16, 2015, File No. 001-10865)
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10.18*	Form of Employment Agreement between AMAG Pharmaceuticals, Inc. and each of its executive officers (other than William K. Heiden) (incorporated herein by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015, File No. 001-10865)

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10.20	Lease Agreement, dated as of May 22, 2008, by and between AMAG Pharmaceuticals, Inc. and Mortimer B. Zuckerman and Edward H. Linde, trustees of 92 Hayden Avenue Trust under Declaration of Trust dated August 18, 1983. This Lease Agreement was assigned in June 2013. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 29, 2008, File No. 0-14732)
10.21	Assignment and Assumption of Lease, dated as of June 10, 2013, by and among AMAG Pharmaceuticals, Inc., Mortimer B. Zuckerman and Edward H. Linde, trustees of 92 Hayden Avenue Trust under Declaration of Trust dated August 18, 1983 and Shire Human Genetic Therapies, Inc. (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed June 13, 2013, File No. 001-10865)
10.22	Lease Agreement, dated as of June 10, 2013, by and between AMAG Pharmaceuticals, Inc. and BP BAY COLONY LLC (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 13, 2013, File No. 001-10865)
10.23	First Amendment to Lease Agreement, dated June 10, 2013, by and between AMAG Pharmaceuticals, Inc. and BP BAY COLONY LLC, dated March 24, 2015 (incorporated herein by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, File No. 001-10865)
10.24	Second Amendment to Lease Agreement, dated June 10, 2013, by and between AMAG Pharmaceuticals, Inc. and BP BAY COLONY LLC, dated December 4, 2015 (incorporated herein by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015, File No. 001-10865)
10.25	Third Amendment to Lease Agreement, dated June 10, 2013, by and between AMAG Pharmaceuticals, Inc. and BP BAY COLONY LLC, dated December 7, 2015 (incorporated herein by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015, File No. 001-10865)
10.26	License Agreement between AMAG Pharmaceuticals, Inc. and Abeona Therapeutics, Inc. (formerly known as PlasmaTech Biopharmaceuticals, Inc. and Access Pharmaceuticals, Inc.) dated as of June 6, 2013 (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, File No. 001-10865) (confidential treatment previously granted)
10.27	Commercial Supply Agreement, dated effective as of August 29, 2012, by and between AMAG Pharmaceuticals, Inc. and Sigma-Aldrich, Inc. (incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012, File No. 001-10865) (confidential treatment previously granted)
10.28	Amendment No.1 to Commercial Supply Agreement, dated October 3, 2013, by and between AMAG Pharmaceuticals, Inc. and Sigma-Aldrich, Inc. (incorporated herein by reference to Exhibit 10.54 to the Company's Annual Report on Form 10-K for the year ended December 31, 2013, File No. 001-10865) (confidential treatment previously granted)
10.29	Amendment No. 2 to Commercial Supply Agreement, dated April 28, 2015, by and between AMAG Pharmaceuticals, Inc. and Sigma-Aldrich, Inc. (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, File No. 001-10865) (confidential treatment previously granted)
10.30	Amendment No. 3 to Commercial Supply Agreement, dated October 19, 2015, by and between the Company and Sigma-Aldrich, Inc. (incorporated herein by reference to Exhibit 10.36 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015, File No. 001-10865) (confidential treatment previously granted)
10.31	Pharmaceutical Manufacturing and Supply Agreement, dated effective as of January 8, 2010, by and between AMAG Pharmaceuticals, Inc. and Patheon Manufacturing Services LLC (as assignee from DSM Pharmaceuticals, Inc.) (incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012, File No. 001-10865) (confidential treatment previously granted)
10.32	Amendment No. 1 to Pharmaceutical Manufacturing and Supply Agreement, dated July 5, 2014, by and between AMAG Pharmaceuticals, Inc. and Patheon Manufacturing Services LLC (as assignee from DSM Pharmaceuticals, Inc.) (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, File No. 001-10865)
10.33	Amendment No. 2 to Pharmaceutical Manufacturing and Supply Agreement, dated June 19, 2015, by and between AMAG Pharmaceuticals, Inc. and Patheon Manufacturing Services LLC (as assignee from DPI Newco LLC as assignee from DSM Pharmaceuticals, Inc.) (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, File No. 001-10865) (confidential treatment previously granted)

10.34+	Amended and Restated Technical Transfer and Supply Agreement, dated as of December 19, 2016, by and between AMAG Pharmaceuticals, Inc. and the Pfizer CentreOne Group of Pfizer, Inc. (Certain confidential information contained in this exhibit was omitted by means of redacting a portion of the text and replacing it with [***]. This exhibit has been filed separately with the SEC without any redactions pursuant to a Confidential Treatment Request under Rule 24b-2 of the Securities and Exchange Act of 1934, as amended)
10.35	Development and License Agreement, dated September 30, 2014, by and between Lumara Health Inc and Antares Pharma, Inc. (incorporated herein by reference to Exhibit 10.42 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015, File No. 001-10865) (confidential treatment previously granted)
10.36	License Agreement, dated January 8, 2017, by and between AMAG Pharmaceuticals, Inc. and Palatin Technologies, Inc., (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed February 3, 2017, File No. 001-10865) (Certain confidential information contained in this exhibit was omitted by means of redacting a portion of the text and replacing it with [***]. This exhibit has been filed separately with the SEC without any redactions pursuant to a Confidential Treatment Request under Rule 24b-2 of the Securities and Exchange Act of 1934, as amended)
10.37	Termination Agreement, dated December 29, 2014, by and between AMAG Pharmaceuticals, Inc. and Takeda Pharmaceutical Company Limited (incorporated herein by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011, File No. 001-10865) (confidential treatment previously granted)
10.38	Underwriting Agreement, dated as of February 11, 2014, among AMAG Pharmaceuticals, Inc. and J.P. Morgan Securities LLC, on its own behalf and as representative of the several underwriters named in Schedule 1 thereto (incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.39	Base Call Option Transaction Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association, London Branch (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.40	Base Call Option Transaction Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and Royal Bank of Canada (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.41	Base Call Option Transaction Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and Morgan Stanley & Co. International plc (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.42	Base Warrants Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association, London Branch (incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.43	Amendment to Warrant Transaction, dated as of February 23, 2015, by and between AMAG Pharmaceuticals, Inc. and J.P. Morgan Securities LLC, as agent (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, File No. 001-10865)
10.44	Base Warrants Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and Royal Bank of Canada (incorporated herein by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.45	Base Warrants Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and Morgan Stanley & Co. International plc (incorporated herein by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.46	Additional Call Option Transaction Confirmation, dated as of February 13, 2014, between AMAG Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association, London Branch (incorporated herein by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.47	Additional Call Option Transaction Confirmation, dated as of February 13, 2014, between AMAG Pharmaceuticals, Inc. and Royal Bank of Canada (incorporated herein by reference to Exhibit 10.8 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.48	Additional Call Option Transaction Confirmation, dated as of February 13, 2014, between AMAG Pharmaceuticals, Inc. and Morgan Stanley & Co. International plc (incorporated herein by reference to Exhibit 10.9 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)

10.49	Additional Warrants Confirmation, dated as of February 13, 2014, between AMAG Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association, London Branch (incorporated herein by reference to Exhibit 10.10 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.50	Additional Warrants Confirmation, dated as of February 13, 2014, between AMAG Pharmaceuticals, Inc. and Royal Bank of Canada (incorporated herein by reference to Exhibit 10.11 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.51	Additional Warrants Confirmation, dated as of February 13, 2014, between AMAG Pharmaceuticals, Inc. and Morgan Stanley & Co. International plc (incorporated herein by reference to Exhibit 10.12 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.52	Credit Agreement, dated as of November 12, 2014, by and among AMAG Pharmaceuticals, Inc., the financial institutions and agents listed therein, and Jefferies Finance LLC (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed November 12, 2014, File No. 001-10865)
10.53	First Amendment to Credit Agreement, dated March 31, 2015, by and among AMAG Pharmaceuticals, Inc., the Lenders named therein, and Jefferies Finance LLC, as administrative agent (incorporated herein by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, File No. 001-10865)
10.54	Credit Agreement, dated as of August 17, 2015, by and among AMAG Pharmaceuticals, Inc., the financial institutions and agents listed therein, and Jefferies Finance LLC (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 17, 2015, File No. 001-10865)
10.55	Underwriting Agreement, dated as of July 30, 2015, among AMAG Pharmaceuticals, Inc., Jefferies LLC and Barclays Capital Inc., as representatives of the underwriters named therein (incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed July 31, 2015, File No. 001-10865)
10.56	Underwriting Agreement, dated as of February 25, 2015, among AMAG Pharmaceuticals, Inc., J.P. Morgan Securities LLC and Deutsche Bank Securities Inc., as representatives of the underwriters named therein (incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed February 26, 2015, File No. 001-10865)
21.1+	Subsidiaries of AMAG Pharmaceuticals, Inc.
23.1+	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm
24.1	Power of Attorney (included on the signature page(s) hereto)
31.1+	Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2+	Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS+	XBRL Instance Document
101.SCH+	XBRL Taxonomy Extension Schema Document
101.CAL+	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB+	XBRL Taxonomy Extension Label Linkbase Document
101.PRE+	XBRL Taxonomy Extension Presentation Linkbase Document

+	Exhibits marked with a plus sign ("+") are filed herewith.
++	Exhibits marked with a double plus sign ("++") are furnished herewith.
*	Exhibits marked with a single asterisk reference management contracts, compensatory plans or arrangements, filed in response to Item 15(a)(3) of the instructions to Form 10-K.
	The other exhibits listed have previously been filed with the SEC and are incorporated herein by reference, as indicated.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[…***…]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT UNDER RULE 24B-2 PROMULGATED UNDER THE SECURITIES ACT OF 1934, AS AMENDED.

AMENDED AND RESTATED TECHNICAL TRANSFER AND SUPPLY AGREEMENT

by and between

PFIZER INC.

and

AMAG PHARMACEUTICALS, INC.

Dated as of December 19, 2016

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[…***…]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT UNDER RULE 24B-2 PROMULGATED UNDER THE SECURITIES ACT OF 1934, AS AMENDED.

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EXHIBIT 12.4XI

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AMENDED AND RESTATED

TECHNICAL TRANSFER AND SUPPLY AGREEMENT

THIS AMENDED AND RESTATED TECHNICAL TRANSFER AND SUPPLY AGREEMENT (this ***"Agreement"***) is made as of this 19th day of December, 2016 (the ***"Effective Date"***) by and between AMAG Pharmaceuticals, Inc. (as successor in interest to Hologic, Inc. and K-V Pharmaceutical Company, via Lumara Health, Inc.) having a principal place of business at 1100 Winter Street, Waltham, Massachusetts 02451 (***"AMAG"***) and the Pfizer CentreOne group of Pfizer, Inc., (as successor in interest to the One 2 One group of Hospira Worldwide, Inc.) doing business at 275 North Field Drive, Lake Forest, Illinois, 60045, (U.S.A.) (***"Pfizer"***).

WITNESSETH:

WHEREAS, under a Development and Supply Agreement dated as of 17 September 2009 (***"Original Agreement"***) Pfizer has been manufacturing for AMAG […***…] dosage form of Hydroxyprogesterone Caproate Injection, filled and finished in a […***…] glass vial and sold under proprietary name, Makena™ (formerly, Gestiva™);

WHEREAS, pursuant to a First Amendment Agreement signed by the parties effective as of 28 March 2014 (***"First Amendment"***), Pfizer formally accepted the assignment of the Original Agreement to K-V Pharmaceutical Company and agreed to perform certain development activities for and manufacture a […***…] form of the Makena product filled and finished in a […***…] glass vial and subject to certain other terms and conditions as set forth in the First Amendment;

WHEREAS, pursuant to a Second Amendment dated as of 13 April 2015 (***"Second Amendment"***), Pfizer acknowledged the assignment of the Original Agreement from K-V Pharmaceutical Company (via Lumara Health, Inc.) to AMAG and agreed to perform certain commercial stability studies on the […***…] form of the Product;

WHEREAS, the parties have since been engaged in negotiations on a draft of a third amendment (***"Draft Third Amendment"***) under which the parties have agreed to include in the Original Agreement commercial terms and conditions regarding prices, price revisions, minimum purchase obligations and other obligations;

WHEREAS, the parties have discussed the terms and conditions of a technical transfer program, under which Pfizer will transfer the manufacture of the Makena product from its […***…] facility to its higher-containment fill-and-finish facility in […***…]; and

WHEREAS, in view of the above, both parties have agreed to amend and restate in their entirety the Original Agreement, as amended by the First Amendment and the Second Amendment

in accordance with the terms and conditions as set forth below for the purposes set forth in these recitals.

AGREEMENT

NOW THEREFORE, in consideration of the mutual covenants and representations contained in this Agreement and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the parties agree as follows:

ARTICLE 1
DEFINITIONS

Certain Defined Terms

As used in this Agreement:

1.1 *"*[…***…] ***Product****"* means the Drug in final dosage form, filled in a […***…] vial and if requested in writing by AMAG, shall include labeling and secondary packaging meeting the […***…] Product Specifications.

1.2 ***"***[…***…] ***Product"*** means the Drug in final dosage form, filled in a […***…] vial and, if requested in writing by AMAG, shall include labeling and secondary packaging meeting the Product Specifications.

1.3 ***"Active Pharmaceutical Ingredient"*** or ***"API"*** means the active pharmaceutical ingredient of the Drug in bulk form that AMAG will provide to Pfizer for incorporation into the Products, as specified in the Statement of Work.

1.4 ***"Active Pharmaceutical Ingredient Specifications"*** means the detailed description and parameters of the API, as set forth on Exhibit 1.4.

1.5 ***"Adverse Drug Experience(s)"*** has the meaning as set forth in 21 CFR 310.305 or the substantial equivalent provisions of other Applicable Laws.

1.6 ***"Affiliate"*** means any corporation, firm, partnership or other legal entity, which directly or indirectly controls, is controlled by or is under common control with a party to this Agreement. A party will be deemed to "control" another entity if it (a) owns at least fifty percent (50%) of the equity (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of such other entity, or (b) has the power by contract or otherwise to vote on or direct the management and policies of the entity.

1.7 ***"Applicable Law"*** means all laws applicable to the manufacture, processing, distribution, sale and use of the Product as may be amended and in effect from time to time, including the FD&C Act and all applicable federal, state and local laws and regulations, all applicable cGMP and all other applicable laws and regulations, of any other applicable jurisdiction.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[…***…]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT UNDER RULE 24B-2 PROMULGATED UNDER THE SECURITIES ACT OF 1934, AS AMENDED.

1.8 ***"Business Day"*** means any day of the week which is not a Saturday, Sunday or legal holiday observed by the United States Federal Government and the State governments of Illinois, Massachusetts, Michigan or Kansas.

1.9 ***"Certificate of Analysis"*** means a document, signed by an authorized representative of Pfizer, describing the Product Specifications of and testing methods applied to the Product, and the results thereof. A Certificate of Analysis can also mean a document, signed by an authorized representative of AMAG, describing the API Specifications of and testing methods applied to the API, and the results thereof.

1.10 ***"Certificate of Compliance"*** means a document signed by an authorized representative of Pfizer attesting that a particular lot, batch or run was manufactured in accordance with cGMP, Applicable Law, and the Product Specifications. The Certificate of Compliance may be included within the Certificate of Analysis, or separately, if required by AMAG for regulatory purposes or Applicable Law.

1.11 ***"cGMP"*** means those principles and guidelines of good manufacturing practices as current Good Manufacturing Practices are defined in the FDA rules and regulations, including the United States regulations set forth at 21 CFR Parts 210-211, as appropriate and as the same may be amended from time to time, and the corresponding requirements of any other applicable jurisdiction.

1.12 ***"Commercial Year"*** means each period of twelve (12) consecutive calendar months during this Agreement beginning on January 1st and ending December 31st.

1.13 ***"Components"*** means the excipients, the vials and the component parts of the vials into which the Drug will be filled, and the labeling, packaging, ancillary goods, shipping materials and other items to be procured by Pfizer from various Components supplier(s) to manufacture the Products in accordance with the Product Specifications.

1.14 ***"Confidential Information"*** means any and all information disclosed hereunder in writing and identified as being confidential or, if disclosed orally, visually or through some other media, is identified as confidential at the time of disclosure and is summarized in writing within […***…] of such disclosure and identified as being confidential, except any portion thereof which:

(a) is known to the recipient at the time of the disclosure, as evidenced by its written records or other competent evidence;

(b) is disclosed to the recipient by a Third Party lawfully in possession of such information and not under an obligation of nondisclosure;

(c) is or becomes patented, published or otherwise part of the public domain through no fault of the recipient;

(d) is developed by or for the recipient independently of Confidential Information disclosed hereunder, as evidenced by the recipient's written records or other competent evidence; or;

(e) is required by law to be disclosed by the recipient, provided, however, that the recipient gives the other party hereto prompt notice of such legal requirement such that such other party shall have the opportunity to apply for confidential treatment of such Confidential Information.

1.15 ***"Drug"*** means the human pharmaceutical compound, Hydroxyprogesterone Caproate.

1.16 ***"Drug Master File"*** or ***"DMF"*** as used in Section 4.3, means the drug master file (as such term is defined in 21 C.F.R. Part 314.420) that may be used to provide confidential, detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of drug products intended for human use.

1.17 "***Facility***" means Pfizer's pharmaceutical manufacturing plant at […***…], or its manufacturing plant in […***…], as the case may be.

1.18 ***"FDA"*** means the United States Food and Drug Administration or any successor entity thereto.

1.19 ***"FD&C Act"*** means the United States Federal Food, Drug and Cosmetic Act (21 U.S.C. 301), as amended from time to time.

1.20 ***"Intellectual Property"*** or ***"IP"*** means all inventions, formulations, processes, works of authorship, and any and all rights under U.S. and/or foreign patents, trade secrets, know-how, copyrights, trademarks and other industrial or intangible property rights of a similar nature and moral rights; all rights pursuant to grants and/or registrations worldwide in connection with the foregoing and all other rights with respect thereto; all rights under applications for any such grant or registration, all rights of priority under international conventions to make such applications and the right to control their prosecution, and all rights under amendments, continuations, divisions and continuations-in-part of such application; and all rights under corrections, reissues, patents of addition, extensions and renewals of any such grant, registration and/or right.

1.21 ***"Manufacturing Process"*** means any and all processes (or any step in any process) that is provided to Pfizer by AMAG and that will be used to manufacture the Products, as evidenced in the batch documentation and/or development reports.

1.22 ***"Master Batch Record"*** shall mean the document that defines the manufacturing methods, materials, and other procedures, directions and controls associated with the manufacture and testing of the Products, which may be amended in writing from time to time by mutual agreement of the parties.

1.23 ***"MSDS"*** means the Material Safety Data Sheet for the Products or the API containing such information as may be required by applicable government agencies.

1.24 ***"Product"*** means, individually, either the […***…] Product or the […***…] Product, as the context may require or collectively, the […***…] and the […***…] Products.

1.25 ***"Product Specifications"*** means those product, labeling and performance specifications for the Products filed with the relevant Regulatory Authority, including Product formulae, labeling, and materials required for the manufacture of the Product that is to be purchased and supplied under this Agreement, as such are set forth on Exhibit 1.25, which specifications may be amended by the parties from time to time in accordance with this Agreement.

1.26 ***"Quality & Technical Agreement"*** means the quality agreement, negotiated and signed by authorized representatives of the parties, that governs the essential quality obligations of them in the manufacture, testing and release of the Products hereunder. The Quality & Technical Agreement may be amended or revised from time to time by the mutual written agreement of the parties.

1.27 ***"Regulatory Approval"*** means the approval (including any supplements, amendments, pre- and post-marketing approvals), and pricing and reimbursement approvals, licenses, registrations or authorizations of any relevant Regulatory Authority, including the FDA, necessary for the manufacture, distribution, sale or use of the Product in the Territory.

1.28 ***"Regulatory Authority"*** means any federal, state or local or other regulatory agency, department, bureau or other governmental entity (including the FDA), which is responsible for issuing approvals, licenses, registrations or authorizations necessary for the manufacture, import, sale and use of the Product in the Territory.

1.29 ***"Specially Regulated Waste"*** means any hazardous waste, as defined by 40 CFR *261 et seq.,* requiring specified treatment and disposal by rules promulgated under federal, state or other relevant laws intended to address such types of waste materials that arise from the manufacture of the Product.

1.30 ***"Term"*** means, individually the Initial Term of this Agreement, or collectively the Initial Term and any Renewal Term, as those defined terms are used herein.

1.31 ***"Territory"*** means the United States of America, including the District of Columbia, the Commonwealth of Puerto Rico, all territories and possessions of the United States of America, United States military bases, and any other location over which the FDA has jurisdiction to regulate medicinal products intended for human use.

1.32 ***"Third Party"*** means any party other than Pfizer or AMAG and their respective Affiliates.

1.33 ***"Waste"*** means all rejects, improper goods, garbage, refuse, remainder, residue, waste water or other discarded material, including solid, liquid, semisolid, or contained gaseous material that arises from the manufacture of the Product, including rejected, excess or unsuitable materials, API and Products. The term Waste does not include any Specially Regulated Waste.

1.34 ***"Water Content Specification"*** means the following specification of the Product Specifications: NMT 0.20% w/w.

ARTICLE 2
PROJECT OVERVIEW

2.1 General Principles

The parties hereby undertake to plan and execute a technical transfer project (***"Project"***) to transfer the manufacture of the Product from the […***…] Facility to the […***…] Facility. The Project will include the activities and applicable timelines that are set forth on Exhibit 2.1 (***"Statement of Work"***). The parties will make all reasonable efforts to finalize the Statement of Work as soon as possible to enable the technical transfer activities to commence prior to the end of the […***…], with an anticipated finish date to occur no later than the […***…].

2.2 Commercially Reasonable Efforts

Each party shall use all commercially reasonable efforts successfully to complete the Project. However, the parties acknowledge and agree that neither of them can guarantee that the Project will be successful, nor warrants that a marketable product will result from the Project.

ARTICLE 3
SERVICE FEES; SCOPE CHANGES; PROJECT MANAGEMENT

3.1 Transfer Fees

AMAG shall pay Pfizer a […***…] technical transfer fee (the ***"Transfer Fee"***) for its work under the Project in accordance with the payment schedule set forth in Exhibit 2.1.

3.2 Stability Studies

As outlined in the Statement of Work, Pfizer will prepare pre-market and market-life stability batches of Products and perform stability studies (***"Stability Work"***). The essential obligations of the parties regarding Stability Work and the charges therefor are set forth on Exhibit 3.2.

3.3 Changes in Project Scope

(a) ***Changes; Proposal*** In the event (i) AMAG requests that changes be made to any material aspect of the Project or the Product Specifications, or (ii) technical difficulties require

that Pfizer perform either additional work or repeat work, and such additional work is required not because of Pfizer's fault or negligence, or (iii) the parties mutually agree to conduct additional work related to the subject matter of this Agreement, Pfizer shall provide AMAG with terms and conditions of any such additional, repeat or new work, including the scope of work, pricing, timeframes and responsibilities in a proposal to be mutually agreed upon in writing and signed by both parties (each, a ***"Proposal"***). Pfizer's pricing will reflect professional service fees quoted at a rate of […***…]. Each Proposal shall reference this Agreement, shall be implemented as a change order, a statement of work or an amendment to this Agreement and the terms and conditions of this Agreement shall govern and control any and all such additional, repeat or new work; *provided, however*, that if any provision of any Proposal conflicts with this Agreement, the terms of this Agreement shall prevail with respect to all terms except pricing terms.

(b) ***Expansion of Territory***. AMAG shall give Pfizer reasonable prior notice in the event that it desires to pursue marketing and sales activities for the Product in countries or geographic regions outside of the Territory. The parties will then determine the preparatory work that may be required (if any) and upon agreement, Pfizer shall provide AMAG with all necessary additional technical/developmental and regulatory support, including, for example, regulatory support for AMAG's supplemental regulatory filings, packaging and product development, labeling, and relevant Regulatory Authority inspections. Any additional technical/developmental and regulatory support for such other countries or geographic regions may be considered a change in Project scope and the Parties will agree to the reasonable incremental costs of such additional support in accordance with Section 3.3(a). Any additional pre-approval inspections of the Facility that may be required by relevant Regulatory Authorities as a result shall be reimbursed in accordance with Section 7.5(b).

(c) ***Assignment Fee***. In the event that AMAG assigns or otherwise transfers substantially all of its rights and obligations under this Agreement to a Third party pursuant to Section 12.5, either to a commercial licensing partner or an acquirer of AMAG's business, then in each case, Pfizer will be entitled to charge AMAG an assignment fee up to an amount […***…] to cover the anticipated expenses it will incur as a result of the assignment.

3.4 Steering Committee; Project Manager

(a) ***Steering Committee***. Pfizer and AMAG will jointly constitute a team (***"Steering Committee"***) comprised of not less than two (2) members from each party (or such number as the parties mutually agree). The Steering Committee will meet not less than twice annually to address any relevant issue a party wishes to call to the attention of the Steering Committee, to review past performance on mutually agreed upon metrics, discuss future partnership objectives, and to oversee the relationship between AMAG and Pfizer. The Steering Committee will be considered as a working committee that will have as its goal the prompt and mutually agreeable resolution of any financial, technical or quality issues that may arise in order to advance and preserve a harmonious relationship established by and between Pfizer and AMAG. Either party may change its representatives on the Steering Committee at any time by written notice to the other party.

(b) ***Project Team; Project Manager***. Promptly upon execution of this Agreement, Pfizer and AMAG shall each designate such of their respective employees from product development, quality assurance, manufacturing, and project management to form a team (***"Project Team"***) to direct the activities to be carried out under the Statement of Work. Each party shall also designate one of its employees to act as its project manager (each, a ***"Project Manager"***), who will be primarily responsible for communicating all instructions and information concerning the Project to the members of the Project Team. The Project Team and/or the Project Managers shall consult periodically during the performance of the Services, through face-to-face meetings, telephone conferences and/or videoconferences, at times to be mutually agreed upon by the Project Managers. Each party may appoint a substitute or replacement Project Manager or a member(s) of the Project Team in the absence of its original Project Manager or original member(s) of the Project Team by notifying the other party in writing of such substitution or replacement. Neither the Project Managers nor the Project Team shall have the right to modify, amend or waive any provision of this Agreement.

3.5 Technical Transfer Supplies

Based on AMAG's final Product formulations, concentration and fill volume and the parties' agreement to the final Product Specifications, Pfizer will manufacture the Products as engineering batches and stability batches (***"Transfer Supplies"***) at the prices set forth in the Statement of Work. The parties acknowledge that Transfer Supplies may include products utilized for technical transfer purposes only (e.g., in engineering runs, or to be used as stability testing materials), which are not intended for commercial sale in the market, except as otherwise permitted by Applicable Law. In accordance with a schedule to be mutually agreed by the parties, AMAG shall issue its purchase order(s) for such Transfer Supplies at least […***…] before any requested delivery date. For the sake of clarity, all relevant provisions of Articles 5, 7, 8 and 9 shall apply to the manufacture and delivery of the Transfer Supplies.

ARTICLE 4
REGULATORY SUBMISSIONS; APPROVALS

4.1 Regulatory Assistance

Except as otherwise provided herein, AMAG will be solely responsible for obtaining and maintaining any Regulatory Approvals, licences, registrations or authorizations of any relevant Regulatory Authority required for the manufacture, distribution, sale and use of the Product in the Territory.

(a) ***General Review***. In consideration of the Transfer Fees that AMAG will pay under the Statement of Work, upon AMAG's request, Pfizer will review those portions of AMAG's proposed regulatory submissions as relate to Pfizer's manufacturing, packaging and quality control, quality assurance, facilities, personnel, procedures and organization before the submissions are filed with relevant Regulatory Authorities. Pfizer will use its commercially reasonable efforts to complete

its review of AMAG's submissions as soon as possible, but no later than […***…] after receipt and will promptly inform AMAG of any anticipated delays.

(b) ***Responses to Regulatory Authorities***. At AMAG's request, Pfizer shall consult with and advise AMAG in responding to questions from the FDA regarding AMAG's regulatory submission for the Product, *provided, however,* that AMAG shall have the final control over such submissions. In the event that the FDA or other Regulatory Authority responds to AMAG's regulatory submission that requires a response (including, for example, a technical response to an FDA finding of a deficiency, should one arise) and AMAG requests Pfizer's review and consultation on such matter which is beyond the scope of the development services to be provided as set forth in the Statement of Work, Pfizer shall provide AMAG with cost estimates (based on a professional services rate quoted at […***…] for any such additional review and consultation. If AMAG approves such costs in writing, AMAG shall reimburse Pfizer for such approved costs upon completion of the work and within […***…] of receipt of Pfizer's invoice.

4.2 Facility Approvals

Pfizer will secure and maintain in good order, at its sole cost and expense, such current governmental registrations, licences and permits as are required by Regulatory Authorities in order for Pfizer to perform all of its obligations under this Agreement and to manufacture the Products at the Facility.

4.3 Access to Drug Master Files

Pfizer will grant AMAG reference rights to all Drug Master Files necessary to support AMAG's regulatory filings for the Product. To affect this, Pfizer will execute certain letters of authorization, which will be delivered to the appropriate Regulatory Authorities to permit them to consult Pfizer's DMFs in their review of AMAG's Product regulatory submissions. Pfizer will send copies of such authorization letters to AMAG. Pfizer will update its DMFs annually and will inform AMAG prior to making any modifications thereto in order to permit AMAG to amend or supplement any affected regulatory submissions and filings for Product.

4.4 User Fees

AMAG will pay any Regulatory Authority user fees which may become payable for the Product.

4.5 Ownership of Regulatory Approvals

The parties agree that AMAG will be the sole and exclusive owner of all right, title and interest in and to all Regulatory Approvals related to the API and Product and any submissions for such Regulatory Approvals. Pfizer will reasonably assist AMAG in the preparation of all documents necessary to affect AMAG's rights in such Regulatory Approval applications and submissions. AMAG will provide to Pfizer for its files a final copy of the CMC section of any such applications

and/or submissions for Regulatory Approval. Except as provided in Sections 3.3(a) and 7.5(b), […***…].

ARTICLE 5
PRODUCT MANUFACTURING

5.1 Purchase and Sale of Products

Pursuant to the terms and conditions of this Agreement and during the Term (subject to the successful completion of the Project), Pfizer shall manufacture, sell and deliver Product to AMAG, and AMAG shall purchase and take delivery of no less than […***…].

5.2 Manufacturing Standards; Changes

(a) ***Product Specifications***. The Product Specifications are set forth on Exhibit 1.25. The Product Specifications may be modified from time to time in accordance with the provisions of Section 5.2(b) and Section 7.7.

(b) ***Changes.*** Pfizer will manufacture the Product in accordance with the Specifications, cGMP and all Applicable Laws, as then in effect. The parties agree that if AMAG wishes to amend any aspect of its Manufacturing Process or the Product Specifications (***"Discretionary Changes"***), AMAG will provide written notice thereof to Pfizer for Pfizer's review and approval, which approval Pfizer will not unreasonably withhold. Furthermore, each party will promptly notify the other of any new instructions or changes to the Product Specifications that are required by any Regulatory Authority, change in Applicable Laws or other regulatory requirements, or by medical concerns related to the toxicity, safety and/or efficacy of the Products (***"Required Changes"***). The parties will confer with respect to the best means to comply with such instructions or change requirements; *provided, however*, that Pfizer will comply with any reasonable instructions issued by AMAG with respect to implementing any Required Changes. An analytical improvement will be considered to be a Discretionary Change unless requested or required by a Regulatory Authority, in which case such improvement will be considered a Required Change. All Discretionary or Required Changes will be implemented in accordance with the change control provisions of the Quality & Technical Agreement.

(c) ***Costs of Changes.*** Except as may otherwise be agreed in the Statement of Work, Pfizer will be responsible for any and all costs with respect to Required Changes that are required to bring its manufacturing operations into compliance with Applicable Laws, and AMAG will be responsible for any and all other costs related to Required Changes affecting the Product. Any Discretionary Changes to the Product Specifications or the Manufacturing Process initiated by either party will be agreed to by the parties, including which party or parties will be responsible for the funding of such Discretionary Changes.

5.3 Pre-Transfer Approval Manufacture

Pfizer agrees to manufacture and supply those quantities of Product requested in firm Purchase Orders issued by AMAG that are necessary to validate Pfizer's […***…] Facility, obtain Regulatory Approval(s) and build AMAG's inventory in anticipation of supplying Products from the […***…] Facility (***"Validation Batches"***). The parties acknowledge that as Validation Batches may be sold as commercial products in accordance with Applicable Law, AMAG will pay for such Validation Batches at the commercial prices set forth in Section 6.11(a) and in accordance with the terms and conditions of this Agreement, irrespective of whether the Products ultimately receive all necessary Regulatory Approval unless the failure to receive Regulatory Approval is due the negligence or willful misconduct of Pfizer.

5.4 Active Pharmaceutical Ingredient

(a) ***API Supply***. Unless otherwise provided in the Project Statement of Work or this Agreement, the following provisions will apply to supplies of API by AMAG to Pfizer.

(i) ***AMAG API Supply***. Pfizer will manufacture the Product for AMAG from API that AMAG shall supply to Pfizer […***…]. AMAG will supply API to Pfizer in quantities sufficient to satisfy Pfizer's gross manufacturing requirements of the Product on lead times discussed and agreed by the Project Managers, but in no event later than […***…] prior to the scheduled start of manufacture. Pfizer will use the API received from AMAG only for the technical transfer or activities contemplated by this Agreement and the manufacture of Product for AMAG. AMAG will deliver the API, […***…], the relevant Facility pursuant to […***…] purchase orders that Pfizer issues to AMAG.

(ii) ***API Documentation; Samples***. With each delivery of API, AMAG will include a Certificate of Analysis, signed by an authorized individual of AMAG (or its designated API supplier) containing basic information regarding the API, including (A) the manufacturing date of the batch/lot delivered, (B) the batch/lot number, and (C) the quantity of API in such batch/lot as shipped to Pfizer. AMAG will also supply a separate sample ("tailgate" sample; "satellite" sample) for each container of API supplied.

(iii) ***Incoming Testing***. Within […***…] of Pfizer's receipt of any API supplied by AMAG, Pfizer will (A) perform an identification test on the API and confirm the shipment quantity, (B) perform any other tests mutually agreed upon in writing, and (C) notify AMAG of any inaccuracies with respect to quantity or of any claim that any portion of the shipment fails the identification or other test. In the event Pfizer notifies AMAG of any deficiency in the quantity or quality of API received, AMAG will promptly ship to Pfizer, […***…], the quantity of API necessary to complete the API shipment. In the event Pfizer notifies AMAG that the API shipment does not conform to the Active Pharmaceutical Ingredient Specifications, AMAG will have the right to confirm such findings at the Facility.

(iv) ***API Dispute Resolution***. If AMAG determines that such shipment of API conforms to the API Specifications, the parties will submit samples of such shipment to a mutually acceptable independent laboratory for testing. If such independent laboratory determines that the

shipment conforms to the API Specifications, Pfizer will bear […***…] expenses of shipping and testing such shipment samples. If AMAG or such independent laboratory confirms that such shipment does not meet the API Specifications, AMAG will replace, […***…] to Pfizer, the portion of the API shipment which does not conform to the API Specifications and bear […***…] expenses of shipping and testing the shipment samples. Pfizer will dispose of any nonconforming portion of any API shipment as directed by AMAG, at AMAG's expense.

(b) ***Title***. Notwithstanding the DDP shipping terms of Section 5.4(a)(i), AMAG will retain title to the API while it is in the Pfizer facility. Pfizer will assume responsibility for the safekeeping, storage, handling and risk of loss for all shipments of API delivered hereunder and accepted by Pfizer, subject to the limitation in Section 5.4(c). Subject to AMAG's ability to supply, Pfizer agrees to hold in storage […***…] at the […***…] Facility a stock of API sufficient to meet Pfizer's manufacturing obligations of the Product for Purchase Orders placed by AMAG within the Firm Order Period. Notwithstanding the foregoing, the parties may agree to different amounts of API stock to be held at the […***…] Facility during the remainder of the time that Product will be manufactured at the […***…] Facility.

(c) ***Loss and Replacement of API***. In the event of loss or damage of any API delivered hereunder or the failure of Product to meet Product Specifications, AMAG will supply to Pfizer replacement API according to the terms set forth in Section 5.4(a), except as otherwise provided herein. If the replacement of such API results from the negligent acts or omissions by Pfizer in the manufacture, handling or storage of Product or API, AMAG will supply to Pfizer replacement API and Pfizer will be responsible for […***…].

(d) ***Maximum Liability***. Notwithstanding any of the foregoing, in no event shall Pfizer's aggregate liability for the replacement of API exceed […***…]. This Section 5.4(d) states AMAG's sole remedy, and Pfizer's sole liability, for any loss, damage, or misuse of API. The parties acknowledge that these limitations will apply to standard batch sizes manufactured for commercial sale and that the limitations will be reduced on a pro rata basis for batches of Transfer Supplies that are manufactured on a materially smaller scale.

5.5 Facility; Dedicated Equipment

(a) ***Facilities and Equipment***. Except as provided below, Pfizer will provide, […***…], all facilities, equipment, machinery, and materials to manufacture the Product in accordance with the Product Specifications, and the professional and other labor necessary for the successful performance of its obligations hereunder.

(b) ***Dedicated Equipment***. At present, the parties do not anticipate the need for any specialized equipment to manufacture the Product in accordance with cGMP and the Specifications. However, if in the future such need arises, Pfizer will advise AMAG of any specialized or dedicated equipment (***"Dedicated Equipment"***) that is required and the estimated costs associated with the purchase, installation and validation of the Dedicated Equipment. Pfizer will pay the cost of the Dedicated Equipment, subject to AMAG's prior written approval of such costs, which approval will not be unreasonably withheld or conditioned. Upon such approval, Pfizer will then purchase, install and validate the equipment and bill AMAG for the associated costs. AMAG will make payment to Pfizer no later than […***…] after receipt of Pfizer's invoice. Title to the Dedicated Equipment shall be and remain in AMAG's name. Pfizer shall (and shall cause its Affiliates to) (i) label the

Dedicated Equipment as the property of AMAG, (ii) use the Dedicated Equipment solely for the manufacture of the Product for and on behalf of AMAG, (iii) keep the Dedicated Equipment free of liens, claims and encumbrances, (iv) operate the Dedicated Equipment in accordance with the manufacturer's instructions, and (v) maintain the Dedicated Equipment in good working condition and in compliance with cGMP and Applicable Laws. Upon the expiry or earlier termination of this Agreement, Pfizer will return or otherwise dispose of Dedicated Equipment in accordance with Section 10.5(b).

5.6 Components; Materials

Unless otherwise agreed, Pfizer will be responsible for the procurement and qualification of the Components and other raw materials required for the manufacture of the Product. Pfizer will procure all of the Components from suppliers that have been approved and qualified by Pfizer in accordance with Pfizer's internal vendor qualification and approval processes. The parties understand and agree that AMAG will have reviewed and approved the Components and Component suppliers listed in the Product Specifications. Under no circumstances will Pfizer have any liability to AMAG, nor will Pfizer be deemed to be in breach of this Agreement, if Pfizer is unable to supply the Product to AMAG due to a failure of such suppliers to provide such Components to Pfizer; *provided, however*, that Pfizer has used commercially reasonable efforts to obtain the relevant Components from approved Component suppliers in accordance with AMAG's Rolling Forecast and Purchase Orders during the Firm Order Period.

5.7 Product Labeling

(a) ***Labeling***. Pfizer shall label the Product in accordance with the Product Specifications using content provided by AMAG. AMAG shall control the content and type of all labeling and packaging (and any changes or supplements thereto) for the Product and shall have the responsibility, […***…], for (i) ensuring such content is compliant with the Regulatory Approval and all Applicable Law, and (ii) any changes or supplements to such content, including the expense of securing any approvals required by any applicable Regulatory Authority for any such changes or supplements. Pfizer shall be responsible for obtaining such labels (and any changes or supplements thereto) in accordance with content specified by AMAG.

(b) ***Labeling Changes***. Should AMAG request or be required to make any modifications to Product labeling and packaging, it shall submit a written change order to Pfizer containing the requested or required modifications, together with any documentation specifying the content of the new labeling and packaging, including all necessary photo-ready art (or its substantial equivalent). Pfizer shall promptly provide AMAG with a statement of charges for the work to be performed, reflecting professional service fees quoted at a rate of […***…] and its estimated timeline for implementing the changes. Upon written approval by AMAG, which approval shall not be unreasonably withheld, Pfizer will perform all requested or required labeling and packaging work. AMAG shall pay Pfizer for the work performed, in addition to reimbursing Pfizer for the cost of any existing labeling and packaging that has become obsolete as a result of such changes; *provided, however*, that obsolescence charges do not exceed the amount of labels reasonably required by

Pfizer based on the first […***…] of the most recent […***…] rolling forecast provided under Section 6.2 or such other amount as mutually agreed upon in writing.

(c) ***Bulk Product Supply***. As may be specified by AMAG in AMAG's Purchase Orders from time to time, Pfizer will label and package quantities of the Products as unlabeled "Brite Stock" for bulk shipment to AMAG or its designated agent, in accordance with the provisions set forth in the Quality & Technical Agreement.

5.8 Product Testing and Release

(a) ***Test Methods***. Upon completion of manufacture, Pfizer will test each batch of Products for conformance with the Product Specifications and cGMP in accordance with agreed-upon quality control test methods set forth on Exhibit 7.1, the Quality & Technical Agreement or as otherwise requested by AMAG.

(b) ***Documentation***. After Pfizer has carried out and reviewed all testing in accordance with its quality control processes, procedures and other agreed test methods, Pfizer will provide AMAG with a Certificate of Analysis (and a Certificate of Compliance, if so required) confirming that the batch was manufactured in conformity with the applicable Product Specifications. Pfizer will also provide copies of batch records and all other documents and records as required by the Quality & Technical Agreement, as well as such samples of the batch as AMAG may reasonably request. AMAG will review all of the documentation and discuss its observations, if any, with Pfizer. Once all observations are resolved, and AMAG has reviewed and approved all of the documentation provided by Pfizer, AMAG will approve the batch by providing to Pfizer its authorization to release the batch for delivery (***"Release Authorization"***). Pfizer will then make the batch available to AMAG at the Facility.

(c) ***Inspection; Rejection***. AMAG shall inspect, perform its quality assurance tests, and accept or reject, the corresponding batch as conforming or non-conforming with the Product Specifications no later than […***…] from the date of AMAG's receipt of all documents and records required by the Quality & Technical Agreement (and if, applicable, batch samples). If AMAG rejects the batch as being non-conforming, it shall promptly notify Pfizer. If, as a result of further review and testing, Pfizer determines that the batch does conform to the Product Specifications or is otherwise not defective, the parties shall submit samples of such batch to a mutually acceptable independent laboratory for testing, in accordance with Section 5.8(f).

(d) ***Deemed Acceptance***. Any Product that AMAG does not reject within the […***…] time period will be deemed accepted, and all claims with respect to Product not conforming with the Product Specifications will be deemed to have been waived by AMAG, except as to latent defects, as that term is defined in Section 5.8(h).

(e) ***Product Quantity***. If the quantity of Products produced in any batch manufactured and proffered for delivery to AMAG is materially less than the quantity specified in the applicable AMAG Purchase Order, then the parties will meet to discuss in good faith and agree to one or more remedies to resolve the shortage in a fair and equitable manner. For purposes of clarity, "materially less" shall mean a batch of Products with an abnormally high number of units either rejected or set aside at Pfizer's determination for sampling, stability or for other reasons outside of the ordinary course of manufacturing and based on historic experience at the […***…] Facility.

(f) ***Disputes Regarding Non-Conformity; Independent Testing***. Where the parties have submitted batch samples to an independent laboratory for conformance testing, if such laboratory determines that the batch conformed to the Product Specifications, AMAG shall bear all expenses of shipping and testing such batch samples. If such laboratory confirms that such shipment did not meet the Product Specifications, Pfizer shall replace, […***…], that portion of the batch which does not conform to the Product Specifications, and shall bear […***…] expenses of shipping and testing the batch samples. Any nonconforming portion of any batch shall be disposed of as directed by AMAG, at Pfizer's expense. The independent laboratory's results will be in writing and will be final and binding, save for manifest error on the face of its report. Pfizer will furnish the independent laboratory with such instructions regarding the storage, handling and potential hazards of any Product as are provided to or developed by Pfizer by or on behalf of AMAG.

(g) ***Replacement; Disposition of Rejected Product***. Pfizer shall use all reasonable efforts to replace, […***…], that portion of the batch which does not conform to the Product Specifications as soon as possible, given manufacturing capacities and scheduling at the Facility; *provided, however*, that AMAG provides sufficient replacement API to Pfizer in accordance with the provisions of Section 5.4(c). Pfizer shall dispose of any rejected Products at its own cost and expense.

(h) ***Latent Defects***. Notwithstanding the acceptance provisions of Section 5.8(c) and Section 5.8(d), AMAG will have the right to reject any batch of Products that are subsequently found to be non-conforming due to latent defects. For purposes of this Section 5.8(h), "latent defects" are any defects in the Product which are not discoverable using ordinary diligence and reasonable care in applying the quality control and test methods specified in the Quality & Technical Agreement, render the Product not conforming to Product Specifications and are solely caused by Pfizer. The parties will consult to confirm the cause of the latent defects. If the parties do not agree as to whether the Product is non-conforming, they will submit samples of such Product for independent testing in accordance with Section 5.8(f). If it is confirmed that the cause of the latent defect is attributable to Pfizer, then Pfizer will replace […***…] all such latently defective Products with Products that meet the Product Specifications, subject to the provisions of Section 5.4(c) and the limitations of Section 5.4(d). All other relevant provisions of this Section 5.8 will apply to the inspection, testing and release of such replacement Products.

5.9 Waste

Pfizer will be responsible for the removal and disposal of all Waste resulting from Pfizer's manufacturing of the Product, consistent with the Product's MSDS; […***…]. Pfizer will ensure that Specially Regulated Waste is disposed only at approved sites and through waste management handlers that have been approved in writing by AMAG. Pfizer will document the disposal and destruction of Specially Regulated Waste in writing and provide copies of the written documentation to an authorized representative of AMAG. AMAG will have the right, but not the obligation, to witness the actual disposal of Specially Regulated Waste. AMAG will provide the MSDS for the API and the MSDS for the Product to Pfizer at Pfizer's written request.

5.10 Miscellaneous

(a) ***Process Rework***. Pfizer will not rework or reprocess a Product unless authorized in advance by AMAG in writing and there is a validated process for such rework or reprocessing of Product. Re-inspection does not constitute rework or reprocessing. Process rework that may become necessary as a result of AMAG's changes will be billed separately at a reasonable fee to be mutually agreed between the parties in writing.

(b) ***Sub-Lots***. Should AMAG desire Pfizer to split a manufacturing lot of Product into two (2) or more sub-lots during packaging, Pfizer will charge a split fee of […***…] for each sub-lot packaged.

ARTICLE 6
FORECASTS; ORDERS; DELIVERY; INVOICING

6.1 […***…] Product Supply Forecast

For capacity planning purposes, by […***…] of each Commercial Year AMAG will provide Pfizer with a non-binding, written forecast of its estimated annual requirements of the Product during each of the next […***…] ("***Annual Forecast***").

6.2 Rolling Forecast

During each calendar quarter thereafter, AMAG will provide to Pfizer a good faith, estimated rolling forecast of the quantity of Products that AMAG expects to order for the coming […***…] period of time (each, a ***"Rolling Forecast"***). The first […***…] of each Rolling Forecast shall be considered a binding commitment upon AMAG to purchase quantities described therein and a binding commitment upon Pfizer to produce and deliver such quantities on the delivery dates described therein (***"Firm Order Period"***). The last […***…] of each Rolling Forecast shall be non-binding upon the Parties.

6.3 Purchase Orders

AMAG shall submit each order for Product (***"Purchase Order"***) to Pfizer at least […***…] prior to AMAG's requested delivery date. Pfizer shall use its commercially reasonable efforts to meet the delivery dates set forth in each Purchase Orders. All Purchase Orders shall reference this Agreement and shall be governed exclusively by the terms contained herein. AMAG shall set forth in each Purchase Order (a) the quantity of Product ordered, (b) the amount of API required to fill the Purchase Order, (c) the specified delivery date and delivery instructions, and (d) the price to be paid for the Product.

6.4 Purchase Order Acceptance

Pfizer will confirm each Purchase Order issued in accordance with Section 6.3 […***…] after receipt and shall confirm in writing to AMAG its acceptance of the Purchase Order, the delivery date(s), the quantity of Products ordered and the purchase price to be paid by AMAG.

6.5 Excess Quantities

Pfizer will accept all Purchase Orders specifying quantities of Product up to […***…] in excess of the quantities listed in the corresponding Firm Order Period. Pfizer will not be obligated to supply quantities of Product over and above such […***…] excess amount (***"Non-Binding Excess"***) but will use commercially reasonable efforts to manufacture and deliver to AMAG all or part of the Non-Binding Excess as soon as reasonably practicable.

6.6 Format of Forecasts and Purchase Orders

AMAG will submit each Rolling Forecast and all Purchase Orders electronically in spreadsheet form and will specify the quantities of Products in units and the Pfizer product number (list number/inventory number).

6.7 Purchase Order Changes; Cancellations

(a) ***Changes***. If AMAG requests that changes be made to any of its Purchase Orders within the Firm Order period, Pfizer will attempt to accommodate such changes within reasonable manufacturing capabilities and efficiencies. If Pfizer can accommodate such changes, Pfizer will advise AMAG of any costs associated therewith. If AMAG indicates in writing to Pfizer that it should proceed to make the changes, AMAG will be deemed to have accepted the obligation to pay Pfizer for such costs. If Pfizer cannot accommodate such change, AMAG will nonetheless be bound to its original Purchase Orders.

(b) ***Cancellations***. If AMAG cancels any Purchase Order […***…], Pfizer will be relieved of its manufacturing obligations relating to such order but AMAG will not be relieved of its payment obligation unless Pfizer agrees to waive such obligation in writing. Furthermore, if AMAG does not supply sufficient API (without providing appropriate notification to Pfizer and allowing for a period for both companies to evaluate the impact of such delay in API delivery) to allow Pfizer to fulfill any Purchase Order or acts improperly in any other manner effectively to prevent Pfizer's ability to perform, such action shall be deemed a cancellation and AMAG will remain liable for the full amount of the Purchase Order, regardless of whether Pfizer manufactures the Product or whether AMAG takes delivery of the Product.

6.8 Shortage of Supply

Shortage of Supply. In the event that Pfizer is unable to manufacture the Product in accordance with AMAG's Purchase Orders, Pfizer shall notify AMAG as soon as possible. If the inability is not (a) caused by an event of *force majeure,* (b) attributable in whole or in part to AMAG's acts or omissions or breach of its obligations under this Agreement, or (c) attributable in whole or in part to Pfizer's Component suppliers' acts or omissions, then Pfizer shall be solely responsible for undertaking all commercially reasonable measures to minimize any possible shortage of Product to AMAG as a result of its manufacturing issues. If Pfizer cannot undertake such measures promptly, then either party may request that the Project Managers convene a meeting to discuss possible

remedial action, which may include a reduction in AMAG's Minimum Purchase Requirements for the applicable Commercial Year.

6.9 Delivery

Pfizer will deliver the Product to AMAG […***…] (Incoterms 2010), the relevant Facility. […***…]. Pfizer will not deliver any Product to AMAG until (a) Pfizer has released such Product pursuant to the Specifications and the terms of the Quality & Technical Agreement, and (b) AMAG has issued to Pfizer its Release Authorization. […***…]. For any shipments outside of the United States, AMAG will be the exporter of record; *provided, however*, that Pfizer will assist AMAG, […***…], in the preparation of any required export documentation. AMAG will be responsible for all shipping validation and transportation quality control. Should AMAG request or require Pfizer to include electronic temperature monitoring devices (***"Loggers"***) with any shipping cartons of the Product, it will comply with Pfizer's policies on the use of and responsibilities for Loggers set forth on Exhibit 6.9.

6.10 Storage Fee

(a) ***Commercial Products***. AMAG will use its commercially reasonable efforts to take delivery of all Products from the Facility no later than […***…] after the date of insurance of its Release Authorization. If AMAG anticipates that it will not be able to meet the delivery date, it will notify Pfizer promptly that Pfizer should store the Products at the Facility on an interim basis and indicate a date certain on which it will take delivery. Pfizer will have the right to charge AMAG a storage fee of […***…] during this interim period. […***…].

(b) ***Storage of Transfer Supplies***. Product generated from any engineering, registration or process validation or verification batched will be stored […***…] at Pfizer's […***…] Facility at controlled room temperature until FDA has granted Regulatory Approval for the manufacture of the Products at that site.

6.11 Prices and Adjustments

(a) ***Pricing***. Effective as of […***…], Pfizer shall invoice AMAG for the Products it delivers to AMAG at the Price(s) as set forth in the table below. Each invoice shall reference the Price(s) in effect on the date of Pfizer's invoice. All pricing is firm through […***…].

Product	Size	Price Per Unit ($)	Quote #
Makena	[…***…]	[…***…]	10248
Makena	[…***…]	[…***…]	10249
Makena	[…***…]	[…***…]	10250
Makena	[…***…]	[…***…]	10251

(b) […***…]

(c) […***…]

(d) ***Comprehensive Pricing***. For the avoidance of doubt, the Product pricing includes all finished and bulk packaging supplies (*i.e.,* labeling, packaging shipping and bulk shipping cases and pallets).

6.12 Invoices; Payment

Pfizer will invoice AMAG […***…]. AMAG will make payment of all amounts in Pfizer's invoices […***…] from the date of receipt of Pfizer's invoice. In the event of a good faith dispute between the parties as to the amount due, AMAG will pay the undisputed amount and the parties will attempt to resolve the disputed payment within […***…].

6.13 Taxes

AMAG shall pay all federal, state, county or municipal sales or use tax, excise, customs charges, duties or similar charge, or any other tax assessment (other than that assessed against income), licence, fee or other charge lawfully assessed or charged on the manufacture, sale or transportation of the Product that Pfizer manufactures, sells and delivers pursuant to this Agreement. In particular, AMAG will be responsible for and pay all applicable annual establishment fees specified in the Prescription Drug User Fee Amendments to the FD&C Act, with respect to the Product. For the avoidance of doubt, AMAG shall not be required to pay any such annual fees as relate to the Pfizer Facility, which shall be Pfizer's sole and exclusive obligation. AMAG shall provide Pfizer with copies of any state tax exemption form(s) if it intends to claim exemption for sales or use taxes in any state(s) where the Product is to be shipped.

6.14 Continuous Improvements

Pfizer shall use reasonable commercial efforts to identify any opportunity to reduce the cost of manufacturing the Product and shall notify AMAG of such cost reduction opportunities (***"Cost Reduction Program"***). AMAG and Pfizer agree to confer in good faith to capitalize on such opportunities by sharing in the cost of implementation. Any cost savings realized from the Cost Reduction Program shall be shared in proportion to each party's financial contribution to such program's development and implementation costs.

ARTICLE 7
QUALITY ASSURANCE

7.1 Quality Control

Pfizer will apply its quality control procedures and in-plant quality control checks on the manufacture of Product for AMAG in the same manner as Pfizer applies such procedures and checks to products of similar nature manufactured for sale by Pfizer. Pfizer will also test and release all batches of Product in accordance with the test methods described in Exhibit 7.1 to ensure that the Products meet the requirements of the Product Specifications and are manufactured in accordance with cGMP.

7.2 Quality & Technical Agreement

The parties have entered into a Quality & Technical Agreement dated June 25, 2012 and amended June 10, 2014, which agreement shall continue to govern the quality assurance aspects of Pfizer's manufacture of Product at its […***…] Facility. Notwithstanding the foregoing, authorized personnel of the parties must negotiate and conclude a new Quality & Technical Agreement as necessary for purposes of this Agreement and the Statement of Work and before any cGMP manufacture of Product can take place at the Pfizer […***…] Facility. Upon its execution, the new Quality & Technical Agreement shall be deemed to be incorporated by reference herein.

7.3 Documentation; Batch Records; Retention Samples

(a) ***Quality Assurance Documentation.*** Pfizer will prepare such records documenting the technical transfer work as foreseen in the Project Statement of Work or as are otherwise reasonably requested by AMAG. Pfizer will prepare batch manufacturing records, which include the information relating to the manufacturing, packaging and quality operations for each lot of Product at the time such operations occur. Pfizer will prepare all technical transfer work and batch records in accordance with Applicable Laws, the Quality & Technical Agreement, cGMP and any similar regulations of applicable Regulatory Authorities and Pfizer's standard operating procedures. Upon AMAG's request, Pfizer will provide AMAG with copies of such technical transfer records and batch production records, including manufacturing and analytical records.

(b) ***Document Retention***. Pfizer will retain all records documenting the technical transfer work and all records relating to the manufacture of each batch of Products for not less than […***…] or for such other period as required by Applicable Law. Thereafter, Pfizer will not destroy such records without giving AMAG prior written notice and the opportunity further to store such records or to have such records shipped to AMAG, at AMAG's cost and expense.

(c) ***Retention Samples***. Pfizer will be responsible for storing and maintaining retention samples of each batch of Product delivered to AMAG and associated API and other raw materials in accordance with cGMP and the Quality & Technical Agreement.

7.4 AMAG Audits Rights

(a) ***General Audit.*** Upon […***…] prior written notice to Pfizer, AMAG shall have the right to have representatives visit the Facility during normal business hours to perform a quality assurance audit and inspection to review Pfizer's records and its production Facilities relating to the manufacturing, assembly and/or packaging of Product and assess its compliance with cGMP and quality assurance standards and to discuss any related issues with Pfizer's manufacturing and management personnel. Pfizer shall provide AMAG with copies of Pfizer's manufacturing records (including the Master Batch Record) and other relevant documentation relating to the Products for the purposes of assuring Product quality and compliance with agreed-upon manufacturing procedures. Such general audits shall (i) be limited to not more than […***…] designated by or representing AMAG, (ii) last for […***…], and (iii) may be conducted not more […***…]. Any

auditors who are not employees of AMAG shall be required to enter into confidentiality agreements with Pfizer and AMAG containing terms of confidentiality at least as stringent as those set forth in Article 11.

(b) ***For Cause Audits***. AMAG shall also have the right to conduct "for-cause" audits to address significant product or safety concerns as discovered through Product failures related to Pfizer's manufacture of the Product. Product failures would include issues related to stability, out of specification, sterility, labeling or container integrity. AMAG shall notify Pfizer in writing in advance of the audit and thereafter, AMAG and Pfizer shall mutually determine the timing of the audit. Each for-cause audit shall be limited to […***…] designated by or representing AMAG for […***…], except if the parties mutually agree that a longer for-cause audit period is necessary.

(c) ***Confidential Information in Audits***. Audits by AMAG or its designees may involve the transfer of Confidential Information, and any such Confidential Information shall be subject to the terms of Article 11 hereof. The results of such audits and inspections shall be considered Confidential Information under Article 11 and shall not be disclosed to Third parties, […***…], unless required by law and only then upon prior written notice to Pfizer.

7.5 Regulatory Authority Inspections

(a) ***Inspections***. Pfizer also agrees to allow the FDA and any other relevant Regulatory Authority to conduct any Pre-Approval Inspection (***"PAI"***) or other audit they require of the […***…] Facility and Pfizer agrees to cooperate with the FDA and any other relevant Regulatory Authority in connection with such inspection. Pfizer will provide AMAG with notice of any PAI as soon as practicable. The parties shall consult regarding the nature, extent, duration of such inspection so as to determine whether AMAG may have an interest to send its personnel or representatives to the Facility. Upon agreement, Pfizer shall allow such representatives to be present at the Facility during the FDA inspection to the extent permitted by Applicable Law.

(b) ***Additional PAIs***. In the event that AMAG has requested to expand the Territory and a Regulatory Authority other than the FDA requests or requires a PAI audit of the Facility in connection therewith, Pfizer will be entitled to charge a supplementary audit fee of […***…] per each such PAI.

7.6 Customer Representative

(a) In addition to the audit rights stated in Section 7.4, Pfizer shall also permit a representative of AMAG (***"Customer Representative")*** to be present in the relevant Facility to view certain Product manufacturing steps from time-time when the Products are being manufactured, provided that such Customer Representative (i) schedules the visit at least […***…] in advance (ii) complies with all applicable state and federal laws prior to and during such visits, and (iii) adheres to all applicable Pfizer corporate and security policies and procedures. While at the Facility, the Customer Representative must be escorted by a Pfizer employee and will have access solely such areas of the Facility that are (iv) reasonably related to view the manufacturing

steps for the Product, (v) food-service areas, (vi) designated office space as may be allocated to the Customer Representative, (vii) public areas within the facility, or (viii) as otherwise authorized by Pfizer. AMAG acknowledges and agrees that such Customer Representative visiting the Facility shall be bound by terms of confidentiality no less restrictive than those set forth in Article 11.

(b) With respect to any Customer Representative, Pfizer shall provide […***…] AMAG (i) access to an on-site workspace, (ii) a conference room (if necessary for meetings), access to which shall be available per the scheduling process used by Pfizer employees, (iii) parking facilities and toilet facilities, and (iv) reasonable access to and use of telephone, facsimile and photocopying services as necessary.

7.7 Change in Product Specifications; Manufacturing Process

Except as otherwise provided in Section 5.2, and as foreseen in the technical transfer Project as set forth in the Statement of Work detailing the technical transfer of the Product to the […***…] Facility, each of AMAG and Pfizer agrees that it will not change the Product Specifications or any aspect of the Manufacturing Process (including change of the Components, equipment, processes or procedures used to manufacture Product) without the prior written approval of the other party, which approval will not be unreasonably withheld, delayed, or conditioned. Upon agreement, the parties will implement all such changes in accordance with the change control provisions of the relevant Quality & Technical Agreement.

7.8 Failed Batch

In accordance with the Quality & Technical Agreement, Pfizer will investigate, and cooperate fully with AMAG in investigating, any batch of Product that fails to comply with cGMP or fails to meet the Product Specifications or any Regulatory Authority requirements. Pfizer will keep AMAG informed of the status of any investigation and, upon completion of the investigation, will provide AMAG with a final written report describing the cause of the failure and summarizing the results of the investigation.

7.9 Complaints and Adverse Drug Experiences

Each party will promptly advise the other of any complaints, notices of Adverse Drug Experience(s) or event reports, safety issues or toxicity issues relating to the Products of which it becomes aware, and which may be the result of, or have an effect on, the Product manufacturing operations performed by Pfizer. AMAG will be responsible for all reporting of such information to Regulatory Authorities. Pfizer will promptly evaluate any complaint or notice of Adverse Drug Experience(s) and reasonably assist AMAG in responding to the same.

7.10 Product Recalls

(a) ***Recalls***. In the event (i) any Regulatory Authority or other national government authority issues a request, directive or order that the Product be recalled, (ii) a court of competent

jurisdiction orders such a recall, or (iii) AMAG or Pfizer reasonably determines that Product should be recalled, the parties will take all appropriate corrective actions, and will cooperate in any governmental investigations surrounding the recall.

(b) ***Product Replacement; Expenses***. In the event that such recall results from a breach of Pfizer's express warranties under Sections 8.3(a) and 8.3(b), Pfizer will be responsible for replacing the quantity of Products that were recalled […***…]. Pfizer will use all commercially reasonable efforts to replace such Product as soon as practicable, given scheduling at the Facility. […***…].

7.11 Water Content Specification

(a) ***Water Content Specification Failures***. Both parties acknowledge that Pfizer manufactures the Product as a non-aqueous solution in production environments that use water for injection ubiquitously. Despite all reasonable efforts that Pfizer may take at both the […***…] Facilities to mitigate the risk for water in the Product, there remains a possibility that Pfizer will not meet the designated Water Content Specification of NMT 0.20% w/w. If technical difficulties arise with Water Content Specification in one (1) of more batches of Product, the parties agree that the following terms and conditions shall apply.

(b) ***Water Content Specification Remediation***. All provisions in the Agreement regarding responsibilities for re-manufacturing of failed batches, replacement of API, recalls and the like will be tolled until the parties have discussed, examined and determined the root cause of the failure to meet the Water Content Specification. Provided that Pfizer has used all reasonable efforts to transfer, validate and implement the remediation measures described in Section 7.11(c), below, and the parties agree that Pfizer should perform either additional work or repeat work to mitigate any risks relating to the Water Content Specification, Pfizer shall provide AMAG with terms and conditions of any such additional, repeat or new work, including the scope of work, pricing, timeframes and responsibilities in a separate Proposal. In the event the root cause of the failure to meet the Water Content Specification is due to the gross negligence or wilful misconduct of Pfizer, the parties shall agree to any additional or repeat work and which party shall bear the responsibility for such work. Pfizer's pricing will be in accordance with the provisions of Section 3.3(a). Pfizer will then carry out the work contained in the Proposal and any necessary changes will be made to the Product Specifications and implemented in accordance with the change control provisions of the relevant Quality & Technical Agreement. […***…].

(c) ***Technical Transfer of Water Specification Remediation*** . Pfizer will ensure that it includes in the technical transfer Statement of Work, all information, data, work product and results (including specifications, processes and implementation) regarding the remediation work on the Water Specification performed at the […***…] Facility. Notwithstanding any of the foregoing, Pfizer shall be required to meet the Water Content Specification, and the exceptions described herein shall not longer apply, after Pfizer has delivered to AMAG […***…] batches of conforming commercial Product manufactured at the […***…] Facility.

ARTICLE 8
WARRANTIES; COVENANTS; INDEMNIFICATION

8.1 Mutual Representations and Warranties

Each party represents, warrants and covenants to the other party that:

(a) ***Good Standing***. It is duly incorporated, validly existing and in good standing under the laws of the state in which it is incorporated;

(b) ***Power and Authority***. It has the corporate power and authority to enter into this Agreement and perform its obligations hereunder and the execution, delivery and performance of this Agreement and the performance of its obligations hereunder have been duly authorized and approved by all necessary action and no other action on the part of it is necessary to authorize the execution, delivery and performance of this Agreement;

(c) ***Existence of Claims***. There are no suits, claims, or proceedings pending, or to its best knowledge and belief, after due inquiry, threatened against it or any of its Affiliates in any court or by or before any governmental body or agency which would affect its ability to perform its obligations under this Agreement; and

(d) ***No Conflicts***. The performance of its obligations under this Agreement will not result in a material violation or breach of any agreement, contract, commitment or obligation to which it is a party or by which it is bound and will not conflict with or constitute a default under its corporate charter or bylaws.

8.2 AMAG's Representations, Warranties and Covenants

AMAG represents and warrants to Pfizer that:

(a) all API that AMAG provides to Pfizer will, at the time of delivery, not be adulterated or misbranded within the meaning of the FD&C Act or within the meaning of any other Applicable Law in which the definitions of adulteration and misbranding are substantially the same as those contained in the FD&C Act, as the FD&C Act and such laws are constituted and effective at the time of delivery, and will not be an article which, under the provisions of Sections 404 and 505 of the Act, may not be introduced into Interstate Commerce;

(b) all API that AMAG provides to Pfizer will have been manufactured in accordance with all applicable cGMP (including ICH Q7A) and meets the API Specifications;

(c) all specifications, including API Specifications and Product Specifications that AMAG provides to Pfizer will conform to the Regulatory Approval (and any modifications or amendments thereto) that AMAG files with the FDA and other relevant Regulatory Authorities;

(d) it will not sell any Product into any regulatory jurisdiction unless and until it receives and/or maintains the necessary Regulatory Approval(s); and

(e) AMAG's Intellectual Property, proprietary technology, Manufacturing Processes or other proprietary rights that AMAG provides to Pfizer under this Agreement does not infringe any patents or know-how of a Third Party.

8.3 Pfizer's Representations, Warranties and Covenants

Pfizer represents and warrants to AMAG that:

(a) all Product that Pfizer delivers to AMAG hereunder will, at the time of delivery, not be adulterated or misbranded within the meaning of the FD&C Act or within the meaning of all Applicable Law in which the definitions of adulteration and misbranding are substantially the same as those contained in the FD&C Act, as the FD&C Act and such laws are constituted and effective at the time of delivery and will not be an article which may not under the provisions of Sections 404 and 505 of the FD&C Act be introduced into interstate commerce;

(b) all Product Pfizer delivers to AMAG hereunder will, at the time of delivery, be free from defects in material and workmanship and will be manufactured (i) in accordance and conformity with the Product Specifications, and (ii) in compliance with all Applicable Laws, including those relating to the environment, food or drugs and occupational health and safety, including those enforced or promulgated by the FDA (including compliance with cGMP); and

(c) in its performance of its obligations under this Agreement, Pfizer will not knowingly incorporate into the Manufacturing Process any patents or know-how of a Third party for which it does not have a licence that permits it to do so and/or to be able to grant to AMAG the licences and other rights otherwise required to be granted to AMAG hereunder.

(d) The foregoing warranties will not extend to any nonconformity or defect which relates to or is caused by API supplied by AMAG to Pfizer. Subject to Pfizer's indemnity obligations in Section 8.5, the replacement provisions of Sections 5.4(c), 5.4(d), 5.8(g), 5.8(h) and 7.10(b) will be AMAG's sole and exclusive remedies for nonconforming or defective Products.

(e) PFIZER MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE PRODUCTS. PFIZER HEREBY DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

8.4 Indemnification by AMAG

AMAG hereby agrees to save, defend, indemnify and hold harmless Pfizer and its Affiliates and their respective officers, directors, employees, contractors, consultants and agents (each, a "***Pfizer Indemnitee***") from and against any and all losses, damages, liabilities, expenses and costs,

including reasonable legal expense and attorneys' fees ("***Losses***"), to which any Pfizer Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third party (a "***Claim***") against a Pfizer Indemnitee arising or resulting directly or indirectly from (a) AMAG's breach of any representation or warranty set forth in Section 8.1 or Sections 8.2(a) - 8.2(e), (b) infringement of any Intellectual Property right of any Third party relating to the API Specifications, Product Specifications, API, Drug, Product or the Manufacturing Process, other than Pfizer's processes used in the manufacture of the Product pursuant to this Agreement, (c) the use of or lack of safety or efficacy of the Product, or (d) any negligent or wrongful act or omission on the part of AMAG, its employees, agents or representatives and which relate to AMAG's performance hereunder except, in each case, to the extent such Losses result from the negligence or willful misconduct of any Pfizer Indemnitee or the breach by Pfizer of any express warranty or representation made by Pfizer in this Agreement.

8.5 Indemnification by Pfizer

Pfizer will indemnify and hold harmless AMAG and its Affiliates and their respective officers, directors, employees, contractors, consultants and agents (each, a ***"AMAG Indemnitee***") from and against any and all Losses to which any AMAG Indemnitee may become subject as a result of any Claim against a AMAG Indemnitee arising or resulting, directly or indirectly, from (a) Pfizer's breach of any representation or warranty set forth in Section 8.1 or Sections 8.3(a) and 8.3(b), (b) infringement of any Intellectual Property right of any Third party relating to Pfizer's manufacturing processes used in the manufacture of Product pursuant to this Agreement (excluding the API Specifications, Product Specifications, API, Drug, Product or the Manufacturing Process), or (c) any negligent or wrongful act or omission on the part of Pfizer, its employees, agents or representatives and which relate to Pfizer's performance hereunder except, in each case, to the extent such Losses result from the negligence or willful misconduct of any AMAG Indemnitee or the breach by AMAG of any express warranty or representation made by AMAG in this Agreement.

8.6 Conditions of Indemnification

If either party seeks indemnification from the other hereunder, it will promptly give notice to the other party of any Claim and will cooperate fully with the other party in the investigation and defense of all such Claim. The indemnifying party will have the option to assume the other party's defense in any such Claim with counsel reasonably satisfactory to the other party. In the event the indemnifying party assumes such defense, the indemnified party will have the right, but not the obligation, to be represented by counsel of its own selection and at its own expense. No settlement or compromise will be binding on a party hereto without its prior written consent, such consent not to be unreasonably withheld.

8.7 No Consequential Damages

NEITHER PARTY WILL BE LIABLE TO THE OTHER FOR INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE, EXEMPLARY OR CONSEQUENTIAL DAMAGES, LOST PROFITS, BUSINESS OR USE RESULTING FROM ANY BREACH OF THIS AGREEMENT, EVEN IF

SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY THEREOF, AND REGARDLESS OF THE LEGAL OR EQUITABLE THEORY (CONTRACT, TORT, OR OTHERWISE).

ARTICLE 9
INTELLECTUAL PROPERTY RIGHTS

9.1 Pfizer Intellectual Property

Pfizer has granted no license, express or implied, to AMAG to use Pfizer proprietary technology, know-how or other proprietary rights (a) existing as of the Effective Date, or (b) developed by or for Pfizer on or after the Effective Date outside the scope of any Project undertaken by Pfizer pursuant to this Agreement. Pfizer shall be the sole owner of any proprietary technology, know-how or other proprietary rights developed by or for Pfizer pursuant to any Project undertaken by Pfizer (the ***"Project Inventions"***). However, Pfizer shall grant to AMAG, and does hereby grant to AMAG, an exclusive (even as to Pfizer), royalty-free, paid up, worldwide, perpetual license under such Project Inventions to make, have made, use, offer for sale, sell, and/or import Drug and Product.

9.2 AMAG Intellectual Property

AMAG has granted no license, express or implied, to Pfizer to use AMAG's proprietary technology, know-how or other proprietary rights other than for the purposes of this Agreement.

ARTICLE 10
TERM AND TERMINATION

10.1 Term

[…***…].

10.2 […***…]

[…***…].

10.3 General Termination Rights

Either party may terminate this Agreement:

(a) ***Bankruptcy***. Immediately by providing written notice to the other party: (i) if proceedings in voluntary or involuntary bankruptcy are initiated by, on behalf of or against the other party (and, in the case of any such involuntary proceeding, not dismissed […***…]; or (ii) if the other party is adjudicated bankrupt, files a petition under applicable insolvency laws, is dissolved or has a receiver appointed for substantially all of its property; or

(b) ***Material Breach***. By giving to the other party […***…] prior written notice upon the breach of any warranty or any other material provision of this Agreement by the other party if the breach is not cured within […***…] after written notice thereof to the party in default; or

(c) ***Force Majeure***. Upon simple notice to the other party should the other party continue to be unable to perform its obligations under this Agreement for a period in excess of […***…] by reason of *force majeure*, in accordance with Section 12.1(a).

10.4 Termination in Part Due to Regulatory Changes; Manufacturing Issues

Pfizer may terminate this Agreement with respect to the manufacture of the Product at the […***…] Facility:

(a) ***Regulatory Authority Mandates***. In the event that the FDA or any other Regulatory Authority issues a regulation, directive, guideline or other guidance (*e.g.,* prohibiting or placing onerous burdens on manufacturing of hormonal or other specialty classes of medicinal products in the same facility where other standard pharmaceuticals are manufactured) and that materially affects Pfizer's ability to manufacture and supply the Product or any other Pfizer products at its […***…] manufacturing plant; or

(b) ***Manufacturing Issues***. In the event that Pfizer experiences quality issues, manufacturing problems or other related circumstances that (i) arise in the course of manufacturing the Product for AMAG, (ii) are beyond Pfizer's reasonable ability to control in the current configuration of the […***…] Facility (including cross-contamination of other lines or products, EHS-related problems; *etc.*), and (iii) adversely affect Pfizer's ability to manufacture at the […***…] manufacturing plant the Product […***…].

(c) ***Notice of Termination in Part***. In such case, Pfizer shall promptly notify AMAG in writing, setting out a detailed description of the circumstances. The parties will consult in good faith to attempt to find a commercially reasonable solution for at least […***…]. If the parties are not able to find such a commercially reasonable solution, Pfizer may provide notice to AMAG that it will terminate manufacture of the Product at the […***…] Facility no later than […***…] after notice, or for such shorter period if so mandated by the FDA or other Regulatory Authority (***"Notice Period"***).

(d) ***Manufacturing Obligations During Notice Period***. During the Notice Period, AMAG shall have the right to purchase, and Pfizer the obligation to manufacture and supply, Products in accordance with the principles set forth in this Section 10.4(d). The parties agree (i) in each […***…] period during the Notice Period, AMAG's Purchase Orders shall not exceed the average total of […***…] of its orders during the most recent Firm Order Period (as defined in this Agreement), and (ii) that such orders permit final test, release and delivery of Products no later than […***…]. Except to complete AMAG's Purchase Orders during the Notice Period, Pfizer shall be not be obligated to deviate from its processes for manufacturing the Products or incur any additional costs or expenses and shall use its best efforts to meet AMAG's requirements.

(e) ***Termination of Obligations***. In the event that Pfizer is required or permitted to give termination notice hereunder and the technical transfer Project is completed, validation batches of Product are successfully manufactured at the […***…] Facility and the […***…] site PAI is issued and approved, any remaining obligations to manufacture Product at the McPherson Facility, either under this Section 10.4 or under this Agreement, will lapse and no longer be of any effect.

10.5 Consequences of Termination

Except as provided in Section 10.4, upon expiry or termination of this Agreement for whatever reason the parties will wind-up this Agreement and settle all outstanding issues in accordance with the principles described below.

(a) ***Cessation of Manufacturing***. Pfizer will cease all manufacturing-in-progress and other ongoing activities in an orderly manner, unless Pfizer reasonably determines that manufacturing-in-progress or other ongoing activities must be completed in order to comply with applicable laws and regulations.

(b) ***Disposition of Inventory, API, Dedicated Equipment***. At a time to be mutually agreed between the parties, Pfizer will return to AMAG, at AMAG's option and election (i) any quantities of work-in-progress at price(s) to be mutually agreed, (ii) any inventory of API remaining in Pfizer's possession, and (iii) all items of Dedicated Equipment. All expenses associated with the preparation, packing and delivery of the work-in-progress, API, and Dedicated Equipment shall be borne by AMAG, unless termination shall have been as a result of a material breach by Pfizer, in which case Pfizer will be responsible for such expenses. If AMAG does not elect to take back the work-in-progress, API, or Dedicated Equipment, Pfizer have the discretion to dispose of such items as it deems appropriate.

(c) ***Reimbursement for Components and Materials***. In addition, AMAG will reimburse Pfizer for Pfizer's cost of all Components and other raw materials purchased and on hand or on order, if such Components and materials were ordered by Pfizer based on AMAG's Product forecasts, and Pfizer cannot reasonably use such Components and materials for other purposes. Pfizer will invoice AMAG for all amounts due hereunder and AMAG will pay such invoice on the terms set forth in Section 6.12.

(d) ***Return of Confidential Information***. Upon expiry or earlier termination of this Agreement for any reason, each party shall immediately return to the other all of the other party's Confidential Information, in any form or medium disclosed by the disclosing party. In lieu of returning all Confidential Information, each party shall have the option to destroy any Confidential Information in place and/or purge it from its respective electronic information systems; *provided, however*, that neither party shall be required to destroy any computer files stored securely by a party that are created during automatic system back-up. Notwithstanding the foregoing, each party shall be allowed to retain one (1) copy of the other's Confidential Information to ensure continuing compliance with Article 11.

10.6 Accrued Obligations

Termination of this Agreement will not relieve either party of any liability which has accrued prior to the effective date of such termination, nor will it prejudice either party's right to obtain

performance of any obligation provided for in this Agreement, which by its express terms or context survive termination.

10.7 Nonexclusive Rights and Remedies

Termination is not an election of remedies. Except as otherwise provided herein, all rights and remedies of the parties provided under this Agreement are not exclusive and are in addition to any other rights and remedies provided by law or under this Agreement.

10.8 Survival

The terms, provisions, representations, and warranties contained in this Agreement that by their sense and context are intended to survive the performance hereof by either or both parties will so survive the completion of performance and termination of this Agreement, including, confidentiality obligations and the making of any and all payments due hereunder.

ARTICLE 11
CONFIDENTIAL INFORMATION

11.1 Nondisclosure

It is contemplated that in the course of the performance of this Agreement each party may, from time to time, disclose Confidential Information to the other. Pfizer agrees that, except as expressly provided herein, it will not disclose Confidential Information received from AMAG, and will not use Confidential Information disclosed to it by AMAG, for any purpose other than to fulfill Pfizer's obligations hereunder. AMAG agrees that, except as expressly provided herein, it will not disclose Confidential Information received from Pfizer, and will not use Confidential Information disclosed to it by Pfizer, for any purpose other than to fulfill AMAG's obligations hereunder. Each party will use reasonable and customary precautions to safeguard the other party's Confidential Information, including ensuring that it will limit the permitted disclosures of the other's Confidential Information only to those persons who have a "need to know" such Confidential Information and ensuring that all employees, consultants and agents who are given access to such Confidential Information are informed of the confidential and proprietary nature of such Confidential Information and have contractual or professional confidentiality and non-use obligations that are at least as restrictive as those contained in this Agreement.

11.2 Exceptions to Duty of Nondisclosure

Notwithstanding the above, nothing contained in this Agreement will preclude AMAG or Pfizer from utilizing Confidential Information as may be necessary in prosecuting the patent rights of AMAG pursuant to Article 9, obtaining Regulatory Approval(s), manufacturing the Product pursuant to the terms and conditions of this Agreement, or complying with Applicable Laws or court orders (*provided, however*, that the party disclosing such information uses reasonable efforts to seek confidential treatment of such information, except as required to file and prosecute such

patent applications). The obligations of the parties relating to Confidential Information will expire […***…] after the termination of this Agreement.

11.3 Public Announcements

Neither party will make any public announcement concerning the transactions contemplated herein, or make any public statement which includes the name of the other party or any of its Affiliates, or otherwise use the name of the other party or any of its Affiliates in any public statement or document, except as may be required by law or judicial order, without the written consent of the other party, which consent will not be unreasonably withheld. Subject to any legal or judicial disclosure obligation, any such public announcement proposed by a party that names the other party will first be provided in draft to the other party.

11.4 Injunctive Relief

The parties acknowledge that either party's breach of this Article 11 may cause the other party irreparable injury for which it would not have an adequate remedy at law. In the event of a breach, the non-breaching party may be entitled to injunctive relief in addition to any other remedies it may have at law or in equity.

ARTICLE 12
MISCELLANEOUS

12.1 Force Majeure and Failure of Suppliers.

(a) ***Force Majeure***. Neither party will be considered to be in breach of this Agreement if a delay in the performance of any of its duties or obligations hereunder (except the payment of money) has been caused by or is the result of an act of God, acts of a public enemy, acts of terrorism, insurrections, riots, embargoes, labor disputes, including strikes, lockouts, job actions, boycotts, fires, explosions, floods, shortages of material or energy, or other unforeseeable causes beyond the control and without the fault or negligence of the party so affected (each an event of ***"force majeure"***). The performance of the affected party will be extended for a period equal to the period of such delay; *provided, however*, that affected party will give prompt notice to the other party of such cause, and will promptly take whatever reasonable steps are necessary to relieve the effect of such *force majeure* and resume compliance with this Agreement as soon as possible. Should the event of *force majeure* continue for a period longer than […***…], then the party not so affected may terminate this Agreement in accordance with Section 10.3(c).

(b) ***Transfer of Production***. If Pfizer becomes subject to an event of *force majeure* which interferes with production of Product at the Facility, the parties will mutually agree on implementation of an agreed-upon action plan to transfer production of Product to another Pfizer manufacturing facility. The parties will, after the execution of this Agreement and at the request of either party, meet to discuss and define such an action plan.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[…***…]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT UNDER RULE 24B-2 PROMULGATED UNDER THE SECURITIES ACT OF 1934, AS AMENDED.

12.2 Notices

All notices, requests, claims, demands and other communications between the parties will be in writing. All notices will be given (a) by delivery in person, (b) by a nationally recognized next day courier service, (c) by first class, registered or certified mail, postage prepaid, (d) by facsimile, or (e) by PDF scanned copy sent by electronic mail to the following addresses of the respective parties:

If to AMAG:

AMAG Pharmaceuticals, Inc.
1100 Winter Street
Waltham, MA 02451

Attention: SVP Technical Operations
Email: smcmillan@amagpharma.com

With a copy to:

AMAG Pharmaceuticals, Inc.
1100 Winter Street
Waltham, MA 02451

Attention: General Counsel
Email: jvittiglio@amagpharma.com

If to Pfizer:

Pfizer Worldwide, Inc.
275 North Field Drive
Lake Forest, Illinois 60045

Attention: V.P. Contract Manufacturing
Facsimile: (224) 212-3210
Email: kevin.orfan@prizer.com

With copy to:

Pfizer Inc.
235 East 42nd Street
New York, NY 10017

Attention: General Counsel
Facsimile: (212) 309 0874
Email: generalcounsel@pfizer.com

Notices will be effective (w) upon receipt, if personally delivered, (x) is sent by courier, one (1) Business Day after the delivery time promised by the nationally recognized next day courier service, (y) if delivered by facsimile or electronic mail, on first Business Day after the date of receipt by the transmitting person of written confirmation of successful transmission (which confirmation may be produced by the transmitting person's facsimile or electronic mail equipment), or (z) four (4) Business Days after being deposited in the United States mail, with proper postage and documentation, for first-class registered or certified mail, prepaid. A party may change its address listed above by written notice to the other party.

12.3 Governing Law

This Agreement will be construed, interpreted and governed by the laws of the State of New York, excluding its choice of law provisions. The United Nations Convention on the International Sale of Goods is hereby expressly excluded.

12.4 Alternative Dispute Resolution

The parties recognize that bona fide disputes may arise which relate to the parties' rights and obligations under this Agreement. The parties agree that except as provided in Section 11.4, any such dispute will be resolved by alternative dispute resolution in accordance with the procedures set forth in Exhibit 12.4.

12.5 Assignment

Neither party will assign this Agreement nor any part thereof without the prior written consent of the other party; *provided, however*, that either party may, without such consent, assign the rights and obligations of this Agreement (a) to one of its Affiliates, subsidiaries or parent corporation, and (b) in connection with the transfer, sale or divestiture of substantially all of its business to which this Agreement pertains or in the event of its spin-off, merger or consolidation with another company. Any permitted assignee will assume all obligations of its assignor under this Agreement. No assignment will relieve either party of responsibility for the performance of any accrued obligation which such party then has hereunder.

12.6 Severability

This Agreement is subject to the restrictions, limitations, terms and conditions of all applicable governmental regulations, approvals and clearances. If any term or provision of this Agreement will for any reason be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other term or provision hereof, and this Agreement will be interpreted and construed as if such term or provision, to the extent the same will have been held to be invalid, illegal or unenforceable, had never been contained herein.

12.7 Modification of Agreement; Waiver

No waiver or modification of any of the terms of this Agreement will be valid unless in writing and signed by authorized representatives of both parties. Failure by either party to enforce any such rights under this Agreement will not be construed as a waiver of such rights, nor will a waiver by either party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances

12.8 Relationship of the Parties

The relationship of the parties under this Agreement is that of independent contractors. Nothing contained in this Agreement or the performance of any obligations under this Agreement will create an association, partnership, joint venture, or relationship of principal and agent, master and servant, or employer and employee between the parties hereto. Neither party has any express or implied right or authority under this Agreement to assume or create any obligations or make any representations or warranties on behalf of or in the name of the other party or its Affiliates.

12.9 Insurance

Each party will procure and maintain, at its own expense, for the duration of the Agreement, and for […***…] thereafter if written on a claims made or occurrence reported form, the types of insurance specified below with carriers rated A- VII or better with A. M. Best or like rating agencies:

(a) Workers' Compensation in accordance with applicable statutory requirements and minimum […***…] Employers Liability and each party shall provide a waiver of subrogation in favor of the other party and its affiliate;

(b) Commercial General Liability including premises operations, products & completed operations, blanket contractual liability, personal injury and advertising injury including fire legal liability for bodily injury and property damage in an amount not less than […***…] per occurrence and not less than […***…] in the aggregate;

(c) Commercial Automobile Liability for owned, hired and non-owned motor vehicles with a combined single limit in an amount not less than […***…] each occurrence;

(d) Marine Insurance covering all shipments from warehouse to warehouse as described on the bill of lading at full replacement cost, except as otherwise provided herein.

Each party will include the other party and its Affiliates, directors, officers, employees and agents as additional insureds with respect to Commercial General Liability (via CG20101185 or its equivalent), Commercial Automobile Liability and Excess Liability but only as required by written contract. Prior to commencement of the development services, and annually thereafter, each party will furnish to the other party certificates of insurance evidencing the insurance coverages stated above. At least […***…] written notice to the other party shall be provided prior to any cancellation, non-renewal or material change in said coverage. In the case of cancellation, non-renewal or material change in said coverage, each party will promptly provide to the other party a new certificate of insurance evidencing that the coverage meets the requirements in this Section 12.9. Each party, to the extent of its negligence, agrees that its insurance will act as primary and noncontributory from any other valid and collectible insurance maintained by the other party. Each party may, at its option, satisfy, in whole or in part, its obligation under this Section 12.9 through its self- insurance program. […***…]. Each party shall provide a waiver of subrogation in favor of the other party and its affiliates on all required coverages, above. All deductibles/retentions are the sole responsibility of the named insured.

12.10 Exhibits

All Exhibits referred to herein are hereby incorporated by reference.

12.11 Binding Effect

This Agreement will be binding upon and inure to the benefit of each of the parties and such party's successors and permitted assigns.

12.12 Debarment Warranty

Pfizer and AMAG represent and warrant that neither party uses nor will use in the future use in any capacity the services of any person debarred under Section (a) or (b) of 21 U.S.C. Section 335a.

12.13 Compliance with Laws

Each party will comply with all Applicable Laws, statutes, rules and regulations governing its performance of the terms of this Agreement.

12.14 Entire Agreement

This Agreement and the Quality & Technical Agreement, together with the Exhibits referenced and incorporated herein, constitute the entire agreement between the parties concerning the subject matter hereof and supersede all written or oral prior agreements or understandings with respect thereto. If there is any conflict, discrepancy, or inconsistency between the terms of the Quality & Technical Agreement, this Agreement or other form used by the parties, the Quality & Technical Agreement will control as regards all issues related to quality assurance; in all other cases, the Agreement will control.

12.15 Construction

In construing this Agreement, unless expressly specified otherwise (a) references to Articles, Sections and Exhibits are to articles, sections of, and exhibits to, this Agreement, (b) except where the context otherwise requires, use of either gender includes the other gender, and use of the singular includes the plural and vice versa, (c) headings and titles are for convenience only and do not affect the interpretation of this Agreement, (d) any list or examples following the word "including" will be interpreted without limitation to the generality of the preceding words, (e) except where the context otherwise requires, the word "or" is used in the inclusive sense, (f) all references to "dollars" or "$" herein will mean United States Dollars, and (g) each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions. Any terms or conditions contained in an invoice that are inconsistent or in conflict with this Agreement will be deemed not to be a part of such invoice.

12.16 Counterparts

This Agreement may be executed in any number of counterparts, each of which will be deemed an original, and all of which together will constitute one and the same instrument. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail will be deemed to be original signatures. Any party delivering an executed counterpart of this Agreement by facsimile or electronic mail will also deliver an original executed counterpart, but the failure to do so will not affect the validity, enforceability or binding effect of this Agreement.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[…***…]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT UNDER RULE 24B-2 PROMULGATED UNDER THE SECURITIES ACT OF 1934, AS AMENDED.

THE IMMEDIATELY FOLLOWING PAGE IS THE EXECUTION PAGE

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[…***…]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT UNDER RULE 24B-2 PROMULGATED UNDER THE SECURITIES ACT OF 1934, AS AMENDED.

IN WITNESS WHEREOF, the parties intending to be bound by the terms and conditions hereof have caused this Agreement to be signed by their duly authorized representatives as of the date first above written.

PFIZER INC.

By: /s/ Kevin Orfan
(Signature)

Name: Kevin Orfan

Title: Vice President
Pfizer CentreOne
Global Pharmaceutical Services

AMAG PHARMACEUTICALS, INC.

By: /s/ William K. Heiden
(Signature)

Name: William K. Heiden
Chief Executive Officer

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EXHIBIT 1.4

API Specifications

Active Pharmaceutical Ingredient, Hydroxyprogesterone Caproate USP, Specifications

Test Method	Acceptance Criteria	Method of Acceptance
Appearance (Visual)	[…***…]	Pfizer to Test
Color (Visual)	[…***…]	Vendor CoA
Visible impurities (Visual)	[…***…]	Vendor CoA
Identification - IR (USP <197K>)	[…***…]	Pfizer to Test
Assay (UV Spectroscopy)	[…***…]	Vendor CoA
Free Caproic Acid (USP Titrimetric Assay)	[…***…]	Vendor CoA
Melting Point (USP <741> Class Ia)	[…***…]	Vendor CoA
Related Substances (Ordinary Impurities)- TLC (USP <466>)	[…***…]	Vendor CoA
Residual Solvents (Gas Chromatography) USP <467> Cyclohexane Hexane Methanol Methylene chloride	[…***…]	Vendor CoA
Specific Rotation (USP <781S>; 25°C/1% in chloroform/anhydrous substance)	[…***…]	Vendor CoA
Water – KF (USP <921>, Method I)	[…***…]	Vendor CoA
Bioburden EP2.6.12 / USP <61> *(Total Viable Aerobic Count)*	[…***…]	Pfizer to test
Bacterial Endotoxin (USP <85>; Gel-Clot Limit Test)	[…***…]	Pfizer to test

EXHIBIT 1.25

Product Specifications

AMAG and Pfizer will consult and use all reasonable efforts to prepare and complete the Product Specifications no later than […***…] after the Effective Date. Upon completion, the Product Specifications shall be attached to this Exhibit 1.25 and shall be made an integral part of this Agreement.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[…***…]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT UNDER RULE 24B-2 PROMULGATED UNDER THE SECURITIES ACT OF 1934, AS AMENDED.

EXHIBIT 2.1

Project Statement of Work

[…***…]

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EXHIBIT 2.1

Project Statement of Work (cont'd)

[…***…]

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EXHIBIT 2.1

Project Statement of Work (cont'd)

[…***…]

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EXHIBIT 2.1

Project Statement of Work (cont'd)

[…***…]

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[…***…]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT UNDER RULE 24B-2 PROMULGATED UNDER THE SECURITIES ACT OF 1934, AS AMENDED.

EXHIBIT 2.1

Project Statement of Work (cont'd)

[…***…]

EXHIBIT 3.2

Stability Studies

Stability Testing	Req.	Not Req.	N/A	Responsibility		Cost
				Pfizer	Client	
Engineering stability		X				N/A
Registration batch stability	X			X		[…***…]
Annual Commercial Product stability	X					[…***…]
Total Cost:	**TBD**					[…***…]
Payment:	[…***…]					
Timing:	**TBD**					

EXHIBIT 6.9

Pfizer Logger Policies

The following policies shall apply for all shipments of Commercial Products and Development Supplies (including drug product samples from development Batches) in which a Pfizer CentreOne customer AMAG requests or requires that electronic temperature monitoring devices (***"Loggers"***) be included in the shipment as a means of supplementary assurance of complying with the controlled room temperature storage/shipping conditions under which the products should be maintained.

It is Pfizer's policy that if a Pfizer CentreOne Customer desires to include Loggers in shipments of tested and released Commercial Products, the Pfizer CentreOne Customer must supply the Loggers at its own cost and responsibility.

For shipments of Development Supplies or drug product samples from development Batches, it is Pfizer's preference that the Pfizer CentreOne Customer also supply the Loggers at its own cost and expense. However, as an accommodation to its Pfizer CentreOne Customer, Pfizer is willing to provide standard, non-specialized Loggers to be included the Development Supply or drug product sample shipment as a supplementary means of assuring that the shipment has been made under controlled room temperature storage/shipping conditions. Pfizer procures Loggers from reputable third party vendors and relies on the representations and warranties of these vendors for the quality and correct functioning of the Temptale devices. Although Pfizer will do

a preliminary check on the Loggers to ensure that they are functioning as intended before placing them in the drug product shipment packing and containers, it will perform no detailed testing or undertake any special calibration before use.

Pfizer therefore cannot be responsible and will not be liable to any Pfizer CentreOne Customer for any and all losses, damages, liabilities, expenses and costs arising from any claim or allegation that the Loggers supplied by Pfizer have failed in their intended use during shipment of the Development Supplies or drug product samples. The Pfizer CentreOne Customer acknowledges and agrees that the failure or improper functioning of the Pfizer-supplied Loggers will not give rise to any cause of action against Pfizer or serve as a basis for the Pfizer CentreOne Customer to reject the shipment of the Development Supplies or drug product samples.

In addition, if Pfizer is requested to provide Loggers on accommodation, Pfizer will only supply the Temptale devices. It is the Pfizer CentreOne Customer's responsibility to have acquired the hardware and software from the Temptale manufacturer that is necessary to read the data collected by the Temptale during shipment.

The Pfizer CentreOne Customer may be requested to sign a document acknowledging its understanding and acceptance of the above-stated Temptale policies.

EXHIBIT 7.1

Product Test Methods

In consultation with AMAG, no later than […***…] after the Effective Date, Pfizer will use all reasonable efforts to prepare and complete documentation describing the procedures, methods and protocols by which the Product will be tested and released, as specified in Section 7.1 of this Agreement. Upon completion, such documentation shall be attached to this Exhibit 7.1 and shall be made an integral part of this Agreement.

EXHIBIT 12.4

Alternative Dispute Resolution

The Parties recognize that bona fide disputes as to certain matters may arise from time to time during the term of this Agreement which relate to either party's rights and/or obligations. To have such a dispute resolved by this Alternative Dispute Resolution ***("ADR")*** provision, a party first must send written notice of the dispute to the other party for attempted resolution by good faith negotiations between their respective presidents (or their designee(s), provided any such designee has the authority to act on behalf of such party to effectuate any such resolution) of the affected subsidiaries, divisions, or business units within […***…] days after such notice is received (all references to ***"days"*** in this ADR provision are to calendar days).

If the matter has not been resolved within […***…] days of the notice of dispute, or if the Parties fail to meet within such […***…] days, either party may initiate an ADR proceeding as provided herein. The Parties shall have the right to be represented by counsel in such a proceeding.

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1. To begin an ADR proceeding, a party shall provide written notice to the other party of the issues to be resolved by ADR. Within […***…] days after its receipt of such notice, the other party may, by written notice to the party initiating the ADR, add additional issues to be resolved within the same ADR.

2. Within […***…] days following receipt of the original ADR notice, the Parties shall select a mutually acceptable neutral having requisite legal expertise and credentials (including with respect to the substantive law of the State of New York) to preside in the resolution of any disputes in this ADR proceeding. If the Parties are unable to agree on a mutually acceptable neutral within such period, either party may request the President of the CPR Institute for Dispute Resolution (***"CPR"***), 366 Madison Avenue, 14th Floor, New York, New York 10017, to select a neutral pursuant to the following procedures:

(a) The CPR shall submit to the Parties a list of not less than […***…] candidates within […***…] days after receipt of the request, along with a Curriculum Vita for each candidate. No candidate shall be an employee, director, or shareholder of either party or any of their subsidiaries or Affiliates.

(b) Such list shall include a statement of disclosure by each candidate of any circumstances likely to affect his or her impartiality.

(c) Each party shall number the candidates in order of preference (with the number one (1) signifying the greatest preference) and shall deliver the list to the CPR within […***…] days following receipt of the list of candidates. If a party believes a conflict of interest exists regarding any of the candidates, that party shall provide a written explanation of the conflict to the CPR along with its list showing its order of preference for the candidates. Any party failing to return a list of preferences on time shall be deemed to have no order of preference.

(d) If the Parties collectively have identified fewer than […***…] candidates deemed to have conflicts, the CPR immediately shall designate as the neutral the candidate for whom the Parties collectively have indicated the greatest preference. If a tie should result between two candidates, the CPR may designate either candidate. If the Parties collectively have identified […***…] or more candidates deemed to have conflicts, the CPR shall review the explanations regarding conflicts and, in its sole discretion, may either (i) immediately designate as the neutral the candidate for whom the Parties collectively have indicated the greatest preference, or (ii) issue a new list of not less than […***…] candidates, in which case the procedures set forth in subparagraphs 2(a)-2(d) shall be repeated.

3. No earlier than […***…] days or later than […***…] days after selection, the neutral shall hold a hearing to resolve each of the issues identified by the Parties. The ADR proceeding shall take place at a location agreed upon by the Parties. If the Parties cannot agree, the neutral shall designate a location other than the principal place of business of either party or any of their subsidiaries or Affiliates.

4. At least […***…] days prior to the hearing, each party shall submit the following to the other party and the neutral:

(a) a copy of all exhibits on which such party intends to rely in any oral or written presentation to the neutral;

(b) a list of any witnesses such party intends to call at the hearing, and a short summary of the anticipated testimony of each witness;

(c) a proposed ruling on each issue to be resolved, together with a request for a specific damage award or other remedy for each issue. The proposed rulings and remedies shall not contain any recitation of the facts or any legal arguments and shall not exceed one (1) page per issue.

(d) a brief in support of such party's proposed rulings and remedies, provided that the brief shall not exceed forty (40) pages. This page limitation shall apply regardless of the number of issues raised in the ADR proceeding.

Except as expressly set forth in subparagraphs 4(a)-4(d), no discovery shall be required or permitted by any means, including depositions, interrogatories, requests for admissions, or production of documents.

5. The hearing shall be conducted on […***…] consecutive days and shall be governed by the following rules:

(a) Each party shall be entitled to […***…] hours of hearing time to present its case. The neutral shall determine whether each party has had the […***…] hours to which it is entitled.

(b) Each party shall be entitled, but not required, to make an opening statement, to present regular and rebuttal testimony, documents or other evidence, to cross-examine witnesses, and to make a closing argument. Cross-examination of witnesses shall occur immediately after their direct testimony, and cross-examination time shall be charged against the party conducting the cross-examination.

(c) The party initiating the ADR shall begin the hearing and, if it chooses to make an opening statement, shall address not only issues it raised but also any issues raised by the responding party. The responding party, if it chooses to make an opening statement, also shall address all issues raised in the ADR. Thereafter, the presentation of regular and rebuttal testimony and documents, other evidence, and closing arguments shall proceed in the same sequence.

(d) Except when testifying, witnesses shall be excluded from the hearing until closing arguments.

(e) Settlement negotiations, including any statements made therein, shall not be admissible under any circumstances. Affidavits prepared for purposes of the ADR hearing also shall not be admissible. As to all other matters, the neutral shall have sole discretion regarding the admissibility of any evidence.

6. Within […***…] days following completion of the hearing, each party may submit to the other party and the neutral a post-hearing brief in support of its proposed rulings and remedies, provided that such brief shall not contain or discuss any new evidence and shall not exceed […***…] pages. This page limitation shall apply regardless of the number of issues raised in the ADR proceeding.

7. The neutral shall rule on each disputed issue within […***…] days following completion of the hearing. Such ruling shall adopt in its entirety the proposed ruling and remedy of one of the Parties on each disputed issue but may adopt one party's proposed rulings and remedies on some issues and the other party's

proposed rulings and remedies on other issues. The neutral shall not issue any written opinion or otherwise explain the basis of the ruling or award.

8. The neutral shall be paid a reasonable fee plus expenses. These fees and expenses, along with the reasonable legal fees and expenses of the prevailing party (including all expert witness fees and expenses), the fees and expenses of a court reporter, and any expenses for a hearing room, shall be paid as follows:

(a) If the neutral rules in favor of one party on all disputed issues in the ADR, the losing party shall pay […***…] of such fees and expenses.

(b) If the neutral rules in favor of one party on some issues and the other party on other issues, the neutral shall issue with the rulings a written determination as to how such fees and expenses shall be allocated between the Parties. The neutral shall allocate fees and expenses in a way that bears a reasonable relationship to the outcome of the ADR, with the party prevailing on more issues, or on issues of greater value or gravity, recovering a relatively larger share of its legal fees and expenses.

9. The rulings of the neutral and the allocation of fees and expenses shall be binding, non-reviewable (except for an alleged act of corruption or fraud on the part of the arbitrator), and non-appealable, and may be entered as a final judgment in any court having jurisdiction.

10. Except as provided in paragraph 9 or as required by law, the existence of the dispute, any settlement negotiations, the ADR hearing, any submissions (including exhibits, testimony, proposed rulings, and briefs), and the rulings shall be deemed Confidential Information. The neutral shall have the authority to impose sanctions for unauthorized disclosure of Confidential Information.

12. The neutral may not award any form of damages or relief prohibited by Section 8.7 of the Agreement.

13. The neutral shall have the authority to grant injunctive relief and other specific performance.

14. The neutral shall, in rendering its decision, apply the substantive law of the State of New York, without regard to its conflict of laws provisions.

15. The hearings shall be conducted in the English language.

Exhibit 21.1

AMAG Pharmaceuticals, Inc.

Subsidiaries of the registrant

AMAG Pharmaceuticals Canada Corporation, a Nova Scotia unlimited liability company

AMAG Europe Limited, a UK private limited company

AMAG Securities Corporation, a Massachusetts corporation

AMAG Pharma USA, Inc., a Delaware corporation

FP1096, Inc., a Pennsylvania corporation

AMAG Pharmaceuticals IP Ltd., a Delaware corporation

Drugtech Sárl, a Swiss company

Lumara Health Services Ltd., a Missouri corporation

CBR Acquisition Holdings Corp., a Delaware corporation

Cbr Systems, Inc., a Delaware corporation

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statements on Forms S-3 (File Nos. 333-202009 and 333-202252) and Forms S-8 (File Nos. 333-82292, 333-131656, 333-148682, 333-159938, 333-168786, 333-182821, 333-190435, 333-197873, 333-203924 and 333-211277) of AMAG Pharmaceuticals, Inc. of our report dated February 17, 2017 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts

February 17, 2017

Exhibit 31.1

CERTIFICATIONS

I, William K. Heiden, certify that:

1. I have reviewed this Annual Report on Form 10-K of AMAG Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 17, 2017

/s/ William K. Heiden

William K. Heiden
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Edward Myles, certify that:

1. I have reviewed this Annual Report on Form 10-K of AMAG Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 17, 2017

/s/ Edward Myles

Edward Myles

Senior Vice President of Finance, Chief Financial Officer and Treasurer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of AMAG Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, William K. Heiden, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ William K. Heiden

William K. Heiden
Chief Executive Officer
(Principal Executive Officer)

February 17, 2017

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of AMAG Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Edward Myles, Senior Vice President of Finance, Chief Financial Officer and Treasurer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Edward Myles

Edward Myles

Senior Vice President of Finance, Chief Financial Officer and Treasurer

(Principal Financial Officer)

February 17, 2017