

**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, 2017

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
(State or Other Jurisdiction of
Incorporation or Organization)

1100 Winter Street
Waltham, Massachusetts
(Address of Principal Executive Offices)

04-2742593
(I.R.S. Employer
Identification No.)

02451
(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
Preferred Share Purchase Rights

NASDAQ Global Select Market

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, a smaller reporting company or emerging growth company. See definition of "accelerated filer," "large accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant 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, 2017 was approximately \$644.7 million based on the closing price of \$18.40 of the Common Stock of the registrant as reported on the NASDAQ Global Select Market on such date. As of February 27, 2018, there were 34,088,933 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.

AMAG PHARMACEUTICALS, INC.
FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2017
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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: beliefs that newborn stem cells have the potential to play a valuable role in the development of regenerative medicine, our plans to continue to expand the impact of our portfolio by delivering on our growth strategy; beliefs that healthcare professionals and patients will prefer the Makena auto-injector over the intramuscular administration; expectations of the timing of entry of a Makena generic to the market; expected timing of submission of the bremelanotide NDA; expectations regarding the IDA patient population; beliefs regarding the growth opportunities for Feraheme in the IV iron market; our expected investment in label expansion for Intrarosa and plans to raise awareness and education of dyspareunia and VVA and the results of such efforts; the timing and amounts of milestone and royalty payments; plans to grow our portfolio; expectations and plans as to regulatory and commercial developments and activities, including requirements and initiatives for clinical trials, post-approval commitments for our products; expected results of our strategic commercialization efforts; the market for our maternal health portfolio; expectations as to what impact recent and upcoming regulatory developments will have on our business and competition; expectations regarding our intellectual property, including patent protection, and the impact generics and other competition could have on each of our products and our business generally, including the timing and number of generic entrants; the market opportunities for each of our products and services; expectations regarding third-party reimbursement and the behaviors of payers, healthcare providers and other industry participants; plans regarding our sales and marketing initiatives, including our contracting, pricing and discounting strategies and efforts to increase patient compliance and access; 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; our inventory levels and the availability of raw materials; the strategic fit of Intrarosa and bremelanotide in our product portfolio; our expectations regarding customer returns and other revenue-related reserves and accruals; the impact of recent tax reform legislation; 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 expenses, efforts and challenges in research and development 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, goodwill; impairment; amortization and other income (expense); estimates, beliefs and judgments related to our impairment analysis; our investing activities; estimates and beliefs related to our debt, including our 2023 Senior Notes and the Convertible Notes; 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 revenue, cash, 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 maternal and women's health, anemia management and cancer supportive care, including Makena[®] (hydroxyprogesterone caproate injection), Intrarosa[®] (prasterone) vaginal inserts, Feraheme[®] (ferumoxytol injection) for intravenous ("IV") use, and MuGard[®] Mucoadhesive Oral Wound Rinse. In addition, in February 2017, we acquired the rights to research, develop and commercialize bremelanotide in North America. Through services related to the preservation of umbilical cord blood stem cell and cord tissue units 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 intend 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 additional products and companies that align with our existing therapeutic areas or 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 regulatory status and the nature of our rights. Currently, we market and sell our pharmaceutical products solely in the U.S. and market and sell the CBR Services primarily in the U.S.

Product, Product Candidate or Service	Uses/Potential Uses	Regulatory Status	Nature of Rights
Makena [®] (hydroxyprogesterone caproate injection) (5 mL multi-dose vial and 1 mL single-dose preservative-free 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)	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 in February 2018. Launch expected March 2018.	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 certain countries in South America.
Feraheme [®] (ferumoxytol injection)	IV iron replacement therapeutic agent for the treatment of iron deficiency anemia ("IDA") in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron as well as patients who have CKD.	Approved and marketed.	Own worldwide rights.

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Product, Product Candidate or Service	Uses/Potential Uses	Regulatory Status	Nature of Rights
Intrarosa®(prasterone) vaginal inserts	A steroid indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy (“VVA”), due to menopause. Intrarosa is also under investigation for the treatment of hypoactive sexual desire disorder (“HSDD”), a type of FSD in post-menopausal women.	Approved and marketed. Phase 3 trial initiated by Endoceutics in the third quarter of 2017.	Exclusively license rights to develop and commercialize Intrarosa in the U.S. for the treatment of VVA and female sexual dysfunction (“FSD”) from Endoceutics, Inc. (“Endoceutics”), subject to certain rights retained by Endoceutics.
MuGuard® 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 MuGuard in the U.S. from Abeona Therapeutics, Inc. (“Abeona”).
Bremelanotide (Auto-injector device)	An investigational product designed to be an as desired therapy for the treatment of HSDD in pre-menopausal women.	New Drug Application (“NDA”) expected to be filed in the first quarter of 2018.	Exclusively license rights to research, develop and sell bremelanotide in North America from Palatin Technologies, Inc. (“Palatin”).
Digoxin immune fab (“DIF”)	A polyclonal antibody for the treatment of severe preeclampsia in pregnant women.	Phase 2b/3a trial initiated in the second quarter of 2017.	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 currently 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 U.S. Food and Drug Administration (the “FDA”) in February 2011 as an intramuscular (“IM”) injection (the “Makena IM product”) packaged in a multi-dose vial and as of February 2016 was also available in a single-dose preservative-free vial. In February 2018, Makena was also approved by the FDA for administration via a pre-filled subcutaneous auto-injector (the “Makena auto-injector”), a drug-device combination product. Makena is administered weekly by a healthcare professional 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. We currently sell Makena (and expect to sell the auto-injector) primarily to specialty pharmacies, specialty distributors, and pharmacies which, in turn, sell Makena to healthcare providers, hospitals, government agencies and integrated delivery systems. In 2017, sales of Makena accounted for approximately 63% of our total net revenues.

The approval of the auto-injector was based in part on data from a pharmacokinetic (“PK”) study, which demonstrated comparable bioavailability between the subcutaneous auto-injector product and the Makena IM product in 120 healthy post-menopausal women. No serious adverse events were reported in the PK study and the drug was generally well tolerated. The most common side effects of Makena include injection site reactions (pain, swelling, itching, bruising, or a hard bump), hives, itching, nausea, and diarrhea. The most common side effect reported with the Makena auto-injector (and higher than with the Makena IM product) was injection site pain.

The Makena auto-injector was designed with features, such as a shorter, thinner, non-visible needle compared to the Makena IM product, to help address some of the known barriers to treatment of recurrent preterm birth, including the lack of patient acceptance and adherence. As such, based on market research we conducted, we believe that many healthcare professionals and patients will prefer the auto-injector over the IM administration. However, some healthcare professionals and/or patients may continue to employ the IM method of administration. The orphan drug exclusivity period that was granted to

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the Makena product in 2011, expired on February 3, 2018 and accordingly, we expect to face generic competition to the Makena IM product in mid-2018, however generics could enter the market at any time. In anticipation of generic competition, we have entered into an agreement with a generic partner and are prepared to launch our own authorized generic upon the first entry of a generic Makena injection in order to participate in the expected generic market for Makena.

Preterm Birth

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 reaffirmed in January 2017. The SMFM Clinical Guidelines recommend the use of an IM HPC injection to reduce the risk of recurrent preterm birth for clinically indicated patients. Further, in its January 2017 reaffirmation of the 2012 SMFM Clinical Guidelines, the SMFM stated that vaginal progesterone should not be considered a substitute for HPC in women with a history of spontaneous preterm birth.

Preterm birth is defined as a birth prior to 37 weeks of pregnancy. According to the Centers of Disease Control and Prevention (the “CDC”), preterm birth affected nearly 400,000 babies born in the U.S. in 2016, or one of every ten infants, with approximately 70% considered late preterm births. In the CDC's September 2017 National Center for Health Statistics Report, it noted that the preterm birth rate rose in 2016 for the second straight year and attributed the rise primarily to an increase in late preterm births, defined as a birth between 34 and 36 weeks of pregnancy. Although the causes of preterm birth 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 use in women who have 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 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 elevated 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. We expect to complete the studies by December 2018 and October 2020, respectively.

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 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.

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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 services required to collect, process, and store umbilical cord blood stem cells and cord tissue, the FDA regulates such services as products.

The CBR Services include the collection, processing and storage of both umbilical cord blood and cord tissue. As of December 31, 2017, CBR stored approximately 700,000 umbilical cord blood and cord tissue units, which we estimate to represent nearly 40% of all privately stored cord blood and cord tissue units in the U.S. In 2017, revenue from the CBR Services accounted for approximately 19% of our total net revenues.

CBR partners with reputable research institutions on FDA-regulated clinical trials investigating the use of cord blood in regenerative medicine applications across a wide variety of conditions that have no cure today, including autism, acquired hearing loss 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 discussed further 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 and is FDA-registered. 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 mostly outside of the U.S. for their potential to treat heart disease, autoimmune disorders and orthopedic conditions. Approximately 79% of the stem cell units released by CBR have been used for experimental regenerative therapies.

Feraheme

Overview

Feraheme was approved for marketing by the FDA in June 2009 for the treatment of IDA in adult patients with CKD only and was commercially launched shortly thereafter. In February 2018, we received FDA approval to expand the Feraheme label to treat all eligible adult IDA patients who have intolerance to oral iron or have had unsatisfactory response to oral iron in addition to patients who have CKD. In 2017, sales of Feraheme for the treatment of CKD accounted for approximately 17% of our total net revenues.

The recently expanded Feraheme label is supported by two positive pivotal Phase 3 trials evaluating Feraheme versus iron sucrose or placebo in a broad population of patients with IDA. It was also supported by positive results from a third Phase 3 randomized, double-blind non-inferiority trial that evaluated the incidence of moderate-to-severe hypersensitivity reactions

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(including anaphylaxis) and moderate-to-severe hypotension with Feraheme compared to Injectafer® (ferric carboxymaltose injection) (the “Feraheme comparator trial”). Approximately 2,000 IDA patients were randomized in a 1:1 ratio into one of two treatment groups, those receiving 1.02 grams of Feraheme infusion or those receiving 1.5 grams of Injectafer® infusion. The Feraheme comparator trial demonstrated non-inferiority to Injectafer® based on the primary endpoint of the incidence of moderate-to-severe hypersensitivity reactions (including anaphylaxis) and moderate-to-severe hypotension (Feraheme incidence 0.6%; Injectafer® incidence 0.7%). The Feraheme comparator trial also met an additional safety endpoint based on a composite of the incidence of moderate-to-severe hypersensitivity reactions, serious cardiovascular events, and/or death (Feraheme incidence 1.3%; Injectafer® incidence 2.0%). In addition, the Feraheme comparator trial met important secondary efficacy endpoints: the demonstration of non-inferiority to Injectafer® comparing mean improvement in (a) hemoglobin per gram of iron administered from baseline to week 5 (1.35 g/dL Feraheme versus 1.10 g/dL Injectafer®) and (b) hemoglobin per course of treatment from baseline to week 5 (Feraheme: 1.38 g/dL; Injectafer: 1.63 g/dL). Adverse event rates were similar across both treatment groups, however, the incidence of severe hypophosphatemia (defined by blood phosphorous of <0.6 mmol/L at week 2) was less in the patients receiving Feraheme (0.4% of patients) compared to those receiving Injectafer® (38.7% of patients).

Iron Deficiency Anemia

Currently there are two methods of iron therapy used to treat IDA: oral iron supplements and IV iron. 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. We believe that IV iron is underutilized in IDA patients, and thus a significant opportunity remains to grow the market for IV iron in this patient population.

IDA is widely prevalent in many different patient populations. For many of these patients, treatment with oral iron is unsatisfactory or is not tolerated. It is estimated that more than 4.5 million people in the U.S. have IDA (CKD and non-CKD) and we estimate that a small fraction of the patients who are diagnosed with IDA regardless of the underlying cause are currently being treated with IV iron. We estimate that the size of the total 2017 U.S. non-dialysis IV iron replacement therapy market was approximately 1.2 million grams. We believe that approximately half, or 600,000 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, inflammatory diseases, chemotherapy-induced anemia and abnormal uterine bleeding (“AUB”).

- **Chronic Kidney Disease:** 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. Anemia, a common condition among CKD patients, is associated with cardiovascular complications, decreased quality of life, hospitalizations, and increased mortality. Anemia can develop early during the course of CKD and worsens with advancing kidney disease. 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.
- **Gastrointestinal Disease:** It is estimated that approximately 40% - 80% of IDA patients have gastrointestinal diseases. IDA in patients with gastrointestinal diseases is likely caused by blood loss and/or the inadequate intake or absorption of iron. Oral iron has been used to treat IDA in patients with gastrointestinal diseases, but its efficacy is variable due to inconsistent bioavailability and absorption, the high incidence of gastrointestinal side effects and patient noncompliance.
- **Cancer and chemotherapy-induced anemia:** IDA is also common in patients with cancer, and it is estimated that 32% - 60% of cancer patients have iron deficiency, most of whom are anemic. Iron supplementation through both oral and IV administration plays an important role in treating anemia in cancer patients. While there may be some differences in the underlying causes of anemia and iron deficiency in cancer patients who are receiving chemotherapy and those who are not, patients in both categories may develop absolute IDA due to blood loss and/or the inadequate intake or absorption of iron. Oral iron has been used to treat IDA in cancer patients, but its efficacy is variable due to inconsistent bioavailability and absorption, a high incidence of gastrointestinal side effects, potential interactions with

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other treatments, and patient noncompliance. IV iron has been shown in clinical trials to be well tolerated in the cancer patient population in both patients who are receiving chemotherapy and those who are not.

- **Abnormal Uterine Bleeding:** IDA is commonly associated with AUB, which is defined as chronic, heavy, or prolonged uterine bleeding that can result from multiple causes, including uterine abnormalities, blood disorders, pregnancy, intrauterine devices, medications, and heavy menstrual bleeding. IDA in patients with AUB, regardless of the cause, requires treatment with iron supplementation, either by oral or IV administration.

With the expanded label, in addition to an expanded opportunity within hematology and oncology centers, our authorized wholesalers and specialty distributors can now sell Feraheme to obstetricians and gynecologists, gastroenterologists and rheumatologists.

Paragraph IV certification

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 ferumoxytol. A generic version of ferumoxytol 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’s 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’s ferumoxytol products would infringe our patents. If the litigation is resolved in favor of the applicant or the challenged patent expires during the 30 month stay period, the stay is lifted and the FDA may thereafter approve the application based on the applicable standards for approval. By the filing of this complaint, we believe the 30 month stay was triggered and that Sandoz is prohibited from marketing its ferumoxytol product, even if it receives conditional approval from the FDA until the earliest of (a) August 5, 2018 (30 months from the date we received Sandoz’s notice of certification), (b) the conclusion of litigation in Sandoz’s favor, or (c) expiration of the patent(s). On May 2, 2016, Sandoz filed a response to our patent infringement suit and the trial is scheduled for March 19, 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.*”

Post-Approval Commitments for Feraheme

As part of our post-approval Pediatric Research Equity Act (“PREA”) requirement to support pediatric labeling of Feraheme for the treatment of CKD, we had initiated a randomized, active-controlled pediatric study of Feraheme for the treatment of IDA in pediatric CKD patients. During 2015, we suspended this trial due to difficulty in enrollment. In December 2016, we met with the FDA to advance the development of a plan in order to satisfy this post-approval commitment for Feraheme and subsequently proposed a protocol to the FDA for a new pediatric study. Following recent interactions with the FDA regarding the adequacy of our proposed protocol, we amended the protocol and intend to initiate a new pediatric study in the second quarter of 2018. Further, as part of our post-approval PREA requirement to support pediatric labeling of Feraheme for the treatment of IDA for the recently approved broader label, we are required to submit a final protocol to the FDA in July 2018 with the final report submission due to the FDA in November 2022.

Intrarosa

Overview

In February 2017, we entered into a license agreement (the “Endoceutics License Agreement”) with Endoceutics pursuant to which Endoceutics granted 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 combinations with other active pharmaceutical ingredients, in the U.S. for the treatment of VVA and FSD. In April 2017, we entered into an exclusive commercial supply agreement with Endoceutics, pursuant to which Endoceutics, itself or through affiliates or contract manufacturers, agreed to manufacture and supply Intrarosa to us (the “Endoceutics Supply Agreement”). In July 2017, we announced the commercial availability of Intrarosa at pharmacies throughout the U.S.

To support the July 2017 launch of Intrarosa, we hired a new 170 person commercial team, including a sales force of nearly 140 sales representatives dedicated to Intrarosa. This newly established sales force provides additional flexibility as our portfolio evolves, including for the potential expansion of the Intrarosa label, the potential launch of bremelanotide and for future products we may acquire or develop in the women’s health space.

In addition, Endoceutics initiated a 600 patient placebo-controlled, double blind randomized Phase 3 clinical study in the third quarter of 2017 to support an application for U.S. regulatory approval of Intrarosa for the treatment of HSDD in post-menopausal women. We and Endoceutics have agreed to share the direct costs related to two clinical studies, including the HSDD trial, based upon a negotiated allocation with us funding up to \$20.0 million. If the studies are successful, we will file a supplemental New Drug Application (“sNDA”) with the FDA for the treatment of HSDD in post-menopausal women. Furthermore, each party’s commercialization activities and budget are described in a commercialization plan, which is updated annually. Additional details regarding the Endoceutics License Agreement and the Endoceutics Supply Agreement can be found below under the heading “*Collaboration, License and Other Strategic Agreements - Endoceutics*”.

Intrarosa is the only FDA-approved, vaginally administered, daily non-estrogen steroid, which is prescribed for the treatment of moderate to severe dyspareunia, a symptom of VVA, due to menopause. Intrarosa contains prasterone, a synthetic version of the inactive endogenous (i.e. occurring in the body) sex hormone precursor, DHEA. Prasterone is converted by enzymes in the body 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 of Intrarosa is not fully established. The effectiveness of Intrarosa on moderate to severe dyspareunia in post-menopausal women 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: (a) most bothersome symptom (moderate to severe dyspareunia), (b) the percentage of vaginal superficial cells, (c) the percentage of parabasal cells, and (d) 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. Intrarosa is contraindicated in women with undiagnosed abnormal genital bleeding. 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 and Dyspareunia

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 of VVA. Of the 32 million women who suffer from symptoms of VVA, we estimate there are approximately 20 million women in the U.S. who suffer from dyspareunia, a symptom of VVA, the majority of which we believe suffer from moderate to severe dyspareunia. We estimate that of those women, only 1.7 million are currently being treated with prescription therapy. The Women’s Health Initiative, a long-term national health study, which focused on strategies related to estrogen replacement therapy in post-menopausal women, led to class labeling for all estrogen-containing products, including a boxed safety warning. Intrarosa is not subject to a boxed warning nor any limitations to duration of use as are all other currently approved prescription products to treat VVA.

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 June 2013 license agreement with Abeona (the “MuGard Rights”). MuGard was launched in the U.S. by Abeona in 2010 after receiving 510(k) clearance from the FDA.

Bremelanotide

Overview

In January 2017, we entered into a license agreement (the “Palatin License Agreement”) with Palatin pursuant to which we acquired (a) an exclusive license in all countries of North America (the “Palatin Territory”), with the right to grant sub-licenses, to research, develop and commercialize bremelanotide and any other products containing bremelanotide (collectively, the “Bremelanotide Products”), an investigational product designed to treat acquired HSDD in pre-menopausal women, (b) a worldwide non-exclusive license, with the right to grant sub-licenses, to manufacture the Bremelanotide Products, and (c) a non-exclusive license in all countries outside the Palatin Territory, with the right to grant sub-licenses, to research and develop (but not commercialize) the Bremelanotide Products. Additional details regarding the Palatin License Agreement can be found below under the heading “*Collaboration, License and Other Strategic Agreements-Palatin.*”

Bremelanotide, a melanocortin 4 receptor agonist, is currently being developed for the treatment of acquired HSDD in pre-menopausal women. Bremelanotide is designed to be an as desired therapy used in anticipation of sexual activity and self-administered by the patient in the thigh or abdomen via a single-use subcutaneous auto-injector. Two Phase 3 bremelanotide studies conducted by Palatin for the treatment of HSDD in pre-menopausal women met the pre-specified co-primary efficacy endpoints of 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 bremelanotide 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”) Question 13 scores. For women taking bremelanotide compared to placebo, the change from baseline in FSFI-D 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 bremelanotide compared to placebo of 0.54 vs. 0.24 and 0.63 vs. 0.21. The FSDS-DAO Question 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 bremelanotide 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 $p=0.0053$. These studies also demonstrated statistically significant mean changes in FSFS-DAO Question 13 scores for women taking bremelanotide compared to placebo of -0.7 vs. -0.4 for both studies. 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 arm, 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 and were transient. Approximately 17% of patients discontinued participation in the bremelanotide arm due to adverse events in both studies versus 2% in placebo. 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 gathered additional data on the safety of long-term and repeated use of bremelanotide. Nearly 80% of patients who completed the randomized portion of the study elected to remain in the open-label portion of the study. All of the patients in the extension study, which was completed in 2017, received bremelanotide. The adverse events in the extension portion of the study were consistent with that of the controlled study described above. We expect to submit an NDA for bremelanotide in the first quarter of 2018.

The Phase 3 bremelanotide 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 acquired HSDD, female sexual arousal disorder or both. The 1.75 mg dose demonstrated clinically meaningful and statistically significant results for all predefined endpoints and was generally well-tolerated and was therefore selected as the dose to take into the Phase 3 trials.

Female Sexual Dysfunction and Hypoactive Sexual Desire Disorder

FSD is defined as persistent or recurring problems during one or more of the stages of a woman's sexual response. It is multi-dimensional and can be caused by physiological, psychological, emotional and/or relational factors. FSD can also have a

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major impact on a woman's sexual relationships, interpersonal relationships, quality of life, and even their general well-being. HSDD is the most common type of FSD and is characterized by a lack of sexual thoughts and desire for sexual activity, which causes a woman distress or puts a strain on the relationship with her partner, and cannot be accounted for by another medical physical or psychiatric condition, co-morbidity of another condition or the effects of a medication. Studies suggest that approximately 15 million women in the U.S. are affected by HSDD and approximately 5.8 million of these women are premenopausal and have a primary diagnosis of HSDD. Despite one FDA-approved HSDD therapy on the market today for premenopausal 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 premenopausal women suffering from low desire with associated distress are unaware that HSDD is a treatable medical condition. As a result, assuming FDA approval of our NDA for bremelanotide, we expect that the initial focus of our bremelanotide commercialization efforts will be raising awareness and education about the disease for both healthcare professionals and patients with this disorder. We have launched an unbranded condition awareness campaign to healthcare professionals and will be expanding it to patients later in 2018.

Collaboration, License and Other Strategic Agreements

Endoceutics

Under the terms of the Endoceutics License Agreement, which we entered into with Endoceutics in February 2017, we made an upfront payment of \$50.0 million and issued 600,000 shares of unregistered common stock to Endoceutics, which had a value of \$13.5 million, as measured on April 3, 2017, the date of closing. Of these 600,000 shares, 300,000 were subject to a 180-day lock-up provision, and the other 300,000 are subject to a one-year lock-up provision. In addition, we paid Endoceutics \$10.0 million in the third quarter of 2017 upon the delivery by Endoceutics of Intrarosa launch quantities and have agreed to make a payment of \$10.0 million in April 2018 on the first anniversary of the closing. The anniversary payment is reflected in accrued expenses at December 31, 2017. During 2017, we recorded a total of \$83.5 million of consideration paid, of which \$77.7 million was allocated to the Intrarosa developed technology intangible asset and \$5.8 million was recorded as in-process research and development expense based on their relative fair values.

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 U.S. sales up to \$150.0 million to mid twenty percent for any calendar year net sales that exceed \$1.0 billion (such royalty rate to be dependent on the aggregate annual net sales of Intrarosa in the U.S.) for the commercial life of Intrarosa, subject to certain deductions. 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 annual net U.S. sales of Intrarosa exceed \$150.0 million, and a second milestone payment of \$30.0 million, which would be triggered when annual net U.S. sales of Intrarosa exceed \$300.0 million. If annual net U.S. sales of Intrarosa exceed \$500.0 million, there are additional sales milestone payments totaling up to \$850.0 million, which would be triggered at various sales thresholds.

We have the exclusive right to commercialize Intrarosa for the treatment of VVA and 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 and, if approved, FSD in the U.S. Endoceutics has the right to directly conduct additional commercialization activities for Intrarosa for the treatment of VVA and FSD in the U.S. and has the right to conduct activities related generally to the field of intracrinology, in each case, subject to our review and approval and our right to withhold approval in certain instances. Each party's commercialization activities and budget are described in a commercialization plan, which is updated annually.

In connection with the Endoceutics License Agreement, we entered into the Endoceutics Supply Agreement with Endoceutics, which provides for the exclusive commercial supply by Endoceutics, itself or through affiliates or contract manufacturers, to manufacture and supply Intrarosa, subject to certain rights for us to manufacture and supply Intrarosa in the event of a cessation notice or supply failure.

Under the Endoceutics License Agreement, except as permitted under the Endoceutics License Agreement or the Endoceutics Supply Agreement, and except for any compounds or products affecting the melanocortin receptor pathway, including without limitation, bremelanotide (collectively, "Excluded Products"), we are not permitted to research, develop, manufacture, or commercialize (a) DHEA for delivery by any route of administration anywhere in world, (b) any compound (including DHEA) or product for use in VVA anywhere in the world, or (c) 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

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would be a Competing Product in the United States but that (a) does not contain DHEA and (b) 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 for 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 its terms, including by either party for material breach that is either uncured after a 90-day notice period (subject to certain extensions and dispute resolutions provisions). 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 the 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 Endoceutics License Agreement) in the U.S. or in at least three countries within the European Union.

Palatin

Under the terms of the Palatin License Agreement, which we entered into with Palatin in January 2017, we paid Palatin \$60.0 million as a one-time upfront payment in 2017 and subject to agreed-upon deductions, we reimbursed Palatin approximately \$25.0 million for reasonable, documented, out-of-pocket expenses incurred by Palatin in connection with the development and regulatory activities necessary to submit an NDA in the U.S. for bremelanotide for the treatment of acquired HSDD in pre-menopausal women. In addition, the Palatin License Agreement requires us to make future contingent payments of (a) up to \$80.0 million upon achievement of certain regulatory milestones, including \$20.0 million upon the acceptance by the FDA of our NDA for bremelanotide and \$60.0 million upon FDA approval, and (b) up to \$300.0 million of aggregate sales milestone payments upon the achievement of certain annual net sales in North America over the course of the license. The first sales milestone payment of \$25.0 million will be triggered when bremelanotide annual net sales in North America exceed \$250.0 million. We are also obligated to pay Palatin tiered royalties on annual net sales in North America of the Bremelanotide Products, on a product-by-product basis, in the Palatin 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 Bremelanotide Product in such country, (b) the expiration of the regulatory exclusivity period for such Bremelanotide Product in such country and (c) 10 years following the first commercial sale of such Bremelanotide Product in such country. These royalties are subject to reduction in the event that: (a) we must license additional third-party intellectual property in order to develop, manufacture or commercialize a Bremelanotide Product or (b) generic competition occurs with respect to a Bremelanotide 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 Bremelanotide Product in a given country, the license for such Bremelanotide 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 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 Phase 2b/3a clinical study, which began in the second 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

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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. 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. In addition, we are required to pay Antares sales milestone payments upon the achievement of certain annual net sales. 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 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 Abeona 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 and possessions (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 in the MuGard Territory 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. 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.

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.

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. Our third-party drug product 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

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demand for all of our drug products in order to minimize risks of supply disruption. For example, although we do not currently have a manufacturer for the production of HPC, our supply chain practices have resulted in inventory of HPC, which we believe to be sufficient to meet demand until we can obtain FDA approval of a new drug substance manufacturer. 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 product candidates.

We own a facility located in Tucson, Arizona, which stores all of our customers' cord blood and cord tissue samples. We rely solely on third-party contract manufacturers and service providers for certain materials required to support the CBR Services, including to supply proprietary materials, some of whom are sole source providers. 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 regulated materials, and enforces regulations to ensure that establishments that perform such services do so in accordance with current Good Tissue Practices.

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 will be automatically extended thereafter for additional 18 month periods, unless canceled by us or Pfizer within an agreed-upon notice period. We also have an agreement with Piramal Pharma Solutions (formerly Coldstream Laboratories, Inc.) as a second source manufacturer for the Makena 1 mL drug product. In addition, we have entered into an agreement with a supplier of the active pharmaceutical ingredient ("API") for use in the finished Makena product. We also intend to enter into an agreement with a second source supplier to produce Makena API. Both API suppliers have filed with the FDA for approval of their sites.

Antares is the exclusive supplier for the auto-injection system devices needed for the Makena auto-injector, and Antares is responsible for the manufacture and supply of the device and assembly of the Makena auto-injector. The Antares Agreement terminates at the end of the Antares 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. In addition, we are responsible for providing Antares with the supply of the Makena drug substance in pre-filled syringes to be used in the assembly of the finished auto-injector product. We also expect to enter into a manufacturing agreement for the production of the pre-filled syringes. We intend to enter into a commercial supply agreement with Antares.

We entered into a distribution and supply agreement in December 2017 with a generic partner to launch an authorized generic of the IM formulation of Makena upon the first entry of generic competition.

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 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 all of our API from SAFC. The SAFC Agreement has an initial term that ends December 31, 2020, which may be automatically extended thereafter for additional two year periods, unless canceled 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.

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We have also entered into a manufacturing and supply agreement with a second source supplier to produce feromoxtyol finished drug product in addition to Patheon. This supplier has filed with the FDA for approval of its site and we anticipate a decision in 2018.

Intrarosa

Under the terms of the Endoceutics Supply Agreement, Endoceutics, itself or through affiliates or contract manufacturers, agreed to manufacture and supply Intrarosa to us and is 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 Endoceutics Supply Agreement). Under the Endoceutics Supply Agreement, Endoceutics has agreed to maintain a second source supplier for the manufacture of the drug product and identify, validate and transfer manufacturing intellectual property to the second source supplier by 2019. The Endoceutics 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.

MuGard

Under the terms of the MuGard License Agreement, Abeona is responsible for all aspects of manufacturing MuGard. We have entered into a supply agreement with Abeona under which we purchase MuGard inventory from Abeona. 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.

Bremelanotide

Under the Palatin License Agreement, we assumed a long-term commercial supply agreement for drug product manufacture and assembly services for bremelanotide. 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 our products 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 or obtaining rights to patents in the U.S. and in foreign countries. One of our U.S. Feraheme patents received a patent term extension under the Hatch-Waxman Act and will expire in June 2023, and the other U.S. patents relating to Feraheme will expire in 2020. In December 2017, we were issued a U.S. patent related to the Makena auto-injector product, which will expire in 2036, and we have a pending patent application related to the Makena auto-injector product. In addition, we have a license to

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several U.S. patents and patent applications from Antares related to the Makena auto-injector device and drug-device combination with expiration dates between 2019 and 2034. We intend to request Orange Book listing of our and Antares' eligible patents. There are no issued patents covering the Makena IM product or the CBR Services.

Under the Palatin License Agreement, we have exclusive rights to a number of U.S. and foreign patents and applications 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 other patents include claims directed to methods of treating FSD by subcutaneous administration of compositions that include bremelanotide with terms expiring in 2033. Any one of these issued patents may be granted up to five years of patent term extension (up to a maximum patent term of 14 years after regulatory approval) pursuant to the Hatch-Waxman Act. Whether any of these patents will be granted patent term extension 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.

Under the terms of the Endoceutics License Agreement, we received rights to U.S. patents and applications related to Intrarosa that are owned by Endoceutics. One issued patent includes drug product claims with a term that expires in 2031. Two additional issued patents include method of use claims and pharmaceutical dosage form claims with terms that expire in 2028, either of which may be granted up to five years of patent term extension (up to a maximum patent term of 14 years after regulatory approval pursuant to the Hatch-Waxman Act). However, there is no guarantee that the FDA will grant such an extension.

Under the Abeona License Agreement, we have exclusive rights to two U.S. patents related to MuGard that are owned by Abeona. These Abeona patents include liquid composition claims and will expire in 2022.

Additionally, we have an agreement with Velo that gives us an exclusive option to acquire the rights to DIF, 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.

With regard to pending patent applications we own or have rights to, even though further patents may be issued on such applications, we cannot be sure that any such patents will be issued on a timely basis, if at all, or with a scope that provides our products with additional protection. The claims of issued patents related to any of our products may not provide meaningful protection for the product, and third parties may challenge the validity or scope of any such issued patents. Additionally, the claims of our issued patents may be narrowed or invalidated by administrative proceedings, such as interference or derivation, *inter partes* review, post grant review or reexamination proceedings before the United States Patent and Trademark Office. In addition, existing or future patents of third parties may limit our ability to commercialize our products.

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

Competition

The pharmaceutical and cord blood banking industries are intensely competitive and subject to rapid technological change. Makena competition currently comes mainly from pharmacies that compound a non-FDA approved version of Makena, which is sold at a much lower list price and is less regulated than Makena. However, we expect the competitive landscape for Makena to impose even greater challenges upon our commercialization efforts when generic formulations of Makena IM product enter the market, which could happen at any time given the expiration of orphan drug exclusivity in February 2018. Many of our competitors for Feraheme and Intrarosa 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 bremelanotide, including from an already FDA-approved product for the treatment of HSDD. Our existing or potential competitors for all our products and services have or may develop products or services that are more widely accepted than ours, are viewed as more safe, effective, convenient or easier to administer, have been on the market longer and have stronger patient/provider loyalty, have been approved for a larger patient population, are less expensive or offer more attractive insurance coverage, discounts, reimbursements, incentives or rebates and may have or receive patent protection that dominates, blocks, makes obsolete or adversely affects our product development or business.

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Makena

Makena is currently 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. Its largest competitor has historically been compounding pharmacies, which have been manufacturing formulations of HPC, the active ingredient in Makena and commonly referred to as “c17P”, for many years at a lower cost than Makena. The FDA implemented the Drug Quality and Security Act (“DQSA”) in 2013, which amended the Federal Food, Drug and Cosmetic Act (the “FDC Act”), with respect to the regulation and monitoring of the manufacturing of compounded 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. Although we continue to educate healthcare professionals 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 c17P made by pharmacy compounders in lieu of prescribing Makena.

The Makena IM product no longer has market exclusivity and we expect that going forward, Makena's primary competitors will be generic formulations of HPC injection, which could enter the market through the approval of ANDAs that use Makena as a reference listed drug and allow generic competitors to rely on Makena's safety and efficacy trials instead of conducting their own studies. We currently believe that several companies filed ANDAs during 2017 seeking approval for generic versions of HPC injection. The specific timing of potential approval of a generic HPC injection ANDA is uncertain, however we believe that Makena could face generic competition by mid-2018. We have partnered with a generics company to launch and market an authorized generic of the Makena IM product to allow us to offset some of the impact of generics to branded Makena, including if a generic enters the market more quickly than we anticipate. If a generic version of Makena becomes available in the market, governmental and payer pressures to reduce pharmaceutical costs may cause physicians to prescribe the generic formulation rather than the branded Makena, and could materially and adversely affect the level of sales and the price at which we could sell Makena.

Following the entry of generic competitors to Makena, the longer-term durability of the Makena franchise will be highly dependent on our ability to successfully commercialize the Makena auto-injector, which was approved by the FDA in February 2018. The Makena auto-injector is intended to provide healthcare professionals and patients with an alternative treatment method to the Makena IM product. We plan to launch the Makena auto-injector in March 2018. Upon the entry of a generic version of Makena to the market, the auto-injector will compete with generic versions of the Makena IM product, including our own authorized generic, discussed above. We have limited experience in the development or commercialization of an auto-injector product and in order to compete with potential generic entrants and retain sufficient Makena revenues, we will need to differentiate our auto-injector product from the IM generic products by successfully executing on the following strategies:

- Rapidly driving awareness of the availability and benefits of the Makena auto-injector and converting current IM prescribers to the Makena auto-injector;
- Provide training on the use of the auto-injector to healthcare providers, as well as the benefits of the subcutaneous delivery in light of the obstetrical community's limited experience prescribing and using auto-injectors; and
- Provide an easy and convenient process for patients and healthcare providers to prescribe, acquire and administer the Makena auto-injector.

In addition, due to the lower cost of the generics, if physicians, patients and payers do not fully appreciate the potential benefits of the Makena auto-injector, payers may require treatment with the generic, which could cause sales of Makena to decline. Further, if healthcare professionals prefer the IM method of administration to the auto-injector method, they will not utilize the auto-injector and we could lose a significant amount of our Makena revenue and market share to the generic competitors. We expect the Makena auto-injector to be priced at parity with the Makena IM product at launch to help ensure timely and affordable access.

Makena also competes with products that may be prescribed off-label (i.e., outside of indications approved by the FDA) such as the generic version of Delalutin, a product which contains the same active ingredient as Makena, but which was approved for conditions other than reducing the risk of preterm birth and is not therapeutically equivalent to Makena. Further, other companies are or may be working on developing additional formulations or routes of administration for products that reduce or prevent preterm birth. For example, an oral HPC product is currently in development and has been granted orphan drug designation by the FDA.

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Based on market research we have conducted, we estimate that the following represents the 2017 and 2016 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.

	2017	2016
Makena	50%	42%
c17P	20%	28%
Other therapies or untreated	30%	30%

For a detailed discussion regarding the risks and uncertainties related to competition for Makena, please refer to our Risk Factors, “*We no longer have market exclusivity for Makena and generic competitors are seeking approval to market generic versions of Makena, which would cause sales of Makena to significantly decline and have an adverse impact on our business and results of operation.*” and “*Competition in the pharmaceutical and biopharmaceutical industries, including from companies marketing generic products, is intense and 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.*”

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 in 2010. CBR was the first major company in the U.S. to offer umbilical cord tissue storage in 2010, and in 2017, most private U.S. cord blood banks now offer this service. The relatively low barriers to entry allow competitors to easily enter the market, and some of these competitors offer, or may in the future offer, additional bio-banking services to their customers, such as noninvasive prenatal testing, newborn screening, whole genome sequencing and/or placenta banking services and have more advanced collection kits and storage bags, which could make them more attractive to consumers than CBR. We also face competition from public banks, as families may choose to use public banks over private banks based on considerations such as the higher cost of private banking, the rate that cord blood is used within public banks versus private banks, the altruistic value to society of public banking and the perception that publicly stored cord blood is of a higher quality because private cord blood banks are not subject to the same regulatory oversight as public banks. New entrants to the market could affect our market share or put downward pressure on the pricing of the CBR Services or may offer and promote similar services at lower prices. In addition, new entrants may not abide by industry guidelines, regulations and standards, including quality, compliance and marketing standards 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 by 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, with nearly 40% of the private bank market. 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 which have regional focuses. CBR differentiates itself from almost all of its competitors through its size, brand recognition, longevity, investments in research and its commercial reach.

Feraheme

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

- 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, Inc. (“American Regent”), a subsidiary of Luitpold Pharmaceuticals, Inc. (a business unit of Daiichi Sankyo Group);
- Injectafer®, a ferric carboxymaltose injection, which is approved to treat IDA in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron. Injectafer® is also indicated for IDA in adult patients with

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non-dialysis dependent CKD. Injectafer® is marketed in the U.S. by American Regent, the same distributor of Venofer®;

- Ferlecit®, a sodium ferric gluconate, which is marketed by Sanofi-Aventis U.S. LLC, is approved for use only in hemodialysis patients;
- A generic version of Ferlecit® 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.

In addition to the currently marketed products described above, Feraheme may also compete with Auryxia® (ferric citrate), an oral phosphate binder, which is marketed by Keryx Biopharmaceuticals, Inc., and which recently received a second indication for the treatment of IDA in adult patients with CKD not on dialysis. Further, Pharmacosmos A/S is developing Monofer® (iron isomaltoside) and has commenced a Phase 3 trial in the U.S. In addition, there are several hypoxia inducible factor stabilizers in various stages of development to treat anemia related to CKD.

We may face challenges retaining our existing Feraheme customers, gaining sales to new customers and gaining market share despite the February 2018 approval of Feraheme's broader label. For example, since Injectafer® was approved in 2013 with a broader indication than the original Feraheme indication, physicians may have increased their use of Injectafer® and other physicians may have begun to use Injectafer®, making it more difficult for us to cause these physicians to use Feraheme in the future. In addition, manufacturers of Injectafer® may have entered into commercial contracts with key customers or group purchasing organizations ("GPOs"), which would limit our ability to enter into favorable pricing arrangements. Further, Daiichi Sankyo Group has a substantially larger sales force to market Injectafer® than we do to market Feraheme, which allows them to reach a broader group of healthcare professionals.

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. Feraheme may 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 our complaint, we believe the 30 month stay was triggered and that Sandoz is prohibited from marketing its ferumoxytol product, even if it receives conditional approval from the FDA until the earliest of (a) August 5, 2018 (30 months from the date we received Sandoz's a notice of certification), (b) the conclusion of litigation in Sandoz's favor, or (c) expiration of the patent(s). In May 2016, Sandoz filed a response to our patent infringement suit and the trial is scheduled for March 19, 2018.

Based on sales data provided to us in January 2018 by IQVIA, we estimate that the size of the total 2017 U.S. non-dialysis IV iron replacement therapy market was approximately 1.2 million grams, which represents an increase of approximately 10% over 2016. During 2017 and 2016, Feraheme competed in the CKD portion of this market, which we estimate is approximately half of the total market. Based on this IQVIA data, the following represents the 2017 and 2016 U.S. market share allocation of the total non-dialysis IV iron market based on the volume of IV iron administered:

	2017 U.S. Non-dialysis IV Iron Market (1.2 million grams)	2016 U.S. Non-dialysis IV Iron Market (1.1 million grams)
Venoferr®	35%	38%
Injectafer®	26%	21%
INFeD®	15%	15%
Feraheme	12%	13%
Generic sodium ferric gluconate	9%	9%
Ferlecit®	3%	4%

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.

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Intrarosa

Intrarosa faces competition from the following approved products:

- Estrace® Cream (Estradiol vaginal cream, USP 0.01%) (“Estrace”), a vaginal cream for the treatment of VVA marketed by Allergan PLC;
- Estradiol® Vaginal Cream USP, 0.01% (generic version of Estrace®), including a generic marketed by Mylan N.V., which was launched in December 2017, a generic marketed by Teva Pharmaceuticals USA, Inc., a subsidiary of Teva Pharmaceutical Industries Ltd. (“Teva”), which was launched in January 2018 and a generic marketed by Perrigo PLC, which was launched in January 2018;
- Vagifem® (estradiol vaginal inserts) (“Vagifem”), a suppository marketed by Novo Nordisk A/S for the treatment of VVA;
- Estradiol vaginal inserts USP (generic versions of Vagifem®), including Yuvaferm, which was launched in October 2016 and is marketed by Amneal Pharmaceuticals LLC and a generic marketed by Teva, which was launched in July 2017;
- Premarin Vaginal Cream®, a vaginal cream for the treatment of VVA marketed by Pfizer, Inc. (“Pfizer”);
- Estring®(estradiol vaginal ring), a vaginal ring marketed by Pfizer for the treatment of VVA due to menopause;
- Osphena®, an oral therapy marketed by Duchesnay Inc. for the treatment of moderate to severe dyspareunia due to menopause; and
- Over the counter and compounded remedies that are marketed for dyspareunia and over the counter and compounded products that contain DHEA.

The actual market size and market dynamics for moderate to severe dyspareunia due to menopause is uncertain. While we believe that Intrarosa, as the only FDA approved, local non-estrogen-containing drug to treat moderate to severe dyspareunia, has competitive advantages compared to estrogen-containing therapies, we may not be able to realize this perceived advantage in the market. For example, Osphena®, is an oral non-estrogen product, which has a modified boxed warning. Our commercial opportunity could be reduced if physicians or patients perceive that other products are more effective, or convenient or safer 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. Some of the products that Intrarosa competes with have a broader indication for VVA and receive reimbursement from governmental healthcare programs. Although we have been able to gain coverage for Intrarosa with commercial health plans, given the increasing number of generic competitors, payers may choose to implement step edits or prior authorizations prior to Intrarosa use. Intrarosa is generally classified as a Tier 3 drug, and as a result patients do not receive full reimbursement by third-party commercial payers and do not receive any reimbursement from governmental healthcare programs. Many patients are therefore subject to substantial copays or deductible requirements. The Center for Medicare & Medicaid Services (“CMS”) has historically not covered or paid for products to treat sexual dysfunctions, which currently include dyspareunia, under Medicare Part D. As a result, Medicare coverage of Intrarosa has been limited. 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 of estrogens and compounded products, which are often priced lower than branded products.

In addition, TherapeuticsMD, Inc. is developing TX-004HR, an applicator-free vaginal estrogen softgel capsule for the treatment of dyspareunia, which has, per the target timeframes in the Prescription Drug User Fee Act (“PDUFA”), a target action date for completion of the FDA’s review of May 2018 (“PDUFA date”).

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 that compete with MuGard, including the use of ice chips during chemotherapy treatments, various medicinal mouthwashes, topical anesthetics and

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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.

Bremelanotide

If bremelanotide is approved for marketing by the FDA and if we are successful in launching and commercializing it, we expect bremelanotide will face competition. Addyi® (flibanserin) was introduced into the market in October 2015 for the treatment of HSDD in pre-menopausal women and is marketed by Sprout2 Inc. (“Sprout”). 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 being developed to be taken on a chronic, typically once-daily, basis. Emotional Brain BV, a Netherlands company, 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 2b studies. 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, or other companies which may sell their products off-label for indications other than FSD.

While we believe that bremelanotide will have competitive advantages for treating HSDD, such as desired use and length of the therapeutic effect compared to chronic or daily use hormones and other drugs, we may not be able to realize these perceived advantages in the market, in part because bremelanotide 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 or certain side effects that were observed in the Phase 3 studies, such as nausea, may impact bremelanotide’s ability to achieve significant market acceptance, especially if an oral therapy is available as an alternative.

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 50% of the at-risk patient population. Our sales and marketing teams use a variety of strategies and focused, multi-channel methods to promote Makena, including dedicating a 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 have partnered with a leading provider of home nursing services (which had previously utilized compounded HPC) pursuant to which the provider performs at-home administration of Makena and co-promotes Makena to certain healthcare providers.

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, including confirming insurance coverage, providing education and support on prior authorizations (when applicable), and working in collaboration with a payer-preferred pharmacy and home health agency to help ensure timely initiation of therapy. The Makena Care Connection also screens eligible patients for and enrolls eligible patients in financial assistance programs including (a) our copay savings program, which helps lower the out-of-pocket cost for commercially insured patients whose plan covers Makena, and (b) our patient assistance program, which provides a full course of therapy at no cost to eligible uninsured and commercially underinsured patients. Additionally, the Makena Care Connection offers education and adherence support to eligible patients to assist with increasing patient compliance by encouraging adherence to the weekly Makena injection schedule.

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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 potential customers 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, approximately 8,000 families have been enrolled. Further, the Newborn Possibilities Program has been expanded with the launch of the first registry aimed at collecting family health data on diseases and conditions common among registry participants to help target medical research on those that may be treatable with newborn stem cell therapy. Currently, over 145,000 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 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, and scientific meetings and conferences. In addition, through AMAG Assist[™], we provide customer service and other related programs for Feraheme including financial and prescription support services, a patient assistance program for eligible uninsured or under-insured patients and a customer service call center.

The recent label expansion for Feraheme to include all eligible IDA patients in the U.S. doubles the size of the addressable patient population for Feraheme. We believe this expanded label will allow for increased penetration in existing accounts thereby increasing the likelihood of broadening the number of customers utilizing Feraheme within the IV iron marketplace. Additionally, with the expanded label, Feraheme may be promoted as an option for patients who have intolerance to oral iron or have unsatisfactory response to oral iron therapy that are in treatment settings where we already have sales teams, such as obstetricians and gynecologists. 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 such patients. Our sales team will work to educate healthcare providers who manage IDA patients to expand the IV iron use in physicians' offices, clinics, and hospitals where IDA patients are treated.

Intrarosa

In July 2017, Intrarosa became available for healthcare provider prescribing and can be ordered through wholesalers and retail pharmacies. As part of our launch strategy, and critical to the commercial success of Intrarosa, we are executing on an integrated marketing plan designed to drive awareness of dyspareunia and the potential benefits of Intrarosa to increase the likelihood that healthcare providers and patients will view Intrarosa as an accessible and viable treatment option. 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 dyspareunia, a symptom of VVA, as a treatable medical condition and are often not aware of treatment options. We have and plan to continue to undertake informational and educational programs such as speaker programs to help spread awareness of dyspareunia and VVA and the benefits of Intrarosa for the conditions indicated. In addition, we have implemented a sampling program, which makes samples of Intrarosa available to healthcare providers through our sales representatives or via our website to areas where we do not have sales representatives. We also currently offer a comprehensive copay savings program to patients and are developing patient-specific marketing programs around the condition of dyspareunia and Intrarosa utilizing digital marketing and social media platforms.

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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 marketing programs may include promotional materials to individual physicians or other healthcare professionals.

We market and sell MuGard to wholesalers and specialty pharmacies. Patients primarily receive MuGard through specialty pharmacies, which receive prescriptions from physicians directly or from AMAG Assist, which acts as our MuGard patient reimbursement and support center. We utilize AMAG Assist 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 2017, 2016 and 2015. 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, including in connection with its termination in 2015.

	Years Ended December 31,		
	2017	2016	2015
AmerisourceBergen Drug Corporation	21%	22%	25%
McKesson Corporation	19%	11%	12%
Takeda Pharmaceuticals Company Limited	—%	—%	11%

The loss of the above 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, promotion and post-approval monitoring and reporting of pharmaceutical products and medical devices. In addition, under the Public Health Service Act and its implementing regulations, we are required to register our cord blood and cord tissue banking facility 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, among other requirements, the safety and efficacy of the drug candidate can be established based on the results of preclinical and clinical studies.

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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 trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with good clinical practices (“GCPs”), which include the requirement that all research subjects provide their informed consent for their participation in any clinical testing. Prior to beginning a clinical trial, an IND - a request for authorization from the FDA to administer an investigational new drug to humans in clinical trials - must be submitted to FDA and must become effective. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from each clinical trial site’s institutional review board (“IRB”), before any trials may be initiated, and the IRB must monitor the trial until completed. Additional ongoing regulatory requirements apply throughout the course of a clinical trial, including requirements governing the reporting of certain ongoing clinical trials and clinical trial results to public registries.

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 investigational product 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 investigational product 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.

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 preclinical tests and studies, as the FDA requires submission of all relevant data available from pertinent nonclinical studies and clinical trials, as well as, among other required information, 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 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 (the FDA conducts a preliminary review of all NDAs within the first 60 days after submission before accepting them for filing), depending on the nature of the drug. The FDA has a number of programs intended to help expedite testing, review, and approval of drug candidates that meet the applicable eligibility criteria. For example, under the provisions of the FDA’s Subpart H Accelerated Approval regulations, accelerated approval may be permitted based on an appropriate 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.

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 and route of administration. In addition, with certain exceptions, the generic product must have the same labeling as the product to which it refers. At the same time, the FDA must also determine that the generic drug is

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“bioequivalent” to the innovator drug. Under the statute, a generic drug is bioequivalent to the previously approved product if, in relevant part, “the rate and extent of absorption of the [generic] drug do not show a significant difference from the rate and extent of absorption of the listed drug.”

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 above under “*Feraheme - Overview - Paragraph IV certification*” for additional details on a Paragraph IV certification notice letter regarding an ANDA submitted to the FDA by Sandoz.

If the applicant has provided a Paragraph IV certification to the FDA, the applicant must also send appropriate notice of the Paragraph IV certification to the NDA and patent holders within 20 days of the ANDA or 505(b)(2) application (a marketing application in which sponsors may rely on investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted) being accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) application until the earlier of expiration of the patent, a decision in the infringement case that is favorable to the ANDA or 505(b)(2) applicant, or 30 months after the receipt of the Paragraph IV notice (which can be extended if the reference product has 5-year exclusivity and the ANDA or 505(b)(2) application is submitted between four and five years after approval of the reference product).

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-approval 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-approval 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, to provide additional information on safety and efficacy. In addition, the FDA and the sponsor may agree to the conduct of certain post-market studies, known as post-marketing commitments, to further obtain safety and efficacy information. The results of such post-marketing requirement or commitment studies may be negative and could lead to limitations on the further marketing of a product, including safety labeling changes. Also, under PREA, 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 in the specified age group or where the drug is not likely to be used in a substantial number of pediatric patients in that age group. 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 require 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

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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-approval clinical trial is completed, we are subject to the requirement that all promotional materials be submitted for review to the FDA’s Office of Promotional Drug Products at least 30 days prior to the intended time of initial dissemination of the promotional labeling or initial publication of the advertisement. 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 should be issued for violations of “regulatory significance” for which the failure to adequately and promptly achieve correction may result in agency consideration of 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 Section 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 Section 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

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for such individual patient in certain circumstances. Under both Sections 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 for any person, including a prescription drug or medical device manufacturer, to knowingly and willfully solicit, offer, receive, or pay any remuneration, directly or indirectly, in cash or in kind, in exchange for, or to intended 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, for which payment may be made 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, administrative civil monetary penalties and exclusion from participation in federal healthcare programs. Many states have enacted similar anti-kickback laws, including in 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 imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for reimbursement of drugs or services for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government. 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 government may deem manufacturers to have “caused” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Claims which include items or services resulting from a violation of the federal Anti-Kickback Statute are false or fraudulent claims for purposes of the FCA. 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 Health Insurance Portability and Accountability Act of 1996, (“HIPAA”) as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”), and their respective implementing regulations, which imposes criminal and civil liability for knowingly and willfully executing a scheme, or attempting to execute a scheme, to defraud any healthcare benefit program, including private payers, or falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.
- The Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the “ACA”), which imposed new annual reporting requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program, for certain payments and “transfers of value” provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

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- 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 are also subject to regulation by numerous regulatory authorities including CMS, other divisions of the Department of Health and Human Services, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission (the “FTC”), the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments.

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 with all federal, state, and foreign regulations. If we or our representatives fail to comply with any of these laws or regulations, a range of fines, penalties, and/or other sanctions could be imposed on us, including, but not limited to, restrictions on how we market and sell our products, significant fines, exclusions from government healthcare programs, including Medicare and Medicaid, litigation, or other sanctions. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could also have an adverse effect on our business, financial condition and results of operations. Such investigations or suits may also result in related shareholder lawsuits, which can also have an adverse effect on our business.

Other Regulatory Requirements

Several states have enacted legislation requiring manufacturers 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 ACA 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 HIPAA. HIPAA imposes, among other things, specified requirements on covered entities and their business associates relating to the privacy and security of individually identifiable health information including mandatory contractual terms and required implementation of technical safeguards of such information. 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 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

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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.

U. S. Healthcare Reform

Our revenue and operations could be affected by changes in healthcare spending and policy in the U.S. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to health care availability, the method of delivery or payment for health care products and services could negatively impact our business, operations and financial condition. The U.S. Congress and state legislatures from time to time propose and adopt initiatives aimed at cost containment, which could impact our ability to sell our products profitably. For example, the ACA substantially changed the way healthcare is financed by both governmental and private insurers. Since its enactment, however, there have been modifications and challenges to numerous aspects of the ACA. In 2018, litigation, regulation, and legislation related to the ACA are likely to continue, with unpredictable and uncertain results. The full impact of the ACA, any law repealing, replacing, and/or modifying elements of it, and the political uncertainty surrounding any repeal or replacement legislation on our business remains unclear.

Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. In addition, the U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs to limit the growth of government paid healthcare costs. Individual states in the U.S. have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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.

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Drug-Device Combination Regulation

Combination products are defined by the FDA to include products composed of two or more regulated components (e.g., a drug and a device). Drugs and devices each have their own regulatory requirements, and combination products may have additional requirements. The Makena auto-injector and the bremelanotide product, if approved, are considered drug-device combination products and are regulated under this framework.

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 obtain 510(k) clearance by demonstrating 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. For example, the FDA requires that device manufacturers maintain particular 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. 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, depending on the FDA’s specific findings, require us to notify healthcare 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 received 510(k) clearance from the FDA in 2006 and 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 under the classification processes applicable to pre-amendments devices, 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 level of reimbursement from third-party payers, including state and federal government, managed care organizations, private health insurers and other organizations.

Third-party payers are increasingly challenging the prices charged for pharmaceutical products (including combination products), and continue to institute cost containment measures to control or influence the purchase of pharmaceutical products. The determination of coverage for a product may be a separate process from setting the price or reimbursement rate that a payer will pay for a product. Payers may place restrictions on coverage through various mechanisms, 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; (d) restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs; and (e) other coverage policies that limit access to certain drugs for certain uses based on the payer-specific coverage policy. Reimbursement by payers depends on a number of factors, including determination that the product is competitively priced, safe and effective, appropriate for the specific patient, and cost-effective.

Medicaid is a joint federal and state health insurance program that is administered by the states for low-income children, families, pregnant women, and people with disabilities. 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. The amount of the rebate is determined by law and will be adjusted upward if average manufacture price (“AMP”) increases more than inflation as measured by the Consumer Price Index - Urban. Each quarter, the rebate amount is calculated based on our report of current AMP and best price for each of our products to CMS. The requirements for calculating AMP and best price are complex. We are required to report revisions to AMP or best price previously reported within a certain period, which revisions could affect our rebate liability for prior quarters. Further, recent changes to the Medicaid Drug Rebate Program, effective April of 2016, require state Medicaid programs to reimburse certain

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brand name covered outpatient drugs at actual acquisition cost plus a dispensing fee. If we fail to provide information timely or we are found to have knowingly submitted false information to the government, the statute governing the Medicaid Drug Rebate program provides for civil monetary penalties.

Medicare is a federal health insurance program, administered by CMS, for people who are 65 or older, and certain people with disabilities or certain conditions, irrespective of their age. Medicare Part B covers products that are administered by physicians or other healthcare practitioners; are provided in connection certain durable medical equipment; or are certain oral anti-cancer drugs and certain oral immunosuppressive drugs. We are required to provide average sales price (“ASP”) information to CMS on a quarterly basis. The submitted information is used to calculate a Medicare payment rate using ASP plus a specified percentage. These rates are adjusted periodically. If we fail to provide information timely or we are found to have knowingly submitted false information to the government, the governing statutes provides for civil monetary penalties.

Medicare Part D provides coverage to enrolled Medicare patients for self-administered drugs (i.e. drugs that do not need to be injected or otherwise administered by a physician), including combination products. Medicare Part D is a voluntary prescription drug benefit, administered by private prescription drug plan sponsors approved by the U.S. government. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs; and each drug plan establishes its own Medicare Part D formulary for prescription drug coverage and pricing, which the drug plan may modify from time to time. The prescription drug plans negotiate pricing with the manufacturers and may condition formulary placement on the availability of manufacturer discounts. Manufacturers, including us, are required to provide a 50% discount on brand name prescription drugs utilized by Medicare Part D beneficiaries when those beneficiaries reach the coverage gap in their drug benefits.

Effective January 2018, CMS adopted a policy to pay for separately payable, non-pass-through drugs and biologicals other than vaccines purchased through the 340B Drug Pricing Program under the Public Health Services Act (the “340B Program”), with certain exceptions, at the ASP minus 22.5% rather than ASP plus 6%. Drugs not purchased under the 340B Program will continue to be paid for at a rate of ASP plus 6%. The effect of this change is on the overall 340B Program is unclear. However, there will be significant increases in budget pressure, which may adversely impact premium priced agents, such as Feraheme and Makena.

Our products are available for purchase by authorized users of the Federal Supply Schedule (“FSS”), pursuant to a contract with the Department of Veterans Affairs (“VA”), in which we are required to offer deeply discounted pricing to four federal agencies: VA; Department of Defense (“DOD”); the Coast Guard; and Public Health Services (“PHS”) (including the Indian Health Service) (together the “Big Four”). Coverage under Medicaid, Medicare and the PHS pharmaceutical pricing program is conditioned upon FSS participation. FSS pricing is not to exceed the price we charge our most-favored non-federal customer for a product. In addition, prices for drugs purchased by the Big Four (including products purchased by military personnel and dependents through the TRICARE retail pharmacy program), are subject to a cap on pricing equal to 76% of the non-federal average manufacturer price (non-FAMP). An additional discount applies if non-FAMP increases more than inflation, as measured by the Consumer Price Index - Urban. If we fail to provide information timely or we are found to have knowingly submitted false information, the governing statute provides for civil monetary penalties.

Federal law requires that any company participating in the Medicaid Drug Rebate program also participate in the Public Health Service’s 340B Program in order for federal funds to be available for the manufacturer’s drugs under Medicaid and Medicare Part B. The 340B 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. In addition, we may, but are not required to, offer these covered entities a price lower than the 340B ceiling price. The ACA also obligates the Health Resources and Services Administration (the “HRSA”), the agency which administers the 340B Program, to promulgate various regulations and implement processes to improve the integrity of the 340B Program. The status of new and pending regulations and guidance is uncertain under the new presidential administration and its impact.

Federal, state and local governments continue to consider legislation to limit the growth of healthcare costs, including the cost of prescription drugs and combination products. In 2017, we saw several states and local government either implement or consider implementing price transparency legislation that may prevent or limit our ability to take price increases at certain rates or frequencies. For example, in 2017, California enacted a new law, that went into effect on January 1, 2018, to facilitate greater transparency in brand-name and generic drug pricing through the implementation of specific price reporting requirements for pharmaceutical manufacturers. The extent and timing of these changes are not known, but future legislation could limit the price and/or payment for prescription drugs. If adequate reimbursement levels are not maintained by

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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 may be impaired, thereby reducing anticipated revenues and profitability.

Backlog

We had a \$7.6 million and \$7.1 million product sales backlog as of December 31, 2017 and 2016, respectively. We expect to recognize the \$7.6 million in the first quarter of 2018, 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 23, 2018, we had 762 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.

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 2017 and 2016. Revenues from customers outside of the U.S. amounted to approximately 12% of our total revenues for 2015 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 \$75.0 million, \$66.1 million, and \$42.9 million during 2017, 2016 and 2015, respectively. We expect our research and development expenses to increase in 2018 as compared to 2017 due to the preparation of filing the NDA for bremelanotide and post-approval commitments for Feraheme and Makena. We also expect to invest in studies that could potentially expand the labels for Intrarosa and bremelanotide. Further, we expect to incur increased costs associated with manufacturing process development and the manufacture of drug product for bremelanotide.

Segment Reporting

We conduct our operations in one business segment as further described in Note B, “*Summary of Significant Accounting Policies*,” 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

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(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 Business and Industry

Our ability to successfully commercialize our products and services, including our ability to achieve their widespread market acceptance, is critical to the success of our business.

Most of our resources are dedicated to the commercialization of our products and services and in preparation for the commercialization of our product candidate, bremelanotide, for which we expect to file a New Drug Application in the first quarter of 2018. Our ability to generate significant revenue in the near-term will depend almost entirely on our ability to execute on our commercialization plans and the level of market adoption for, and the continued use of, our products and services (and, if approved, our product candidates) by physicians, hospitals, patients, and/or healthcare payers, including government payers, consumers, managed care organizations and specialty pharmacies. If we are not successful in commercializing our products or services, including achieving and maintaining an adequate level of market adoption, our profitability and our future business prospects will be adversely impacted.

The degree of commercial success and market acceptance of our products, services and product candidates will depend on a number of factors, including the following:

- The competitive landscape for our products, including the timing of new competing products (including generics) or services entering the market, and the level and speed at which competing products (current or new) experience market acceptance;
- Our ability to retain or grow our current customer base and maintain and efficiently deploy our expanded sales force and an experienced commercialization team to compete in the market, especially given the diverse nature of our product and services portfolio;
- Our ability to maintain commercially viable manufacturing processes that are compliant with applicable laws and regulations (including current good manufacturing practices (“cGMP”)), and generate sufficient inventory of our products for commercial sale and clinical use and sufficient inventory of supplies to perform our services;
- Our ability to successfully and timely launch new and expanded products, such as the Makena auto-injector and Feraheme’s newly approved broader indication;
- Actual or perceived advantages or disadvantages of our products, services or product candidate, including the safety and efficacy profile or the potential convenience and ease of administration, over alternative treatments or services, including generic versions;

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- Our ability to engage with and educate healthcare providers and consumers to increase awareness and understanding of the underlying disease states that our products treat or the value of the underlying purpose of our products or services, including moderate to severe dyspareunia and hypoactive sexual desire disorder (“HSDD”), and recurrent preterm birth;
- Current and future restrictions or limitations on our approved or future indications and patient populations or other adverse regulatory actions;
- The relative price, constraints on pricing and the impact of price increases on our products or services, the availability and adequacy of reimbursement from government and third-party payers, and the willingness and ability of patients to pay for our products or services, including the willingness of healthcare providers to prescribe our products if more economical options are available;
- The success and timing of regulatory approval for current or future product candidates or indications, including our ability to obtain regulatory approval for bremelanotide in the U.S. and whether the U.S. Food and Drug Administration (the “FDA”) imposes any restrictions on its distribution;
- The performance of our manufacturers, license partners, distributors, providers and other business partners, over which we have limited control;
- The timely approval of new active pharmaceutical ingredient (“API”) suppliers for Makena;
- Our ability to maintain compliance with all applicable FDA or accrediting organization regulations; and
- Our and our partners' ability to enforce intellectual property rights in and to our products to prohibit a third-party from marketing a competing product (including a generic product) and our ability to avoid third-party patent interference or intellectual property infringement claims.

Makena

Our ability to continue successfully commercializing Makena is dependent upon a number of factors, including our ability to differentiate Makena from other treatment options, especially after generic competitors enter the market. The outcome of our commercialization efforts will likely be adversely impacted by the timing and number of generic competitors that enter the market given the expiration of Makena's orphan drug exclusivity in February 2018. As part of our strategy to offer an alternative to our intramuscular (“IM”) formulation of Makena (the “Makena IM product”), we have developed the Makena subcutaneous auto-injector (the “Makena auto-injector”) for which we received FDA approval to market and sell in February 2018. We plan to launch this line extension product in March 2018. Our ability to maintain Makena market share and generate consistent revenues once we face generic competition is substantially dependent upon our ability to successfully launch the Makena auto-injector and rapidly convert current IM prescribers to the Makena auto-injector. We have limited experience in the commercialization of an auto-injector product. Our level of continued commercial success for the Makena franchise will depend on our ability to:

- Launch and commercialize the Makena auto-injector in a timely manner;
- Differentiate the benefits of the Makena auto-injector over the Makena IM product to prescribers, patients and third-party payers;
- Gain or maintain insurance coverage for the Makena auto-injector for patients through both commercial insurance companies and government programs such as Medicaid, and ensure that such insurance coverage does not create difficulties for physicians or patients to gain access to Makena, such as through requiring use of generic formulations prior to use of the branded Makena IM product or the Makena auto-injector;
- Provide training on the use of an auto-injector device to healthcare providers;
- Manufacture the auto-injector on a commercial scale;
- Maintain and defend the patent rights that we own or have licensed related to the Makena auto-injector;
- Increase patient compliance, including by optimizing efficiency by increasing home administration and reducing the turn around time from enrollment to the start of therapy; and

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- Ensure an easy and convenient process for patients and healthcare providers to prescribe, acquire and administer the Makena auto-injector.

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

Although we intend to launch our own authorized generic formulation of Makena upon the first generic hydroxyprogesterone caproate (“HPC”) injection entrant to the market to mitigate the anticipated decrease in Makena revenue as generic entrants gain market share, our Makena revenues may fall below expectations and as a result, our financial condition and results of operations could be adversely impacted. For more information on generic competition, please see Risk Factor *“We no longer have market exclusivity for Makena and generic competitors are seeking approval to market generic versions of Makena, which would cause sales of Makena to significantly decline and have an adverse impact on our business and results of operation.”*

CBR

The growth of our CBR Services depends on our ability to effectively compete with the growing number of blood banks, which often offer lower pricing and extended services. In addition, our ability to grow our CBR revenue depends, in part, on our ability to educate consumers and healthcare providers on the value of preserving newborn stem cells, rather than discarding the cells or opting for delayed 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. Professional medical organizations periodically recommend certain practices that may negatively impact our business. 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 our CBR Services. For example, in January 2017, the American College of Obstetrics and Gynecology (“ACOG”) issued a new opinion on DCC. 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, or be unable to, bank their newborn’s cord blood stem cells.

CBR’s commercial growth is also dependent upon realizing the potential for cord blood stem cell and cord tissue science and upon increasing its recognition and adoption, as well as actual and perceived value and utility, among the medical community. CBR’s success will be limited if applications are not developed, the FDA does not approve those applications, and if the medical community does not embrace, a broader set of applications than is currently established. There is no guarantee that any further applications will be recognized. Further, 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 and patients may decide not to preserve, or continue preserving, their child’s cord blood stem cells and cord tissue for such expanded uses.

Feraheme

Our ability to grow Feraheme’s market share, including our ability to maximize its market potential following the February 2018 approval of the expanded label to include all eligible adult patients with IDA, depends primarily on our ability to clinically differentiate Feraheme from its competitors, expand access through our contracting strategy and otherwise successfully execute our launch plan for the broader label. We believe the expanded label doubles the size of our addressable market; however, if we are unable to capture Feraheme’s anticipated market share of the total IV iron market, if we have overestimated the size of such market or if the estimates we used to derive Feraheme’s potential are incorrect, our profitability as well as our long-term business prospects could be adversely affected.

In addition, new safety or drug interaction issues may arise as Feraheme is used over longer periods of time by a wider group of patients, especially in light of the expanded label, some of whom may be taking other medicines or have additional underlying health problems. If issues arise, we may be required to, among other things, implement a risk evaluation and mitigation strategy (“REMS”), provide additional warnings and/or restrictions related to Feraheme’s current or future indications, notify healthcare providers of new safety information, narrow our approved indications, change the rate of administration, conduct additional post-approval studies and clinical trials, alter or terminate future trials for additional uses of Feraheme, or even remove Feraheme from the market. For example, our Feraheme label was changed in March 2015 to

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include, among other things, the addition of a boxed warning and a change in the Dosing and Administration section to indicate that Feraheme should only be administered by IV infusion (replacing injection). These or any future changes to the label could adversely impact our ability to successfully compete in the IV iron market and could have an adverse impact on potential sales of Feraheme or require us to expend significant additional funds.

Intrarosa

One of the most critical steps in successfully commercializing Intrarosa, is to drive awareness of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy (“VVA”), due to menopause and the potential benefits of Intrarosa. 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 or its symptoms, including dyspareunia due to menopause, as a treatable medical condition and are often not aware of treatment options. We plan to undertake certain informational and educational programs to help spread awareness of dyspareunia and VVA and the benefits of Intrarosa for the conditions indicated and such programs may not be successful, will be costly and may not result in the anticipated return on our investment. The market for VVA therapies, including Intrarosa's indication (i.e., women suffering from moderate to severe dyspareunia due to menopause), 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 their healthcare professionals. If we have over-estimated the market opportunity for Intrarosa, if we are unable to successfully spread awareness and educate the community about VVA generally (and moderate to severe dyspareunia in particular), or if our marketing efforts are unsuccessful and we cannot increase market share, then our business and results of operations could be materially and adversely affected.

In addition, we have limited experience with licensed products and with commercializing a drug in the field of post-menopausal women's health symptoms. Our future commercial success will significantly depend upon our ability to effectively maintain our commercial team and to leverage our relationships in the obstetrics and gynecology community. 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. For example, in order to create affordable access for patients due to the limited reimbursement coverage for Intrarosa, we offer patients a comprehensive copay savings program and samples, which has and will continue to impact our Intrarosa revenue. Any failure to achieve expectations could adversely affect our profitability.

Bremelanotide

We have limited experience with development-stage, investigational products such as bremelanotide, and the successful development and commercialization of bremelanotide is dependent upon our ability to obtain regulatory approval for bremelanotide in the U.S. on favorable terms. In addition, our ability to successfully commercialize bremelanotide, if approved, depends significantly on the level of success we have in raising awareness and understanding of HSDD, a type of female sexual dysfunction (“FSD”), and its treatment options, and the potential benefits of bremelanotide in treating HSDD as compared to alternative treatment options. For example, bremelanotide will be sold as a self-administered auto-injector and if patients or healthcare providers are hesitant or apprehensive to use an auto-injector product, our commercialization efforts may not be successful. For more information on bremelanotide, please see Risk Factor “*We have limited experience with development stage products and cannot ensure that we will be successful in gaining approval of our product candidates on a timely basis, or at all, including bremelanotide, or that such approval, if obtained, will not contain restrictions that the FDA may impose on the use or distribution of such product candidates.*”

We no longer have market exclusivity for Makena and generic competitors are seeking approval to market generic versions of Makena, which would cause sales of Makena to significantly decline and 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 an Abbreviated New Drug Application (“ANDA”) for generic versions of brand name drugs like Makena. Generics are generally significantly less expensive than branded versions and government and other pressures to reduce pharmaceutical costs may result in a generic product being utilized before or in preference to the branded version of our products under third-party reimbursement programs or substituted by pharmacies under prescriptions written for the original listed drug.

Since acquiring Lumara Health Inc. (“Lumara Health”) in 2014, the majority of our revenue has come from our Makena product. Following the expiration of its orphan drug exclusivity in February 2018, the Makena IM product is now subject to generic competition, which will subject us to increased competition and could significantly reduce the market share of the Makena brand name product. We currently believe that several companies filed ANDAs during 2017 seeking approval for

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generic versions of Makena. The specific timing of potential approval of a generic HPC ANDA is uncertain, however we believe that Makena will face generic competition sometime in mid-2018.

The long-term success of the Makena franchise will be highly dependent on our ability to successfully commercialize the Makena auto-injector, which was approved for commercialization in February 2018, and which is intended to provide us with an alternative treatment method to the Makena IM product. Although there is no direct competition with the Makena auto-injector, the auto-injector will compete with generic versions of the Makena IM product, including our own authorized generic of the Makena IM product, discussed below. Physicians may choose to prescribe the generic formulation either because of the lower cost of the generics or because of 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, which could cause sales of Makena to decline. We may not be able to convince patients or healthcare providers to use or to switch from using the IM method of administration to the auto-injector if the auto-injector is not priced competitively, does not provide comparable insurance coverage or if patients or healthcare providers are hesitant or apprehensive to use an auto-injector product. If we do not convert a sufficient number of patients to the auto-injector method, we could lose a significant amount of our Makena revenue and market share to generic competitors.

In addition, we have entered into an agreement with a generic partner to launch an authorized generic of the Makena IM product, which we intend to launch upon the first generic Makena entrant to the market to allow us to offset some of the impact of generics to branded Makena, including if a generic enters the market more quickly than we anticipate. We will be relying on our generic partner to successfully bring the authorized generic of Makena to market and for our successful commercialization thereafter. We have no experience working with a generic vendor and they may not be able enter into contracts with purchasers on favorable terms, or at all. Further, we are responsible for supplying product to our authorized generic partner and if there are problems in the supply chain, we will be subject to certain penalties, which could be substantial. If we and our partner are not able to capture sufficient market share, or if generics are sold at a significant discount to Makena's price, it could materially and adversely affect the level of sales and the price at which we can sell Makena and, ultimately, our stock price and results of operations.

Competition in the pharmaceutical and biopharmaceutical industries, including from companies marketing generic products, is intense and 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. Our existing or potential competitors have or may develop products or services that are more widely accepted than ours, are viewed as more safe, effective, convenient or easier to administer, have been on the market longer and have stronger patient/provider loyalty, have been approved for a larger patient population, are less expensive or offer more attractive insurance coverage, discounts, reimbursements, incentives or rebates and may have or receive patent protection that dominates, blocks, makes obsolete or adversely affects our product development or business. Any such advantages enjoyed by our competitors could reduce our revenues and the value of our commercialization and product development efforts.

Makena competition currently comes mainly from pharmacies that compound a non-FDA approved version of Makena, which is sold at a much lower list price and is less regulated than Makena. However, we expect the competitive landscape for Makena to impose even greater challenges upon our commercialization efforts when generic formulations of HPC injection enter the market. For more information on generic competition, please see Risk Factor *"We no longer have market exclusivity for Makena and generic competitors are seeking approval to market generic versions of Makena, which would cause sales of Makena to significantly decline and have an adverse impact on our business and results of operation."* We also expect to continue to face competition for Makena from products that may be prescribed off-label (i.e., outside of indications approved by the FDA) such as the generic version of Delalutin, as well as products currently in development which offer additional formulations or routes of administration that doctors believe may reduce or prevent preterm birth, such as an oral HPC product.

Many of our competitors for Feraheme and Intrarosa 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. Feraheme competes primarily with Injectafer®, a ferric carboxymaltose injection, Venofer®, an iron sucrose complex, and INFeD®, an iron dextran product and there are a number of oral iron replacement therapies either approved, such as Auryxia® (ferric citrate), an oral phosphate binder, or in development, such as Monofer® (iron isomaltoside), and hypoxia inducible factor stabilizers.

Intrarosa faces competition primarily from Estrace® Cream (Estradiol vaginal cream, USP 0.01%), a vaginal cream for the treatment of VVA, Vagifem® (estradiol vaginal inserts), a suppository for the treatment of VVA, and Premarin Vaginal Cream®, a vaginal cream for the treatment of VVA as well as generic versions of these products and over the counter and

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compounded remedies to treat VVA and dyspareunia. In addition, TherapeuticsMD, Inc. is developing TX-004HR, a vaginal estrogen softgel capsule for the treatment of dyspareunia, which has a PDUFA date in May 2018.

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. CBR competes primarily with ViaCord®, a subsidiary of PerkinElmer, Inc., Cryo-Cell International, Inc.® and StemCyte™, which are all private blood banks. In addition to these three competitors, CBR competes with more than 20 other private blood banks in the U.S. as well as public blood banks.

We also expect to face competition for bremelanotide, if approved, including from Addyi®, an FDA-approved product for treatment of HSDD in premenopausal women as a daily-use oral drug. In addition, we are aware of several other drugs at various stages of development, most of which are being developed to be taken on a chronic, typically once-daily, basis. However, Emotional Brain BV, a Netherlands company, 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 2b studies. 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, or other companies which may sell their products off-label for indications other than FSD.

If we are unable to compete effectively against existing and future competitors and existing and future alternative products or services, our business, financial condition and results of operations may be materially adversely affected. For further details on our competition, please see Item I, “*Business - Competition*”.

We are completely dependent on third parties to manufacture our drug products and to provide materials required to support our CBR Services 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 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 manufacturing organizations (“CMOs”) and our licensors (who, in turn, may also rely on CMOs) 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 cGMP regulations and other regulatory requirements on a timely basis and with terms that are favorable to us, if at all. Further, our ability to have our drug 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 CMO’s and our licensors’ manufacturing facilities. Any difficulties, disruptions, or delays in the manufacturing process or supply chain could result in product defects, 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.

For example, although we believe we have sufficient Makena IM product in inventory to meet demand, our primary drug product manufacturer has experienced issues regarding the delivery of products, including Makena, and we do not currently have a manufacturer for the production of Makena API. Given that our current inventory of Makena API is being used to manufacture multiple presentations of Makena (including the auto-injector and authorized generic product), any such disruptions or delays could result in an inability to meet commercial demand.

Additionally, we recently received approval for the Makena auto-injector, which will require us to contract for the manufacture of these devices at commercial scale. We have no experience manufacturing an auto-injector product and are currently in discussions with third-party manufacturers to secure commercial supply of certain components. We may encounter difficulties in the production of the Makena auto-injector, 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 or our inability to meet our demand for the auto-injector product. In addition, we do not currently have back-up suppliers for the Makena auto-injector manufacturers. Establishing an alternative supplier for the auto-injector device is a long and costly process and may not be successful. While we take precautions to mitigate potential interruptions, any failure at our manufacturers could result in a shortage of our Makena inventory.

Further, we are dependent upon Endoceutics to manufacture commercial supply of Intrarosa. Endoceutics has limited experience overseeing CMOs for products at commercial scale, which imposes significant and complex regulatory and compliance obligations. Endoceutics has and may continue to face challenges and difficulties with its CMO in satisfying such obligations, particularly since such CMO has limited experience manufacturing prescription drugs.

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We also rely upon third-party contractors to assist in supporting the CBR Services, including to supply proprietary materials. Although we believe we have sufficient contingency plans in place, if current suppliers need to be changed or suffer disruption, 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.

In addition, bremelanotide 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 the bremelanotide auto-injector sub-assemblies and may not be able to enter into such agreements on acceptable terms, if at all, including the cost of goods.

We rely on third-party manufacturers for many aspects of our manufacturing process for our products and in some cases we rely on single source manufacturers without a qualified alternative manufacturer. Securing additional third-party contract manufacturers will require significant time for validating the necessary manufacturing processes, gaining regulatory approval, and implementing 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. Furthermore, none of our current third-party drug product manufacturers or licensors manufacture for us exclusively and as such they may exhaust some or all of their resources meeting the demand of other parties or themselves.

Further, we, our licensors and our respective CMOs 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 as part of the administration of 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 materials such that they no longer meet our standards;
- Lack of sufficient quantities or profit on the production of materials to interest suppliers;
- Labor disputes or shortages;
- Disruption due to natural disasters; or
- Import or export problems.

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.

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 for 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.

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 or 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 or to prevent others from doing so. 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

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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. In addition, our owned or licensed intellectual property might be subject to liens or encumbrances, which, as a result, may not provide us with sufficient rights to exclude others from developing and commercializing products similar or identical to ours. Therefore, the patents issued or licensed to us may provide us with little or no competitive advantage.

We currently hold a number of U.S. patents for our products, including the following:

- One patent related to Feraheme that will expire in June 2023 and other patents related to Feraheme that expire in 2020.
- One patent related to the Makena auto-injector product that will expire in 2036.

We also rely on licensed patents for the protection of the products we commercialize. Under our current license agreements we have rights to a number of U.S. and foreign patents and applications, including the following:

- Patents licensed from Palatin Technologies, Inc. (“Palatin”) related to bremelanotide that expire in 2020 and 2033 (one of which may be extended by up to five years under the Hatch-Waxman act).
- Patents licensed from Endoceutics, Inc. (“Endoceutics”) related to Intrarosa that expire in 2028 and 2031 (one of which may be extended by up to five years under the Hatch-Waxman act).
- Patents licensed from Antares Pharma, Inc. related to the Makena auto-injector product that expire between 2019 and 2034.
- Patents licensed from Abeona Therapeutics, Inc. related to MuGard that expire in 2022.

These and any other patents owned by or licensed to us may be contested in litigation or reexamined or reviewed by the United States Patent and Trademark Office (the “USPTO”). Even if we come to a mutually acceptable settlement arrangement with an adverse party, we or they may become subject to increased regulatory scrutiny or be subject to formal or informal requests or investigations, including by the FDA, the Department of Justice or the Federal Trade Commission (“FTC”). If any present or future patents relied on for the development or commercialization of our products are narrowed, invalidated or held unenforceable, this could have an adverse effect on our business and financial results.

In addition, although we believe that the patents related to each of our products were rightfully issued and the respective portfolios give us sufficient freedom to operate, a third-party could assert that the development, manufacture or commercialization of any of our products infringes its patents or other proprietary rights, potentially resulting in harm to our business and financial results. Further, the intellectual property rights that we own or license might be subject to liens or other encumbrances. If we are required to defend against such claims or to protect our own or our licensed proprietary rights against others, it could result in substantial financial and business costs as well as 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).

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 or administrative proceedings, including interference or derivation, inter partes review, post grant review or reexamination proceedings before the USPTO. For example, the outcome of our ongoing litigation with Sandoz may impact our patent protection and potentially the competitive landscape for Feraheme. Even if we are successful, such litigation, or similar suits we may face in the future, will be expensive and will consume considerable time and other resources, which could materially and adversely impact our business, especially if we have to divert resources from our commercialization or business development efforts.

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. However, these agreements may be breached and we may not have adequate remedies for any such breaches, and our trade secrets and other confidential information might become known. In addition, we cannot be certain that others will not independently develop substantially

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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.

A generic competitor is seeking approval of a generic version of Feraheme and the market entry of such generic or any future generic competitors would limit Feraheme sales and have an adverse impact on our business and results of operation.

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 a patented brand name drug, 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 the brand name drug. 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 Feraheme (ferumoxytol). In its Paragraph IV certification 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 and the trial is currently scheduled for March 19, 2018. If such patents are not upheld or if the generic competitor is found not to infringe such patents, then we will likely face generic competition soon after such resolution. 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 is expensive and consumes 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 our branded product, such as 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 to the market. Such a market entry would likely limit our sales, which would have an adverse impact on our business and results of operations.

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, especially in light of potential generic competition, 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 level of reimbursement from third-party payers, including state and federal governmental payers such as Medicare and Medicaid, managed care organizations, private health insurers and other organizations. 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 continue to institute cost containment measures to control or 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 prescribe alternative products, including generics, which would have an adverse effect on our ability to generate revenues.

In addition, the possible introduction of generic competition to our products, including Intrarosa, Makena and Feraheme, may also affect the reimbursement policies of government authorities and third-party payers, such as private health insurers and HMOs. These organizations determine which medications they will pay for and establish reimbursement levels. Cost containment is a primary concern in the U.S. healthcare industry and government authorities and these third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for branded medications when there is a generic available. If generic products become available in the market, insurance companies and government payers, such as state Medicaid agencies, which currently provide coverage for our products may make it more difficult for physicians to prescribe our products by charging higher copays, requiring prior authorizations, implementing step edits or not providing reimbursement at all. Even if reimbursement is available, the level of such reimbursement could be reduced or limited. Reimbursement levels or the lack of reimbursement may impact the demand for, or the price of, our brand name products. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products, and/or our financial results from the sale of related products could be negatively and materially impacted.

Intrarosa is dependent on third-party reimbursement to reach its market potential. Payers frequently employ a tiered system in reimbursing end-users for pharmaceutical products, with tier designation affecting copay or deductible amounts. While some of the products that Intrarosa competes with receive reimbursement from governmental healthcare programs, Intrarosa is

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generally classified as a Tier 3 drug, and therefore 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 name products. In addition, given the increasing number of generic competitors entering the VVA and dyspareunia market, payers may choose to implement step edits or prior authorizations prior to Intrarosa use, which could adversely impact our projected Intrarosa revenues and profitability. If Intrarosa does not receive adequate reimbursement coverage, the growth in Intrarosa sales may not meet our expectations or receive more favorable third-party reimbursement than its competitors, and our business, financial condition and results of operations may be materially adversely affected.

There is also significant uncertainty concerning the extent and scope of third-party reimbursement for products treating HSDD. 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 and products treating women's health conditions, such as Intrarosa. If this is the case, we expect that commercial payers will likely cover bremelanotide as a non-preferred product, which normally requires a higher copay or deductible than preferred 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 bremelanotide. If bremelanotide does not receive adequate reimbursement coverage, if approved, 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 bremelanotide to have significant copay or deductible requirements and to be only partially reimbursed by third-party payers, demand for bremelanotide may be tied to discretionary spending levels of the targeted patient population. Thus, any downturn in the economy could result in weakened demand for bremelanotide.

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 "ACA") 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 (the "340B Program"). In addition, federal budgetary concerns and the current 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 ACA. A key focus of the current presidential administration and Republican majorities in both houses of the U.S. Congress is to "repeal and replace" all or portions of the ACA. Since its enactment, however, there have been modifications and challenges to numerous aspects of the ACA, including the repeal of the so-called "individual mandate" which imposed a tax on individuals who were eligible for, but did not enroll in, health insurance plans. In 2018, litigation, regulation, and legislation related to the ACA are likely to continue, with unpredictable and uncertain results. The full impact of the ACA, any law repealing, replacing, and/or modifying elements of it, and the political uncertainty surrounding any repeal or replacement legislation on our business remains unclear. The extent, timing and details of the changes are not currently known, but the federally funded healthcare 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. 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.

Further, government agencies that oversee reimbursements such as Centers for Medicare & Medicaid Services ("CMS") may adopt policies that impact the reimbursement rate to our customers, which may in turn impact our net product revenues. For example, effective January 1, 2018, CMS adopted a policy to pay for separately payable, non-pass-through drugs and biologicals other than vaccines purchased through the 340B Program, with certain exceptions, at the average sales price ("ASP") minus 22.5% rather than ASP plus 6%. Drugs not purchased under the 340B Program will continue to be paid for at a rate of ASP plus 6%. The effect of this change on the overall 340B Program and our 340B eligible customers is unclear.

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However, there will be significant increases in budget pressure for our customers, which may adversely impact premium priced agents, such as Feraheme and Makena.

We have limited experience with development stage products and cannot ensure that we will be successful in gaining approval of our product candidates on a timely basis, or at all, including bremelanotide, or that such approval, if obtained, will not contain restrictions that the FDA may impose on the use or distribution of such product candidates.

Our long-term success and revenue growth will depend upon our ability to continue to successfully develop new products. Drug development is inherently risky and the FDA imposes substantial requirements on the development of such candidates to become eligible for marketing approval. The FDA has substantial discretion in the approval process and may decide that our data is insufficient for approval. Clinical data is often susceptible to varying interpretations, and many companies in the pharmaceutical and biotechnology industries that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain FDA approval for their products. The FDA could also determine that our manufacturing processes are not properly designed, are not conducted in accordance with federal laws or otherwise not properly managed. If we do not obtain FDA approval for our product candidates, including bremelanotide, as discussed below, or if we experience significant delays or setbacks in obtaining approval, our ability to grow our business and leverage our product portfolio and the future prospects of our business could be materially adversely affected.

In January 2017, we acquired an exclusive license from Palatin to research, develop and commercialize bremelanotide in North America. During 2016, Palatin 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 bremelanotide versus placebo, in each case, delivered via an auto-injector. In both clinical trials, bremelanotide 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, the 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 bremelanotide arm due to adverse events in both studies. We currently expect to submit the bremelanotide NDA in the first quarter of 2018.

Despite the successful completion of the Phase 3 clinical trials, the approval of bremelanotide for commercial sale in the U.S. could be delayed or denied or we may be required to conduct additional studies for a number of reasons, including:

- The FDA may determine that bremelanotide does not demonstrate safety and efficacy in accordance with regulatory agency standards based on the results of the Phase 3 trials, including the co-primary and secondary endpoints and safety results;
- The FDA may determine that the magnitude of efficacy demonstrated in the bremelanotide studies does not amount to a clinically meaningful benefit to pre-menopausal women with HSDD and thus that the product cannot be approved despite statistically significant efficacy results;
- The FDA could analyze and/or interpret data from preclinical testing and clinical trials in different ways than we or Palatin interpret them;
- The auto-injector device that we plan to use to administer bremelanotide may not be adequate or may not be considered adequate by the FDA;
- We may be unable to establish, and obtain FDA approval for, a commercially viable manufacturing process for bremelanotide in a timely manner, or at all;
- Adverse medical events reported during the trials, including increases in blood pressure noted in prior clinical trials and a serious adverse event of hepatitis of unknown etiology;
- 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 current good clinical practices regulations ("cGCP"), including the failure to pass FDA inspections of clinical trial sites; and
- The FDA may change their approval policies or adopt new regulations.

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Any failure or delay in obtaining regulatory approval for bremelanotide 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 we are required to conduct additional studies, our share price could decline significantly.

Even if regulatory approval to market bremelanotide 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 bremelanotide's approval. 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.

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 our license agreements with Palatin and Endoceutics. 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, or that such transactions will be successfully integrated into our business.

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 bremelanotide, the market for bremelanotide or Intrarosa or the cost of goods for bremelanotide or Intrarosa is different from what we predicted in our model, the anticipated financial benefits of bremelanotide or Intrarosa may not be achieved. 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 write-offs or impairments, which may be larger than anticipated or impact our financial statements more quickly than anticipated. Such transactions may also require us to incur additional and significant 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.

In addition, our cash 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. 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. For example, certain 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, any equity or equity-linked issuance, whether as consideration for a strategic transaction or in a financing transaction, could cause our stockholders to experience significant dilution.

Even if we do acquire or license additional products or businesses, the management of a license arrangement, collaboration, or other strategic arrangement and/or integration of an acquired asset or company may disrupt our ongoing business and require management resources that otherwise would be available for ongoing commercialization efforts and development of our existing enterprise. 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 bremelanotide license, we added a development stage product to our portfolio and therefore needed to enhance our research and development expertise for product candidates.

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Our expanded portfolio may further 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.

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 bremelanotide, 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 have significantly expanded the size of our product portfolio and our overall organization and we may experience difficulties in managing this or future expansion.

In recent years, we more than tripled the size of our employee-base and we have considerably expanded our product portfolio by obtaining certain development and commercialization rights to bremelanotide and Intrarosa during 2017. Management, personnel, systems and facilities that we currently have in place may not be adequate to support this recent growth (especially given that we did not acquire any rights to any infrastructure or personnel under our arrangements with Palatin and Endoceutics), 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, if we add products to our portfolio through licenses or acquisitions, 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.

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 and in one clinical study, certain complications or events associated with pregnancy occurred more often in women who received Makena, including 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 Intrarosa and bremelanotide, if approved, are introduced to the

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market, more serious adverse reactions than those reported during clinical trials could arise. We could also be subject to liability for the loss of or damage to cord blood or cord tissue units. 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 and any resulting litigation, whether or not they have merit, may generate negative publicity and could decrease demand for our products, cause other parties to submit claims or demands, subject us to product recalls, 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 a litigation and, as a result, our business could be materially harmed and, as with any product liability litigation, regardless of the outcome, these claims or suits may generate negative publicity, cause other parties to submit claims or demands, harm our reputation and divert management's time and attention. These lawsuits may also 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.

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 Intrarosa and bremelanotide 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, we are dependent upon the contributions of Endoceutics, which is a small company organized outside of the U.S. with limited operations, experience and resources, including to exclusively provide us with all commercial supply and conduct certain clinical and commercialization activities. 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 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. For example, Endoceutics' assets, including the intellectual property licensed to us, are subject to a security interest held by a third-party lender, and therefore our rights and remedies under the license agreement may be impaired or inadequate. 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. In addition, we must work collaboratively with our partners to conduct various activities and if we cannot do so effectively, disagreements could arise. Such disagreements could delay the related program or result in distraction or expensive arbitration or litigation, which may not be resolved in our favor.

Our license and purchase agreements contain complex provisions and impose various milestone payment, royalty, insurance, diligence, reporting and other obligations on us. If we fail to comply with our obligations, our partners 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, or we may incur additional costs or may be required to litigate any disputes. If our partners allege that we have breached our obligations under such arrangements, even if such allegations are without merit, defending such allegations, including complying with any audit, reporting or dispute resolution provisions of such agreement, or conducting any investigations, can be expensive and utilize considerable amounts of management's time and efforts. For example, under the terms of our agreement with Lumara Health, the former shareholders of Lumara Health through its shareholder representatives can exercise a right to review our books and records related to the calculation of revenue which trigger the milestone payments owed to Lumara Health. Termination of a license agreement or reduction or elimination of our licensed rights may result in our

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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”), contract research manufacturers, 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 or our partners contract with, and plan to continue to contract with, certain CROs to provide clinical trial services for the development of Intrarosa to treat 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, CBR is dependent upon third-parties to perform tests which must be conducted in compliance with the FDA regulations that govern those functions.

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 many 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. For example, we rely on Endoceutics, 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 supply, research and development, or the regulatory process for 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.

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 or increase our profitability. Because of the specialized nature of our business, including 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).

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.

Risks Related to Regulatory Matters

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 ACA, 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 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 (the “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.

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 or state healthcare fraud and abuse laws, marketing disclosure laws or other federal or state 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 and state 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 and state 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 encourage 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

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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 the provisions of the FDA's "Subpart H" Accelerated Approval regulations, 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.

We have developed and implemented a corporate compliance program based on what we believe are current best practices in the pharmaceutical industry; however, relevant compliance 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 and state 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.

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

The regulations governing the calculations, price reporting and payment obligations are complex and subject to interpretation by various government and regulatory agencies, as well as the courts. Reasonable assumptions have been made where there is lack of regulations or clear guidance and such assumption involve subjective decisions and estimates. We are required to report any revisions to our calculation, price reporting and payment obligations previously reported or paid. Such revisions could affect our liability to federal and state payers and also adversely impact our reported financial results of operations in the period of such restatement.

Uncertainty exists as new laws, regulations, judicial decisions, or new interpretations of existing laws, or regulations related to our calculations, price reporting or payments obligations increases the chances of 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. In addition, it is possible that future healthcare reform measures could be adopted which could result in increased pressure on pricing and reimbursement of our products and thus have an adverse impact on our financial position or business operations.

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Further, state Medicaid programs may be slow to invoice pharmaceutical companies for calculated 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.

In addition to retroactive rebates and the potential for 340B Program refunds, if we are found to have knowingly submitted any false price information related to the Medicaid Drug Rebate Program to CMS, we may be liable for civil monetary penalties. 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 program or Tricare Retail Pharmacy Program, whether due to a misstated Federal Ceiling Price 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 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 services, 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. Failure to comply with such regulatory requirements or the later discovery of previously unknown problems with the manufacture, distributions and storage of 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 or 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-approval obligations;

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- 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 or suspension of clinical trials;
- For human cells, tissues and cellular and tissue-based products (“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.

In addition, if our products face any safety or efficacy issues, including drug interaction problems, under 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 REMS where necessary to assure safe use of the drug; or
- Removing an already approved product from the market.

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 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 drug products, seek commercialization in other jurisdictions, or in support of our current indications. Similarly, our licensors are conducting certain clinical trials to gain approval in various indications for drug 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 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 bremelanotide for the treatment of HSDD in pre-menopausal women or Intrarosa for the treatment of HSDD in post-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

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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 New Drug Applications or equivalent foreign filings, enforcement actions, injunctions or criminal prosecution and suspension of manufacturing authorizations. For example, in early 2017, one of our manufacturers received a warning letter from the FDA, which it has not yet completely resolved. 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 products to be used for commercial sale. If a 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 products for ongoing stability after it has been released for commercial sale. If a particular batch of 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.

The FDA has required post-approval 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-approval 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 Subpart H. 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 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-approval 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-approval 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.

The regulatory landscape for cord blood and cord tissue banking is complex and evolving, and we could therefore 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 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

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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 healthcare provider network, will be able to obtain or maintain any necessary licenses required to conduct our business under the current or future regulatory regime, which could in turn negatively impact our business and ability to comply with regulations. If any of these events were to occur, our business could be materially and adversely affected.

Our 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. For example, based on events that occurred prior to our acquisition of CBR, CBR is required to comply with an FTC Order through April 29, 2033. 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.

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In addition, in the course of our business, 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.

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.

Risks Related to our Financial Condition and Results

Our level of indebtedness and the terms of our outstanding debt 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.

As of December 31, 2017, we had approximately \$816.0 million of total debt outstanding, including \$475.0 million aggregate principal amount of our senior notes due September 1, 2023 bearing interest at 7.875% annually (the “2023 Senior Notes”), issued in August 2015, \$21.4 million aggregate principal amount of our convertible notes due February 15, 2019 bearing interest at 2.5% annually (the “2019 Convertible Notes”), issued in February 2014, and \$320.0 million aggregate principal amount of our convertible notes due June 1, 2022 bearing interest at 3.25% annually (the “2022 Convertible Notes” and, together with the 2019 Convertible Notes, the “Convertible Notes”), issued in May 2017. Our high level of indebtedness, or restrictions in an indenture governing such 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 the terms of such 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 the remaining 2023 Senior Notes or Convertible Notes tendered to us if there is a change of control, which would constitute a default under the indenture governing the 2023 Senior Notes;
- Require us to use a substantial portion of our cash flow from operations to pay interest and principal, which would reduce the funds available for working capital, capital expenditures and other general corporate purposes;
- Limit our ability to obtain additional financing for working capital, capital expenditures, acquisitions and other investments or general corporate purposes, which may limit the ability to execute our business strategy;

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- Heighten our vulnerability to downturns in our business, our industry or in the general economy, and restrict us from exploiting business opportunities or making acquisitions;
- Place us at a competitive disadvantage compared to those of our competitors that may have proportionately less debt;
- Limit management's discretion in operating our business or pursuing additional portfolio expansion opportunities; and
- Limit our flexibility in planning for, or reacting to, changes in our business, the industry in which we operate or the general economy.

Our ability to make scheduled payments of the principal of, or to pay interest on our indebtedness, including the 2023 Senior Notes, the 2022 Convertible Notes and the 2019 Convertible Notes ("our current Note 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 repay 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 Note obligations. In addition, if for any reason we are unable to meet our debt service and repayment obligations, we could be in default under the terms of the agreements governing our indebtedness, which could allow our creditors at that time to declare all outstanding indebtedness to be due and payable, and could further trigger cross-acceleration or cross-default rights between our applicable debt agreements. Under these circumstances, we may not have sufficient funds to satisfy our debt obligations.

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. 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 the indenture governing the applicable 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 (which includes certain change of control transactions, stockholder-approved liquidations and dissolutions and certain stock exchange delisting events) 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 the 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.

We may need additional capital to achieve our business objectives and to service our debt obligations, including our 2023 Senior Notes, the Convertible Notes and contingent payments that may become due under our strategic transaction arrangements, 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 any restrictive covenants in the documents governing our current or future 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.

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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 Note obligations or any cash milestone payments to our partners upon the achievement of sales or regulatory 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. We may also suffer reputational harm and be viewed as an undesirable acquirer or business development partner if we are unable to make the required payments under our strategic transaction arrangements. In addition, 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.

We have in the past, and may in the future, enter into term loans and credit facilities with various banking institutions. Our ability and the terms on which we can borrow will be subject to the state of our operations and the debt market, which is unpredictable and beyond the scope of our control. We may not be able to borrow required amounts on favorable terms, including favorable interest rates, or at all. Further, borrowings under such facilities may bear interest at variable rates exposing us to interest rate risk.

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 April 2017, we entered into a shareholder rights plan, which expires on April 6, 2018, to help preserve our tax assets by deterring certain stockholders from increasing their percentage ownership in our stock; however, such a plan 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 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.

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In December 2017, comprehensive federal tax reform was enacted that significantly changes the taxation of business entities. The changes include, but are not limited to, a permanent reduction to the federal corporate income tax rate, limitations on the deductibility of business interest expense, accelerated expensing of capital expenditures, and disallowance of certain deductions that had been previously allowed. The legislation is highly complex and unclear in certain respects and will require interpretations and regulations by the Internal Revenue Service and state tax authorities. Additionally, the legislation could be subject to potential amendments and technical corrections, any of which could lessen or increase certain adverse impacts of the legislation. Thus, the impact of certain aspects of the legislation is currently unclear and could have an adverse impact on our financial condition, results of operations or cash flows.

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.

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 sales and services revenue; product sales allowances and accruals; allowance for doubtful accounts, marketable securities; 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; income taxes, including valuation allowances, 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 2018, we issued financial guidance, including expected 2018 total revenue and profitability metrics, which is likewise based on estimates and the judgment of management. If, for any reason, we are unable to realize our projected 2018 revenue or profitability, we may not realize our publicly announced financial guidance. If we fail to realize, or if we change or update any element of, our publicly disclosed financial guidance or other expectations about our business, our stock price could decline in value.

As part of our revenue recognition policy, our estimates of product returns, rebates and chargebacks, 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 adversely affect our financial position and results of operations.

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In addition, to determine the required quantities of our products 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.

We have significant goodwill and other intangible assets. Consequently, potential impairment of goodwill and other intangibles may significantly impact our profitability.

Goodwill and other intangibles represent a significant portion of our assets. As of December 31, 2017 and 2016, goodwill and other net intangibles comprised approximately 73% and 70%, respectively, of our total assets. Goodwill and other intangible assets are subject to an impairment analysis, which involves judgment and assumptions, whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Additionally, goodwill and indefinite-lived assets are subject to an impairment test at least annually. For the years ended December 31, 2017 and 2016, we recorded intangible asset impairment charges of \$319.2 million and \$16.0 million, respectively. The procedures, judgments and assumptions used in our goodwill and intangible assets impairment testing, and the results of our testing, are discussed in Item 7 of this report “Management’s Discussion and Analysis of Financial Condition and Results of Operations” under the captions “*Critical Accounting Policies*” and “*Results of Operations*”. Events giving rise to impairment of goodwill or intangible assets are an inherent risk in the pharmaceutical industry and often cannot be predicted. As a result of the significance of goodwill and other intangible assets, our results of operations and financial position in a future period could be negatively impacted should additional impairments of our goodwill or other intangible assets occur.

Risks Related to Our Common Stock

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 \$11.93 and \$25.20 in the fifty-two week period through February 23, 2018. 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.

Our operating results will likely fluctuate, including as a result of wholesaler, distributor and customer buying patterns, as such 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, including the decline in Makena sales and the extent to which sales of the Makena auto-injector and the Makena authorized generic are able to offset the expected decrease in sales of Makena;
- If we have overestimated the size of the market and market potential for any of our products or services;

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- The loss of a key customer or group purchasing organizations (“GPOs”);
- 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, the Palatin License Agreement and the Endoceutics License Agreement;
- 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;
- Costs associated with our obligations under the Palatin License Agreement and Endoceutics 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 goodwill or other accruals or changes in the timing and availability of government or customer discounts, rebates and incentives;
- The implementation of new or revised accounting or tax rules or policies; and
- 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, particularly in light of the recent tax reform.

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.

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.

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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 acquirer) to purchase significant amounts of additional shares of our common stock at dilutive prices. The rights issued pursuant to our shareholder rights plan 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, which 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.

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 611 Gateway Boulevard, South San Francisco, California. The lease expires in July 2022.

See Note O, "*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 O, "*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 23, 2018, the closing price of our common stock, as reported on the NASDAQ, was \$19.65 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, 2017		
First quarter	\$ 36.60	\$ 19.95
Second quarter	\$ 24.85	\$ 16.00
Third quarter	\$ 20.85	\$ 16.05
Fourth quarter	\$ 19.50	\$ 11.93
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

Stockholders

On February 23, 2018, we had approximately 90 stockholders of record of our common stock, and we believe that the number of beneficial holders of our common stock was approximately 8,900 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, 2017.

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, 2017 through October 31, 2017	1,633	\$ 15.80	—	2,547,771
November 1, 2017 through November 30, 2017	2,953	12.98	1,025,153	1,821,469
December 1, 2017 through December 31, 2017	3,090	14.01	341,113	1,547,656
Total	7,676	\$ 13.99	1,366,266	

⁽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 repurchased 1.4 million shares of our common stock during the fourth quarter of 2017. We have repurchased and retired \$39.5 million cumulatively of our common stock under our share repurchase program to date. These shares

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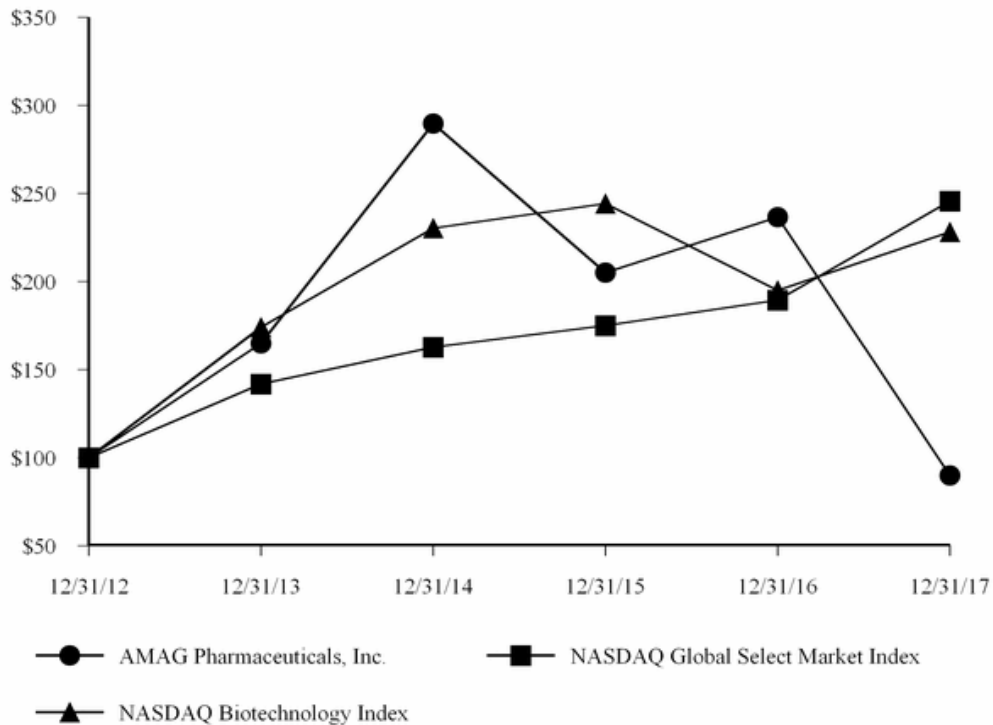
were purchased pursuant to a repurchase program authorized by our board of directors that was announced in January 2016 to repurchase up to \$60.0 million of our common stock, of which \$20.5 million remains outstanding as of December 31, 2017. The repurchase program does not have an expiration date 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, 2017.

Five-Year Comparative Stock Performance

The following graph compares the yearly percentage change in the cumulative total stockholder return on our common stock with the cumulative total return on the NASDAQ Global Select Market Index and the NASDAQ Biotechnology Index over the past five years. The comparisons assume \$100 was invested on December 31, 2012 in our common stock, the NASDAQ Global Select Market Index and the NASDAQ Biotechnology Index, and assumes reinvestment of dividends, if any.



	12/31/2012	12/31/2013	12/31/2014	12/31/2015	12/31/2016	12/31/2017
AMAG Pharmaceuticals, Inc.	100.00	165.06	289.73	205.23	236.57	90.07
NASDAQ Global Select Market Index	100.00	141.84	162.90	175.05	189.46	245.70
NASDAQ Biotechnology Index	100.00	174.05	230.33	244.29	194.95	228.29

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 Research Data Group, Inc., a source we believe is reliable.

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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, 2017, 2016, 2015, 2014 and 2013. 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,				
	2017	2016	2015 ⁽¹⁾	2014 ⁽²⁾	2013
(in thousands, except per share data)					
Statements of Operations Data					
Revenues:					
Product sales, net	\$ 495,645	\$ 432,170	\$ 341,816	\$ 109,998	\$ 71,692
Service revenues, net	114,177	99,604	24,132	—	—
License fee, collaboration and other revenues ⁽³⁾	124	317	52,328	14,386	9,164
Total revenues	<u>609,946</u>	<u>532,091</u>	<u>418,276</u>	<u>124,384</u>	<u>80,856</u>
Costs and expenses:					
Cost of product sales (excluding impairment) ⁽⁴⁾	161,349	96,314	78,509	20,306	11,960
Cost of services	21,817	20,575	9,992	—	—
Research and development expenses	75,017	66,084	42,878	24,160	20,564
Acquired in-process research and development ⁽⁵⁾	65,845	—	—	—	—
Selling, general and administrative expenses ⁽⁶⁾	259,933	249,870	160,309	72,254	59,167
Impairment of intangible assets ⁽⁷⁾	319,246	19,663	—	—	—
Acquisition-related costs	—	—	11,232	9,478	782
Restructuring expenses	—	715	4,136	2,023	—
Total costs and expenses	<u>903,207</u>	<u>453,221</u>	<u>307,056</u>	<u>128,221</u>	<u>92,473</u>
Operating (loss) income	<u>(293,261)</u>	<u>78,870</u>	<u>111,220</u>	<u>(3,837)</u>	<u>(11,617)</u>
Other income (expense):					
Interest expense	(68,382)	(73,153)	(53,251)	(14,697)	—
Loss on debt extinguishment ⁽⁸⁾	(10,926)	—	(10,449)	—	—
Interest and dividend income	2,810	3,149	1,512	975	1,051
Other income (expense) ⁽⁸⁾	(335)	189	(9,188)	217	964
Total other (expense) income	<u>(76,833)</u>	<u>(69,815)</u>	<u>(71,376)</u>	<u>(13,505)</u>	<u>2,015</u>
(Loss) income before income taxes	(370,094)	9,055	39,844	(17,342)	(9,602)
Income tax (benefit) expense ⁽⁹⁾	(170,866)	11,538	7,065	(153,159)	—
Net (loss) income	<u>\$ (199,228)</u>	<u>\$ (2,483)</u>	<u>\$ 32,779</u>	<u>\$ 135,817</u>	<u>\$ (9,602)</u>
Net (loss) income per share:					
Basic	\$ (5.71)	\$ (0.07)	\$ 1.04	\$ 6.06	\$ (0.44)
Diluted	\$ (5.71)	\$ (0.07)	\$ 0.93	\$ 5.45	\$ (0.44)
Weighted average shares outstanding used to compute net (loss) income per share:					
Basic	34,907	34,346	31,471	22,416	21,703
Diluted	34,907	34,346	35,308	25,225	21,703

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	As of December 31,				
	2017	2016	2015	2014	2013
Balance Sheet Data					
Cash, cash equivalents and investments	\$ 328,707	\$ 579,086	\$ 466,331	\$ 144,186	\$ 213,789
Working capital (current assets less current liabilities)	\$ 204,150	\$ 405,681	\$ 360,753	\$ 107,548	\$ 211,284
Total assets	\$ 1,853,236	\$ 2,478,426	\$ 2,476,210	\$ 1,388,933	\$ 265,459
Long-term liabilities	\$ 785,274	\$ 1,231,160	\$ 1,298,025	\$ 762,492	\$ 59,930
Stockholders' equity	\$ 790,244	\$ 934,389	\$ 932,264	\$ 459,953	\$ 172,408

- (1) Includes the results of operations of CBR during the post-acquisition period from August 17, 2015 through December 31, 2015.
- (2) Includes the results of operations of Lumara Health during the post-acquisition period from November 12, 2014 through December 31, 2014.
- (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 2017, 2016, 2015, and 2014 included approximately \$130.4 million, \$77.8 million, \$63.3 million, and \$6.1 million of non-cash expense related to the amortization of intangible assets and the step-up of Lumara Health's inventories at the acquisition date, respectively.
- (5) Reflects \$65.8 million related primarily to a \$60.0 million one-time upfront payment under the terms of the Palatin License Agreement, and \$5.8 million, which represented a portion of the consideration recorded in 2017 under the terms of the Endoceutics License Agreement.
- (6) 2016 reflects a full year recognition of CBR Services selling, general and administrative expenses 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 milestone payments. In addition, 2015 reflects a full year recognition of Makena-related selling, general and administrative expenses compared to a partial period in 2014 following our November 2014 acquisition of Lumara Health.
- (7) In 2017, we recognized a \$319.2 million impairment charge related to the Makena base technology intangible asset. In 2016, we recognized \$19.7 million of charges related to the impairment of the remaining net intangible asset for the MuGard Rights, the remaining CBR-favorable lease intangible asset and the CBR trade names and trademarks intangible asset.
- (8) Reflects \$10.9 million and \$10.4 million loss on debt extinguishment in 2017 and 2015, respectively, due to the early repayment of the 2015 Term Loan Facility and 2014 Term Loan Facility, respectively. In addition, 2015 includes \$9.2 million of other expense associated with the financing of the CBR acquisition.
- (9) The \$170.9 million income tax benefit in 2017 was primarily driven by the deferred tax benefit related to the Makena base technology intangible asset impairment and amortization. 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.

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 maternal and women's health, anemia management and cancer supportive care, including Makena[®] (hydroxyprogesterone caproate injection), Intrarosa[®] (prasterone) vaginal inserts, Feraheme[®] (ferumoxytol injection) for intravenous ("IV") use, and MuGard[®] Mucoadhesive Oral Wound Rinse. In addition, in February 2017, we acquired the rights to research, develop and commercialize bremelanotide in North America. Through services related to the preservation of umbilical cord blood stem cell and cord tissue units 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 intend 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 additional products and companies that align with our existing therapeutic areas or 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, Product Candidates and Services

Makena

Makena is currently 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 U.S. Food and Drug Administration (the "FDA") in February 2011 as an intramuscular ("IM") injection (the "Makena IM product") packaged in a multi-dose vial and as of February 2016 was also available in a single-dose preservative-free vial. In February 2018, Makena was also approved by the FDA for administration via a pre-filled subcutaneous auto-injector (the "Makena auto-injector"), a drug-device combination product. Makena is administered weekly by a healthcare professional 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. In 2017, sales of Makena accounted for approximately 63% of our total net revenues.

The Makena auto-injector was designed with features, such as a shorter, thinner, non-visible needle compared to the Makena IM product, to help address some of the known barriers to treatment of recurrent preterm birth, including the lack of patient acceptance and adherence. As such, based on market research we conducted, we believe that many healthcare professionals and patients will prefer the auto-injector over the IM administration. However, some healthcare professionals and/or patients may continue to employ the IM method of administration. The orphan drug exclusivity period that was granted to the Makena product in 2011, expired on February 3, 2018 and accordingly, we expect to face generic competition to the Makena IM product in mid-2018, however generics could enter the market at any time. In anticipation of generic competition, we have entered into an agreement with a generic partner and are prepared to launch our own authorized generic upon the first entry of a generic Makena injection in order to participate in the expected generic market for Makena.

CBR Services

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 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 services required to collect, process, and store umbilical cord blood stem cells and cord tissue, the FDA regulates such services as products.

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The CBR Services include the collection, processing and storage of both umbilical cord blood and cord tissue. As of December 31, 2017, CBR stored approximately 700,000 umbilical cord blood and cord tissue units, which we estimate to represent nearly 40% of all privately stored cord blood and cord tissue units in the U.S. In 2017, revenue from the CBR Services accounted for approximately 19% of our total net revenues.

Feraheme

Feraheme was approved for marketing by the FDA in June 2009 for the treatment of IDA in adult patients with chronic kidney disease (“CKD”) only and was commercially launched shortly thereafter. In February 2018, we received FDA approval to expand the Feraheme label to treat all eligible adult IDA patients who have intolerance to oral iron or have had unsatisfactory response to oral iron in addition to patients who have CKD. In 2017, sales of Feraheme for the treatment of CKD accounted for approximately 17% of our total net revenues.

Intrarosa

In February 2017, we entered into a license agreement (the “Endoceutics License Agreement”) with Endoceutics, Inc. (“Endoceutics”) pursuant to which Endoceutics granted us rights to Intrarosa, an FDA-approved product for the treatment of moderate to severe dyspareunia (pain during sexual intercourse), a symptom of vulvar and vaginal atrophy, due to menopause.

To support the July 2017 launch of Intrarosa, we hired a new 170 person commercial team, including a sales force of nearly 140 sales representatives dedicated to Intrarosa. This newly established sales force provides additional flexibility as our portfolio evolves, including for the potential expansion of the Intrarosa label, the potential launch of bremelanotide and for future products we may acquire or develop in the women’s health space.

In addition, Endoceutics initiated a clinical study in the third quarter of 2017 to support an application for U.S. regulatory approval of Intrarosa for the treatment of hypoactive sexual desire disorder (“HSDD”) in post-menopausal women. We and Endoceutics have agreed to share the direct costs related to two clinical studies based upon a negotiated allocation with us funding up to \$20.0 million, including the HSDD trial. If the studies are successful, we will file a supplemental New Drug Application (“sNDA”) with the FDA for the treatment of HSDD in post-menopausal women. Furthermore, each party’s commercialization activities and budget are described in a commercialization plan, which is updated annually. Additional details regarding the Endoceutics License Agreement can be found in Note P, “*Collaboration, License and Other Strategic Agreements*,” to our consolidated financial statements included in this Annual Report on Form 10-K.

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 June 2013 license agreement with Abeona Therapeutics, Inc. (“Abeona”) (the “MuGard Rights”). MuGard was launched in the U.S. by Abeona in 2010 after receiving 510(k) clearance from the FDA.

Bremelanotide

In January 2017, we entered into a license agreement with Palatin Technologies, Inc. (“Palatin”) pursuant to which Palatin granted us the North American rights to research, develop and commercialize bremelanotide, which is being developed for the treatment of HSDD, the most common type of female sexual dysfunction, in pre-menopausal women. We currently expect to submit an NDA in the first quarter of 2018 for the treatment of HSDD in pre-menopausal women. Additional details regarding the license with Palatin (the “Palatin License Agreement”) can be found in Note P, “*Collaboration, License and Other Strategic Agreements*,” to our consolidated financial statements included in this Annual Report on Form 10-K.

Velo

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 began in the second 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 P, “*Collaboration, License and Other Strategic Agreements*,” to our consolidated financial statements included in this Annual Report on Form 10-K.

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. ("GAAP"). 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; valuation of marketable securities; business combinations and asset acquisitions, including acquisition-related contingent consideration; goodwill; intangible assets; equity-based compensation; and income taxes.

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 2015 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, 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.

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

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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 our products have a range of three years to five years. 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 products, 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 2017, 2016, or 2015. To date, our product returns 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.

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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 2017 and 2016, we refined 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 refinement resulted in a \$1.2 million increase and a \$6.1 million reduction of our estimated Medicaid rebate reserve related to prior period Makena sales in 2017 and 2016, respectively. 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the “ACA”) 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 ACA 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 2017, 2016, and 2015 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 ACA exempts “orphan drugs” such as Makena from 340B ceiling price requirements for the covered entity types newly added to the program by the ACA.

In addition, the number of 340B institutions, which provide drugs at reduced rates, was expanded by the ACA to include additional hospitals. As a result, the volume of Feraheme business sold to 340B eligible entities has increased since the implementation of the ACA. Feraheme sales to 340B eligible entities comprised approximately 29%, of our total Feraheme sales in grams for 2017 and 20% of our total Feraheme sales in grams for each of 2016 and 2015. 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 2017, 2016, and 2015. 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. Since its enactment, there have been modifications and challenges to numerous aspects of the legislation. In 2018, litigation, regulation, and legislation related to the ACA are likely to continue, with unpredictable and uncertain results. The full impact of the ACA, any law repealing, replacing, and/or modifying elements of it, and the political uncertainty surrounding any repeal or replacement legislation on our business remains unclear. Federal budgetary concerns and the current 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 ACA. A key focus of the current presidential administration and Republican majorities in both houses of the U.S. Congress to “repeal and replace” all or portions of the ACA. Notably:

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- In 2012, the U.S. Supreme Court heard challenges to the constitutionality of the individual mandate and the viability of certain provisions of the ACA. The Supreme Court's decision upheld most of the ACA and determined that requiring individuals to maintain "minimum essential" health insurance coverage or pay a penalty to the Internal Revenue Service was within Congress's constitutional taxing authority. However, as a result of tax reform legislation passed in late December 2017, the individual mandate has been eliminated. The long ranging effects of the elimination of the individual mandate on the viability of the ACA are unknown at this time.
- On January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices.
- On October 13, 2017, President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

The extent, timing and details of the changes are not currently 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.

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, 18 year and lifetime storage options 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 annual storage services is determined based on vendor specific objective evidence as we have standalone renewals to support the selling price.

Valuation of Marketable Securities

We account for and classify our marketable securities as either “available-for-sale,” “held-to-maturity,” or “trading debt securities,” in accordance with the accounting guidance related to the accounting and classification of certain investments in marketable securities. The determination of the appropriate classification by us is based primarily on management’s ability and intent to sell the marketable security at the time of purchase. As of December 31, 2017 and 2016, all of our marketable securities were classified as available-for-sale.

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 marketable securities 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 marketable 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 analysis 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.

Business Combinations and Asset Acquisitions

The purchase price allocation for business combinations requires extensive use of accounting estimates and judgments to allocate the purchase price to the identifiable tangible and intangible assets acquired and liabilities assumed based on their respective fair values. We early adopted ASU No. 2017-01, “*Business Combinations (Topic 805): Clarifying the Definition of a Business*” (“ASU 2017-01”) as of January 1, 2017. Under ASU 2017-01, we first determine whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets. If this threshold is met, the single asset or group of assets, as applicable, is not a business.

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 may require 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.

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.

Goodwill

We test goodwill at the reporting unit level for impairment on an annual basis and between annual tests if events and circumstances indicate it is more likely than not that the fair value of a reporting unit is less than its carrying value. Events that could indicate impairment and trigger an interim impairment assessment include, but are not limited to, an adverse change in current economic and market conditions, including a significant prolonged decline in market capitalization, a significant adverse change in legal factors, unexpected adverse business conditions, and an adverse action or assessment by a regulator. Our annual impairment test date is October 31. We have determined that we operate in a single operating segment and have a single reporting unit.

In performing our goodwill impairment tests during 2017, we utilized the approach prescribed under ASC 350, as amended by ASU 2017-04, *Intangibles — Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*, which we adopted on January 1, 2017 (“ASU 2017-04”). ASU 2017-04 requires that an entity 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.

Prior to our adoption of ASU 2017-04, we utilized the two-step approach prescribed under ASC 350 in performing our goodwill impairment tests. The first step required a comparison of the reporting unit’s carrying value to its fair value. If the carrying value of a reporting unit exceeded its estimated fair value, a second step was required to measure the amount of impairment loss, if any. The second step of the goodwill impairment test compared the implied fair value of a reporting unit’s goodwill to its carrying value. The second step required us to perform a hypothetical purchase price allocation as of the measurement date and estimate the fair value of net tangible and intangible assets. The fair value of intangible assets is determined as described above and is subject to significant judgment. We conducted our 2016 and 2015 annual goodwill impairment tests using the market approach, as more fully described below, in making our impairment test conclusions.

When we perform any goodwill impairment test, the estimated fair value of our reporting unit is determined using an income approach that utilizes a discounted cash flow (“DCF”) model or, a market approach, when appropriate, which assesses our market capitalization as adjusted for a control premium, or a combination thereof. The DCF model is based upon expected future after-tax operating cash flows of the reporting unit discounted to a present value using a risk-adjusted discount rate. Estimates of future cash flows require management to make significant assumptions concerning (i) future operating performance, including future sales, long-term growth rates, operating margins, variations in the amount and timing of cash flows and the probability of achieving the estimated cash flows (ii) the probability of regulatory approvals, and (iii) future economic conditions, all of which may differ from actual future cash flows. These assumptions are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy. The discount rate, which is intended to reflect the risks inherent in future cash flow projections, used in the DCF model, is based on estimates of the weighted average cost of capital (“WACC”) of market participants relative to our reporting unit. Financial and credit market volatility can directly impact certain inputs and assumptions used to develop the WACC. Any changes in these assumptions may affect our fair value estimate and the result of an impairment test. We believe the discount rates and other inputs and assumptions are consistent with those that a market participant would use. In addition, in order to assess the reasonableness of the fair value of our reporting unit as calculated under the DCF model, we also compare the reporting unit’s fair value to our market capitalization and calculate an implied control premium (the excess sum of the reporting unit’s fair value over its market capitalization). We evaluate the implied control premium by comparing it to control premiums of recent comparable market transactions, as applicable. Throughout 2017 and as of December 31, 2017, our market capitalization has been lower than our stockholders’ equity, or book value. We believe that a market participant buyer would be required to pay a control premium for our business that would cover the difference between our market capitalization and our book value.

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Assumptions related to revenue, growth rates and operating margin are based on management's annual and ongoing forecasting, budgeting and planning processes and represent our best estimate of the future results of operations across the company as of that point in time. These estimates are subject to many assumptions, such as the economic environment in which our reporting unit operates, expectations of regulatory approval of our products in development or under review with the FDA, demand for our products and competitor actions. If we were to apply different assumptions, or if the outcome of regulatory or other developments, or actual demand for our products and competitor actions, are inconsistent with our assumptions, our estimated discounted future cash flows and the resulting estimated fair value of our reporting unit would increase or decrease, and could result in the fair value of our reporting unit being less than its carrying value in an impairment test.

Intangible Assets

We amortize our intangible assets that have finite lives based either the straight-line method, or if reliably determinable, based on the pattern in which the economic benefit of the asset is expected to be utilized. When facts and circumstances exist that may indicate that an intangible asset is potentially impaired, management compares the projected undiscounted future cash flows associated with the asset over its estimated useful life against the carrying amount. An impairment loss, if any, is measured as the excess of the carrying amount of the asset over its fair value.

If we acquire a business as defined under applicable accounting standards, then the acquired in-process research and development ("IPR&D") is capitalized as an intangible asset. If we acquire an asset or a group of assets that do not meet the definition of a business, then the acquired IPR&D is expensed on its acquisition date. Future costs to develop these assets are recorded to research and development expense as they are incurred.

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 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.

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 advisers 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

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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, such as total shareholder return, 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, where vesting is dependent on future services, 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

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, 2017, we maintained a valuation allowance on certain of our state NOL and credit carryforwards.

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.

On December 22, 2017, the Tax Cuts and Jobs Act (the “2017 Tax Act”), was enacted. The 2017 Tax Act includes significant changes to the U.S. corporate income tax system, including a reduction of the federal corporate income tax rate from 35% to 21%, effective January 1, 2018. The SEC staff issued Staff Accounting Bulletin No. 118 to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the 2017 Tax Act. We have recognized the provisional tax impacts related to the revaluation of deferred tax assets and liabilities and included these

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amounts in our consolidated financial statements for the year ended December 31, 2017. While we believe these estimates are reasonable, the ultimate impact may differ from these provisional amounts due to further review of the enacted legislation, changes in interpretations and assumptions we have made, and additional accounting and regulatory guidance that may be issued.

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 T, “*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 - 2017 as compared to 2016

Revenues

Total revenues for 2017 and 2016 consisted of the following (in thousands except for percentages):

	Years Ended December 31,		2017 to 2016	
	2017	2016	\$ Change	% Change
Product sales, net				
Makena	\$ 387,158	\$ 334,050	\$ 53,108	16 %
Feraheme	105,930	97,058	8,872	9 %
Intrarosa	1,816	—	1,816	N/A
MuGard	741	1,062	(321)	(30)%
Total	495,645	432,170	63,475	15 %
Service revenues, net	114,177	99,604	14,573	15 %
License fee, collaboration and other revenues	124	317	(193)	(61)%
Total revenues	\$ 609,946	\$ 532,091	\$ 77,855	15 %

Our total revenues for 2017 increased by \$77.9 million as compared to 2016, due primarily to increases in volume across substantially all of our products and our services.

The following table sets forth customers who represented 10% or more of our total revenues for 2017 and 2016:

	Years Ended December 31,	
	2017	2016
AmerisourceBergen Drug Corporation	21%	22%
McKesson Corporation	19%	11%

[Table of Contents](#)**Product Sales**

Total gross product sales were offset by product sales allowances and accruals for 2017 and 2016 as follows (in thousands except for percentages):

	Years Ended December 31,				2017 to 2016	
	2017	Percent of gross product sales	2016	Percent of gross product sales	\$ Change	% Change
Gross product sales	\$ 920,061		\$ 748,839		\$ 171,222	23%
Provision for product sales allowances and accruals:						
Contractual adjustments	310,588	34%	229,686	31%	80,902	35%
Governmental rebates	113,828	12%	86,983	12%	26,845	31%
Total provision for product sales allowances and accruals	424,416	46%	316,669	43%	107,747	34%
Product sales, net	<u>\$ 495,645</u>		<u>\$ 432,170</u>		<u>\$ 63,475</u>	15%

Gross product sales increased by \$171.2 million, or approximately 23%, during 2017 as compared to 2016 primarily due to increases of \$126.1 million and \$39.7 million of Makena and Feraheme gross sales, respectively. Of the \$126.1 million increase in gross Makena sales, \$112.7 million was due to increased volume and \$13.4 million was due to price increases. Of the \$39.7 million increase in gross Feraheme sales, \$27.7 million was due to price increases and \$12.1 million was due to increased volume. This total increase in gross product sales was partially offset by \$107.7 million of additional allowances and accruals in 2017 as compared to 2016. The increase in contractual adjustments as a percentage of gross product sales primarily related to a change in mix of business to commercial customers.

Net product sales increased by \$63.5 million, or approximately 15%, during 2017 as compared to 2016 primarily due to a \$53.1 million increase in net Makena sales and a \$8.9 million increase in net Feraheme sales.

We expect total product sales to decrease in 2018 due to expected generic erosion of the market for the Makena IM product. The degree of this decrease will be impacted by the timing, number and behavior of generic entrants. We expect sales of Intrarosa and the Makena auto-injector to contribute positive growth. We also expect Feraheme sales to increase in 2018, however the hurricane-related shortage of saline, which is used in the administration of Feraheme, will impact Feraheme volumes in early 2018.

Product Sales Allowances and Accruals

We recognize 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.

During 2017 and 2016, we refined 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 refinement resulted in a \$1.2 million increase and \$6.1 million decrease, respectively, of our estimated Medicaid rebate reserve related to prior period Makena sales. We may refine 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.

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An analysis of the amount of our product reserves for 2017 and 2016, is as follows (in thousands):

	Contractual Adjustments	Governmental Rebates	Total
Balance at January 1, 2016	\$ 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
Current provisions relating to sales in current year	314,537	112,167	426,704
Adjustments relating to sales in prior years	(3,949)	1,661	(2,288)
Payments/returns relating to sales in current year	(253,545)	(61,569)	(315,114)
Payments/returns relating to sales in prior years	(42,479)	(53,060)	(95,539)
Balance at December 31, 2017	\$ 62,164	\$ 50,598	\$ 112,762

During 2017 and 2016, we implemented gross price increases for Feraheme and Makena, 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 unit.

In 2018, 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

CBR Services include the collection, processing and storage of both umbilical cord blood and cord tissue. The \$14.6 million increase in service revenues recorded in 2017 as compared to 2016 was due to increased recurring revenue from new enrollments as well as a lower purchase accounting adjustment to the CBR deferred revenue balance in 2017 as compared to 2016. We expect service revenues to increase in 2018 due to increasing new enrollments of cord blood and cord tissue units in our storage facility, improved pricing strategies and recurring revenue from our growing base of stored units.

Costs and Expenses

Cost of Product Sales

Cost of product sales for 2017 and 2016 were as follows (in thousands except for percentages):

	Years Ended December 31,		2017 to 2016	
	2017	2016	\$ Change	% Change
Cost of product sales	\$ 161,349	\$ 96,314	\$ 65,035	68%
Percentage of net product sales	33%	22%		

Our cost of product sales are primarily comprised of manufacturing costs, costs of managing our contract manufacturers, costs for quality assurance and quality control associated with our 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 "Impairment of Intangible Assets." The \$65.0 million increase in our cost of product sales for 2017 as compared to 2016 was primarily attributable to a \$58.2 million net increase in amortization of the Makena base technology intangible asset due to the change in its estimated useful life in 2017 and the Intrarosa developed technology intangible asset, a \$6.6 million increase due to increased volume across substantially all of our products and our services, a \$3.0 million increase due to overhead costs and inventory write-offs, partially offset by a \$2.9 million decrease in amortization of the inventory step-up.

We expect our cost of product sales, as a percentage of net product sales, to increase in 2018 as compared to 2017 primarily due to increased amortization of the Makena base technology intangible asset. In addition, during 2018, we expect to

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pay royalty obligations for Intrarosa and the Makena auto-injector, which will contribute to the increase in cost of product sales as a percentage of net product sales.

Cost of Services

Cost of services for 2017 and 2016 were as follows (in thousands except for percentages):

	Years Ended December 31,		2017 to 2016	
	2017	2016	\$ Change	% Change
Cost of services	\$ 21,817	\$ 20,575	\$ 1,242	6%
Percentage of service revenues	19%	21%		

Cost of services includes the transportation of the umbilical cord blood stem cells and cord tissue from the hospital and direct material plus labor costs for processing, cryogenic storage and collection kit materials. We expect our cost of services as a percentage of service revenues to remain relatively constant in 2018 as compared to 2017.

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.

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.

Research and development expenses for 2017 and 2016 consisted of the following (in thousands except for percentages):

	Years Ended December 31,		2017 to 2016	
	2017	2016	\$ Change	% Change
External research and development expenses				
Bremelanotide-related costs	\$ 27,832	\$ —	\$ 27,832	N/A
Makena-related costs	12,971	19,113	(6,142)	(32)%
Feraheme-related costs	7,699	28,067	(20,368)	(73)%
Other external costs	6,393	3,252	3,141	97%
Intrarosa-related costs	1,058	—	1,058	N/A
Total	55,953	50,432	5,521	11%
Internal research and development expenses	19,064	15,652	3,412	22%
Total research and development expenses	\$ 75,017	\$ 66,084	\$ 8,933	14%

Total research and development expenses incurred in 2017 increased by \$8.9 million, or 14%, as compared to 2016. The increase was due primarily to \$27.8 million incurred in connection with our reimbursement of costs to Palatin associated with the development and regulatory activities for our bremelanotide NDA submission expected to be filed in the first quarter of 2018. This increase was partially offset by a \$6.1 million decrease related to costs incurred for the Makena auto-injector program and a \$20.4 million decrease in Feraheme-related spending as the result of the completion in 2016 of the Phase 3 clinical trial to expand the Feraheme label.

We have a number of ongoing research and development programs that we are conducting independently or in collaboration with third parties. We expect our research and development expenses to increase in 2018 as compared to 2017 due

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to the preparation of filing the NDA for bremelanotide and post approval commitments for Feraheme and Makena, including pediatric requirements for Feraheme and commitments required under the FDA's "Subpart H" accelerated approval regulations. Further, we expect to incur increased costs associated with manufacturing process development and the manufacture of drug product for bremelanotide to support its ultimate commercialization. We also expect to invest in studies that could potentially expand the labels for Intrarosa and bremelanotide. We cannot determine with certainty the duration and completion costs of our current or future clinical trials of our products or product candidates as the duration, costs and timing of clinical trials depends on a variety of factors including the uncertainties of future clinical and preclinical studies, uncertainties in clinical trial enrollment rates and significant and changing government regulation.

In-Process Research and Development

During 2017, we recorded acquired IPR&D expense of \$65.8 million related to the \$60.0 million one-time upfront payment for the bremelanotide license rights and \$5.8 million, which represented a portion of the \$83.5 million of consideration recorded to date under the terms of the Endoceutics License Agreement for indications that are under development. We did not record any IPR&D expenses during 2016.

In 2018, we expect to pay a \$20.0 million regulatory milestone payment to Palatin, which will be recorded as IPR&D costs, upon the FDA acceptance of the bremelanotide NDA, pursuant to the terms of the Palatin License Agreement.

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, 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 2017 and 2016 consisted of the following (in thousands except for percentages):

	Years Ended December 31,		2017 to 2016	
	2017	2016	\$ Change	% Change
Compensation, payroll taxes and benefits	\$ 130,996	\$ 78,295	\$ 52,701	67%
Professional, consulting and other outside services	141,743	114,813	26,930	23%
Fair value of contingent consideration liability	(47,686)	25,683	(73,369)	>(100 %)
Amortization expense related to customer relationship intangible	15,719	12,529	3,190	25%
Equity-based compensation expense	19,161	18,550	611	3%
Total selling, general and administrative expenses	<u>\$ 259,933</u>	<u>\$ 249,870</u>	<u>\$ 10,063</u>	4%

Total selling, general and administrative expenses, excluding the \$73.4 million decrease to the contingent consideration liability expense, described below, increased by \$83.4 million, or approximately 37%, as compared to the same period in 2016 due to the following:

- \$52.7 million increase in compensation, payroll taxes and benefits primarily due to increased personnel costs associated with the addition of our women's health commercial team and other organizational growth to support the July 2017 launch of Intrarosa;
- \$26.9 million increase in sales and marketing, consulting, professional fees, and other expenses primarily due to costs related to the July 2017 launch and commercialization of Intrarosa, increased costs associated with the expansion of our women's health sales force and litigation expense related to our ongoing Sandoz patent infringement litigation; and
- \$3.2 million increase in amortization expense related to CBR.

In addition, total selling, general and administrative expenses for 2017 reflects a \$73.4 million decrease driven by a \$47.7 million decrease to the fair value of contingent consideration liability expense in 2017 primarily due to a change in our estimated Makena revenues and associated milestone payments, as discussed in more detail in Note E "Fair Value Measurements" to our consolidated financial statements included in this Annual Report on Form 10-K.

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We expect that total selling, general and administrative expenses, excluding any impact from the Makena contingent consideration liability expense, will increase in 2018 as compared to 2017 due to a full year of expenses related to our Intrrosa commercial efforts, launch activities for the Feraheme expanded label and the Makena auto-injector and pre-launch activities for brexelanotide.

Impairment of Intangible Assets

During the third quarter of 2017, we received new information from a variety of sources, including from external consulting firms and our authorized generic partner, regarding the potential competitive landscape for the Makena IM product upon loss of orphan drug exclusivity in February 2018. The information received from one of our external consulting firms included competitive intelligence information, which indicated that several generic manufacturers had either likely filed an Abbreviated New Drug Application (“ANDA”) with the FDA in the third quarter of 2017 or were likely to file an ANDA in the fourth quarter of 2017. During the third quarter of 2017, we also began negotiations with our own authorized generic partner and gained industry insight into how the competitive landscape of the market might evolve once multiple generics entered. This information, combined with continued progress on our own authorized generic strategy, was incorporated into our revised long-range revenue forecasts for the Makena IM product during the third quarter of 2017. This new information received in the third quarter, altered our previous assumptions, including the potential number of generic entrants and potential timing of entry following the loss of its orphan drug exclusivity, which significantly impacted our long-term revenue forecast for the Makena IM product.

We determined that the revised long-term forecast, resulting from the information received in the third quarter of 2017, constituted a triggering event with respect to our Makena base technology intangible asset, which relates solely to the Makena IM product. We determined that as of September 30, 2017, the fair value of the Makena base technology intangible asset was less than the carrying value and accordingly, we recorded an impairment charge of \$319.2 million. No additional impairments of intangible assets were determined to be necessary during our annual impairment testing in the fourth quarter of 2017.

During the year ended December 31, 2016, we recognized an impairment loss on our intangible assets of \$19.7 million, primarily due to a \$15.7 million impairment charge for the MuGard Rights and a \$3.7 million impairment related to a portion of the CBR trade names and trademarks indefinite-lived intangible asset.

Other Income (Expense)

Other income (expense) for 2017 and 2016 consisted of the following (in thousands except for percentages):

	Years Ended December 31,		2017 to 2016	
	2017	2016	\$ Change	% Change
Interest expense	\$ (68,382)	\$ (73,153)	\$ 4,771	(7)%
Loss on debt extinguishment	(10,926)	—	(10,926)	N/A
Interest and dividend income	2,810	3,149	(339)	(11)%
Other (expense) income	(335)	189	(524)	>(100)%
Total other income (expense)	\$ (76,833)	\$ (69,815)	\$ (7,018)	10%

Other income (expense) for 2017 increased by \$7.0 million as compared to 2016 primarily as the result of the following:

- \$10.9 million loss on debt extinguishment in 2017 from the early repayment of the outstanding principal amount of the 2015 Term Loan Facility (as defined below) and the repurchase of a portion of the 2023 Senior Notes; and
- \$4.8 million decrease of interest expense as compared to 2016 primarily as the result of the repayment of the 2015 Term Loan Facility.

We expect our other income (expense) to decrease in 2018 as compared to 2017 as the loss on debt extinguishment during 2017 is not expected to reoccur.

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Income Tax (Benefit) Expense

The following table summarizes our effective tax rate and income tax (benefit) expense for 2017 and 2016 (in thousands except for percentages):

	Years Ended December 31,	
	2017	2016
Effective tax rate	46%	127%
Income tax (benefit) expense	\$ (170,866)	\$ 11,538

For 2017, we recognized an income tax benefit of \$170.9 million, representing an effective tax rate of 46%. The difference between the expected statutory federal tax rate of 35% and the 46% effective tax rate for 2017 was primarily attributable to the impact of federal tax reform, as discussed below, contingent consideration associated with Lumara Health, federal research and orphan drug tax credits generated during the year, and the impact of state income taxes, partially offset by equity-based compensation expenses and an increase to our valuation allowance.

On December 22, 2017, the 2017 Tax Act was enacted. The 2017 Tax Act includes significant changes to the U.S. corporate income tax system, including a reduction of the federal corporate income tax rate from 35% to 21%, effective January 1, 2018. As a result of the reduction in the federal tax rate, we revalued our ending net deferred tax liabilities at December 31, 2017 and recognized a provisional \$17.6 million tax benefit. See Note J, "Income Taxes," for additional information regarding the 2017 Tax Act.

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 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, partially offset by the benefit of the federal research and development and orphan drug tax credits generated during the year.

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
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.

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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 product sales were offset by product sales allowances and accruals for 2016 as compared to 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 product sales	\$ 748,839		\$ 561,255		\$ 187,584	33%
Provision for product sales allowances and accruals:						
Contractual adjustments	229,686	31%	161,665	29%	68,021	42%
Governmental rebates	86,983	12%	57,774	10%	29,209	51%
Total provision for product sales allowances and accruals	316,669	43%	219,439	39%	97,230	44%
Product sales, net	<u>\$ 432,170</u>		<u>\$ 341,816</u>		<u>\$ 90,354</u>	26%

Gross 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, respectively. 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. This total increase in gross product sales was partially offset by \$97.2 million of additional allowances and accruals in 2016 as compared to 2015.

Net 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.

Product Sales Allowances and Accruals

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.

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

	<u>Contractual Adjustments</u>	<u>Governmental Rebates</u>	<u>Total</u>
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	<u>\$ 30,177</u>	<u>\$ 25,767</u>	<u>\$ 55,944</u>
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	<u><u>\$ 47,600</u></u>	<u><u>\$ 51,399</u></u>	<u><u>\$ 98,999</u></u>

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.

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.

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.

Costs and Expenses

Cost of Product Sales

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

	<u>Years Ended December 31,</u>		<u>2016 to 2015</u>	
	<u>2016</u>	<u>2015</u>	<u>\$ Change</u>	<u>% Change</u>
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, 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 in inventory write-offs and \$3.5 million decrease in inventory step-up.

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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.

Research and Development Expenses

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.

Selling, General and Administrative Expenses

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 56%, as compared to 2015 for the following reasons:

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- \$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.

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.

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.

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	3,149	1,512	1,637	>100 %
Other income (expense)	189	(9,188)	9,377	>(100)%
Total other (expense) income	\$ (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:

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- \$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 contractual interest expense and amortization of debt issuance costs and debt discount 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 2015.

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, partially 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.

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 our products and sell the CBR Services, develop and seek U.S. regulatory approval for bremelanotide for the treatment of HSDD. 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.

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Cash, cash equivalents, investments and certain financial obligations as of December 31, 2017 and 2016 consisted of the following (in thousands except for percentages):

	December 31,		\$ Change	% Change
	2017	2016		
Cash and cash equivalents	\$ 192,114	\$ 274,305	\$ (82,191)	(30)%
Investments	136,593	304,781	(168,188)	(55)%
Total	\$ 328,707	\$ 579,086	\$ (250,379)	(43)%
Outstanding principal on 2023 Senior Notes	\$ 475,000	\$ 500,000	\$ (25,000)	(5)%
Outstanding principal on 2022 Convertible Notes	320,000	—	320,000	N/A
Outstanding principal on 2019 Convertible Notes	21,417	199,998	(178,581)	(89)%
Outstanding principal on 2015 Term Loan Facility	—	328,125	(328,125)	(100)%
Total	\$ 816,417	\$ 1,028,123	\$ (211,706)	(21)%

Cash Flows

The following table presents a summary of the primary sources and uses of cash for the years ended December 31, 2017, 2016 and 2015 (in thousands):

(In thousands, except percentages)	For the Years Ended December 31			2017 compared to 2016	2016 compared to 2015
	2017	2016	2015		
Net cash provided by operating activities	\$ 107,908	\$ 246,222	\$ 95,981	\$ (138,314)	\$ 150,241
Net cash provided by (used in) investing activities	\$ 102,920	\$ (72,704)	\$ (899,041)	\$ 175,624	\$ 826,337
Net cash (used in) provided by financing activities	\$ (293,019)	\$ (127,918)	\$ 912,469	\$ (165,101)	\$ (1,040,387)
Net (decrease) increase in cash and cash equivalents	\$ (82,191)	\$ 45,600	\$ 109,409	\$ (127,791)	\$ (63,809)

Operating Activities

Cash flows from operating activities represent the cash receipts and disbursements related to all of our activities other than investing and financing activities. We expect cash provided from operating activities will continue to be our primary source of funds to finance operating needs and capital expenditures. We have historically financed our operating and capital expenditures primarily through cash flows earned through our operations. We expect to continue funding our current and planned operating requirements principally through our cash flows from operations.

Operating cash flow is derived by adjusting our net income for:

- Non-cash operating items such as depreciation and amortization, impairment charges, acquired IPR&D and equity-based compensation;
- Changes in operating assets and liabilities which reflect timing differences between the receipt and payment of cash associated with transactions and when they are recognized in results of operations; and
- Changes associated with the fair value of contingent payments associated with our acquisitions of businesses.

For 2017 compared to 2016, net cash flows provided by operations decreased by \$138.3 million, driven primarily by a \$85.3 million decrease in net income as adjusted for non-cash charges and a \$53.0 million decrease due to changes in operating assets and liabilities.

For 2016 compared to 2015, net cash flows provided by operations increased by \$150.2 million driven primarily by a \$39.0 million increase in net income as adjusted for non-cash charges and a \$111.3 million increase due to changes in operating assets and liabilities.

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Investing Activities

Cash flows provided from investing activities was \$102.9 million in 2017. This increase was due to proceeds from sales of investments, net of purchases of \$167.7 million, offset by a payment for Intrarosa developed technology of \$55.8 million and capital expenditures of \$9.0 million. Cash used in investing activities in 2016 was \$72.7 million. This was due to purchases of investments, net of proceeds of \$67.2 million and \$5.5 million of capital expenditures.

For 2016 compared to 2015, the decrease in net cash flows used in investing activities of \$826.3 million was primarily due to the 2015 Acquisition of CBR of \$682.4 million and a net decrease in the purchase and sales of our investments of \$148.5 million.

Financing Activities

Cash used in financing activities was \$293.0 million in 2017. This use of cash was driven by the early retirement of \$328.1 million of our 2015 Term Loan (as defined below), the repurchase of a substantial portion of our 2019 Convertible Notes (as defined below) for \$191.7 million, and the repurchase of \$19.5 million of common stock, partially offset by the issuance of \$320.0 million 2022 Convertible Notes (as defined below). Cash used in financing activities in 2016 was \$127.9 million driven primarily by payments of contingent consideration of \$92.1 million, repurchase of common stock of \$20.0 million and principal debt payments of \$17.5 million.

For 2016 compared to 2015, the increase in cash used in financing activities of \$1.0 billion was primarily attributable to \$834.8 million of proceeds from long term debt offerings in 2015 and \$407.5 million in net proceeds from the aggregate issuance of common stock from our March 2015 and August 2015 public offerings, partially offset by \$92.1 million in contingent consideration payments made in 2016 to the former Lumara shareholders, \$20.0 million of cash paid in 2016 for the repurchase of shares under our share repurchase program and \$17.5 million of mandatory debt principal payments in 2016.

Future Liquidity Considerations

We expect that our cash, cash equivalents and investments balances will be positively impacted by operating profits in 2018. We expect cash generated by operating profits may be offset by the \$50.0 million milestone payment that we may pay in the first half of 2018 to the former Lumara Health security holders based on the achievement of a net sales milestone of Makena, a \$20 million milestone payment expected to be made to Palatin upon the acceptance by the FDA of our NDA for bremelanotide, a \$10.0 million milestone payment expected to be made to Endoceutics in April 2018 upon the first anniversary of the close of the Endoceutics license, interest to be paid and cash taxes, primarily state taxes due during year. We believe that our cash, cash equivalents and investments as of December 31, 2017, 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 the second quarter of 2017, we issued \$320.0 million aggregate principal amount of convertible senior notes due 2022 (the "2022 Convertible Notes"), as discussed in more detail in Note Q, "Debt," to our consolidated financial statements included in this Annual Report on Form 10-K and received net proceeds of \$310.4 million from the sale of the 2022 Convertible Notes, after deducting fees and expenses of \$9.6 million. The 2022 Convertible Notes are senior unsecured obligations and bear interest at a rate of 3.25% per year, payable semi-annually in arrears on June 1 and December 1 of each year, beginning on December 1, 2017. The 2022 Convertible Notes will mature on June 1, 2022, unless earlier repurchased or converted. Upon conversion of the 2022 Convertible Notes, such 2022 Convertible Notes will be convertible into, at our election, cash, shares of our common stock, or a combination thereof, at a conversion rate of 36.5464 shares of common stock per \$1,000 principal amount of the 2022 Convertible Notes, which corresponds to an initial conversion price of approximately \$27.36 per share of our common stock. The conversion rate is subject to adjustment from time to time. The 2022 Convertible Notes were not convertible as of December 31, 2017.

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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. On May 11, 2017, we repaid the remaining \$321.8 million of outstanding borrowings and accrued interest of, and terminated, the 2015 Term Loan Facility and recognized a \$9.7 million loss on debt extinguishment. In October 2017, we repurchased \$25.0 million principal of the 2023 Senior Notes in a privately negotiated transaction with cash on hand. For additional information, see Note Q, “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 “2019 Convertible Notes”). In May 2017 and September 2017, we entered into privately negotiated transactions with certain investors to repurchase approximately \$158.9 million and \$19.6 million, respectively, aggregate principal amount of the 2019 Convertible Notes for an aggregate repurchase price of approximately \$171.3 million and \$21.4 million, respectively, including accrued interest, as discussed in more detail in Note Q, “Debt,” to our consolidated financial statements included in this Annual Report on Form 10-K. The remaining 2019 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 2019 Convertible Notes will mature on February 15, 2019, unless repurchased or converted earlier. The 2019 Convertible Notes will be convertible into cash, shares of our common stock, or a combination thereof, at our election, at a conversion rate of 36.9079 shares of common stock per \$1,000 principal amount of the 2019 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. The 2019 Convertible Notes were not convertible as of December 31, 2017.

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 2017, we repurchased and retired 1,366,266 shares of common stock under this repurchase program for \$19.5 million, at an average purchase price of \$14.27 per share. 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.

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, debt obligations (including interest payments), and other purchase obligations. Future lease obligations and purchase commitments, as of December 31, 2017, 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	\$ 10,943	\$ 2,792	\$ 6,289	\$ 1,862	\$ —
Purchase commitments	16,476	16,476	—	—	—
2019 Convertible Notes	22,019	535	21,484	—	—
2022 Convertible Notes	366,800	10,400	20,800	335,600	—
2023 Senior Notes	690,087	37,406	74,813	74,813	503,055
Total	1,106,325	67,609	123,386	412,275	503,055

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

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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, the Landlord holds a security deposit in the form of an irrevocable letter of credit, which is classified on our balance sheet as a long-term asset and was \$0.7 million and \$0.6 million as of December 31, 2017 and 2016, respectively.

We lease certain real property located at 611 Gateway Boulevard, South San Francisco, California. The lease expires in July 2022.

Facility-related rent expense, net of deferred rent amortization, for all the leased properties was \$3.0 million, \$2.8 million, and \$1.5 million for 2017, 2016 and 2015, respectively.

Purchase Obligations

Purchase obligations primarily represent minimum purchase commitments for inventory. As of December 31, 2017, our minimum purchase commitments totaled \$16.5 million.

Contingent Consideration Related to Business Combinations

In connection with our acquisition of Lumara Health in November 2014, we agreed to pay up to \$350.0 million in milestone payments based on the achievement of certain sales thresholds. Due to the contingent nature of these milestone payments, we cannot predict the amount or timing of such payments with certainty. During 2017 and 2016, we paid \$50.0 million and \$100.0 million of these milestone payments, respectively. Subject to achieving specified sales thresholds, we expect to pay a \$50.0 million milestone payment in the first half of 2018.

As of December 31, 2017, 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. Velo began its Phase 2b/3a clinical study in the second quarter of 2017, and until we exercise our option, no contingencies related to this agreement have been recorded in our consolidated financial statements as of December 31, 2017.

Under the terms of the Endoceutics License Agreement, which we entered into with Endoceutics in February 2017, we have agreed to make a payment to Endoceutics of \$10.0 million in April 2018 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 the 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). 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.

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Under the terms of the Palatin License Agreement, which we entered into with Palatin in January 2017, we have agreed to make future contingent payments of (a) up to \$80.0 million upon achievement of certain regulatory milestones, including \$20.0 million upon the acceptance by the FDA of our NDA for bremelanotide and \$60.0 million upon FDA approval, and (b) up to \$300.0 million of aggregate sales milestone payments upon the achievement of certain annual net sales over the course of the license. The first sales milestone of \$25.0 million will be triggered when bremelanotide annual net sales exceed \$250.0 million. We are also obligated to pay Palatin tiered royalties on annual net sales of bremelanotide, on a product-by-product basis, in all countries of North America ranging from the high-single digits to the low double-digits.

In connection with the development and license agreement entered into with Antares Pharma, Inc. (“Antares”), 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 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. In addition, we are required to pay Antares sales milestone payments upon the achievement of certain annual net sales.

Other Commitments

Under the terms of the Endoceutics License Agreement, we have committed to an annual minimum marketing spend for Intrarosa and are also required to provide funding of approximately \$20.0 million for clinical studies being conducted by Endoceutics to support an application for U.S. regulatory approval of Intrarosa for the treatment of HSDD in post-menopausal women.

Employment 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 O, “*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 O, “*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, 2017, 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, 2017 and 2016, our investments equaled \$136.6 million and \$304.8 million, respectively, and were invested in corporate debt securities, U.S. treasury and government agency securities, commercial paper, and certificates of deposit. 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

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principal plus accrued interest. If market interest rates for comparable investments were to increase or decrease immediately and uniformly by 50 basis points, or one-half of a percentage point, from levels as of December 31, 2017 and 2016, this would have resulted in a hypothetical change in fair value of our investments of approximately \$0.7 million and \$1.4 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.

Equity Price Risk

Convertible Notes

On May 10, 2017, we issued \$320.0 million aggregate principal amount of the 2022 Convertible Notes. The 2022 Convertible Notes are senior unsecured obligations and bear interest at a rate of 3.25% per year, payable semi-annually in arrears on June 1 and December 1 of each year, beginning on December 1, 2017. The 2022 Convertible Notes will mature on June 1, 2022, unless earlier repurchased or converted. Upon conversion of the 2022 Convertible Notes, such 2022 Convertible Notes will be convertible into, at our election, cash, shares of our common stock, or a combination thereof, at a conversion rate of 36.5464 shares of common stock per \$1,000 principal amount of the 2022 Convertible Notes, which corresponds to an initial conversion price of approximately \$27.36 per share of our common stock. As of December 31, 2017, the fair value of the Convertible Notes was \$282.9 million.

On February 14, 2014, we issued \$200.0 million aggregate principal amount of 2019 Convertible Notes. The 2019 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. In May 2017 and September 2017, we entered into privately negotiated transactions with certain investors to repurchase approximately \$158.9 million and \$19.6 million, respectively, aggregate principal amount of the 2019 Convertible Notes. The remaining 2019 Convertible Notes will mature on February 15, 2019, unless repurchased or converted earlier. The 2019 Convertible Notes will be convertible into cash, shares of our common stock, or a combination thereof, at our election, 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, 2017, the fair value of the 2019 Convertible Notes was \$21.6 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.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA:

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MANAGEMENT'S ANNUAL REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Management is responsible for establishing and maintaining adequate internal control 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, 2017 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, 2017.

The effectiveness of our internal control over financial reporting as of December 31, 2017, 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 Stockholders of AMAG Pharmaceuticals, Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of AMAG Pharmaceuticals, Inc. and its subsidiaries as of December 31, 2017 and 2016, and the related consolidated statements of operations, comprehensive (loss) income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2017, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2017, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2017 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, 2017, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Change in Accounting Principle

As discussed in Note T to the consolidated financial statements, the Company changed the manner in which it accounts for and presents the income tax effects of share based payment transactions in 2017.

Basis for Opinions

The Company's management is responsible for these consolidated 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 the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. 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.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (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

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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 28, 2018

We have served as the Company's auditor since 1982.

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

	As of December 31,	
	2017	2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 192,114	\$ 274,305
Marketable securities	136,593	304,781
Accounts receivable, net	103,501	92,375
Inventories	37,356	37,258
Prepaid and other current assets	12,304	9,839
Total current assets	481,868	718,558
Property, plant and equipment, net	25,996	24,460
Goodwill	639,484	639,484
Intangible assets, net	704,470	1,092,178
Restricted cash	656	2,593
Other long-term assets	762	1,153
Total assets	\$ 1,853,236	\$ 2,478,426
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 10,335	\$ 3,684
Accrued expenses	175,490	156,008
Current portion of long-term debt	—	21,166
Current portion of acquisition-related contingent consideration	49,399	97,068
Deferred revenues	42,494	34,951
Total current liabilities	277,718	312,877
Long-term liabilities:		
Long-term debt, net	466,291	785,992
Convertible notes, net	268,392	179,363
Acquisition-related contingent consideration	686	50,927
Deferred tax liabilities	23,927	197,066
Deferred revenues	24,387	14,850
Other long-term liabilities	1,591	2,962
Total liabilities	1,062,992	1,544,037
Commitments and Contingencies (Note O)		
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; 34,083,112 and 34,336,147 shares issued and outstanding at December 31, 2017 and December 31, 2016, respectively	341	343
Additional paid-in capital	1,271,628	1,238,031
Accumulated other comprehensive loss	(3,908)	(3,838)
Accumulated deficit	(477,817)	(300,147)
Total stockholders' equity	790,244	934,389
Total liabilities and stockholders' equity	\$ 1,853,236	\$ 2,478,426

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,		
	2017	2016	2015
Revenues:			
Product sales, net	\$ 495,645	\$ 432,170	\$ 341,816
Service revenues, net	114,177	99,604	24,132
License fee, collaboration and other revenues	124	317	52,328
Total revenues	609,946	532,091	418,276
Costs and expenses:			
Cost of product sales (excluding impairment)	161,349	96,314	78,509
Cost of services	21,817	20,575	9,992
Research and development expenses	75,017	66,084	42,878
Acquired in-process research and development	65,845	—	—
Selling, general and administrative expenses	259,933	249,870	160,309
Impairment of intangible assets	319,246	19,663	—
Acquisition-related costs	—	—	11,232
Restructuring expenses	—	715	4,136
Total costs and expenses	903,207	453,221	307,056
Operating (loss) income	(293,261)	78,870	111,220
Other income (expense):			
Interest expense	(68,382)	(73,153)	(53,251)
Loss on debt extinguishment	(10,926)	—	(10,449)
Interest and dividend income	2,810	3,149	1,512
Other income (expense)	(335)	189	(9,188)
Total other income (expense)	(76,833)	(69,815)	(71,376)
(Loss) income before income taxes	(370,094)	9,055	39,844
Income tax (benefit) expense	(170,866)	11,538	7,065
Net (loss) income	\$ (199,228)	\$ (2,483)	\$ 32,779
Net (loss) income per share:			
Basic	\$ (5.71)	\$ (0.07)	\$ 1.04
Diluted	\$ (5.71)	\$ (0.07)	\$ 0.93
Weighted average shares outstanding used to compute net (loss) income per share:			
Basic	34,907	34,346	31,471
Diluted	34,907	34,346	35,308

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

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

	Years Ended December 31,		
	2017	2016	2015
Net (loss) income	\$ (199,228)	\$ (2,483)	\$ 32,779
Other comprehensive (loss) income			
Unrealized (losses) gains on marketable securities:			
Holding (losses) gains arising during period, net of tax	(70)	261	(4)
Reclassification adjustment for gains (losses) included in net (loss) income, net of tax	—	106	(584)
Net unrealized (losses) gains on securities	(70)	367	(588)
Total comprehensive (loss) income	<u>\$ (199,298)</u>	<u>\$ (2,116)</u>	<u>\$ 32,191</u>

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		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
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 losses 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
Settlement of warrants	—	—	323	—	—	323
Equity component of the 2022 Convertible Notes, net of issuance costs and taxes	—	—	43,236	—	—	43,236
Cumulative effect of previously unrecognized excess tax benefits related to stock compensation	—	—	—	—	21,558	21,558
Equity component of debt repurchase	—	—	(27,988)	—	—	(27,988)
Shares issued in connection with Endoceutics License Agreement	600,000	6	13,494	—	—	13,500
Repurchase and retirement of common stock pursuant to the 2016 Share Repurchase Program	(1,366,266)	(14)	(19,453)	—	—	(19,467)
Issuance of common stock under employee stock purchase plan	120,580	1	1,593	—	—	1,594
Net shares issued in connection with the exercise of stock options and vesting of restricted stock units, net of withholdings	392,651	5	(1,272)	—	—	(1,267)
Non-cash equity based compensation	—	—	23,664	—	—	23,664
Unrealized losses on securities, net of tax	—	—	—	(70)	—	(70)
Net loss	—	—	—	—	(199,228)	(199,228)
Balance at December 31, 2017	34,083,112	\$ 341	\$ 1,271,628	\$ (3,908)	\$ (477,817)	\$ 790,244

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

AMAG PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(IN THOUSANDS)

	Years Ended December 31,		
	2017	2016	2015
Cash flows from operating activities:			
Net (loss) income	\$ (199,228)	\$ (2,483)	\$ 32,779
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Depreciation and amortization	155,538	99,886	69,103
Impairment of intangible assets	319,246	19,663	—
Provision for bad debt expense	3,852	3,209	—
Amortization of premium/discount on purchased securities	302	624	2,152
Write-down of inventory to net realizable value	—	—	1,235
Gain (loss) on disposal of property and equipment	265	—	—
Non-cash equity-based compensation expense	23,664	22,543	17,237
Non-cash IPR&D expense	945	—	—
Non-cash loss on debt extinguishment	10,301	—	6,426
Amortization of debt discount and debt issuance costs	14,395	12,105	11,379
(Loss) gain on sale of investments, net	70	38	(14)
Change in fair value of contingent consideration	(47,686)	25,683	4,271
Deferred income taxes	(178,421)	7,279	5,007
Changes in operating assets and liabilities:			
Accounts receivable, net	(14,978)	(9,906)	(36,913)
Inventories	(2,331)	(2,355)	(5,237)
Receivable from collaboration	—	428	4,090
Prepaid and other current assets	(285)	4,095	4,034
Accounts payable and accrued expenses	16,834	49,037	7,876
Deferred revenues	17,080	24,522	(22,197)
Payment of contingent consideration in excess of acquisition date fair value	(10,432)	(8,116)	—
Repayment of term loan attributable to original issue discount	—	—	(12,491)
Other assets and liabilities	(1,223)	(30)	7,244
Net cash provided by operating activities	<u>107,908</u>	<u>246,222</u>	<u>95,981</u>
Cash flows from investing activities:			
Acquisition of Lumara Health, net of acquired cash	—	—	562
Acquisition of CBR, net	—	—	(682,356)
Proceeds from sales or maturities of investments	294,957	127,479	208,966
Purchase of investments	(127,249)	(194,723)	(424,759)
Acquisition of Intrarosa developed technology	(55,800)	—	—
Change in restricted cash	—	—	(195)
Capital expenditures	(8,988)	(5,460)	(1,259)
Net cash provided by (used in) investing activities	<u>102,920</u>	<u>(72,704)</u>	<u>(899,041)</u>

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

AMAG PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)
(IN THOUSANDS)

	Years Ended December 31,		
	2017	2016	2015
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	(353,125)	(17,502)	(327,509)
Proceeds from long-term debt	—	—	834,750
Proceeds from 2022 Convertible Notes issuance	320,000	—	—
Payments to repurchase 2019 Convertible Notes	(191,730)	—	—
Proceeds to settle warrants	323	—	—
Payment of convertible debt issuance costs	(9,553)	—	(10,004)
Payment of contingent consideration	(39,793)	(92,130)	(456)
Payment to former CBR shareholders	—	—	(7,195)
Payments for repurchases of common stock	(19,466)	(20,000)	—
Proceeds from the issuance and exercise of common stock options	3,021	3,885	15,406
Payments of employee tax withholding related to equity-based compensation	(2,696)	(2,171)	—
Net cash (used in) provided by financing activities	(293,019)	(127,918)	912,469
Net (decrease) increase in cash and cash equivalents	(82,191)	45,600	109,409
Cash and cash equivalents at beginning of the year	274,305	228,705	119,296
Cash and cash equivalents at end of the year	<u>\$ 192,114</u>	<u>\$ 274,305</u>	<u>\$ 228,705</u>
Supplemental data of cash flow information:			
Cash paid for taxes	\$ 5,296	\$ 5,309	\$ 2,373
Cash paid for interest	\$ 56,959	\$ 62,381	\$ 28,014
Non-cash investing activities:			
Fair value of common stock issued in connection with the acquisition of the Intrarosa intangible asset	\$ 12,555	\$ —	\$ —
Contingent consideration accrued for the acquisition of the Intrarosa intangible asset	\$ 9,300	\$ —	\$ —

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 maternal and women's health, anemia management and cancer supportive care, including Makena[®] (hydroxyprogesterone caproate injection), Intrarosa[®] (prasterone) vaginal inserts, Feraheme[®] (ferumoxytol injection) for intravenous ("IV") use, and MuGard[®] Mucoadhesive Oral Wound Rinse. In addition, in February 2017, we acquired the rights to research, develop and commercialize brexelanotide in North America. Through services related to the preservation of umbilical cord blood stem cell and cord tissue units 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 ability to successfully commercialize our products and services, intense competition, including from generic products; maintaining and defending the proprietary nature of our technology; our dependence upon third-party manufacturers and our potential inability to obtain raw or other materials; our reliance on and the extent of reimbursement from third parties for the use of our products, including the impact of generic competitors, Makena's high Medicaid reimbursement concentration and the limited level of reimbursement for Intrarosa; our ability to expand our product portfolio through business development transactions; the approval of brexelanotide and our ability to commercialize brexelanotide, if approved; employee retention and our ability to manage our expanded product portfolio and operations; potential litigation, including securities and product liability suits; our ability to work effectively and collaboratively with our licensors; our reliance on other third parties in our business, including to conduct our clinical trials and undertake our product and distribution; our ability to attract and retain key employees; if our storage facility in Tucson, Arizona is damaged or destroyed; our potential failure to comply with federal and state healthcare fraud and abuse laws, marketing disclosure laws, cord blood and tissue regulations and laws or other federal and state laws and regulations and potential civil or criminal penalties as a result thereof; uncertainties regarding reporting and payment obligations under government pricing programs; post-approval commitments for Makena; our ability to comply with data protection laws and regulations; the impact of disruptions to our information technology systems; our level of and ability to repay our indebtedness; our access to sufficient capital; the availability of net operating loss carryforwards and other tax assets; potential differences between actual future results and the estimates or assumptions used by us in preparation of our consolidated financial statements, including goodwill and intangible assets; the volatility of our stock price; the potential fluctuation of our operating results; and provisions in our charter, by-laws and certain contracts that discourage an acquisition of our company.

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 its August 17, 2015 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; marketable securities; 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, inclusive of valuation allowances, 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 marketable securities with a maturity of three months or less as of the acquisition date to be cash equivalents. At December 31, 2017 and 2016, substantially all of our cash and cash equivalents were held in either commercial bank accounts or money market funds.

Marketable Securities

We account for and classify our marketable securities as either “available-for-sale,” “held-to-maturity,” or “trading debt securities,” in accordance with the accounting guidance related to the accounting and classification of certain investments in marketable securities. The determination of the appropriate classification by us is based primarily on management’s ability and intent to sell the debt security at the time of purchase. As of December 31, 2017 and 2016, all of our marketable securities were classified as available-for-sale.

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 marketable securities 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 marketable 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 analysis 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.

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 U.S. Food and Drug Administration (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, our products have a shelf-life ranging from three to five years. As a result of comparison to internal sales forecasts, we expect to fully realize the carrying value of our 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, 2017 and 2016, we classified \$0.7 million and \$2.6 million of our cash as restricted cash, respectively. The December 31, 2016 balance included both \$2.0 million held in a restricted fund previously established by Lumara Health, Inc. (“Lumara Health”) in connection with its Chapter 11 plan of reorganization to pay potential claims against its former directors and officers, as well as a \$0.6 million security deposit delivered to the landlord of our Waltham, Massachusetts

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headquarters in the form of an irrevocable letter of credit. In December 2017, the \$2.0 million previously established by Lumara in connection with its Chapter 11 plan of reorganization was unrestricted and the funds were moved into operating cash.

Concentrations and Significant Customer Information

Financial instruments which potentially subject us to concentrations of credit risk consist principally of cash and cash equivalents, marketable securities, 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, 2017, 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, Feraheme, Mugard, Intrarosa, bremelanotide, and marketing and selling the CBR Services. 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 2017, 2016 and 2015:

	Years Ended December 31,		
	2017	2016	2015
AmerisourceBergen Drug Corporation	21%	22%	25%
McKesson Corporation	19%	11%	11%
Takeda Pharmaceuticals Company Limited	—%	—%	12%

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. All of the revenues generated during 2017 and 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 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. We did not experience any significant bad debts and have not established an allowance for doubtful accounts on our product sales at December 31, 2017 and 2016.

Customers which represented greater than 10% of our accounts receivable balance as of December 31, 2017 and 2016 were as follows:

	December 31,	
	2017	2016
AmerisourceBergen Drug Corporation	27%	13%
McKesson Corporation	22%	32%

We are currently dependent on a single supplier for Feraheme drug substance (produced in two separate facilities) and finished drug product as well as for drug substance and fill finish services for Intrarosa. 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.

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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 and Asset Acquisitions

The purchase price allocation for business combinations requires extensive use of accounting estimates and judgments to allocate the purchase price to the identifiable tangible and intangible assets acquired and liabilities assumed based on their respective fair values. We early adopted ASU No. 2017-01, “*Business Combinations (Topic 805): Clarifying the Definition of a Business* (“ASU 2017-01”) as of January 1, 2017. Under ASU 2017-01, we first determine whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets. If this threshold is met, the single asset or group of assets, as applicable, is not a business.

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 may require 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.

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

We test goodwill at the reporting unit level for impairment on an annual basis and between annual tests if events and

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circumstances indicate it is more likely than not that the fair value of a reporting unit is less than its carrying value. Events that could indicate impairment and trigger an interim impairment assessment include, but are not limited to, an adverse change in current economic and market conditions, including a significant prolonged decline in market capitalization, a significant adverse change in legal factors, unexpected adverse business conditions, and an adverse action or assessment by a regulator. Our annual impairment test date is October 31. We have determined that we operate in a single operating segment and have a single reporting unit.

In performing our goodwill impairment tests during 2017, we utilized the approach prescribed under the Accounting Standards Codification (“ASC”) 350, as amended by Accounting Standards Update (“ASU”) 2017-04, *Intangibles — Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*, which we adopted on January 1, 2017 (“ASU 2017-04”). ASU 2017-04 requires that an entity 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.

Prior to our adoption of ASU 2017-04, we utilized the two-step approach prescribed under ASC 350 in performing our goodwill impairment tests. The first step required a comparison of the reporting unit’s carrying value to its fair value. If the carrying value of a reporting unit exceeded its estimated fair value, a second step was required to measure the amount of impairment loss, if any. The second step of the goodwill impairment test compared the implied fair value of a reporting unit’s goodwill to its carrying value. The second step required us to perform a hypothetical purchase price allocation as of the measurement date and estimate the fair value of net tangible and intangible assets. The fair value of intangible assets is determined as described below and is subject to significant judgment.

Intangible Assets

We amortize our intangible assets that have finite lives based on either the straight-line method, or if reliably determinable, based on the pattern in which the economic benefit of the asset is expected to be utilized. 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.

If we acquire a business as defined under applicable accounting standards, then the acquired IPR&D is capitalized as an intangible asset. If we acquire an asset or a group of assets that do not meet the definition of a business, then the acquired IPR&D is expensed on its acquisition date. Future costs to develop these assets are recorded to research and development expense as they are incurred.

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 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.

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.

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;

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- 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.

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, Feraheme, and Intrarosa; (b) service revenues associated with the CBR Services; and (c) 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, 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 product sales, which primarily represented revenues from Makena and Feraheme for 2017, 2016 and 2015 were offset by provisions for allowances and accruals as follows (in thousands):

	Years Ended December 31,		
	2017	2016	2015
Gross product sales	\$ 920,061	\$ 748,839	\$ 561,255
Provision for product sales allowances and accruals:			
Contractual adjustments	310,588	229,686	161,665
Governmental rebates	113,828	86,983	57,774
Total provision for product sales allowances and accruals	424,416	316,669	219,439
Product sales, net	\$ 495,645	\$ 432,170	\$ 341,816

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

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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 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 our products have a range of three years to five years. 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.

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We expect that wholesalers and healthcare providers will not stock significant inventory due to the cost of the products, 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 2017, 2016, or 2015. To date, our product returns 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 2017 and 2016, we refined 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 refinement resulted in a \$1.2 million increase and a \$6.1 million reduction of our estimated Medicaid rebate reserve related to prior period Makena sales in 2017 and 2016, respectively. 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, 18 year and lifetime storage options 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 annual 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.

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 print media advertising space were \$22.7 million, \$16.4 million and \$8.0 million for the years ended December 31, 2017, 2016 and 2015, 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 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

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awards ultimately expected to vest, we must make certain judgments about whether employees, officers, directors, consultants and advisers 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, such as total shareholder return, 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 whose vesting is dependent on future service 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

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 business. As of December 31, 2017, we maintained a valuation allowance on certain of our state NOL and credit carryforwards.

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.

On December 22, 2017, the Tax Cuts and Jobs Act (the “2017 Tax Act”), was enacted. The 2017 Tax Act includes significant changes to the U.S. corporate income tax system, including a reduction of the federal corporate income tax rate from

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35% to 21%, effective January 1, 2018. The SEC staff issued Staff Accounting Bulletin No. 118 to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the 2017 Tax Act. We have recognized the provisional tax impacts related to the revaluation of deferred tax assets and liabilities and included these amounts in our consolidated financial statements for the year ended December 31, 2017. While we believe these estimates are reasonable, the ultimate impact may differ from these provisional amounts due to further review of the enacted legislation, changes in interpretations and assumptions we have made, and additional accounting and regulatory guidance that may be issued.

Comprehensive (Loss) Income

Our comprehensive (loss) income consists of net (loss) income and other comprehensive (loss) income. Other comprehensive (loss) income includes changes in equity that are excluded from net (loss) income, which for all periods presented in these consolidated financial statements related to unrealized holding gains and losses on available-for-sale marketable securities, net of tax.

Basic and Diluted Net (Loss) Income 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, diluted net income per common share would be computed assuming the impact of the conversion of the 2.5% convertible senior notes due in 2019 (the "2019 Convertible Notes") and the 3.25% convertible senior notes due in 2022 (the "2022 Convertible Notes"), the exercise of outstanding stock options, the vesting of RSUs, and the exercise of warrants.

We have a choice to settle the conversion obligation of our 2022 Convertible Notes and the 2019 Convertible Notes (together, the "Convertible Notes") in cash, shares or any combination of the two. Prior to May 2017, and pursuant to certain covenants in our six-year \$350.0 million term loan facility (the "2015 Term Loan Facility"), which was repaid in full in May 2017, we were restricted from settling the conversion obligation in whole or in part with cash unless certain conditions in the 2015 Term Loan Facility were satisfied. Prior to the repayment of the 2015 Term Loan Facility, we utilized the if-converted method to reflect the impact of the conversion of the Convertible Notes. Our current policy is to settle the principal balance of the Convertible Notes in cash. As such, subsequent to the repayment of the 2015 Term Loan Facility, we apply the treasury stock method to these securities and the dilution related to the conversion premium, if any, of the Convertible Notes is included in the calculation of diluted weighted-average shares outstanding to the extent each issuance is dilutive based on the average stock price during each reporting period being greater than the conversion price of the respective Convertible Notes.

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 2017, 2016 and 2015 were as follows (in thousands, except per share data):

	Years Ended December 31,		
	2017	2016	2015
Net (loss) income	\$ (199,228)	\$ (2,483)	\$ 32,779
Weighted average common shares outstanding	34,907	34,346	31,471
Effect of dilutive securities:			
Warrants	—	—	2,466
Stock options and RSUs	—	—	1,371
Shares used in calculating dilutive net (loss) income per share	34,907	34,346	35,308
Net (loss) income per share:			
Basic	\$ (5.71)	\$ (0.07)	\$ 1.04
Diluted	\$ (5.71)	\$ (0.07)	\$ 0.93

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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 (loss) income per share because their inclusion would have been anti-dilutive (in thousands):

	Years Ended December 31,		
	2017	2016	2015
Options to purchase shares of common stock	3,531	2,590	1,619
Shares of common stock issuable upon the vesting of RSUs	1,070	613	167
Warrants	1,008	7,382	—
2022 Convertible Notes	11,695	—	—
2019 Convertible Notes	790	7,382	7,382
Total	18,094	17,967	9,168

In connection with the issuance of the 2019 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 remaining 2019 Convertible Notes. During 2017 and 2015, the average common stock price was below the exercise price of the warrants and during 2016, the average common stock price was above the exercise price of the warrants.

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.

C. BUSINESS COMBINATIONS

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 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

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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, Net,*” for additional information.

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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.

Unaudited Pro Forma Supplemental Information

The following supplemental unaudited pro forma information presents our revenue and net income on a pro forma combined basis, including CBR, assuming that the CBR acquisition occurred on January 1, 2015. 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. The pro forma amount does not include any then expected cost savings or restructuring action which might have been achievable or might have occurred subsequent to the acquisition CBR, or the impact of any non-recurring activity. The following table presents the unaudited pro forma consolidated result (in thousands):

	Year Ended December 31, 2015
Pro forma revenues	490,451
Pro forma net income	28,217

The pro forma adjustments reflected in the pro forma net income 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 net income 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 were adjusted accordingly. This pro forma financial information is not necessarily indicative of our consolidated operating results that would have been reported had the transaction 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. The goodwill resulting from the CBR acquisition is not deductible for income tax purposes.

D. MARKETABLE SECURITIES

As of December 31, 2017 and 2016, our marketable securities 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 marketable securities.

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The following is a summary of our marketable securities as of December 31, 2017 and 2016 (in thousands):

Description of Securities:	December 31, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term investments:*				
Corporate debt securities	\$ 57,257	\$ —	\$ (68)	\$ 57,189
U.S. treasury and government agency securities	1,999	—	(13)	1,986
Commercial paper	1,999	—	—	1,999
Certificates of deposit	9,151	—	—	9,151
Total short-term investments	70,406	—	(81)	70,325
Long-term investments:**				
Corporate debt securities	59,282	1	(320)	58,963
U.S. treasury and government agency securities	7,381	—	(76)	7,305
Total long-term investments	66,663	1	(396)	66,268
Total investments	\$ 137,069	\$ 1	\$ (477)	\$ 136,593

Description of Securities:	December 31, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term investments:*				
Corporate debt securities	\$ 106,430	\$ 3	\$ (69)	\$ 106,364
U.S. treasury and government agency securities	1,021	—	—	1,021
Commercial paper	40,560	—	—	40,560
Certificates of deposit	6,000	—	—	6,000
Total short-term investments	154,011	3	(69)	153,945
Long-term investments:**				
Corporate debt securities	139,742	32	(281)	139,493
U.S. treasury and government agency securities	11,395	—	(52)	11,343
Total long-term investments	151,137	32	(333)	150,836
Total investments	\$ 305,148	\$ 35	\$ (402)	\$ 304,781

* Represents marketable securities with a remaining maturity of less than one year.

** Represents marketable securities with a remaining maturity of one to three years.

Impairments and Unrealized Gains and Losses on Marketable Securities

We did not recognize any other-than-temporary impairment losses in our consolidated statements of operations related to our marketable securities during 2017, 2016 and 2015. We considered various factors, including the length of time that each security was in a realized loss position and our ability and intent to hold these securities until recovery of their amortized cost basis occurs. As of December 31, 2017, we have no material losses 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 marketable securities could have a material adverse effect on our earnings in future periods.

E. FAIR VALUE MEASUREMENTS

We apply the provisions of Accounting Standards Codification Topic 820, *Fair Value Measurements* (“ASC 820”) for our financial assets and liabilities that are re-measured and reported at fair value each reporting period and our nonfinancial assets and liabilities that are re-measured and reported at fair value on a non-recurring basis. Fair value is the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining fair value, we consider the principal or most advantageous market in which it would transact and consider assumptions that market participants would use when pricing the asset or liability. ASC 820 establishes a three-level valuation hierarchy for disclosure of fair value measurements. Financial assets and liabilities are categorized within the valuation hierarchy based upon the lowest level of input that is significant to the measurement of fair value. The three levels of the hierarchy are defined as follows:

- Level 1—Inputs to the valuation methodology are quoted market prices for identical assets or liabilities.
- Level 2—Inputs to the valuation methodology are other observable inputs, including quoted market prices for similar assets or liabilities and market-corroborated inputs.
- Level 3—Inputs to the valuation methodology are unobservable inputs based on management’s best estimate of inputs market participants would use in pricing the asset or liability at the measurement date, including assumptions about risk.

The following tables represent the fair value hierarchy as of December 31, 2017 and 2016, for those assets and liabilities that we measure at fair value on a recurring basis (in thousands):

	Fair Value Measurements at December 31, 2017 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	\$ 4,591	\$ 4,591	\$ —	\$ —
Corporate debt securities	116,152	—	116,152	—
U.S. treasury and government agency securities	9,291	—	9,291	—
Commercial paper	1,999	—	1,999	—
Certificates of deposit	9,151	—	9,151	—
Total Assets	\$ 141,184	\$ 4,591	\$ 136,593	\$ —
Liabilities:				
Contingent consideration - Lumara Health	\$ 49,187	\$ —	\$ —	\$ 49,187
Contingent consideration - MuGard	898	—	—	898
Total Liabilities	\$ 50,085	\$ —	\$ —	\$ 50,085

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

Marketable securities

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 marketable securities 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 analysis of prices received from third parties to determine whether prices are reasonable estimates of fair value. After completing our analysis, we did not adjust or override any fair value measurements provided by our pricing services as of December 31, 2017 or 2016. In addition, there were no transfers or reclassifications of any securities between Level 1 and Level 2 during 2017 or 2016.

Contingent consideration

In accordance with GAAP, for asset acquisitions, such as Intrarosa, we record contingent consideration for obligations we consider to be probable and estimable and these liabilities are not adjusted to fair value. As of December 31, 2017, \$10.0 million of contingent consideration was recorded in accrued expenses and is required to be paid to Endoceutics, Inc. (“Endoceutics”) in April 2018 on the first anniversary of the closing of a license agreement we entered into with Endoceutics (the “Endoceutics License Agreement”). We recorded contingent consideration related to the November 2014 acquisition of Lumara Health 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.

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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, 2016	\$ 222,559
Payments made	(100,246)
Adjustments to fair value of contingent consideration	25,682
Balance as of December 31, 2016	\$ 147,995
Payments made	(50,224)
Adjustments to fair value of contingent consideration	(47,686)
Balance as of December 31, 2017	<u>\$ 50,085</u>

During 2017, we adjusted the fair value of our contingent consideration liability by approximately \$47.7 million, primarily due to a decrease to the Makena contingent consideration based on a revision of our long-term forecast of total projected net Makena sales, which impacted both the amount and timing of future milestone payments. In addition, during 2017 we paid a \$50.0 million sales milestone to the former stockholders of Lumara Health and a \$0.2 million royalty payment for MuGard. We have classified \$49.2 million of the Makena contingent consideration and \$0.2 million of the MuGard contingent consideration as short-term liabilities in our consolidated balance sheet as of December 31, 2017.

The \$25.7 million adjustment to the fair value of the contingent consideration liability in 2016 was 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. In addition, during 2016 we made a \$100.0 million sales milestone payment to the former stockholders of Lumara Health.

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, 2017, the total undiscounted milestone payment amounts we could pay in connection with the Lumara Health acquisition was \$200.0 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 14% as of December 31, 2017. In addition, as of December 31, 2017, 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, 2017, the estimated fair value of our 2023 Senior Notes (as defined below), the 2022 Convertible Notes and the 2019 Convertible Notes was \$463.7 million, \$282.9 million and \$21.6 million, respectively, which differed from their carrying values. See Note Q, "Debt," for additional information on our debt obligations.

F. INVENTORIES

Our major classes of inventories were as follows as of December 31, 2017 and 2016 (in thousands):

	December 31,	
	2017	2016
Raw materials	\$ 12,418	\$ 14,382
Work in process	4,146	3,924
Finished goods	20,792	18,952
Total inventories	<u>\$ 37,356</u>	<u>\$ 37,258</u>

G. PROPERTY, PLANT AND EQUIPMENT, NET

Property, plant and equipment, net consisted of the following as of December 31, 2017 and 2016 (in thousands):

	December 31,	
	2017	2016
Land	\$ 700	\$ 700
Land improvements	300	300
Building and improvements	9,552	9,500
Computer equipment and software	14,073	13,866
Furniture and fixtures	2,512	2,401
Leasehold improvements	4,959	3,718
Laboratory and production equipment	8,030	6,449
Construction in progress	5,360	1,619
	<u>45,486</u>	<u>38,553</u>
Less: accumulated depreciation	(19,490)	(14,093)
Property, plant and equipment, net	<u>\$ 25,996</u>	<u>\$ 24,460</u>

During 2017, 2016 and 2015, depreciation expense was \$7.2 million, \$9.2 million, and \$3.9 million, respectively.

H. GOODWILL AND INTANGIBLE ASSETS, NET

Goodwill

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

Balance at January 1, 2016	\$ 639,188
Measurement period adjustments related to Lumara Health acquisition	296
Balance as of December 31, 2017 and 2016	<u>639,484</u>

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. As of December 31, 2017, we had no accumulated impairment losses related to goodwill.

We test goodwill at the reporting unit level for impairment on an annual basis and between annual tests if events and circumstances indicate it is more likely than not that the fair value of a reporting unit is less than its carrying value. Events that could indicate impairment and trigger an interim impairment assessment include, but are not limited to, an adverse change in current economic and market conditions, including a significant prolonged decline in market capitalization, a significant adverse change in legal factors, unexpected adverse business conditions, and an adverse action or assessment by a regulator. Our annual impairment test date is October 31. We have determined that we operate in a single operating segment and have a single reporting unit.

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In performing our goodwill impairment tests during 2017, we utilized the approach prescribed under ASC 350, as amended by ASU 2017-04 which requires that an entity 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.

When we perform any goodwill impairment test, the estimated fair value of our reporting unit is determined using an income approach that utilizes a discounted cash flow ("DCF") model or, a market approach, when appropriate, which assesses our market capitalization as adjusted for a control premium, or a combination thereof. The DCF model is based upon expected future after-tax operating cash flows of the reporting unit discounted to a present value using a risk-adjusted discount rate. Estimates of future cash flows require management to make significant assumptions concerning (i) future operating performance, including future sales, long-term growth rates, operating margins, variations in the amount and timing of cash flows and the probability of achieving the estimated cash flows (ii) the probability of regulatory approvals, and (iii) future economic conditions, all of which may differ from actual future cash flows. These assumptions are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy. The discount rate, which is intended to reflect the risks inherent in future cash flow projections, used in the DCF model, is based on estimates of the weighted average cost of capital ("WACC") of market participants relative to our reporting unit. Financial and credit market volatility can directly impact certain inputs and assumptions used to develop the WACC. Any changes in these assumptions may affect our fair value estimate and the result of an impairment test. We believe the discount rates and other inputs and assumptions are consistent with those that a market participant would use. In addition, in order to assess the reasonableness of the fair value of our reporting unit as calculated under the DCF model, we also compare the reporting unit's fair value to our market capitalization and calculate an implied control premium (the excess sum of the reporting unit's fair value over its market capitalization). We evaluate the implied control premium by comparing it to control premiums of recent comparable market transactions, as applicable. Throughout 2017 and as of December 31, 2017, our market capitalization was lower than our stockholders' equity, or book value. We believe that a market participant buyer would be required to pay a control premium for our business that would cover the difference between our market capitalization and our book value.

During the third quarter of 2017, we determined that the significant reduction in the long-term forecasted cash flows of our largest product, Makena, which led to a \$319.2 million impairment of the Makena base technology intangible asset, was an indicator that an interim impairment test of goodwill was necessary at September 30, 2017. We performed a quantitative goodwill impairment test at September 30, 2017 in accordance with ASU 2017-04, to both assess whether a goodwill impairment existed and if so, the amount of the impairment loss. We considered our market capitalization, as adjusted for a control premium, to be one indicator of the fair value of our reporting unit. On September 30, 2017, our stock price closed at \$18.45, resulting in a market capitalization of approximately \$653.0 million, which was 18% below the carrying amount of the reporting unit as of September 30, 2017.

As described in the accounting guidance for evaluating long-lived assets for impairment, an entity's fair value may include a control premium in addition to the quoted market price to determine the fair value of a single reporting unit entity, as an acquiring entity is often willing to pay more for equity securities that give it a controlling interest than an investor would pay for a number of equity securities representing less than a controlling interest. This accounting guidance also indicates that the quoted market price of an individual security need not be the sole measurement basis of the fair value of a single reporting unit. During the third quarter of 2017, we obtained a control premium analysis which benchmarked average control premiums paid in prior merger and acquisition transactions among biotechnology and pharmaceutical companies. The analysis indicated that control premiums vary depending on facts and circumstances for each transaction. The range of control premiums observed was between 30% and 83%, with a mean of 64%. Management believes that using this market approach of assessing reasonable control premiums provided a sufficient basis to assess whether the fair value of our reporting unit, including a range of reasonable control premiums, was above its carrying amount as of September 30, 2017. Incorporating control premiums in this range to our September 30, 2017 market capitalization of \$653.0 million resulted in a fair value which was at least 6% greater (at the low end of the range) than the carrying amount of our net assets as of September 30, 2017. As a result of this review, we determined that there was no impairment of our goodwill at September 30, 2017.

On October 31, 2017 (the "measurement date"), we conducted our 2017 annual goodwill impairment test using an income approach, specifically a DCF model, and a market approach to estimate the fair value of our reporting unit as of the measurement date. We used a range of discount rates between 10.0% and 19.5% across our commercial products and product candidates, which resulted in a weighted average discount rate of 13.6% to determine the fair value of our reporting unit. We believe the discount rate and other inputs and assumptions are consistent with those that a market participant would use. In addition, we believe we utilized reasonable estimates and assumptions about future revenues, cost projections, and cash flows as of the measurement date. As a corroborating step in our 2017 annual impairment assessment, we compared our implied control premium, as determined by the difference between the fair value of our reporting unit as estimated by our DCF analysis and our market capitalization, to control premiums of recent comparable market transactions. The results indicated that the implied control premium was within the range of control premiums observed in prior merger and acquisition transactions

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among biotechnology and pharmaceutical companies. We believe that using this market approach further corroborated our DCF fair value assessment at October 31, 2017. As a result of our DCF analysis, we determined that the fair value of our reporting unit exceeded its carrying value by 18% and as such, no impairment was recorded as of October 31, 2017. In performing a sensitivity analysis, had we increased the weighted average discount rate by 1%, the fair value of the reporting unit would have still exceeded the carrying value. In addition, we determined that there were no other indicators of impairment through December 31, 2017 requiring further assessment.

Assumptions related to revenue, growth rates and operating margin are based on management’s annual and ongoing forecasting, budgeting and planning processes and represent our best estimate of the future results of operations across the company as of that point in time. These estimates are subject to many assumptions, such as the economic environment in which our reporting unit operates, expectations of regulatory approval of our products in development or under review with the FDA, demand for our products and competitor actions. If we were to apply different assumptions, or if the outcome of regulatory or other developments, or actual demand for our products and competitor actions, are inconsistent with our assumptions, our estimated discounted future cash flows and the resulting estimated fair value of our reporting unit would increase or decrease, and could result in the fair value of our reporting unit being less than its carrying value in an impairment test.

Prior to our adoption of ASU 2017-04, we utilized the two-step approach prescribed under ASC 350 in performing our goodwill impairment tests. The first step required a comparison of the reporting unit’s carrying value to its fair value. If the carrying value of a reporting unit exceeded its estimated fair value, a second step was required to measure the amount of impairment loss, if any. The second step of the goodwill impairment test compared the implied fair value of a reporting unit’s goodwill to its carrying value. The second step required us to perform a hypothetical purchase price allocation as of the measurement date and estimate the fair value of net tangible and intangible assets. The fair value of intangible assets is determined as described above and is subject to significant judgment. We conducted our 2016 and 2015 annual goodwill impairment tests on October 31 of each respective year. We used the market approach, as more fully described above, in making our impairment test conclusions. As a result of our analysis, our reporting unit had a fair value well in excess of its carrying value for both 2016 and 2015, and as such, no impairments were recorded in either of the respective periods.

Intangible Assets

	December 31, 2017				December 31, 2016			
	Cost	Accumulated		Net	Cost	Accumulated		Net
		Amortization	Impairments			Amortization	Impairments	
Amortizable intangible assets:								
Makena base technology	\$ 797,100	\$ 255,754	\$ 319,246	\$ 222,100	\$ 797,100	\$ 128,732	\$ —	\$ 668,368
CBR customer relationships	297,000	29,309	—	267,691	297,000	13,590	—	283,410
Intrarosa developed technology	77,655	3,376	—	74,279	—	—	—	—
CBR Favorable lease	—	—	—	—	358	119	239	—
MuGard Rights	—	—	—	—	16,893	1,169	15,724	—
	<u>1,171,755</u>	<u>288,439</u>	<u>319,246</u>	<u>564,070</u>	<u>1,111,351</u>	<u>143,610</u>	<u>15,963</u>	<u>951,778</u>
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	—	3,700	61,300
Total intangible assets	<u>\$ 1,315,855</u>	<u>\$ 288,439</u>	<u>\$ 322,946</u>	<u>\$ 704,470</u>	<u>\$ 1,255,451</u>	<u>\$ 143,610</u>	<u>\$ 19,663</u>	<u>\$ 1,092,178</u>

The Makena base technology and IPR&D intangible assets were acquired in November 2014 in connection with our acquisition of Lumara Health. During the third quarter of 2017, we received new information from a variety of sources, including from external consulting firms and our authorized generic partner, regarding the potential competitive landscape for the Makena intramuscular (“IM”) product (the “Makena IM product”) upon loss of orphan drug exclusivity in February 2018. The information received from one of our external consulting firms included competitive intelligence information, which indicated that several generic manufacturers had either likely filed an Abbreviated New Drug Application (“ANDA”) with the FDA in the third quarter of 2017 or were likely to file an ANDA in the fourth quarter of 2017. During the third quarter of 2017, we also began negotiations with our own authorized generic partner and gained industry insight into how the competitive landscape of the market might evolve once multiple generics entered. This information, combined with continued progress on our own authorized generic strategy, was incorporated into our revised long-range revenue forecasts for the Makena IM product during the third quarter of 2017. This new information received in the third quarter, altered our previous

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assumptions, including the potential number of generic entrants and potential timing of entry following the loss of its orphan drug exclusivity, which significantly impacted our long-term revenue forecast for the Makena IM product.

We determined that the revised long-term forecast resulting from the information received in the third quarter of 2017 constituted a triggering event with respect to our Makena base technology intangible asset, which relates solely to the Makena IM product. We estimated that the sum of the undiscounted projected cash flows of the Makena IM product was less than the carrying value of the corresponding intangible asset. Therefore, we reassessed the fair value of the Makena base technology intangible asset using an income approach, a Level 3 measurement technique. We determined that as of September 30, 2017, the fair value of the Makena base technology intangible asset was less than the carrying value and accordingly, we recorded an impairment charge of \$319.2 million, which was recorded within a separate operating expense line item in our consolidated statements of operations.

Amortization of the Makena base technology asset is being recognized using an economic consumption model. Prior to the third quarter of 2017, this asset was being amortized over 20 years from the acquisition date, which we believed was an appropriate amortization period. During the third quarter of 2017, we reassessed the remaining useful life of the Makena base technology intangible asset. Based on the revised long-term forecast for the Makena IM product, we believe that the substantive period of revenue from the Makena IM asset will be through 2024 and thus concluded that seven years is an appropriate amortization period based on its revised estimated remaining economic life. Accordingly, we prospectively adjusted the remaining useful life of the Makena base technology intangible asset to seven years.

Further, during the third and fourth quarters of 2017, we evaluated our Makena IPR&D intangible asset, which is related to the Makena auto-injector, for impairment and concluded that its fair value was greater than its carrying value, and therefore it was not impaired. Furthermore, additional information may become available, which may cause us to identify additional impairment charges. Such charges could have a material adverse effect on our earnings in future periods.

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 CBR 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. In May 4, 2016, we entered into a sublease arrangement for a portion of our former 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. As part of our 2017 annual impairment test, we evaluated our CBR trade name and trademark intangible assets and concluded that its fair value was greater than its carrying value and therefore it was not impaired. As part of our 2016 annual impairment test, we recorded an impairment charge of \$3.7 million 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 Intrarosa developed technology was acquired in April 2017 from Endoceutics. Amortization of the Intrarosa developed technology is being recognized on a straight line basis over 11.5 years.

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 payers 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.

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As of December 31, 2017, the weighted average remaining amortization period for our finite-lived intangible assets was approximately 10.8 years. Total amortization expense for 2017, 2016 and 2015, was \$146.1 million, \$84.9 million and \$53.5 million, respectively. Amortization expense for the Makena base technology, Intrarosa developed technology, and the MuGard Rights is recorded in cost of product sales in our consolidated statements of operations. Amortization expense for the CBR related intangible assets 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, 2018	\$ 188,574
Year Ending December 31, 2019	39,527
Year Ending December 31, 2020	31,907
Year Ending December 31, 2021	31,696
Year Ending December 31, 2022	31,640
Thereafter	240,726
Total	<u>\$ 564,070</u>

I. CURRENT AND LONG-TERM LIABILITIES

Accrued Expenses

Accrued expenses consisted of the following as of December 31, 2017 and 2016 (in thousands):

	December 31,	
	2017	2016
Commercial rebates, fees and returns	\$ 102,357	\$ 89,466
Professional, license, and other fees and expenses	28,692	24,248
Salaries, bonuses, and other compensation	19,099	14,823
Interest expense	13,525	16,683
Intrarosa-related license fees	10,000	—
Accrued research and development	1,817	10,714
Restructuring expense	—	74
Total accrued expenses	<u>\$ 175,490</u>	<u>\$ 156,008</u>

Deferred Revenues

Our deferred revenue balances as of December 31, 2017 and 2016 of \$66.9 million and \$49.8 million respectively, 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.

J. INCOME TAXES

For the years ended December 31, 2017, 2016, and 2015, all of our profit or loss before income taxes was from U.S. operations. The income tax (benefit) expense consisted of the following (in thousands):

	Years Ended December 31,		
	2017	2016	2015
Current:			
Federal	\$ 2,180	\$ —	\$ —
State	5,375	4,259	2,058
Total current	\$ 7,555	\$ 4,259	\$ 2,058
Deferred:			
Federal	\$ (167,667)	\$ 9,815	\$ 9,819
State	(10,754)	(2,536)	(4,812)
Total deferred	\$ (178,421)	\$ 7,279	\$ 5,007
Total income tax (benefit) expense	\$ (170,866)	\$ 11,538	\$ 7,065

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

	Years Ended December 31,		
	2017	2016	2015
Statutory U.S. federal tax rate	35.0 %	35.0 %	35.0 %
State taxes, net of federal benefit	3.4	6.4	0.1
Impact of 2017 tax reform on deferred tax balance	4.8	—	—
Equity-based compensation expense	(1.0)	34.0	0.4
Contingent consideration	4.5	69.9	4.7
Transaction costs	—	—	3.9
Other permanent items, net	(0.6)	21.2	3.2
Tax credits	0.7	(32.3)	(1.7)
Write-down of acquired state net operating losses	—	114.2	—
Valuation allowance	(0.8)	(115.2)	(28.0)
Other, net	0.2	(5.8)	0.1
Effective tax rate	46.2 %	127.4 %	17.7 %

For the year ended December 31, 2017, we recognized an income tax benefit of \$170.9 million, representing an effective tax rate of 46.2%. The difference between the expected statutory federal tax rate of 35.0% and the effective tax rate of 46.2% for the year ended December 31, 2017, was primarily attributable to the impact of the 2017 federal tax reform legislation, as discussed below, contingent consideration associated with Lumara Health, federal research and orphan drug tax credits generated during the year, and the impact of state income taxes, partially offset by equity-based compensation expenses and an increase to our valuation allowance.

On December 22, 2017, the Tax Cuts and Jobs Act (the “2017 Tax Act”), was enacted. The 2017 Tax Act includes significant changes to the U.S. corporate income tax system, including a reduction of the federal corporate income tax rate from 35.0% to 21.0%, effective January 1, 2018. 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. As a result of the reduction in the federal tax rate from 35.0% to 21.0%, we revalued our ending net deferred tax liabilities at December 31, 2017 and recognized a provisional \$17.6 million tax benefit. We are still assessing the implications of the 2017 Tax Act on both a federal and state level, as further discussed below.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 (“SAB 118”) to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the 2017 Tax Act. SAB 118 allows us to record provisional amounts during a measurement period which is similar to the measurement period used when accounting for business combinations. We have recognized the provisional tax impacts related to the revaluation of deferred tax

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assets and liabilities and included these amounts in our consolidated financial statements for the year ended December 31, 2017. While we believe these estimates are reasonable, the ultimate impact may differ from these provisional amounts due to further review of the enacted legislation, changes in interpretations and assumptions we have made, and additional accounting and regulatory guidance that may be issued.

For the year ended December 31, 2016, we recognized 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 127.4% 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, partially 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 statutory tax rate and the effective tax rate was primarily attributable to 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.

See Note C, “*Business Combinations*,” for more information on the CBR acquisition.

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. The components of our deferred tax assets and liabilities were as follows (in thousands):

	December 31,	
	2017	2016
Assets		
Net operating loss carryforwards	\$ 61,070	\$ 116,275
Tax credit carryforwards	15,892	9,415
Deferred revenue	3,420	1,811
Equity-based compensation expense	6,401	8,045
Capitalized research & development	7,872	18,284
Reserves	4,273	8,018
Contingent consideration	1,406	4,140
Other	6,777	9,769
Valuation allowance	(5,597)	(1,429)
Liabilities		
Property, plant and equipment depreciation	(1,501)	(2,145)
Intangible assets and inventory	(107,906)	(367,667)
Debt instruments	(15,744)	(1,040)
Other	(290)	(542)
Net deferred tax liabilities	<u>\$ (23,927)</u>	<u>\$ (197,066)</u>

The valuation allowance increased by approximately \$4.2 million for the year ended December 31, 2017, which was primarily attributable to the establishment of a valuation allowance on certain state NOL and credit carryforwards. During the year ended December 31, 2017, we entered into a three-year cumulative loss position and established a valuation allowance on certain deferred tax assets to the extent that our existing taxable temporary differences would not be available as a source of income to realize the benefits of those deferred tax assets. At December 31, 2017, the valuation allowance related primarily to certain of our state NOL and credit carryforwards.

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At December 31, 2017, we had federal and state NOL carryforwards of approximately \$265.8 million and \$90.9 million, respectively, of which \$165.5 million and \$16.6 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, 2017 were \$10.9 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. The federal and state NOLs expire at various dates through 2037. We have federal tax credits of approximately \$14.8 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 \$1.4 million to offset future tax liabilities. These federal and state tax credits will expire periodically through 2037 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, 2017 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 NOLs and tax credits acquired from Lumara health are subject to restrictions under Section 382. These restricted NOLs 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, 2017 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. A reconciliation of our changes in unrecognized tax benefits is as follows (in thousands):

	Years Ended December 31,		
	2017	2016	2015
Unrecognized tax benefits at the beginning of the year	\$ 13,330	\$ 12,695	\$ —
Additions based on tax positions related to the current year	574	300	12,695
Additions for tax positions from prior years	340	379	—
Subtractions for federal tax reform	(3,296)	—	—
Subtractions for tax positions from prior years	(78)	(44)	—
Unrecognized tax benefits at the end of the year	\$ 10,870	\$ 13,330	\$ 12,695

Included in the balance of unrecognized tax benefits as of December 31, 2017, 2016, and 2015 are \$10.7 million, \$13.0 million, and \$12.4 million, respectively, of unrecognized tax benefits that would impact the effective tax rate if recognized.

Our unrecognized tax benefits as of December 31, 2017 decreased by \$2.5 million as compared to December 31, 2016 primarily due to the change in the federal tax rate, which reduced the future value of our federal NOLs and the corresponding value of the unrecognized tax benefits related to those NOLs. This decrease was partially offset by tax reserves established on R&D tax credits.

Our unrecognized tax benefits as of December 31, 2016 increased by \$0.6 million as compared to December 31, 2015 primarily due 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. Our unrecognized tax benefits as of December 31, 2015 were attributable to the results of those studies, which identified uncertain tax positions 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.

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We have recorded minimal interest or penalties on unrecognized tax benefits since inception. We recognize both accrued interest and penalties related to unrecognized tax benefits in income tax expense. We do not expect our unrecognized 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, 2014, although carryforward attributes that were generated prior to tax year 2014 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 LOSS

The table below presents information about the effects of net income (loss) of significant amounts reclassified out of accumulated other comprehensive loss, net of tax, associated with unrealized gains on securities during 2017 and 2016 (in thousands):

	December 31,	
	2017	2016
Beginning balance	\$ (3,838)	\$ (4,205)
Other comprehensive (loss) income before reclassifications	(70)	261
Reclassification adjustment for gains included in net loss	—	106
Ending balance	<u>\$ (3,908)</u>	<u>\$ (3,838)</u>

L. EQUITY-BASED COMPENSATION

We currently maintain three equity compensation plans, namely our Fourth Amended and Restated 2007 Equity Incentive Plan, as amended (the “2007 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. During the fourth quarter of 2017, the then outstanding awards under our Amended and Restated 2000 Stock Plan (the “2000 Plan”) expired.

Our 2007 Plan was originally approved by our stockholders in November 2007, and succeeded our 2000 Plan, which has expired and 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 were included in the number of shares that were issued under the 2007 Plan. In addition, any shares subject to outstanding awards granted under the 2000 Plan that expired or terminated for any reason prior to exercise were added to the total number of shares of our stock available for issuance under the 2007 Plan. In May 2017, our stockholders approved an amendment to our 2007 Plan to, among other things, increase the number of shares available for issuance thereunder by 2,485,000 shares. The total number of shares available for issuance under the 2007 Plan was 9,494,365 as of December 31, 2017 and there were 2,715,012 shares remaining available for issuance under the 2007 Plan. As of December 31, 2017, all outstanding options under the 2007 Plan as of December 31, 2017 have either a seven or 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, 2017, there were 21,108 shares remaining available for issuance under the Lumara Health 2013 Plan, which are available for grants to certain employees, officers, directors, consultants, and advisers 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 provide 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

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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, 2017, 199,904 shares have been issued under our 2015 ESPP.

During 2017, we also granted equity through inducement grants outside of our equity compensation 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 2017:

	2007 Equity Plan	2000 Equity Plan	2013 Lumara Equity Plan	Inducement Grants	Total
Outstanding at December 31, 2016	2,158,822	5,200	134,181	814,975	3,113,178
Granted	1,044,817	—	10,075	91,100	1,145,992
Exercised	(92,529)	—	—	—	(92,529)
Expired or terminated	(520,737)	(5,200)	(18,720)	(90,625)	(635,282)
Outstanding at December 31, 2017	2,590,373	—	125,536	815,450	3,531,359

Restricted Stock Units

The following table summarizes RSU activity during 2017:

	2007 Equity Plan	2000 Equity Plan	2013 Lumara Equity Plan	Inducement Grants	Total
Outstanding at December 31, 2016	773,804	—	27,694	135,456	936,954
Granted	797,027	—	—	24,300	821,327
Vested	(361,548)	—	(13,330)	(56,312)	(431,190)
Expired or terminated	(242,660)	—	(2,753)	(11,903)	(257,316)
Outstanding at December 31, 2017	966,623	—	11,611	91,541	1,069,775

In February 2017, we granted RSUs under our 2007 Plan to certain members of our senior management covering a maximum of 191,250 shares of common stock. These performance-based RSUs will vest, if at all, on February 22, 2020, based on our total shareholder return ("TSR") performance measured against the median TSR of a defined group of companies over a three-year period. As of December 31, 2017, the maximum shares of common stock that may be issued under these awards is 162,750. The maximum aggregate total fair value of these RSUs is \$3.2 million, which is being recognized as expense over a period of three years from the date of grant, net of any estimated and actual forfeitures.

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Equity-based compensation expense

Equity-based compensation expense for 2017, 2016 and 2015 consisted of the following (in thousands):

	Years Ended December 31,		
	2017	2016	2015
Cost of product sales and services	\$ 1,278	\$ 520	\$ 371
Research and development	3,225	3,476	2,992
Selling, general and administrative	19,161	18,547	13,874
Total equity-based compensation expense	\$ 23,664	\$ 22,543	\$ 17,237
Income tax effect	(6,884)	(6,232)	(4,885)
After-tax effect of equity-based compensation expense	\$ 16,780	\$ 16,311	\$ 12,352

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.

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,					
	2017		2016		2015	
	Employees	Non-Employee Directors	Employees	Non-Employee Directors	Employees	Non-Employee Directors
Risk free interest rate (%)	1.86	1.61	1.32	1.10	1.55	1.24
Expected volatility (%)	53	57	49	54	47	46
Expected option term (years)	5.0	4.0	5.0	3.0	5.0	4.0
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 2017, 2016 and 2015, 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, 2017:

	December 31, 2017			
	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (\$ in thousands)
Outstanding at beginning of year	3,113,178	\$ 31.97	—	\$ —
Granted	1,145,992	20.11	—	—
Exercised	(92,529)	15.39	—	—
Expired and/or forfeited	(635,282)	33.56	—	—
Outstanding at end of year	3,531,359	\$ 28.27	7.2	\$ 55
Outstanding at end of year - vested and unvested expected to vest	3,267,530	\$ 28.37	7.1	\$ 55
Exercisable at end of year	1,871,179	\$ 29.33	5.8	\$ 55

The weighted average grant date fair value of stock options granted during 2017, 2016 and 2015 was \$9.52, \$10.63 and \$23.57, respectively. A total of 699,701 stock options vested during 2017. The aggregate intrinsic value of options exercised during 2017, 2016 and 2015, excluding purchases made pursuant to our 2015 ESPP, measured as of the exercise date, was

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approximately \$0.4 million, \$1.5 million and \$31.2 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, 2017:

	December 31, 2017	
	Restricted Stock Units	Weighted Average Grant Date Fair Value
Outstanding at beginning of year	936,954	\$ 28.78
Granted	821,327	24.18
Vested	(431,190)	28.45
Forfeited	(257,316)	25.95
Outstanding at end of year	1,069,775	\$ 26.07
Outstanding at end of year and expected to vest	886,876	\$ 26.19

The weighted average grant date fair value of RSUs granted during 2017, 2016 and 2015 was \$24.18, \$22.28 and \$52.71, respectively. The total fair value of RSUs that vested during 2017, 2016 and 2015 was \$12.3 million, \$9.1 million and \$3.5 million, respectively.

At December 31, 2017, the amount of unrecorded equity-based compensation expense for both option and RSU awards, attributable to future periods was approximately \$34.3 million. Of this amount, \$17.0 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 2.4 years, \$14.9 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 1.7 years, and \$2.4 million was associated with performance-based RSUs and is expected to be amortized on a straight-line basis to expense over a weighted average period of approximately 2.1 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. As of December 31, 2017 our 401(k) Plan provided, among other things, for a company contribution of 3% of each employee's combined salary and certain other compensation for the plan year. Effective January 1, 2018, the company contribution increased to 4%. 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 \$2.9 million, \$2.2 million and \$1.7 million for 2017, 2016 and 2015, respectively.

N. STOCKHOLDERS' EQUITY

Preferred Stock and our 2017 NOL Rights Agreement

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. Following the expiration of our prior rights agreement and in an effort to protect stockholder value by continuing to help preserve our substantial tax assets associated with NOLs and certain other deferred tax assets, our Board entered into a new shareholder rights plan with American Stock Transfer & Trust Company, LLC, as Rights Agent, in April 2017 (which was approved by our stockholders at our May 2017 annual meeting of stockholders and which is essentially a restatement of the prior rights agreement, but with an expiration date of April 6, 2018, subject to earlier expiration as described below) (the "2017 NOL Rights Agreement").

Our business operations have generated significant NOLs, and we may generate additional NOLs in future years. Under federal tax laws, we generally can use our NOLs and certain related tax credits to offset ordinary income tax paid in our prior two tax years or on our future taxable income for up to 20 years, when they "expire" for such purposes. Until they expire, we

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can “carry forward” NOLs and certain related tax credits that we do not use in any particular year to offset taxable income in future years. Our ability to utilize our NOLs to offset future taxable income may be significantly limited if we experience an “ownership change,” as determined under Section 382 of the Internal Revenue Code of 1986, as amended (“Section 382”). Under Section 382, an “ownership change” occurs if a stockholder or a group of stockholders that is deemed to own at least 5% of our outstanding stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a rolling three-year period. If an ownership change occurs, Section 382 would impose an annual limit on the amount of our NOLs that we can use to offset taxable income equal to the product of the total value of our outstanding equity immediately prior to the ownership change (reduced by certain items specified in Section 382) and the federal long-term tax-exempt interest rate in effect for the month of the ownership change. The 2017 NOL Rights Agreement is intended to act as a deterrent to any person or group acquiring 4.99% or more of our outstanding common stock without the prior approval of our Board.

Under the 2017 NOL Rights Agreement, stockholders of record as of April 17, 2017 (the “Record Date”) were issued one preferred share purchase right (a “Right”) for each outstanding share of common stock, par value \$0.01 per share (the “Common Shares”), outstanding as of the Record Date. The Rights will also attach to new Common Shares issued after the Record Date. Each Right entitles the registered holder to purchase from us one one-thousandth of a share of our Series A Junior Participating Preferred Stock, par value \$0.01 per share (the “Preferred Shares”) at a price of \$80 per one one-thousandth of a Preferred Share (the “Purchase Price”), subject to adjustment. Each Preferred Share is designed to be the economic equivalent of 1,000 Common Shares.

The Rights will separate from the common stock and become exercisable on the earlier of (a) the tenth day after a public announcement that a person or group of affiliated or associated persons, has become an “Acquiring Person” (as such term is defined in the 2017 NOL Rights Agreement) or (b) ten business days (or such later date as the Board may determine) following the commencement of, or announcement of an intention to make, a tender offer or exchange offer which would result in the beneficial ownership by an Acquiring Person of 4.99% (or, in the case of a Grandfathered Person, the Grandfathered Percentage applicable to such Grandfathered Person (as such terms are defined in the 2017 NOL Rights Agreement)) or more of the outstanding Common Shares (the earlier of such dates being called the “Distribution Date”).

In the event that we are acquired in a merger or other business combination transaction or 50% or more of our consolidated assets or earning power are sold to an Acquiring Person, its affiliates or associates or certain other persons in which such persons have an interest, proper provision will be made so that each such holder of a Right will thereafter have the right to receive, upon the exercise thereof at the then current exercise price of the Right, that number of shares of common stock of the acquiring company which at the time of such transaction will have a market value of two times the exercise price of the Right.

The Rights will expire on the earliest of the close of business on (1) April 6, 2018, (2) the effective date of the repeal of Section 382 or any successor statute if the Board determines that the 2017 NOL Rights Agreement is no longer necessary or desirable for the preservation of tax benefits or (3) the first day of a taxable year of the Company to which the Board determines that no tax benefits may be carried forward (the “Final Expiration Date”), unless the Final Expiration Date is extended or unless the Rights are earlier redeemed or exchanged by us.

The terms of the Rights generally may be amended by the Board without the consent of the holders of the Rights, except that from and after the time that the Rights are no longer redeemable, no such amendment may adversely affect the interests of the holders of the Rights (excluding the interests of any Acquiring Person and any group of affiliated or associated persons).

There can be no assurance that the 2017 NOL Rights Agreement will result in us being able to preserve all or any of the substantial tax assets associated with NOLs and other tax benefits.

Share Repurchase Program

In January 2016, we announced that our Board 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 2017, we repurchased and retired 1,366,266 shares of common stock under this repurchase program for \$19.5 million, at an average purchase price of \$14.27 per share. 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. As of December 31, 2017, \$20.5 million remains available for the repurchase of shares under the program.

O. 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, 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, the Landlord hold a security deposit of \$0.7 million and \$0.6 million in the form of an irrevocable letter of credit which is classified on our balance sheet as a long-term asset as of December 31, 2017 and 2016, respectively.

We lease certain real property located at 611 Gateway Boulevard, South San Francisco, California. The lease expires in July 2022.

Facility-related rent expense, net of deferred rent amortization, for all the leased properties was \$3.0 million, \$2.8 million, and \$1.5 million for 2017, 2016 and 2015, respectively.

Future minimum payments under our non-cancelable facility-related leases as of December 31, 2017 are as follows (in thousands):

Period	Future Minimum Lease Payments
Year Ending December 31, 2018	\$ 2,792
Year Ending December 31, 2019	3,100
Year Ending December 31, 2020	3,189
Year Ending December 31, 2021	1,488
Year Ending December 31, 2022	374
Total	<u>\$ 10,943</u>

Purchase Obligations

Purchase obligations primarily represent minimum purchase commitments for inventory. As of December 31, 2017, our minimum purchase commitments totaled \$16.5 million.

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 through December 31, 2019, of which, \$50.0 million and \$100.0 million were paid in 2017 and 2016, respectively, 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 any future payments with certainty.

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Contingent Regulatory and Commercial Milestone Payments

In connection with the Endoceutics License Agreement, we are required to pay Endoceutics \$10.0 million in April 2018 on the first anniversary of the closing. In addition, we are required to pay Endoceutics 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 of Intrarosa exceed \$300.0 million. If annual net U.S. sales of Intrarosa exceed \$500.0 million, there are additional sales milestone payments totaling up to \$850.0 million, which would be triggered at various sales thresholds. We are also obligated 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 \$1.0 billion 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) 10 years after the first commercial sale of Intrarosa for the treatment of vulvar and vaginal atrophy (“VVA”) or female sexual dysfunction (“FSD”) in the U.S. (as applicable), (b) for generic competition and (c) for third-party payments, subject to an aggregate cap on such deductions of royalties otherwise payable to Endoceutics.

In connection with the license agreement we entered into with Palatin Technologies, Inc. (“Palatin”) in January 2017 (the “Palatin License Agreement”), we are required to pay Palatin up to \$380.0 million in regulatory and commercial milestone payments including up to \$80.0 million upon achievement of certain regulatory milestones, including \$20.0 million upon the acceptance by the FDA of our New Drug Application (“NDA”) for bremelanotide and \$60.0 million upon FDA approval, and up to \$300.0 million of aggregate sales milestone payments upon the achievement of certain annual net sales over the course of the license. We are also obligated to pay Palatin tiered royalties on annual net sales of the Bremelanotide Products (as defined below), on a product-by-product basis, in the Palatin Territory, as defined below, ranging from the high-single digits to the low double-digits.

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 P, “*Collaboration, License and Other Strategic Agreements*,” for more information on the Velo option. Velo began its Phase 2b/3a clinical study in the second quarter of 2017, and until we exercise our option, no contingencies related to this agreement have been recorded in our consolidated financial statements as of December 31, 2017.

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. Antares is also entitled to sales-based milestone payments.

Employment 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 and our policy provides significant coverage. As a result, we believe the estimated fair value of these indemnification obligations is likely to be immaterial.

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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 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. If the litigation is resolved in favor of the applicant or the challenged patent expires during the 30 month stay period, the stay is lifted and the FDA may thereafter approve the application based on the applicable standards for approval. By the filing of this complaint, we believe the 30 month stay was triggered and that Sandoz is prohibited from marketing its ferumoxytol product, even if it receives conditional approval from the FDA until the earliest of (a) August 5, 2018 (30 months from the date we received Sandoz’s notice of certification), (b) the conclusion of litigation in Sandoz’s favor, or (c) expiration of the patent(s). On May 2, 2016, Sandoz filed a response to our patent infringement suit and the trial is scheduled for March 19, 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. 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 providing a brief overview of the DQSA for context, which we believe was helpful, including: (a) how the statute outlined that large-scale compounding of products that are copies or near-copies of

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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. We believe we have fully cooperated with the FTC and we have had no further interactions with the FTC on this matter since we provided our response to the FTC in August 2015.

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, 2017.

P. 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-stage development assets. As of December 31, 2017, we were a party to the following collaborations:

Endoceutics

In February 2017, we entered into the Endoceutics License Agreement with Endoceutics. Pursuant to the Endoceutics License Agreement, Endoceutics granted 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 combinations with other active pharmaceutical ingredients, in the U.S. for the treatment of VVA and FSD. The transactions contemplated by the Endoceutics License Agreement closed on April 3, 2017. We accounted for the Endoceutics License Agreement as an asset acquisition under ASU No. 2017-01, described in Note T, *Recently Issued and Proposed Accounting Pronouncements*.

Upon the closing of the Endoceutics License Agreement, we made an upfront payment of \$50.0 million and issued 600,000 shares of unregistered common stock to Endoceutics, which had a value of \$13.5 million, as measured on April 3, 2017, the date of closing. Of these 600,000 shares, 300,000 were subject to a 180-day lock-up provision, and the other 300,000 are subject to a one-year lock-up provision. In addition, we paid Endoceutics \$10.0 million in the third quarter of 2017 upon the delivery by Endoceutics of Intrarosa launch quantities and have agreed to make a payment of \$10.0 million in April 2018 on the first anniversary of the closing. The anniversary payment is reflected in accrued expenses at December 31, 2017. In the second quarter of 2017, we recorded a total of \$83.5 million of consideration paid, of which \$77.7 million was allocated to the Intrarosa developed technology intangible asset and \$5.8 million was recorded as IPR&D expense based on their relative fair values.

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 U.S. sales up to \$150.0 million to mid twenty percent for any calendar year net sales that exceed \$1.0 billion 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) 10 years after the first commercial sale of Intrarosa for the treatment of VVA or FSD in the U.S. (as applicable), (b) for generic competition and (c) for third-party payments, subject to an aggregate cap on such deductions of royalties otherwise payable to Endoceutics. Endoceutics is also

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eligible to receive certain sales milestone payments, including a first sales milestone payment of \$15.0 million, which would be triggered when annual net U.S. sales of Intrarosa exceed \$150.0 million, and a second milestone payment of \$30.0 million, which would be triggered when annual net U.S. sales of Intrarosa exceed \$300.0 million. If annual net U.S. sales of Intrarosa exceed \$500.0 million, there are additional sales milestone payments totaling up to \$850.0 million, which would be triggered at various sales thresholds.

In the third quarter of 2017, Endoceutics initiated a clinical study to support an application for U.S. regulatory approval for Intrarosa for the treatment of hypoactive sexual desire disorder (“HSDD”) in post-menopausal women. 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 have the exclusive right to commercialize Intrarosa for the treatment of VVA and 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 and, if approved, FSD in the U.S. Endoceutics has the right to directly conduct additional commercialization activities for Intrarosa for the treatment of VVA and FSD in the U.S. and has the right to conduct activities related generally to the field of intracrinology, in each case, subject to our review and approval and our right to withhold approval in certain instances. Each party’s commercialization activities and budget are described in a commercialization plan, which is updated annually.

In April 2017, we entered into an exclusive commercial supply agreement with Endoceutics pursuant to which Endoceutics, itself or through affiliates or contract manufacturers, agreed to manufacture and supply Intrarosa to us (the “Endoceutics Supply Agreement”) and will 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 Endoceutics Supply Agreement). Under the Endoceutics Supply Agreement, Endoceutics has agreed to maintain at all times a second source supplier for the manufacture of DHEA and the drug product and to identify, validate and transfer manufacturing intellectual property to the second source supplier by April 2019. The Endoceutics 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.

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.

Palatin

In January 2017, we entered into the Palatin License Agreement with Palatin under which we acquired (a) an exclusive license in all countries of North America (the “Palatin Territory”), with the right to grant sub-licenses, to research, develop and commercialize bremelanotide and any other products containing bremelanotide (collectively, the “Bremelanotide Products”), an investigational product designed to be a treatment for HSDD in pre-menopausal women, (b) a worldwide non-exclusive license, with the right to grant sub-licenses, to manufacture the Bremelanotide Products, and (c) a non-exclusive license in all countries outside the Palatin Territory, with the right to grant sub-licenses, to research and develop (but not commercialize) the Bremelanotide Products. Following the satisfaction of the conditions to closing under the Palatin License Agreement, the transaction closed in February 2017. We accounted for the Palatin License Agreement as an asset acquisition under ASU No. 2017-01.

Under the terms of the Palatin License Agreement, in February 2017 we paid Palatin \$60.0 million as a one-time upfront payment and subject to agreed-upon deductions reimbursed Palatin approximately \$25.0 million for reasonable, documented, out-of-pocket expenses incurred by Palatin in connection with the development and regulatory activities necessary to submit an NDA in the U.S. for bremelanotide for the treatment of HSDD in pre-menopausal women. As of December 31, 2017, we have fulfilled these payment obligations to Palatin. The \$60.0 million upfront payment made in February 2017 to Palatin was recorded as IPR&D expense as the product candidate had not received regulatory approval.

In addition, the Palatin License Agreement requires us to make future contingent payments of (a) up to \$80.0 million upon achievement of certain regulatory milestones, including \$20.0 million upon the acceptance by the FDA of our NDA for bremelanotide and \$60.0 million upon FDA approval, and (b) up to \$300.0 million of aggregate sales milestone payments upon the achievement of certain annual net sales in North America over the course of the license. The first sales milestone payment

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of \$25.0 million will be triggered when bremelanotide annual net sales in North America exceed \$250.0 million. We are also obligated to pay Palatin tiered royalties on annual net sales in North America of the Bremelanotide Products, on a product-by-product basis, in the Palatin 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 Bremelanotide Product in such country, (b) the expiration of the regulatory exclusivity period for such Bremelanotide Product in such country and (c) 10 years following the first commercial sale of such Bremelanotide Product in such country. These royalties are subject to reduction in the event that: (a) we must license additional third-party intellectual property in order to develop, manufacture or commercialize a Bremelanotide Product or (b) generic competition occurs with respect to a Bremelanotide 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 Bremelanotide Product in a given country, the license for such Bremelanotide 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 Palatin License Agreement.

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 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 began in the second 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. In the event the royalty rate applicable to the quarter in which a milestone payment threshold is first achieved is zero, the applicable milestone payment amount will increase by 50%.

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

Through our acquisition of Lumara Health, we are party to a development and license agreement with Antares, 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. 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. In addition, we are required to pay Antares sales milestone payments upon the achievement of certain annual net sales. 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 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 and possessions (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 in the MuGard Territory 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. 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.

Q. DEBT

Our outstanding debt obligations as of December 31, 2017 and December 31, 2016 consisted of the following (in thousands):

	December 31,	
	2017	2016
2023 Senior Notes	\$ 466,291	\$ 489,612
2022 Convertible Notes	248,194	—
2019 Convertible Notes	20,198	179,363
2015 Term Loan Facility	—	317,546
Total long-term debt	734,683	986,521
Less: current maturities	—	21,166
Long-term debt, net of current maturities	\$ 734,683	\$ 965,355

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.

In October 2017, we repurchased \$25.0 million of the 2023 Senior Notes in a privately negotiated transaction, resulting in a loss on extinguishment of debt of \$1.1 million. At December 31, 2017, the principal amount of the outstanding borrowings was \$475.0 million and the carrying value of the outstanding borrowings, net of issuance costs and other lender fees and expenses, was \$466.3 million.

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

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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.

Convertible Notes

The outstanding balances of our Convertible Notes as of December 31, 2017 consisted of the following (in thousands):

	2022 Convertible Notes	2019 Convertible Notes	Total
Liability component:			
Principal	\$ 320,000	\$ 21,417	\$ 341,417
Less: debt discount and issuance costs, net	71,806	1,219	73,025
Net carrying amount	\$ 248,194	\$ 20,198	\$ 268,392
Gross equity component	\$ 72,576	\$ 9,905	\$ 82,481

In accordance with accounting guidance for debt with conversion and other options, we separately account for the liability and equity components of our Convertible Notes by allocating the proceeds between the liability component and the embedded conversion option (the “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. The carrying amount of the liability components 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 (the “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.

2022 Convertible Notes

In the second quarter of 2017, we issued \$320.0 million aggregate principal amount of convertible senior notes due in 2022 (the “2022 Convertible Notes”) and received net proceeds of \$310.4 million from the sale of the 2022 Convertible Notes, after deducting fees and expenses of \$9.6 million. The approximately \$9.6 million of debt issuance costs 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 \$9.6 million of debt issuance costs, \$2.2 million was allocated to the Equity Component and recorded as a reduction to additional paid-in capital and \$7.4 million was allocated to the liability component and is now recorded as a reduction of the 2022 Convertible Notes in our consolidated balance sheet. The portion allocated to the liability component is amortized to interest expense using the effective interest method over five years.

The 2022 Convertible Notes are governed by the terms of an indenture between us, as issuer, and Wilmington Trust, National Association, as the trustee. The 2022 Convertible Notes are senior unsecured obligations and bear interest at a rate of 3.25% per year, payable semi-annually in arrears on June 1 and December 1 of each year, beginning on December 1, 2017. The 2022 Convertible Notes will mature on June 1, 2022, unless earlier repurchased or converted. Upon conversion of the 2022 Convertible Notes, such 2022 Convertible Notes will be convertible into, at our election, cash, shares of our common stock, or a combination thereof, at a conversion rate of 36.5464 shares of common stock per \$1,000 principal amount of the 2022 Convertible Notes, which corresponds to an initial conversion price of approximately \$27.36 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 March 1, 2022, holders may convert their 2022 Convertible Notes at their option only under the following circumstances:

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- 1) during any calendar quarter (and only during such calendar quarter) commencing after the calendar quarter ending September 30, 2017, 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 2022 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 events.

On or after March 1, 2022, until the close of business on the business day immediately preceding the maturity date, holders may convert all or any portion of their 2022 Convertible Notes, in multiples of \$1,000 principal amount, at the option of the holder regardless of the foregoing circumstances. The 2022 Convertible Notes were not convertible as of December 31, 2017.

We determined the expected life of the debt was equal to the five-year term on the 2022 Convertible Notes. The effective interest rate on the liability component was 9.49% for the period from the date of issuance through December 31, 2017. As of December 31, 2017, the “if-converted value” did not exceed the remaining principal amount of the 2022 Convertible Notes.

2019 Convertible Notes

In February 2014, we issued \$200.0 million aggregate principal amount of the 2019 Convertible Notes. We received net proceeds of \$193.3 million from the sale of the 2019 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 2019 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). In May 2017 and September 2017, we entered into privately negotiated transactions with certain investors to repurchase approximately \$158.9 million and \$19.6 million, respectively, aggregate principal amount of the 2019 Convertible Notes for an aggregate repurchase price of approximately \$171.3 million and \$21.4 million, respectively, including accrued interest. Pursuant to ASC Topic 470, *Debt* (“ASC 470”), the accounting for the May 2017 repurchase of the 2019 Convertible Notes was evaluated on a creditor-by-creditor basis with regard to the 2022 Convertible Notes to determine modification versus extinguishment accounting. We concluded that the May 2017 repurchase of the 2019 Convertible Notes should be accounted for as an extinguishment and we recorded a debt extinguishment gain of \$0.2 million related to the difference between the consideration paid, the fair value of the liability component and carrying values at the repurchase date. As a result of the September 2017 repurchase of the 2019 Convertible Notes, we recorded a debt extinguishment loss of \$0.3 million related to the difference between the consideration paid, the fair value of the liability component and carrying value at the repurchase date.

The 2019 Convertible Notes are governed by the terms of an indenture between us, as issuer, and Wilmington Trust, National Association, as the trustee. The 2019 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 2019 Convertible Notes will mature on February 15, 2019 repurchased or converted. Upon conversion of the remaining 2019 Convertible Notes, such 2019 Convertible Notes will be convertible into, at our election, cash, shares of our common stock, or a combination thereof, at a conversion rate of 36.9079 shares of common stock per \$1,000 principal amount of the 2019 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 2019 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 measurement period in which the trading price per \$1,000 principal amount of the 2019 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 events.

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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 2019 Convertible Notes, in multiples of \$1,000 principal amount, at the option of the holder, regardless of the foregoing circumstances. The 2019 Convertible Notes were not convertible as of December 31, 2017.

We determined the expected life of the debt was equal to the five-year term of the 2019 Convertible Notes. The effective interest rate on the liability component was 7.79% for the period from the date of issuance through December 31, 2017. As of December 31, 2017, the “if-converted value” did not exceed the remaining principal amount of the 2019 Convertible Notes.

Convertible Notes Interest Expense

The following table sets forth total interest expense recognized related to the Convertible Notes during 2017, 2016, and 2015 (in thousands):

	Years Ended December 31,		
	2017	2016	2015
Contractual interest expense	\$ 8,961	\$ 5,000	\$ 5,000
Amortization of debt issuance costs	1,275	1,072	985
Amortization of debt discount	11,071	7,544	6,927
Total interest expense	\$ 21,307	\$ 13,616	\$ 12,912

Convertible Bond Hedge and Warrant Transactions

In connection with the pricing of the 2019 Convertible Notes and in order to reduce the potential dilution to our common stock and/or offset cash payments due upon conversion of the 2019 Convertible Notes, in February 2014 we entered into convertible bond hedge transactions and separate warrant transactions of our common stock underlying the aggregate principal amount of the 2019 Convertible Notes with the call spread counterparties. In connection with the May 2017 and September 2017 repurchases of the 2019 Convertible Notes, as discussed above, we entered into agreements with the call spread counterparties to terminate a portion of the then existing convertible bond hedge transactions in an amount corresponding to the amount of such 2019 Convertible Notes repurchased and to terminate a portion of the then-existing warrant transactions.

As of December 31, 2017, the remaining bond hedge transactions covered approximately 0.8 million shares of our common stock underlying the remaining \$21.4 million principal amount of the 2019 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 2019 Convertible Notes are converted. If upon conversion of the 2019 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 were separate transactions entered into by us and were not part of the terms of the 2019 Convertible Notes or the warrants, discussed below. Holders of the 2019 Convertible Notes will not have any rights with respect to the convertible bond hedges.

As of December 31, 2017, the remaining warrant transactions covered approximately 1.0 million shares of our common stock underlying the remaining \$21.4 million principal amount of the 2019 Convertible Notes. The initial exercise price of the warrants is \$34.12 per share, subject to adjustment upon certain events, which was 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.

As part of the May 2017 agreements to partially terminate the bond hedge and warrant transactions, we received approximately \$0.3 million, which we recorded as a net increase to additional paid-in capital during 2017.

2015 Term Loan Facility

In August 2015, 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, under which we borrowed the full amount.

The 2015 Term Loan Facility included 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 ended December 31, 2016. We prepaid \$3.0 million of the debt in April 2017.

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In May 2017, we repaid the remaining \$321.8 million of outstanding borrowings and accrued interest of the 2015 Term Loan Facility and, in accordance with ASC 470, recognized a \$9.7 million loss on debt extinguishment.

Future Payments

Future annual principal payments on our long-term debt as of December 31, 2017 were as follows (in thousands):

Period	Future Annual Principal Payments
Year Ending December 31, 2018	\$ —
Year Ending December 31, 2019	21,417
Year Ending December 31, 2020	—
Year Ending December 31, 2021	—
Year Ending December 31, 2022	320,000
Thereafter	475,000
Total	\$ 816,417

R. CONSOLIDATED QUARTERLY FINANCIAL DATA - UNAUDITED

The following tables provide unaudited consolidated quarterly financial data for 2017 and 2016 (in thousands, except per share data):

	March 31, 2017	June 30, 2017	September 30, 2017	December 31, 2017
Total revenues	\$ 139,472	\$ 158,394	\$ 153,741	\$ 158,338
Gross profit ⁽¹⁾	106,889	120,731	(202,149)	82,064
Operating expenses	146,913	117,091	47,581	89,210
Net (loss) income	\$ (36,560)	\$ (14,066)	\$ (152,061)	\$ 3,460
Net (loss) income per share - basic	\$ (1.06)	\$ (0.40)	\$ (4.31)	\$ 0.10
Net (loss) income per share - diluted	\$ (1.06)	\$ (0.40)	\$ (4.31)	\$ 0.10
	March 31, 2016	June 30, 2016	September 30, 2016	December 31, 2016
Total revenues	\$ 109,300	\$ 127,419	\$ 143,782	\$ 151,591
Gross profit ⁽²⁾	85,474	84,563	113,092	116,349
Operating expenses	78,026	66,486	74,332	101,764
Net (loss) income	\$ (7,527)	\$ (596)	\$ 16,196	\$ (10,557)
Net (loss) income per share - basic	\$ (0.22)	\$ (0.02)	\$ 0.47	\$ (0.31)
Net (loss) income per share - diluted	\$ (0.22)	\$ (0.02)	\$ 0.43	\$ (0.31)

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

- ⁽¹⁾ Gross profit for the third quarter of 2017 included an impairment charge of \$319.2 million relating to the Makena base technology intangible asset.
- ⁽²⁾ Gross profit for the second quarter of 2016 included an impairment charge of \$15.7 million relating to the MuGard Rights intangible asset.

S. VALUATION AND QUALIFYING ACCOUNTS (IN THOUSANDS)

	Balance at Beginning of Period	Additions ⁽¹⁾	Deductions Charged to Reserves	Balance at End of Period
Year ended December 31, 2017:				
Allowance for doubtful accounts ⁽¹⁾	\$ 3,161	\$ 3,852	\$ (3,308)	\$ 3,705
Accounts receivable allowances ⁽²⁾	\$ 9,533	\$ 168,945	\$ (166,418)	\$ 12,060
Rebates, fees and returns reserves ⁽¹⁾	\$ 89,466	\$ 255,471	\$ (244,235)	\$ 100,702
Valuation allowance for deferred tax assets ⁽³⁾	\$ 1,429	\$ 4,732	\$ (564)	\$ 5,597
Year ended December 31, 2016:				
Allowance for doubtful accounts ⁽¹⁾	\$ 900	\$ 3,209	\$ (948)	\$ 3,161
Accounts receivable allowances ⁽²⁾	\$ 10,783	\$ 122,792	\$ (124,042)	\$ 9,533
Rebates, fees and returns reserves ⁽¹⁾	\$ 45,162	\$ 186,941	\$ (142,637)	\$ 89,466
Valuation allowance for deferred tax assets ⁽³⁾	\$ 11,859	\$ 632	\$ (11,062)	\$ 1,429
Year ended December 31, 2015:				
Allowance for doubtful accounts ⁽¹⁾	\$ —	\$ 900	\$ —	\$ 900
Accounts receivable allowances ⁽²⁾	\$ 11,618	\$ 93,887	\$ (94,722)	\$ 10,783
Rebates, fees and returns reserves ⁽¹⁾	\$ 43,892	\$ 120,293	\$ (119,023)	\$ 45,162
Valuation allowance for deferred tax assets ⁽³⁾	\$ 33,557	\$ —	\$ (21,698)	\$ 11,859

⁽¹⁾ Addition 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.

⁽²⁾ Accounts receivable allowances represent discounts and other chargebacks related to the provision for our product sales.

⁽³⁾ The valuation allowance for deferred tax assets includes purchase accounting adjustments and other activity related to our acquisition of Lumara Health. At December 31, 2017, the valuation allowance related primarily to certain of our state NOL and credit carryforwards.

T. 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 No. 2017-01. This 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. As discussed in Note B. *Summary of Significant Accounting Policies*, we have early 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 November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* (“ASU 2016-18”), which requires amounts generally described as restricted cash and restricted cash equivalents to be included with cash and cash equivalents when reconciling beginning-of-period and end-of-period total amounts shown on the statement of cash flows. We will adopt the standard on January 1, 2018 using the retrospective approach. The adoption of ASU 2016-18 is not expected to have a material effect on the Company’s consolidated financial statements.

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 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

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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. The adoption of ASU 2016-15 is not expected to have a material effect on the Company's 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"). This 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. We adopted ASU 2016-09 during the first quarter of 2017 and will now record all excess tax benefits and deficiencies related to share-based compensation in our condensed consolidated statements of operations as discrete events in the interim reporting period in which the benefit or deficiency occurs. Such benefits and deficiencies will not be considered in the calculation of our annual estimated effective tax rate. Any excess tax benefits that were not previously recognized because the related tax deduction had not reduced current taxes payable (i.e. was not realized) are to be recorded using a modified retrospective transition method through a cumulative-effect adjustment to retained earnings as of the beginning of the period in which the new guidance is adopted. We recorded a cumulative-effect adjustment to our accumulated deficit from previously unrecognized excess tax benefits of \$21.6 million during the first quarter of 2017. Lastly, we will continue to use the current method of estimated forfeitures each period rather than accounting for forfeitures as they occur.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). This statement 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 statement 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 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 the Company's consolidated financial statements.

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 606, 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, *Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers*, which amends

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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. 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, which for us was January 1, 2017. 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. During the fourth quarter of 2017 we finalized our assessments over the impact that these new standards will have on our consolidated results of operations, financial position and disclosures and are finalizing our accounting policies. As of December 31, 2017, we have not identified any accounting changes that would materially impact the amount of reported revenues with respect to our product or service revenues. However, we expect to capitalize incremental contract acquisition costs (specifically sales commissions related to the CBR Services) and amortize over the contractual relationship with the customer. We currently plan to adopt the standard using the “modified retrospective method.” Under that method, we will apply the rules to contracts that are not completed as of January 1, 2018, and recognize the cumulative effect of initially applying the standard as an adjustment to the opening balance of retained earnings. As of December 31, 2017, we expect to recognize an immaterial adjustment to retained earnings reflecting the cumulative impact for the accounting changes related to contract acquisition costs upon adoption of these new standards. There are also certain considerations related to internal control over financial reporting that are associated with implementing Topic 606. We are evaluating our internal control framework over revenue recognition to identify any changes that may need to be made in response to the new guidance. In addition, disclosure requirements under the new guidance in Topic 606 have been significantly expanded in comparison to the disclosure requirements under the current guidance. We will have completed the design and implementation of the appropriate controls to obtain and disclose the information required under Topic 606 in our first quarter of 2018.

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, 2017, 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, 2017 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, 2017 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, 2017.

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, 2017.

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, 2017.

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, 2017.

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, 2017.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES:

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) Financial Statements:

The financial statements are filed as part of this Annual Report on Form 10-K under “Item 8. Financial Statements and Supplementary Data.”

(2) Financial Statement Schedules:

The financial statement schedules are omitted as they are either not applicable or the information required is presented in the financial statements and notes thereto under “Item 8. Financial Statements and Supplementary Data.”

(3) Exhibits:

See Exhibit Index immediately preceding the signature page of this Annual Report on Form 10-K.

ITEM 16. FORM 10-K SUMMARY:

None.

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
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	Restated Certificate of Incorporation of AMAG Pharmaceuticals, Inc. (incorporated herein by reference to Exhibits 3.1 and 4.1 to 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 of 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	Amended and Restated Certificate of Designation of Series A Junior Participating Preferred Stock (incorporated herein by reference to Exhibits 3.1 to the Company's Current Report on Form 8-K filed April 10, 2017, File No. 001-10865)
4.5	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. 001-14732)
4.6	Rights Agreement, dated as of April 7, 2017 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 April 10, 2017, File No. 001-10865)
4.7	Form of Right Certificate (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed April 10, 2017, File No. 001-10865)
4.8	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)
4.9	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)
4.10	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)
4.11	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)
4.12	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)
4.13	Indenture, dated as of May 10, 2017, 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 May 15, 2017, File No. 001-10865)
4.14	First Supplemental Indenture, dated as of May 10, 2017, 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 May 15, 2017, File No. 001-10865)
4.15	Form of 3.25% Convertible Senior Note due 2022 (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed May 15, 2017, File No. 001-10865)
10.1*	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. 001-14732)
10.2*	AMAG Pharmaceuticals, Inc.'s Amended and Restated Non-Employee Director Compensation Policy (incorporated herein by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, File No. 001-10865)

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10.3*	<u>AMAG Pharmaceuticals, Inc.'s Fourth 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 20, 2017, File No. 001-10865)</u>
10.4*	<u>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)</u>
105*	<u>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)</u>
10.6*+	<u>Form of Incentive Stock Option Agreement for AMAG Pharmaceuticals, Inc. Employees under AMAG Pharmaceuticals, Inc.'s Fourth Amended and Restated 2007 Equity Incentive Plan and the Lumara Health Inc. Amended and Restated 2013 Incentive Compensation Plan</u>
10.7*+	<u>Form of Non-Qualified Stock Option Agreement for AMAG Pharmaceuticals, Inc. Employees under AMAG Pharmaceuticals, Inc.'s Fourth Amended and Restated 2017 Equity Incentive Plan and the Lumara Health Inc. Amended and Restated 2013 Incentive Compensation Plan</u>
10.8*+	<u>Form of Restricted Stock Unit Agreement for AMAG Pharmaceuticals, Inc. Employees under AMAG Pharmaceuticals, Inc.'s Fourth Amended and Restated 2007 Equity Incentive Plan and the Lumara Health Inc. Amended and Restated 2013 Incentive Compensation Plan</u>
10.9*+	<u>Form of Non-Qualified Stock Option Agreement for Non-Employee Directors under AMAG Pharmaceuticals, Inc.'s Fourth Amended and Restated 2007 Equity Incentive Plan</u>
10.10*+	<u>Form of Restricted Stock Unit Agreement for Non-Employee Directors under AMAG Pharmaceuticals, Inc.'s Fourth Amended and Restated 2007 Equity Incentive Plan</u>
10.11*	<u>Form of 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)</u>
10.12*+	<u>Form of Non-Qualified Stock Option Agreement - Non-Plan Inducement Grant</u>
10.13*+	<u>Form of Restricted Stock Unit Agreement - Non-Plan Inducement Grant</u>
10.14*	<u>AMAG Pharmaceuticals, Inc. Long-Term Incentive Plan (incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, File No. 001-10865)</u>
10.15*	<u>Form of Award Notice under the AMAG Pharmaceuticals, Inc. Long-term Incentive Plan (incorporated herein by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, File No. 001-10865)</u>
10.16*	<u>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)</u>
10.17*	<u>Amended and Restated 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)</u>
10.18*	<u>Amendment to Amended and Restated Employment Agreement, dated as of November 29, 2017, between AMAG Pharmaceuticals, Inc. and William K. Heiden (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed November 30, 2017, File No. 001-10865)</u>
10.19	<u>Indenture of Lease, dated as of May 22, 2008, by and between AMAG Pharmaceuticals, Inc., as tenant, 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)</u>
10.20	<u>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)</u>
10.21	<u>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)</u>
10.22	<u>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)</u>

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- 10.23 [Second Amendment to Lease Agreement, dated June 10, 2013, by and between AMAG Pharmaceuticals, Inc. and BP BAY COLONY LLC, dated December 4, 2015 \(incorporated herein by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015, File No. 001-10865\)](#)
- 10.24 [Third Amendment to Lease Agreement, dated June 10, 2013, by and between AMAG Pharmaceuticals, Inc. and BP BAY COLONY LLC, dated December 7, 2015 \(incorporated herein by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015, File No. 001-10865\)](#)
- 10.25 [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 \(incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, File No. 001-10865\) \(confidential treatment previously granted\)](#)
- 10.26 [Commercial Supply Agreement, dated effective as of August 29, 2012, by and between AMAG Pharmaceuticals, Inc. and Sigma-Aldrich, Inc. \(incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012, File No. 001-10865\) \(confidential treatment previously granted\)](#)
- 10.27 [Amendment No.1 to Commercial Supply Agreement, dated October 3, 2013, by and between AMAG Pharmaceuticals, Inc. and Sigma-Aldrich, Inc. \(incorporated herein by reference to Exhibit 10.54 to the Company's Annual Report on Form 10-K for the year ended December 31, 2013, File No. 001-10865\) \(confidential treatment previously granted\)](#)
- 10.28 [Amendment No. 2 to Commercial Supply Agreement, dated April 28, 2015, by and between AMAG Pharmaceuticals, Inc. and Sigma-Aldrich, Inc. \(incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, File No. 001-10865\) \(confidential treatment previously granted\)](#)
- 10.29 [Amendment No. 3 to Commercial Supply Agreement, dated October 19, 2015, by and between the Company and Sigma-Aldrich, Inc. \(incorporated herein by reference to Exhibit 10.36 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015, File No. 001-10865\) \(confidential treatment previously granted\)](#)
- 10.30 [Pharmaceutical Manufacturing and Supply Agreement, dated effective as of January 8, 2010, by and between AMAG Pharmaceuticals, Inc. and Patheon Manufacturing Services LLC \(as assignee from DSM Pharmaceuticals, Inc.\) \(incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012, File No. 001-10865\) \(confidential treatment previously granted\)](#)
- 10.31 [Amendment No. 1 to Pharmaceutical Manufacturing and Supply Agreement, dated July 5, 2014, by and between AMAG Pharmaceuticals, Inc. and Patheon Manufacturing Services LLC \(as assignee from DSM Pharmaceuticals, Inc.\) \(incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, File No. 001-10865\)](#)
- 10.32 [Amendment No. 2 to Pharmaceutical Manufacturing and Supply Agreement, dated June 19, 2015, by and between AMAG Pharmaceuticals, Inc. and Patheon Manufacturing Services LLC \(as assignee from DPI Newco LLC as assignee from DSM Pharmaceuticals, Inc.\) \(incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, File No. 001-10865\) \(confidential treatment previously granted\)](#)
- 10.33 [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. \(incorporated herein by reference to Exhibit 10.34 to the Company's Annual Report on Form 10-K for the year ended December 31, 2016\) \(confidential treatment previously granted\)](#)
- 10.34 [Development and License Agreement, dated September 30, 2014, by and between Lumara Health Inc and Antares Pharma, Inc. \(incorporated herein by reference to Exhibit 10.42 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015, File No. 001-10865\) \(confidential treatment previously granted\)](#)
- 10.35 [License Agreement, dated January 8, 2017, by and between AMAG Pharmaceuticals, Inc. and Palatin Technologies, Inc., \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed February 3, 2017, File No. 001-10865\) \(confidential treatment previously granted\)](#)
- 10.36 [Base Call Option Transaction Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association, London Branch \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865\)](#)
- 10.37 [Base Call Option Transaction Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and Royal Bank of Canada \(incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865\)](#)

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10.38	<u>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)</u>
10.39	<u>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)</u>
10.40	<u>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)</u>
10.41	<u>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)</u>
10.42	<u>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)</u>
10.43	<u>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)</u>
10.44	<u>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)</u>
10.45	<u>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)</u>
10.46	<u>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)</u>
10.47	<u>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)</u>
10.48	<u>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)</u>
10.49	<u>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)</u>
10.50	<u>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)</u>
10.51	<u>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)</u>
10.52	<u>License Agreement, dated as of February 13, 2017, by and between AMAG Pharmaceuticals, Inc. and Endoceutics Inc. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed April 5, 2017, File No. 001-10865) (confidential treatment previously granted)</u>
10.53	<u>Manufacturing and Supply Agreement, dated as of April 5, 2017, by and between AMAG Pharmaceuticals, Inc. and Endoceutics Inc. (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed April 5, 2017, File No. 001-10865) (confidential treatment previously granted)</u>
21.1+	<u>Subsidiaries of AMAG Pharmaceuticals, Inc.</u>
23.1+	<u>Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm</u>

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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 and not marked with a “+” or “++” have previously been filed with the SEC and are incorporated herein by reference, as indicated.

**AMAG PHARMACEUTICALS, INC.
INCENTIVE STOCK OPTION AGREEMENT
FOR COMPANY EMPLOYEES**

Name of Optionee:

No. of Option Shares:

Option Exercise Price per Share:

\$ _____
[FMV on Grant Date]

Grant Date:

Expiration Date:

[up to 10 years]

Pursuant to the AMAG Pharmaceuticals, Inc. Fourth Amended and Restated 2007 Equity Incentive Plan as amended through the date hereof (the "Plan"), AMAG Pharmaceuticals, Inc. (the "Company") hereby grants to the Optionee named above an option (the "Stock Option") to purchase on or prior to the Expiration Date specified above all or part of the number of shares of Common Stock, par value \$0.01 per share (the "Stock"), of the Company specified above at the Option Exercise Price per Share specified above subject to the terms and conditions set forth herein and in the Plan.

1. Exercisability Schedule. No portion of this Stock Option may be exercised until such portion shall have become exercisable. Except as set forth below, and subject to the discretion of the Administrator (as defined in Section 2 of the Plan) to accelerate the exercisability schedule hereunder, this Stock Option shall be exercisable with respect to the following number of Option Shares on the dates indicated so long as the Optionee remains in a Business Relationship (as defined in Section 3 below) on such dates:

<u>Incremental Number of Option Shares Exercisable*</u>	<u>Exercisability Date</u>
_____ (___ %)	_____
_____ (___ %)	_____
_____ (___ %)	_____
_____ (___ %)	_____

* Max. of \$100,000 per yr.

Once exercisable, this Stock Option shall continue to be exercisable at any time or times prior to the close of business on the Expiration Date, subject to the provisions hereof and of the Plan.

2. Manner of Exercise.

(a) The Optionee may exercise this Stock Option only in the following manner: from time to time on or prior to the Expiration Date of this Stock Option, the Optionee may give written or electronic notice to the Company to the attention of the Company's Treasurer or his or her designee of his or her election to purchase some or all of the Option Shares purchasable at the time of such notice. This notice shall specify the number of Option Shares to be purchased.

Payment of the purchase price for the Option Shares may be made by one or more of the following methods: (i) in cash, by certified or bank check or other instrument acceptable to the Company; (ii) subject to the Company's approval, through the delivery (or attestation to the ownership) of shares of Stock that have been purchased by the Optionee on the open market or that are beneficially owned by the Optionee and are not then subject to any restrictions under any Company plan and that otherwise satisfy any holding periods as may be required by the Administrator; (iii) by the Optionee delivering to the Company a properly executed exercise notice together with irrevocable instructions to a broker to promptly deliver to the Company cash or a check payable and acceptable to the Company to pay the option purchase price, provided that in the event the Optionee chooses to pay the option purchase price as so provided, the Optionee and the broker shall comply with such procedures and enter into such agreements of indemnity and other agreements as the Company shall prescribe as a condition of such payment procedure; or (iv) a combination of (i), (ii) and (iii) above. Payment instruments will be received subject to collection.

The transfer to the Optionee on the records of the Company or of the transfer agent of the Option Shares will be contingent upon (i) the Company's receipt from the Optionee of the full purchase price for the Option Shares, as set forth above, (ii) the fulfillment of any other requirements contained herein or in the Plan or in any other agreement or provision of laws, and (iii) the receipt by the Company of any agreement, statement or other evidence that the Company may require to satisfy itself that the issuance of Stock to be purchased pursuant to the exercise of Stock Options under the Plan and any subsequent resale of the shares of Stock will be in compliance with applicable laws and regulations. In the event the Optionee chooses to pay the purchase price by previously-owned shares of Stock through the attestation method, the number of shares of Stock transferred to the Optionee upon the exercise of the Stock Option shall be net of the Shares attested to.

(b) The shares of Stock purchased upon exercise of this Stock Option shall be transferred to the Optionee on the records of the Company or of the transfer agent upon compliance to the satisfaction of the Company with all requirements under applicable laws or regulations in connection with such transfer and with the requirements hereof and of the Plan. The determination of the Company as to such compliance shall be final and binding on the Optionee. The Optionee shall not be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Stock subject to this Stock Option unless and until this Stock Option shall have been exercised pursuant to the terms hereof, the Company or the transfer agent shall have transferred the shares to the Optionee, and the Optionee's name shall have been entered as the stockholder of record on the books of the Company. Thereupon, the Optionee shall have full voting, dividend and other ownership rights with respect to such shares of Stock.

(c) Notwithstanding any other provision hereof or of the Plan, no portion of this Stock Option shall be exercisable after the Expiration Date hereof.

(d) Without derogating from the foregoing, “statutory option stock” (as defined below) may be tendered in payment of the exercise price of this Stock Option even if the stock to be so tendered has not, at the time of tender, been held by the Optionee for the applicable minimum statutory holding period required to receive the tax benefits afforded under Section 421(a) of the Code with respect to such stock. The Optionee acknowledges that the tender of such “statutory option stock” may have adverse tax consequences to the Optionee. As used above, the term “statutory option stock” means stock acquired through the exercise of an incentive stock option or an option granted under an employee stock purchase plan. The tender of statutory option stock in payment of the exercise price of this Option shall be accompanied by written representation (in form satisfactory to the Company) stating whether such stock has been held by the Optionee for the applicable minimum statutory holding period.

3. Termination of Business Relationship.

(a) If the Optionee’s Business Relationship (as defined below) is terminated, the period within which to exercise the Stock Option may be subject to earlier termination as follows:

(i) If the Optionee’s Business Relationship is terminated by reason of the Optionee’s death or disability (as determined by the Company) or, if the Optionee dies or becomes disabled within the three-month period following the date the Optionee’s Business Relationship terminates for any other reason, any portion of this Stock Option outstanding on the date of termination, may be exercised, to the extent exercisable on such date, for a period of twelve months from the date of death or disability or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date the Optionee’s Business Relationship is terminated shall terminate immediately and be of no further force or effect.

(ii) If the Optionee’s Business Relationship is terminated for any reason other than death or disability, any portion of this Stock Option outstanding on such date may be exercised, to the extent exercisable on the date of termination, for a period of three months from the date of termination or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date the Optionee’s Business Relationship is terminated shall terminate immediately and be of no further force or effect.

(iii) Notwithstanding the foregoing, if the Optionee, prior to the termination date of this Stock Option, (i) violates any provision of any employment agreement or any confidentiality or other agreement between the Optionee and the Company, (ii) commits any felony or any crime involving moral turpitude under the laws of the United States or any state thereof, (iii) attempts to commit, or participate in, a fraud or act of dishonesty against the Company, or (iv) commits gross misconduct, the right to exercise this Stock Option shall terminate immediately upon written notice to the Optionee from the Company describing such violation or act.

The Company's determination of the reason for termination of the Optionee's Business Relationship shall be conclusive and binding on the Optionee and his or her representatives or legatees. Notwithstanding the foregoing, under certain circumstances set forth in the Employment Agreement dated as of [] by and between the Company and the Optionee (the "Employment Agreement"), and subject to compliance by the Optionee with the requirements of the Employment Agreement related to such circumstances, the vesting of the unvested portion of this Stock Option may be accelerated as provided in and subject to the terms of the Employment Agreement.

(b) For purposes hereof, "Business Relationship" means service to the Company or any of its Subsidiaries, or its or their successors, in the capacity of an employee, officer, director, consultant or advisor. For purposes hereof, a Business Relationship shall not be considered as having terminated during any military leave, sick leave, or other leave of absence if approved in writing by the Company and if such written approval, or applicable law, contractually obligates the Company to continue the Business Relationship of the Optionee after the approved period of absence (an "Approved Leave of Absence"). For purposes hereof, a Business Relationship shall include a consulting arrangement between the Optionee and the Company that immediately follows termination of employment, but only if so stated in a written consulting agreement executed by the Company.

4. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Stock Option shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

5. Transferability. This Agreement is personal to the Optionee, is non-assignable and is not transferable in any manner, by operation of law or otherwise, other than by will or the laws of descent and distribution. This Stock Option is exercisable, during the Optionee's lifetime, only by the Optionee, and thereafter, only by the Optionee's legal representative or legatee. Notwithstanding the foregoing, this Stock Option may be transferred pursuant to a domestic relations order; provided, however, that an "incentive stock option" under Section 422 of the Internal Revenue Code of 1986, as amended (the "Code") may be deemed to be a nonqualified stock option as a result of such transfer.

6. Status of the Stock Option. This Stock Option is intended to qualify as an "incentive stock option" under Section 422 of the Code, but the Company does not represent or warrant that this Stock Option qualifies as such. The Optionee should consult with his or her own tax advisors regarding the tax effects of this Stock Option and the requirements necessary to obtain favorable income tax treatment under Section 422 of the Code, including, but not limited to, holding period requirements. To the extent any portion of this Stock Option does not so qualify as an "incentive stock option," such portion shall be deemed to be a non-qualified stock option. If the Optionee intends to dispose or does dispose (whether by sale, gift, transfer or otherwise) of any Option Shares within the one-year period beginning on the date after the transfer of such shares to him or her, or within the two-year period beginning on the day after the grant of this Stock Option, he or she will so notify the Company within 30 days after such disposition.

7. Tax Withholding. The Optionee shall, not later than the date as of which the exercise of this Stock Option becomes a taxable event for Federal income tax purposes, pay to the Company or make arrangements satisfactory to the Company for payment of any Federal, state, and local taxes required by law to be withheld on account of such taxable event. The Company shall have the authority to cause the required tax withholding obligation to be satisfied, in whole or in part, by withholding from shares of Stock to be issued to the Optionee a number of shares of Stock with an aggregate Fair Market Value that would satisfy the withholding amount due; provided, however, that the amount withheld does not exceed the maximum tax rate, or such lesser amount as determined by the Administrator.

8. No Obligation to Continue Business Relationship. Neither the Company nor any Subsidiary is obligated by or as a result of the Plan or this Agreement to continue the Optionee's Business Relationship, and neither the Plan nor this Agreement shall interfere in any way with the right of the Company or any Subsidiary to terminate the Business Relationship of the Optionee at any time.

9. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Stock Option and supersedes all prior agreements and discussions between the parties concerning such subject matter.

10. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the "Relevant Companies") may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of the Plan and/or this Agreement (the "Relevant Information"). By entering into this Agreement, the Optionee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Optionee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Optionee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

11. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business to the attention of the Company's Treasurer and shall be mailed or delivered to the Optionee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

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**SIGNATURE PAGE TO AMAG PHARMACEUTICALS, INC.
INCENTIVE STOCK OPTION AGREEMENT**

AMAG PHARMACEUTICALS, INC.

By: _____
Name: William K. Heiden
Title: President and Chief Executive Officer

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned, and the undersigned acknowledges receipt of a copy of this entire Agreement, a copy of the Plan, and a copy of the Plan's related prospectus. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Optionee (including through an online acceptance process) is acceptable.

Dated: _____
Optionee's Signature

Optionee's name and address:

**AMAG PHARMACEUTICALS, INC.
NON-QUALIFIED STOCK OPTION AGREEMENT
FOR COMPANY EMPLOYEES**

Name of Optionee:

No. of Option Shares:

Option Exercise Price per Share:

\$ _____

[FMV on Grant Date]

Grant Date:

Expiration Date:

[up to 10 years]

Pursuant to the AMAG Pharmaceuticals, Inc. Fourth Amended and Restated 2007 Equity Incentive Plan as amended through the date hereof (the "Plan"), AMAG Pharmaceuticals, Inc. (the "Company") hereby grants to the Optionee named above an option (the "Stock Option") to purchase on or prior to the Expiration Date specified above all or part of the number of shares of Common Stock, par value \$0.01 per share (the "Stock") of the Company specified above at the Option Exercise Price per Share specified above subject to the terms and conditions set forth herein and in the Plan. This Stock Option is not intended to be an "incentive stock option" under Section 422 of the Internal Revenue Code of 1986, as amended.

1. Exercisability Schedule. No portion of this Stock Option may be exercised until such portion shall have become exercisable. Except as set forth below, and subject to the discretion of the Administrator (as defined in Section 2 of the Plan) to accelerate the exercisability schedule hereunder, this Stock Option shall be exercisable with respect to the following number of Option Shares on the dates indicated so long as the Optionee remains in a Business Relationship (as defined in Section 3 below) on such dates:

<u>Incremental Number of Option Shares Exercisable</u>	<u>Exercisability Date</u>
_____ (___ %)	_____
_____ (___ %)	_____
_____ (___ %)	_____
_____ (___ %)	_____

Once exercisable, this Stock Option shall continue to be exercisable at any time or times prior to the close of business on the Expiration Date, subject to the provisions hereof and of the Plan.

2. Manner of Exercise.

(a) The Optionee may exercise this Stock Option only in the following manner: from time to time on or prior to the Expiration Date of this Stock Option, the Optionee may give written or electronic notice to the Company to the attention of the Company's Treasurer or his or her designee of his or her election to purchase some or all of the Option Shares purchasable at the time of such notice. This notice shall specify the number of Option Shares to be purchased.

Payment of the purchase price for the Option Shares may be made by one or more of the following methods: (i) in cash, by certified or bank check or other instrument acceptable to the Company; (ii) subject to the Company's approval, through the delivery (or attestation to the ownership) of shares of Stock that have been purchased by the Optionee on the open market or that are beneficially owned by the Optionee and are not then subject to any restrictions under any Company plan and that otherwise satisfy any holding periods as may be required by the Administrator; (iii) by the Optionee delivering to the Company a properly executed exercise notice together with irrevocable instructions to a broker to promptly deliver to the Company cash or a check payable and acceptable to the Company to pay the option purchase price, provided that in the event the Optionee chooses to pay the option purchase price as so provided, the Optionee and the broker shall comply with such procedures and enter into such agreements of indemnity and other agreements as the Company shall prescribe as a condition of such payment procedure; or (iv) a combination of (i), (ii) and (iii) above. Payment instruments will be received subject to collection.

The transfer to the Optionee on the records of the Company or of the transfer agent of the Option Shares will be contingent upon (i) the Company's receipt from the Optionee of the full purchase price for the Option Shares, as set forth above, (ii) the fulfillment of any other requirements contained herein or in the Plan or in any other agreement or provision of laws, and (iii) the receipt by the Company of any agreement, statement or other evidence that the Company may require to satisfy itself that the issuance of Stock to be purchased pursuant to the exercise of Stock Options under the Plan and any subsequent resale of the shares of Stock will be in compliance with applicable laws and regulations. In the event the Optionee chooses to pay the purchase price by previously-owned shares of Stock through the attestation method, the number of shares of Stock transferred to the Optionee upon the exercise of the Stock Option shall be net of the Shares attested to.

(b) The shares of Stock purchased upon exercise of this Stock Option shall be transferred to the Optionee on the records of the Company or of the transfer agent upon compliance to the satisfaction of the Company with all requirements under applicable laws or regulations in connection with such transfer and with the requirements hereof and of the Plan. The determination of the Company as to such compliance shall be final and binding on the Optionee. The Optionee shall not be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Stock subject to this Stock Option unless and until this Stock Option shall have been exercised pursuant to the terms hereof, the Company or the transfer agent shall have transferred the shares to the Optionee, and the Optionee's name shall have been entered as the stockholder of record on the books of the Company. Thereupon, the Optionee shall have full voting, dividend and other ownership rights with respect to such shares of Stock.

(c) Notwithstanding any other provision hereof or of the Plan, no portion of this Stock Option shall be exercisable after the Expiration Date hereof.

(d) Without derogating from the foregoing, "statutory option stock" (as defined below) may be tendered in payment of the exercise price of this Stock Option even if the stock to be so tendered has not, at the time of tender, been held by the Optionee for the applicable minimum statutory holding period required to receive the tax benefits afforded under Section 421(a) of the Code with respect to such stock. The Optionee acknowledges that the tender of such "statutory option stock" may have adverse tax consequences to the Optionee. As used above, the term "statutory option stock" means stock acquired through the exercise of an incentive stock option or an option granted under an employee stock purchase plan. The tender of statutory option stock in payment of the exercise price of this Option shall be accompanied by written representation (in form

satisfactory to the Company) stating whether such stock has been held by the Optionee for the applicable minimum statutory holding period.

3. Termination of Business Relationship.

(a) If the Optionee's Business Relationship (as defined below) is terminated, the period within which to exercise the Stock Option may be subject to earlier termination as follows:

(i) If the Optionee's Business Relationship is terminated by reason of the Optionee's death or disability (as determined by the Company) or, if the Optionee dies or becomes disabled within the three-month period following the date the Optionee's Business Relationship terminates for any other reason, any portion of this Stock Option outstanding on the date of termination, may be exercised, to the extent exercisable on such date, for a period of twelve months from the date of death or disability or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date the Optionee's Business Relationship is terminated shall terminate immediately and be of no further force or effect.

(ii) If the Optionee's Business Relationship is terminated for any reason other than death or disability, any portion of this Stock Option outstanding on such date may be exercised, to the extent exercisable on the date of termination, for a period of three months from the date of termination or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date the Optionee's Business Relationship is terminated shall terminate immediately and be of no further force or effect.

(iii) Notwithstanding the foregoing, if the Optionee, prior to the termination date of this Stock Option, (i) violates any provision of any employment agreement or any confidentiality or other agreement between the Optionee and the Company, (ii) commits any felony or any crime involving moral turpitude under the laws of the United States or any state thereof, (iii) attempts to commit, or participate in, a fraud or act of dishonesty against the Company, or (iv) commits gross misconduct, the right to exercise this Stock Option shall terminate immediately upon written notice to the Optionee from the Company describing such violation or act.

The Company's determination of the reason for termination of the Optionee's Business Relationship shall be conclusive and binding on the Optionee and his or her representatives or legatees.

(b) For purposes hereof, "Business Relationship" means service to the Company or any of its Subsidiaries, or its or their successors, in the capacity of an employee, officer, director, consultant or advisor. For purposes hereof, a Business Relationship shall not be considered as having terminated during any military leave, sick leave, or other leave of absence if approved in writing by the Company and if such written approval, or applicable law, contractually obligates the Company to continue the Business Relationship of the Optionee after the approved period of absence (an "Approved Leave of Absence"). For purposes hereof, a Business Relationship shall include a consulting arrangement between the Optionee and the Company that immediately follows termination of employment, but only if so stated in a written consulting agreement executed by the Company.

4. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Stock Option shall be subject to and governed by all the terms and conditions of the Plan, including the

powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

5. Transferability. This Agreement is personal to the Optionee, is non-assignable and is not transferable in any manner, by operation of law or otherwise, other than by will or the laws of descent and distribution. This Stock Option is exercisable, during the Optionee's lifetime, only by the Optionee, and thereafter, only by the Optionee's legal representative or legatee. Notwithstanding the foregoing, this Stock Option may be transferred pursuant to a domestic relations order.

6. Tax Withholding. The Optionee shall, not later than the date as of which the exercise of this Stock Option becomes a taxable event for Federal income tax purposes, pay to the Company or make arrangements satisfactory to the Company for payment of any Federal, state, and local taxes required by law to be withheld on account of such taxable event. The Company shall have the authority to cause the required tax withholding obligation to be satisfied, in whole or in part, by withholding from shares of Stock to be issued to the Optionee a number of shares of Stock with an aggregate Fair Market Value that would satisfy the withholding amount due; provided, however, that the amount withheld does not exceed the maximum tax rate, or such lesser amount as determined by the Administrator.

7. No Obligation to Continue Business Relationship. Neither the Company nor any Subsidiary is obligated by or as a result of the Plan or this Agreement to continue the Optionee's Business Relationship, and neither the Plan nor this Agreement shall interfere in any way with the right of the Company or any Subsidiary to terminate the Business Relationship of the Optionee at any time.

8. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Stock Option and supersedes all prior agreements and discussions between the parties concerning such subject matter.

9. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the "Relevant Companies") may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of the Plan and/or this Agreement (the "Relevant Information"). By entering into this Agreement, the Optionee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Optionee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Optionee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

10. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business to the attention of the Company's Treasurer and shall be mailed or delivered to the Optionee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

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**SIGNATURE PAGE TO AMAG PHARMACEUTICALS, INC.
NON-QUALIFIED STOCK OPTION AGREEMENT**

AMAG PHARMACEUTICALS, INC.

By: _____
Name: William K. Heiden
Title: President and Chief Executive Officer

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned, and the undersigned acknowledges receipt of a copy of this entire Agreement, a copy of the Plan, and a copy of the Plan's related prospectus. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Optionee (including through an online acceptance process) is acceptable.

Dated: _____
Optionee's Signature

Optionee's name and address:

**AMAG PHARMACEUTICALS, INC.
RESTRICTED STOCK UNIT AWARD AGREEMENT
FOR COMPANY EMPLOYEES**

Name of Grantee: _____

No. of Restricted Stock Units: _____

Grant Date: _____

Pursuant to the AMAG Pharmaceuticals, Inc. Fourth Amended and Restated 2007 Equity Incentive Plan (the "Plan"), AMAG Pharmaceuticals, Inc. (the "Company") hereby grants an award of the number of Restricted Stock Units listed above (an "Award") to the Grantee named above. Each Restricted Stock Unit shall relate to one share of Common Stock, par value \$0.01 per share (the "Stock") of the Company.

1. Restrictions on Transfer of Award. This Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of by the Grantee, and any shares of Stock issuable with respect to the Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of until (i) the Restricted Stock Units have vested as provided in Section 2 of this Agreement and (ii) shares of Stock have been issued to the Grantee in accordance with the terms of the Plan and this Agreement.

2. Vesting of Restricted Stock Units. The restrictions and conditions of Section 1 of this Agreement shall lapse on the Vesting Date or Dates specified in the following schedule so long as the Grantee remains in a Business Relationship (as defined in Section 3 below) on such Dates. If a series of Vesting Dates is specified, then the restrictions and conditions in Section 1 shall lapse only with respect to the number of Restricted Stock Units specified as vested on such date.

<u>Incremental Number of Restricted Stock Units Vested</u>	<u>Vesting Date</u>
_____ (___ %)	_____
_____ (___ %)	_____
_____ (___ %)	_____

The Administrator may at any time accelerate the vesting schedule specified in this Section 2.

3. Termination of Business Relationship.

(a) If the Grantee's Business Relationship terminates for any reason (including death or disability) prior to the satisfaction of the vesting conditions set forth in Section 2 above, any Restricted Stock Units that have not vested as of such date shall

automatically and without notice terminate and be forfeited, and neither the Grantee nor any of his or her successors, heirs, assigns, or personal representatives will thereafter have any further rights or interests in such unvested Restricted Stock Units. Notwithstanding the foregoing, under certain circumstances set forth in the Employment Agreement dated as of [] by and between the Company and the Grantee (the "Employment Agreement"), and subject to compliance by the Grantee with the requirements of the Employment Agreement related to such circumstances, the vesting of unvested Restricted Stock Units may be accelerated as provided in and subject to the terms of the Employment Agreement.

(b) "Business Relationship" means service to the Company or any of its Subsidiaries, or its or their successors, in the capacity of an employee, officer, director, consultant or advisor. For purposes hereof, a Business Relationship shall not be considered as having terminated during any military leave, sick leave, or other leave of absence if approved in writing by the Company and if such written approval, or applicable law, contractually obligates the Company to continue the Business Relationship of the Grantee after the approved period of absence (an "Approved Leave of Absence"). For purposes hereof, a Business Relationship shall include a consulting arrangement between the Grantee and the Company that immediately follows termination of employment, but only if so stated in a written consulting agreement executed by the Company.

4. Issuance of Shares of Stock. As soon as practicable following each Vesting Date, the Company shall issue to the Grantee the number of shares of Stock equal to the aggregate number of Restricted Stock Units that have vested pursuant to Section 2 of this Agreement on such date and the Grantee shall thereafter have all the rights of a stockholder of the Company with respect to such shares; provided, however, if a Vesting Date shall occur during either a regularly scheduled or special "blackout period" wherein the Grantee is precluded from selling shares of Stock, the receipt of the corresponding underlying shares issuable with respect to such Vesting Date pursuant to this Agreement shall be deferred until after the expiration of such blackout period unless such underlying shares are covered by a previously established Company-approved 10b5-1 plan of the Grantee, in which case the underlying shares shall be issued in accordance with the terms of such 10b5-1 plan; provided, however, that the issuance of such shares shall not be deferred any later than the later of: (a) December 31st of the calendar year in which such vesting occurs, or (b) the 15th day of the third calendar month following such vesting date, and if such settlement occurs while either a regularly scheduled or special "blackout period" is still in effect, neither the Company nor the Grantee may sell any shares issued in settlement thereof to satisfy any tax or withholding obligations except in compliance with the Company's Statement of Company Policy Regarding Insider Training and other applicable requirements and laws.

5. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Agreement shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

6. Tax Withholding. The Grantee shall, not later than the date as of which the

receipt of this Award becomes a taxable event for Federal income tax purposes, pay to the Company or make arrangements satisfactory to the Company for payment of any Federal, state, and local taxes required by law to be withheld on account of such taxable event. The Company shall have the authority to cause the required tax withholding obligation to be satisfied, in whole or in part, by withholding from shares of Stock to be issued to the Grantee a number of shares of Stock with an aggregate Fair Market Value that would satisfy the withholding amount due; provided, however, that the amount withheld does not exceed the maximum tax rate, or such lesser amount as determined by the Administrator.

7. Section 409A of the Code. This Agreement shall be interpreted in such a manner that all provisions relating to the settlement of the Award are exempt from the requirements of Section 409A of the Code as “short-term deferrals” as described in Section 409A of the Code.

8. No Obligation to Continue Business Relationship. Neither the Company nor any Subsidiary is obligated by or as a result of the Plan or this Agreement to continue the Grantee’s Business Relationship, and neither the Plan nor this Agreement shall interfere in any way with the right of the Company or any Subsidiary to terminate the Business Relationship of the Grantee at any time.

9. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Award and supersedes all prior agreements and discussions between the parties concerning such subject matter.

10. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the “Relevant Companies”) may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of the Plan and/or this Agreement (the “Relevant Information”). By entering into this Agreement, the Grantee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Grantee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Grantee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

11. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business to the attention of the Company’s Treasurer and shall be mailed or delivered to the Grantee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

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**SIGNATURE PAGE TO AMAG PHARMACEUTICALS, INC.
RESTRICTED STOCK UNIT AWARD AGREEMENT**

AMAG PHARMACEUTICALS, INC.

By: _____
Name: William K. Heiden
Title: President and Chief Executive Officer

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned, and the undersigned acknowledges receipt of a copy of this entire Agreement, a copy of the Plan, and a copy of the Plan's related prospectus. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Grantee (including through an online acceptance process) is acceptable.

Dated: _____
Grantee's Signature

Grantee's name and address:

**AMAG PHARMACEUTICALS, INC.
NON-QUALIFIED STOCK OPTION AGREEMENT
FOR NON-EMPLOYEE DIRECTORS**

Name of Optionee:

No. of Option Shares:

Option Exercise Price per Share:

\$

[FMV on Grant Date]

Grant Date:

Expiration Date:

[No more than 10 years]

Pursuant to the AMAG Pharmaceuticals, Inc. Fourth Amended and Restated 2007 Equity Incentive Plan (the "Plan"), AMAG Pharmaceuticals, Inc. (the "Company") hereby grants to the Optionee named above, who is a Director of the Company but is not an employee of the Company, an option (the "Stock Option") to purchase on or prior to the Expiration Date specified above all or part of the number of shares of Common Stock, par value \$0.01 per share (the "Stock"), of the Company specified above at the Option Exercise Price per Share specified above subject to the terms and conditions set forth herein and in the Plan. This Stock Option is not intended to be an "incentive stock option" under Section 422 of the Internal Revenue Code of 1986, as amended.

1. Exercisability Schedule. No portion of this Stock Option may be exercised until such portion shall have become exercisable. Except as set forth below, and subject to the discretion of the Administrator (as defined in Section 2 of the Plan) to accelerate the exercisability schedule hereunder, this Stock Option shall be exercisable with respect to the following number of Option Shares on the dates indicated so long as the Optionee maintains a Business Relationship with the Company (as defined below) on such dates:

<u>Incremental Number of Option Shares Exercisable</u>	<u>Exercisability Date</u>
[1/12 of [Number]]	June 1, 20XX
[1/12 of [Number]]	July 1, 20XX
[1/12 of [Number]]	August 1, 20XX
[1/12 of [Number]]	September 1, 20XX
[1/12 of [Number]]	October 1, 20XX
[1/12 of [Number]]	November 1, 20XX
[1/12 of [Number]]	December 1, 20XX
[1/12 of [Number]]	January 1, 20XX
[1/12 of [Number]]	February 1, 20XX
[1/12 of [Number]]	March 1, 20XX
[1/12 of [Number]]	April 1, 20XX
[1/12 of [Number]]	May 1, 20XX

Once exercisable, this Stock Option shall continue to be exercisable at any time or times prior to the close of business on the Expiration Date, subject to the provisions hereof and of the Plan.

“Business Relationship” means service to the Company or its successor in the capacity of an employee, officer, director, consultant, or advisor.

2. Manner of Exercise.

(a) The Optionee may exercise this Stock Option only in the following manner: from time to time on or prior to the Expiration Date of this Stock Option, the Optionee may give written or electronic notice to the Company to the attention of the Company’s Treasurer or his or her designee of his or her election to purchase some or all of the Option Shares purchasable at the time of such notice. This notice shall specify the number of Option Shares to be purchased.

Payment of the purchase price for the Option Shares may be made by one or more of the following methods: (i) in cash, by certified or bank check or other instrument acceptable to the Company; (ii) subject to the Company’s approval, through the delivery (or attestation to the ownership) of shares of Stock that have been purchased by the Optionee on the open market or that are beneficially owned by the Optionee and are not then subject to any restrictions under any Company plan and that otherwise satisfy any holding periods as may be required by the Administrator; (iii) by the Optionee delivering to the Company a properly executed exercise notice together with irrevocable instructions to a broker to promptly deliver to the Company cash or a check payable and acceptable to the Company to pay the option purchase price, provided that in the event the Optionee chooses to pay the option purchase price as so provided, the Optionee and the broker shall comply with such procedures and enter into such agreements of indemnity and other agreements as the Company shall prescribe as a condition of such payment procedure; or (iv) a combination of (i), (ii) and (iii) above. Payment instruments will be received subject to collection.

The transfer to the Optionee on the records of the Company or of the transfer agent of the Option Shares will be contingent upon (i) the Company's receipt from the Optionee of the full purchase price for the Option Shares, as set forth above, (ii) the fulfillment of any other requirements contained herein or in the Plan or in any other agreement or provision of laws, and (iii) the receipt by the Company of any agreement, statement or other evidence that the Company may require to satisfy itself that the issuance of Stock to be purchased pursuant to the exercise of Stock Options under the Plan and any subsequent resale of the shares of Stock will be in compliance with applicable laws and regulations. In the event the Optionee chooses to pay the purchase price by previously-owned shares of Stock through the attestation method, the number of shares of Stock transferred to the Optionee upon the exercise of the Stock Option shall be net of the Shares attested to.

(b) The shares of Stock purchased upon exercise of this Stock Option shall be transferred to the Optionee on the records of the Company or of the transfer agent upon compliance to the satisfaction of the Company with all requirements under applicable laws or regulations in connection with such transfer and with the requirements hereof and of the Plan. The determination of the Company as to such compliance shall be final and binding on the Optionee. The Optionee shall not be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Stock subject to this Stock Option unless and until this Stock Option shall have been exercised pursuant to the terms hereof, the Company or the transfer agent shall have transferred the shares to the Optionee, and the Optionee's name shall have been entered as the stockholder of record on the books of the Company. Thereupon, the Optionee shall have full voting, dividend and other ownership rights with respect to such shares of Stock.

(c) Notwithstanding any other provision hereof or of the Plan, no portion of this Stock Option shall be exercisable after the Expiration Date hereof.

3. Termination of Business Relationship.

(a) If the Optionee ceases to maintain a Business Relationship with the Company, the period within which to exercise the Stock Option may be subject to earlier termination as follows:

(i) If the Optionee ceases to maintain a Business Relationship with the Company by reason of the Optionee's death or disability (as determined by the Company) or, if the Optionee dies or becomes disabled within the three-month period following the date the Optionee ceases to maintain a Business Relationship with the Company, any portion of this Stock Option outstanding on the date the Optionee ceases to maintain a Business Relationship with the Company, may be exercised, to the extent exercisable on such date, for a period of three years from the date of death or disability or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date the Optionee ceases to maintain a Business Relationship with the Company shall terminate immediately and be of no further force or effect.

(ii) If the Optionee ceases to maintain a Business Relationship with the Company for any reason other than death or disability, any portion of this Stock Option

outstanding on such date may be exercised, to the extent exercisable on such date, for a period of three years from the date the Optionee ceased to maintain a Business Relationship with the Company or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date the Optionee ceases to maintain a Business Relationship with the Company shall terminate immediately and be of no further force or effect.

(iii) Notwithstanding the foregoing, if the Optionee, prior to the termination date of this Stock Option, (i) violates any provision of any confidentiality, consulting or other agreement between the Optionee and the Company, (ii) commits any felony or any crime involving moral turpitude under the laws of the United States or any state thereof, (iii) attempts to commit, or participate in, a fraud or act of dishonesty against the Company, or (iv) commits gross misconduct, the right to exercise this Stock Option shall terminate immediately upon written notice to the Optionee from the Company describing such violation or act.

4. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Stock Option shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

5. Transferability. This Agreement is personal to the Optionee, is non-assignable and is not transferable in any manner, by operation of law or otherwise, other than by will or the laws of descent and distribution. This Stock Option is exercisable, during the Optionee's lifetime, only by the Optionee, and thereafter, only by the Optionee's legal representative or legatee. Notwithstanding the foregoing, this Stock Option may be transferred pursuant to a domestic relations order.

6. No Obligation to Continue Service. Neither the Plan nor this Stock Option confers upon the Optionee any rights with respect to continued service as a member of the Board or to the Company.

7. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Stock Option and supersedes all prior agreements and discussions between the parties concerning such subject matter.

8. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the "Relevant Companies") may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of the Plan and/or this Agreement (the "Relevant Information"). By entering into this Agreement, the Optionee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Optionee may have with respect to the Relevant Information; (iii) authorizes the

Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Optionee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

9. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business to the attention of the Company's Treasurer and shall be mailed or delivered to the Optionee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

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**SIGNATURE PAGE TO AMAG PHARMACEUTICALS, INC.
NON-QUALIFIED STOCK OPTION AGREEMENT**

AMAG PHARMACEUTICALS, INC.

By: _____
Name: William K. Heiden
Title: President and Chief Executive Officer

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned, and the undersigned acknowledges receipt of a copy of this entire Agreement, a copy of the Plan, and a copy of the Plan's related prospectus. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Optionee (including through an online acceptance process) is acceptable.

Dated: _____
Optionee's Signature

Optionee's name and address:

**AMAG PHARMACEUTICALS, INC.
RESTRICTED STOCK UNIT AWARD AGREEMENT
FOR NON-EMPLOYEE DIRECTORS**

Name of Grantee: _____

No. of Restricted Stock Units: _____

Grant Date: _____

Pursuant to the AMAG Pharmaceuticals, Inc. Fourth Amended and Restated 2007 Equity Incentive Plan (the “Plan”), AMAG Pharmaceuticals, Inc. (the “Company”) hereby grants an award of the number of Restricted Stock Units listed above (an “Award”) to the Grantee named above. Each Restricted Stock Unit shall relate to one share of Common Stock, par value \$0.01 per share (the “Stock”) of the Company.

1. Restrictions on Transfer of Award. This Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of by the Grantee, and any shares of Stock issuable with respect to the Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of until (i) the Restricted Stock Units have vested as provided in Section 2 of this Agreement and (ii) shares of Stock have been issued to the Grantee in accordance with the terms of the Plan and this Agreement.

2. Vesting of Restricted Stock Units. The restrictions and conditions of Section 1 of this Agreement shall lapse on the Vesting Date or Dates specified in the following schedule so long as the Grantee maintains a Business Relationship with the Company (as defined below) on such Dates. If a series of Vesting Dates is specified, then the restrictions and conditions in Section 1 of this Agreement shall lapse only with respect to the number of Restricted Stock Units specified as vested on such date.

<u>Incremental Number of Restricted Stock Units Vested</u>	<u>Vesting Date</u>
[1/12 of [Number]]	June 1, 20XX
[1/12 of [Number]]	July 1, 20XX
[1/12 of [Number]]	August 1, 20XX
[1/12 of [Number]]	September 1, 20XX
[1/12 of [Number]]	October 1, 20XX
[1/12 of [Number]]	November 1, 20XX
[1/12 of [Number]]	December 1, 20XX
[1/12 of [Number]]	January 1, 20XX
[1/12 of [Number]]	February 1, 20XX
[1/12 of [Number]]	March 1, 20XX
[1/12 of [Number]]	April 1, 20XX
[1/12 of [Number]]	May 1, 20XX

The Administrator may at any time accelerate the vesting schedule specified in this Section 2.

“Business Relationship” means service to the Company or its successor in the capacity of an employee, officer, director, consultant, or advisor.

3. Termination of Business Relationship. If the Grantee ceases to maintain a Business Relationship with the Company for any reason (including death or disability) prior to the satisfaction of the vesting conditions set forth in Section 2 above, any Restricted Stock Units that have not vested as of such date shall automatically and without notice terminate and be forfeited, and neither the Grantee nor any of his or her successors, heirs, assigns, or personal representatives will thereafter have any further rights or interests in such unvested Restricted Stock Units.

4. Issuance of Shares of Stock. The Company shall issue to the Grantee, on the earlier of (a) the first anniversary of the Grant Date or (b) as soon as practicable (but not later than 90 days) following the date of termination of the Grantee’s service, provided that such termination constitutes a “separation from service” as such term is defined in Treasury Regulation Section 1.409A-1(h), (in either case, the “Delivery Date”), the number of shares of Stock equal to the aggregate number of Restricted Stock Units that have vested pursuant to Section 2 of this Agreement, provided that, if the Delivery Date shall occur during either a regularly scheduled or special “blackout period” of the Company wherein Grantee is precluded from selling shares of the Company’s Stock, the receipt of the shares of Stock pursuant to this Agreement shall be deferred until immediately after the expiration of such blackout period, unless such shares are covered by a previously established Company-approved 10b5-1 plan of the Grantee, in which case the shares shall be issued in accordance with the terms of such 10b5-1 plan. The shares the receipt of which was deferred as provided above shall be issued to the Grantee as soon as practicable after the expiration of the blackout period. Notwithstanding the above, in no event may the shares be issued to the Grantee later than the later of: (i) December 31st of the calendar year in which the Delivery Date occurs, or (ii) the 75th day following the Delivery Date; provided that the Grantee acknowledges and agrees that if the shares are issued to the Grantee pursuant to this sentence while either a regularly scheduled or special “blackout period” is still in effect with respect to the Company or the Grantee, neither the Company nor the Grantee may sell any shares of the Company’s Stock to satisfy any tax obligations except in compliance with the Company’s insider trading policies and requirements and applicable laws; provided further, that the Grantee acknowledges that the exact date of issuance of the shares shall be at the sole and exclusive discretion of the Company in accordance with this Section 4. The form of such issuance (*e.g.*, a stock certificate or electronic entry evidencing such shares) shall be determined by the Company. Upon such issuance, the Grantee shall thereafter have all the rights of a stockholder of the Company with respect to such shares.

5. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Agreement shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this

Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

6. Section 409A of the Code. The parties intend that this Award will be administered in accordance with Section 409A of the Code. To the extent that any provision of this Award is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments and provisions hereunder comply with Section 409A of the Code. Anything in this Agreement to the contrary notwithstanding, if at the time of the Grantee's separation from service within the meaning of Section 409A of the Code, the Company determines that the Grantee is a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent the shares of Stock that the Grantee becomes entitled to receive under this Agreement on account of the Grantee's separation from service would be considered deferred compensation otherwise subject to the 20 percent additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such shares of Stock shall not be issued until the date that is the earlier of (a) six months and one day after the Grantee's separation from service, or (b) the Grantee's death. The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h).

7. No Obligation to Continue Service. Neither the Plan nor this Award confers upon the Grantee any rights with respect to continued service as a member of the Board or to the Company.

8. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Award and supersedes all prior agreements and discussions between the parties concerning such subject matter.

9. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the "Relevant Companies") may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of the Plan and/or this Agreement (the "Relevant Information"). By entering into this Agreement, the Grantee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Grantee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Grantee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

10. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business to the attention of the Treasurer of the Company and shall be mailed or delivered to the Grantee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

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**SIGNATURE PAGE TO AMAG PHARMACEUTICALS, INC.
RESTRICTED STOCK UNIT AWARD AGREEMENT**

AMAG PHARMACEUTICALS, INC.

By: _____
Name: William K. Heiden
Title: President and Chief Executive Officer

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned, and the undersigned acknowledges receipt of a copy of this entire Agreement, a copy of the Plan, and a copy of the Plan's related prospectus. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Grantee (including through an online acceptance process) is acceptable.

Dated: _____

Grantee's Signature

Grantee's name and address:

**AMAG PHARMACEUTICALS, INC.
NON-QUALIFIED STOCK OPTION AGREEMENT
NON-PLAN INDUCEMENT GRANT**

Name of Optionee:

No. of Option Shares:

Option Exercise Price per Share:

\$ _____

[FMV on Grant Date]

Grant Date:

Expiration Date:

AMAG Pharmaceuticals, Inc. (the "Company") hereby grants to the Optionee named above an option (the "Stock Option") to purchase on or prior to the Expiration Date specified above all or part of the number of shares of Common Stock, par value \$0.01 per share (the "Stock") of the Company specified above at the Option Exercise Price per Share specified above, as an inducement grant made pursuant to Rule 5635(c)(4) of the NASDAQ Listing Rules subject to the terms and conditions set forth herein and in the Plan. For the avoidance of doubt, this Stock Option is not issued under the Company's Fourth Amended and Restated 2007 Equity Incentive Plan, as amended through the date hereof (the "Plan") and does not reduce the share reserve under the Plan. However, for purposes of interpreting the applicable provisions of this Stock Option, the terms and conditions of the Plan (other than those applicable to the share reserve) shall govern and apply to this Stock Option as if such Stock Option had actually been issued under the Plan. This Stock Option is not intended to be an "incentive stock option" under Section 422 of the Internal Revenue Code of 1986, as amended.

1. Exercisability Schedule. No portion of this Stock Option may be exercised until such portion shall have become exercisable. Except as set forth below, and subject to the discretion of the Administrator (as defined in Section 2 of the Plan) to accelerate the exercisability schedule hereunder, this Stock Option shall be exercisable with respect to the following number of Option Shares on the dates indicated so long as the Optionee remains in a Business Relationship (as defined in Section 3 below) on such dates:

Incremental Number of
Option Shares Exercisable

Exercisability Date

_____ (___%)
_____ (___%)
_____ (___%)
_____ (___%)

Once exercisable, this Stock Option shall continue to be exercisable at any time or times prior to the close of business on the Expiration Date, subject to the provisions hereof and of the Plan.

2. Manner of Exercise.

(a) The Optionee may exercise this Stock Option only in the following manner: from time to time on or prior to the Expiration Date of this Stock Option, the Optionee may give written or electronic notice to the Company to the attention of the Company's Treasurer or his or her designee of his or her election to purchase some or all of the Option Shares purchasable at the time of such notice. This notice shall specify the number of Option Shares to be purchased.

Payment of the purchase price for the Option Shares may be made by one or more of the following methods: (i) in cash, by certified or bank check or other instrument acceptable to the Company; (ii) subject to the Company's approval, through the delivery (or attestation to the ownership) of shares of Stock that have been purchased by the Optionee on the open market or that are beneficially owned by the Optionee and are not then subject to any restrictions under any Company plan and that otherwise satisfy any holding periods as may be required by the Administrator; (iii) by the Optionee delivering to the Company a properly executed exercise notice together with irrevocable instructions to a broker to promptly deliver to the Company cash or a check payable and acceptable to the Company to pay the option purchase price, provided that in the event the Optionee chooses to pay the option purchase price as so provided, the Optionee and the broker shall comply with such procedures and enter into such agreements of indemnity and other agreements as the Company shall prescribe as a condition of such payment procedure; or (iv) a combination of (i), (ii) and (iii) above. Payment instruments will be received subject to collection.

The transfer to the Optionee on the records of the Company or of the transfer agent of the Option Shares will be contingent upon (i) the Company's receipt from the Optionee of the full purchase price for the Option Shares, as set forth above, (ii) the fulfillment of any other requirements contained herein or in the Plan or in any other agreement or provision of laws, and (iii) the receipt by the Company of any agreement, statement or other evidence that the Company may require to satisfy itself that the issuance of Stock to be purchased pursuant to the exercise of Stock Options under the Plan and any subsequent resale of the shares of Stock will be in compliance with applicable laws and regulations. In the event the Optionee chooses to pay the purchase price by previously-owned shares of Stock through the attestation method, the number

of shares of Stock transferred to the Optionee upon the exercise of the Stock Option shall be net of the Shares attested to.

(b) The shares of Stock purchased upon exercise of this Stock Option shall be transferred to the Optionee on the records of the Company or of the transfer agent upon compliance to the satisfaction of the Company with all requirements under applicable laws or regulations in connection with such transfer and with the requirements hereof and of the Plan. The determination of the Company as to such compliance shall be final and binding on the Optionee. The Optionee shall not be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Stock subject to this Stock Option unless and until this Stock Option shall have been exercised pursuant to the terms hereof, the Company or the transfer agent shall have transferred the shares to the Optionee, and the Optionee's name shall have been entered as the stockholder of record on the books of the Company. Thereupon, the Optionee shall have full voting, dividend and other ownership rights with respect to such shares of Stock.

(c) Notwithstanding any other provision hereof or of the Plan, no portion of this Stock Option shall be exercisable after the Expiration Date hereof.

(d) Without derogating from the foregoing, "statutory option stock" (as defined below) may be tendered in payment of the exercise price of this Stock Option even if the stock to be so tendered has not, at the time of tender, been held by the Optionee for the applicable minimum statutory holding period required to receive the tax benefits afforded under Section 421(a) of the Code with respect to such stock. The Optionee acknowledges that the tender of such "statutory option stock" may have adverse tax consequences to the Optionee. As used above, the term "statutory option stock" means stock acquired through the exercise of an incentive stock option or an option granted under an employee stock purchase plan. The tender of statutory option stock in payment of the exercise price of this Option shall be accompanied by written representation (in form satisfactory to the Company) stating whether such stock has been held by the Optionee for the applicable minimum statutory holding period.

3. Termination of Business Relationship.

(a) If the Optionee's Business Relationship (as defined below) is terminated, the period within which to exercise the Stock Option may be subject to earlier termination as follows:

(i) If the Optionee's Business Relationship is terminated by reason of the Optionee's death or disability (as determined by the Company) or, if the Optionee dies or becomes disabled within the three-month period following the date the Optionee's Business Relationship terminates for any other reason, any portion of this Stock Option outstanding on the date of termination, may be exercised, to the extent exercisable on such date, for a period of twelve months from the date of death or disability or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date the Optionee's Business Relationship is terminated shall terminate immediately and be of no further force or effect.

(ii) If the Optionee's Business Relationship is terminated for any reason other than death or disability, any portion of this Stock Option outstanding on such date may be exercised, to the extent exercisable on the date of termination, for a period of three months from the date of termination or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date the Optionee's Business Relationship is terminated shall terminate immediately and be of no further force or effect.

(iii) Notwithstanding the foregoing, if the Optionee, prior to the termination date of this Stock Option, (i) violates any provision of any employment agreement or any confidentiality or other agreement between the Optionee and the Company, (ii) commits any felony or any crime involving moral turpitude under the laws of the United States or any state thereof, (iii) attempts to commit, or participate in, a fraud or act of dishonesty against the Company, or (iv) commits gross misconduct, the right to exercise this Stock Option shall terminate immediately upon written notice to the Optionee from the Company describing such violation or act.

The Company's determination of the reason for termination of the Optionee's Business Relationship shall be conclusive and binding on the Optionee and his or her representatives or legatees. Notwithstanding the foregoing, under certain circumstances set forth in the Employment Agreement dated as of [] by and between the Company and the Optionee (the "Employment Agreement"), and subject to compliance by the Optionee with the requirements of the Employment Agreement related to such circumstances, the vesting of the unvested portion of this Stock Option may be accelerated as provided in and subject to the terms of the Employment Agreement.

(b) For purposes hereof, "Business Relationship" means service to the Company or any of its Subsidiaries, or its or their successors, in the capacity of an employee, officer, director, consultant or advisor. For purposes hereof, a Business Relationship shall not be considered as having terminated during any military leave, sick leave, or other leave of absence if approved in writing by the Company and if such written approval, or applicable law, contractually obligates the Company to continue the Business Relationship of the Optionee after the approved period of absence (an "Approved Leave of Absence"). For purposes hereof, a Business Relationship shall include a consulting arrangement between the Optionee and the Company that immediately follows termination of employment, but only if so stated in a written consulting agreement executed by the Company.

4. Incorporation of Plan. As stated above, this Stock Option is not granted pursuant to the Plan. Instead, this Stock Option is granted as an inducement grant pursuant to Rule 5635(c)(4) of the NASDAQ Listing Rules. However, for purposes of interpreting the application provisions of this Stock Option, the terms and conditions of the Plan (other than those applicable to the share reserve), including the powers of the Administrator set forth in Section 2(b), shall govern and apply to this Stock Option as if such Stock Option had actually been issued under the

Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

5. Transferability. This Agreement is personal to the Optionee, is non-assignable and is not transferable in any manner, by operation of law or otherwise, other than by will or the laws of descent and distribution. This Stock Option is exercisable, during the Optionee's lifetime, only by the Optionee, and thereafter, only by the Optionee's legal representative or legatee. Notwithstanding the foregoing, this Stock Option may be transferred pursuant to a domestic relations order.

6. Tax Withholding. The Optionee shall, not later than the date as of which the exercise of this Stock Option becomes a taxable event for Federal income tax purposes, pay to the Company or make arrangements satisfactory to the Company for payment of any Federal, state, and local taxes required by law to be withheld on account of such taxable event. The Company shall have the authority to cause the required tax withholding obligation to be satisfied, in whole or in part, by withholding from shares of Stock to be issued to the Optionee a number of shares of Stock with an aggregate Fair Market Value that would satisfy the withholding amount due; provided, however, that the amount withheld does not exceed the maximum tax rate, or such lesser amount as determined by the Administrator.

7. No Obligation to Continue Business Relationship. Neither the Company nor any Subsidiary is obligated by or as a result of the Plan or this Agreement to continue the Optionee's Business Relationship, and neither the Plan nor this Agreement shall interfere in any way with the right of the Company or any Subsidiary to terminate the Business Relationship of the Optionee at any time.

8. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Stock Option and supersedes all prior agreements and discussions between the parties concerning such subject matter.

9. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the "Relevant Companies") may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of the Plan and/or this Agreement (the "Relevant Information"). By entering into this Agreement, the Optionee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Optionee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Optionee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

10. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business to the attention of the Company's Treasurer and shall be mailed or delivered to the Optionee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

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**SIGNATURE PAGE TO AMAG PHARMACEUTICALS, INC.
NON-QUALIFIED STOCK OPTION AGREEMENT**

AMAG PHARMACEUTICALS, INC.

By: _____
Name: William K. Heiden
Title: President and Chief Executive Officer

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned, and the undersigned acknowledges receipt of a copy of this entire Agreement, a copy of the Plan, and a copy of the Plan's related prospectus. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Optionee (including through an online acceptance process) is acceptable.

Dated: _____
Optionee's Signature

Optionee's name and address:

**AMAG PHARMACEUTICALS, INC.
RESTRICTED STOCK UNIT AWARD AGREEMENT
NON-PLAN INDUCEMENT GRANT**

Name of Grantee: _____

No. of Restricted Stock Units: _____

Grant Date: _____

AMAG Pharmaceuticals, Inc. (the “Company”) hereby grants an award of the number of Restricted Stock Units listed above (an “Award”) to the Grantee named above, as an inducement grant made pursuant to Rule 5635(c)(4) of the NASDAQ Listing Rules. Each Restricted Stock Unit shall relate to one share of Common Stock, par value \$0.01 per share (the “Stock”) of the Company. For the avoidance of doubt, this Award is not issued under the Company’s Fourth Amended and Restated 2007 Equity Incentive Plan, as amended through the date hereof (the “Plan”) and does not reduce the share reserve under the Plan. However, for purposes of interpreting the applicable provisions of this Award, the terms and conditions of the Plan (other than those applicable to the share reserve) shall govern and apply to this Award as if such Award had actually been issued under the Plan.

1. Restrictions on Transfer of Award. This Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of by the Grantee, and any shares of Stock issuable with respect to the Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of until (i) the Restricted Stock Units have vested as provided in Section 2 of this Agreement and (ii) shares of Stock have been issued to the Grantee in accordance with the terms of the Plan and this Agreement.

2. Vesting of Restricted Stock Units. The restrictions and conditions of Section 1 of this Agreement shall lapse on the Vesting Date or Dates specified in the following schedule so long as the Grantee remains in a Business Relationship (as defined in Section 3 below) on such Dates. If a series of Vesting Dates is specified, then the restrictions and conditions in Section 1 shall lapse only with respect to the number of Restricted Stock Units specified as vested on such date.

<u>Incremental Number of Restricted Stock Units Vested</u>	<u>Vesting Date</u>
_____ (___ %)	_____
_____ (___ %)	_____
_____ (___ %)	_____

The Administrator may at any time accelerate the vesting schedule specified in this Section 2.

3. Termination of Business Relationship.

(a) If the Grantee's Business Relationship terminates for any reason (including death or disability) prior to the satisfaction of the vesting conditions set forth in Section 2 above, any Restricted Stock Units that have not vested as of such date shall automatically and without notice terminate and be forfeited, and neither the Grantee nor any of his or her successors, heirs, assigns, or personal representatives will thereafter have any further rights or interests in such unvested Restricted Stock Units. Notwithstanding the foregoing, under certain circumstances set forth in the Employment Agreement dated as of [] by and between the Company and the Grantee (the "Employment Agreement"), and subject to compliance by the Grantee with the requirements of the Employment Agreement related to such circumstances, the vesting of unvested Restricted Stock Units may be accelerated as provided in and subject to the terms of the Employment Agreement.

(b) "Business Relationship" means service to the Company or any of its Subsidiaries, or its or their successors, in the capacity of an employee, officer, director, consultant or advisor. For purposes hereof, a Business Relationship shall not be considered as having terminated during any military leave, sick leave, or other leave of absence if approved in writing by the Company and if such written approval, or applicable law, contractually obligates the Company to continue the Business Relationship of the Grantee after the approved period of absence (an "Approved Leave of Absence"). For purposes hereof, a Business Relationship shall include a consulting arrangement between the Grantee and the Company that immediately follows termination of employment, but only if so stated in a written consulting agreement executed by the Company.

4. Issuance of Shares of Stock. As soon as practicable following each Vesting Date, the Company shall issue to the Grantee the number of shares of Stock equal to the aggregate number of Restricted Stock Units that have vested pursuant to Section 2 of this Agreement on such date and the Grantee shall thereafter have all the rights of a stockholder of the Company with respect to such shares; provided, however, if a Vesting Date shall occur during either a regularly scheduled or special "blackout period" wherein the Grantee is precluded from selling shares of Stock, the receipt of the corresponding underlying shares issuable with respect to such Vesting Date pursuant to this Agreement shall be deferred until after the expiration of such blackout period unless such underlying shares are covered by a previously established Company-approved 10b5-1 plan of the Grantee, in which case the underlying shares shall be issued in accordance with the terms of such 10b5-1 plan; provided, however, that the issuance of such shares shall not be deferred any later than the later of: (a) December 31st of the calendar year in which such vesting occurs, or (b) the 15th day of the third calendar month following such vesting date, and if such settlement occurs while either a regularly scheduled or special "blackout period" is still in effect, neither the Company nor the Grantee may sell any shares issued in settlement thereof to satisfy any tax or withholding obligations except in compliance with the Company's Statement of Company Policy Regarding Insider Training and other applicable requirements and laws.

5. Incorporation of Plan. As stated above, this Award is not granted pursuant to the Plan. Instead, this Award is granted as an inducement grant pursuant to Rule 5635(c)(4) of the

NASDAQ Listing Rules. However, for purposes of interpreting the application provisions of this Award, the terms and conditions of the Plan (other than those applicable to the share reserve), including the powers of the Administrator set forth in Section 2(b), shall govern and apply to this Award as if such Award had actually been issued under the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

6. Tax Withholding. The Grantee shall, not later than the date as of which the receipt of this Award becomes a taxable event for Federal income tax purposes, pay to the Company or make arrangements satisfactory to the Company for payment of any Federal, state, and local taxes required by law to be withheld on account of such taxable event. The Company shall have the authority to cause the required tax withholding obligation to be satisfied, in whole or in part, by withholding from shares of Stock to be issued to the Grantee a number of shares of Stock with an aggregate Fair Market Value that would satisfy the withholding amount due; provided, however, that the amount withheld does not exceed the maximum tax rate, or such lesser amount as determined by the Administrator.

7. Section 409A of the Code. This Agreement shall be interpreted in such a manner that all provisions relating to the settlement of the Award are exempt from the requirements of Section 409A of the Code as “short-term deferrals” as described in Section 409A of the Code.

8. No Obligation to Continue Business Relationship. Neither the Company nor any Subsidiary is obligated by or as a result of the Plan or this Agreement to continue the Grantee’s Business Relationship, and neither the Plan nor this Agreement shall interfere in any way with the right of the Company or any Subsidiary to terminate the Business Relationship of the Grantee at any time.

9. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Award and supersedes all prior agreements and discussions between the parties concerning such subject matter.

10. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the “Relevant Companies”) may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of the Plan and/or this Agreement (the “Relevant Information”). By entering into this Agreement, the Grantee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Grantee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Grantee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

11. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business to the attention of the Company's Treasurer and shall be mailed or delivered to the Grantee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

**SIGNATURE PAGE TO AMAG PHARMACEUTICALS, INC.
RESTRICTED STOCK UNIT AWARD AGREEMENT**

AMAG PHARMACEUTICALS, INC.

By: _____
Name: William K. Heiden
Title: President and Chief Executive Officer

The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned, and the undersigned acknowledges receipt of a copy of this entire Agreement, a copy of the Plan, and a copy of the Plan's related prospectus. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Grantee (including through an online acceptance process) is acceptable.

Dated: _____

Grantee's Signature

Grantee's name and address:

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

Drugtech Sàrl, a Swiss company

Lumara Health Services Ltd., a Missouri corporation

CBR Acquisition Holdings Corp., a Delaware corporation

Cbr Systems, Inc., a Delaware corporation

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. 333-131656, 333-148682, 333-159938, 333-168786, 333-182821, 333-190435, 333-197873, 333-203924, 333-211277 and 333-218911) of AMAG Pharmaceuticals, Inc. of our report dated February 28, 2018 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 28, 2018

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 28, 2018

/s/ William K. Heiden

William K. Heiden
President and Chief Executive Officer
(Principal Executive Officer)

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 28, 2018

/s/ Edward Myles

Edward Myles

Executive Vice President of Finance, Chief Financial Officer and Treasurer
(Principal Financial Officer)

**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, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, William K. Heiden, President and 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

President and Chief Executive Officer

(Principal Executive Officer)

February 28, 2018

**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, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Edward Myles, Executive 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

Executive Vice President of Finance, Chief Financial Officer and Treasurer
(Principal Financial Officer)

February 28, 2018
