Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended December 31, 2015

or

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

For the transition period from to

Commission file number 001-10865

AMAG Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation or Organization)	**04-2742593** (I.R.S. Employer Identification No.)
1100 Winter Street **Waltham, Massachusetts** (Address of Principal Executive Offices)	**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, or a smaller reporting company. See definition of "accelerated filer," "large accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☒	Accelerated filer ☐	Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller Reporting Company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). **Yes ☐ No ☒**

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

DOCUMENTS INCORPORATED BY REFERENCE

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

AMAG PHARMACEUTICALS, INC.
FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2015
TABLE OF CONTENTS

PART I

Item 1.	Business	2
Item 1A.	Risk Factors	31
Item 1B.	Unresolved Staff Comments	63
Item 2.	Properties	64
Item 3.	Legal Proceedings	64
Item 4.	Mine Safety Disclosures	64

PART II

Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	65
Item 6.	Selected Financial Data	67
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	69
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	98
Item 8.	Financial Statements and Supplementary Data	100
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	156
Item 9A.	Controls and Procedures	156
Item 9B.	Other Information	156

PART III

Item 10.	Directors, Executive Officers and Corporate Governance	157
Item 11.	Executive Compensation	157
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	157
Item 13.	Certain Relationships and Related Transactions, and Director Independence	157
Item 14.	Principal Accountant Fees and Services	157

PART IV

Item 15.	Exhibits and Financial Statement Schedules	158
	Signatures	164

PART I

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

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

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

ITEM 1. BUSINESS:

Overview

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

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

Products and Services

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

Product or Service	Uses/Potential Uses	U.S. Regulatory Status	Nature of Rights to Product or Service
Makena® (hydroxyprogesterone caproate injection) (5 mL multidose vial)	A progestin indicated to reduce the risk of preterm birth in women pregnant with a single baby who have a history of singleton spontaneous preterm birth.	Approved and marketed.	Own worldwide rights.
Makena® (hydroxyprogesterone caproate injection) (1 mL single-dose vial)	A progestin indicated to reduce the risk of preterm birth in women pregnant with a single baby who have a history of singleton spontaneous preterm birth.	Prior approval supplement for Hospira, Inc. ("Hospira") approved February 2016. Prior approval supplement submitted to the FDA in October 2014 for Coldstream Laboratories, Inc. ("Coldstream"). Working with Coldstream to respond to complete response letter.	Own worldwide rights.
Makena® (hydroxyprogesterone caproate injection) (Auto-injector device)	An auto-injector device for subcutaneous administration of *Makena*.	Supplemental new drug application ("sNDA") expected to be filed in the first quarter of 2017.	Own worldwide rights to drug product; exclusively license rights to auto-injector device from Antares Pharma, Inc. ("Antares").
Feraheme® (ferumoxytol)	IV iron replacement therapeutic agent for the treatment of iron deficiency anemia ("IDA") in adult patients with chronic kidney disease ("CKD").	Approved and marketed.	Own worldwide rights.
Feraheme® (ferumoxytol)	IV iron replacement therapeutic agent for the treatment of patients with a history of unsatisfactory oral iron therapy or in whom oral iron cannot be used.	sNDA filed December 2012. Phase 3 clinical trial to be initiated in the first quarter of 2016.	Own worldwide rights.
MuGard® Mucoadhesive Oral Wound Rinse	Management of oral mucositis/stomatitis and all types of oral wounds.	Cleared and marketed.	Exclusively license rights to develop and sell MuGard in the U.S. from Abeona Therapeutics, Inc. ("Abeona").
Digoxin immune fab	A polyclonal antibody for the treatment of severe preeclampsia in pregnant women.	In clinical development.	Own option to obtain exclusive license from Velo Bio LLC ("Velo") to U.S. rights upon completion of Phase 2b/3a development.
Cord Blood Registry®	Services related to the collection, processing and storage of umbilical cord blood and cord tissue units.	Privately banked umbilical cord blood stem cells and cord tissue are regulated by the FDA in the U.S. (no prior approval needed). Facilities are inspected by the FDA.	Services are marketed and sold primarily in the U.S. and we have certain commercial agreements in Chili, Mexico and the Dominican Republic.

Makena

Overview

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

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

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

Preterm Birth

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

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

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

Post-Approval Commitments for Makena

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

Next Generation Development Programs

To enhance the product profile of *Makena* for patients and their healthcare providers, we are pursuing a next generation development program for *Makena*, including new routes of administration and the use of new delivery technologies, as well as reformulation technologies, some elements of which could provide new intellectual property or data exclusivity beyond February 2018. As part of this program, in July 2015, we filed a prior approval supplement to the original *Makena* New Drug Application ("NDA") with the FDA seeking approval of Hospira, our current manufacturer of the multidose vial, to be approved to manufacture the single-dose preservative-free formulation of *Makena*. In February 2016, the prior approval supplement for Hospira was approved. In addition, in October 2014, we filed a prior approval supplement to the original *Makena* NDA with the FDA seeking approval of a single-dose preservative-free formulation of *Makena* to be manufactured by Coldstream. In May 2015, we received a complete response letter from the FDA for the Coldstream prior approval supplement requesting additional information related to manufacturing procedures for the single-dose preservative-free formulation and we are currently working with Coldstream to develop the required information requested by the FDA in the complete response letter in order to provide a response to the FDA. In light of the recent approval of the Hospira prior approval supplement, we are planning for a commercial launch of the single-dose preservative-free formulation in the second quarter of 2016. *Makena* is currently available in a 5-dose (5 mL) vial.

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

CBR Services

Overview

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

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

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

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

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

Cord Blood and Cord Tissue

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

***Feraheme* for the treatment of IDA in patients with CKD**

Overview

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

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

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

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

On February 5, 2016, we received a Paragraph IV certification notice letter regarding an Abbreviated New Drug Application (an "ANDA") submitted to the FDA by Sandoz Inc. ("Sandoz") requesting approval to engage in commercial manufacture, use and sale of a generic version of ferumoxytol. A generic version of *Feraheme* can be marketed only with the approval of the FDA of the respective application for such generic version. The Drug Price Competition and Patent Term Restoration Act of 1984, as amended (the "Hatch-Waxman Act") requires an applicant whose subject drug is a drug listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," also known as the "Orange Book," to notify the patent-holder of their application and potential infringement of their patent rights. The Paragraph IV certification notice is required to contain a detailed factual and legal statement explaining the basis for the applicant's opinion that the proposed product does not infringe the subject patents, that such patents are invalid, or both. Receipt of the certification notice triggers a 45 day window during which we may bring a patent infringement suit in federal district court against the applicant seeking approval of a product. In its notice letter, Sandoz claims that our ferumoxytol patents are invalid, unenforceable and/or not infringed by Sandoz's manufacture, use, sale or offer for sale of the generic version. We are evaluating the notice letter and intend to vigorously enforce our intellectual property rights relating to ferumoxytol. We plan to initiate a patent infringement suit to defend the patents identified in the notice letter. If we were to commence such a suit, the FDA is generally prohibited from granting approval of an application until the earliest of 30 months from the date the FDA accepted the application for filing, the conclusion of litigation in the generic's favor, or expiration of the patent(s) (though such stay may be shortened or lengthened if either party fails to cooperate in the litigation). If the litigation is resolved in favor of the applicant or the challenged patent expires during the 30-month stay period, the stay is lifted and the FDA may thereafter

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

Chronic kidney disease, anemia, and iron deficiency

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

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

Post-Marketing Commitments of Feraheme in CKD

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

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

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

Overview

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

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

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

MuGard

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

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

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

Recent Financings

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

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

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

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

Collaboration, License and Other Strategic Agreements

Velo

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

Antares

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

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

Abeona

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

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

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

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

Takeda

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

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

Manufacturing

Overview

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

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

Makena

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

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

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

Feraheme

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

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

Raw Materials

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

Patents, Trademarks and Trade Secrets

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

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

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

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

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

Competition

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

Makena

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

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

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

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

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

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

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

CBR Services

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

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

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

Feraheme

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

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

- Venofer®, an iron sucrose complex, which is approved for use in hemodialysis, peritoneal dialysis, non-dialysis dependent CKD patients and pediatric CKD patients and is marketed in the U.S. by Fresenius Medical Care North America and American Regent Laboratories, Inc. ("American Regent"), a subsidiary of Luitpold Pharmaceuticals, Inc. Venofer® is typically administered as a slow intravenous injection over two to five minutes in doses of 100 to 200 milligrams, thus requiring five to ten physician visits to reach a standard one gram therapeutic course;

- Injectafer®, a ferric carboxymaltose injection, was approved in the U.S. in July 2013 to treat IDA in adult patients who have intolerance to oral iron or have had an unsatisfactory response to oral iron. Injectafer® is also indicated for IDA in adult patients with non-dialysis dependent CKD. Injectafer® is marketed in the U.S. by American Regent, the same distributor of Venofer®. The labeled administration of Injectafer® is two slow injections or infusion of 750 milligrams each separated by at least seven days for a total cumulative dose of 1,500 milligrams, or one and a half grams per therapeutic course;

- Ferrlecit®, a sodium ferric gluconate, which is marketed by Sanofi-Aventis U.S. LLC, is approved for use only in hemodialysis patients. The recommended dose of Ferrlecit® and the generic version of Ferrlecit® is 125 milligrams administered by intravenous infusion over one hour per dialysis session or undiluted as a slow intravenous injection per dialysis session, thus requiring eight physician visits to reach a standard one gram therapeutic course;

- A generic version of Ferrlecit® marketed by Teva Pharmaceuticals, Inc.; and

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

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

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

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

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

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

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

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

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

MuGard

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

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

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

Sales, Marketing and Distribution

Makena

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

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

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

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

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

CBR Services

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

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

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

Feraheme

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

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

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

MuGard

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

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

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

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

Product Supply Chain

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

Major Customers

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

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

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

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

Government Regulation

Overview

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

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

Pharmaceutical Product Approval Process

Clinical Development

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

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

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

Submission and FDA Review of NDAs/sNDAs

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

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

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

Abbreviated New Drug Application

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

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

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

Adverse Event Reporting

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

FDA Post-Approval Requirements

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

FDA Regulation of our Products and Services

FDA Regulation of Product Marketing and Promotion

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

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

FDA Regulation of Manufacturing Facilities

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

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

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

Orphan Drug Exclusivity

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

Drug Quality and Security Act

In November 2013, the DQSA legislation was implemented to amend the FDC Act with respect to the regulation and monitoring of the manufacturing of compounding drugs. Among other provisions of the DQSA, compounding pharmacies may now elect to register as an "outsourcing facility" under FDC Act 503B. Registration as an outsourcing facility requires that drugs be compounded according to cGMP standards; that facilities report adverse events to the FDA; and that facilities be subject to a risk-based inspection schedule, among other requirements. Additionally, FDC Act 503A describes the conditions that must be satisfied for drug products compounded by a licensed pharmacist or licensed physician to be exempt from approval, labeling, and cGMP requirements. To qualify for these exemptions, a compounded drug product must, among other things, be compounded for an identified patient based on a valid prescription or in limited quantities before the receipt of a prescription for such individual patient in certain circumstances. Under both 503A and 503B of the FDC Act, compounding pharmacies may not compound regularly or in inordinate amounts any drug products that are "essentially copies of commercially available drug products."

Fraud and Abuse Regulation

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

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

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

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

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

Other U.S. Regulatory Requirements

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

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

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

Regulation of Cord Blood and Cord Tissue Banking

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

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

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

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

Medical Device Regulation

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

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

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

Pharmaceutical Pricing and Reimbursement

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Backlog

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

Employees

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

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

Foreign Operations

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

Research and Development

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

Segment Reporting

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

Code of Ethics

Our Board of Directors has adopted a code of ethics that applies to our officers, directors and employees. We have posted the text of our code of ethics on our website at *http://www.amagpharma.com* in the "Investors" section. We will provide to any person without charge a copy of such code of ethics, upon request in writing to Investor Relations, AMAG Pharmaceuticals, Inc., 1100 Winter Street, Waltham, MA 02451. In addition, should any changes be made to our code of ethics, we intend to disclose within four business days on our website (or in any other medium required by law or the NASDAQ): (a) the date and nature of any amendment to our code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (b) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver, and the date of the waiver.

Available Information

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

ITEM 1A. RISK FACTORS:

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

Risks Related to Our Products and Services

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

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

- Actual or perceived safety or efficacy issues;
- Restrictions on current or future labels or other regulatory actions;
- The introduction or greater acceptance of competing products or services, including generic products, products that may be prescribed off-label (i.e., outside of indications approved by the U.S. Food and Drug Administration (the "FDA")), products made by compounding pharmacies or cryopreservation services offered by other cord blood banks;
- Change in consumers' perception of the value of the cryopreservation of cord blood and/or cord tissue;
- Constraints on product or service pricing or the impact of price increases;
- The success of our commercialization efforts, such as our ability to retain or grow our current customer base, realize the benefit of our current orphan drug exclusivity and successfully implement our next generation development programs; and
- Changes in reimbursement policies or adverse regulatory or legislative developments.

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

- Requiring us to conduct post-approval clinical studies to assess known risks or new signals of serious risks, or to evaluate unexpected serious risks;
- Mandating changes to a product's label;
- Requiring us to implement a risk evaluation and mitigation strategy ("REMS") where necessary to assure safe use of the drug; or
- Removing an already approved product from the market.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Further, we and our third-party product manufacturers currently purchase certain raw and other materials used to manufacture our products from third-party suppliers and, at present, do not have long-term supply contracts with most of these third parties. These third-party suppliers may cease to produce the raw or other materials used in *Feraheme* and *Makena* or otherwise fail to supply these materials to us or our third-party manufacturers or fail to supply sufficient quantities of these materials to us or our third-party manufacturers in a timely manner for a number of reasons, including but not limited to the following:

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

- Lack of sufficient quantities or profit on the production of raw materials to interest suppliers;
- Labor disputes or shortages; or
- Import or export problems.

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

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

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

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

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

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

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

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

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

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

In addition, the U.S. government continues to propose and pass legislation designed to reduce the cost of healthcare for patients. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "Healthcare Reform Act") includes certain cost containment measures including an increase to the minimum rebates for products covered by Medicaid programs, the extension of such rebates to drugs dispensed to Medicaid beneficiaries enrolled in Medicaid managed care organizations and the expansion of the 340B Drug pricing Program under the Public Health Services Act. In addition, federal budgetary concerns could result in the implementation of significant federal spending cuts, including cuts in Medicare and other health related spending in the near-term. The magnitude of the impact of these laws on our business is uncertain. Further, in recent years, some states have also passed legislation to control the prices of drugs as well as begun a move toward managed care to relieve some of their Medicaid cost burden. Given that almost half of *Makena* patients are Medicaid beneficiaries, the impact of future legislative changes may have a significant and adverse impact on *Makena* sales. Further, while Medicare is the predominant payer for *Feraheme*, Medicare payment policy, in time, can also influence pricing and reimbursement in the non-Medicare markets, as private third-party payers and state Medicaid plans frequently adopt Medicare principles in setting reimbursement methodologies. These and any future changes in government regulation or private third-party payers' reimbursement policies may reduce the extent of reimbursement for our products and adversely affect our future operating results.

Risks Related to *Makena*

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

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

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

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

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

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

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

- The size of the pool of patients who meet the FDA-approved indication for *Makena;*
- The actual or perceived safety and efficacy of *Makena*;
- Our ability to increase patient compliance in line with the current label;
- Our ability to gain or maintain insurance coverage for *Makena* for patients through both commercial insurance companies and government programs such as Medicaid, and that such insurance coverage does not create difficulties for physicians or patients to gain access to *Makena*, such as through prior authorizations to non-preferred status on hospital or insurance formularies; and
- Our ability to successfully leverage our commercial organization and distribution networks in marketing, selling and supplying *Makena.*

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

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

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

For example, we are working to develop an auto-injector device for subcutaneous administration of *Makena* (the "auto-injector"), which could possibly provide *Makena* with additional exclusivity through the combination of potential additional orphan drug exclusivity and patent protection on the new dosing, route of administration and auto-injector. Although our current timelines anticipate a launch of the auto-injector prior to the loss of current exclusivity in February 2018, this is only an estimate and we can make no assurances that the development work necessary to obtain approval, including the results of planned bioequivalence clinical studies, will yield the anticipated results, or that the FDA will approve the auto-injector on the expected timelines or at all. Further, we can make no assurances that clinical data or other information that we generate or submit will be adequate for the FDA to grant new orphan drug exclusivity for the auto-injector. The degree of protection afforded by any intellectual property that we may in-license or develop may not enable us to protect or commercially exploit the auto-injector technology, providing us with little or no competitive advantage. In addition, there is a risk that others may circumvent any patents licensed or issued to us relating to the auto-injector, including any intellectual property covering the injector device, or that another company may develop a product that circumvents any new orphan drug exclusivity.

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

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

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

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

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

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

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

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

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

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

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

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

Makena was approved by the FDA in February 2011 under the provisions of the FDA's "Subpart H" Accelerated Approval regulations. As a condition of approval under Subpart H, the FDA required that *Makena*'s sponsor perform certain adequate and well-controlled post-marketing clinical studies to verify and describe the clinical benefits of *Makena* as well as fulfill certain other post-approval commitments. Given the patient population (i.e., women pregnant and at an increased high risk for recurrent preterm delivery based on their pregnancy history) and the informed risk of receiving a placebo instead of the active approved drug, the pool of prospective subjects for such clinical trials in the U.S. is small, and we have therefore sought enrollment on a global scale. These factors make the enrollment process slow, difficult, time-consuming and costly. If the required post-marketing studies fail to verify the clinical benefits of the drug, if a sufficient number of participants cannot be enrolled, or if we fail to perform the required post-marketing studies with due diligence, the FDA has the authority to withdraw approval of the drug following a hearing conducted under the FDA's regulations, which would have a materially adverse impact on our business. We cannot be certain of the results of the confirmatory clinical studies or what action the FDA may take if the results of those studies are not as expected based on clinical data that FDA has already reviewed or if such studies are not completed in a timely manner.

Risks Related to CBR

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to *Feraheme*

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

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

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

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

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

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

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

Efforts to pursue a broader indication could also have a negative impact on the commercialization of *Feraheme* in its current indication if information submitted for purposes of the broader indication and any reevaluation of existing data, such as reports of serious anaphylaxis, cardiovascular events, and death, results in requirements to provide additional warnings and/or restrictions on our *Feraheme* label/package insert, change the rate of administration of *Feraheme*, notify healthcare providers of changes to the label/package insert, narrow the current indication, alter or terminate current or future trials for *Feraheme* or incur significant costs related to post-marketing requirements/commitments. Such adverse developments could put us at a disadvantage to our competitors and cause healthcare providers to choose to treat all of their IDA patients with competing IV irons based on the actual or perceived safety and efficacy of *Feraheme* in light of such activities.

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

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

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

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

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

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

Market acceptance of *Feraheme* may suffer as a result of competing iron replacement therapy products, in part because most of these products have been on the market longer and are currently widely used by physicians, and because certain of these products are approved for the treatment of IDA in a broader group of patients. For example, in July 2013, Injectafer® was approved by the FDA for the treatment of IDA in adult patients who have an unsatisfactory response to oral iron or who have intolerance to oral iron, which is a broader indication than our current *Feraheme* indication. Injectafer® is approved in the U.S. with a recommended dose of two slow injections or infusions of 750 milligrams each separated by at least seven days apart for a total of 1,500 milligrams. Given the 2015 changes to the *Feraheme* label, which provide, among other changes, that *Feraheme* be administered to patients by infusion over at least 15 minutes (replacing injection), *Feraheme* has lost a competitive advantage to Injectafer® and other IV irons. Further, we may not be able to offer discounts, incentives or rebates to new or existing customers on terms as appealing as Injectafer® or other IV irons. Even if we eventually obtain labeling of *Feraheme* in a broader population, Injectafer® will have already been available for a considerable period of time. During this period, physicians may continue to increase their use of Injectafer®, new physicians may begin to use Injectafer®, and physicians will gain increased familiarity with the product, making it more difficult for us to cause these physicians to use *Feraheme* in the future. In addition, manufacturers of Injectafer® may enter into commercial contracts with key customers or group purchasing organizations ("GPOs") during this period, which could prevent or make it more difficult for *Feraheme* to retain its existing customers, gain sales to new customers and gain market share in its existing indication with customers or GPOs, and may make entry into the non-CKD market difficult if we were to receive approval for the broader patient population in the future. If we are not able to differentiate *Feraheme* from other marketed IV iron products, including Injectafer®, or convince physicians and other customers of *Feraheme's* safe and effective use, our ability to maintain a premium price, generate revenues and maintain profitability, and our long-term business prospects could be adversely affected.

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

- Our ability to demonstrate to healthcare providers, particularly hematologists, oncologists, hospitals, nephrologists, and others who may purchase or prescribe *Feraheme*, the clinical efficacy and safety of *Feraheme* as an alternative to currently marketed IV iron products which treat IDA in adult CKD patients;
- Our ability to convince physicians and other healthcare providers to use IV iron, and *Feraheme* in particular, rather than oral iron, which is the current treatment of choice of most physicians for treating IDA in adult CKD patients;
- The actual or perceived safety and efficacy profile of *Feraheme* as compared to alternative iron replacement therapeutic agents;
- The relative price and level of reimbursement for *Feraheme* from payers, including government payers, such as Medicare and Medicaid, and private payers as compared to the price and level of reimbursement for alternative IV iron products;
- The actual or perceived convenience and ease of administration of *Feraheme* as compared to alternative iron replacement therapeutic agents, including iron administered orally, in light of recent or potential changes to the methods of *Feraheme* administration;
- Our ability to execute on our contracting strategy and offer competitive discounts, rebates and other incentives, which can result in increasing the rebates we are required to pay under the Medicaid Drug Rebate program and the discounts we are required to offer under the 340B drug pricing program;
- Current and future limitations on the approved indications and patient populations for *Feraheme*;
- The introduction of generic versions of ferumoxytol, which may occur in the near-term given the ANDA submitted to the FDA by Sandoz requesting approval to engage in commercial manufacture, use and sale of a generic version of ferumoxytol; and
- The effectiveness of our commercial organization and distribution networks in marketing, selling and supplying *Feraheme*.

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

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

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

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

Regulatory Risks

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

We expect that the Healthcare Reform Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase our product sales. These changes might impact existing government healthcare programs and may result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program. Changes that may affect our business include, but are not limited to, those governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under the health insurance exchanges, expansion of the 340B drug pricing program, and fraud and abuse enforcement. For example, beginning April 1, 2013, Medicare payments for all items and services under Part A and B, including drugs and biologicals, and most payments to plans under Medicare Part D were reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011 ("BCA") as amended by the American Taxpayer Relief Act of 2012. The BCA requires sequestration for most federal programs, excluding Medicaid, Social Security, and certain other programs. The BCA caps the cuts to Medicare payments for items and services at 2% and subsequent legislation extended the 2% reduction, on average, to 2025. In addition, various healthcare reform proposals have emerged at the state level in the U.S.

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

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

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

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

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

Further, the FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. For drug products like *Makena* that are approved by the FDA under the FDA's accelerated approval regulations, unless otherwise informed by the FDA, the sponsor must submit promotional materials at least 30 days prior to the intended time of initial dissemination of the promotional materials, which delays and may negatively impact our commercial team's ability to implement changes to *Makena*'s marketing materials, thereby negatively impacting revenues. Moreover, under Subpart H, the FDA may also withdraw approval of *Makena* if, among other things, the promotional materials are false or misleading, or other evidence demonstrates that *Makena* is not shown to be safe or effective under its conditions of use.

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

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

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

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

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

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

If we have to restate our calculation of government price reports, we may be forced to refund certain monies back to payers to comply with federal pricing agreements. Such a restatement of our government price reports would also adversely impact our reported financial results of operations in the period of such restatement. As a result, our price reporting calculations remain subject to the risk of errors and our methodologies for calculating these prices could be challenged under the FCA or other laws. In addition, the Healthcare Reform Act modified the rules related to certain price reports, among other things. Presently, uncertainty exists as many of the specific determinations necessary to implement this new legislation have yet to be decided and communicated to industry participants. This uncertainty in the interpretation of the legislation increases the chances of an error in price reporting, which could in turn lead to a legal challenge, restatement or investigation. On February 1, 2016, CMS issued a final regulation to implement the changes to the Medicaid Drug Rebate Program under the Health Reform Act. This regulation becomes effective on April 1, 2016. We are evaluating the impact of this regulation on our business and operations.

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

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

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

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

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

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

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

- Warning letters, public warnings and untitled letters;
- Court-ordered seizures or injunctions;
- Civil or criminal penalties, or criminal prosecutions;
- Variation, suspension or withdrawal of regulatory approvals for our products or services;
- Changes to the package insert of our products, such as additional warnings regarding potential side effects or potential limitations on the current dosage and administration;

- Requirements to communicate with physicians and other customers about concerns related to actual or potential safety, efficacy, or other issues involving our products and services;
- Implementation of risk mitigation programs and post-marketing obligations;
- Restrictions on our continued manufacturing, marketing, distribution or sale of our products, or the ability to continue to market our services;
- Temporary or permanent closing of the facilities of our third-party contract manufacturers;
- Interruption of clinical trials;
- For HCT/Ps, including umbilical cord blood stem cells and cord tissue, recalls, destruction orders, or cease manufacturing orders; and
- Refusal by regulators to consider or approve applications for additional indications.

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

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

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

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

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

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

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

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

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

Risks Related to Our Business Generally

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

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

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

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

- make it more difficult for us to satisfy our financial obligations under our current debt obligations, or other indebtedness, as well as our contractual and commercial commitments, and could increase the risk that we may default on our debt obligations;
- prevent us from raising the funds necessary to repurchase 2023 Senior Notes tendered to us if there is a change of control, which would constitute a default under the indenture governing the 2023 Senior Notes, the Convertible Notes and the 2015 Term Loan Facility;
- require us to use a substantial portion of our cash flow from operations to pay interest and principal on our current debt obligations or other indebtedness, which would reduce the funds available for working capital, capital expenditures and other general corporate purposes;
- limit our ability to obtain additional financing for working capital, capital expenditures, acquisitions and other investments or general corporate purposes, which may limit the ability to execute our business strategy;

- heighten our vulnerability to downturns in our business, our industry or in the general economy, and restrict us from exploiting business opportunities or making acquisitions;
- place us at a competitive disadvantage compared to those of our competitors that may have proportionately less debt;
- limit management's discretion in operating our business;
- limit our flexibility in planning for, or reacting to, changes in our business, the industry in which we operate or the general economy; and
- result in higher interest expense if interest rates increase and we have outstanding floating rate borrowings such as our 2015 Term Loan Facility.

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

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

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

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

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

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

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

- paying dividends, redeeming subordinated indebtedness or making other restricted payments, including certain investments;
- incurring or guaranteeing additional indebtedness or issuing preferred stock;
- creating or incurring liens;
- consummating a merger;
- consolidation or sale of all or substantially all of our or our subsidiaries' assets;
- entering into transactions with affiliates;
- transferring or selling assets;
- engaging in businesses other than our current businesses and reasonably related extensions thereof;
- designating subsidiaries as unrestricted subsidiaries; and
- allowing to exist certain restrictions on the ability of restricted subsidiaries to pay dividends or make other payments to us.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- Product revenues;
- The loss of a key customer or GPO;
- Costs and liabilities incurred in connection with business development activities or business development transactions into which we may enter;
- Costs associated with the commercialization of our products and services;
- *Makena* milestone payments we may be required to pay to the former shareholders of Lumara Health pursuant to the Lumara Agreement;
- Tax payments and of principal and interest payments in connection with our debt obligations, including the 2015 Term Loan Facility, the 2023 Notes and our Convertible Notes;
- Costs associated with the manufacture of our products and collection, processing and storage services, including costs of raw and other materials and costs associated with maintaining commercial inventory and qualifying additional manufacturing capacities and alternative suppliers;
- The recognition of deferred tax assets during periods in which we generate taxable income and our ability to preserve our net operating loss carryforwards and other tax assets;
- Costs associated with our ongoing and planned clinical studies of *Feraheme,* including costs associated with pursuing a broader indication of *Feraheme*;
- Costs associated with the ongoing and planned clinical studies of *Makena* in connection with current or future post-approval commitments, and our pursuit of our multi-pronged next generation development programs for *Makena*;
- Any changes to the mix of our business;
- Costs associated with manufacturing batch failures or inventory write-offs due to out-of-specification release testing or ongoing stability testing that results in a batch no longer meeting specifications;

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

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

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

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

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

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

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

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

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

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

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

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

In addition, the trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us and our business. We do not control these or any other analysts. Furthermore, there are many large, well-established, publicly traded companies active in our industry and market, which may mean that it is less likely that we will receive widespread analyst coverage. In addition, our future operating results are subject to substantial uncertainty, and our stock price could decline significantly if we fail to meet or exceed analysts' forecasts and expectations. If any of the analysts who cover us downgrade our stock, lower their price target or issue commentary or observations about us or our stock that are perceived by the market as negative, our stock price would likely decline rapidly. In addition, if these analysts cease coverage of our company, we could lose visibility in the market, which in turn could also cause our stock price to decline.

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

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

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

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

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

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

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

- the ability of our Board to increase or decrease the size of the Board without stockholder approval;
- advance notice requirements for the nomination of candidates for election to our Board and for proposals to be brought before our annual meeting of stockholders;
- the authority of our Board to designate the terms of and issue new series of preferred stock without stockholder approval;
- non-cumulative voting for directors; and
- limitations on the ability of our stockholders to call special meetings of stockholders.

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

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

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

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

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

We are increasingly dependent upon information technology systems, infrastructure, and data to operate our business. In the ordinary course of business, we collect, store, and transmit large amounts of confidential information (including but not limited to intellectual property, proprietary business information, and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party vendors who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of third-party vendors with whom we contract, and the large amounts of confidential information stored on those systems, make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third-party vendors, and/or business partners, or from cyber-attacks by malicious third parties. Cyber-attacks are increasing in their frequency, sophistication, and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, denial-of-service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information. Significant disruptions of our information technology systems or security breaches could adversely affect our business operations and/or result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including but not limited to trade secrets or other intellectual property, proprietary business information, and personal information), and could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our patients or employees, could harm our reputation, require us to comply with federal and/or state breach notification laws and foreign law equivalents, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. Security breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures to protect our information technology systems and infrastructure, there can be no assurance that such measures will prevent service interruptions or security breaches that could adversely affect our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS:

None.

ITEM 2. PROPERTIES:

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

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

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

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

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

ITEM 3. LEGAL PROCEEDINGS

We accrue a liability for legal contingencies when we believe that it is both probable that a liability has been incurred and that we can reasonably estimate the amount of the loss. We review these accruals and adjust them to reflect ongoing negotiations, settlements, rulings, advice of legal counsel and other relevant information. To the extent new information is obtained and our views on the probable outcomes of claims, suits, assessments, investigations or legal proceedings change, changes in our accrued liabilities would be recorded in the period in which such determination is made. For certain matters referenced below, the liability is not probable or the amount cannot be reasonably estimated and, therefore, accruals have not been made. In addition, in accordance with the relevant authoritative guidance, for any matters in which the likelihood of material loss is at least reasonably possible, we will provide disclosure of the possible loss or range of loss. If a reasonable estimate cannot be made, however, we will provide disclosure to that effect. See Note P, "*Commitments and Contingencies*" to our consolidated financial statements included in this Annual Report on Form 10-K for a description of our legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

PART II

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

Market Information

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

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

Stockholders

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

Dividends

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

Repurchases of Equity Securities

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

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

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

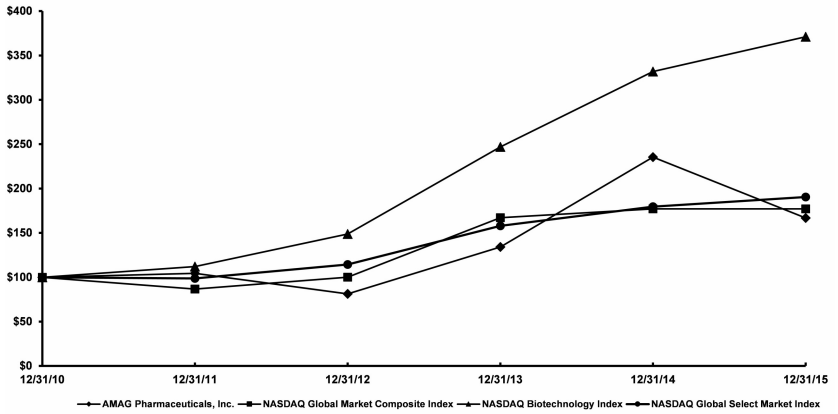
In January 2016, we announced a repurchase program to repurchase up to $60.0 million in shares of our common stock. The repurchase program does not have an expiration date and may be suspended for periods or discontinued at any time.

Securities Authorized for Issuance Under Equity Compensation Plans

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

Five-Year Comparative Stock Performance

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



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

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

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

ITEM 6. SELECTED FINANCIAL DATA:

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

	Years Ended December 31,				
	2015 (1)	2014 (2)	2013	2012	2011
	(in thousands, except per share data)				
Statement of Operations Data					
Revenues:					
U.S. product sales, net	$ 341,816	$ 109,998	$ 71,692	$ 58,903	$ 52,928
Service revenues, net	24,132	—	—	—	—
License fee, collaboration and other revenues (3)	52,328	14,386	9,164	26,475	8,321
Total revenues	418,276	124,384	80,856	85,378	61,249
Costs and expenses:					
Cost of product sales (4)	78,509	20,306	11,960	14,220	10,531
Cost of services	9,992	—	—	—	—
Research and development expenses	42,878	24,160	20,564	33,296	58,140
Selling, general and administrative expenses	160,309	72,254	59,167	53,071	68,863
Acquisition-related costs	11,232	9,478	782	—	—
Restructuring expenses	4,136	2,023	—	2,215	3,508
Total costs and expenses	307,056	128,221	92,473	102,802	141,042
Operating income (loss)	111,220	(3,837)	(11,617)	(17,424)	(79,793)
Other income (expense):					
Interest expense (5)	(53,251)	(14,697)	—	—	—
Loss on debt extinguishment (5)	(10,449)	—	—	—	—
Interest and dividend income, net	1,512	975	1,051	1,286	1,747
Other income (expense) (5)	(9,188)	217	964	(1,466)	(193)
Total other income (expense)	(71,376)	(13,505)	2,015	(180)	1,554
Net income (loss) before income taxes	39,844	(17,342)	(9,602)	(17,604)	(78,239)
Income tax expense (benefit) (6)	7,065	(153,159)	—	(854)	(1,170)
Net income (loss)	$ 32,779	$ 135,817	$ (9,602)	$ (16,750)	$ (77,069)
Net income (loss) per share:					
Basic	$ 1.04	$ 6.06	$ (0.44)	$ (0.78)	$ (3.64)
Diluted	$ 0.93	$ 5.45	$ (0.44)	$ (0.78)	$ (3.64)
Weighted average shares outstanding used to compute net income (loss) per share:					
Basic	31,471	22,416	21,703	21,392	21,189
Diluted	35,308	25,225	21,703	21,392	21,189

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

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

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

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

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

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

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

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

AMAG's Portfolio of Products and Services

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

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

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

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

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

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

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

Makena Developments

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

We have continued to advance our multi-pronged next generation development programs for *Makena* (which we previously referred to as our lifecycle management program) seeking to enhance the product profile for patients and their healthcare providers. We are working to develop an auto-injector device for subcutaneous administration of *Makena*, including chemistry, manufacturing and controls ("CMC") development with Antares Pharma, Inc. ("Antares") and pilot clinical studies to establish the appropriate subcutaneous dose. We are planning for a single-dose pharmacokinetics ("PK") bioequivalence study to capture certain clinical measures to support clinical superiority of the auto-injector compared to the existing intramuscular injection. We are also in the early stages of developing a longer-acting formulation of *Makena*, including conducting formulation work and pre-clinical studies to optimize the drug release profile.

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

Feraheme Developments

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

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

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

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

Recent Financings

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

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

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

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

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

Critical Accounting Policies

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

1. Revenue Recognition and Related Sales Allowances and Accruals

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

- Persuasive evidence of an arrangement exists;
- Delivery of product has occurred or services have been rendered;
- The sales price charged is fixed or determinable; and
- Collection is reasonably assured.

Product Revenue

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

Classification of Product Sales Allowances and Accruals

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

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

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

Discounts

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

Chargebacks

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

Distributor/Wholesaler and Group Purchasing Organization Fees

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

Product Returns

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

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

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

Government and Other Rebates

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

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

Healthcare Reform Legislation

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

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

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

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

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

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

Multiple Element Arrangements

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

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

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

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

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

Service Revenue

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

License Fee, Collaboration and Other Revenues

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

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

- The milestone consideration received is commensurate with either the level of effort required to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from our performance to achieve the milestone;
- The milestone is related solely to our past performance; and
- The milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement.

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

2. Business Combinations

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

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

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

Goodwill and Intangible Assets

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

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

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

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

- Probability of successfully completing clinical trials and obtaining regulatory approval;
- Market size, market growth projections, and market share;
- Estimates regarding the timing of and the expected costs to advance our clinical programs to commercialization;
- Estimates of future cash flows from potential product sales; and
- A discount rate.

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

Acquisition-related Contingent Consideration

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

3. Valuation of investments

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

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

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

4. Equity-Based Compensation

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

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

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

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

5. Income Taxes

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

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

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

Impact of Recently Issued and Proposed Accounting Pronouncements

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

Results of Operations - 2015 as compared to 2014

Revenues

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

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

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

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

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

Product Sales

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

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

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

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

Product Sales Allowances and Accruals

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

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

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

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

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

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

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

Service Revenues

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

License Fee, Collaboration and Other Revenues

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

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

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

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

Costs and Expenses

Cost of Product Sales

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

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

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

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

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

Cost of Services

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

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

Research and Development Expenses

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

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

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

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

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

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

Research and Development Activities

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

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

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

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

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

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

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

Selling, General and Administrative Expenses

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

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

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

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

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

- $27.0 million increase in sales and marketing consulting, professional fees, and other expenses primarily due to costs related to *Makena* marketing activities since the November 2014 acquisition and CBR activities since the August 2015 acquisition;

- $17.2 million increase in general and administrative consulting, professional fees and other expenses primarily due to increased costs associated with consulting, finance, legal, and other infrastructure activities in support of our product portfolio expansion as well as costs associated with Lumara Health and CBR after the November 2014 and August 2015 acquisitions, respectively;

- $7.0 million increase in equity-based compensation expense due primarily to the expense associated with equity awards to new and existing employees, including additional employees from the Lumara Health and CBR acquisitions as well as one-time charges associated with the departure of certain of our executive officers during 2015; and

- $5.0 million increase to the contingent consideration liability due to a $6.7 million increase to the Lumara Health-related contingent consideration, partially offset by a $1.7 million reduction of the *MuGard*-related contingent consideration primarily resulting from a 2015 revision of our total projected *MuGard* sales.

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

Acquisition-related costs

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

Restructuring Expenses

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

Other Income (Expense)

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

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

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

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

- $10.4 million loss on debt extinguishment as the result of the early repayment in 2015 of the remaining $323.0 million outstanding principal amount of the 2014 Term Loan Facility; and

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

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

Income Tax Expense (Benefit)

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

Results of Operations - 2014 as compared to 2013

Revenues

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

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

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

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

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

Product Sales

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

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

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

Product Sales Allowances and Accruals

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

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

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

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

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

License Fee, Collaboration and Other Revenues

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

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

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

Costs and Expenses

Cost of Product Sales

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

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

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

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

- $2.6 million increase in costs related to sales of *Feraheme* to Takeda, including the accelerated recognition of product costs previously deferred as a result of the Takeda Termination Agreement; and

- $2.2 million decrease due to a lower average cost per vial of *Feraheme* sold, partially offset by a $1.7 million increase due to a higher volume of *Feraheme* vials sold in 2014.

Research and Development Expenses

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

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

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

Selling, General and Administrative Expenses

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

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

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

- $8.4 million increase in compensation, payroll taxes and benefits primarily due to increased costs associated with additional personnel in our commercial functions, including the Lumara Health sales force acquired in connection with the November 2014 acquisition of Lumara Health, and increased costs associated with certain of our general and administrative functions, including the addition of Lumara Health employees;

- $3.3 million increase in sales and marketing consulting, professional fees, and other expenses primarily due to costs related to *Makena* marketing activities since the November 2014 acquisition, and increased consulting costs related to the commercialization of *MuGard*;

- $1.9 increase in general and administrative consulting, professional fees and other expenses primarily due to increased costs associated with business development, consulting and other legal-related activities in support of

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

- $1.8 million decrease to the contingent consideration liability due to a $3.4 million reduction of the *MuGard*-related contingent consideration primarily resulting from a 2014 revision of our total projected *MuGard* sales, partially offset by a $1.6 million increase to the Lumara Health-related contingent consideration; and

- $1.2 million increase in equity-based compensation expense due primarily to one-time charges associated with the departure of our former Senior Vice President of Business Development and Chief Business Officer in June 2014 as well as the expense associated with equity awards to new and existing employees.

Acquisition-related costs

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

Restructuring Expenses

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

Other Income (Expense)

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

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

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

Income Tax Benefit

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

Liquidity and Capital Resources

General

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

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

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

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

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

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

Borrowings and Other Liabilities

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

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

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

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

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

Share Repurchase Program

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

Cash Flow Activity for the Year Ended December 31, 2015

Cash flows from operating activities

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

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

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

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

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

Cash flows from investing activities

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

Cash flows from financing activities

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

Cash Flow Activity for the Year Ended December 31, 2014

Cash flows from operating activities

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

- Non-cash operating items resulting in a net decrease of $128.2 million, including deferred income taxes, equity-based compensation expense, a write-down of inventory, amortization of debt discount and debt issuance costs, amortization of premium/discount on purchased securities, change in fair value of contingent consideration, depreciation and amortization, and other non-cash items;
- $0.3 million of cash provided by operating activities due to increases in accounts receivable, inventories and prepaid and other current assets;
- $10.7 million of cash provided by operating activities due to increases in accounts payable and accrued expenses;
- $9.2 million of cash used in operating activities due to decreases in deferred revenues and other long-term liabilities; and
- $2.0 million of cash provided by operating activities due to decreases in other long-term assets.

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

Cash flows from investing activities

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

Cash flows from financing activities

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

Cash Flow Activity for the Year Ended December 31, 2013

Cash flows from operating activities

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

- Non-cash operating items resulting in a net increase of $16.1 million including equity-based compensation expense, depreciation and amortization, amortization of premium/discount on purchased securities, change in fair value of contingent consideration, gains on the sale of assets, a write-down of inventory, and other non-cash items;
- An aggregate decrease in deferred revenues and other long-term liabilities of $6.9 million;
- An aggregate decrease of $5.7 million in accounts payable and accrued expenses;
- An aggregate decrease of $1.3 million in accounts receivable, prepaid assets and inventories; and
- An increase of $2.0 million in other long-term assets.

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

Cash flows from investing activities

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

Cash flows from financing activities

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

Contractual Obligations

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

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

Facility Lease Obligations

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

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

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

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

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

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

Purchase Commitments

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

Contingent Consideration Related to Business Combinations

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

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

Contingent Regulatory and Commercial Milestone Payments

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

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

Other Funding Commitments

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

Severance Arrangements

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

Indemnification Obligations

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

Legal Proceedings

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

Off-Balance Sheet Arrangements

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

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

Interest Rate Risk

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

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

Equity Price Risk

Convertible Notes

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

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

Convertible Bond Hedge and Warrant Transactions

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

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA:

Index To Consolidated Financial Statements

Management's Annual Report on Internal Control over Financial Reporting	101
Report of Independent Registered Public Accounting Firm	102
Consolidated Balance Sheets - as of December 31, 2015 and 2014	103
Consolidated Statements of Operations - for the years ended December 31, 2015, 2014 and 2013	104
Consolidated Statements of Comprehensive Income (Loss) - for the years ended December 31, 2015, 2014 and 2013	105
Consolidated Statements of Stockholders' Equity - as of December 31, 2015, 2014 and 2013	106
Consolidated Statements of Cash Flows- for the years ended December 31, 2015, 2014 and 2013	107
Notes to Consolidated Financial Statements	108

MANAGEMENT'S ANNUAL REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

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

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

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

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

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

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

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

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

Boston, Massachusetts
February 24, 2016

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

	As of December 31,	
	2015	2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 228,705	$ 119,296
Investments	237,626	24,890
Accounts receivable, net	85,678	38,172
Inventories	40,645	40,610
Receivable from collaboration	428	4,518
Deferred tax assets	—	32,094
Prepaid and other current assets	13,592	14,456
Total current assets	606,674	274,036
Property, plant and equipment, net	28,725	1,519
Goodwill	639,188	205,824
Intangible assets, net	1,196,771	887,908
Restricted cash	2,593	2,397
Other long-term assets	13,481	17,249
Total assets	$ 2,487,432	$ 1,388,933
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,906	$ 7,301
Accrued expenses	106,363	80,093
Current portion of long-term debt	17,500	34,000
Current portion of acquisition-related contingent consideration	96,967	718
Deferred revenues	20,185	44,376
Total current liabilities	245,921	166,488
Long-term liabilities:		
Long-term debt, net	811,250	293,905
Convertible 2.5% notes, net	174,390	167,441
Acquisition-related contingent consideration	125,592	217,984
Deferred tax liabilities	189,145	77,619
Deferred revenues	5,093	—
Other long-term liabilities	3,777	5,543
Total liabilities	1,555,168	928,980
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value $0.01 per share, 2,000,000 shares authorized; none issued	—	—
Common stock, par value $0.01 per share, 117,500,000 shares authorized at December 31, 2015 and 58,750,000 authorized at December 31, 2014; 34,733,117 and 25,599,550 shares issued and outstanding at December 31, 2015 and 2014, respectively	347	256
Additional paid-in capital	1,233,786	793,757
Accumulated other comprehensive loss	(4,205)	(3,617)
Accumulated deficit	(297,664)	(330,443)
Total stockholders' equity	932,264	459,953
Total liabilities and stockholders' equity	$ 2,487,432	$ 1,388,933

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

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

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

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

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

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

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2012	21,507	$ 215	$ 632,487	$ (3,247)	$ (456,658)	$ 172,797
Net shares issued in connection with the exercise of stock options and restricted stock units	252	3	1,274	—	—	1,277
Shares issued in connection with employee stock purchase plan	14	—	176	—	—	176
Non-cash equity-based compensation	—	—	8,004	—	—	8,004
Unrealized losses on securities	—	—	—	(244)	—	(244)
Net loss	—	—	—	—	(9,602)	(9,602)
Balance at December 31, 2013	21,773	218	641,941	(3,491)	(466,260)	172,408
Equity component of Convertible Notes, net of issuance costs	—	—	36,907	—	—	36,907
Purchase of convertible bond hedges, net of tax	—	—	(39,760)	—	—	(39,760)
Sale of warrants	—	—	25,620	—	—	25,620
Net shares issued in connection with the acquisition of Lumara Health	3,210	32	111,932	—	—	111,964
Net shares issued in connection with the exercise of stock options and vesting of restricted stock units	617	6	8,492	—	—	8,498
Non-cash equity-based compensation	—	—	8,625	—	—	8,625
Unrealized losses on securities	—	—	—	(126)	—	(126)
Net income	—	—	—	—	135,817	135,817
Balance at December 31, 2014	25,600	256	793,757	(3,617)	(330,443)	459,953
Shares issued in connection with financings, net of issuance costs of $24.7 million	8,196	82	407,395	—	—	407,477
Net shares issued in connection with the exercise of stock options and vesting of restricted stock units	937	9	15,397	—	—	15,406
Non-cash equity-based compensation	—	—	17,237	—	—	17,237
Unrealized losses on securities, net of tax	—	—	—	(588)	—	(588)
Net income	—	—	—	—	32,779	32,779
Balance at December 31, 2015	34,733	$ 347	$ 1,233,786	$ (4,205)	$ (297,664)	$ 932,264

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

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

	Years Ended December 31,		
	2015	2014	2013
Cash flows from operating activities:			
Net income (loss)	$ 32,779	$ 135,817	$ (9,602)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	69,103	6,984	3,085
Amortization of premium/discount on purchased securities	2,152	2,080	2,758
Write-down of inventory to net realizable value	1,235	1,309	2,175
Gain (loss) on disposal of property and equipment	—	(103)	(924)
Non-cash equity-based compensation expense	17,237	8,625	8,004
Non-cash loss on debt extinguishment	6,426	—	—
Amortization of debt discount and debt issuance costs	11,379	6,870	—
Gains on investments, net	(14)	(114)	(40)
Change in fair value of contingent consideration	4,271	(681)	1,074
Deferred income taxes	5,007	(153,159)	—
Changes in operating assets and liabilities:			
Accounts receivable, net	(36,913)	3,588	(432)
Inventories	(5,237)	(1,360)	(1,040)
Receivable from collaboration	4,090	(4,239)	(15)
Prepaid and other current assets	4,034	2,331	2,817
Other long-term assets	9,209	1,964	(1,964)
Accounts payable and accrued expenses	7,876	10,694	(5,730)
Deferred revenues	(22,197)	(8,384)	(6,694)
Other long-term liabilities	(1,965)	(808)	(246)
Repayment of term loan attributable to original issue discount	(12,491)	—	—
Net cash provided by (used in) operating activities	95,981	11,414	(6,774)
Cash flows from investing activities:			
Acquisition of Lumara Health, net of acquired cash	562	(595,602)	—
Acquisition of CBR, net	(682,356)	—	—
Proceeds from sales or maturities of investments	208,966	223,568	106,030
Purchase of investments	(424,759)	(63,747)	(115,046)
Acquisition of MuGard Rights and inventory	—	—	(3,434)
Change in restricted cash	(195)	2,883	(2,823)
Capital expenditures, net of proceeds from sale of assets	(1,259)	(44)	1,338
Net cash (used in) investing activities	(899,041)	(432,942)	(13,935)
Cash flows from financing activities:			
Proceeds from the issuance of common stock, net of underwriting discount and other expenses	407,477	—	—
Long-term debt principal payments	(327,509)	—	—
Proceeds from issuance of convertible 2.5% notes	—	200,000	—
Proceeds from 2015 term loan	344,750	—	—
Proceeds from long-term debt	490,000	327,509	—
Payment of debt issuance costs	(10,004)	(7,760)	—
Proceeds from issuance of warrants	—	25,620	—
Purchase of convertible bond hedges	—	(39,760)	—
Payment of contingent consideration	(456)	(270)	(51)
Payment to former CBR shareholders	(7,195)	—	—
Proceeds from the exercise of stock options	15,406	8,499	1,277
Proceeds from the issuance of common stock under ESPP	—	—	176
Net cash provided by financing activities	912,469	513,838	1,402
Net increase (decrease) in cash and cash equivalents	109,409	92,310	(19,307)
Cash and cash equivalents at beginning of the year	119,296	26,986	46,293
Cash and cash equivalents at end of the year	$ 228,705	$ 119,296	$ 26,986
Supplemental data of cash flow information:			
Cash paid for taxes	$ 2,373	$ —	$ —
Cash paid for interest	$ 28,014	$ 2,500	$ —
Non-cash investing activities:			
Fair value of acquisition-related contingent consideration	$ —	$ 205,000	$ 13,700
Fair value of common stock issued in connection with the Lumara Health acquisition	$ —	$ 111,964	$ —

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

AMAG PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

A. DESCRIPTION OF BUSINESS

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

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

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

B. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the U.S. ("GAAP") and include the accounts of our wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. Our results of operations for 2015 include the results of CBR, subsequent to August 17, 2015, the date of acquisition. See Note C, "*Business Combinations*," for additional information.

Use of Estimates and Assumptions

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

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

Cash and Cash Equivalents

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

Investments

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

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

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

Fair Value Measurements

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

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

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

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

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

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

Inventory

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

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

Restricted Cash

As of December 31, 2015 and 2014, we classified $2.6 million and $2.4 million as restricted cash, respectively, which included $2.0 million held in a restricted fund previously established by Lumara Health Inc. (“Lumara Health”) in connection with its Chapter 11 plan of reorganization to pay potential claims against its former directors and officers. In addition, the restricted cash balances included a $0.6 million and a $0.4 million security deposit delivered to the landlord of our Waltham, Massachusetts headquarters in the form of an irrevocable letter of credit as of December 31, 2015 and 2014, respectively.

Concentrations and Significant Customer Information

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

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

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

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

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

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

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

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

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

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

Property, Plant and Equipment

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

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

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

Business Combinations

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

Acquisition-Related Contingent Consideration

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

Goodwill and Intangible Assets

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

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

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

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

Patents

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

Revenue Recognition and Related Sales Allowances and Accruals

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

- Persuasive evidence of an arrangement exists;
- Delivery of product has occurred or services have been rendered;
- The sales price charged is fixed or determinable; and
- Collection is reasonably assured.

Product Revenue

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

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

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

Classification of Product Sales Allowances and Accruals

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

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

Discounts

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

Chargebacks

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

Distributor/Wholesaler and Group Purchasing Organization Fees

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

Product Returns

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

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

Government and Other Rebates

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

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

Multiple Element Arrangements

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

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

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

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

Service Revenue

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

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

License Fee, Collaboration and Other Revenues

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

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

- The milestone consideration received is commensurate with either the level of effort required to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from our performance to achieve the milestone;
- The milestone is related solely to our past performance; and
- The milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement.

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

Research and Development Expenses

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

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

Advertising Costs

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

Shipping and Handling Costs

We bill customers of our CBR Services a fee for the shipping of the collection kits to CBR.

Equity-Based Compensation

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

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

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

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

Income Taxes

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using future enacted rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of our deferred tax assets will not be realized.

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

Comprehensive Income (Loss)

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

Basic and Diluted Net Income (Loss) per Share

We compute basic net income (loss) per share by dividing net income (loss) by the weighted average number of common shares outstanding during the relevant period. Diluted net income (loss) per common share has been computed by dividing net income (loss) by the diluted number of common shares outstanding during the period. Except where the result would be antidilutive to net income (loss), diluted net income (loss) per common share would be computed assuming the impact of the conversion of the $200.0 million of 2.5% convertible senior notes due February 15, 2019 (the "Convertible Notes"), the exercise of outstanding stock options, the vesting of RSUs, and the exercise of warrants.

We have a choice to settle the conversion obligation under the Convertible Notes in cash, shares or any combination of the two. Pursuant to certain covenants in our six-year $350.0 million term loan facility (the "2015 Term Loan Facility"), which we entered into in 2015 to partially fund the acquisition of CBR, we may be restricted from settling the conversion obligation in whole or in part with cash unless certain conditions in the 2015 Term Loan Facility are satisfied. Since the November 2014 acquisition of Lumara Health, we utilized the if-converted method to reflect the impact of the conversion of the Convertible Notes. This method assumes the conversion of the Convertible Notes into shares of our common stock and reflects the elimination of the interest expense related to the Convertible Notes. Prior to the acquisition of Lumara Health in November 2014, we intended to settle the principal value of the Convertible Notes in cash and the excess conversion premium in shares. We utilized the treasury stock method to reflect the dilutive effect of the conversion premium in 2014, as if it were a freestanding written call option on our shares prior to the November 2014 acquisition of Lumara Health. The impact of the conversion premium has been considered in the calculation of diluted net income per share for 2014 by applying the closing price of our common stock on December 31, 2014 to calculate the number of shares issuable under the conversion premium.

The dilutive effect of the warrants, stock options and RSUs has been calculated using the treasury stock method.

The components of basic and diluted net income (loss) per share for 2015, 2014 and 2013 were as follows (in thousands, except per share data):

	Years Ended December 31,		
	2015	2014	2013
Net income (loss) - basic	$ 32,779	$ 135,817	$ (9,602)
Dilutive effect of convertible 2.5% notes	—	1,654	—
Net income (loss) - diluted	$ 32,779	$ 137,471	$ (9,602)
Weighted average common shares outstanding	31,471	22,416	21,703
Effect of dilutive securities:			
Warrants	2,466	—	—
Stock options and RSUs	1,371	520	—
Convertible 2.5% notes	—	2,289	—
Shares used in calculating dilutive net income (loss) per share	35,308	25,225	21,703
Net income (loss) per share:			
Basic	$ 1.04	$ 6.06	$ (0.44)
Diluted	$ 0.93	$ 5.45	$ (0.44)

The following table sets forth the potential common shares issuable upon the exercise of outstanding options, the vesting of RSUs, the exercise of warrants (prior to consideration of the treasury stock method), and the conversion of the 2.5% Convertible Notes, which were excluded from our computation of diluted net income (loss) per share because their inclusion would have been anti-dilutive (in thousands):

	Years Ended December 31,		
	2015	2014	2013
Options to purchase shares of common stock	1,619	2,708	2,820
Shares of common stock issuable upon the vesting of RSUs	167	322	465
Warrants	—	7,382	—
Convertible 2.5% notes	7,382	—	—
Total	9,168	10,412	3,285

In connection with the issuance of the Convertible Notes, in February 2014, we entered into convertible bond hedges. The convertible bond hedges are not included for purposes of calculating the number of diluted shares outstanding, as their effect would be anti-dilutive. The convertible bond hedges are generally expected, but not guaranteed, to reduce the potential dilution and/or offset the cash payments we are required to make upon conversion of the Convertible Notes. During 2015, the average common stock price was above the exercise price of the warrants and during 2014, the average common stock price was below the exercise price of the warrants.

Reclassifications

Certain amounts in prior periods have been reclassified in order to conform to the current period presentation. In 2015, we reclassified certain immaterial revenue amounts in 2014 and 2013 within the consolidated statements of operations to more accurately reflect the underlying revenue type.

C. BUSINESS COMBINATIONS

As part of our strategy to expand our portfolio, in August 2015, we acquired CBR and in November 2014, we acquired Lumara Health and its product *Makena*. In addition, in June 2013, we entered into a license agreement (the "MuGard License Agreement") with Abeona Therapeutics, Inc. ("Abeona") (formerly known as PlasmaTech Biopharmaceuticals, Inc. and Access Pharmaceuticals, Inc.) pursuant to which we acquired the U.S. commercial rights to *MuGard* for the management of oral mucositis and stomatitis (the "MuGard Rights").

CBR Acquisition

On August 17, 2015 (the "CBR Acquisition Date"), we acquired CBR from CBR Acquisition Holdings Corp. for $700.0 million in cash consideration, subject to estimated working capital, indebtedness and other adjustments. We believe CBR is a strong strategic fit for our growing business and offers a unique opportunity to reach a broader population of expectant mothers who may benefit from our product offerings in the maternal health space, including *Makena*.

We accounted for the acquisition of CBR as a business combination using the acquisition method of accounting. Under the acquisition method of accounting, the total purchase price of an acquisition is allocated to the net tangible and identifiable intangible assets acquired and liabilities assumed based on their estimated fair values as of the date of acquisition. We have made a preliminary allocation of the purchase price to the net tangible and intangible assets acquired and liabilities assumed, based on available information and various assumptions we believe are reasonable, with the remaining purchase price recorded as goodwill.

The following table summarizes the components of the total purchase price paid for CBR, as adjusted for the final net working capital, indebtedness and other adjustments (in thousands):

	Total Acquisition Date Fair Value
Cash consideration	$ 700,000
Estimated working capital, indebtedness and other adjustments	(17,837)
Purchase price paid at closing	682,163
Cash paid on finalization of the net working capital, indebtedness and other adjustments	193
Total purchase price	$ 682,356

The following table summarizes the preliminary fair values assigned to the CBR assets acquired and liabilities assumed by us along with the resulting goodwill at the CBR Acquisition Date (in thousands):

	Total Acquisition Date Fair Value
Accounts receivable	$ 8,660
Inventories	3,825
Prepaid and other current assets	8,360
Restricted cash - short-term	30,752
Property, plant and equipment	29,401
Customer relationships	297,000
Trade name and trademarks	65,000
Favorable lease asset	358
Deferred income tax assets	5,155
Other long-term assets	198
Accounts payable	(2,853)
Accrued expenses	(13,798)
Deferred revenues - short-term	(3,100)
Payable to former CBR shareholders	(37,947)
Deferred income tax liabilities	(149,530)
Other long-term liabilities	(200)
Total estimated identifiable net assets	$ 241,281
Goodwill	441,075
Total	$ 682,356

Measurement period adjustments recorded in the fourth quarter of 2015, which are reflected in the table above, consisted primarily of reductions to accounts receivable, inventories, prepaid and other current assets and property, plant

and equipment totaling $1.9 million and increases to accrued expenses and long-term liabilities totaling $0.5 million, which resulted in an increase to goodwill of $1.8 million, net of $0.6 million of deferred taxes. These measurement period adjustments have been reflected as current period adjustments in the fourth quarter of 2015 in accordance with the guidance in Accounting Standards Update ("ASU") 2015-16, *Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments* ("ASU 2015-16"), which we early adopted in the third quarter of 2015. Any remaining adjustments to the preliminary fair value of these acquired assets and liabilities assumed will be made as soon as practicable but not later than one year from the CBR Acquisition Date.

The gross contractual amount of accounts receivable at the CBR Acquisition Date of $11.7 million was adjusted to its fair value of $8.7 million. The fair value amounts for CBR's customer relationships, trade names and trademarks were determined based on assumptions that market participants would use in pricing an asset, based on the most advantageous market for the assets (i.e., its highest and best use). We determined the fair value of the customer relationships, using an income approach, which is a valuation technique that provides an estimate of the fair value of an asset based on market participant expectations of the cash flows an asset would generate over its remaining life. Some of the more significant assumptions used in the income approach from the perspective of a market participant include the estimated net cash flows for each year for the identifiable intangible asset, the discount rate that measures the risk inherent in each cash flow stream, as well as other factors. The fair value of the trade names and trademarks was determined using the relief from royalty method, which is also an income approach. We believe the fair values assigned to the CBR customer relationships, and the trade names and trademarks are based upon reasonable estimates and assumptions given available facts and circumstances as of the CBR Acquisition Date. If these assets are not successful, sales and profitability may be adversely affected in future periods, and as a result, the value of the assets may become impaired.

The customer relationships will be amortized to selling, general and administrative expenses based on an economic consumption model over an expected useful life of approximately 20 years. The trade names and trademark intangible asset is deemed to be an indefinite-lived asset, which is not amortized but will be subject to periodic assessments of impairment.

Based on the fair value adjustments primarily related to deferred revenue and identifiable intangible assets acquired, we recorded a net deferred tax liability of $144.3 million in our consolidated balance sheet as of December 31, 2015 using a combined federal and state statutory income tax rate of 37%. The net deferred tax liability represents the $149.5 million of deferred tax liabilities recorded in acquisition accounting, primarily related to the fair value adjustments to CBR's deferred revenue and identifiable intangible assets, offset by $5.2 million of deferred tax assets acquired from CBR. These tax estimates are preliminary and subject to change based on, among other things, any adjustments to management's determination of the fair values of the tangible and identifiable intangible assets acquired and liabilities assumed by jurisdiction, the deductibility of acquisition-related costs and other costs recorded by CBR prior to the acquisition, and management's assessment of the combined company's ability to utilize the future benefits from acquired and legacy deferred tax assets.

We incurred approximately $11.2 million of acquisition-related costs in 2015 related to the CBR acquisition. These costs primarily represented financial advisory fees, legal fees, due diligence and other costs and expenses.

In connection with the CBR acquisition, we incurred a $6.8 million bridge loan commitment fee, which was included in other income (expense) in our 2015 condensed consolidated statement of operations and paid in the third quarter of 2015.

During the post-acquisition period in 2015, CBR generated approximately $24.1 million of revenue. Separate disclosure of CBR's earnings for the post-acquisition period in 2015 is not practicable due to the integration of CBR's operations into our business upon acquisition.

Lumara Health Acquisition

On November 12, 2014 (the "Lumara Health Acquisition Date"), we acquired Lumara Health at which time Lumara Health became our wholly-owned subsidiary. By virtue of the acquisition, we acquired Lumara Health's existing commercial product, *Makena*. Under the terms of the acquisition agreement, we acquired 100% of the equity ownership

of Lumara Health, excluding the assets and liabilities of the Women's Health Division and certain other assets and liabilities, which were divested by Lumara Health prior to closing, for $600.0 million in cash, subject to certain net working capital and other adjustments, and issued approximately 3.2 million shares of our common stock, having a value of approximately $112.0 million at the time of closing, to the holders of common stock of Lumara Health. The acquisition of Lumara Health provided a strategic commercial entry into the maternal health business. The addition of Lumara Health's rapidly growing *Makena* product, the only FDA-approved therapy to reduce the risk of preterm birth in certain at-risk women, added a complementary commercial platform to our portfolio and transformed us into a multi-product specialty pharmaceutical company.

We agreed to pay additional merger consideration, up to a maximum of $350.0 million, based upon the achievement of certain net sales milestones of *Makena* for the period from December 1, 2014 through December 31, 2019 as follows:

- A one-time payment of $100.0 million payable upon achievement of $300.0 million in aggregate net sales in any consecutive 12-month period, commencing in the month following the Lumara Health Acquisition Date ("the First Milestone"); plus
- A one-time payment of $100.0 million payable upon achievement of $400.0 million in aggregate net sales in any consecutive 12-month period commencing in the month following the last month in the First Milestone period (the "Second Milestone"); if the Third Milestone payment (described below) has been or is required to be made prior to achieving the Second Milestone, the Second Milestone payment shall be reduced from $100.0 million to $50.0 million; plus
- A one-time payment of $50.0 million payable if aggregate net sales equal or exceed $700.0 million in any consecutive 24 calendar month period (which may include the First Milestone period) (the "Third Milestone"); however, no Third Milestone payment will be made if the Second Milestone payment has been or is required to be made in the full amount of $100.0 million; plus
- A one-time payment of $100.0 million payable upon achievement of $500.0 million in aggregate net sales in any consecutive 12 month period commencing in the month following the last month in the Second Milestone period (the "Fourth Milestone"); plus
- A one-time payment of $50.0 million payable upon achievement of $200.0 million in aggregate net sales in each of the five (5) consecutive calendar years from and including the 2015 calendar year to the 2019 calendar year (the "Fifth Milestone").

In the event that the conditions to more than one contingent payment are met in any calendar year, any portion of the total amount of contingent payment due in such calendar year in excess of $100.0 million shall be deferred until the next calendar year in which less than $100.0 million in contingent payments is due. This contingent consideration is recorded as a liability and measured at fair value based upon significant unobservable inputs.

The following table summarizes the components of the total purchase price paid for Lumara Health, as adjusted for the final net working capital and other adjustments (in thousands):

	Total Acquisition Date Fair Value
Cash consideration	$ 600,000
Fair value of AMAG common stock issued	111,964
Fair value of contingent milestone payments	205,000
Estimated working capital and other adjustments	821
Purchase price paid at closing	917,785
Less:	
Cash received on finalization of the net working capital and other adjustments	(562)
Cash acquired from Lumara Health	(5,219)
Total purchase price	$ 912,004

At the closing, $35.0 million of the cash consideration was contributed to a separate escrow fund (the "Indemnification Escrow") to secure the former Lumara Health security holders' obligations to indemnify us for certain matters, including breaches of representations and warranties, covenants included in the Lumara Agreement, payments made by us to dissenting stockholders, specified tax claims, excess parachute claims, and certain claims related to the Women's Health Division of Lumara Health, which was divested by Lumara Health prior to the closing. The portion of the Indemnification Escrow that has not been reduced by any claims by us and is not subject to any unresolved claims will be released to the former Lumara Health security holders at the earlier of (a) March 15, 2016 or (b) five days after the date on which our audited financial statements for our fiscal year ending December 31, 2015 are filed with the Securities and Exchange Commission.

The fair value of the 3.2 million shares of AMAG common stock was determined based on the closing price of our common stock on the NASDAQ Global Select Market ("NASDAQ") of $34.88 per share on November 11, 2014, the closing price immediately prior to the closing of the transaction.

The fair value of the contingent milestone payments was determined based on our probability-adjusted discounted cash flows estimated to be realized from the net sales of *Makena* from December 1, 2014 through December 31, 2019. The cash flows were discounted at a rate of 5%, which we believe is reasonable given the level of certainty of the pay-out.

The following table summarizes the fair values assigned to assets acquired and liabilities assumed by us along with the resulting goodwill at the Lumara Health Acquisition Date, as adjusted for certain measurement period adjustments for Lumara Health recorded during 2015 (in thousands):

	Total Acquisition Date Fair Value
Accounts receivable	$ 36,852
Inventories	30,300
Prepaid and other current assets	3,322
Deferred income tax assets	102,355
Property and equipment	60
Makena Base Technology	797,100
IPR&D	79,100
Restricted cash - long term	1,997
Other long-term assets	3,412
Accounts payable	(3,807)
Accrued expenses	(36,561)
Deferred income tax liabilities	(295,676)
Other long-term liabilities	(4,563)
Total estimated identifiable net assets	$ 713,891
Goodwill	198,113
Total	$ 912,004

During 2015, we finalized the fair values assigned to the assets acquired and liabilities assumed by us at the Lumara Health Acquisition Date. The measurement period adjustments recorded in 2015 consisted primarily of a $7.2 million reduction to our *Makena* revenue reserves and a $5.4 million reduction related to net deferred tax liabilities, partially offset by a $4.5 million increase in the purchase price associated with the final settlement of net working capital with the former stockholders. These measurement period adjustments have been reflected as current period adjustments during 2015 in accordance with the guidance in ASU 2015-16.

The gross contractual amount of accounts receivable at the Lumara Health Acquisition Date was $40.5 million. The $30.3 million fair value of inventories included a fair value step-up adjustment of $26.1 million, which will be amortized and recognized as cost of product sales in our consolidated statements of operations as the related inventories are sold. We recognized $11.6 million and $1.3 million of the fair value adjustment as cost of product sales during the years ended December 31, 2015 and December 31, 2014, respectively. An additional $1.2 million of the fair value adjustment was recognized as research and development expense during the year ended December 31, 2015. The remaining $12.0 million is estimated to be recognized as follows: $4.8 million in 2016, $4.0 million in 2017 and $3.2 million in 2018.

The fair value amounts for the *Makena* base technology ("Makena Base Technology") and IPR&D were determined based on assumptions that market participants would use in pricing an asset, based on the most advantageous market for the assets (i.e., its highest and best use). We determined the fair value of the Makena Base Technology and the IPR&D using the income approach. Some of the more significant assumptions used in the income approach for these assets include the estimated net cash flows for each year for each project or product, the discount rate that measures the risk inherent in each future cash flow stream, the assessment of each asset's life cycle, competitive trends impacting the asset and each cash flow stream as well as other factors, including the major risks and uncertainties associated with the timely and successful completion of the IPR&D projects, such as legal and regulatory risk.

The fair value of the acquired IPR&D asset represents the value assigned to acquired research and development projects that, as of the Lumara Health Acquisition Date, had not established technological feasibility and had no alternative future use, including certain programs associated with the *Makena* next generation development programs to extend the brand franchise beyond the February 2018 exclusivity date, such as new routes of administration, the use of new delivery technologies, as well as reformulation technologies. We believe the fair values assigned to the Makena Base Technology and IPR&D assets are based upon reasonable estimates and assumptions given available facts and circumstances as of the Lumara Health Acquisition Date. If these assets are not successful or successfully developed, sales and profitability may be adversely affected in future periods, and as a result, the value of the assets may become impaired.

Both AMAG and Lumara Health had deferred tax assets for which full valuation allowances were provided in the pre-acquisition financial statements. However, we considered certain of the deferred tax liabilities recorded in acquisition accounting as sources of income to support realization of Lumara Health's deferred tax assets. We recorded a net deferred tax liability of $193.3 million in our consolidated balance sheet in acquisition accounting using a combined federal and state statutory income tax rate of 38.8%. The net deferred tax liability represents the $295.7 million of deferred tax liabilities recorded in acquisition accounting (primarily related to the fair value adjustments to Lumara Health's inventories and identifiable intangible assets) offset by $102.4 million of deferred tax assets acquired from Lumara Health which we have determined, are 'more likely than not' to be realized. See Note J, "*Income Taxes*," for additional information.

We incurred approximately $9.5 million of acquisition-related costs in 2014 related to the acquisition of Lumara Health. These costs primarily represented financial advisory fees, legal fees, due diligence and other costs and expenses.

During the post-acquisition period in fiscal 2014, Lumara Health generated $22.5 million of revenue from sales of *Makena*. Separate disclosure of Lumara Health's earnings for the post-acquisition period in fiscal 2014 is not practicable due to the integration of Lumara Health's operations into our business upon acquisition.

Unaudited Pro Forma Supplemental Information

The following supplemental unaudited pro forma information presents our revenue and net income (loss) on a pro forma combined basis, including CBR and Lumara Health, assuming that the CBR acquisition occurred on January 1, 2014 and that the Lumara Health acquisition occurred on January 1, 2013. For purposes of preparing the following pro forma information, certain items recorded during 2015, such as the $11.2 million of acquisition-related costs, the $10.4 million loss on debt extinguishment, and $9.2 million of other one-time fees and expenses incurred in connection with the CBR acquisition financing, are excluded from 2015 and reflected in 2014. In addition, certain items recorded in 2014, such as the $153.2 million tax benefit and the $9.5 million of acquisition-related costs incurred in connection with the acquisition of Lumara Health, are excluded from 2014 and reflected in 2013. Further, the pro forma combined net income (loss) in fiscal 2013 does not give effect to the elimination of approximately $385.9 million of non-recurring reorganization gains, net of losses and expenses, realized in connection with Lumara Health's exit from bankruptcy in September 2013 as such amounts are not directly related to the acquisition of Lumara Health. The pro forma amounts do not include any expected cost savings or restructuring actions which may be achievable or may occur subsequent to the acquisition of Lumara Health or CBR, or the impact of any non-recurring activity. The following table presents the unaudited pro forma consolidated results (in thousands):

	Years Ended December 31,		
	2015	2014	2013
Pro forma combined revenues	$ 490,451	$ 364,447	$ 179,561
Pro forma combined net income (loss)	$ 28,217	$ (57,739)	$ 463,522

The pro forma adjustments reflected in the pro forma combined net income (loss) in the above table primarily represent adjustments to historical amortization of intangible assets, to historical depreciation of property, plant and equipment, and reductions to historical CBR revenues due to fair value purchase accounting adjustments to intangible assets, property, plant and equipment and deferred revenue. In addition, the pro forma combined net income (loss) includes increased interest expense due to the increase in term loan borrowings and the issuance of $500.0 million aggregate principal amount of 7.875% Senior Notes due 2023 (the "2023 Senior Notes") in connection with the CBR acquisition. Income taxes for all periods were adjusted accordingly. This pro forma financial information is not necessarily indicative of our consolidated operating results that would have been reported had the transactions been completed as described herein, nor is such information necessarily indicative of our consolidated results for any future period.

Goodwill

In connection with the CBR acquisition, we recognized $441.1 million of goodwill, primarily due to the synergies expected from combining our operations with CBR and to deferred tax liabilities recorded on the fair value adjustments, primarily those relating to intangible assets and deferred revenue. In connection with the Lumara Health acquisition, we recognized $198.1 million of goodwill, primarily due to the net deferred tax liabilities recorded on the fair value adjustments to Lumara Health's inventories and identifiable intangible asset. The $639.2 million of goodwill resulting from the CBR and Lumara Health acquisitions is not deductible for income tax purposes.

MuGard License Agreement

In June 2013, we entered into the MuGard License Agreement with Abeona, under which we obtained an exclusive, royalty-bearing license, with the right to grant sublicenses, to certain intellectual property rights, including know-how, patents and trademarks, to use, import, offer for sale, sell, manufacture and commercialize *MuGard* in the U.S. and its territories (the "U.S. Territory").

In consideration for the license, we paid Abeona an upfront payment of $3.3 million on June 6, 2013 (the "MuGard License Date"). We are required to pay royalties to Abeona on future net sales of *MuGard* until the later of (a) the expiration of the licensed patents or (b) the tenth anniversary of the first commercial sale of *MuGard* under the MuGard License Agreement in the U.S. Territory ("the "MuGard Royalty Term"). These tiered, double-digit royalty rates decrease for any part of the MuGard Royalty Term occurring after the expiration of the licensed patents and are subject to off-set against certain of our expenses. After the expiration of the MuGard Royalty Term, the license shall become a fully paid-up, royalty-free and perpetual license in the U.S. Territory.

We did not assume any pre-existing liabilities related to the *MuGard* business, contingent or otherwise, arising prior to the MuGard License Date. We accounted for the acquisition of the MuGard Rights as a business combination under the acquisition method of accounting since we acquired the U.S. commercial rights for *MuGard* and inventory, and obtained access to certain related regulatory assets and product supply, employees and other assets, including certain patent and trademark rights, contracts, and related books and records, held by Abeona, which are exclusively related to *MuGard*. In addition, during the term of the MuGard License Agreement, we will have control over sales, distribution and marketing of *MuGard* in the U.S. as Abeona has assigned to us all of its right, title and interest in *MuGard*-related internet and social media outlets and other sales, marketing and promotional materials currently owned or controlled by Abeona. Abeona will no longer commercialize, market, promote, sell or make public communications relating to *MuGard* in the U.S Territory, except as may be agreed to by us. Abeona has also agreed to not, directly or indirectly, research, develop, market, sell or commercialize any medical devices that directly compete with *MuGard* for the treatment of any diseases or conditions of the oropharyngeal cavity in the U.S. Territory.

The following table summarizes the total consideration for the MuGard Rights (in thousands):

	Total Acquisition Date Fair Value
Cash	$ 3,434
Acquisition-related contingent consideration	13,700
Total consideration	$ 17,134

During 2013, we completed the valuation for the acquisition of the MuGard Rights and determined the fair value of the contingent consideration and the intangible asset as of the MuGard License Date to be $13.7 million and $16.9 million, respectively. The acquisition date fair value of the contingent consideration was determined based on various market factors, including an analysis of estimated sales and using a discount rate of approximately 15%.

The following table summarizes the fair values of the assets acquired related to the business combination as of the MuGard License Date (in thousands):

	Total Acquisition Date Fair Value
MuGard intangible asset	$ 16,893
Inventory	241
Total identifiable assets acquired	$ 17,134

We incurred approximately $0.8 million of acquisition-related costs in 2013, which were primarily related to professional and legal fees.

Pro forma results of operations would not be materially different as a result of the acquisition of the MuGard Rights and therefore are not presented.

D. INVESTMENTS

As of December 31, 2015 and 2014, our investments equaled $237.6 million and $24.9 million, respectively, and consisted of securities classified as available-for-sale in accordance with accounting standards which provide guidance related to accounting and classification of certain investments in debt and equity securities.

The following is a summary of our investments as of December 31, 2015 and 2014 (in thousands):

	December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities				
Due in one year or less	$ 27,964	$ —	$ (38)	$ 27,926
Due in one to three years	173,652	3	(904)	172,751
Commercial paper				
Due in one year or less	34,452	2	(5)	34,449
Municipal securities				
Due in one year or less	2,500	—	—	2,500
Total investments	$238,568	$ 5	$ (947)	$237,626

	December 31, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities				
Due in one year or less	$ 11,656	$ 3	$ (4)	$ 11,655
Due in one to three years	13,258	10	(33)	13,235
Total investments	$ 24,914	$ 13	$ (37)	$ 24,890

Impairments and Unrealized Gains and Losses on Investments

We did not recognize any other-than-temporary impairment losses in our consolidated statements of operations related to our securities during 2015, 2014 or 2013. We considered various factors, including the length of time that each security was in an unrealized loss position and our ability and intent to hold these securities until the recovery of their amortized cost basis occurs. As of December 31, 2015, none of our investments has been in an unrealized loss position for more than one year. Future events may occur, or additional information may become available, which may cause us to identify credit losses where we do not expect to receive cash flows sufficient to recover the entire amortized cost basis

of a security and may necessitate the recording of future realized losses on securities in our portfolio. Significant losses in the estimated fair values of our investments could have a material adverse effect on our earnings in future periods.

E. FAIR VALUE MEASUREMENTS

The following tables represent the fair value hierarchy as of December 31, 2015 and 2014, for those assets and liabilities that we measure at fair value on a recurring basis (in thousands):

	Fair Value Measurements at December 31, 2015 Using:			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds	$ 73,676	$ 73,676	$ —	$ —
Corporate debt securities	200,677	—	200,677	—
Commercial paper	34,449	—	34,449	—
Municipal securities	2,500	—	2,500	—
Total Assets	$ 311,302	$ 73,676	$ 237,626	$ —
Liabilities:				
Contingent consideration - Lumara Health	$ 214,895	$ —	$ —	$ 214,895
Contingent consideration - MuGard	7,664	—	—	7,664
Total Liabilities	$ 222,559	$ —	$ —	$ 222,559

	Fair Value Measurements at December 31, 2014 Using:			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds	$ 77,254	$ 77,254	$ —	$ —
Corporate debt securities	24,890	—	24,890	—
Total Assets	$ 102,144	$ 77,254	$ 24,890	$ —
Liabilities:				
Contingent consideration - Lumara Health	$ 206,600	$ —	$ —	$ 206,600
Contingent consideration - MuGard	12,102	—	—	12,102
Total Liabilities	$ 218,702	$ —	$ —	$ 218,702

Investments

Our money market funds are classified as Level 1 assets under the fair value hierarchy as these assets have been valued using quoted market prices in active markets and do not have any restrictions on redemption. Our investments are classified as Level 2 assets under the fair value hierarchy as these assets were primarily determined from independent pricing services, which normally derive security prices from recently reported trades for identical or similar securities, making adjustments based upon other significant observable market transactions. At the end of each reporting period, we perform quantitative and qualitative analyses of prices received from third parties to determine whether prices are reasonable estimates of fair value. After completing our analyses, we did not adjust or override any fair value measurements provided by our pricing services as of December 31, 2015 or 2014. In addition, there were no transfers or reclassifications of any securities between Level 1 and Level 2 during 2015 or 2014.

Contingent consideration

We accounted for the acquisitions of each of Lumara Health, CBR and the MuGard Rights as business combinations

under the acquisition method of accounting. Additional details regarding our acquisitions and license agreements can be found in Note C, "*Business Combinations.*" There were no contingent consideration obligations related to the CBR acquisition. The fair value measurements of contingent consideration obligations and the related intangible assets arising from business combinations are classified as Level 3 assets under the fair value hierarchy as these assets have been valued using unobservable inputs. These inputs include: (a) the estimated amount and timing of projected cash flows; (b) the probability of the achievement of the factors on which the contingency is based; and (c) the risk-adjusted discount rate used to present value the probability-weighted cash flows. Significant increases or decreases in any of those inputs in isolation could result in a significantly lower or higher fair value measurement.

The following table presents a reconciliation of contingent consideration obligations related to the acquisition of Lumara Health and the MuGard Rights (in thousands):

Balance as of January 1, 2014	$ 14,550
Payments made	(270)
Adjustments to fair value of contingent consideration	(681)
Acquisition date fair value of Lumara Health contingent consideration	205,000
Other adjustments	103
Balance as of December 31, 2014	$ 218,702
Payments made	(456)
Adjustments to fair value of contingent consideration	4,271
Other adjustments	42
Balance as of December 31, 2015	$ 222,559

The $4.3 million increase in adjustments to the fair value of the contingent consideration liability in 2015 were due primarily to a $8.3 million increase to the *Makena* contingent consideration related to the time value of money, partially offset by a $4.0 million reduction to the *MuGard* contingent consideration due to changes in estimated amounts and timing of cash flows related to the royalties we expect to pay to Abeona under the MuGard License Agreement as a result of an update to the total forecasted net sales for *MuGard*. During 2014, we also revised our forecast of total projected net sales for *MuGard* and reassessed the fair value of the contingent consideration liability related to the MuGard Rights. As a result, we reduced our contingent consideration liability by $2.3 million for year ended December 31, 2014. This reduction was partially offset by a $1.6 million increase to the *Makena* contingent consideration liability related to the time value of money. These adjustments were included in selling, general and administrative expenses in our consolidated statements of operations. We have classified $96.4 million of the *Makena* contingent consideration and $0.6 million of the *MuGard* contingent consideration as short-term liabilities in our consolidated balance sheet as of December 31, 2015.

The fair value of the contingent milestone payments payable by us to the former stockholders of Lumara Health was determined based on our probability-adjusted discounted cash flows estimated to be realized from the net sales of *Makena* from December 1, 2014 through December 31, 2019. The cash flows were discounted at a rate of 5%, which we believe is reasonable given the estimated likelihood of the pay-out. As of December 31, 2015, the total undiscounted milestone payment amounts we could pay in connection with the Lumara Health acquisition is $350.0 million over the period from December 1, 2014 to December 31, 2019.

The fair value of the contingent royalty payments payable by us to Abeona was determined based on various market factors, including an analysis of estimated sales using a discount rate of approximately 12%. As of December 31, 2015, we estimate that the undiscounted royalty amounts we could pay under the MuGard License Agreement, based on current projections, may range from $9.0 million to $13.0 million over a ten year period beginning on June 6, 2013, the acquisition date, which is our best estimate of the period over which we expect the majority of the asset's cash flows to be derived.

We believe the estimated fair values of Lumara Health and the MuGard Rights are based on reasonable assumptions, however, our actual results may vary significantly from the estimated results.

Debt

We estimate the fair value of our debt obligations by using quoted market prices obtained from third-party pricing services, which is classified as a Level 2 input. As of December 31, 2015, the estimated fair value of our 2023 Senior Notes was $437.5 million. As of December 31, 2015 and 2014, the estimated fair value of our 2.5% Convertible Notes was approximately $246.0 million and $332.0 million, respectively, which differed from their carrying values. In addition, the estimated fair value of our 2015 and 2014 term loan facilities was $337.8 million and $342.0 million, which differed from their carry values. See Note R, "*Debt*" for additional information on our debt obligations.

F. INVENTORIES

Our major classes of inventories were as follows as of December 31, 2015 and 2014 (in thousands):

	December 31,	
	2015	2014
Raw materials	$ 19,673	$ 14,188
Work in process	1,985	5,965
Finished goods	18,987	20,457
Inventories included in current assets	40,645	40,610
Included in other long-term assets:		
Raw materials	—	7,798
Total inventories	$ 40,645	$ 48,408

Total inventories as of December 31, 2015 decreased by $7.8 million as compared to 2014 primarily due to inventory sold to customers, partially offset by the inclusion of CBR inventory acquired in connection with the August 2015 acquisition of CBR, which consists of cord blood and cord tissue collection kits, and processing bags. Additionally, during 2015 we expensed $3.6 million of *Makena* inventory and $1.0 million of *Feraheme* commercial inventory, respectively, which may not be saleable and which was recorded in cost of product sales in our consolidated statements of operations. The $3.6 million of expensed *Makena* inventory included a fair value adjustment of $3.3 million. During 2014, we expensed $0.7 million of *Feraheme* commercial inventory, which we determined would be solely used in development activities at our third-party suppliers and which we recorded in research and development expenses in our consolidated statements of operations.

As of December 31, 2015, we believed that FDA approval and subsequent commercialization of the single-dose preservative-free formulation of *Makena* was probable and therefore capitalized approximately $3.8 million of inventory related to the single-dose preservative-free formulation of *Makena*, which included a fair value adjustment of $1.5 million. In February 2016, we received FDA approval for the single-dose formulation of *Makena* for inventory produced at Hospira, Inc. and we expect to begin commercialization of it in the second quarter of 2016.

In the fourth quarter of 2014, we recorded the acquired *Makena* inventory at fair value of $30.3 million, which required a $26.1 million step-up adjustment to recognize the inventory at its expected net realizable value. We are amortizing and recognizing the step-up adjustment as cost of product sales in our consolidated statements of operations as the related inventories are sold and we record step-up costs associated with clinical trial material as research and development expense.

See Note C, "*Business Combinations*," for additional information.

G. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consisted of the following as of December 31, 2015 and 2014 (in thousands):

	December 31,	
	2015	2014
Land	$ 700	$ —
Land improvements	300	—
Building and improvements	9,500	—
Computer equipment and software	13,193	894
Furniture and fixtures	1,725	680
Leasehold improvements	1,717	430
Laboratory and production equipment	5,683	493
Construction in progress	786	—
	33,604	2,497
Less: accumulated depreciation	(4,879)	(978)
Property, plant and equipment, net	$ 28,725	$ 1,519

During 2015, we acquired land and a building in Tucson, Arizona as well as other fixed assets in connection with the CBR acquisition.

During 2015, 2014 and 2013 we incurred $3.9 million, $0.5 million and $3.0 million of depreciation expense, respectively. The $3.0 million of depreciation expense in 2013 included $1.9 million of accelerated depreciation expense related to fixed assets at our prior office facility that was sold.

H. GOODWILL AND INTANGIBLE ASSETS, NET

Goodwill

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

Balance at January 1, 2014	$ —
Goodwill acquired through Lumara Health acquisition	205,824
Balance as of December 31, 2014	205,824
Goodwill acquired through CBR acquisition	441,075
Measurement period adjustments related to Lumara Health acquisition	(7,711)
Balance as of December 31, 2015	$ 639,188

The measurement period adjustments related to the Lumara Health acquisition were comprised primarily of a $7.2 million reduction associated with adjustments to our *Makena* revenue reserves and a $5.4 million reduction related to net deferred tax liabilities, partially offset by a $4.5 million increase associated with the final settlement of net working capital with the former stockholders of Lumara Health. These current period adjustments have been recorded in accordance with the guidance in ASU 2015-16, which we early adopted in 2015. As of December 31, 2015, we had no accumulated impairment losses related to goodwill. See Note C, "*Business Combinations*," for additional information.

Intangible Assets

As of December 31, 2015 and 2014, our identifiable intangible assets consisted of the following (in thousands):

	December 31, 2015			December 31, 2014		
	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Amortizable intangible assets:						
Makena Base Technology	$ 797,100	$ 56,540	$ 740,560	$797,100	$ 4,834	$792,266
CBR customer relationships	297,000	1,061	295,939	—	—	—
Favorable lease	358	63	295	—	—	—
MuGard Rights	16,893	1,016	15,877	16,893	351	16,542
	1,111,351	58,680	1,052,671	813,993	5,185	808,808
Indefinite-lived intangible assets:						
Makena IPR&D	79,100	—	79,100	79,100	—	79,100
CBR trade names and trademarks	65,000	—	65,000	—	—	—
Total intangible assets	$1,255,451	$ 58,680	$1,196,771	$893,093	$ 5,185	$887,908

As of December 31, 2015, the weighted average remaining amortization period for our finite-lived intangible assets was 8.9 years.

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

The CBR intangible assets (the CBR customer relationships, favorable lease and trade names and trademarks) were acquired in August 2015 in connection with our acquisition of CBR. Amortization of the CBR customer relationships is being recognized using an estimated useful life of twenty years, which we believe is an appropriate amortization period due to the estimated economic lives of the CBR intangible assets. The favorable lease is being amortized on a straight-line basis over the remaining term of the lease.

The MuGard Rights were acquired from Abeona in June 2013. Amortization of the MuGard Rights is being recognized using an economic consumption model over ten years, which represents our best estimate of the period over which we expect the majority of the asset's cash flows to be derived. We believe this is the best approximation of the period over which we will derive the majority of value of the MuGard Rights. We have assessed the MuGard Rights for potential impairment at December 31, 2015 and concluded that the projected undiscounted cash flows continued to exceed the carrying value of this intangible asset. However, if we are not able to expand reimbursement and coverage for *MuGard* as planned and therefore revenues do not increase as projected, this intangible may be subject to future potential impairment.

See Note C, "*Business Combinations*," for additional information on our intangible assets.

Total amortization expense for 2015, 2014 and 2013 was $53.5 million, $5.1 million, and less than $0.1 million, respectively. The increase in amortization expense is due to the amortization of the *Makena* and CBR related intangible assets. Amortization expense for *Makena* and *MuGard* is recorded in cost of product sales in our consolidated statements of operations. Amortization expense for CBR related intangibles is recorded in selling, general and administrative

expenses in our consolidated statements of operations. We expect amortization expense related to our finite-lived intangible assets to be as follows (in thousands):

Period	Estimated Amortization Expense
Year Ending December 31, 2016	$ 77,704
Year Ending December 31, 2017	92,816
Year Ending December 31, 2018	100,251
Year Ending December 31, 2019	71,467
Year Ending December 31, 2020	48,890
Thereafter	661,543
Total	$ 1,052,671

I. CURRENT AND LONG-TERM LIABILITIES

Accrued Expenses

Accrued expenses consisted of the following as of December 31, 2015 and 2014 (in thousands):

	December 31,	
	2015	2014
Commercial rebates, fees and returns	$ 45,161	$ 44,807
Professional, license, and other fees and expenses	27,070	15,857
Interest expense	18,411	7,300
Salaries, bonuses, and other compensation	12,838	10,176
Restructuring expense	2,883	1,953
Total accrued expenses	$ 106,363	$ 80,093

Deferred Revenues

Our deferred revenues balance as of December 31, 2015 is primarily related to our CBR service revenues and includes: (i) amounts collected in advance of unit processing and (ii) amounts associated with unearned storage fees collected at the beginning of the storage contract term, net of allocated discounts. Our deferred revenues balance as of December 31, 2014 included amortization of upfront payments and milestone payments recognized under the Takeda Agreement, under which Takeda had exclusive rights to develop and commercialize *Feraheme* as a therapeutic agent in certain agreed-upon territories outside of the U.S. In December 2014, we entered into a termination agreement with Takeda (the "Takeda Termination Agreement"), which terminated the obligations between the parties on a rolling basis, with final termination effective in June 2015. In connection with the final termination of the Takeda Agreement, in 2015 we recognized into revenues the remaining balance of $44.4 million of deferred revenue related to the upfront and milestone payments we received from Takeda during the life of the agreement and recorded it in license fee, collaboration and other revenues in our 2015 consolidated statement of operations.

Other Long-Term Liabilities

Other long-term liabilities at December 31, 2015 and 2014 consisted of deferred rent related to the lease of our principal executive offices in Waltham, Massachusetts as well as our lease obligations assumed under the lease of Lumara Health's former principal executive offices in St. Louis, Missouri, which was terminated in May 2015. In addition, other long-term liabilities include future payments to be made to certain states in compliance with a 2011 Lumara Health Settlement Agreement with the Department of Justice, which resolved certain claims under the qui tam provisions of the False Claims Act.

J. INCOME TAXES

For the years ended December 31, 2015, 2014, and 2013, all of our profit or loss before income taxes was from U.S. operations. The income tax expense (benefit) consisted of the following (in thousands):

	Years Ended December 31,		
	2015	2014	2013
Current:			
Federal	$ —	$ —	$ —
State	2,058	—	—
Total current	$ 2,058	$ —	$ —
Deferred:			
Federal	$ 9,819	$ (142,884)	$ —
State	(4,812)	(10,275)	—
Total deferred	$ 5,007	$ (153,159)	$ —
Total income tax expense (benefit)	$ 7,065	$ (153,159)	$ —

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

	Years Ended December 31,		
	2015	2014	2013
Statutory U.S. federal tax rate	35.0 %	(34.0)%	(34.0)%
State taxes, net of federal benefit	0.1	(7.9)	2.4
Equity-based compensation expense	0.4	10.6	9.4
Contingent consideration	4.7	3.1	—
Transaction costs	3.9	9.7	—
Other permanent items, net	3.2	3.2	5.3
Tax credits	(1.7)	(3.0)	0.5
Valuation allowance	(28.0)	(864.9)	16.4
Other, net	0.1	—	—
Effective tax rate	17.7 %	(883.2)%	(0.0) %

For the year ended December 31, 2015, we recognized income tax expense of $7.1 million, representing an effective tax rate of 17.7%. The difference between the expected statutory federal tax rate of 35.0% and the 17.7% effective tax rate for 2015 was primarily attributable to the impact of a valuation allowance release related to certain deferred tax assets, partially offset by non-deductible transaction costs associated with the acquisition of CBR, and non-deductible contingent consideration expense associated with Lumara Health.

We released a portion of our valuation allowance for the year ended December 31, 2014, due to taxable temporary differences available as a source of income as a result of the Lumara Health acquisition. As of December 31, 2014, we maintained a partial valuation allowance as we benefitted only those deferred tax assets to the extent that existing taxable temporary differences could be used as a source of future income to realize the benefits of those deferred tax assets. During the year ended December 31, 2015, we achieved a positive income position, and also acquired additional taxable temporary differences available as a source of income as a result of the CBR acquisition. Based primarily on this evidence, we have concluded that the majority of our deferred tax assets are more likely than not to be realized.

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

included certain non-deductible stock compensation expenses, non-deductible transaction costs and contingent consideration associated with the acquisition of Lumara Health, and other non-deductible expenses for tax purposes. We did not recognize any federal or state income tax expense or benefit for the year ended December 31, 2013 as we were subject to a full valuation allowance.

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

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using future enacted rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized. As of December 31, 2015, we elected to early adopt new guidance issued by the FASB in November 2015 (ASU 2015-17), which simplifies the presentation of deferred income taxes by eliminating the need for entities to separate deferred income tax liabilities and assets into current and noncurrent amounts in a classified statement of financial position. We adopted this guidance prospectively and, as a result, prior consolidated balance sheets were not retrospectively adjusted. As of December 31, 2014, we allocated the valuation allowance between current and noncurrent deferred tax assets and liabilities. As a result of this allocation, we had recorded a long-term deferred tax liability of $77.6 million and a short-term deferred tax asset of $32.1 million on the balance sheet. The components of our deferred tax assets and liabilities were as follows (in thousands):

	December 31,	
	2015	2014
Assets		
Net operating loss carryforwards	$ 172,944	$ 188,873
Tax credit carryforwards	6,262	24,574
Deferred revenue	626	17,216
Equity-based compensation expense	5,464	3,436
Capitalized research & development	25,216	32,359
Intangibles	—	272
Debt instruments	—	731
Reserves	8,900	7,782
Property, plant and equipment	—	61
Other	10,894	5,014
Liabilities		
Property, plant and equipment depreciation	(2,844)	—
Intangible assets and inventory	(400,357)	(290,491)
Debt instruments	(1,213)	—
Other	(3,178)	(1,795)
	(177,286)	(11,968)
Valuation allowance	(11,859)	(33,557)
Net deferred taxes	$ (189,145)	$ (45,525)

The decrease in our tax credit carryforwards is primarily related to the results of studies of research and development ("R&D") tax credits and other tax attributes completed during the year ended December 31, 2015. The studies resulted in the write-off of federal and state R&D credit carryforwards of $3.1 million and $2.8 million, respectively. Additionally, uncertain tax benefits of $12.7 million were recorded related to the federal and state R&D credit carryforwards and net operating loss ("NOL") carryforwards. The uncertain tax benefits are described in more detail below. A valuation allowance was recorded against the R&D credit carryforwards and other tax attributes for the year ended December 31, 2014.

The valuation allowance decreased by approximately $21.7 million for the year ended December 31, 2015 primarily due to the results of the R&D tax credit study, as well as our conclusion that it is more likely than not that we will realize the benefit of the majority of our deferred tax assets, as discussed above. At December 31, 2015, the remaining valuation allowance related primarily to our federal capital loss carryforward and our state NOL carryforwards acquired from Lumara Health.

At December 31, 2015, we had federal and state NOL carryforwards of approximately $502.5 million and $415.3 million, respectively of which $280.5 million and $275.0 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, 2015 were $24.6 million of state NOL carryforwards which were acquired as part of the CBR transaction. The state NOL carryforwards acquired from Lumara Health are subject to a full valuation allowance as it is not more likely than not that they will be realized. We also had federal capital loss carryforwards of $1.7 million to offset future capital gains. At December 31, 2015, $55.6 million and $30.5 million of federal and state NOLs, respectively, related to excess equity-based compensation tax deductions the benefits for which will be recorded to additional paid-in capital when recognized through a reduction of cash taxes paid. The federal and state NOLs expire at various dates through 2035. The capital loss carryforwards will expire through 2017. We have federal tax credits of approximately $5.5 million to offset future tax liabilities of which $1.9 million were acquired as part of the Lumara Health transaction. We have state tax credits of $1.1 million to offset future tax liabilities. These federal and state tax credits will expire periodically through 2035 if not utilized.

Utilization of our NOLs and 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, 2015 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. However, future changes in ownership after December 31, 2015 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.

We had no uncertain tax benefits recorded prior to 2015. During the year ended December 31, 2015, we added $12.7 million of uncertain tax benefits related to tax positions of prior tax years, as discussed below.

During the year ended December 31, 2015, we completed studies of our historical R&D tax credits and other tax attributes, including those acquired in connection with the Lumara Health transaction. The increase in our unrecognized tax benefits is attributable to the results of these studies, which identified uncertain tax benefits of $12.7 million related to federal and state R&D credits and NOL carryforwards. These amounts have been recorded as a reduction to our deferred tax assets. 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.

The amount of uncertain tax benefits that, if recognized, would impact our effective tax rate is $12.4 million. We have not recorded any interest or penalties on any unrecognized benefits since inception. We would recognize both accrued interest and penalties related to unrecognized benefits in income tax expense. We do not expect our uncertain tax benefits to change significantly in the next 12 months.

The statute of limitations for assessment by the Internal Revenue Service (the "IRS") and most state tax authorities is closed for tax years prior to December 31, 2012, although carryforward attributes that were generated prior to tax year 2012 may still be adjusted upon examination by the IRS or state tax authorities if they either have been or will be used in a future period. We file income tax returns in the U.S. federal and various state jurisdictions. There are currently no federal or state audits in progress.

K. ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)

The table below presents information about the effects of net income (loss) of significant amounts reclassified out of accumulated other comprehensive income (loss) ("AOCI"), net of tax, associated with unrealized gains (losses) on securities during 2015 and 2014 (in thousands):

	December 31,	
	2015	2014
Beginning balance	$ (3,617)	$ (3,491)
Other comprehensive income (loss) before reclassifications	(4)	(191)
Gain (loss) reclassified from accumulated other comprehensive income (loss)	(584)	65
Ending balance	$ (4,205)	$ (3,617)

L. EQUITY-BASED COMPENSATION

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

Our 2007 Plan was originally approved by our stockholders in November 2007, and succeeded our 2000 Plan, under which no further grants may be made under the 2000 Plan. Any shares that remained available for issuance under the 2000 Plan as of the date of adoption of the 2007 Plan are included in the number of shares that may be issued under the 2007 Plan. Any shares subject to outstanding awards granted under the 2000 Plan that expire or terminate for any reason prior to exercise will be added to the total number of shares of our stock available for issuance under the 2007 Plan. The total number of shares issuable pursuant to awards under this plan is 6,215,325, including the 1,700,000 shares which were added to the 2007 Plan upon approval by our stockholders of an amendment to our 2007 Plan at our Meeting of Stockholders held on May 21, 2015 (the "2015 Annual Meeting"). As of December 31, 2015, there were 2,231,795 shares remaining available for issuance under the 2007 Plan, which excludes shares subject to outstanding awards under the 2000 Plan. All outstanding options under the 2007 Plan have either a seven or ten-year term and all outstanding options under the 2000 Plan have a ten-year term.

In November 2014, we assumed the Lumara Health 2013 Plan in connection with the acquisition of Lumara Health. The total number of shares issuable pursuant to awards under this plan as of the effective date of the acquisition and after taking into account any adjustments as a result of the acquisition, was 200,000 shares. As of December 31, 2015, there were 39,984 shares remaining available for issuance under the Lumara Health 2013 Plan, which are available for grants to certain employees, officers, directors, consultants, and advisors of AMAG and our subsidiaries who are newly-hired or who previously performed services for Lumara Health. All outstanding options under the Lumara Health 2013 Plan have a ten-year term.

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

At our 2015 Annual Meeting, our stockholders approved our 2015 ESPP, which authorizes the issuance of up to 200,000 shares of our common stock to eligible employees. The terms of the 2015 ESPP permit eligible employees to purchase shares (subject to certain plan and tax limitations) in semi-annual offerings through payroll deductions of up to an annual maximum of 10% of the employee's "compensation" as defined in the 2015 ESPP. Shares are purchased at a price equal to 85% of the fair market value of our common stock on either the first or last business day of the offering

period, whichever is lower. Plan periods consist of six-month periods typically commencing June 1 and ending November 30 and commencing December 1 and ending May 31. As of December 31, 2015, no shares have been issued under our 2015 ESPP.

During 2015, 2014 and 2013, we also granted equity through inducement grants outside of these plans to certain newly hired executive officers and certain employees. All outstanding stock options granted as inducement awards have an exercise price equal to the closing price of a share of our common stock on the grant date.

Stock Options

The following table summarizes stock option activity in our equity plans for the twelve months ended December 31, 2015:

	2007 Equity Plan	2000 Equity Plan	2013 Lumara Equity Plan	Total
Outstanding at December 31, 2014	2,051,017	35,266	44,000	2,130,283
Granted	919,675	—	76,000	995,675
Exercised	(657,724)	(21,226)	—	(678,950)
Expired or terminated	(349,806)	—	(24,000)	(373,806)
Outstanding at December 31, 2015	1,963,162	14,040	96,000	2,073,202

Restricted Stock Units

The following table summarizes RSU activity in our equity plans for the twelve months ended December 31, 2015:

	2007 Equity Plan	2000 Equity Plan	2013 Lumara Equity Plan	Total
Outstanding at December 31, 2014	360,826	—	20,000	380,826
Granted	268,954	—	60,225	329,179
Vested	(73,432)	—	(11,666)	(85,098)
Expired or terminated	(110,018)	—	(16,209)	(126,227)
Outstanding at December 31, 2015	446,330	—	52,350	498,680

Other Equity Compensation Grants

During 2015, 2014 and 2013, our Board granted options to purchase 220,000, 165,000 and 270,000 shares of our common stock, respectively, and 82,250, 87,900 and 115,000 RSUs, respectively, to certain new-hire employees, to induce them to accept employment with us (collectively, "Inducement Awards"). 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.

Since we first began issuing inducement grants outside of our plans in 2012 as permitted under the NASDAQ Stock Market listing rules, we have issued a total of 1,646,250 shares of common stock pursuant to inducement grants, of which 243,875 stock options and 90,001 RSUs have been expired or terminated and of which 186,250 options have been exercised and 139,474 shares of common stock have been issued pursuant to RSUs that became fully vested. As of December 31, 2015, there were 830,975 options and 155,675 RSUs outstanding under Inducement Awards.

In August 2014, we granted certain members of our senior management performance-based RSUs under our 2007 Plan covering a maximum of 195,000 shares of common stock, which will be earned, if at all, based on the achievement of certain (a) targets based upon the calculated value expected to be realized with respect to certain business and corporate development transactions and (b) stock price minimums, during the 30-month period ending January 2, 2017,

measured as of January 4, 2016 and January 2, 2017. Fifty percent of the RSU grant that was earned through January 4, 2016 vested as of such date, and 100% of the RSU grant that is earned through January 2, 2017 (less the portion previously vested) shall vest as of January 2, 2017, subject to the continued employment of the grantee through each such date. As of January 4, 2016, the first measurement date, 60,000 shares were cancelled due to employee terminations, 83,070 shares were earned and 41,535 shares vested. The maximum total fair value of these RSUs is $2.1 million, which will be recognized to expense over a period of approximately three years from the date the vesting conditions outlined in these grants are deemed probable, net of any estimated and actual forfeitures. We recognized $0.2 million and $0.1 million of expense related to these awards during 2015 and 2014, respectively, based on the target for expected value to be realized that was considered probable of occurring at that time.

In February 2013, we granted RSUs under our 2007 Plan to certain members of our senior management covering a maximum of 82,500 shares of common stock, which are subject to a performance condition tied to the price of our common stock. At the end of the three-year period performance period ended December 31, 2015, the RSUs earned based on the achievement of the target stock price range were vested on January 15, 2016. On this date, 36,600 shares vested based upon the achievement of the target stock price. There were 27,500 shares cancelled due to employee terminations and another 18,400 shares cancelled due to non-achievement of the maximum target stock price range. The maximum total fair value of these RSUs was $0.5 million, which was recognized to expense over a period of three years from the date of grant, net of actual forfeitures.

Equity-based compensation expense

Equity-based compensation expense for 2015, 2014 and 2013 consisted of the following (in thousands):

	Years Ended December 31,		
	2015	2014	2013
Cost of product sales	$ 371	$ 122	$ 121
Research and development	2,992	1,596	2,149
Selling, general and administrative	13,874	6,907	5,734
Total equity-based compensation expense	$ 17,237	$ 8,625	$ 8,004
Income tax effect	(4,885)	—	—
After-tax effect of equity-based compensation expense	$ 12,352	$ 8,625	$ 8,004

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

As a result of our historical net losses, there was no income tax effect on our equity-based compensation expense for 2014 and 2013.

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

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

	Years Ended December 31,					
	2015		2014		2013	
	Employees	Non-Employee Directors	Employees	Non-Employee Directors	Employees	Non-Employee Directors
Risk free interest rate (%)	1.55	1.24	1.56	1.28	0.95	0.85
Expected volatility (%)	47	46	47	46	59	46
Expected option term (years)	5.00	4.00	5.00	4.00	5.00	4.00
Dividend yield	none	none	none	none	none	none

Risk free interest rates utilized are based upon published U.S. Treasury yields at the date of the grant for the expected option term. During 2015, 2014 and 2013, 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, 2015:

	December 31, 2015			
	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value ($ in millions)
Outstanding at beginning of year	2,996,383	$ 22.60	—	$ —
Granted	1,215,675	55.72	—	—
Exercised	(836,450)	21.58	—	—
Expired and/or forfeited	(471,431)	33.66	—	—
Outstanding at end of year	2,904,177	$ 34.97	7.8	$ 17,114
Outstanding at end of year - vested and unvested expected to vest	2,632,232	$ 34.40	7.8	$ 16,039
Exercisable at end of year	948,034	$ 23.44	6.1	$ 9,402

The weighted average grant date fair value of stock options granted during 2015, 2014 and 2013 was $23.57, $10.63 and $8.60, respectively. A total of 846,011 stock options vested during 2015. The aggregate intrinsic value of options exercised during 2015, 2014 and 2013, excluding purchases made pursuant to our employee stock purchase plans, measured as of the exercise date, was approximately $31.2 million, $5.9 million and $1.0 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, 2015:

	December 31, 2015	
	Restricted Stock Units	Weighted Average Grant Date Fair Value
Outstanding at beginning of year	541,226	$ 20.62
Granted	411,429	52.71
Vested	(149,572)	23.56
Forfeited	(148,728)	34.78
Outstanding at end of year	654,355	$ 36.90
Outstanding at end of year and expected to vest	567,954	$ 36.85

The weighted average grant date fair value of RSUs granted during 2015, 2014 and 2013 was $52.71, $22.88 and $16.31, respectively. The total grant date fair value of RSUs that vested during 2015, 2014 and 2013 was $3.5 million, $2.7 million and $2.8 million, respectively.

At December 31, 2015, the amount of unrecorded equity-based compensation expense for both option and RSU awards, net of forfeitures, attributable to future periods was approximately $44.8 million. Of this amount, $28.2 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 three years, and $16.6 million was associated with RSUs and is expected to be amortized on a straight-line basis to expense over a weighted average period of approximately two years. Such amounts will be amortized primarily to research and development or selling, general and administrative expense. These future estimates are subject to change based upon a variety of future events, which include, but are not limited to, changes in estimated forfeiture rates, employee turnover, and the issuance of new stock options and other equity-based awards.

M. EMPLOYEE SAVINGS PLAN

We provide a 401(k) Plan to our employees by which they may defer compensation for income tax purposes under Section 401(k) of the Internal Revenue Code. Each employee may elect to defer a percentage of his or her salary up to a specified maximum. Our 401(k) Plan provides, among other things, for a company contribution of 3% of each employee's combined salary and certain other compensation for the plan year. Salary deferred by employees and contributions by us to the 401(k) Plan are not taxable to employees until withdrawn from the 401(k) Plan and contributions are deductible by us when made. The amount of our company contribution for the 401(k) Plan was $1.8 million, $0.8 million and $0.7 million for 2015, 2014 and 2013, respectively.

N. STOCKHOLDERS' EQUITY

Preferred Stock

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

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

On September 26, 2014, we adopted another amendment to our Rights Agreement (which was approved by our stockholders at our 2015 annual meeting of stockholders) to help preserve our substantial tax assets associated with NOLs and other tax benefits by deterring certain stockholders from increasing their percentage ownership in our stock (the "NOL Amendment"). The NOL Amendment shortens the expiration date of the Rights Agreement from September 17, 2019 to March 31, 2017, decreases the exercise price of the rights from $250.00 to $80.00 in connection therewith, and makes changes to the definition of "beneficial ownership," as used in the Rights Agreement, as amended, to make it consistent with how ownership is defined under Section 382 of the Internal Revenue Code of 1986, as amended. The original Rights Agreement provided for a dividend distribution of one preferred share purchase right (a "Right") for each outstanding share of our common stock, which dividend was paid on September 17, 2009. Rights will separate from the common stock and will become exercisable upon the earlier of (a) the close of business on the 10th calendar day following the first public announcement that a person or group of affiliated or associated persons has acquired beneficial

ownership of 4.99% or more (which percentage had been 20% before the NOL Amendment) of the outstanding shares of common stock, other than as a result of repurchases of stock by us or certain inadvertent actions by a stockholder or (b) the close of business on the 10th business day (or such later day as the Board may determine) following the commencement of a tender offer or exchange offer that could result, upon its consummation, in a person or group becoming the beneficial owner of 4.99% or more (which percentage had been 20% before the NOL Amendment) of the outstanding shares of common stock (the earlier of such dates being herein referred to as the "Distribution Date").

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

Common Stock Transactions

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

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

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

Share Repurchase Program

In January 2016, we announced that our Board 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.

O. BUSINESS SEGMENTS

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

P. COMMITMENTS AND CONTINGENCIES

Commitments

Our long-term contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business. These include commitments related to our facility leases, purchases of inventory and other purchases related to our products, debt obligations, and other purchase obligations.

Facility Lease Obligations

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

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

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

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

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

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

Future minimum payments under our non-cancelable facility-related leases as of December 31, 2015 are as follows (in thousands):

Period	Minimum Lease Payments
Year Ending December 31, 2016	$ 2,967
Year Ending December 31, 2017	2,925
Year Ending December 31, 2018	2,123
Year Ending December 31, 2019	2,258
Year Ending December 31, 2020	2,330
Thereafter	1,165
Total	$ 13,768

Purchase Commitments

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

Contingent Consideration Related to Business Combinations

In connection with our acquisition of Lumara Health in November 2014, we agreed to pay up to an additional $350.0 million based on the achievement of certain sales milestones. Due to the contingent nature of these milestone

payments, we cannot predict the amount or timing of such payments with certainty. See Note C, "*Business Combinations*," for more information on the Lumara Health acquisition and related milestone payments.

Contingent Regulatory and Commercial Milestone Payments

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

In connection with 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 "Product") commencing on Product launch in a particular country until the Product is no longer developed, marketed, sold or offered for sale in such country (the "Antares Royalty Term"). The royalty rates range from high single digit to low double digits and are tiered based on levels of net sales of Products and decrease after the expiration of licensed patents or where there are generic equivalents to the Product being sold in a particular country.

Other Funding Commitments

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

Severance Arrangements

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

Indemnification Obligations

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

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

Contingencies

Legal Proceedings

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

Sandoz Paragraph IV Certification Letter

On February 5, 2016, we received a Paragraph IV certification notice letter regarding an Abbreviated New Drug Application submitted to the FDA by Sandoz Inc. ("Sandoz") requesting approval to engage in commercial manufacture, use and sale of a generic version of ferumoxytol. A generic version of *Feraheme* can be marketed only with the approval of the FDA of the respective application for such generic version. The Drug Price Competition and Patent Term Restoration Act of 1984, as amended, requires an applicant whose subject drug is a drug listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," also known as the "Orange Book," to notify the patent-holder of their application and potential infringement of their patent rights. The Paragraph IV certification notice is required to contain a detailed factual and legal statement explaining the basis for the applicant's opinion that the proposed product does not infringe the subject patents, that such patents are invalid, or both. Receipt of the certification notice triggers a 45 day window during which we may bring a patent infringement suit in federal district court against the applicant seeking approval of a product. In its notice letter, Sandoz claims that our ferumoxytol patents are invalid, unenforceable and/or not infringed by Sandoz's manufacture, use, sale or offer for sale of the generic version. We are evaluating the notice letter and intend to vigorously enforce our intellectual property rights relating to ferumoxytol. We plan to initiate a patent infringement suit to defend the patents identified in the notice letter. If we were to commence such a suit, the FDA is generally prohibited from granting approval of an application until the earliest of 30 months from the date the FDA accepted the application for filing, the conclusion of litigation in the generic's favor, or expiration of the patent(s) (though such stay may be shortened or lengthened if either party fails to cooperate in the litigation). If the litigation is resolved in favor of the applicant or the challenged patent expires during the 30-month stay period, the stay is lifted and the FDA may thereafter approve the application based on the applicable standards for approval.

European Patent Organization Appeal

In July 2010, Sandoz filed with the European Patent Office (the "EPO") an opposition to a previously issued patent which covers ferumoxytol in EU jurisdictions. In October 2012, at an oral hearing, the Opposition Division of the EPO revoked this patent. We recorded a notice of appeal at the EPO in December 2012, which suspended the revocation of our patent. The oral proceedings for the appeal occurred on June 16, 2015, where the decision revoking the patent was set aside and remitted back to the Opposition Division for further consideration. In the event that we do not experience a successful outcome at the Opposition Division, under EU regulations ferumoxytol would still be entitled to eight years of data protection and ten years of market exclusivity from the date of approval, which we believe would create barriers to entry for any generic version of ferumoxytol into the EU market until sometime between 2020 and 2022. This decision had no impact on our revenues for 2015. However, any future unfavorable outcome in this matter could negatively affect the magnitude and timing of future revenues, if we were to resume commercialization efforts in the EU. We do not expect to incur any related liability regardless of the outcome of the appeal and therefore did not record any liability as of December 31, 2015. We continue to believe the patent is valid and intend to vigorously prosecute the patent before the Opposition Division.

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 has engaged in unfair methods of competition with respect to *Makena* or any hydroxyprogesterone caproate product. We are fully cooperating with the FTC and have provided a thorough response to the FTC and are awaiting their review of our response. The FTC noted in its letter that the existence of the investigation does not indicate that the FTC has concluded that Lumara Health or its predecessor has violated the law and we believe that our contracts and practices comply with relevant law and policy, including the federal Drug Quality and Security Act (the "DQSA"), which was enacted in November 2013, and public statements from and enforcement actions by the FDA regarding its implementation of the DQSA. We have provided the FTC with a response that provides a brief overview of the DQSA for context, which we believe will be helpful, including: (i) how the statute outlined that large-scale compounding of products that are copies or near-copies of FDA-approved drugs (like *Makena*) is not in the interests of public safety; (ii) our belief that the DQSA has had a significant impact on the compounding of hydroxyprogesterone caproate; and (iii) 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 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 at December 31, 2015.

Q. COLLABORATION, LICENSE AND OTHER STRATEGIC AGREEMENTS

Our commercial strategy includes expanding our portfolio through the in-license or acquisition of additional pharmaceutical products or companies, including revenue-generating commercial products and late-state development assets. As of December 31, 2015, we were a party to the following collaborations:

Takeda

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

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

Prior to entering into the Takeda Termination Agreement, under the terms of the Amended Takeda Agreement, Takeda was responsible for reimbursing us for certain out-of-pocket regulatory and clinical trial supply costs associated with carrying out our regulatory and clinical research activities under the collaboration agreement. Because we were acting as the principal in carrying out these services, any reimbursement payments received from Takeda were recorded in license fee, collaboration and other revenues in our consolidated statements of operations to match the costs that we

incurred during the period in which we performed those services. We did not record any reimbursement revenues from Takeda during 2015, and recorded $1.7 million and $0.5 million for 2014 and 2013, respectively.

Prior to entering into the Takeda Termination Agreement, at the time of shipment, we deferred recognition of all revenue for *Feraheme* sold to Takeda on our consolidated balance sheets. We recognized revenues from product sales to Takeda, the related cost of product sales, and any royalty revenues due from Takeda, in our consolidated statements of operations at the time Takeda reported to us that sales had been made to their customers. During 2015 and 2014, we recognized $1.1 million and $3.5 million in license fee, collaboration and other revenues, respectively. No cost of product sales were recognized in 2015. In 2014, we recognized $2.8 million of cost of product sales related to the Amended Takeda Agreement, which included all amounts previously deferred prior to the termination of the Amended Takeda Agreement, and we have included in other product sales and royalties, and cost of product sales, respectively, in our consolidated statement of operations.

Velo

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

We have determined that Velo is a variable interest entity ("VIE") as it does not have enough equity to finance its activities without additional financial support. As we do not have the power to direct the activities of the VIE that most significantly affect its economic performance, which we have determined to be the Phase 2b/3a clinical study, we are not the primary beneficiary of and do not consolidate the VIE.

Antares

In September 2014, Lumara Health entered into the Antares Agreement with Antares, which in connection with our acquisition of Lumara Health in November of 2014, grants us an exclusive, worldwide, royalty-bearing license, with the right to sublicense, to certain intellectual property rights, including know-how, patents and trademarks, to develop, use, sell, offer for sale and import and export the Product. In consideration for the license, to support joint meetings and a development strategy with the FDA, and for initial tooling and process validation, Lumara Health paid Antares an up-front payment in October 2014. Under the Antares Agreement, we are responsible for the clinical development and preparation, submission and maintenance of all regulatory applications in each country where we desire to market and sell the Product, including the U.S. We are required to pay royalties to Antares on net sales of the Product commencing on Product launch in a particular country for the Antares Royalty Term. The royalty rates range from high single digit to low double digits and are tiered based on levels of net sales of Products and decrease after the expiration of licensed patents or where there are generic equivalents to the Product being sold in a particular country. Antares is the exclusive supplier of our requirements for the auto-injection system devices for the Products and Antares remains responsible for the manufacture and supply of the devices and assembly of the Product. We are responsible for the supply of the drug to be used in the assembly of the finished Product. The development and license agreement terminates at the end of the Antares Royalty Term, but is subject to early termination by us for convenience, by Antares if we do not submit regulatory filings in the U.S. by a certain date and by either party upon an uncured breach by or bankruptcy of the other party.

Abeona

Please refer to Note C, "*Business Combinations*," for a detailed description of the MuGard License Agreement.

R. DEBT

Our outstanding debt obligations as of December 31, 2015 and December 31, 2014 consisted of the following (in thousands):

	December 31,	
	2015	2014
2023 Senior Notes	$ 490,335	$ —
2015 Term Loan Facility	338,415	—
2.5% Convertible Notes	174,390	167,441
2014 Term Loan Facility	—	327,905
Total long-term debt	1,003,140	495,346
Less: current maturities	17,500	34,000
Long-term debt, net of current maturities	$ 985,640	$ 461,346

2023 Senior Notes

On August 17, 2015, in connection with the CBR acquisition, we completed a private placement of $500.0 million aggregate principal amount of 2023 Senior Notes. The 2023 Senior Notes were issued pursuant to an Indenture, dated as of August 17, 2015 (the "Indenture"), by and among the Company, certain subsidiaries of the Company acting as guarantors of the 2023 Senior Notes and Wilmington Trust, National Association, as trustee. The Indenture contains certain customary negative covenants, which are subject to a number of limitations and exceptions. Certain of the covenants will be suspended during any period in which the 2023 Senior Notes receive investment grade ratings.

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

At December 31, 2015, the carrying value of the outstanding borrowings, net of unamortized original issue costs and other lender fees and expenses, was $490.3 million.

2015 Term Loan Facility

On August 17, 2015, to fund a portion of the purchase price of CBR, we entered into a credit agreement with a group of lenders, including Jefferies Finance LLC as administrative and collateral agent, that provided us with, among other things, a six-year $350.0 million term loan facility. We borrowed the full $350.0 million available under the 2015

Term Loan Facility on August 17, 2015. The credit agreement also allows for the incurrence of incremental loans in an amount up to $225.0 million. At December 31, 2015, the carrying value of the outstanding borrowings, net of unamortized original issue costs and other lender fees and expenses, was $338.4 million. The unamortized original issue costs and other lender fees and expenses, including a prepayment penalty, included $6.8 million of the unamortized original issue costs and other lender fees and expenses from our then existing five-year term loan facility (the "2014 Term Loan Facility") as a result of accounting guidance for the modification of debt arrangements. We also recorded $2.4 million of fees and expenses from the 2014 Term Loan Facility in other income (expense) in our consolidated statement of operations.

The 2015 Term Loan Facility bears interest, at our option, at the London Interbank Offered Rate ("LIBOR") plus a margin of 3.75% or the prime rate plus a margin of 2.75%. The LIBOR is subject to a 1.00% floor and the prime rate is subject to a 2.00% floor. As of December 31, 2015, the stated interest rate, based on the LIBOR, was 4.75%, and the effective interest rate was 5.65%.

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

The 2015 Term Loan Facility includes an annual mandatory prepayment of the debt in an amount equal to 50% of our excess cash flow (as defined in the 2015 Term Loan Facility) as measured on an annual basis, beginning with the year ending December 31, 2016. On or after December 31, 2016, the applicable excess cash flow percentage shall be reduced based on the total net leverage ratio as of the last day of the period. Excess cash flow is generally defined as our adjusted Earnings Before Interest, Taxes, Depreciation and Amortization ("EBITDA") less debt service costs, unfinanced capital expenditures, unfinanced acquisition expenditures, contingent consideration paid, and current income taxes as well as other adjustments specified in the credit agreement.

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

2.5% Convertible Notes

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

The Convertible Notes are governed by the terms of an indenture between us, as issuer, and Wilmington Trust, National Association, as the trustee. The Convertible Notes are senior unsecured obligations and bear interest at a rate of 2.5% per year, payable semi-annually in arrears on February 15 and August 15 of each year. The Convertible Notes will mature on February 15, 2019, unless earlier repurchased or converted. Upon conversion of the Convertible Notes, at a holder's election, such Convertible Notes will be convertible into cash, shares of our common stock, or a combination thereof, at our election (subject to certain limitations in the 2015 Term Loan Facility,) at a conversion rate of approximately 36.9079 shares of common stock per $1,000 principal amount of the Convertible Notes, which corresponds to an initial conversion price of approximately $27.09 per share of our common stock.

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

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

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

(3) upon the occurrence of specified corporate events.

On or after May 15, 2018 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert all or any portion of their Convertible Notes, in multiples of $1,000 principal amount, at the option of the holder regardless of the foregoing circumstances. Based on the last reported sale price of our common stock during the last 30 trading days of 2015, the Convertible Notes were not convertible as of December 31, 2015.

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

Our outstanding Convertible Note balances as December 31, 2015 consisted of the following (in thousands):

	December 31, 2015
Liability component:	
Principal	$ 200,000
Less: debt discount, net	(25,610)
Net carrying amount	$ 174,390
Equity component	$ 38,188

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

We determined the expected life of the debt was equal to the five year term on the Convertible Notes. As of December 31, 2015, the carrying value of the Convertible Notes was $174.4 million. The effective interest rate on the

liability component was 7.23% for the period from the date of issuance through December 31, 2015. As of December 31, 2015, the "if-converted value" exceeded the remaining principal amount of the Convertible Notes by $22.9 million.

The following table sets forth total interest expense recognized related to the Convertible Notes during the years ended December 31, 2015 and December 31, 2014 (in thousands):

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

Convertible Bond Hedge and Warrant Transactions

In connection with the pricing of the Convertible Notes and in order to reduce the potential dilution to our common stock and/or offset cash payments due upon conversion of the Convertible Notes, in February 2014, we entered into convertible bond hedge transactions covering approximately 7.4 million shares of our common stock underlying the $200.0 million aggregate principal amount of the Convertible Notes with the call spread counterparties. The convertible bond hedges have an exercise price of approximately $27.09 per share, subject to adjustment upon certain events, and are exercisable when and if the Convertible Notes are converted. If upon conversion of the Convertible Notes, the price of our common stock is above the exercise price of the convertible bond hedges, the call spread counterparties will deliver shares of our common stock and/or cash with an aggregate value approximately equal to the difference between the price of our common stock at the conversion date and the exercise price, multiplied by the number of shares of our common stock related to the convertible bond hedges being exercised. The convertible bond hedges are separate transactions entered into by us and are not part of the terms of the Convertible Notes or the warrants, discussed below. Holders of the Convertible Notes will not have any rights with respect to the convertible bond hedges. We paid $39.8 million for these convertible bond hedges and recorded this amount as a reduction to additional paid-in capital, net of tax, in 2014.

In February 2014, we also entered into separate warrant transactions with each of the call spread counterparties relating to, in the aggregate, approximately 7.4 million shares of our common stock underlying the $200.0 million aggregate principal amount of the Convertible Notes. The initial exercise price of the warrants is $34.12 per share, subject to adjustment upon certain events, which is 70% above the last reported sale price of our common stock of $20.07 on February 11, 2014. The warrants would separately have a dilutive effect to the extent that the market value per share of our common stock, as measured under the terms of the warrants, exceeds the applicable exercise price of the warrants. The warrants were issued to the call spread counterparties pursuant to the exemption from registration set forth in Section 4(a)(2) of the Securities Act of 1933, as amended. We received $25.7 million for these warrants and recorded this amount to additional paid-in capital in 2014.

Aside from the initial payment of $39.8 million to the call spread counterparties for the convertible bond hedges, which was partially offset by the receipt of $25.7 million for the warrants, we are not required to make any cash payments to the call spread counterparties under the convertible bond hedges and will not receive any proceeds if the warrants are exercised.

2014 Term Loan Facility

In November 2014, we borrowed $340.0 million under the 2014 Term Loan Facility to fund a portion of the purchase price of Lumara Health. On August 17, 2015, we repaid the remaining $323.0 million outstanding principal amount and recognized a $10.4 million loss on debt extinguishment as a result of the early repayment, which we have recorded in other income (expense) in our consolidated statement of operations.

Future Payments

Future annual principal payments on our long-term debt as of December 31, 2015 were as follows:

Year Ending December 31, 2016	$ 17,500
Year Ending December 31, 2017	17,500
Year Ending December 31, 2018	17,500
Year Ending December 31, 2019	217,500
Year Ending December 31, 2020	17,500
Thereafter	758,125
Total	$ 1,045,625

S. RESTRUCTURING

In connection with the CBR and Lumara Health acquisitions, we initiated restructuring programs in the third quarter of 2015 and the fourth quarter of 2014, respectively, which included severance benefits primarily related to certain former CBR and Lumara Health employees. As a result of these restructurings, we recorded charges of approximately $4.1 million and $2.0 million in 2015 and 2014, respectively. In addition, we currently expect to record $0.9 million of additional restructuring charges. We expect to pay substantially all of these restructuring costs by the end of 2016.

The following table outlines the components of our restructuring expenses which were included in current liabilities for 2015 and 2014 (in thousands):

	Years Ended December 31,	
	2015	2014
Accrued restructuring, beginning of period	$ 1,953	$ —
Employee severance, benefits and related costs	3,874	2,023
Payments	(2,944)	(70)
Accrued restructuring, end of period	$ 2,883	$ 1,953

T. CONSOLIDATED QUARTERLY FINANCIAL DATA—UNAUDITED

The following tables provide unaudited consolidated quarterly financial data for 2015 and 2014 (in thousands, except per share data):

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

	March 31, 2014	June 30, 2014	September 30, 2014	December 31, 2014
Total revenues (c)	$ 20,835	$ 24,802	$ 25,494	$ 53,253
Gross profit (c)	17,998	22,059	22,526	41,495
Operating expenses (c)	23,989	20,824	18,233	44,869
Net income (loss) (d)	$ (7,102)	$ (1,547)	$ 1,458	$ 143,008
Net income (loss) per share - basic	$ (0.33)	$ (0.07)	$ 0.07	$ 5.98
Net income (loss) per share - diluted	$ (0.33)	$ (0.07)	$ 0.07	$ 4.67

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

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

(b) In August 2015, we repaid the remaining $323.0 million outstanding principal amount and recognized a $10.4 million loss on debt extinguishment as a result of the early repayment, w

(c) In November 2014, we acquired Lumara Health and recorded $22.5 million in *Makena* sales in 2014 and additional operating costs incurred as a result of the acquisition.

(d) In the fourth quarter of 2014, we recognized a $153.2 million income tax benefit in connection with the 2014 Lumara Health acquisition.

U. VALUATION AND QUALIFYING ACCOUNTS (IN THOUSANDS)

	Balance at Beginning of Period	Additions (a)	Deductions Charged to Reserves	Balance at End of Period
Year ended December 31, 2015:				
Allowance for doubtful accounts (a)	$ —	$ 900	$ —	$ 900
Accounts receivable allowances (b)	$ 11,618	$ 93,887	$ (94,722)	$ 10,783
Rebates, fees and returns reserves	$ 43,892	$ 120,293	$ (119,023)	$ 45,162
Year ended December 31, 2014:				
Accounts receivable allowances (b)	$ 2,728	$ 60,054	$ (51,164)	$ 11,618
Rebates, fees and returns reserves	$ 4,819	$ 52,548	$ (13,475)	$ 43,892
Year ended December 31, 2013:				
Accounts receivable allowances (b)	$ 1,771	$ 37,222	$ (36,265)	$ 2,728
Rebates, fees and returns reserves	$ 3,448	$ 11,850	$ (10,479)	$ 4,819

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

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

V. RECENTLY ISSUED AND PROPOSED ACCOUNTING PRONOUNCEMENTS

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

In November 2015, the FASB issued ASU 2015-17, *Income Taxes (Topic 740); Balance Sheet Classification of Deferred Taxes*. This statement requires entities to present deferred tax assets and deferred tax liabilities as noncurrent in a classified balance sheet. This statement is effective for annual reporting periods beginning after December 15, 2016, and including interim periods within those annual reporting periods, and entities are permitted to apply either prospectively or retrospectively, with early adoption permitted. We early adopted this guidance prospectively in the fourth quarter of 2015 to simplify the current period presentation of our deferred income taxes, noting prior periods were not retrospectively adjusted. For additional information, please see Note J, "*Income Taxes*," to our consolidated financial statements included in this Annual Report on Form 10-K.

In September 2015, the FASB issued ASU 2015-16, *Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments*. This statement eliminates the requirement for an acquirer to retrospectively adjust provisional amounts recorded in a business combination to reflect new information about the facts

and circumstances that existed as of the acquisition date and that, if known, would have affected measurement or recognition of amounts initially recognized. As an alternative, the amendment requires that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. The amendments require that the acquirer record, in the financial statements of the period in which adjustments to provisional amounts are determined, the effect on earnings of changes in depreciation, amortization, or other income effects, if any, as a result of the change to the provisional amounts, calculated as if the accounting had been completed at the acquisition date. The new standard is effective prospectively for fiscal years beginning after December 15, 2015, including interim periods within those fiscal years, with early adoption permitted. The guidance is to be applied prospectively to adjustments to provisional amounts that occur after the effective date of the guidance, with earlier application permitted for financial statements that have not been issued. Additional details regarding our measurement period adjustments can be found in Note C, "*Business Combinations,*" to our consolidated financial statements included in this Annual Report on Form 10-K.

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

In May 2015, the FASB issued ASU 2015-07, *Fair Value Measurement (Topic 820): Disclosures for Investments in Certain Entities That Calculate Net Asset Value per Share (or Its Equivalent)* ("ASU 2015-07"). Under this standard, investments measured at net asset value, as a practical expedient for fair value, will be excluded from the fair value hierarchy. The only criterion for categorizing investments in the fair value hierarchy will be the observability of the inputs. The standard is effective for us for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. Early adoption is permitted, including for financial statement periods that have not yet been issued. We do not expect the adoption of ASU 2015-07 to have a material impact on our disclosures.

In April 2015, the FASB issued ASU No. 2015-03, *Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs* ("ASU 2015-03"). The amendments in ASU 2015-03 require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. In August 2015, the FASB issued ASU No. 2015-15, *Interest – Imputation of Interest (Subtopic 835-30): Presentation and Subsequent Measurement of Debt Issuance Costs Associated with Line-of-Credit Arrangements* ("ASU 2015-15"), which allows presentation of debt issuance costs related to line-of-credit arrangements as either in accordance with the amendments in ASU 2015-03, or as an asset with subsequent amortization of the debt issuance costs ratably over the term of the arrangement. These updates are effective for annual and interim periods beginning on or after December 15, 2015. As of December 31, 2015, we have $11.2 million in debt issuance costs associated with our current debt obligations that would be reclassified from a long-term asset to a reduction in the carrying amount of our debt.

In February 2015, the FASB issued ASU No. 2015-02, "*Consolidation (Topic 810) - Amendments to the Consolidation Analysis*." This statement eliminates the deferral of the requirements of ASU No. 2009-17, "*Consolidations (Topic 810) - Improvements to Financial Reporting by Enterprises Involved with Variable Interest Entities*" for certain interests in investment funds and provides a scope exception from Topic 810 for certain investments in money market funds. The ASU also makes several modifications to the consolidation guidance for VIEs and general partners' investments in limited partnerships, as well as modifications to the evaluation of whether limited partnerships are VIEs or voting interest entities. The guidance is effective for interim and annual reporting periods beginning after December 15, 2015, and early adoption is permitted. The adoption of this standard is not expected to have an impact on our results of operations, cash flows or financial position.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements—Going Concern: Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (*"ASU 2014-15"). ASU 2014-15 is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's

ability to continue as a going concern and to provide related footnote disclosures, if required. ASU 2014-15 will be effective for annual reporting periods ending after December 15, 2016, which will be our fiscal year ending December 31, 2016, and to annual and interim periods thereafter. We are in the process of evaluating the impact of adoption of ASU 2014-15 on our consolidated financial statements and related disclosures and do not expect it to have a material impact our results of operations, cash flows or financial position.

In May 2014, the FASB issued ASU 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 August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers, Topic 606, Deferral of the Effective Date,* which defers the effective date of this standard by one year to annual reporting periods beginning after December 15, 2017, including interim periods within that year, which for us is January 1, 2018. Early adoption is permitted any time after the original effective date, which for us is January 1, 2017. We have not yet selected a transition method and are currently evaluating the impact of this standard on our consolidated financial statements.

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, 2015, 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, 2015 and is incorporated herein by reference.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the fourth quarter of the year ended December 31, 2015 that 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, 2015.

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, 2015.

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, 2015.

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, 2015.

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, 2015.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES:

Exhibit Number	Description
2.1	Agreement and Plan of Merger, dated as of September 28, 2014, by and among Lumara Health Inc., AMAG Pharmaceuticals, Inc., Snowbird, Inc., and Lunar Representative, LLC as the Stockholders' Representative (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed September 29, 2014, File No. 001-10865)
2.2	Stock Purchase Agreement, dated as of June 29, 2015, by and among CBR Holdco, LLC, CBR Acquisition Holdings Corp. and AMAG Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed June 29, 2015, File No. 001-10865)
3.1, 4.1	Certificate of Incorporation of AMAG Pharmaceuticals, Inc., as restated (incorporated herein by reference to Exhibits 3.1 and 4.1to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, File No. 001-10865)
3.2,4.2	Certificate of Amendment to Restated Certificate of Incorporation of AMAG Pharmaceuticals, Inc. as filed on May 21, 2015 with the Delaware Secretary of State (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed May 28, 2015, File No. 001-10865)
3.3, 4.3	Amended and Restated By-Laws of AMAG Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed December 17, 2015, File No. 001-10865)
3.4, 4.4	Certificate of Designation of Series A Junior Participating Preferred Stock (incorporated herein by reference to Exhibits 3.1 and 4.1 to the Company's Current Report on Form 8-K filed September 4, 2009, File No. 0-14732)
4.6	Specimen certificate representing AMAG Pharmaceuticals, Inc.'s Common Stock (incorporated herein by reference to Exhibit 4.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2009, File No. 001-10865)
4.7	Rights Agreement, dated as of September 4, 2009 by and between AMAG Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, LLC (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed September 4, 2009, File No. 0-14732)
4.8	Amendment to Rights Agreement, dated as of May 10, 2012, by and between AMAG Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, LLC (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed May 10, 2012, File No. 001-10865)
4.9	Amendment to Rights Agreement, dated as of February 11, 2014, by and between AMAG Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, LLC (incorporated herein by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
4.10	NOL Amendment to Rights Agreement, dated as of September 26, 2014, by and between AMAG Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, LLC (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed September 29, 2014, File No. 001-10865)
4.11	Form of Rights Certificate (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed September 4, 2009, File No. 0-14732)
4.12	Base Indenture, dated as of February 14, 2014, by and between AMAG Pharmaceuticals, Inc. and Wilmington Trust, National Association (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
4.13	First Supplemental Indenture, dated as of February 14, 2014, by and between AMAG Pharmaceuticals, Inc. and Wilmington Trust, National Association (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
4.14	Form of 2.50% Convertible Senior Note due 2019 (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
4.15	Form of Registration Rights and Lock-up Agreement, dated as of November 12, 2014, by and between AMAG Pharmaceuticals, Inc. and stockholders party thereto (incorporated herein by reference to Exhibit 4.9 to the Company's Registration Statement on Form S-3 filed February 10, 2015, File No. 333-202009)

Exhibit Number	Description
4.16	Indenture, dated as of August 17, 2015, by and among AMAG Pharmaceuticals, Inc., the Guarantors party thereto and Wilmington Trust, National Association, as trustee (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed August 17, 2015, File No. 001-10865)
4.17	Form of 7.875% Senior Note due 2023 (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed August 17, 2015, File No. 001-10865)
10.1*	Representative Form of Indemnification Agreement (incorporated herein by reference to Exhibit 10.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2009, File No. 001-10865)
10.2*	Summary of AMAG Pharmaceuticals, Inc.'s Change of Control Policy applicable to executive officers (incorporated herein by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed February 13, 2006, File No. 0-14732)
10.3*	AMAG Pharmaceuticals, Inc.'s Non-Employee Director Compensation Policy (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, File No. 001-10865)
10.4*	AMAG Pharmaceuticals, Inc.'s Amended and Restated 2000 Stock Plan (incorporated herein by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A filed December 14, 2005, File No. 0-14732)
10.5*	AMAG Pharmaceuticals, Inc.'s Third Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A filed April 19, 2013, File No. 001-10865)
10.6*	First Amendment to the AMAG Pharmaceuticals, Inc. Third Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Appendix B to the Company's Definitive Proxy Statement on Schedule 14A filed April 16, 2015, File No. 001-10865)
10.7*	AMAG Pharmaceuticals, Inc. 2015 Employee Stock Purchase Plan (incorporated herein by reference to Appendix C to the Company's Definitive Proxy Statement on Schedule 14A filed April 16, 2015, File No. 001-10865)
10.8*	Lumara Health Inc. Amended and Restated 2013 Incentive Compensation Plan (incorporated herein by reference to Exhibit 10.6 to the Company's Annual Report on Form 10-K for the year ended December 31, 2014, File No. 001-10865)
10.9*	Form of Incentive Stock Option Agreement for AMAG Pharmaceuticals, Inc. Employees under AMAG Pharmaceuticals, Inc.'s Third Amended and Restated 2007 Equity Incentive Plan and the Lumara Health Inc. Amended and Restated 2013 Incentive Compensation Plan (incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, File No. 001-10865)
10.10*	Form of Non-Qualified Stock Option Agreement for AMAG Pharmaceuticals, Inc. Employees under AMAG Pharmaceuticals, Inc.'s Third Amended and Restated 2017 Equity Incentive Plan and the Lumara Health Inc. Amended and Restated 2013 Incentive Compensation Plan (incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, File No. 001-10865)
10.11*+	Form of Restricted Stock Unit Agreement for AMAG Pharmaceuticals, Inc. - Employees under AMAG Pharmaceuticals, Inc.'s Third Amended and Restated 2007 Equity Incentive Plan and the Lumara Health Inc. Amended and Restated 2013 Incentive Compensation Plan
10.12*	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors under AMAG Pharmaceuticals, Inc.'s Third Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.10 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, File No. 001-10865)
10.13*+	Form of Restricted Stock Unit Agreement for Non-Employee Directors under AMAG Pharmaceuticals, Inc.'s Third Amended and Restated 2007 Equity Incentive Plan
10.14*	Form of February 2013 Performance-based Restricted Stock Unit Agreement under AMAG Pharmaceuticals, Inc.'s Third Amended and Restated 2007 Equity Incentive Plan between AMAG Pharmaceuticals, Inc. and AMAG Pharmaceuticals, Inc.'s executive officers (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, File No. 001-10865)

Exhibit Number	Description
10.15*	Non-Plan Restricted Stock Unit Agreement, by and between AMAG Pharmaceuticals, Inc. and William K. Heiden (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed May 10, 2012, File No. 001-10865)
10.16*	Non-Plan Stock Option Agreement, by and between AMAG Pharmaceuticals, Inc. and William K. Heiden (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed May 10, 2012, File No. 001-10865)
10.17*	Form of Non-Qualified Stock Option Agreement - Non-Plan Inducement Grant (incorporated herein by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-8 filed August 7, 2013, File No. 333-190435)
10.18*+	Form of Restricted Stock Unit Agreement - Non-Plan Inducement Grant
10.19*+	Form of Employment Agreement between AMAG Pharmaceuticals, Inc. and each of its executive officers (other than William K. Heiden)
10.20*	Employment Agreement dated as of February 7, 2014 between AMAG Pharmaceuticals, Inc. and William K. Heiden (incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2014, File No. 001-10865)
10.21*	Notice of Termination between AMAG Pharmaceuticals, Inc. and Edward Jordan dated May 4, 2015 (incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, File No. 001-10865)
10.22*	Notice of Termination between AMAG Pharmaceuticals, Inc. and Scott Townsend dated May 5, 2015 (incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, File No. 001-10865)
10.23	Letter Agreement, dated March 10, 2015, by and between the Company and Lunar Representative, LLC (incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, File No. 001-10865)
10.24	Letter Agreement, dated April 10, 2015, by and between the Company and Lunar Representative, LLC (incorporated herein by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, File No. 001-10865)
10.25	Termination Agreement, dated December 29, 2014, by and between AMAG Pharmaceuticals, Inc. and Takeda Pharmaceutical Company Limited (incorporated herein by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011, File No. 001-10865) (confidential treatment previously granted)
10.26	Lease Agreement, dated as of May 22, 2008, by and between AMAG Pharmaceuticals, Inc. and Mortimer B. Zuckerman and Edward H. Linde, trustees of 92 Hayden Avenue Trust under Declaration of Trust dated August 18, 1983. This Lease Agreement was assigned in June 2013. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 29, 2008, File No. 0-14732)
10.27	Assignment and Assumption of Lease, dated as of June 10, 2013, by and among AMAG Pharmaceuticals, Inc., Mortimer B. Zuckerman and Edward H. Linde, trustees of 92 Hayden Avenue Trust under Declaration of Trust dated August 18, 1983 and Shire Human Genetic Therapies, Inc. (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed June 13, 2013, File No. 001-10865)
10.28	Lease Agreement, dated as of June 10, 2013, by and between AMAG Pharmaceuticals, Inc. and BP BAY COLONY LLC (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 13, 2013, File No. 001-10865)
10.29	First Amendment to Lease Agreement, dated June 10, 2013, by and between AMAG Pharmaceuticals, Inc. and BP BAY COLONY LLC, dated March 24, 2015 (incorporated herein by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, File No. 001-10865)
10.30+	Second Amendment to Lease Agreement, dated June 10, 2013, by and between AMAG Pharmaceuticals, Inc. and BP BAY COLONY LLC, dated December 4, 2015
10.31+	Third Amendment to Lease Agreement, dated June 10, 2013, by and between AMAG Pharmaceuticals, Inc. and BP BAY COLONY LLC, dated December 7, 2015

Exhibit Number	Description
10.32	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)
10.33	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)
10.34	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)
10.35	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)
10.36+	Amendment No. 3 to Commercial Supply Agreement, dated October 19, 2015, by and between the Company and Sigma-Aldrich, Inc. (Certain confidential information contained in this exhibit was omitted by means of redacting a portion of the text and replacing it with [***]. This exhibit has been filed separately with the SEC without any redactions pursuant to a Confidential Treatment Request under Rule 24b-2 of the Securities and Exchange Act of 1934, as amended)
10.37	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)
10.38	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)
10.39	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)
10.40	Development and Supply Agreement, dated as of September 17, 2009, by and between Lumara Health Inc. (as successor in interest to Hologic, Inc.) and Hospira Worldwide, Inc. (incorporated herein by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-K for the year ended December 31, 2014, File No. 001-10865) (confidential treatment previously granted)
10.41	First Amendment to Development and Supply Agreement, dated as of March 28, 2014, by and between Lumara Health Inc. and Hospira Worldwide, Inc. (incorporated herein by reference to Exhibit 10.32 to the Company's Annual Report on Form 10-K for the year ended December 31, 2014, File No. 001-10865) (confidential treatment previously granted)
10.42+	Development and License Agreement, dated September 30, 2014, by and between Lumara Health Inc and Antares Pharma, Inc. (Certain confidential information contained in this exhibit was omitted by means of redacting a portion of the text and replacing it with [***]. This exhibit has been filed separately with the SEC without any redactions pursuant to a Confidential Treatment Request under Rule 24b-2 of the Securities and Exchange Act of 1934, as amended)
10.43	Underwriting Agreement, dated as of February 11, 2014, among AMAG Pharmaceuticals, Inc. and J.P. Morgan Securities LLC, on its own behalf and as representative of the several underwriters named in Schedule 1 thereto (incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)

Exhibit Number	Description
10.44	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)
10.45	Base Call Option Transaction Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and Royal Bank of Canada (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.46	Base Call Option Transaction Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and Morgan Stanley & Co. International plc (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.47	Base Warrants Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association, London Branch (incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.48	Amendment to Warrant Transaction, dated as of February 23, 2015, by and between AMAG Pharmaceuticals, Inc. and J.P. Morgan Securities LLC, as agent (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, File No. 001-10865)
10.49	Base Warrants Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and Royal Bank of Canada (incorporated herein by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.50	Base Warrants Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and Morgan Stanley & Co. International plc (incorporated herein by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.51	Additional Call Option Transaction Confirmation, dated as of February 13, 2014, between AMAG Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association, London Branch (incorporated herein by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.52	Additional Call Option Transaction Confirmation, dated as of February 13, 2014, between AMAG Pharmaceuticals, Inc. and Royal Bank of Canada (incorporated herein by reference to Exhibit 10.8 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.53	Additional Call Option Transaction Confirmation, dated as of February 13, 2014, between AMAG Pharmaceuticals, Inc. and Morgan Stanley & Co. International plc (incorporated herein by reference to Exhibit 10.9 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.54	Additional Warrants Confirmation, dated as of February 13, 2014, between AMAG Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association, London Branch (incorporated herein by reference to Exhibit 10.10 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.55	Additional Warrants Confirmation, dated as of February 13, 2014, between AMAG Pharmaceuticals, Inc. and Royal Bank of Canada (incorporated herein by reference to Exhibit 10.11 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.56	Additional Warrants Confirmation, dated as of February 13, 2014, between AMAG Pharmaceuticals, Inc. and Morgan Stanley & Co. International plc (incorporated herein by reference to Exhibit 10.12 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.57	Credit Agreement, dated as of November 12, 2014, by and among AMAG Pharmaceuticals, Inc., the financial institutions and agents listed therein, and Jefferies Finance LLC (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed November 12, 2014, File No. 001-10865)
10.58	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)

Exhibit Number	Description
10.59	Credit Agreement, dated as of August 17, 2015, by and among AMAG Pharmaceuticals, Inc., the financial institutions and agents listed therein, and Jefferies Finance LLC (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 17, 2015, File No. 001-10865)
10.60	Underwriting Agreement, dated as of July 30, 2015, among AMAG Pharmaceuticals, Inc., Jefferies LLC and Barclays Capital Inc., as representatives of the underwriters named therein (incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed July 31, 2015, File No. 001-10865)
10.61	Underwriting Agreement, dated as of February 25, 2015, among AMAG Pharmaceuticals, Inc., J.P. Morgan Securities LLC and Deutsche Bank Securities Inc., as representatives of the underwriters named therein (incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed February 26, 2015, File No. 001-10865)
21.1+	Subsidiaries of AMAG Pharmaceuticals, Inc.
23.1+	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm
24.1	Power of Attorney (included on the signature page(s) hereto)
31.1+	Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2+	Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS+	XBRL Instance Document
101.SCH+	XBRL Taxonomy Extension Schema Document
101.CAL+	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB+	XBRL Taxonomy Extension Label Linkbase Document
101.PRE+	XBRL Taxonomy Extension Presentation Linkbase Document

\+ Exhibits marked with a plus sign ("+") are filed herewith.

++ Exhibits marked with a double plus sign ("++") are furnished herewith.

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

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

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

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

SIGNATURES

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

AMAG PHARMACEUTICALS, INC.

By: /s/ William K. Heiden
William K. Heiden
Chief Executive Officer
Date: February 24, 2016

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

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

Name	Title	Date
/s/ William K. Heiden William K. Heiden	Chief Executive Officer (Principal Executive Officer) and Director	February 24, 2016
/s/ Frank E. Thomas Frank E. Thomas	Frank E. Thomas President and Chief Operating Officer (Principal Financial and Accounting Officer)	February 24, 2016
/s/ Barbara Deptula Barbara Deptula	Director	February 24, 2016
/s/ John Fallon, M.D. John Fallon, M.D.	Director	February 24, 2016
/s/ Robert J. Perez Robert J. Perez	Director	February 24, 2016
/s/ Lesley Russell, MB. Ch.B., MRCP Lesley Russell, MB. Ch.B., MRCP	Director	February 24, 2016
/s/ Gino Santini Gino Santini	Director	February 24, 2016
/s/ Davey S. Scoon Davey S. Scoon	Director	February 24, 2016
/s/ James Sulat James Sulat	Director	February 24, 2016

Exhibit Number	Description
2.1	Agreement and Plan of Merger, dated as of September 28, 2014, by and among Lumara Health Inc., AMAG Pharmaceuticals, Inc., Snowbird, Inc., and Lunar Representative, LLC as the Stockholders' Representative (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed September 29, 2014, File No. 001-10865)
2.2	Stock Purchase Agreement, dated as of June 29, 2015, by and among CBR Holdco, LLC, CBR Acquisition Holdings Corp. and AMAG Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed June 29, 2015, File No. 001-10865)
3.1, 4.1	Certificate of Incorporation of AMAG Pharmaceuticals, Inc., as restated (incorporated herein by reference to Exhibits 3.1 and 4.1to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, File No. 001-10865)
3.2,4.2	Certificate of Amendment to Restated Certificate of Incorporation of AMAG Pharmaceuticals, Inc. as filed on May 21, 2015 with the Delaware Secretary of State (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed May 28, 2015, File No. 001-10865)
3.3, 4.3	Amended and Restated By-Laws of AMAG Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed December 17, 2015, File No. 001-10865)
3.4, 4.4	Certificate of Designation of Series A Junior Participating Preferred Stock (incorporated herein by reference to Exhibits 3.1 and 4.1 to the Company's Current Report on Form 8-K filed September 4, 2009, File No. 0-14732)
4.6	Specimen certificate representing AMAG Pharmaceuticals, Inc.'s Common Stock (incorporated herein by reference to Exhibit 4.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2009, File No. 001-10865)
4.7	Rights Agreement, dated as of September 4, 2009 by and between AMAG Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, LLC (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed September 4, 2009, File No. 0-14732)
4.8	Amendment to Rights Agreement, dated as of May 10, 2012, by and between AMAG Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, LLC (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed May 10, 2012, File No. 001-10865)
4.9	Amendment to Rights Agreement, dated as of February 11, 2014, by and between AMAG Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, LLC (incorporated herein by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
4.10	NOL Amendment to Rights Agreement, dated as of September 26, 2014, by and between AMAG Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, LLC (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed September 29, 2014, File No. 001-10865)
4.11	Form of Rights Certificate (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed September 4, 2009, File No. 0-14732)
4.12	Base Indenture, dated as of February 14, 2014, by and between AMAG Pharmaceuticals, Inc. and Wilmington Trust, National Association (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
4.13	First Supplemental Indenture, dated as of February 14, 2014, by and between AMAG Pharmaceuticals, Inc. and Wilmington Trust, National Association (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
4.14	Form of 2.50% Convertible Senior Note due 2019 (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
4.15	Form of Registration Rights and Lock-up Agreement, dated as of November 12, 2014, by and between AMAG Pharmaceuticals, Inc. and stockholders party thereto (incorporated herein by reference to Exhibit 4.9 to the Company's Registration Statement on Form S-3 filed February 10, 2015, File No. 333-202009)

Exhibit Number	Description
4.16	Indenture, dated as of August 17, 2015, by and among AMAG Pharmaceuticals, Inc., the Guarantors party thereto and Wilmington Trust, National Association, as trustee (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed August 17, 2015, File No. 001-10865)
4.17	Form of 7.875% Senior Note due 2023 (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed August 17, 2015, File No. 001-10865)
10.1*	Representative Form of Indemnification Agreement (incorporated herein by reference to Exhibit 10.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2009, File No. 001-10865)
10.2*	Summary of AMAG Pharmaceuticals, Inc.'s Change of Control Policy applicable to executive officers (incorporated herein by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed February 13, 2006, File No. 0-14732)
10.3*	AMAG Pharmaceuticals, Inc.'s Non-Employee Director Compensation Policy (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, File No. 001-10865)
10.4*	AMAG Pharmaceuticals, Inc.'s Amended and Restated 2000 Stock Plan (incorporated herein by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A filed December 14, 2005, File No. 0-14732)
10.5*	AMAG Pharmaceuticals, Inc.'s Third Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A filed April 19, 2013, File No. 001-10865)
10.6*	First Amendment to the AMAG Pharmaceuticals, Inc. Third Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Appendix B to the Company's Definitive Proxy Statement on Schedule 14A filed April 16, 2015, File No. 001-10865)
10.7*	AMAG Pharmaceuticals, Inc. 2015 Employee Stock Purchase Plan (incorporated herein by reference to Appendix C to the Company's Definitive Proxy Statement on Schedule 14A filed April 16, 2015, File No. 001-10865)
10.8*	Lumara Health Inc. Amended and Restated 2013 Incentive Compensation Plan (incorporated herein by reference to Exhibit 10.6 to the Company's Annual Report on Form 10-K for the year ended December 31, 2014, File No. 001-10865)
10.9*	Form of Incentive Stock Option Agreement for AMAG Pharmaceuticals, Inc. Employees under AMAG Pharmaceuticals, Inc.'s Third Amended and Restated 2007 Equity Incentive Plan and the Lumara Health Inc. Amended and Restated 2013 Incentive Compensation Plan (incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, File No. 001-10865)
10.10*	Form of Non-Qualified Stock Option Agreement for AMAG Pharmaceuticals, Inc. Employees under AMAG Pharmaceuticals, Inc.'s Third Amended and Restated 2017 Equity Incentive Plan and the Lumara Health Inc. Amended and Restated 2013 Incentive Compensation Plan (incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, File No. 001-10865)
10.11*+	Form of Restricted Stock Unit Agreement for AMAG Pharmaceuticals, Inc. - Employees under AMAG Pharmaceuticals, Inc.'s Third Amended and Restated 2007 Equity Incentive Plan and the Lumara Health Inc. Amended and Restated 2013 Incentive Compensation Plan
10.12*	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors under AMAG Pharmaceuticals, Inc.'s Third Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.10 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, File No. 001-10865)
10.13*+	Form of Restricted Stock Unit Agreement for Non-Employee Directors under AMAG Pharmaceuticals, Inc.'s Third Amended and Restated 2007 Equity Incentive Plan
10.14*	Form of February 2013 Performance-based Restricted Stock Unit Agreement under AMAG Pharmaceuticals, Inc.'s Third Amended and Restated 2007 Equity Incentive Plan between AMAG Pharmaceuticals, Inc. and AMAG Pharmaceuticals, Inc.'s executive officers (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, File No. 001-10865)

Exhibit Number	Description
10.15*	Non-Plan Restricted Stock Unit Agreement, by and between AMAG Pharmaceuticals, Inc. and William K. Heiden (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed May 10, 2012, File No. 001-10865)
10.16*	Non-Plan Stock Option Agreement, by and between AMAG Pharmaceuticals, Inc. and William K. Heiden (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed May 10, 2012, File No. 001-10865)
10.17*	Form of Non-Qualified Stock Option Agreement - Non-Plan Inducement Grant (incorporated herein by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-8 filed August 7, 2013, File No. 333-190435)
10.18*+	Form of Restricted Stock Unit Agreement - Non-Plan Inducement Grant
10.19*+	Form of Employment Agreement between AMAG Pharmaceuticals, Inc. and each of its executive officers (other than William K. Heiden)
10.20*	Employment Agreement dated as of February 7, 2014 between AMAG Pharmaceuticals, Inc. and William K. Heiden (incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2014, File No. 001-10865)
10.21*	Notice of Termination between AMAG Pharmaceuticals, Inc. and Edward Jordan dated May 4, 2015 (incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, File No. 001-10865)
10.22*	Notice of Termination between AMAG Pharmaceuticals, Inc. and Scott Townsend dated May 5, 2015 (incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, File No. 001-10865)
10.23	Letter Agreement, dated March 10, 2015, by and between the Company and Lunar Representative, LLC (incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, File No. 001-10865)
10.24	Letter Agreement, dated April 10, 2015, by and between the Company and Lunar Representative, LLC (incorporated herein by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, File No. 001-10865)
10.25	Termination Agreement, dated December 29, 2014, by and between AMAG Pharmaceuticals, Inc. and Takeda Pharmaceutical Company Limited (incorporated herein by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011, File No. 001-10865) (confidential treatment previously granted)
10.26	Lease Agreement, dated as of May 22, 2008, by and between AMAG Pharmaceuticals, Inc. and Mortimer B. Zuckerman and Edward H. Linde, trustees of 92 Hayden Avenue Trust under Declaration of Trust dated August 18, 1983. This Lease Agreement was assigned in June 2013. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 29, 2008, File No. 0-14732)
10.27	Assignment and Assumption of Lease, dated as of June 10, 2013, by and among AMAG Pharmaceuticals, Inc., Mortimer B. Zuckerman and Edward H. Linde, trustees of 92 Hayden Avenue Trust under Declaration of Trust dated August 18, 1983 and Shire Human Genetic Therapies, Inc. (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed June 13, 2013, File No. 001-10865)
10.28	Lease Agreement, dated as of June 10, 2013, by and between AMAG Pharmaceuticals, Inc. and BP BAY COLONY LLC (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 13, 2013, File No. 001-10865)
10.29	First Amendment to Lease Agreement, dated June 10, 2013, by and between AMAG Pharmaceuticals, Inc. and BP BAY COLONY LLC, dated March 24, 2015 (incorporated herein by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, File No. 001-10865)
10.30+	Second Amendment to Lease Agreement, dated June 10, 2013, by and between AMAG Pharmaceuticals, Inc. and BP BAY COLONY LLC, dated December 4, 2015
10.31+	Third Amendment to Lease Agreement, dated June 10, 2013, by and between AMAG Pharmaceuticals, Inc. and BP BAY COLONY LLC, dated December 7, 2015

Exhibit Number	Description
10.32	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)
10.33	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)
10.34	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)
10.35	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)
10.36+	Amendment No. 3 to Commercial Supply Agreement, dated October 19, 2015, by and between the Company and Sigma-Aldrich, Inc. (Certain confidential information contained in this exhibit was omitted by means of redacting a portion of the text and replacing it with [***]. This exhibit has been filed separately with the SEC without any redactions pursuant to a Confidential Treatment Request under Rule 24b-2 of the Securities and Exchange Act of 1934, as amended)
10.37	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)
10.38	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)
10.39	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)
10.40	Development and Supply Agreement, dated as of September 17, 2009, by and between Lumara Health Inc. (as successor in interest to Hologic, Inc.) and Hospira Worldwide, Inc. (incorporated herein by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-K for the year ended December 31, 2014, File No. 001-10865) (confidential treatment previously granted)
10.41	First Amendment to Development and Supply Agreement, dated as of March 28, 2014, by and between Lumara Health Inc. and Hospira Worldwide, Inc. (incorporated herein by reference to Exhibit 10.32 to the Company's Annual Report on Form 10-K for the year ended December 31, 2014, File No. 001-10865) (confidential treatment previously granted)
10.42+	Development and License Agreement, dated September 30, 2014, by and between Lumara Health Inc and Antares Pharma, Inc. (Certain confidential information contained in this exhibit was omitted by means of redacting a portion of the text and replacing it with [***]. This exhibit has been filed separately with the SEC without any redactions pursuant to a Confidential Treatment Request under Rule 24b-2 of the Securities and Exchange Act of 1934, as amended)
10.43	Underwriting Agreement, dated as of February 11, 2014, among AMAG Pharmaceuticals, Inc. and J.P. Morgan Securities LLC, on its own behalf and as representative of the several underwriters named in Schedule 1 thereto (incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)

Exhibit Number	Description
10.44	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)
10.45	Base Call Option Transaction Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and Royal Bank of Canada (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.46	Base Call Option Transaction Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and Morgan Stanley & Co. International plc (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.47	Base Warrants Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association, London Branch (incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.48	Amendment to Warrant Transaction, dated as of February 23, 2015, by and between AMAG Pharmaceuticals, Inc. and J.P. Morgan Securities LLC, as agent (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, File No. 001-10865)
10.49	Base Warrants Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and Royal Bank of Canada (incorporated herein by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.50	Base Warrants Confirmation, dated as of February 11, 2014, between AMAG Pharmaceuticals, Inc. and Morgan Stanley & Co. International plc (incorporated herein by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.51	Additional Call Option Transaction Confirmation, dated as of February 13, 2014, between AMAG Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association, London Branch (incorporated herein by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.52	Additional Call Option Transaction Confirmation, dated as of February 13, 2014, between AMAG Pharmaceuticals, Inc. and Royal Bank of Canada (incorporated herein by reference to Exhibit 10.8 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.53	Additional Call Option Transaction Confirmation, dated as of February 13, 2014, between AMAG Pharmaceuticals, Inc. and Morgan Stanley & Co. International plc (incorporated herein by reference to Exhibit 10.9 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.54	Additional Warrants Confirmation, dated as of February 13, 2014, between AMAG Pharmaceuticals, Inc. and JPMorgan Chase Bank, National Association, London Branch (incorporated herein by reference to Exhibit 10.10 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.55	Additional Warrants Confirmation, dated as of February 13, 2014, between AMAG Pharmaceuticals, Inc. and Royal Bank of Canada (incorporated herein by reference to Exhibit 10.11 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.56	Additional Warrants Confirmation, dated as of February 13, 2014, between AMAG Pharmaceuticals, Inc. and Morgan Stanley & Co. International plc (incorporated herein by reference to Exhibit 10.12 to the Company's Current Report on Form 8-K filed February 14, 2014, File No. 001-10865)
10.57	Credit Agreement, dated as of November 12, 2014, by and among AMAG Pharmaceuticals, Inc., the financial institutions and agents listed therein, and Jefferies Finance LLC (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed November 12, 2014, File No. 001-10865)
10.58	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)

Exhibit Number	Description
10.59	Credit Agreement, dated as of August 17, 2015, by and among AMAG Pharmaceuticals, Inc., the financial institutions and agents listed therein, and Jefferies Finance LLC (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 17, 2015, File No. 001-10865)
10.60	Underwriting Agreement, dated as of July 30, 2015, among AMAG Pharmaceuticals, Inc., Jefferies LLC and Barclays Capital Inc., as representatives of the underwriters named therein (incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed July 31, 2015, File No. 001-10865)
10.61	Underwriting Agreement, dated as of February 25, 2015, among AMAG Pharmaceuticals, Inc., J.P. Morgan Securities LLC and Deutsche Bank Securities Inc., as representatives of the underwriters named therein (incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed February 26, 2015, File No. 001-10865)
21.1+	Subsidiaries of AMAG Pharmaceuticals, Inc.
23.1+	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm
24.1	Power of Attorney (included on the signature page(s) hereto)
31.1+	Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2+	Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS+	XBRL Instance Document
101.SCH+	XBRL Taxonomy Extension Schema Document
101.CAL+	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB+	XBRL Taxonomy Extension Label Linkbase Document
101.PRE+	XBRL Taxonomy Extension Presentation Linkbase Document

+ Exhibits marked with a plus sign ("+") are filed herewith.

++ Exhibits marked with a double plus sign ("++") are furnished herewith.

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

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

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. Third Amended and Restated 2007 Equity Incentive Plan/Lumara Health Inc. Amended and Restated 2013 Incentive Compensation Plan, as amended through the date hereof (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.

Incremental Number of Restricted Stock Units Vested	Vesting Date
_____ (___%)	_____
_____ (___%)	_____
_____ (___%)	_____

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.

(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"). In the event of an Approved Leave of Absence, vesting of Restricted Stock Units shall be suspended (and all subsequent vesting dates shall be postponed by the length of the period of the Approved Leave of Absence) unless otherwise provided in the Company's written approval of the 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 minimum 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 minimum withholding amount due.

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: 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.
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. Third Amended and Restated 2007 Equity Incentive Plan as amended through the date hereof (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.

Incremental Number of Restricted Stock Units Vested	Vesting Date
[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 third 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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AMAG PHARMACEUTICALS, INC.

By: _____
Name: William K. Heiden
Title: 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.
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 Third 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.

Incremental Number of Restricted Stock Units Vested	Vesting Date
_____ (___%)	_____
_____ (___%)	_____
_____ (___%)	_____

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.

(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"). In the event of an Approved Leave of Absence, vesting of Restricted Stock Units shall be suspended (and all subsequent vesting dates shall be postponed by the length of the period of the Approved Leave of Absence) unless otherwise provided in the Company's written approval of the 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 minimum 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 minimum withholding amount due.

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: 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:

_____

_____

_____

Exhibit 10.19

[AMENDED AND RESTATED] EMPLOYMENT AGREEMENT

This [Amended and Restated] Employment Agreement (the "**Agreement**") is entered into as of [**Date**] (the "**Effective Date**") by and between AMAG Pharmaceuticals, Inc., a Delaware corporation with offices at 1100 Winter Street, Waltham, MA 02451 (together with its subsidiaries and affiliates, the "**Company**"), and [**Executive Name**] of [**Address**] ("**you**").

[WHEREAS, you and the Company previously entered into that certain Employment Agreement, dated [**Date**], which was amended by the Amendment to Employment Agreement, dated [**Date**], the "**Prior Agreement**");

WHEREAS, you and the Company desire to amend and restate the Prior Agreement on the terms and conditions set forth herein.]

NOW THEREFORE, in consideration of the premises and mutual agreements hereinafter set forth, and intending to be legally bound hereby, the parties hereto agree as follows:

1. Position; Duties.

(a) Position. You shall continue to serve as [**Title**] of the Company.

(b) Duties. You shall perform for the Company the duties customarily associated with the office of [**Title**] and such other duties as may be assigned to you from time to time by the Company's [**Title**] or the Company's Board of Directors (the "**Board**") that are consistent with the duties normally performed by those performing the role of the most senior executives of similar entities. You shall devote substantially your full business time and best efforts to the performance of your duties hereunder and the business and affairs of the Company and will not undertake or engage in any other employment, occupation or business enterprise; *provided*, *however*, that you may participate as a member of the board of directors or advisory board of other entities and in professional organizations and civic and charitable organizations; *provided further*, that any such positions are disclosed to the Chief Executive Officer and/or the Board or the Audit Committee thereof and do not materially interfere with your duties and responsibilities to the Company. You shall be based in the Company's principal offices, which currently are in Waltham, Massachusetts.

2. Term. The term of this Agreement shall be for a three (3) year period commencing on the Effective Date unless terminated earlier pursuant to Section 4 below (the "**Initial Term**"). The term of this Agreement shall automatically renew for additional three-year terms (each, a "**Renewal Term**") following the Initial Term and any Renewal Term unless either party provides written notice to the other party at least sixty (60) days before the end of the Initial Term or any Renewal Term, as applicable, that it does not desire to renew this Agreement, in which case this Agreement shall expire at the end of the Initial Term or any Renewal Term, as applicable. The Initial Term and any Renewal Term are referred to herein collectively as the "**Term**."

3. Compensation and Benefits. The Company shall pay you the following compensation and benefits for all services rendered by you under this Agreement (subject to any tax withholdings required by law):

(a) Base Salary. The Company will pay you a base salary at the rate currently in effect and, effective [**Date]**, at the annualized rate of $**[Base Salary**] ("**Base Salary**"), minus withholdings as required by law and other deductions authorized by you, which amount shall be paid in equal installments at the Company's regular payroll intervals, but not less often than monthly. Your base salary may be increased annually by the Board or the Compensation Committee in their sole discretion.

(b) Bonus. You will be eligible to receive an annual performance bonus (the "**Annual Bonus**") of up to [**Bonus Percentage**]% of Base Salary for each fiscal year during the Term of this Agreement based on the extent to which, in the discretion of the Board or the Compensation Committee in consultation with the Chief Executive Officer and/or your supervisor you achieve or exceed specific and measurable individual and Company performance objectives established by the Board or the Compensation Committee in consultation with the Chief Executive Officer and/or your supervisor and communicated to you in advance. The exact amount of the bonus for any year during the Term shall be determined by the Board or the Compensation Committee in its sole discretion and may be more than the target bonus in the event you achieve all of your personal and Company performance objectives or less than the target bonus if you do not achieve all of your personal and Company performance objectives. The Company shall pay the Annual Bonus no later than two and a half months after the end of the fiscal year to which the applicable bonus relates. Unless otherwise provided herein, no bonus shall be deemed to have been earned by you for any year in which you are not actively employed by the Company on the last day of the fiscal year to which the bonus relates.

(c) Equity Compensation. You shall be eligible to receive stock options or other equity compensation under the Company's equity incentive plans as determined by the Board or the Compensation Committee from time to time.

(d) Vacation. You will receive four (4) weeks of paid vacation per calendar year which shall accrue ratably on a monthly basis.

(e) Benefits. You will be eligible to participate in all group health, dental, 401(k) and other insurance and/or benefit plans that the Company may offer to similarly situated executives of the Company from time to time on the same terms as offered to such other executives.

(f) Business Expenses. The Company will reimburse you for all reasonable and usual business expenses incurred by you in the performance of your duties hereunder in accordance with the Company's expense reimbursement policy.

4. Termination. Your employment with the Company may be terminated prior to the expiration of the Term as follows:

(a) Death. This Agreement shall terminate automatically upon your death.

(b) Disability. The Company may terminate your employment in accordance with applicable laws in the event that you shall be prevented, by illness, accident, disability or any other physical or mental condition (to be determined by means of a written opinion of a competent medical doctor chosen by mutual agreement of the Company and you or your personal representative(s)) from substantially performing your duties and responsibilities hereunder for one or more periods totaling one hundred and twenty (120) days in any twelve (12) month period.

(c) By the Company for Cause. The Company may terminate your employment for "Cause" upon written notice to you. For purposes of this Agreement, "**Cause**" shall mean any of: (i) fraud, embezzlement or theft against the Company or any of its affiliates; (ii) you are convicted of, or plead guilty or no contest to, a felony; (iii) willful nonperformance by you (other than by reason of illness) of your material duties hereunder and failure to remedy such nonperformance within ten (10) business days following written notice from the Chief Executive Officer, the Board and/or your supervisor identifying the nonperformance and the actions required to cure it; or (iv) you commit an act of gross negligence, engage in willful misconduct or otherwise act with willful disregard for the Company's best interests, and you fail to remedy such conduct within ten (10) business days following written notice from the Chief Executive Officer, the Board and/or your supervisor identifying the gross negligence, willful misconduct or willful, disregard and the actions required to cure it (if such conduct can be cured).

(d) By the Company Other Than For Death, Disability or Cause. The Company may terminate your employment other than for Cause, disability or death upon thirty (30) days prior written notice to you.

(e) By You For Good Reason or Any Reason. You may terminate your employment at any time without Good Reason upon thirty (30) days prior written notice to the Company and with Good Reason as described in this Section 4(e). For purposes of this Agreement, "**Good Reason**" shall mean that any of the following occurs without your prior written consent: (i) a material adverse change in your title, position, duties or responsibilities; (ii) a material reduction by the Company in your Base Salary or your target Annual Bonus opportunity in the total annual amount that you are then eligible to receive, unless such reduction is in connection with a proportionate reduction of compensation applicable to all other executive officers; (iii) any relocation of your principal place of business to a location more than 50 miles from the Company's current executive offices in Waltham, MA; *provided, however,* that this clause (iii) will not apply to the extent that any new office location is less than 50 miles from your residence; or (iv) a material breach by the Company of any of the terms or provisions of this Agreement. Before you may resign for Good Reason, (i) you must provide written notice to the Company describing the event, condition or conduct giving rise to Good Reason within 30 days of the initial occurrence of the event, condition or conduct; (ii) the Company must fail to remedy or cure the alleged Good Reason within the 30 day period after receipt of such notice; and (iii) you must resign effective not later than 30 days after the end of the cure period.

5. Payment Upon Termination. In the event that your employment with the Company terminates, you will be paid the following (subject to any tax withholdings required by law):

(a) Termination for Any Reason. In the event that your employment terminates for any reason, the Company shall pay you for the following items that were earned and accrued but unpaid as of the date of your termination: (i) your Base Salary; (ii) a cash payment for all accrued, unused vacation calculated at your then Base Salary rate; (iii) reimbursement for any unpaid business expenses; and (iv) such other benefits and payments to which you may be entitled by law or pursuant to the benefit plans of the Company then in effect. In addition, if your employment terminates due to your death, the Board or the Compensation Committee, in consultation with the Chief Executive Officer and/or your supervisor, shall determine the extent to which any of the individual performance objectives established pursuant to Section 3(b) above were met as of the time of your death. If, based on that determination, the Board or the Compensation Committee determines that a bonus is due, the Company shall pay your estate an amount equal to such bonus, pro-rated for the portion of the fiscal year elapsed as of the time of your death,

(b) Termination Without Cause or for Good Reason. In addition to the payments provided for in Section 5(a), in the event that (i) the Company terminates your employment other than for death, disability or Cause pursuant to Section 4(d) or you terminate your employment for Good Reason pursuant to Section 4(e); (ii) you comply fully with all of your obligations under all agreements between the Company and you; and (iii) you execute, deliver to the Company, within 60 days of the termination of your employment, and do not revoke a general release (in a form acceptable to the Company) releasing and waiving any and all claims that you have or may have against the Company, its directors, officers, employees, agents, successors and assigns with respect to your employment (other than any obligation of the Company set forth herein which specifically survives the termination of your employment), then (i) the Company will provide you with 12 months of severance pay based on your then current Base Salary and (ii) all time-based stock options and other time-based equity awards you hold in which you would have vested if you had been employed for an additional 12 months following the date of the termination of your employment shall vest and become exercisable or nonforfeitable on the date that the release referred to above may no longer be revoked. The foregoing severance shall be paid in equal installments over the severance period in accordance with the Company's usual payroll schedule, commencing on the date that the release referred to above may no longer be revoked. This Section 5(b) shall not apply during the one year period following a Change of Control (as defined below) in which case Section 5(c) shall apply. Notwithstanding anything to the contrary herein, if any of the payments and benefits provided for in this Section 5(b) constitute non-qualified deferred compensation subject to Section 409A (as defined below) and, the sixty (60) day period in which you must execute the release begins in one calendar year and ends in another, the payments and benefits provided for in this Section 5(b) shall commence, be made or become effective in the later calendar year.

(c) Change of Control. In the event that (i) within one year from the date a Change of Control (as defined below) of the Company occurs, the Company (for purposes of this Section, such term to include its successor) terminates your employment other than for Cause pursuant to Section 4(c), death or disability or you terminate your employment with Good

Reason; (ii) you comply fully with all of your obligations under all agreements between the Company and you; and (iii) within 60 days of termination of your employment you execute and deliver to the Company and do not revoke a general release (in a form acceptable to the Company) releasing and waiving any and all claims that you have or may have against the Company and its directors, officers, employees, agents, successors and assigns with respect to your employment (other than any obligation of the Company set forth herein which specifically survives the termination of your employment), then:

- the Company will pay you 12 months of severance pay based on your then current Base Salary, with such severance to be paid in equal installments over the severance period in accordance with the Company's usual payroll schedule, commencing on the date that the release referred to above may no longer be revoked;

- the Company will pay you, on the first payroll date after the revocation period of the release set forth above expires, in a lump sum, one times your target annual bonus amount for the year in which the Change of Control occurs;

- the Company will pay or reimburse you for the premiums for continued coverage for you and your eligible dependents in the same amounts and for the same coverage in effect immediately prior to your termination from employment, under the Company's group health and dental plans until the earlier of: (i) 24 months from the date of termination of your employment; or (ii) the date you are provided with health and dental coverage by another employer's health and dental plan (and, for purposes of clarity, if the Company is unable to extend coverage to you under its group health and dental plans due to your termination from active employment status, then, to receive this benefit, you must elect continuation coverage under COBRA and/or purchase an individual insurance policy, and the Company shall have no obligation to pay or reimburse insurance premiums or otherwise provide coverage if you fail to elect COBRA or obtain an individual policy); and

- all time-based, unvested outstanding stock options, restricted stock units and other equity incentives that were granted to you before the Change of Control occurred shall, without further action, become vested in full on the date that the release referred to above may no longer be revoked.

For purposes of this Agreement, "**Change of Control**" shall mean the first to occur of any of the following: (a) any "person" or "group" (as defined in the Securities Exchange Act of 1934, as amended) becomes the beneficial owner of a majority of the combined voting power of the then outstanding voting securities with respect to the election of the Board; (b) any merger, consolidation or similar transaction involving the Company, other than a transaction in which the stockholders of the Company immediately prior to the transaction hold immediately thereafter in the same proportion as immediately prior to the transaction not less than 50% of the combined voting power of the then, voting securities with respect to the election of the Board of Directors of the resulting entity; (c) any sale of all or substantially all of the assets of the Company; or (d) any other acquisition by a third party of all or substantially all of the business or assets of the Company, as determined by the Board, in its sole discretion. The payments, benefits and acceleration of vesting of stock options, restricted stock units and other equity incentives

provided in this Section 5(c) shall override and replace with respect to you any Company wide policy with respect to payments, benefits and/or acceleration of vesting upon a Change of Control. After the one year period following a Change of Control, this Section 5(c) shall no longer apply, and Section 5(b) shall continue to apply. In the event that upon a Change of Control, the Company or the successor to or acquiror of the Company's business (whether by sale of outstanding stock, merger, sale of substantially all the assets or otherwise) elects not to assume all the then unvested outstanding stock options, restricted stock units and other equity incentives that were granted to you before the Change of Control occurred, such securities shall immediately without further action become vested in full effective no later than the effective date of the Change of Control and you shall receive the value of such stock options, restricted stock units and other equity incentives as provided in the applicable acquisition agreement (or if no such provision is made, in the applicable equity incentive plan).

Notwithstanding anything to the contrary herein, if any of the payments and benefits provided for in this Section 5(c) constitute non-qualified deferred compensation subject to Section 409A and the sixty (60) day period in which you must execute the release begins in one calendar year and ends in another, the payments and benefits provided for in this Section 5(c) shall commence, be made or become effective in the later calendar year.

(d) Death/Disability. In addition to the payments provided for in Section 5(a), in the event of your death or the termination of your employment, due to your disability in accordance with Section 4(b) above, all unvested outstanding stock options, restricted stock units and other equity incentives that were held by you at the time of your death or termination of employment due to disability shall immediately become fully vested, and exercisable by you or your personal representatives, heirs or legatees, as the case may be, at any time prior to the expiration of one (1) year from the date of your death or disability, but in no event after the expiration of the term of the applicable equity award agreement.

6. Nonsolicitation Covenant; Non-Competition; Injunctive Relief. In order to protect the Company's confidential information and good will, and in exchange for the additional equity rights granted you under Sections 5(b), your employment or continued employment, and other good and valuable consideration contained in this Agreement, during your employment and for a period of twelve (12) months following the termination of your employment for any reason (the "**Restricted Period**"), you will not directly or indirectly, whether as owner, partner, shareholder, director, manager, consultant, agent, employee, co-venturer or otherwise, engage, participate or invest in any business activity anywhere in the world that (i) develops, manufactures or markets (A) an intravenous iron replacement therapeutic, (B) a mucoadhesive oral wound rinse or other device that is indicated for the management of oral mucositis/stomatitis, or (C) other therapeutic products acquired, developed or researched by the Company during the Term, or (ii) develops, manufactures or markets any products, or performs any services, that are otherwise competitive with or similar to the products or services of the Company, or products or services that the Company has under development or that are the subject of active planning at any time during your employment; provided that this shall not prohibit any possible investment in publicly traded stock of a company representing less than one percent of the stock of such company. In addition, during the Restricted Period, you will not, directly or indirectly, in any manner, other than for the benefit of the Company, (a) call upon, solicit, divert, take away, accept or conduct any business from or with any of the customers or

prospective customers of the Company or any of its suppliers, and/or (b) solicit, entice, attempt to persuade any other employee or consultant of the Company to leave the Company for any reason or otherwise participate in or facilitate the hire, directly or through another entity, of any person who is employed or engaged by the Company or who was employed or engaged by the Company within six (6) months of any attempt to hire such person. You acknowledge and agree that if you violate any of the provisions of this Section, the running of the Restricted Period will be extended by the time during which you engage in such violation(s). You understand that the restrictions contained in this Agreement are necessary for the protection of the business and goodwill of the Company and you consider them to be reasonable for such purpose. Any breach of this Agreement is likely to cause the Company substantial and irrevocable damage and therefore, in the event of such breach, the Company, in addition to such other remedies which may be available, will be entitled to specific performance and other injunctive relief, without the posting of a bond. If you violate this Agreement, in addition to all other remedies available to the Company at law, in equity, and under contract, you agree that you are obligated to pay all the Company's costs of enforcement of this Agreement, including attorneys' fees and expenses. This Section 6 shall supplement, and shall not limit or be limited by, any other restrictive covenant agreement to which you and the Company are parties or any other restrictive covenant obligations you have to the Company.

7. Assignment. This Agreement and the rights and obligations of the parties hereto shall bind and inure to the benefit of any successor of the Company by reorganization, merger or consolidation and any assignee of all or substantially all of its business and properties. Neither this Agreement nor any rights or benefits hereunder may be assigned by you, except that, upon your death, your earned and unpaid economic benefits will be paid to your heirs or beneficiaries.

8. Interpretation and Severability. It is the express intent of the parties that (a) in case any one or more of the provisions contained in this Agreement shall for any reason be held to be excessively broad as to duration, geographical scope, activity or subject, such provision shall be construed by limiting and reducing it as determined by a court of competent jurisdiction, so as to be enforceable to the fullest extent compatible with applicable law; and (b) in case any one or more of the provisions contained in this Agreement cannot be so limited and reduced and for any reason is held to be invalid, illegal or unenforceable, such invalidity, illegality or unenforceability shall not affect the other provisions of this Agreement, and this Agreement shall be construed as if such invalid, illegal or unenforceable provision had never been contained herein.

9. Notices. Any notice that you or the Company are required to give the other under this Agreement shall be given by personal delivery, recognized overnight, courier service, or registered or certified mail, return receipt requested, addressed in your case to you at your last address of record with the Company, or at such other place as you may from time to time designate in writing, and, in the case of the Company, to the Company at its principal office to the attention of the President and Chief Executive Officer, or at such other office as the Company may from time to time designate in writing. The date of actual delivery of any notice under this Section 9 shall be deemed to be the date of receipt thereof.

10. Waiver. No consent to or waiver of any breach or default in the performance of any obligation hereunder shall be deemed or construed to be a consent to or waiver of any other

breach or default in the performance of any of the same or any other obligations hereunder. No waiver hereunder shall be effective unless it is in writing and signed by the waiving party.

11. Complete Agreement; Modification. This Agreement sets forth the entire agreement of the parties with respect to the subject matter hereof, and supersedes any previous oral or written communications, negotiations, representations, understandings, or agreements between them, including the Prior Agreement. Any modification of this Agreement shall be effective only if set forth in a written document signed by you and a duly authorized officer of the Company.

12. Headings. The headings of the Sections hereof are inserted for convenience only and shall not be deemed to constitute a part, or affect the meaning, of this Agreement.

13. Counterparts. This Agreement may be signed in two (2) counterparts, each of which shall be deemed an original and both of which shall together constitute one agreement.

14. Choice of Law; Jurisdiction. This Agreement shall be deemed to have been made in the Commonwealth of Massachusetts, and the validity, interpretation and performance of this Agreement shall be governed by, and construed in accordance with, the laws of Massachusetts, without regard to conflict of law principles. You hereby consent and submit without limitation to the jurisdiction of courts in Massachusetts in connection with any action arising out of this Agreement, and waive any right to object to any such forum as inconvenient or to object to venue in Massachusetts. You agree that, in any action arising out of this Agreement, you will accept service of process by registered mail or the equivalent directed to your last known address or by such other means permitted by such court.

15. Advice of Counsel; No Representations. You acknowledge that you have been advised to review this Agreement with your own legal counsel, that prior to entering into this Agreement, you have had the opportunity to review this Agreement with your attorney, and that the Company has not made any representations, warranties, promises or inducements to you concerning the terms, enforceability or implications of this Agreement other than as are contained in this Agreement.

16. I.R.C. § 409A. Notwithstanding anything to the contrary set forth herein, any payments and benefits provided under this Agreement that constitute "deferred compensation" within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the "**Code**") and the regulations and other guidance thereunder and any state law of similar effect (collectively, the "**Section 409A**") shall not commence in connection with your termination of employment unless and until you have also incurred a "separation from service" (as such term is defined in Treasury Regulation Section 1.409A-1(h) (the "**Separation From Service**"), unless the Company reasonably determines that such amounts may be provided to you without causing you to incur the additional 20% tax under Section 409A.

It is intended that each installment of severance pay provided for in this Agreement is a separate "payment" for purposes of Treasury Regulation Section 1.409A-2(b)(2)(i). For the avoidance of doubt, it is intended that severance payments set forth in this Agreement satisfy, to

the greatest extent possible, the exceptions from the application of Section 409A provided under Treasury Regulation Sections 1.409A-1(b)(4), 1.409A- 1(b)(5), and 1.409A-1(b)(9).

If the Company (or, if applicable, the successor entity thereto) determines that any payments or benefits constitute "deferred compensation" under Section 409A and you are, on the termination of service, a "specified employee" of the Company or any successor entity thereto, as such term is defined in Section 409A(a)(2)(B)(i) of the Code, then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the timing of the payments and benefits shall be delayed until the earlier to occur of: (a) the date that is six months and one day after your Separation From Service, or (b) the date of your death (such applicable date, the "**Specified Employee Initial Payment Date**"). On the Specified Employee Initial Payment Date, the Company (or the successor entity thereto, as applicable) shall (i) pay to you a lump sum amount equal to the sum of the payments and benefits that you would otherwise have received through the Specified Employee Initial Payment Date if the commencement of the payment of such amounts had not been so delayed pursuant to this Section and (ii) commence paying the balance of the payments and benefits in accordance with the applicable payment schedules set forth in this Agreement.

17. Survival. Provisions of this Agreement which by their terms must survive the termination of this Agreement in order to effectuate the intent of the parties will survive any such termination, whether by expiration of the Term, termination of your employment, or otherwise, for such period as may be appropriate under the circumstances. Such provisions include, without limitation, Sections 5 (to the extent severance payments are due under such Section) and 6 of this Agreement.

18. Excise Tax-Related Provisions. If any payment or benefit you would receive pursuant to this Agreement or any other agreement ("**Payment**") would (a) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (b) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "**Excise Tax**"), then such Payment shall be adjusted so that it would equal the Reduced Amount. The "Reduced Amount" shall be either (i) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax or (ii) the total Payment, whichever amount of (i) or (ii), after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in your receipt, on an after-tax basis, of the greater amount of the Payment notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in payments or benefits constituting "parachute payments" is necessary so that the Payment equals the Reduced Amount, any such reduction will occur in a manner necessary to provide you with the greatest post-reduction economic benefit. If more than one manner of reduction of Payments necessary to arrive at the Reduced Amount yields the greatest economic benefit to you, the Payments will be reduced pro rata (the "**Pro Rata Reduction Method**"). Notwithstanding the foregoing, if the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A, then the Pro Rata Reduction Method shall be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for you as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (*e.g.,* being terminated without Cause), shall be eliminated before Payments that

are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A shall be reduced before Payments that are not "deferred compensation" within the meaning of Section 409A.

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SIGNATURE PAGE TO
AMENDED AND RESTATED EMPLOYMENT AGREEMENT

IN WITNESS WHEREOF, the Company and you have executed this Agreement as of the day and year first set forth above.

AMAG Pharmaceuticals, Inc.

By: _____
Name:
Title:

_____
[Executive Name]

The Company enters into this Form Agreement with each of its executive officers, including its named executive officers as such term is defined in Item 402(a) of Regulation S-K, other than its Chief Executive Officer, who is party to an employment agreement with the Company which is filed separately from this Form Agreement. The Form Agreement provides the initial economic terms for each individual's compensation, but because such terms can be adjusted by the Company's Board or Compensation Committee, in its sole discretion, investors are directed to read the Company's most recent proxy statement on Schedule 14A filed with the Commission for a detailed description of the current compensation arrangements of each of the named executive officers.

SECOND AMENDMENT TO LEASE

SECOND AMENDMENT TO LEASE dated as of this 4th day of December, 2015 (the "Effective Date"), by and between BP BAY COLONY LLC, a Delaware limited liability company ("Landlord"), and AMAG PHARMACEUTICALS, INC., a Delaware corporation ("Tenant").

RECITALS

By Lease dated June 10, 2013 (the "Original Lease"), Landlord did lease to Tenant and Tenant did hire and lease from Landlord certain premises containing 32,217 square feet of rentable floor area on the third (3rd) floor of the building (the "Building") known as and numbered Bay Colony Corporate Center, 1100 Winter Street, Waltham, Massachusetts (referred to herein as the "Original Premises").

By First Amendment to Lease dated as of March 24, 2015 (the "First Amendment"), Landlord and Tenant (i) increased the size of the Original Premises by adding thereto an additional 5,934 square feet of rentable floor area located on the third (3rd) floor of the North Wing of the Building, which space is shown on Exhibit A attached to the First Amendment (the "First Additional Premises" and together with the Original Premises, the "Existing Premises") and (ii) extended the Term of the Original Lease for a period of one (1) year, upon all of the same terms and conditions contained in the Original Lease except as otherwise provided in the First Amendment to Lease.

Landlord and Tenant presently are negotiating an amendment to the Lease (the "Third Amendment"), which, if and when executed, is anticipated to (i) increase the size of the Existing Premises by adding thereto an additional 21,000 square feet of rentable floor area located on the second (2nd) floor of the Building (the "Second Additional Premises"), and (ii) extend the Term of the Lease for a period of five (5) year(s) from the date upon which Tenant's Annual Fixed Rent obligations commence with respect to the Second Additional Premises.

In connection with negotiating the Third Amendment, Landlord and Tenant have agreed that Landlord shall provide Tenant with certain temporary premises containing 6,452 square feet of rentable floor area on the second (2nd) floor of the Building (the "Temporary Premises"), substantially as shown on Exhibit A attached hereto, upon all of the same terms and conditions contained in the Lease except as otherwise provided in this Second Amendment to Lease (the "Second Amendment").

Landlord and Tenant are entering into this instrument to set forth said demise of the Temporary Premises, to extend the Term of the Lease and to amend the Lease.

NOW THEREFORE, in consideration of One Dollar ($1.00) and other good and valuable consideration in hand this date paid by each of the parties to the other, the receipt and sufficiency of which are hereby severally acknowledged, and in further consideration of the mutual promises herein contained , Landlord and Tenant hereby agree to and with each other as follows:

1. (A) Notwithstanding anything to the contrary herein or in the Lease contained, Landlord shall make available to Tenant the Temporary Premises from the Temporary Premises Commencement Date (as hereinafter defined) until the Temporary Premises Termination Date (as hereinafter defined). Said demise of the Temporary Premises shall be upon all of the same terms and conditions of the Lease, except as hereinafter set forth:

(i) The Commencement Date in respect of the Temporary Premises shall be November 6, 2015, and Landlord shall deliver the Temporary Premises to Tenant on said date ("Temporary Premises Commencement Date").

(ii) The termination date in respect of the Temporary Premises ("Temporary Premises Termination Date") shall be the date that is the earlier to occur of (i) five (5) days after the date upon which Tenant's Annual Fixed Rent obligations commence with respect to the Second Additional Premises and (ii) July 31, 2016.

(iii) Tenant shall pay Annual Fixed Rent in respect of the Temporary Premises in the amount of $193,560 (i.e., a monthly payment of $16,130), prorated for any partial month.

(iv) Tenant shall have no obligation to pay Annual Fixed Rent or Additional Rent on account of Operating Expenses and Taxes with respect to the Temporary Premises.

(v) Tenant shall pay for electricity with respect to the Temporary Premises as a flat charge, at a rate of $806.50 per month (i.e., $1.50 per rentable square foot per annum). Such amount shall be due and payable in advance on the first day of each calendar month (or part thereof) falling within the Temporary Premises term without offset, notice or demand.

(B) Tenant shall lease the Temporary Premises "as-is", in the condition in which the Temporary Premises are in as of the Effective Date, without any obligation on the part of Landlord to prepare or construct the Temporary Premises for Tenant's occupancy and without any representation by Landlord as to the condition of the Temporary Premises; provided, however, that Landlord shall clean the existing carpeting located in the Temporary Premises prior to the Temporary Premises Commencement Date.

(C) As of the Temporary Premises Termination Date, Tenant shall vacate the Temporary Premises and deliver the Temporary Premises to Landlord in the same condition in which the Existing Premises are required, pursuant to Sections 5.2, 9.6 and 9.17 of the Lease, to be delivered to Landlord at the expiration or prior termination of the Term of the Lease. Notwithstanding anything to the contrary herein contained, Tenant shall be obligated to remove any telecommunications cabling and equipment installed by or for Tenant in the Temporary Premises prior to returning the Temporary Premises to Landlord.

2. From and after the Effective Date, any notices to Tenant under the Lease shall be sent as provided in Section 9.1 1 of the Lease, with a copy to:

AMAG Pharmaceuticals, Inc.
1100 Winter Street
Waltham, MA 0245 l
Attn: Chief Information Officer

From and after the Effective Date, notices to Tenant under the Lease shall not be sent to Goodwin Procter, LLP.

3. (A) Tenant warrants and represents that Tenant has not dealt with any broker in connection with the consummation of this Second Amendment except Colliers International (the "Broker") and in the event any claim is made against Landlord relative to dealings by Tenant with any brokers other than the Broker, Tenant shall defend the claim against Landlord with counsel of Tenant's selection first approved by Landlord (which approval will not be unreasonably withheld) and save harmless and indemnify Landlord on account of loss, cost or damage which may arise by reason of such claim.

(B) Landlord warrants and represents that Landlord has not dealt with any broker in connection with the consummation of this Second Amendment , other than the Broker, and in the event any claim is made against Tenant relative to dealings by Landlord with brokers, Landlord shall defend the claim against Tenant with counsel of Landlord 's selection first approved by Tenant (which approval will not be unreasonably withheld) and save harmless and indemnify Tenant on account of loss, cost or damage which may arise by reason of such claim. Landlord agrees that it would be solely responsible for the payment of brokerage commissions to the Broker, if any were due, in connection with this Second Amendment; provided, however, that Landlord and Tenant each understand that no commission or other payment is due or owing to Broker in connection with the consummation of this Second Amendment.

4. Except as otherwise expressly provided herein, all capitalized terms used herein without definition shall have the same meanings as are set forth in the Lease.

5. Except as herein amended the Lease shall remain unchanged and in full force and effect. All references to the "Lease" shall be deemed to be references to the Lease as amended by the First Amendment and as herein amended.

6. Each of Landlord and Tenant hereby represents and warrants to the other that all necessary action has been taken to enter this Second Amendment and that the person signing this Second Amendment on its behalf has been duly authorized to do so.

7. The parties acknowledge and agree that this Second Amendment may be executed by electronic signature, which shall be considered as an original signature for all purposes and shall have the same force and effect as an original signature. Without limitation,

"electronic signature" shall include faxed versions of an original signature or electronically scanned and transmitted versions (e.g., via pdf) of an original signature.

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EXECUTED as of the date and year first above written.

LANDLORD:

WITNESS:

/s/ Matthew Murry

BP BAY COLONY LLC, a Delaware limited liability company

BY: BP BAY COLONY HOLDINGS LLC, a Delaware limited liability company, its sole member

BY: BOSTON PROPERTIES LIMITED PARTNERSHIP, a Delaware limited partnership, its member

BY: BOSTON PROPERTIES, INC., a Delaware Corporation, its general partner

By: /s/ David C. Provost
Name: David C. Provost
Title: SVP

TENANT:

WITNESS:

/s/ Robert P. Blood

AMAG PHARMACEUTICALS, INC., a Delaware corporation

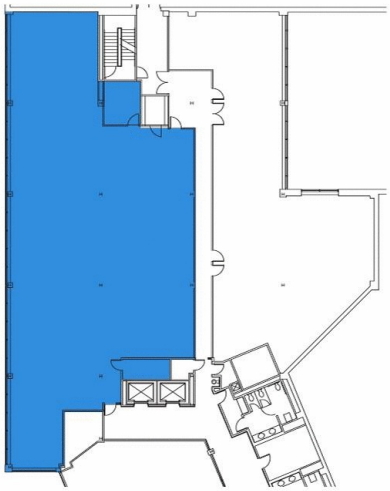
By: /s/ Nathan McBride
Name: Nathan McBride
Title: SVP, CIO AMAG

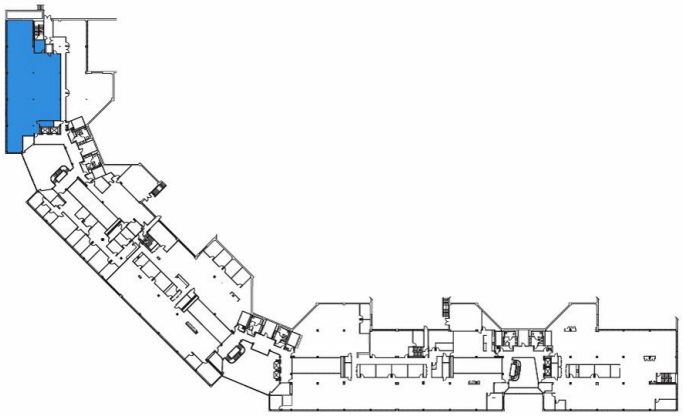
EXHIBIT A

TEMPORARY PREMISES

BAYCOLONY

1100 Winter Street
2nd Floor
6,452 RSF





Boston Properties

Exhibit 10.31

THIRD AMENDMENT TO LEASE

THIRD AMENDMENT TO LEASE dated as of this 7th day of December, 2015 (the "Effective Date"), by and between BP BAY COLONY LLC, a Delaware limited liability company ("Landlord") and AMAG PHARMACEUTICALS, INC., a Delaware corporation ("Tenant").

RECITALS

By Lease dated June 10, 2013 (the "Original Lease"), Landlord did lease to Tenant and Tenant did hire and lease from Landlord certain premises containing 32,217 square feet of rentable floor area (the "Rentable Floor Area of the Original Premises") on the third (3rd) floor of the building (the "Building") known as and numbered Bay Colony Corporate Center, 1100 Winter Street, Waltham, Massachusetts (referred to herein as the "Original Premises").

By First Amendment to Lease dated as of March 24, 2015 (the "First Amendment"), Landlord and Tenant (i) increased the size of the Original Premises by adding thereto an additional 5,934 square feet of rentable floor area (the "Rentable Floor Area of the First Additional Premises") located on the third (3rd) floor of the North Wing of the Building, which space is shown on Exhibit A attached to the First Amendment (the "First Additional Premises" and together with the Original Premises, the "Existing Premises") and (ii) extended the Term of the Original Lease for a period of one (1) year, upon all of the same terms and conditions contained in the Original Lease except as otherwise provided in the First Amendment to Lease. The Rentable Floor Area of the Original Premises, together with the Rentable Floor Area of the First Additional Premises, contains 38,151 square feet of rentable floor area (collectively referred to herein as the "Rentable Floor Area of the Existing Premises").

By Second Amendment to Lease dated as of November 3, 2015 (the "Second Amendment"), Landlord did lease to Tenant and Tenant did hire and lease from Landlord, on a temporary basis, certain premises containing 6,452 square feet of rentable floor area on the second (2nd) floor of the Building, which space is shown on Exhibit A attached to the Second Amendment (the "Temporary Premises"), upon all of the same terms and conditions set forth in the Lease except as otherwise provided in the Second Amendment.

Landlord and Tenant have agreed (i) to increase the size of the Existing Premises by adding thereto an additional 21,154 square feet of rentable floor area (the "Rentable Floor Area of the Second Additional Premises") located on the second (2nd) floor of the Building, which space is shown on Exhibit A attached hereto and made a part hereof (the "Second Additional Premises"), (ii) to modify the Temporary Premises Termination Date as defined in the Second Amendment, and (iii) to extend the Term of the Lease for a period of five (5) year(s) from the Second Additional Premises Rent Commencement Date (as hereinafter defined), upon all of the same terms and conditions contained in the Lease except as otherwise provided in this Third Amendment to Lease (the "Third Amendment").

Landlord and Tenant are entering into this instrument to set forth said leasing of the Second Additional Premises and said modification of the Temporary Premises Termination Date, to extend the Term of the Lease and to amend the Lease.

NOW THEREFORE, in consideration of One Dollar ($1.00) and other good and valuable consideration in hand this date paid by each of the parties to the other, the receipt and sufficiency of which are hereby severally acknowledged, and in further consideration of the mutual promises herein contained, Landlord and Tenant hereby agree to and with each other as follows:

1. Effective as of the date (the "Second Additional Premises Commencement Date") upon which Landlord delivers the Second Additional Premises to Tenant with the Landlord's Work (as hereinafter defined) completed, the Second Additional Premises shall constitute a part of the "Tenant's Premises" demised to Tenant under the Lease, so that the "Tenant's Premises" and, by definition the "Premises" (as defined in Sections 1.1 and 2.1 of the Lease), shall include both the Second Additional Premises and the Existing Premises. Landlord shall use commercially reasonable efforts to complete Landlord's Work by January 1, 2016 (the "Estimated Completion Date"). If Landlord shall have failed substantially to complete Landlord's Work on or before the date which is thirty (30) days subsequent to the Estimated Completion Date (which date shall be extended automatically for such periods of time as Landlord is prevented from proceeding with or completing the same by reason of Force Majeure as defined in Section 6.1 or any Tenant Delay (as defined below) without limiting Landlord's other rights on account thereof), the Annual Fixed Rent and Tenant's payments on account of operating expenses and real estate taxes shall be abated by one (1) day for each day beyond the date which is thirty (30) days subsequent to the Estimated Completion Date (as so extended) that Landlord thus fails to substantially complete the Landlord's Work. The foregoing rent abatement right shall be Tenant's sole and exclusive remedy at law or in equity or otherwise for Landlord's failure to substantially complete the Landlord's Work within the time periods set forth above. For the purposes of this paragraph, a "Tenant Delay" is a delay that is caused by (A) Tenant's failure to timely respond to any request from Landlord, Landlord's architect, Landlord's contractor and/or Landlord's Construction Representative within the time periods set forth in Section 7 of this Third Amendment or in the Work Agreement attached as Exhibit B-1 to the Original Lease, or (B) any other delays caused by Tenant, Tenant's contractors, architects, engineers, or anyone else engaged by Tenant in connection with the preparation of the Second Additional Premises for Tenant's occupancy, including, without limitation, utility companies and other entities furnishing communications, data processing or other service, equipment, or furniture which continues for more than two (2) business days after notice from Landlord.

2. (A) The Term of the Lease, which but for this Second Amendment is scheduled to expire on November 30, 2019, is hereby extended for a period (the "Second Extended Term") commencing on December 1, 2019 and expiring on the date which is five (5) years after the Second Additional Premises Rent Commencement Date (as defined in Section 3 below), unless sooner terminated or extended in accordance with the provisions of the Lease, upon all the same terms and conditions contained in the Lease as herein amended.

(B) Landlord and Tenant acknowledge that Tenant shall continue to have the right to extend the Term of the Lease for one (1) period of five (5) years upon the expiration of the Second Extended Term in accordance with the terms and conditions set forth in Section 9.18 of the Lease (as amended by Section 2 of the First Amendment) except that (i) all references to the "Extended Term" shall be replaced with "Third Extended Term" and (ii) Exhibit K attached to the Lease is hereby deleted in its entirety and replaced with Exhibit B attached hereto and made a part hereof.

(C) The Term of the Lease for the Existing Premises and the Second Additional Premises shall be coterminous. Accordingly, the extension option contained in Section 9.18 of the Lease (as amended by Section 2 of the First Amendment and as amended hereby) shall apply to the Existing Premises and the Second Additional Premises collectively and not to either such space independently.

3. (A) (i) Annual Fixed Rent for the Existing Premises through November 30, 2019 shall continue to be payable as set forth in the Lease.

(ii) From the date which is the earlier to occur of (a) Tenant's occupancy of the Second Additional Premises for business purposes and (b) June 1, 2016 (such earlier date to occur being the "Second Additional Premises Rent Commencement Date") through November 30, 2018, Annual

Fixed Rent for the Second Additional Premises shall be payable at the annual rate of $761,544.00 (being the product of (i) $36.00 and (ii) the Rentable Floor Area of the Second Additional Premises (being 21,154 square feet)).

(iii) From December 1, 2018 through November 30, 2019, Annual Fixed Rent for the Second Additional Premises shall be payable at the annual rate of $782,698.00 (being the product of (i) $37.00 and (ii) the Rentable Floor Area of the Second Additional Premises (being 21,154 square feet)).

(B) (i) During the Second Extended Term, Annual Fixed Rent for the Existing Premises shall be payable at the annual rate of $1,526,040.00 (being the product of $40.00 and (ii) the Rentable Floor Area of the Existing Premises (being 38,151 square feet)).

(ii) During the Second Extended Term, Annual Fixed Rent for the Second Additional Premises shall be payable at the annual rate of $803,852.00 (being the product of (i) $38.00 and (ii) the Rentable Floor Area of the Second Additional Premises (being 21,154 square feet)).

(C) During the Third Extended Term (if exercised), Annual Fixed Rent shall be determined as provided in Section 9.18 of the Lease (as amended).

4. (A) From and after the Second Additional Premises Commencement Date for the purposes of computing Tenant's payments for operating expenses pursuant to Section 2.6 of the Lease with respect to the Second Additional Premises, the following is hereby added to the definition of "Base Operating Expenses" contained in Section 1.1 of the Lease:

> "Base Operating Expenses: With respect to the Second Additional Premises only, Landlord's Operating Expenses (as hereinafter defined in Section 2.6) for calendar year 2016, being the period from January 1, 2016 through December 31, 2016."

The definition of Base Operating Expenses shall remain unchanged with respect to the Existing Premises.

(B) Further, for purposes of determining and calculating Tenant's payments for operating expenses pursuant to Section 2.6 of the Lease respecting the Second Additional Premises, (i) all references in Section 2.6 of the Lease to the "Premises" shall be deemed to be references to the Second Additional Premises; (ii) all references in Section 2.6 of the Lease to the "Rentable Floor Area of the Premises" shall be deemed to be references to the Rentable Floor Area of the Second Additional Premises; and (iii) in the definitions of "Operating Expenses Allocable to the Premises" and "Base Operating Expenses Allocable to the Premises", the reference to the "Rentable Floor Area of the Premises" shall mean said Rentable Floor Area of the Second Additional Premises.

5. (A) From and after the Second Additional Premises Commencement Date, for the purposes of computing Tenant's payments for real estate taxes pursuant to Section 2.7 of the Lease with respect to the Second Additional Premises, the following is hereby added to the definition of "Base Taxes" contained in Section 1.1 of the Lease:

> "Base Taxes: With respect to the Second Additional Premises only, Landlord's Tax Expenses (as hereinafter defined in Section 2.7) for fiscal tax year 2017, being the period from July 1, 2016 through June 30, 2017."

The definition of Base Taxes shall remain unchanged with respect to the Existing Premises.

(B) Further, for purposes of determining and calculating the Tenant's obligations to make payment for real estate taxes pursuant to Section 2.7 of the Lease respecting the Second Additional Premises, (i) all references in Section 2.7 of the Lease to the "Premises" shall be deemed to be references to the Second Additional Premises; (ii) all references in Section 2.7 to the "Rentable Floor Area of the Premises" shall be deemed to be references to the Rentable Floor Area of the Second Additional Premises; and (iii) in the definitions of "Landlord's Tax Expenses Allocable to the Premises" and "Base Taxes Allocable to the Premises" the reference to the "Rentable Floor Area of the Premises" shall mean said Rentable Floor Area of the Second Additional Premises.

6. Effective as of the Second Additional Premises Commencement Date, the definition of "Number of Parking Spaces" contained in Section 1.1 of the Lease (as amended by Section 7 of the First Amendment) shall be deleted in its entirety and the following substituted therefor:

> "One hundred and seventy-eight (178) (being three (3) spaces per 1,000 square feet of Rentable Floor Area of the Premises)."

7. Section 3.1 of the Lease, as it pertains to the Second Additional Premises only, shall be deleted in its entirety and shall be replaced with the following Section 3.1:

> "Section 3.1 Preparation of the Premises
>
> 3.1 Tenant's Work
>
> (A) Tenant shall accept the Second Additional Premises in their as-is condition without any obligation on the Landlord's part to perform any additions, alterations, improvements, demolition or other work therein or pertaining thereto; provided, however that prior to delivery of the Second Additional Premises to Tenant, Landlord shall, at Landlord's sole cost and expense, without inclusion as Landlord's Operating Expenses, complete demolition within the Second Additional Premises, complete certain premises entry work and perform certain work to infill certain of the skylights within the Second Additional Premises, which shall result in the addition of certain new space (but such work shall not result in any change to the Rentable Floor Area of the Second Additional Premises as described above), as further described in Exhibit C attached hereto and made a part hereof (collectively, the "Landlord's Work"). Except with respect to the Landlord's Work, Tenant, at its sole cost and expense, shall perform all work necessary, in Tenant's judgment, to prepare the Second Additional Premises for Tenant's occupancy in accordance with the plans and specifications prepared by Sierra Architects and attached hereto as Exhibit D provided, however, that within thirty (30) days of the Effective Date, Tenant shall provide to Landlord for approval mechanical plans for Tenant's work stamped by McNamara Salvia (as the plans at Exhibit D and the mechanical plans may be modified by any changes described below). If Tenant wishes to use a different architect, Tenant shall select an architect licensed by the Commonwealth of Massachusetts and reasonably approved by Landlord. Tenant shall have the right to change, modify or amend such Plans, subject to (i) the reasonable approval by Landlord of such changes, modifications or amendments, and (ii) the payment of costs stipulated in Subsection 3.1(B) of the Lease in connection with Landlord's review of such amendments to the Plans. All such future approvals, or disapprovals with supporting specific reasons, for subsequent submittals of corrections or changes, shall be provided to Tenant within seven (7) business days of Landlord's receipt.

(B) Tenant, at its sole cost and expense, shall promptly, and with all due diligence, perform Tenant's Work as set forth on the Plans, and, in connection therewith, the Tenant shall obtain all necessary governmental permits and approvals for Tenant's Work. All of Tenant's Work shall be performed strictly in accordance with the Plans and in accordance with applicable Legal Requirements (as defined in Section 3.1(C) hereof) and Insurance Requirements (as defined in Section 5.12 of the Lease). Tenant shall have Tenant's Work performed by Chapman Construction or another contractor or contractors, reasonably approved by Landlord, which contractors shall provide to Landlord such insurance as required by Section 8.14 of the Lease. Landlord shall have the right to provide reasonable rules and regulations relative to the performance of Tenant's Work and any other work which the Tenant may perform under the Lease and Tenant shall abide by all such reasonable rules and regulations and shall cause all of its contractors to so abide including, without limitation, payment for the costs of using Building services; provided, however, that in the event of a conflict between said rules and regulations and the terms of the Lease, the terms of the Lease shall govern. It shall be Tenant's obligation to obtain a certificate of occupancy or other like governmental approval for the use and occupancy of the Second Additional Premises to the extent required by law, and Tenant shall not occupy the Second Additional Premises for the conduct of business until and unless it has obtained such approval and has submitted to Landlord a copy of the same together with waivers of lien from all of Tenant's contractors in form adequate for recording purposes. Tenant shall also prepare and submit to Landlord promptly after Tenant's Work is substantially complete a set of as-built plans in both print and electronic forms showing the work performed by Tenant to the Second Additional Premises, but excluding any wiring or cabling installed by Tenant or Tenant's contractor for Tenant's computer, telephone and other communication systems. Within thirty (30) days after receipt of an invoice from Landlord, Tenant shall pay to Landlord, as Additional Rent, an amount equal to the reasonable third party expenses incurred by Landlord to review Tenant's Plans and Tenant's Work (Landlord hereby agreeing to cap any plan review costs relating to interior, non-structural alterations, additions or improvements that do not impact Building systems at $6,000.00 in connection with any single request for approval).

(C) All construction work required or permitted by the Lease shall be done in a good and workmanlike manner and in compliance with all applicable laws, ordinances, rules, regulations, statutes, by-laws, court decisions, and orders and requirements of all public authorities ("Legal Requirements") and all Insurance Requirements (as defined in Section 5.12 of the Lease); provided, however, that Tenant shall have no obligation to make any changes to the Building (other than the Premises) related to Tenant's Work, except to the extent such changes are necessitated solely by Tenant's Work. All of Tenant's work shall be coordinated with any work being performed by or for Landlord and in such manner as to maintain harmonious labor relations. Each party may inspect the work of the other at reasonable times and shall promptly give notice of observed defects. Each party authorizes the other to rely in connection with design and construction upon approval and other actions on the party's behalf by any Construction Representative of the party named herein or any person hereafter designated in substitution or addition by notice to the party relying. Landlord hereby appoints Luke Bowen as Landlord's Construction Representative, and Tenant hereby appoints Nathan McBride as Tenant's Construction Representative. Tenant acknowledges that Tenant is acting for its own benefit and account and that Tenant will not be acting as Landlord's agent in performing any Tenant Work, accordingly, no contractor, subcontractor or supplier shall have a right to lien Landlord's interest in the Property in connection with any work. Except to the

extent to which Tenant shall have given Landlord notice of any defects or any errors and omissions in Landlord's Work not later than the end of the eleventh (11th) full calendar month next beginning after the Second Additional Premises Commencement Date, Tenant shall be deemed conclusively to have approved Landlord's Work and shall have no claim that Landlord has failed to perform any of Landlord's Work. Landlord agrees to correct or repair at its expense items which are then incomplete or do not conform to the requirements of Landlord's Work and as to which, in either case, Tenant shall have given notice to Landlord, as aforesaid.

(D) Landlord shall provide to Tenant a special allowance equal to Eight Hundred Forty-Six Thousand One Hundred Sixty and 00/100 Dollars ($846,160.00) (being the product of (i) $40.00 and (ii) the Rentable Floor Area of the Second Additional Premises (the "Tenant Allowance")).

The Tenant Allowance shall be used and applied by Tenant solely toward the following (collectively, "Costs"): (i) the costs of labor and materials incurred in the performance of Tenant's Work, any other work contemplated by the Plans, any other work to integrate the Second Additional Premises into the Existing Premises, and any other work approved by the Landlord on the Premises, and (ii) architectural and engineering fees and expenses and the cost of telecommunications and AV wiring, in each case incurred in connection with Tenant's Work, provided, however, that the costs in this subsection (ii) shall be payable from Tenant's Allowance up to an aggregate amount not to exceed $169,232.00.

As a condition precedent to the disbursement of any payments on account of the Tenant Allowance, Tenant shall deliver to Landlord a certificate signed by Tenant specifying the total amount of all Costs of Tenant's Work, including architectural and engineering fees and expenses, and identifying all design professionals, consultants, contractors, service providers, subcontractors and suppliers involved with Tenant's Work (the "Tenant's Costs Certificate"). Tenant shall promptly notify Landlord in writing of any material change in the total amount of all Costs of Tenant's Work as reflected in Tenant's Costs Certificate.

(E) For the purposes hereof, a "Requisition" shall mean written documentation (including invoices from all applicable Tenant's design professionals, consultants, contractors, service providers, subcontractors and suppliers, and such other documentation as the mortgagee of Landlord, if any, may reasonably request) showing in reasonable detail the Tenant's Work completed to date and the cost of all of the items, services and work covered thereby.

Each Requisition shall be accompanied by (i) evidence reasonably satisfactory to Landlord that all of the items, services and work covered by such Requisition have been fully paid by Tenant, (ii) executed lien waivers (partial or final, as applicable) in the forms attached hereto as Exhibit E from all persons or entities that might have a lien as a result of performing any such services or work or furnishing any such items, (iii) a certificate signed by Tenant's architect certifying that the Tenant's Work reflected in such Requisition has been completed substantially in accordance with the approved Plans, and (iv) a certificate signed by Tenant certifying that the amount of the such Requisition does not exceed the cost of the items, services and work covered thereby. Landlord shall have the right, upon reasonable advance notice to Tenant, to inspect Tenant's books and records relating to each Requisition in order to verify the amount

thereof. Tenant shall submit Requisition(s) no more often than once every thirty (30) days.

Provided and on condition that, as of the date on which Tenant submits to Landlord any Requisition (together with all required supporting documentation) (i) Tenant has delivered Tenant's Costs Certificate to Landlord, (ii) Tenant has submitted such Requisition to Landlord not later than the date that is Three Hundred Sixty-Five (365) days after the Second Additional Premises Rent Commencement Date, (iii) there exists no Event of Default, and (iv) there are no liens (unless bonded to the reasonable satisfaction of Landlord) against Tenant's interest in the Lease or against the Building or the Site arising out of Tenant's Work or any litigation in which Tenant is a party, then Landlord shall pay the Costs shown on such Requisition within thirty (30) days after Landlord's receipt thereof; provided, however, that in no event shall Landlord have any obligation to pay or otherwise fund any amount in excess of the Tenant Allowance.

(F) Notwithstanding anything to the contrary herein contained:

(i) In addition to the other requirements applicable to Requisitions generally, as set forth in Section 3.1(E) above, it is understood and agreed that Landlord shall have no obligation to pay Tenant's final Requisition, unless and until (a) Tenant has delivered to Landlord a final set of record drawings for Tenant's Work, (b) Tenant has delivered to Landlord a certificate of substantial completion signed by Tenant's architect, (c) Tenant has executed the Declaration Affixing the Commencement Date of the Second Additional Premises in the form annexed to this Second Amendment as Exhibit F and (d) a certificate of occupancy (which may be a temporary certificate of occupancy, provided that Tenant shall thereafter diligently satisfy all conditions to obtaining a permanent certificate of occupancy) in a timely manner has been approved for issuance by the applicable governmental authority respecting the Second Additional Premises.

(ii) Landlord shall in no event be deemed, by undertaking to pay the Tenant Allowance or otherwise, to have assumed any obligations, in whole or in part, of Tenant to any design professionals, consultants, contractors, vendors, service providers, subcontractors, suppliers, workers, materialmen or other third parties.

(iii) Except with respect to work and/or materials previously paid for by Tenant, as evidenced by paid invoices and written lien waivers provided to Landlord, Landlord shall have the right (but not the obligation) to have portions of the Tenant Allowance paid to directly to Tenant's design professionals, consultants, contractors, service providers, subcontractors or suppliers.

(iv) In the event that Costs are less than the Tenant Allowance, Tenant shall not be entitled to any payment or credit, nor shall there be any application of the same toward Annual Fixed Rent or Additional Rent owed by Tenant under the Lease."

8. Section 9.26 of the Lease (as amended by Section 9 of the First Amendment) is hereby deleted in its entirety and replaced with the following:

"9.26 Right of First Offer

(A) Subject to the provisions of this Section 9.26, and subject to (i) any and

all rights of tenants in the Office Park to lease the Expansion Space (as hereinafter defined) pursuant to the express expansion or extension rights in their respective leases and (ii) Landlord's right to renew or extend the lease of an existing tenant in the Expansion Space (whether or not they have renewal or extension options in their respective leases), and provided that (x) no Event of Default has occurred and remains uncured under the Lease, (y) Tenant has not assigned the Lease or sublet more than 33% of the Premises, except as permitted under Section 5.6.4, and (z) the Lease is still in force and effect, Landlord agrees that during the Term, upon the occurrence of the Expansion Notice Trigger Date (as hereinafter defined), Landlord will give written notice to Tenant offering to lease the Expansion Space to Tenant pursuant to this Section 9.26 ("Landlord's ROFO Notice"). Landlord's ROFO Notice shall specify the estimated delivery date of the Expansion Space, the Annual Fixed Rent, Base Operating Expenses and Base Taxes for the Expansion Space, and any work allowance, free rent period or other material business terms upon which Landlord is willing to lease the Expansion Space.

(B) If Tenant wishes to exercise Tenant's right of first offer, Tenant shall have the right to do so by delivering notice to Landlord of Tenant's desire to lease the entire space described in Landlord's ROFO Notice (it being agreed that Tenant has no right to lease less than such entire space) (the "Tenant's Acceptance Notice"), provided Landlord receives Tenant's Acceptance Notice not later than that date which is ten (10) days after the date of Tenant's receipt of Landlord's ROFO Notice, time being of the essence. If Tenant shall deliver a timely Tenant's Acceptance Notice, then the Lease shall automatically be deemed amended to incorporate the Expansion Space into the Premises on such terms and conditions, without the necessity for the execution of any additional documents; provided, however, Landlord and Tenant agree within fifteen (15) days of Landlord's receipt of Tenant's Acceptance Notice (or fifteen (15) days from the Broker Determination of Annual Fixed Rent, if Tenant requests the same pursuant to the terms hereof) to execute and deliver an amendment to the Lease prepared by Landlord and reasonably approved by Tenant incorporating the Expansion Space into the Premises upon all of the same terms and conditions in the Lease, except that: (i) the Annual Fixed Rent, which shall be as set forth in Landlord's ROFO Notice or as otherwise agreed by the parties during the Negotiation Period (or as determined by Broker Determination, if so requested by Tenant pursuant to the terms hereof) shall be applicable to the Expansion Space; (ii) all other terms and conditions set forth in Landlord's ROFO Notice shall be applicable to the Expansion Space; (iii) the lease term as to the Expansion Space shall be coterminous with the Term (as it may be extended pursuant to Section 2 of this Second Amendment, or as it may be earlier terminated under the Lease); and (iv) those provisions of the Lease which conflict with the specific terms set forth in Landlord's ROFO Notice shall not be applicable to the Expansion Space. If for any reason Tenant shall not so exercise such right within such period, time being of the essence with respect to such exercise, Landlord shall be free to lease the Expansion Space to a third party.

(C) In the event Tenant desires to exercise its right of first offer, but Tenant disagrees with Landlord's determination of the Annual Fixed Rent for the Expansion Space, Tenant shall provide Landlord with Tenant's Acceptance Notice, meeting the requirements set forth above within the time period specified above, but Tenant's Acceptance Notice shall also indicate that Tenant so disagrees, whereupon the parties shall negotiate in good faith for a period of fifteen (15) days (the "Negotiation Period") from the date upon which Landlord receives Tenant's Acceptance Notice to agree upon the Annual Fixed Rent. If the parties do not so agree within the Negotiation Period, then

Tenant shall have the right, by written notice given to Landlord within ten (10) days after the expiration of the Negotiation Period, to submit the Annual Fixed Rent for the Expansion Space to a Broker Determination of the Prevailing Market Rent (as defined in Exhibit B), which Broker Determination shall be made in the manner set forth in Exhibit B. In any event, Tenant's delivery of Tenant's Acceptance Notice shall be deemed to be the irrevocable exercise by Tenant of its right of first offer subject to and in accordance with the provisions of this Section 9.26.

(D) If Landlord determines that possession of the Expansion Space will not be available for delivery to Tenant until on or after that date which is twelve (12) months prior to the end of the Second Extended Term, then: (i) if Tenant has no further right to extend the Term of the Lease (i.e. because Tenant's right to extend the Term of the Lease pursuant to Section 2 above and Section 9.18 of the Lease has been irrevocably waived by Tenant or has lapsed unexercised), then Landlord shall not be obligated to offer the Expansion Space for lease to Tenant, or to deliver a Landlord's ROFO Notice to Tenant with respect thereto, nor shall Tenant have a right to lease the Expansion Space under the terms set forth herein or otherwise, or to receive a Landlord's ROFO Notice with respect thereto, and (ii) if Tenant then has a right to extend the Term of the Lease pursuant to Section 2 above and Section 9.18 of the Lease which has not either lapsed unexercised or been irrevocably waived, then Landlord shall deliver a Landlord's ROFO Notice to Tenant with respect thereto, but Tenant shall have no right to lease such Expansion Space unless, prior to, or simultaneously with, the giving of Tenant's Acceptance Notice, Tenant exercises such extension option, which option may be exercised without regard to any time periods for such exercise set forth in Section 2 above and Section 9.18 of the Lease so long as it is sent in accordance with the timing requirements set forth in this Section 9.26.(D)(ii). Notwithstanding Tenant's exercise of its extension option in accordance with the foregoing, the Annual Fixed Rent for the original Premises for such Extended Term shall be determined at the same time and in the same manner such Annual Fixed Rent would have been determined if Tenant had exercised the extension option within the time periods for such exercise set forth in Section 2 above and Section 9.18 of the Lease.

(E) As used in this Section 9.26, the following terms shall have the meanings set forth below:

(i) "Expansion Space" shall be approximately 16,564 square feet of rentable floor area on the first (1st) floor of the Building, as shown on Exhibit G attached hereto and made a part hereof.

(ii) "Expansion Notice Trigger Date" shall mean the date on which Landlord reaches a stage in negotiations with a third party to lease the Expansion Space that Landlord reasonably believes in good faith could result in the execution of a letter of intent to lease such space with such third party within fourteen (14) days."

9. Landlord acknowledges that Tenant shall have the right to increase the existing generator serving the Premises, including expanding the slab therefor, subject to and in accordance with the terms of the Lease, including, without limitation, Section 5.12 thereof.

10. Section 2(A)(ii) of the Second Amendment is hereby deleted in its entirety and the following is inserted in place thereof:

"(ii) The termination date in respect of the Temporary Premises ("Temporary

Premises Termination Date") shall be the date that is the earlier to occur of (i) five (5) days after the Second Additional Premises Rent Commencement Date and (ii) the date that is seven (7) months after the Second Additional Premises Commencement Date."

11. Section 9.19 of the Lease (as amended by Section 10 of the First Amendment) is hereby deleted in its entirety and replaced with the following:

"9.19 Security Deposit.

(A) (i) The parties hereby acknowledge and agree that Landlord is currently holding a security deposit in the amount of Four Hundred Thousand and 00/100 Dollars ($400,000.00) (the "Existing Security Deposit") in the form of an irrevocable letter of credit issued by Bank of America, N.A. (the "Letter of Credit"). In consideration of Landlord's agreement to extend the Term of the Lease and to lease the Second Additional Premises to Tenant, Tenant shall deliver to Landlord, within thirty (30) days of the Effective Date, an additional security deposit in the amount of One Hundred Ninety-Five Thousand Four Hundred Thirty-Four and 00/100 Dollars ($195,434.00) (the "Additional Security Deposit" and collectively with the Existing Security Deposit, the "Security Deposit") such that the total security deposit held by Landlord under the Lease shall be Five Hundred Ninety-Five Thousand Four Hundred Thirty-Four and 00/100 Dollars ($595,434.00). Such Additional Security Deposit shall be either in the form of an additional irrevocable, unconditional, negotiable letter of credit meeting the requirements of this Section 9.19, or an amendment to the existing Letter of Credit increasing the face amount thereof to Five Hundred Ninety-Five Thousand Four Hundred Thirty-Four and 00/100 Dollars ($595,434.00).

(ii) Tenant agrees that Landlord shall hold the Security Deposit, throughout the Term of the Lease (including any extension thereof), as security for the performance by Tenant of all obligations on the part of Tenant to be kept and performed. Landlord shall have the right from time to time without prejudice to any other remedy Landlord may have on account thereof, to apply such deposit, or any part thereof, to Landlord's damages arising from any Event of Default. If Landlord so applies all or any portion of such deposit, Tenant shall within seven (7) days after notice from Landlord deliver cash to Landlord in an amount sufficient to restore such deposit to the full amount stated in this Section 9.19. While Landlord holds such deposit, Landlord shall have no obligation to pay interest on the same and shall have the right to commingle the same with Landlord's other funds. If Landlord conveys Landlord's interest under the Lease, the deposit, or any part thereof not previously applied, may be turned over by Landlord to Landlord's grantee, and, if so turned over, Tenant agrees to look solely to such grantee for proper application of the deposit in accordance with the terms of this Section 9.19, and the return thereof in accordance herewith.

(iii) Tenant shall have the right to provide such security deposit in one or two letters of credit, as described in Section 9.19(A)(i), and in the form of irrevocable, unconditional, negotiable letters of credit (each, a "**Letter of Credit**"). Each Letter of Credit shall (i) be issued by and drawn on a bank reasonably approved by Landlord and at a minimum having a long term issuer credit rating from Standard and Poor's Professional Rating Service of A or a comparable rating from Moody's Professional Rating Service, (ii) be substantially in the form attached hereto as **Exhibit H**, (iii) permit one or more draws thereunder to be made accompanied only by certification by Landlord or Landlord's managing agent that pursuant to the terms of the Lease, Landlord is entitled to

draw upon such Letter of Credit, (iv) permit transfers at any time without charge, and (v) provide that any notices to Landlord be sent to the notice address provided for Landlord in the Lease. If the credit rating for the issuer of a Letter of Credit falls below the standard set forth in (i) above or if the financial condition of an issuer changes in any other material adverse way, Landlord shall have the right to require that Tenant provide a substitute letter of credit that complies in all respects with the requirements of this Section, and Tenant's failure to provide the same within thirty (30) days following Landlord's written demand therefor shall entitle Landlord to immediately draw upon the subject Letter of Credit. Any such Letter of Credit shall be for a term of two (2) years (or for one (1) year if the issuer thereof regularly and customarily only issues letters of credit for a maximum term of one (1) year) and shall in either case provide for automatic renewals through the date which is ninety (90) days subsequent to the scheduled expiration of the Lease (as the same may be extended) or if the issuer will not grant automatic renewals, each Letter of Credit shall be renewed by Tenant each year and each such renewal shall be delivered to and received by Landlord not later than sixty (60) days before the expiration of the then current Letter of Credit (herein called a "**Renewal Presentation Date**"). In the event of a failure to so deliver any such renewal Letter of Credit on or before the applicable Renewal Presentation Date, Landlord shall be entitled to present the then existing Letter of Credit for payment and to receive the proceeds thereof, which proceeds shall be held as Tenant's security deposit, subject to the terms of this Section 9.19. Any failure or refusal to honor the Letter of Credit shall be at Tenant's sole risk and shall not relieve Tenant of its obligation hereunder with regard to the security deposit. Upon the receipt by Landlord of one or more Letters of Credit meeting the requirements set forth herein, Landlord shall return to Tenant any cash security deposit then being held by Landlord, and thereafter each Letter of Credit shall be held by Landlord in accordance with the terms and conditions of this Section 9.19 as security for Tenant's obligations hereunder.

(B) (i) Landlord shall return a One Hundred Thousand and 00/100 Dollar ($100,000.00) portion of such deposit to Tenant so that the remainder of such deposit shall be Four Hundred Ninety-Five Thousand Four Hundred Thirty-Four and 00/100 Dollars ($495,434.00) (or if such deposit is in the form of a Letter of Credit, Landlord shall either exchange the Letter of Credit for a Letter of Credit delivered by Tenant or accept an amendment to such Letter of Credit, in either case which reduces the amount secured by the Letter of Credit by $100,000.00) on September 19, 2016; provided that (i) no Event of Default has occurred under the Lease and remains uncured as of September 19, 2016, and (ii) Landlord has not applied the Security Deposit, or any portion thereof, to Landlord's damages arising from any Event of Default, whether or not Tenant has restored the amount so applied by Landlord.

(ii) Landlord shall return a Sixty-Five Thousand One Hundred Forty-Five and 00/100 Dollar ($65,145.00) portion of such deposit to Tenant so that the remainder of such deposit shall be Four Hundred Thirty Thousand Two Hundred Eighty-Nine and 00/100 Dollars ($430,289.00) (or if such deposit is in the form of a Letter of Credit, Landlord shall either exchange the Letter of Credit for a Letter of Credit delivered by Tenant or accept an amendment to such Letter of Credit, in either case which reduces the amount secured by the Letter of Credit by $65,145.00 and otherwise in strict conformity with the requirements herein) on the first (1st) anniversary of the Second Additional Premises Rent Commencement Date; provided that (i) no Event of Default has occurred under this Lease and remains uncured as of such first (1st) anniversary, and (ii) Landlord has not applied the Security Deposit, or any portion thereof, to Landlord's damages

arising from any Event of Default, whether or not Tenant has restored the amount so applied by Landlord.

(iii) If Tenant believes that it has satisfied all the conditions precedent to a reduction in the amount of the Security Deposit, then it shall request such reduction in writing to Landlord, which request shall certify to Landlord that all such conditions have been satisfied. If Landlord determines that all of the aforesaid conditions are met, the Security Deposit shall be so reduced in accordance with this Section 9.19. No Letter of Credit shall automatically reduce, but any reduction in the amount thereof shall require Landlord's prior written notice to the issuer of the applicable Letter of Credit of the reduced amount. Promptly after Landlord's receipt of Tenant's request for a reduction as described above, Landlord shall determine whether such a reduction is permitted in accordance with this Section 9.19, and if it is, Landlord shall notify the issuer of the applicable Letter of Credit of the amount to which the Letter of Credit shall be reduced.

(iv) Tenant not then being in default and having performed all of its obligations under the Lease, including the payment of all Annual Fixed Rent, Landlord shall return the deposit, or so much thereof as shall not have theretofore been applied in accordance with the terms of this Section 9.19, to Tenant on the expiration or earlier termination of the term of the Lease (as the same may have been extended) and surrender possession of the Premises by Tenant to Landlord in the condition required in the Lease at such time.

(v) Neither the holder of any mortgage nor the lessor in any ground lease on property which includes the Premises shall ever be responsible to Tenant for the return or application of any such deposit, whether or not it succeeds to the position of Landlord hereunder, unless such deposit shall have been received in hand by such holder or ground lessor."

12. (A) Tenant warrants and represents that Tenant has not dealt with any broker in connection with the consummation of this Third Amendment except Colliers International (the "Broker") and in the event any claim is made against Landlord relative to dealings by Tenant with any brokers other than the Broker, Tenant shall defend the claim against Landlord with counsel of Tenant's selection first approved by Landlord (which approval will not be unreasonably withheld) and save harmless and indemnify Landlord on account of loss, cost or damage which may arise by reason of such claim.

(B) Landlord warrants and represents that Landlord has not dealt with any broker in connection with the consummation of this Third Amendment, other than the Broker, and in the event any claim is made against Tenant relative to dealings by Landlord with brokers, Landlord shall defend the claim against Tenant with counsel of Landlord's selection first approved by Tenant (which approval will not be unreasonably withheld) and save harmless and indemnify Tenant on account of loss, cost or damage which may arise by reason of such claim. Landlord agrees that it shall be solely responsible for the payment of brokerage commissions to the Broker, for the Second Extended Term as further outlined in a separate agreement between Landlord and the Broker.

13. Except as otherwise expressly provided herein, all capitalized terms used herein without definition shall have the same meanings as are set forth in the Lease.

14. Except as herein amended the Lease shall remain unchanged and in full force and effect. All references to the "Lease" shall be deemed to be references to the Lease as amended by the First Amendment, the Second Amendment and as herein amended.

15. Each of Landlord and Tenant hereby represents and warrants to the other that all necessary action has been taken to enter this Third Amendment and that the person signing this Third Amendment on its behalf has been duly authorized to do so.

16. The parties acknowledge and agree that this Second Amendment may be executed by electronic signature, which shall be considered as an original signature for all purposes and shall have the same force and effect as an original signature. Without limitation, "electronic signature" shall include faxed versions of an original signature or electronically scanned and transmitted versions (e.g., via pdf) of an original signature.

[Remainder of page intentionally left blank.]

EXECUTED as of the date and year first above written.

LANDLORD:

WITNESS:

/s/ Matthew Murry

BP BAY COLONY LLC, a Delaware limited liability company

BY: BP BAY COLONY HOLDINGS LLC, a Delaware limited liability company, its sole member

BY: BOSTON PROPERTIES LIMITED PARTNERSHIP, a Delaware limited partnership, its member

BY: BOSTON PROPERTIES, INC., a Delaware Corporation, its general partner

By: /s/ David C. Provost
Name: David C. Provost
Title: SVP

TENANT:

WITNESS:

/s/ Karen M. Holcomb

AMAG PHARMACEUTICALS, INC., a Delaware corporation

By: /s/ William K. Heiden
Name: William K. Heiden
Title: CEO

EXHIBIT A

SECOND ADDITIONAL PREMISES

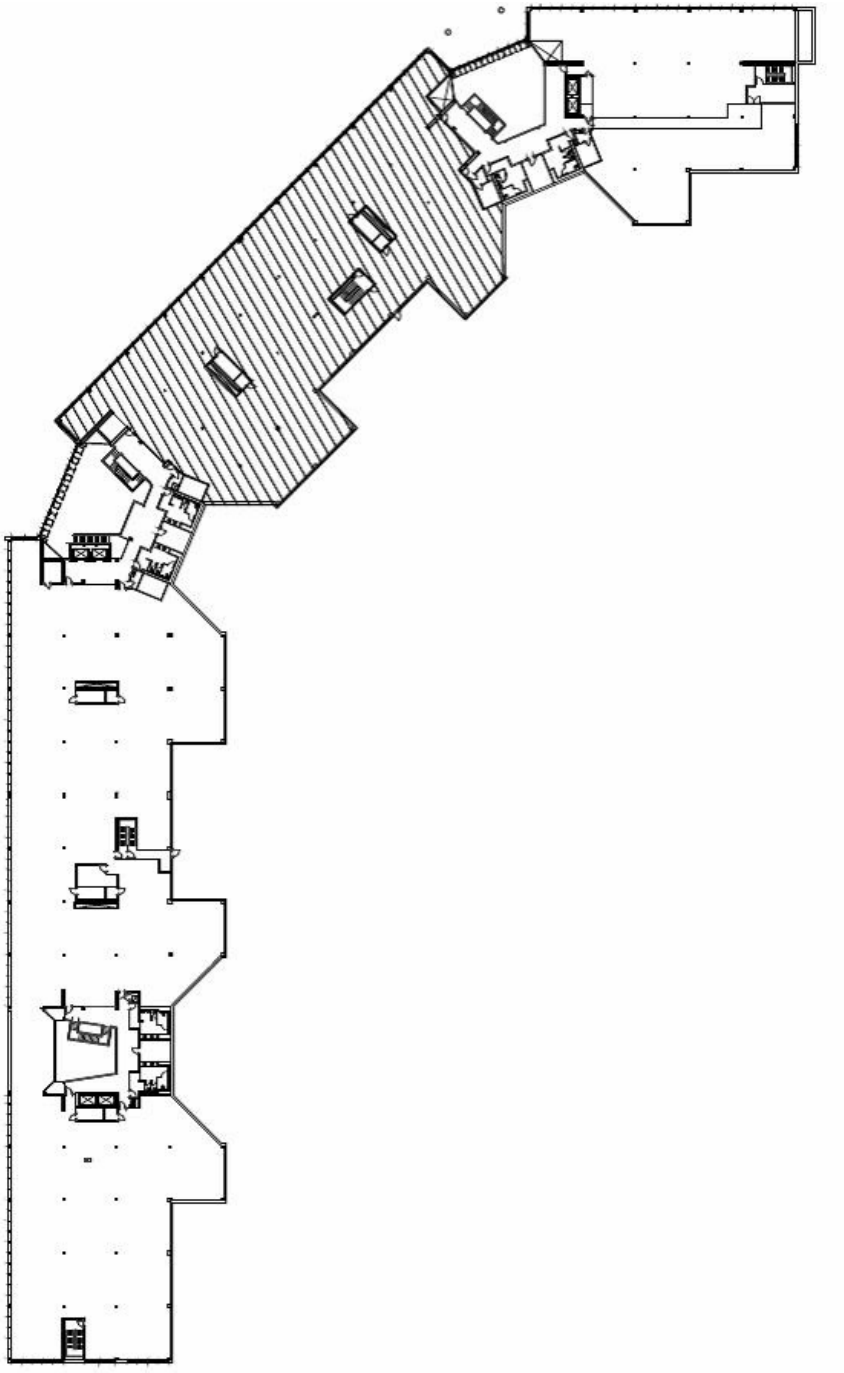


EXHIBIT B

BROKER DETERMINATION OF PREVAILING MARKET RENT

Where in the Lease to which this **Exhibit B** is attached provision is made for a Broker Determination of Prevailing Market Rent, the following procedures and requirements shall apply:

1. Tenant's Request. Tenant shall send a notice to Landlord by the time set for such notice in the applicable section of the Lease, requesting a Broker Determination of the Prevailing Market Rent, which notice to be effective must (i) make explicit reference to the Lease and to the specific section of the Lease pursuant to which said request is being made, (ii) include the name of a broker selected by Tenant to act for Tenant, which broker shall be affiliated with a major Boston commercial real estate brokerage firm selected by Tenant and which broker shall have at least ten (10) years' experience dealing in properties of a nature and type generally similar to the Building located in the Boston West Suburban Market, and (iii) explicitly state that Landlord is required to notify Tenant within thirty (30) days of an additional broker selected by Landlord.

2. Landlord's Response. Within thirty (30) days after Landlord's receipt of Tenant's notice requesting the Broker Determination and stating the name of the broker selected by Tenant, Landlord shall give written notice to Tenant of Landlord's selection of a broker having at least the affiliation and experience referred to above.

3. Selection of Third Broker. Within ten (10) days thereafter the two (2) brokers so selected shall select a third such broker also having at least the affiliation and experience referred to above.

4. Rental Value Determination. Within thirty (30) days after the selection of the third broker, the three (3) brokers so selected, by majority opinion, shall make a determination of the annual fair market rental value of the Premises or the Expansion Space, as applicable, for the period referred to in the Lease. Such annual fair market rental value determination shall take into account all applicable factors and (x) may include provision for annual increases in rent during said term if so determined, (y) shall take into account the as-is condition of the Premises or the Expansion Space, as applicable, and (z) shall take account of, and be expressed in relation to, the tax and operating cost bases and provisions for paying for so-called tenant electricity as contained in the Lease. The brokers shall advise Landlord and Tenant in writing by the expiration of said thirty (30) day period of the annual fair market rental value which as so determined shall be referred to as the Prevailing Market Rent.

5. Resolution of Broker Deadlock. If the Brokers are unable to agree at least by majority on a determination of annual fair market rental value, then the brokers shall send a notice to Landlord and Tenant by the end of the thirty (30) day period for making said determination setting forth their individual determinations of annual fair market rental value, and the highest such determination and the lowest such determination shall be disregarded and the remaining determination shall be deemed to be the determination of annual fair market rental value and shall be referred to as the Prevailing Market Rent.

6. Costs. Each party shall pay the costs and expenses of the broker selected by it and each shall pay one half (1/2) of the costs and expenses of the Third Broker.

7. Failure to Select Broker or Failure of Broker to Serve. If Tenant shall have requested a Broker Determination and Landlord shall not have designated a broker within the time period provided therefor above, then Tenant's Broker shall alone make the determination of Prevailing Market Rent in writing to Landlord and Tenant within thirty (30) days after the expiration of Landlord's right to designate a broker hereunder. If Tenant and Landlord have both designated brokers but the two brokers so designated do not, within a period of fifteen (15) days after the appointment of the second broker, agree upon and

designate the Third Broker willing so to act, the Tenant, the Landlord or either broker previously designated may request the Boston Bar Association (or such organization as may succeed to the Boston Bar Association) to designate the Third Broker willing so to act and a broker so appointed shall, for all purposes, have the same standing and powers as though he had been seasonably appointed by the brokers first appointed. In case of the inability or refusal to serve of any person designated as a broker, or in case any broker for any reason ceases to be such, a broker to fill such vacancy shall be appointed by the Tenant, the Landlord, the brokers first appointed or the Boston Bar Association as the case may be, whichever made the original appointment, or if the person who made the original appointment fails to fill such vacancy, upon application of any broker who continues to act or by the Landlord or Tenant such vacancy may be filled by the Boston Bar Association and any broker so appointed to fill such vacancy shall have the same standing and powers as though originally appointed.

EXHIBIT C

SCOPE OF LANDLORD'S WORK

Demolition Work –

- Demolish existing ceiling, walls and floors
- Turn up sprinkler heads
- Adjust fire alarm/devices accordingly

Infill Work – within existing skylights on 2nd floor between south and central lobby of Building

- Infill addition to be delivered in shell condition
- The floors of the Infill Addition shall be a smooth and level concrete floor sub-floor ready for carpeting or other floor covering
- Landlord shall provide code compliant sprinklers throughout the Infill Addition

Premises Entry Work

- Tenant entry along second floor center lobby to be substantially similar to glass entry in third floor of the Existing Premises.
- Demising wall along entry in second floor south lobby to be substantially similar to demising wall in third floor south lobby of the Existing Premises.

EXHIBIT D

TENANT'S PLANS AND SPECIFICATIONS

EXHIBIT E

FORMS OF LIEN WAIVERS

CONTRACTOR'S PARTIAL WAIVER AND SUBORDINATION OF LIEN

STATE OF _____ Date: _____

_____ COUNTY Application for Payment No.: _____

OWNER: _____

CONTRACTOR: _____

LENDER / MORTGAGEE: None

1.	Original Contract Amount:	$	_____
2.	Approved Change Orders:	$	_____
3.	Adjusted Contract Amount: (line 1 plus line 2)	$	_____
4.	Completed to Date:	$	_____
5.	Less Retainage:	$	_____
6.	Total Payable to Date: (line 4 less line 5)	$	_____
7.	Less Previous Payments:	$	_____
8.	Current Amount Due: (line 6 less line 7)	$	_____
9.	Pending Change Orders:	$	_____
10.	Disputed Claims:	$	_____

The undersigned who has a contract with _____ for furnishing labor or materials or both labor and materials or rental equipment, appliances or tools for the erection, alteration, repair or removal of a building or structure or other improvement of real property known and identified as located in _____ (city or town), _____County, _____ and owned by _____, upon receipt of _____ ($_____) in payment of an invoice/requisition/application for payment dated _____ does hereby:

(a) waive any and all liens and right of lien on such real property for labor or materials, or both labor and materials, or rental equipment, appliances or tools, performed or furnished

through the following date _____ (payment period), except for retainage, unpaid agreed or pending change orders, and disputed claims as stated above;

(b) subordinate any and all liens and right of lien to secure payment for such unpaid, agreed or pending change orders and disputed claims, and such further labor or materials, or both labor and materials, or rental equipment, appliances or tools, except for retainage, performed or furnished at any time through the twenty-fifth day after the end of the above payment period, to the extent of the amount actually advanced by the above lender/mortgagee through such twenty-fifth day.

Signed under the penalties of perjury this _____ day of _____, 20__.

WITNESS:	CONTRACTOR:
Name: _____	Name: _____
Title: _____	Title: _____

SUBCONTRACTOR'S LIEN WAIVER

General Contractor: _____

Subcontractor: _____

Owner: _____

Project: _____

Total Amount Previously Paid: $ _____

Amount Paid This Date: $ _____

Retainage (Including This Payment) Held to Date: $ _____

In consideration of the receipt of the amount of payment set forth above and any and all past payments received from the Contractor in connection with the Project, the undersigned acknowledges and agrees that it has been paid all sums due for all labor, materials and/or equipment furnished by the undersigned to or in connection with the Project and the undersigned hereby releases, discharges, relinquishes and waives any and all claims, suits, liens and rights under any Notice of Identification, Notice of Contract or statement of account with respect to the Owner, the Project and/or against the Contractor on account of any labor, materials and/or equipment furnished through the date hereof.

The undersigned individual represents and warrants that he is the duly authorized representative of the undersigned, empowered and authorized to execute and deliver this document on behalf of the undersigned and that this document binds the undersigned to the extent that the payment referred to herein is received.

The undersigned represents and warrants that it has paid in full each and every sub-subcontractor, laborer and labor and/or material supplier with whom undersigned has dealt in connection with the Project and the undersigned agrees at its sole cost and expense to defend, indemnify and hold harmless the Contractor against any claims, demands, suits, disputes, damages, costs, expenses (including attorneys' fees), liens and/or claims of lien made by such sub-subcontractors, laborers and labor and/or material suppliers arising out of or in any way related to the Project.

Signed under the penalties of perjury as of this _____ day of _____, 20__.

SUBCONTRACTOR:

Signature and Printed Name of Individual Signing this Lien Waiver

WITNESS:

Name:
Title:

Dated:

CONTRACTOR'S WAIVER OF CLAIMS AGAINST OWNER AND ACKNOWLEDGMENT OF FINAL PAYMENT

Commonwealth of Massachusetts Date: _____

COUNTY OF _____ Invoice No.: _____

OWNER: _____

CONTRACTOR: _____

PROJECT: _____

1.	Original Contract Amount:	$ _____
2.	Approved Change Orders:	$ _____
3.	Adjusted Contract Amount:	$ _____
4.	Sums Paid on Account of Contract Amount:	$ _____
5.	Less Final Payment Due:	$ _____

The undersigned being duly sworn hereby attests that when the Final Payment Due as set forth above is paid in full by Owner, such payment shall constitute payment in full for all labor, materials, equipment and work in place furnished by the undersigned in connection with the aforesaid contract and that no further payment is or will be due to the undersigned.

The undersigned hereby attests that it has satisfied all claims against it for items, including by way of illustration but not by way of limitation, items of: labor, materials, insurance, taxes, union benefits, equipment, etc. employed in the prosecution of the work of said contract, and acknowledges that satisfaction of such claims serves as an inducement for the Owner to release the Final Payment Due.

The undersigned hereby agrees to indemnify and hold harmless the Owner from and against all claims arising in connection with its Contract with respect to claims for the furnishing of labor, materials and equipment by others. Said indemnification and hold harmless shall include the reimbursement of all actual attorney's fees and all costs and expenses of every nature, and shall be to the fullest extent permitted by law.

The undersigned hereby irrevocably waives and releases any and all liens and right of lien on such real property and other property of the Owner for labor or materials, or both labor and materials, or rental equipment, appliances or tools, performed or furnished by the undersigned, and anyone claiming by, through, or under the undersigned, in connection with the Project.

The undersigned hereby releases, remises and discharges the Owner, any agent of the Owner and their respective predecessors, successors, assigns, employees, officers, shareholders, directors, and principals, whether disclosed or undisclosed (collectively "Releasees") from and against any and all claims, losses, damages, actions and causes of action (collectively "Claims") which the undersigned and anyone claiming by, through or under the undersigned has or may have against the Releasees, including, without limitation, any claims arising in connection with the Contract and the work performed thereunder.

Notwithstanding anything to the contrary herein, payment to the undersigned of the Final Payment Due sum as set forth above, shall not constitute a waiver by the Owner of any of its rights under the contract including by way of illustration but not by way of limitation guarantees and/or warranties. Payment will not be made until a signed waiver is returned to Owner.

The undersigned individual represents and warrants that he/she is the duly authorized representative of the undersigned, empowered and authorized to execute and deliver this document on behalf of the undersigned.

Signed under the penalties of perjury as of this ___ day of _____, _____.

_____ Corporation

By: _____
Name: _____
Title: _____
Hereunto duly authorized

COMMONWEALTH OF MASSACHUSETTS

COUNTY OF SUFFOLK

On this ___ day of _____, 20___, before me, the undersigned notary public, personally appeared _____, proved to me through satisfactory evidence of identification, to be the person whose name is signed on the preceding or attached document, and acknowledged to me that he/she signed it as _____ for _____, a corporation/partnership voluntarily for its stated purpose.

_____
NOTARY PUBLIC
My Commission Expires:

EXHIBIT F

FORM OF DECLARATION AFFIXING THE
COMMENCEMENT DATE OF SECOND ADDITIONAL PREMISES

THIS AGREEMENT made this day of_____, 201___, by and between ***[LANDLORD]*** (hereinafter "Landlord") and ***[TENANT]*** (hereinafter "Tenant").

W I T N E S S E T H T H A T:

1. This Agreement is made pursuant to Section ***[__]*** of that certain Second Amendment to Lease dated ***[date]***, between Landlord and Tenant (the "Lease").

2. It is hereby stipulated that the Term of the Lease with respect to the Second Additional Premises commenced on ***[commencement date]***, (being the "Commencement Date" under the Lease), and shall end and expire on ***[expiration date]***, unless sooner terminated or extended, as provided for in the Lease.

WITNESS the execution hereof by persons hereunto duly authorized, the date first above written.

LANDLORD:

WITNESS:

BP BAY COLONY LLC, a Delaware limited liability company

_____

BY: BP BAY COLONY HOLDINGS LLC, a Delaware limited liability company, its sole member

BY: BOSTON PROPERTIES LIMITED PARTNERSHIP, a Delaware limited partnership, its member

BY: BOSTON PROPERTIES, INC., a Delaware Corporation, its general partner

BY: _____
Name:
Title:

TENANT:

WITNESS:

AMAG PHARMACEUTICALS, INC.

_____

By: _____
Name:
Title:

EXHIBIT G

EXPANSION SPACE

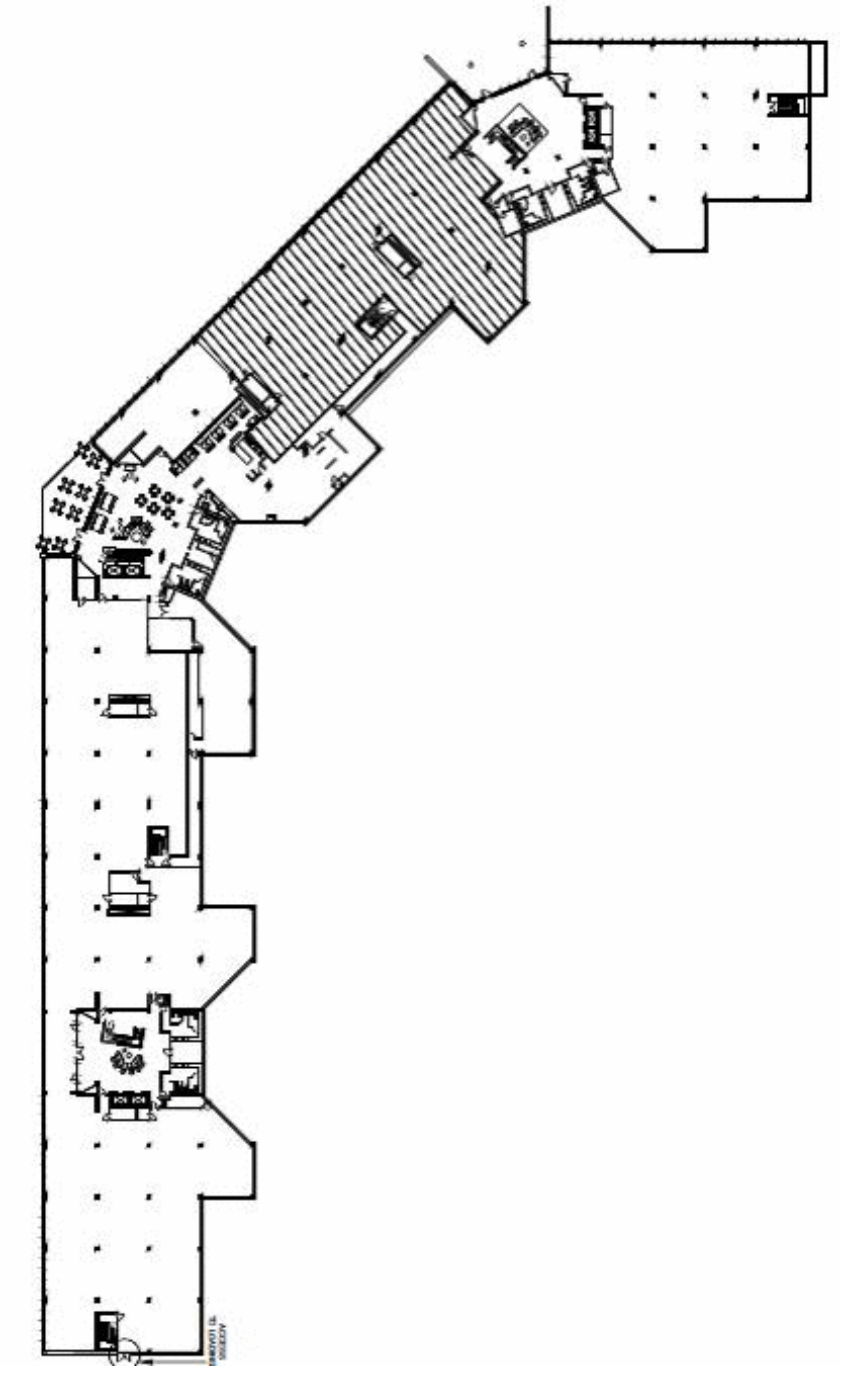


EXHIBIT H

FORM OF LETTER OF CREDIT

[Letterhead of a money center bank acceptable to the Owner]

[Please note the tenant on this Letter of Credit must match the exact tenant entity in the Lease]

[date]

[Landlord]
c/o Boston Properties LP
800 Boylston Street, Suite 1900
Boston, Massachusetts 02199-8103
Attn: Lease Administration, Legal Dept.

Ladies and Gentlemen:

We hereby establish our Irrevocable Letter of Credit and authorize you to draw on us at sight for the account of ***[Tenant]*** ("Applicant"), the aggregate amount of ***[spell out dollar amount]*** and ***[__]***/100 Dollars ***[($)]***. You shall have the right to make partial draws against this Letter of Credit from time to time.

Funds under this Letter of Credit are available to the beneficiary hereof as follows:

Any or all of the sums hereunder may be drawn down at any time and from time to time from and after the date hereof by ***[Landlord]*** ("Beneficiary") when accompanied by this Letter of Credit and a written statement signed by an individual purporting to be an authorized agent of Beneficiary, certifying that such moneys are due and owing to Beneficiary, and a sight draft executed and endorsed by such individual.

This Letter of Credit is transferable in its entirety to any successor in interest to Beneficiary as owner of ***[Property, Address, City/Town, State]***. Should a transfer be desired, such transfer will be subject to the return to us of this advice, together with written instructions. Any fees related to such transfer shall be for the account of the Applicant.

The amount of each draft must be endorsed on the reverse hereof by the negotiating bank. We hereby agree that this Letter of Credit shall be duly honored upon presentation and delivery of the certification specified above.

This Letter of Credit shall expire on ***[Final Expiration Date]***.

Notwithstanding the above expiration date of this Letter of Credit, the term of this Letter of Credit shall be automatically renewed for successive, additional one (1) year periods unless, at least sixty (60) days prior to any such date of expiration, the undersigned shall give written notice to Beneficiary, by certified mail, return receipt requested and at the address set forth above or at such other address as may be given to the undersigned by Beneficiary, that this Letter of Credit will not be renewed.

This Letter of Credit is governed by the Uniform Customs and Practice for Documentary Credits (1993 Revision), International Chamber of Commerce Publication 500.

Very truly yours,

[Name of Issuing Bank]

By: _____
Name: _____
Title: _____

Exhibit 10.36

[***] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

AMENDMENT NO. 3

This Amendment No. 3 ("Amendment"), effective as of August 24, 2015 (the "Effective Date"), entered into by and between (i) AMAG Pharmaceuticals, Inc. ("AMAG" or the "Company") and (ii) Sigma-Aldrich, Inc. ("SAFC"), amends that certain Commercial Supply Agreement between AMAG and SAFC dated August 29, 2012 (the "Commercial Supply Agreement"), as amended October 3, 2013 ("Amendment No. 1") and as amended March 31, 2015 ("Amendment No. 2"), and collectively with the Commercial Supply Agreement, the ("Agreement"). Capitalized terms used but not defined in this Amendment will have the meanings given them in the Agreement.

BACKGROUND

SAFC and AMAG desire to amend the Agreement as set forth in this Amendment.

Now, therefore, in consideration of the premises and the mutual covenants and agreements contained herein, the Parties hereby agree as follows:

AMENDMENTS

1. The second sentence of Section 12.21(b) of the Commercial Supply Agreement, which was added pursuant to Amendment No. 1, and which begins with the words "If the N-1 Plant is not approved..." shall be deleted and restated as:

   If the N-1 Plant is not online and approved by AMAG, such approval not to be unreasonably withheld, by [***], then SAFC shall promptly provide a credit to AMAG of [***]."

Accept as provided herein, all other terms and conditions of the Agreement shall remain in full force and effect unamended.

[Remainder of this page is intentionally left blank]

SIGNATURE PAGE TO AMENDMENT NO. 3

In Witness Whereof, the Parties by their authorized representatives have executed this Amendment as of the Effective Date.

AMAG PHARMACEUTICALS, INC.	**Sigma-Aldrich, Inc.**
By: /s/ Frank E. Thomas	By: /s/ Gilles Cottier
Name: Frank E. Thomas	Name: Gilles Cottier
Title: Chief Operating Officer	Title: Vice President
Date: October 19, 2015	

Exhibit 10.42

[***] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

ANTARES PHARMA, INC.

AND

LUMARA HEALTH INC.

DEVELOPMENT AND LICENSE AGREEMENT

SEPTEMBER 30, 2014

DEVELOPMENT AND LICENSE AGREEMENT

This Development and License Agreement ("Agreement") is made and entered into as of the 30th day of September, 2014 (the "Effective Date") by and between Antares Pharma, Inc., a Delaware corporation, with offices located at 100 Princeton South, Suite 300, Ewing, NJ 08628 ("Antares"), and Lumara Health Inc., a Delaware corporation, with a corporate address at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, MO 63005 ("Lumara"). Antares and Lumara are sometimes referred to herein individually as a "Party" and collectively as the "Parties", and references to "Antares" and "Lumara" shall include their respective Affiliates.

Recitals

WHEREAS, Lumara is engaged in discovering, developing and marketing pharmaceutical products, including 17-alpha hydroxyprogesterone caproate ("HPC").

WHEREAS, Antares is engaged in the research and development of certain drug delivery devices, including auto-injection systems and the development and marketing of pharmaceutical products.

WHEREAS, Lumara desires to obtain, and Antares desires to grant to Lumara, an exclusive, worldwide license to Antares' [***] auto-injection system or similar device for use with HPC in the Field (as defined below) upon the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants and promises contained in this Agreement, the Parties hereto agree as follows:

ARTICLE 1

DEFINITIONS

As used herein, the following terms shall have the following meanings assigned to them in this Article and shall include the plural as well as the singular:

1.1 "**Adverse Event**" means any untoward medical occurrence associated with the use of the Product (whether or not Product Approval has been achieved) in humans or subjects, without regard to a causal relationship between Drug, Device and the event as set forth in 21 CFR 312 & 314, as amended from time to time.

1.2 "**Adverse Event Report**" means any oral, written or electronically transmitted report of any Adverse Event.

1.3 "**Affiliate**" means any Person that directly (or indirectly through one or more intermediaries) controls, is controlled by, or is under common control with a Party. For purposes of this definition only, the terms "controls," "controlled," and "control" means (i) the direct or indirect ability or power to direct or cause the direction of the management and policies of an entity or otherwise direct the affairs of such entity, whether through ownership of equity, voting securities, beneficial interest, by contract, or otherwise, or (ii) the ownership, directly or indirectly, of at least 50% of the voting securities (or other comparable ownership interest for an entity other than a corporation) of a Party.

1.4 "**Antares Device Development**" means the conduct of all activities by Antares or Lumara on their behalf consistent with the Device Development Plan that are reasonably required to complete development of the Device for the use of the Product in the Field, including: (i) regulatory affairs, pre-clinical studies and clinical trials in accordance with the cGLPs, cGCPs and cQSRs or other designated quality standards and Applicable Laws; (ii) all activities relating to developing the ability to manufacture Devices, including, without limitation, tooling development and delivery technologies related to Devices and components thereof, industrial and mechanical design, and manufacturing and quality assurance technical support until such time as manufacturing of Devices intended for commercial sale of Product commences and, thereafter, to the extent required under Applicable Law for continued commercial sale of Product; and usability studies as agreed to by the Parties.

1.5 "**Antares Device Development Payments**" means those payments made by Lumara to Antares, with respect to Antares Device Development as set forth in the Device Development Plan.

1.6 "**Antares' Fully Burdened Manufacturing Costs**" means those costs actually incurred by Antares related directly to the acquisition of materials and their conversion into salable Devices or Products, as the case may be. [***].

1.7 "**Antares Indemnities**" shall have the meaning set forth in Section 16.2 hereof.

1.8 "**Antares Know-How**" means all Information that is owned or Controlled by Antares as of the Effective Date or at any time during the term of this Agreement, and that is useful, necessary, or required for, or related to, the development, manufacture, use, commercialization or exploitation of [***], the Device and/or Product, or to otherwise proceed with the undertakings envisioned by this Agreement. Antares Know-How does not include Antares Patent Rights.

1.9 "**Antares Patent Rights**" means all Patent Rights in the Territory that are owned, including jointly owned, or Controlled by Antares as of the Effective Date or at any time during the term of this Agreement that Cover [***], the Device and/or Product, or that otherwise Cover a method, apparatus, composition or process that is useful, necessary, or required for, or related to, the development, manufacture, use, commercialization or exploitation of [***], the Device and/or Product including improvements and next generations thereof, or to otherwise proceed with the undertakings envisioned by this Agreement, including without limitation the Patent Rights associated with the patents and patent applications identified in **Exhibit B**, and including any Patent Rights within the Program Intellectual Property owned solely or jointly by Antares

hereunder. Antares Patent Rights do not include Antares Know-How.

1.10 "**Antares Sole Invention**" shall have the meaning set forth in Section 12.l(b) hereof.

1.11 "**Antares Trademarks**" means all trademarks, service marks, trade dress, trade names, and Internet domain names (together with the goodwill of the business symbolized by the foregoing), including all registrations and registration applications throughout the Territory that are owned or Controlled by Antares as of the Effective Date or at any time during the term of this Agreement, and that are useful, necessary, or required for, or related to, the development, manufacture, use, commercialization or exploitation, including any packaging, promotional materials, package inserts and labeling, of the Device and/or Product, or to otherwise proceed with the undertakings envisioned by this

Agreement, including without limitation, [***] and such other trademarks identified in **Exhibit C**.

1.12 "**Applicable Laws**" means all applicable statutes, ordinances, regulations, rules and orders of any kind whatsoever of any Governmental Authority, including, without limitation, the Anti-kickback Statute (42 U.S.C. § 1320a-7b, *et. seq.),* Prescription Drug Marketing Act, Generic Drug Enforcement Act of 1992 (21 U.S.C. § 3359, *et. seq.),* the Federal Food Drug and Cosmetics Act, Resource Conservation and Recovery Act, Clean Water Act, Clean Air Act, the Drug Enforcement Act, Occupational Safety and Health Act, cGMP, cGCP, cGLP, cQSR and any comparable laws of any foreign jurisdiction, all as amended from time to time.

1.13 "**cGCP**" means the then current Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials promulgated or endorsed by the U.S. Food and Drug Administration ("FDA") (or in the case of foreign jurisdictions, comparable regulatory standards), including those regulations or guidelines expressed or implied in the regulatory filings made with respect to [***], the Device or Product with the FDA or foreign regulatory agents.

1.14 "**cGLP**" means the then current Good Laboratory Practices promulgated or endorsed by the FDA (or in the case of foreign jurisdictions, comparable regulatory standards), including those procedures expressed or implied in the regulatory filings made with respect to [***], the Device or Product with the FDA or foreign regulatory agents.

1.15 "**cGMP**" means current Good Manufacturing Practices as defined in the U.S. regulations 21 CFR § 210 *et. seq.,* and the European Economic Community Guide to Good Manufacturing Practices for Medicinal Products (Vol. IV Rules Governing Medicinal Products in the European Community 1992), and foreign equivalents.

1.16 "**cQSRs**" means current Quality System Regulations as defined in the U.S. Code of Federal Regulations, 21 CFR Part 820 and, in the case of foreign jurisdictions, comparable regulatory standards.

1.17 "**Calendar Quarter**" means a three-month period ending on March 31, June 30, September 30, or December 31.

1.18 "**Calendar Year**" means the twelve-month period ending on December 31.

1.19 "**Commercially Reasonable Efforts**" means such efforts that are consistent with the efforts and resources normally used by similarly situated companies in the same industry as Lumara in the exercise of its reasonable business discretion relating to the research, development and commercial progression of a potential pharmaceutical product owned by it or to which it has exclusive rights, with similar product characteristics as the Product, which is of similar market potential at a similar stage in its development or product life as the Product, taking into account issues of scientific risk, patent coverage, safety and efficacy, product profile, competitiveness of the marketplace, proprietary

position, the regulatory structure involved and profitability (including pricing and reimbursement status achieved or likely to be achieved) and other relevant factors, including without limitation, technical, legal, scientific and/or medical factors. Without limiting the foregoing, Commercially Reasonable Efforts will include, inter alia, Lumara's: (i) prompt assignment of responsibility for such obligation to specific employee(s) who are held accountable for progress and monitor such progress on an on-going basis, (ii) setting annual objectives for carrying out such obligations, and (iii) allocating resources designed to advance progress with respect to such objectives, provided that the occurrence of any or all of the foregoing events shall not be required to establish use of Commercially Reasonable Efforts.

1.20 **"Confidential Information"** shall have the meaning set forth in Section 17.1 of this Agreement.

1.21 **"Controlled"** means the ability to grant a license or sublicense as provided for herein without violating the terms of any agreement or other arrangement with any Third Person.

1.22 **"Cover"** (including variations thereof such as "Covering", "Covered", and "Coverage") means that the development, manufacture, use, import, export, offer for sale or sale of the item(s) referred to would but for the licenses granted hereunder, infringe a Valid Claim.

1.23 **"Damages"** shall have the meaning set forth in Section 16.2 hereof.

1.24 **"Device"** means the [***] auto-injection system device, designed and developed to incorporate a Prefilled Syringe for delivery of the Drug and any improvements or modifications thereof made pursuant to this Agreement, or such other Antares-proprietary device as agreed to by Antares designed and developed to deliver the Drug pursuant to this Agreement.

1.25 **"Device Development Plan**" shall have the meaning set forth in Section 2.2 of this Agreement, an initial draft of which is attached hereto as **Exhibit D**.

1.26 **"DHF"** means the Design History File that Antares will establish and maintain for Devices inside and outside the Field that will contain or reference all records and submissions necessary to demonstrate that the design was developed in accordance with the approved Device Development Plan.

1.27 **"Discontinuance Election"** shall have the meaning set forth in Section 12.4 hereof.

1.28 **"DMF"** means a Device Master File, or other similar terminology, such as the term is defined in 21 C.F.R. 814.3(d) and is consistent with FDA Pre-Market Approval Manual (HHS Publication FDA 97-4212, January 1998), or comparable filings accepted by any Regulatory Authority in a country or jurisdiction outside the U.S. The DMF shall include, without limitation, the specifications for quality testing, design verification,

process validation and release of Devices, in addition to any other information necessary for development, manufacture and release of Devices.

1.29 **"Drug"** means 17-alpha hydroxyprogesterone caproate.

1.30 **"Effective Date"** shall have the meaning set forth in the first paragraph of this Agreement.

1.31 **"FDA"** means the U.S. Food and Drug Administration, or any successor federal agency, having responsibility over Regulatory Approval in the U.S.

1.32 **"FD&C Act"** means the U.S. Food, Drug and Cosmetic Act (21 U.S.C. §301 *et. seq.),* as amended from time to time, together with any rules and regulations promulgated thereunder. FD&C Act shall also be deemed to include the Applicable Laws pertaining to the Product in any particular country or region in the Territory.

1.33 **"Field"** means all uses of the Drug in humans or animals.

1.34 **"Governmental Authority"** means any court tribunal, arbitrator, agency, commission, official or other instrumentality of any federal, state, or other political subdivision, or supranational body, domestic or foreign.

1.35 **"IND"** means an Investigational New Drug application (together with all additions, deletions, and supplements thereto) filed with the FDA or any equivalents of such items in countries within the Territory outside the U.S.

1.36 **"Information"** means any and all information, data, items, material and knowledge in the Field or otherwise related to drug delivery including, without limitation, any and all suggestions, descriptions, ideas, inventions (whether or not patentable), know-how, trade secrets, techniques, strategies, methods, syntheses, processes, practices, skills, experience, documents, apparatus, devices, chemical formulations, compounds, composition of matter, chemical samples, assays, screens, databases, database structures and data analysis methods in the Field or otherwise related to drug delivery.

1.37 **"Infringed Licensed Technology"** shall have the meaning set forth in Section 15.1 hereof.

1.38 **"Intellectual Property Rights"** means all intellectual property rights, including, without limitation all Patent Rights, copyrights, trademarks, trade secret rights and know-how rights.

1.39 **"Joint Project Team"** shall have the meaning set forth in Section 3.1 hereof.

1.40 **"Joint Invention"** shall have the meaning set forth in Section 12.l(c) hereof.

1.41 "**Licensed Technology**" means Antares Patent Rights, Antares Trademarks and Antares Know-How.

1.42 "**Lumara Indemnities**" shall have the meaning set forth in Section 16.3, hereof.

1.43 "**Lumara Sole Invention**" shall have the meaning set forth in Section 12.l(a) hereof.

1.44 "**Lumara Trademarks**" means all trademarks, service marks, trade dress, trade names, and Internet domain names (together with the goodwill of the business symbolized by the foregoing), including all registrations and registration applications throughout the Territory that are owned or Controlled by Lumara as of the Effective Date or at any time during the term of this Agreement, and that are useful, necessary, or required for, or related to, the development, manufacture, use, commercialization or exploitation, including any packaging, promotional materials, package inserts and labeling, of the Product, or to otherwise proceed with the undertakings envisioned by this Agreement, including without limitation, Makena® and such other trademarks identified in **Exhibit E**.

1.45 "**Manufacturing Agreement**" shall have the meaning set forth in Section 10.1 of this Agreement.

1.46 "**Net Sales**" shall mean, with respect to a Product, the gross amount invoiced by Lumara, its Affiliates or any sublicensee thereof to Third Persons or the sale of the Product in the Territory, less:

(a) Trade, quantity and cash discounts allowed;

(b) Refunds, rebates, chargebacks, retroactive price adjustments, recalls, bad debt, price protection and shelf stock adjustments, and any other allowances or credits which effectively reduce the net selling price, all in accordance with U.S. GAAP;

(c) Actual Product returns and allowances;

(d) Any tax imposed on the production, sale, delivery or use of the Product, including, without limitation, sales, use, excise or value added taxes, with the exception of income taxes;

(e) Payments required by Applicable Law to be made under Medicaid, Medicare or other government special medical assistance programs, annual assessed FDA user fees (including establishment fees for facilities and product fees for the NDA) and similar fees assessed by Regulatory Authorities in other jurisdictions amortized on a Calendar Quarter basis;

(f) Freight, postage, shipping and insurance, handling and other transportation costs actually incurred by Lumara; and

(g) Any other similar and customary deductions which are properly recorded as a reduction of Net Sales under U.S. GAAP consistently applied.

Such amounts shall be determined from the books and records of Lumara or its sublicensee, maintained in accordance with U.S. GAAP or, in the case of sublicensees, such similar accounting principles, consistently applied. Lumara further agrees that in determining such amounts, it will use Lumara's then current standard procedures and methodology, including Lumara's then current standard exchange rate methodology for the translation of foreign currency sales into U.S. dollars or, in the case of sublicensees, such similar methodology, consistently applied.

1.47 **"NDA"** means (a) the single application or set of applications (together with all additions, deletions, and supplements (sNDA) thereto) for Products and/or pre-market approval to make and sell commercially both a formulation of Drug and a compatible commercial Device to be marketed as the Product, filed by Lumara with the appropriate Regulatory Authority within the Territory, and (b) any related registrations with or notifications to the appropriate Regulatory Authority within the Territory.

1.48 **"Orange Book"** means the *Approved Drug Products with Therapeutic Equivalence Evaluations* published and periodically updated by the FDA, including any successor publication or foreign equivalent.

1.49 **"Patent Right(s)"** means (a) patents and patent applications (including provisional applications and applications for certificates of invention); (b) any patents issuing from such patent applications (including certificates of invention); (c) all patents and patent applications claiming the priority date(s) of any of the foregoing; (d) any reissues, substitutions, confirmations, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, continuations-in-part, or divisions of or to any of the foregoing and any patents issuing thereon; (e) term extensions, supplementary protection certificates and other governmental action which provide exclusive rights to a product beyond the original patent expiration date; and (f) all foreign equivalent of any of the foregoing (a)-(e) throughout the world.

1.50 **"Permitted Person"** shall have the meaning set forth in Section 17.2 hereof.

1.51 **"Person"** means a natural person, a corporation, a partnership, a trust, a joint venture, a limited liability company, any Governmental Authority or any other entity or organization.

1.52 **"Prefilled Syringe"** means the prefilled syringe containing the formulated Drug for incorporation into the Device.

1.53 **"Pricing Approval"** means such approval, agreement, determination or governmental decision establishing prices for Product that can be charged to consumers

and/or will be reimbursed by Governmental Authorities in countries in the Territory where Governmental Authorities or Regulatory Authorities of such country approve or determine pricing for pharmaceutical products for reimbursement or otherwise.

1.54 **"Product"** means the fully packaged Device for auto-injection delivery of the Drug incorporating a Prefilled Syringe.

1.55 **"Product Development Program"** means the program of development activities for Antares Device Development set forth in or otherwise contemplated by the Device Development Plan (as amended from time to time) as more fully described in Article 2 of this Agreement.

1.56 **"Product Launch"** means the first commercial sale of a Product by Lumara or its sublicensees in the country at issue following Regulatory Approval and Pricing Approval for such Product in such country.

1.57 **"Program Intellectual Property"** shall have the meaning set forth in Section 12.1 hereof.

1.58 **"Quality Agreement" or "QA"** means the document between the Parties to be entered into pursuant to section 10.3(b) hereof which describes certain quality expectations and responsibilities relating to the development, manufacture, release testing and supply of the Devices and assembly and packaging of the Product and provides Lumara the right to perform quality audits of Antares consistent with the terms of the QA.

1.59 **"Recipient"** shall have the meaning set forth in Section 17.1 hereof.

1.60 **"Regulatory Approval"** means (a) in the U.S., approval by the FDA of any one or more of the following, an NDA, sNDA, 510K or similar application for marketing approval, and satisfaction of any related applicable FDA registration and notification requirements (if any), together with any other approval necessary to make and sell Products commercially in the U.S.; and (b) in any country other than the U.S., approval by Regulatory Authorities having jurisdiction over such country of a single application or set of applications comparable to an NDA or similar application for marketing approval and satisfaction of any related applicable regulatory and notification requirements, if any, together with any other approval necessary to make and sell Products commercially in such country, and the grant of Pricing Approval.

1.61 **"Regulatory Authority"** means, in a particular country or jurisdiction, any applicable government regulatory authority involved in granting Regulatory Approval and/or, to the extent required in such country or jurisdiction, Pricing Approval of Product in such country or jurisdiction, including, without limitation, (a) in the U.S., the FDA, and any other applicable Governmental Authority or Regulatory Authority in the U.S. having jurisdiction over the Product, and any successor Governmental Authority having substantially the same function, and (b) any foreign equivalent thereof and any successor Governmental Authority having substantially the same function.

1.62 "**Regulatory Material**" means regulatory correspondence, submissions, notifications, registrations, approvals and/or other filings, to the extent such material is generated under the terms of this Agreement and is solely related to the Field, made to or with a Regulatory Authority that may be necessary to develop, manufacture, market, sell or otherwise commercialize Product, including, without limitation, clinical trial data, toxicology studies, IND, NDA, 51OK, clinical trial exemption, Pricing Approvals, and any other foreign equivalents.

1.63 "**Royalty Period**" means [***].

1.64 "**Safety Information Document**" shall have the meaning set forth in Section 4.3 hereof.

1.65 "**Serious Adverse Event**" means any Adverse Event with the following conditions: death, life-threatening, hospitalization, persistent or significant disability, congenital anomaly/birth defect, any other serious event requiring medical intervention, or as "Serious Adverse Event" is otherwise defined by other Regulatory Authority or the FDA in 21 CFR 312 & 314 as amended from time to time.

1.66 "**Serious Adverse Event Report**" means any oral, written or electronically transmitted report of any Serious Adverse Event.

1.67 "**Territory**" means the entire world.

1.68 "**Third Person**" means any Person or entity other than Lumara, Antares, or an Affiliate or sublicensee of either of them.

1.69 "**Third Person Claim**" shall have the meaning set forth in Section 16.2 hereof.

1.70 "**Third Person Rights**" shall have the meaning set forth in Section 8.2 hereof.

1.71 "**United States**" or "**U.S.**" means the United States of America, including its territories and possessions.

1.72 "**U.S. Regulatory Approval**" means the first date on which Lumara shall have received Regulatory Approval for a Product in the U.S.

1.73 "**U.S. Regulatory Submission**" means the first submission and acceptance for filing by a Regulatory Authority of all Regulatory Materials necessary for the manufacture, market and sale of Product in the U.S.

1.74 **"Valid Claim"** means any claim in any issued, unexpired patent which has not been held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction following exhaustion of all possible appeal processes, and which has not been admitted to be invalid or unenforceable through reissue, reexamination or disclaimer.

1.75 "[***]" auto injector system, including the specific Device described in **Exhibit F,** [***].

ARTICLE 2

PRODUCT DEVELOPMENT PROGRAM

2.1 Purpose and Scope of Development. In accordance with, and subject to, the terms described herein, the Parties agree to collaborate in the research and development of the Device for the ultimate purposes of manufacturing and commercializing the Product in the Field in the Territory ("Product Development Program").

2.2 **Preparation of Device Development Plan.** In the event Lumara, in its sole discretion, within thirty (30) days after completion of a meeting between Lumara and the FDA regarding Product development decides to continue development of the Product, Antares shall develop and prepare for Lumara's review and acceptance if satisfactory, an update to the Device Development Plan set forth on Exhibit D, which shall include Antares' budgeted costs and project timelines for work to be performed on Antares Device Development and development of the Product by the Parties and paid for by Lumara in milestone-based payment amounts set forth therein as more specifically described in Section 2.4. The Parties may from time to time by mutual agreement amend the Device Development Plan or create additional Device Development Plans to provide for the development of additional Devices and Products.

2.3 **Responsibilities of the Parties .**

(a) General. Each Party shall have responsibility for development activities as set forth in the Device Development Plan.

(b) Lumara's Responsibilities. Lumara shall be responsible for overseeing the overall Product Development Program, undertaking clinical development of the Product through Regulatory Approval, and commercializing the Product, including:

(i) Undertaking clinical development for the Device and Product in accordance with the Device Development Plan;

(ii) Addressing all clinical and development issues that arise during the course of the Product Development Program

(iii) Undertaking regulatory filings for the Product or Drug, including payment of any applicable fees and promptly notifying Antares of correspondence and filings with Regulatory Authorities and providing copies of annual reports related to the Device filed with the Regulatory Authorities within forty-five (45) days after submission, and obtaining marketing approval for the Product in the Territory;

(iv) Providing a preservative-free formulation of formulated Drug in a bulk packaging configuration to be used for Prefilled Syringe filling and finishing;

(v) Providing formulated Drug product into a Prefilled Syringe for assembly with the Device into each Product;

(vi) Investigating and handling of all Product complaints, including filing Adverse Drug Experience ("ADE") reports with the FDA, or foreign equivalent report with the appropriate Regulatory Authority;

(vii) Receiving Product at a destination chosen by Lumara for final Product release and distribution;

(viii) Providing Antares with general, non-proprietary project support from working knowledge of the Drug; and

(ix) Providing distribution, inventory management, sales, promotion and commercialization of the Product.

(c) Antares' Responsibilities. Antares shall be responsible for developing the Device in accordance with the Device Development Plan, for supporting Lumara's development of the Product under the Product Development Program, and for supporting Lumara's commercialization of the Products, including

(i) Developing and supplying the Device in accordance with the agreed to specifications for clinical requirements;

(ii) Providing reasonable support to Lumara's lead on all clinical development, issue resolution and program oversight;

(iii) [***];

(iv) Providing clinical supply of the Devices and Products to Lumara as needed for clinical development;

(v) Providing commercial supply of the fully manufactured and packaged Product to Lumara's chosen destination for final release and distribution by Lumara;

(vi) Providing Lumara general, non-proprietary project support from working knowledge of the Device and prefilled syringe assembly;

(vii) Promptly passing along to Lumara any Product complaints received by Antares and providing reasonable support to Lumara's lead in investigating and handling all Product complaints; and

(viii) Providing appropriate support to Lumara's lead in obtaining Regulatory Approval (including, sNDA approval).

ARTICLE 3

GOVERNANCE AND ADMINISTRATIVE MATTERS

3.1 **Joint Project Team**. No later than forty-five (45) days after the Effective Date, the Parties shall form a Joint Project Team for the Product Development Program. The Joint Project Team shall be responsible for overall direction and management of the Product Development Program. The operation and authority of the Joint Project Team shall be as follows:

(a) Responsibilities. The primary objectives of the Joint Project Team shall include the preparation, modification (if appropriate) and implementation of one or more development plans to address fully, consistent with the terms of this Agreement, the key registration and supply elements reasonably necessary for the research, development, manufacture, and clinical testing registration activities related to Antares Device development and the Device, and any formulation of the Drug specifically developed for use with a Device and Product, (each a "Device Development Plan"). The Joint Project Team shall from time to time review and, if appropriate, recommend revisions to the Device Development Plan. The Joint Project Team also shall monitor the progress of the Product Development Program and periodically review the results of the Product Development Program and make recommendations as appropriate. In addition, no later than one hundred eighty (180) days after the Effective Date, the Joint Project Team shall prepare and adopt the Safety Information Document.

(b) Representation. Each Party shall appoint three (3) representatives, or such other number of representatives as agreed to by the Parties, to serve on the Joint Project Team. The representatives of a Party may be changed from time to time at the discretion of each Party upon written notification by the Party making such change to the other.

(c) Meetings. The Joint Project Team shall meet from time to time as determined by the Joint Project Team members, with the Parties alternating hosting the meeting. It is expected that the Joint Project Team shall meet at least four (4) times per
Calendar Year or as otherwise agreed by the Joint Project Team members. Such meetings
may be in person, via videoconference or via telephone conference at such times and places as are agreeable to the members of the Joint Project Team. Consultants and non-member
employees of the Parties may attend meetings of the Joint Project Team as required to

further the Product Development Program. Minutes of all such meetings setting forth decisions of the Joint Project Team relative to the Product Development Program will be prepared by the Party hosting the meeting and distributed within fifteen (15) business days after the meeting. Such minutes will become official when agreed to by all members of the Joint Project Team no later than fifteen (15) business days after published. Each Party will bear all expenses associated with attendance of its employees and consultants at such meetings.

(d) Decisions. Decisions of the Joint Project Team shall be made by unanimous vote, with each Party having one vote regardless of its number of representatives on the Joint Project Team. If the Joint Project Team is unable to resolve any issue or dispute, then the issue shall be resolved pursuant to Section 20.2 [***].

3.2 **Quarterly Status Report**. During the Product Development Program, each Party shall provide the Joint Project Team with a quarterly status report no later than 15 days after the end of each calendar quarter that generally summarizes research and development efforts conducted by such Party under the Product Development Program during such Calendar Quarter at issue. Such report shall include, without limitation, a general summary of important events and/or milestones achieved, personnel changes, learning points and other matters that the Joint Project Team may deem appropriate.

3.3 **Subcontracting Permitted**. The Parties acknowledge and agree that portions of the work involved in the Product Development Program may be performed on behalf of the Party responsible for such work thereunder by Third Persons provided that the Joint Project Team shall have previously approved using such Third Person.

3.4 **Meeting Expenses**. Each Party will be responsible for its expenses associated with the attendance of its employees and consultants at meetings related to the activities contemplated by this Agreement.

ARTICLE 4

REGULATORY

4.1 **Regulatory Filings**. As of the Effective Date, and pursuant to the terms of this Agreement, Lumara will assume responsibility for all regulatory filings related to the Product, and shall timely file applicable patents to the Orange Book. Antares shall be responsible for preparing, filing and maintaining the Regulatory Material relating to the Device in support of Lumara's regulatory filings. As between the Parties, Lumara shall own all Regulatory Material relating to the Drug and Product in the Field and any future
Drugs or Products in the Field (including but not limited to variants of existing Drug or

Product) developed under the terms of this Agreement, and Antares shall own all Regulatory Material relating to the Device and any future Devices developed under the terms of this Agreement and Lumara shall retain a right to reference such Regulatory Materials during the term of this Agreement and thereafter as necessary to comply with Applicable Laws to maintain Product registration, as otherwise required by any Regulatory Authority, or as otherwise reasonably required by Lumara related to the activities conducted under this Agreement including the development, manufacture, use, sale, offer for sale, import or export of Products conducted under this Agreement.

(a) Preparation, Maintenance and Ownership. Lumara, or its sublicensees, shall be responsible for the preparation of any Regulatory Materials, including regulatory filings and/or suitable applications required in order to conduct clinical trials and achieve Regulatory Approval (including, without limitation, achievement of marketing approval) for the Product and shall be the owner and party of record for all such Regulatory Materials to the extent permitted by Applicable Laws. [***]. Lumara, or its sublicensees, shall further be responsible for managing all interactions regarding such Regulatory Materials with all Regulatory Authorities in the Territory. Antares shall cooperate with Lumara as Lumara reasonably requires in preparing such Regulatory Materials or in managing such interactions with Regulatory Authorities. Lumara, or its sublicensees, shall determine in its discretion those countries of the Territory where marketing is intended.

(b) Access to Device Files. With respect to any DMFs and DHFs of Antares related to the Device inside the Field, and outside the Field to the extent applicable to the Field, for so long as the licenses granted to Lumara hereunder remain in full force and effect, Antares hereby grants to Lumara access to, and a right of reference to, such DMFs and DHFs. For the avoidance of doubt, Lumara's right to access such DMFs and DHFs shall include Lumara's right to incorporate Information otherwise contained in Antares' DMFs and DHFs into any Lumara regulatory submission or Regulatory Material submitted to a Regulatory Authority in the Territory pursuant to the terms of this Agreement.

4.2 **Quality Assurance Audit.** Lumara, at its own expense, shall have the right to conduct quality assurance audits with respect to all facilities, operations, and laboratories where work under this Agreement is conducted by Antares, or on its behalf by subcontractors, (including, without limitation, work conducted by Antares related to the Device Development Plan) and to verify Antares' conformance with applicable cGMP, cGLP, cGCP, cQSRs and other regulatory requirements including, without limitation, verifying appropriate inventory control and material accountability systems with respect to the Device, Prefilled Syringes and Products. Such audits shall only be conducted upon reasonable notice during business hours. [***].

4.3 **Adverse Event Reporting**. During the Product Development Program, and until and after Regulatory Approval of the Product and, and until and after Product Launch, Lumara will report Adverse Events and Serious Adverse Events which occur during the development of Product to Antares and the relevant Regulatory Authorities promptly according to the applicable regulations. Antares will cooperate and provide Lumara with all information and assistance necessary or desirable for Lumara to carry out and comply with any regulatory requirements of such Regulatory Authorities. In addition, Antares will report to Lumara Adverse Events and Serious Adverse Events which occur during the development of the Device and Product and, after Product Launch, Antares will report to Lumara Serious Adverse Events and spontaneously reported Adverse Events of which it becomes aware and has the right to disclose, as such events relate to the use of Devices for other products, within two (2) working days of Antares' initial receipt of such information, in order that Lumara can fulfill its obligations to the appropriate regulatory authorities. Finally, Antares will supply specially formatted safety information to Lumara upon request, with reasonable notice, in order that Lumara can comply with FDA requirements for annual reports and safety updates. The specific details concerning the type of safety information, the appropriate format for such safety information, and the process for exchange of such information will be developed by the Joint Project Committee consistent with the requirements of the then current Lumara adverse reporting policies and consistent with those policies of the relevant Regulatory Authority ("Safety Information Document").

4.4 **Product Complaints**. Antares shall refer any complaints (including medical complaints) which it receives concerning the Device or the Product to Lumara within thirty-six (36) hours of Antares' receipt of such complaint; provided that all complaints concerning actual Product tampering, contamination or mix-up (e.g., wrong ingredients) shall be delivered within twenty-four (24) hours of Antares' receipt thereof. Antares shall not take any further action in connection with any such complaints without the consent of Lumara, but shall cooperate in the investigation and closure within [***] of any such complaints at the request of Lumara.

4.5 **Regulatory Inspections**. Antares shall promptly advise Lumara of any notice of regulatory inspection or other regulatory action related to this Agreement or any Device or Product and shall permit Lumara to be present during any inspection and to participate in the preparation of any response thereto.

ARTICLE 5

LICENSE

5.1 **Exclusive License to Lumara**. Antares hereby grants to Lumara a sole and exclusive, royalty-bearing license in the Territory, with the right to sublicense, subject to Antares' prior written consent which consent shall not be unreasonably withheld or delayed, through one or more levels of sublicensees, under the Licensed Technology (subject to Section 12.6) and Antares' interest in Program Intellectual Property to develop,

use, sell, offer for sale and import and export Products and Devices for use in Products in the Field. [***]. Without limiting the generality of the foregoing license grant, Lumara acknowledges that the foregoing license grant does not grant Lumara the right under the Licensed Technology to sell, offer for sale, import or export any product that delivers the Drug other than a Product developed by the Parties under the Product Development Program pursuant to this Agreement without Antares' prior written consent. For avoidance of doubt, nothing herein shall prevent Lumara from developing, selling, offering for sale, importing or exporting any product that delivers the Drug and that does not require a license to Licensed Technology. Further notwithstanding the foregoing exclusive license grant to Lumara, Antares shall retain during the Product Development Program nonexclusive rights to Licensed Technology described in this Section 5.1 but only to the extent useful or necessary to fulfill its obligations under the Product Development Program or other obligations hereunder.

5.2 **Assistance.** Each Party shall promptly provide the other with all Information included in Licensed Technology, in the case of Antares, or in Intellectual Property Rights owned or controlled by Lumara, in the case of Lumara, that is, in each case, reasonably useful or necessary for the other Party to exploit the licenses granted in this Agreement or to perform such Party's obligations. Moreover, each Party shall provide the other with reasonable technical assistance in connection with such disclosure of Information.

5.3 **Right to Intellectual Property.** The Parties agree that all rights and licenses granted under or pursuant to Article 5 and Article 12 of this Agreement are, [***].

5.4 **License to Antares.** Subject to the terms and conditions of this Agreement, Lumara hereby grants to Antares during the term of this Agreement a non-exclusive, royalty-free license in the Field in the Territory under Intellectual Property Rights owned or controlled by Lumara and Lumara's interest in Program Intellectual Property to use, export and import the Drug solely for the purposes of fulfilling its obligations under this Agreement.

ARTICLE 6

EXCLUSIVITY

6.1 **Exclusivity Restrictions**. [***].

6.2 **No Restriction on Lumara**. Notwithstanding anything contained within this Agreement, Lumara shall not be restricted or limited in any way by this Agreement (except with respect to a Product) with respect to its right to develop, seek regulatory approval for, manufacture, sell, distribute, license, import, export or otherwise commercialize the Drug or any product containing, or delivering the Drug in the Territory.

ARTICLE 7

COMMERCIAL RIGHTS

7.1 **Marketing and Commercialization**. Subject to the terms described in this Agreement, Lumara shall have the sole and exclusive right, at its own expense, to obtain Regulatory Approval, and to market, sell, promote, distribute and otherwise commercialize Products in the Field, including, without limitation, preparation of promotional materials, direct-to-consumer advertising, samples, and sales representatives, in each country in the Territory that Lumara elects to market the Product as Lumara may deem appropriate. Lumara shall control the marketing plans for Product in the Field, and the packaging materials for the Product which, unless Lumara determines otherwise, shall be sold solely under Lumara's trademarks, trade dress and logos, with the exception of trademarks, trade dress and logo applied to the Devices, which shall be the sole responsibility of Antares. Lumara agrees to use Commercially Reasonable Efforts to effect a Product Launch of the first Product in the U.S. within 90 days of receiving final Regulatory Approval in the U.S. for such Product provided that Lumara shall not be required to effect a Product Launch unless and until Product stability tests have qualified a Product shelf life of at least 15 months.

7.2 [***].

ARTICLE 8

COMPENSATION TO ANTARES

8.1 Up-Front Payments

(a) Letter Agreement Payment. Antares acknowledges that Lumara made an initial Antares Device Development Payment to Antares in the amount of [***] upon execution of that certain Letter Agreement between Antares Pharm, Inc. and Lumara Health Inc. dated June 10, 2014 which led to this Agreement, [***] of which shall be used for the purpose set forth in Section 8.l(b), and [***] of which shall be used for the purpose set forth in Section 8.l(c).

(b) Development and License Agreement Payment. Within ten (10) days after the Effective Date of this Agreement, Lumara shall pay Antares an additional Antares Device Development Payment of [***].

(c) Tooling and Process Validation Payment. Within ten (10) days after the Effective Date of this Agreement, Lumara shall pay Antares an additional Antares Device Development Payment of [***] for the purpose of initiating tooling and process validation for the 1 mL dose shown as item 3.1 on page 13 of the initial Device Development Plan attached hereto.

8.2 Royalties

(a) Royalty Rates. Subject to the provisions of this Agreement, beginning upon Product Launch and during the Royalty Period for such Product, Lumara shall pay Antares on a Calendar Quarterly basis the lesser of any of the following royalties that apply to each particular Product sold in a particular country:

(i) For aggregate annual worldwide Net Sales of Products up to and including [***], and for aggregate annual worldwide Net Sales of Products greater than [***], on Lumara's Net Sales for those Products that are Covered by a Valid Claim of a patent within the Licensed Technology in the country in which such Products are sold. It is understood that such royalties will be applied incrementally; or

(ii) [***] on Lumara's Net Sales for those Products that are not Covered by a Valid Claim of a patent within the Licensed Technology in the country in which such Products are sold; or

(iii) [***] on Lumara's Net Sales of Product in a country in the Territory in which there are [***] products with an Orange Book (or foreign equivalent) listed, A-rated substitutable generic equivalent to the Product being sold.

(iv) [***].

(b) Royalty Calculations. Royalties shall be calculated on a Product-by-Product and country-by-country basis from the Net Sales of each individual Product. By way of example, if the annual aggregate worldwide Net Sales of a Product equals [***] in a given year, Lumara would pay Antares royalties for that year of (i) [***] on Net Sales of each Product sold in a country having a patent covering the sale of such Product in such country for such sales occurring prior to reaching aggregate worldwide annual Net Sales of [***], (ii) [***] on Net Sales of each Product sold in a country having a patent covering the sale of such Product in such country for such sales occurring after reaching aggregate worldwide annual Net Sales of [***], it being understood that royalties will be applied incrementally, (iii) [***] on Net Sales of each Product sold in a country having no patent covering the sale of such Product in such country, (iv) [***] on Net Sales of each Product sold in a country where such Product is subject to two (2) or fewer generic products (as described above) even if the sale of such Product is otherwise covered by a patent in such country and (v) [***].

(c) Multiple Patents. Royalties payable under this Section 8.2 will be payable only once with respect to a particular sale of Product regardless of there being more than one Antares Patent Right applicable to such Product.

(d) Access to Third Person Rights. If at any time during the term of this Agreement access to a Third Person's intellectual property rights becomes necessary, advantageous or reasonably useful to make, use, sell, offer for sale and/or import a Product in the Field ("Third Person Rights"), Lumara or Antares shall have the right to acquire access to such Third Person Rights via a license or otherwise as described in this Section 8.2(d). Any decision to access such Third Person Rights will be discussed by the Joint Project Team. To the extent such Third Person Rights are solely related to the Drug, Lumara may acquire access to such Third Person Rights and shall be responsible for any acquisition cost to be paid to such Third Person (i.e., all consideration paid in connection with such acquisition including, without limitation, signing-fees, milestone payments and royalties) ("Access Costs") relating to such access. To the extent such Third Person Rights are unrelated to the Drug incorporated in the Product but is otherwise related to the Product, Antares will have the first right, but not the obligation, to acquire access for Lumara to such Third Person Rights, in which case Antares shall be responsible for any related Access Costs. If Antares fails to acquire access to such Third Person Rights within a reasonable period of time following discussion by the Joint Project Team (but not to exceed ninety (90) days), Lumara will have the right, but not the obligation, to acquire such

access, in which case Lumara shall be responsible for any related Access Costs, provided, however, that Lumara may credit any such Access Costs incurred against any royalties or other payments otherwise payable to Antares under this Agreement.

(e) Current Royalty Obligations (as of Effective Date). Notwithstanding anything to the contrary in this Agreement (including, without limitation, Section 8.2(e)), both Parties acknowledge and hereby agree that each is solely responsible for any and all royalty obligations that have accrued or may accrue in the future with respect to any agreements and/or arrangements that such Party may have agreed to prior to the Effective Date.

(f) Royalty Payments. Lumara shall pay royalties owed to Antares under this Section 8.2 as follows:

(1) *Duration of Royalties Paid for Products.* During the Royalty Period (such period being determined for each Product on an individual Product basis and country-by-country basis), royalty payments hereunder shall be paid by Lumara to Antares on Net Sales of each Product for the particular country and Product at issue.

(2) *Payment Terms.* Royalty payments due Antares under this Section 8.2 will be paid by Lumara for Net Sales made by Lumara not later than [***] following the end of each Calendar Quarter and each such royalty payment shall be accompanied by a report in writing showing the Calendar Quarter for which such royalty payment applies on a Product-by-Product basis, the amount of Net Sales during such Calendar Quarter for which a royalty payment is due on a country-by-country basis and the total royalty payment due. Notwithstanding the foregoing, with respect to any sublicensee's sales of Product, Lumara shall report its sublicensee's Net Sales to Antares (and pay any royalties on such sublicensee's Net Sales to Antares not previously paid by Lumara's sublicensee) as of the next Calendar Quarter payment from the time Lumara receives such information from its sublicensee. Antares or its representatives shall have the right to audit Lumara's records with respect to such reports in accordance with Section 11.2 of this Agreement.

8.3 **Milestones.** In addition to the royalty payments provided in Section 8.2 above, Lumara shall make the following non-refundable milestone payments to Antares with respect to the Product within sixty (60) days following the first occurrence of each of the following events:

Milestone Events	**Payment (U.S. Dollars)**
First time Calendar Year Net Sales for a Product total at least [***].	[***]
First time Calendar Year Net Sales for a Product total at least [***].	[***]
Total Milestone Payments	[***]

Each such milestone payment shall be made by Lumara to Antares only once, and only for the first Product to reach such milestone, regardless of how many times such milestone is reached by the Parties during the term of this Agreement. In no event shall Lumara be required to pay more than one milestone payment with respect to Net Sales made in the same Calendar Year, or shall Lumara be required to make aggregate milestone payments to Antares under this Agreement in excess of [***]. The Parties agree that milestone payments are not, and shall not be deemed to be, royalties for purposes of Section 365(n) of the U.S. Bankruptcy Code.

8.4 **Development Expenses**. [***]. Lumara shall pay Antares the development-milestone based payments set forth in the Device Development Plan to complete all development of the Device under this Agreement. Lumara shall only fund Antares' portion of the manufacturing development expenses to the extent such expenses were previously agreed to by the Parties in the Device Development Plan. Antares shall provide technical advice, consulting and other information as Lumara may reasonably request. Lumara shall pay Antares for such manufacturing development expenses within thirty (30) days after the completion and invoice approved by Lumara, to Lumara's satisfaction of each related milestone set forth in the Device Development Plan, and only the amounts corresponding to each such milestone as set forth therein in full satisfaction of the corresponding manufacturing development expenses.

8.5 **Currency of Payment/Exchange Rates**. All payments to be made under this Agreement shall be made in U.S. Dollars, regardless of the country(ies) in which sales are made. For the purposes of computing Net Sales in a currency other than U.S. Dollars, such currency shall be converted into U.S. Dollars as calculated at the average rates of exchange for the applicable period as published by the Federal Reserve Bank of New York.

8.6 **Taxes**. Any and all taxes levied on account of royalties or milestone payments accruing under this Article 8 shall be paid by Antares. If laws or regulations require withholding of taxes, such taxes will be deducted by Lumara or its sublicensee from such remittable royalties or milestone payments and will be paid by Lumara or its sublicensee to the proper taxing authority. Proof of each payment shall be sent to Antares within ninety (90) days following December 31st of each reporting year. During the term of this Agreement, Antares and Lumara agree to treat sales as if the sales are made by a U.S. company.

8.7 **No Surviving Royalties.** For clarification, notwithstanding any applicable continuation of the licenses provided in Article 5 of this Agreement, Lumara shall have no further obligation to make royalty payments following the expiration or termination of this Agreement.

ARTICLE 9

USE OUTSIDE FIELD

Each Party shall have a non-exclusive right, with the right to grant licenses and sublicenses, to use the Joint Inventions for all other uses outside the Field, [***].

ARTICLE 10

SUPPLY OF DEVICES

10.1 **Exclusive Supplier.** The Parties hereby acknowledge that Antares is the exclusive supplier of all of Lumara's requirements for the Devices and Product within the Territory during the term of this Agreement, [***].

10.2 **Manufacturing of the Product.** Within sixty (60) days following the Effective Date of this Agreement, the Parties shall meet to discuss manufacturing arrangements related to the Product. The Parties agree that Antares shall be the supplier, or be responsible for the manufacture through a Third Person, of the Device and assembly and packaging of the Product, and the Parties shall enter into a mutually acceptable manufacturing agreement providing for such manufacture and supply of the Device and Product (the "Manufacturing Agreement") within [***] of the Effective Date of this Agreement. The Manufacturing Agreement shall include those terms set forth in Section 10.3 below, and such other terms as the Parties may agree. To the extent Antares utilizes any Third Person to perform some or all of its obligations under the Manufacturing Agreement, such Third Person, and the terms upon which it shall provide

services for Antares, shall be subject to approval by Lumara in its sole discretion. From the Effective Date of this Agreement until the execution of the Manufacturing Agreement, Lumara may submit purchase orders to Antares to purchase quantities of the Device, provided, however, that no less than [***] Devices may be ordered on any individual purchase order.

10.3 **Manufacturing Agreement.** The Manufacturing Agreement shall provide for the following terms, in addition to other terms typically included in manufacturing agreements for devices in the medical device industry.

(a) *Responsibilities of the Parties.* Antares will be responsible for Device manufacturing and Product assembly and finishing, and any portion of such Device manufacturing and Product assembly and packaging performed by Third Persons on Antares' behalf, including, without limitation, activities such as maintaining the DHF and DMF, complaint investigation, and the oversight of production. Lumara or its designee will be responsible for manufacture and formulation of any Drug and the Prefilled Syringe for assembly with the Device into the Product by Antares and for final Product release for sale. Antares will work with Lumara to integrate the Device, Drug and Prefilled Syringe into a Product for commercial sale. Antares and Lumara will together identify appropriate Third Persons for various aspects of Device manufacturing and Product assembly and packaging. While it is anticipated that Antares and Lumara will make any decision for such Third Person selection jointly, Antares will have final decision-making authority regarding the use of a Third Person to manufacture any aspect of the Device, and Lumara will have final decision-making authority regarding the use of a Third Person to manufacture any aspect of the Product other than the Device, and Lumara shall have the right to specify the final assembly packaging and labeling for Product, including the combination of the components thereof and with respect to final release of the Product for sale.

(b) *Development of QA.* No later than [***] after the Effective Date, the Parties shall prepare and adopt the QA. The Parties shall, at least annually, review the QA and shall modify it from time to time as necessary through a written amendment to the QA signed on behalf of each of the Parties by an authorized representative.

(c) *Manufacturing.* Subject to the te1ms and conditions of the Manufacturing Agreement, Antares, or the Third Person acting on its behalf, will manufacture Devices and assemble and package Product for Lumara at the times and in the quantities set forth by Lumara in forecasts and purchase orders as more specifically provided in the Manufacturing Agreement. Antares, and the Third Person acting on its behalf, will ensure that each shipment of Devices: (i) will have been manufactured in accordance with the specifications, cGMP, and cQSR, in effect at the time of Manufacture, (ii) will not be adulterated or misbranded within the meaning of the FD&C Act by Antares, the Third Person acting on its behalf, or their agents, and (iii) will not have been manufactured or sold in violation of any Applicable Laws in any material respect.

(d) *Manufacturing Decisions.* Antares shall have final decision-making authority with respect to any manufacturing issue related to manufacture of Devices so long as such decisions and decision-making does not impede Lumara's right to

commercialize Products hereunder, and Lumara shall have final decision-making authority with respect to any manufacturing issue related to the release for sale of Products.

(e) *Device Cost.* The cost to Lumara of the Device and Product to be delivered by Antares will be as follows:

(i) Cost of each Device loaded with a Prefilled Syringe (supplied by Lumara) to Lumara for clinical development and other non-commercial uses will be Antares' Fully Burdened Manufacturing Cost for the Device [***].

(ii) Cost of each fully assembled and packaged Product to Lumara will be Antares' Fully Burdened Manufacturing Cost for the Device and assembly and packaging of the Product plus [***]. Parties estimate the cost plus [***] per device (exclusive of the cost of the Prefilled Syringe supplied by Lumara).

Antares warrants that the costs to manufacture the Devices and assemble and package the Products listed above are best estimates based upon: (i) [***] and (ii) volume projections provided by Lumara of Product sales in the Field. [***].

(f) *Back-up Supplier.* At Lumara's request, and at Lumara's cost to the extent requested, Antares will qualify at least one back-up supplier for each critical component of the Device, as determined to be appropriate as part of the Device Development Plan. Notwithstanding the foregoing, Antares shall at Antares' cost develop, implement and maintain a redundancy plan reasonably acceptable to Lumara for molds, tooling and assemblies required for manufacturing the Devices, as more specifically set forth in **Exhibit G.**

(g) *Product Recall.* Lumara, after consultation with Antares, shall have the right and responsibility to determine whether Product must or should be recalled. Lumara shall also be responsible for managing such recalls and Antares will cooperate with Lumara as Lumara may reasonably request. Lumara shall be responsible for all costs incurred due to a Product recall, provided, however, that to the extent that a recall relates to Antares' failure to deliver the Device in accordance with the specifications or relates to assembly and packaging Product, [***], Antares shall, in addition to repairing, replacing or refunding the purchase price of the

non-conforming Products (at the option of Lumara), reimburse Lumara for the direct and verifiable costs related to the recall. Antares' liability for any such direct and verifiable costs relating to a recall shall not exceed the amount paid to Antares by Lumara for Product during the [***] period preceding the date of the recall. Product recall costs incurred by Antares shall be specifically excluded from Antares Fully Burdened Manufacturing Cost.

(h) *Subcontracting.* To ensure that the quality of the Products (and/or major components thereof) is maintained, Antares agrees to notify and consult with Lumara in advance in the event that Antares desires to subcontract the manufacture of any of the Products (and/or major components thereof), provided that any such subcontract shall be consistent with and subject to the applicable obligations of Antares under this Agreement, including without limitation, obligations to maintain quality, practice GMP where applicable and satisfy regulatory compliance requirements, and that such subcontract shall not adversely affect the supply of Products to Lumara under this Agreement.

ARTICLE 11

RECORD-KEEPING AND AUDITS

11.1 **Records Retention**. The Parties shall keep complete and accurate records pertaining to the development, use and sale of Products in sufficient detail to permit the other Party to confirm, in the case of Antares, its research, development and manufacturing efforts hereunder, and in the case of Lumara, its development and commercialization efforts, and the accuracy of calculations of all payments due hereunder.

11.2 **Audit Request**. Each of the Parties shall have the right to request in writing an audit of the records described in Section 11.1, at its own expense, once on an annual basis, to determine, with respect to any of the two (2) preceding Calendar Years, the correctness of any report or payment made under this Agreement. If a Party desires to audit such records, it shall utilize an independent, certified public accountant reasonably acceptable to the other Party, to examine financial records and may utilize an independent scientist reasonably acceptable to the other Party to audit scientific records. Such accountant/scientist shall be instructed to provide the Party desiring the audit a report on the findings of the agreed upon procedures which verifies any previous report made, payment submitted, or work performed by the audited Party during such period. The expense of such audit shall be borne by the auditing Party; provided, however, that if an error in favor of the auditing Party of more than [***] is discovered, then such expenses shall be paid by the audited Party. If the audit determines that additional amounts are owed to Antares, or that amounts were overpaid to Antares, during the audit period, Lumara shall pay Antares the additional amount owed to Antares, or Antares shall pay Lumara the overpaid amount, within forty-five (45) days of the date on which the paying Party receives the audit report. Any Information received by a Party pursuant to this Section 11.2 shall be deemed to be Confidential Information hereunder.

11.3 **Survival.** This Article 11 shall survive any termination of this Agreement for a period of two (2) years.

ARTICLE 12

PROGRAM INTELLECTUAL PROPERTY

12.1 **Ownership of Program Intellectual Property.** Any and all Information, data, items, material and knowledge including, without limitation, any and all suggestions, descriptions, ideas, inventions (whether or not patentable), know-how, trade secrets, techniques, strategies, methods, syntheses, processes, practices, skills, experience, documents, apparatus, devices, chemical formulations, compounds, composition of matter, chemical samples, assays, screens, databases, database structures and data analysis methods discovered, generated or developed within the scope and during the course of the Product Development Program regardless of inventorship ("Program Intellectual Property") shall be the property of the Parties as follows:

(a) Program Intellectual Property Relating to Drug. Program Intellectual Property that relates solely to the Drug, but not to the Device (e.g., including, without limitation, uses for the Drug, methods or processes for using or manufacturing the Drug, formulations applicable to the Drug, dosing, absorption and blood levels of the Drug, including, without limitation, relating to sub-cutaneous absorption of the Drug, and analogs, derivatives, fragments, mimetics, conjugates and any excipients thereof) shall be the sole property of Lumara. Antares hereby assigns all of its rights, including all Patent Rights, to such Program Intellectual Property to Lumara, and such Program Intellectual Property so assigned shall be deemed to be “Lumara Sole Inventions".

(b) Program Intellectual Property Relating to Device. Program Intellectual Property that relates solely to the Device, but not to the Drug (e.g., including, without limitation, uses for the Device, improvements to the Device, and methods or processes for manufacturing the Device) shall be the sole property of Antares. Lumara hereby assigns all of its rights, including all Patent Rights, to such Program Intellectual Property to Antares, and such Program Intellectual Property so assigned shall be deemed to be "Antares Sole Inventions".

(c) Program Intellectual Property Relating to Combination of Drug and Device. Program Intellectual Property that relates to the combination of the Drug and the Device (e.g., including, without limitation, uses for the Product, improvements to the Product, results from using the Product and methods or processes for manufacturing the Product) shall be jointly owned by Lumara and Antares. Lumara hereby assigns an undivided joint interest in its ownership rights, including all Patent Rights, to such Program Intellectual Property to Antares, and Antares hereby assigns an undivided joint interest in its ownership rights, including all Patent Rights, to such Program Intellectual Property to Lumara, and such Program Intellectual Property so assigned by shall be deemed to be "Joint Inventions". Except as otherwise provided for under the exclusive license granted to

Lumara under Article 5 for use as Program Intellectual Property inside the Field, and under the provisions of Article 9 for use by either Party outside the Field, neither Party may use or license or sublicense the Joint Inventions without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed

(d) Other Program Intellectual Property. The U.S. laws of inventorship shall govern the ownership of all other Program Intellectual Property that is not assigned to either Antares or Lumara pursuant to the ownership provisions of Sections 12.l(a), (b) or (c) hereof.

12.2 **Cooperation.** Each Party shall cooperate with the other in completing any patent applications or obtaining any other Patent Rights relating to both Sole and Joint Inventions that will be owned by the other Party. Each Party shall also cooperate with the other in executing and delivering any instrument required to assign, convey or transfer to such other Party its interest should such assignment, conveyance or transfer be required by the terms of this Agreement.

12.3 **Ownership Review**. No Party shall file a patent application on Program Intellectual Property until ownership as described in Section 12.1 is reasonably determined by the Parties after such Parties have had a reasonable opportunity to review and discuss the particular Program Intellectual Property at issue.

12.4 **Patent Filings**. Antares shall be responsible at its own cost for the filing, prosecution and maintenance of all Antares Patent Rights including without limitation those listed on **Exhibit B** and shall not allow any such Antares Patent Rights to lapse without following the provisions of this Section 12.4. Upon written request by Lumara within 60 days after each Calendar Year-end, Antares shall provide Lumara with a report describing the status of the Antares Patent Rights. Such report shall include, at a minimum, the patent country, patent and application numbers, filing date, issue date, expiration date and any other relevant information.

(a) Antares may, in the exercise of its sole discretion and at its own cost, prepare, file, prosecute and/or maintain patent applications for the Antares Sole Inventions and shall be responsible for related interference proceedings. Lumara may, in the exercise of its sole discretion and at its own cost, prepare, file, prosecute and/or maintain patent applications for Lumara Sole Inventions and shall be responsible for related interference proceedings. The Parties shall utilize an outside law firm acceptable to both Parties to prepare, file, prosecute and/or maintain patent applications for Joint Inventions and shall be responsible for related interference proceedings. The Parties shall share equally the costs associated with the use of such outside law firm in accordance with the terms of this Section 12.4.

(b) Should any Party not wish to file, prosecute, maintain or issue any patent application for a Joint Invention in any particular country, that Party will so notify the other Party of its intentions ("Discontinuance Election"). Upon receipt of such Discontinuance Election, the other Party may elect to have the right to file, prosecute, maintain or issue any such patent or patent application at its own expense by providing

written notice of the same within thirty (30) days of its receipt of the Discontinuance Election. Upon such election: (i) the discontinuing Party shall grant the other Party any necessary authority to file, prosecute, issue and maintain such patent application and/or patent at issue; and (ii) shall assign such patent or patent application to the other Party. Until such assignment is complete, the discontinuing Party shall take reasonable efforts to maintain or otherwise ensure that patent protection will not be lost with respect to such patent and/or patent application provided the other Party does not unreasonably delay the assignment thereof.

12.5 **Public Disclosure.** Each Party agrees to make every reasonable effort to delay any public disclosure of the subject matter of any patent application related to Program Intellectual Property of which it is aware until after the filing of such patent application.

12.6 **Product Trademarks**

(a) Lumara will work collaboratively with Antares on the development, selection, and registration of Antares Trademarks and Lumara Trademarks, or any combinations thereof, appropriate for the Product and the particular countries within the Territory. In the event that Lumara and Antares fail to reasonably agree upon a selection of Antares Trademarks and Lumara Trademarks for the particular countries in the Territory, then Lumara shall have final decision-making authority with respect to such selection.

(b) Acknowledgement of Rights in Antares Trademarks. Lumara acknowledges that Antares is the owner of all right, title and interest in and to the Antares Trademarks, and Lumara agrees not to adopt or use any of the Antares Trademarks in any manner whatsoever except as expressly provided in this Agreement. Lumara agrees not to apply for registration of any Antares Trademarks in the Territory or for any mark confusingly similar thereto.

(c) Acknowledgement of Rights in Lumara Trademarks. Antares acknowledges that Lumara is the owner of all right, title and interest in and to the Lumara Trademarks, and Antares agrees not to adopt or use any of the Lumara Trademarks in any manner whatsoever except as expressly provided in this Agreement with respect to the manufacture and supply of Product to Lumara. Antares agrees not to apply for registration of any Lumara Trademarks in the Territory or for any mark confusingly similar thereto.

(d) Use of Antares Trademarks. Lumara agrees that the Antares Trademarks shall be used solely in connection with the marketing and sale of the Products and in accordance with Antares' specifications as to style, color and typeface as may be determined pursuant to Section 12.6(a). Antares shall at all times maintain quality control and final approval over all Products and Devices exhibiting Antares Trademarks. Lumara hereby agrees to notify Antares promptly of any infringement of any Antares Trademark in the Territory that Lumara has knowledge of.

ARTICLE 13

REPRESENTATIONS, AND WARRANTIES AND COVENANTS

13.1 **Antares Representations.** Antares hereby represents, warrants and covenants to Lumara as follows:

(a) Intellectual Property. That Antares has the requisite legal title and ownership under the Licensed Technology, including without limitation such Antares Patent Rights and Antares Trademarks listed in Exhibits B and C, respectively, necessary for it to fulfill its obligations under this Agreement, including, without limitation, the granting of the exclusive licenses in Article 5. There is no pending or threatened litigation, arbitration, government proceeding, or government investigation (and Antares has not received any communication relating thereto) which alleges that Antares' past activities relating to [***] devices or activities proposed under this Agreement, including, without limitation activities with respect to the Antares Patent Rights, infringe or misappropriate any of the Intellectual Property Rights of any Third Person. To the best knowledge of Antares, there is no Patent Right or other Intellectual Property Right of any Third Person that would be infringed or misappropriated by Lumara fulfilling any of its obligations or exercising any of its rights under this Agreement.

(b) No Prior License. That as of and prior to the Effective Date, Antares has not granted any license under Licensed Technology to develop, make, use, sell, offer for sale and/or import or export the Device and Product in the Field. Lumara shall have no liability on account of amounts due to any Third Person under any agreements of Antares.

(c) Exclusivity. That Antares hereby represents that as of the Effective Date, it does not have a commercial development and/or marketing agreement with any Third Person for the Device in the Field nor is Antares developing any Device for use in the Field except as provided for in this Agreement.

(d) Full Disclosures. That Antares has provided Lumara with all information that Lumara has requested for deciding the merits of entering into this Agreement.

(e) Employee Obligations. That all of its employees, officers, independent contractors and consultants who will work on the Product Development Program have legal obligations requiring, in the case of employees and officers, assignment to Antares of all inventions made during the course of, and as a result of, their association with Antares and obligating the individual to maintain as confidential the confidential information of Antares, as well as the confidential information of a Third Person which Antares may receive.

(f) Compliance with Laws. That in carrying out its work under the Product Development Program such work shall be carried out in compliance with any Applicable Laws including, without limitation, federal, state, or local laws, regulations, or guidelines governing the work at the site where such work is being conducted. Moreover, Antares represents and warrants that in connection with carrying out its work under the Product Development Program, as applicable, based on the specific work to be conducted, it will carry out such work under the Product Development Program in accordance with current cGLP, cGCP, cGMP and cQSRs.

(g) No Debarment. That it will comply at all times with the provisions of the Generic Drug Enforcement Act of 1992, and will upon request certify in writing to Lumara that none of it, its employees, or any person providing services to Antares in connection with the collaboration contemplated by this Agreement have been debarred under the provisions of such Act.

(h) Product Warranty. That all Devices and Products manufactured by Antares, or a Third Person on behalf of Antares, when delivered to Lumara:

(i) will be merchantable and fit for the purpose for which they are intended, (ii) will comply with applicable specifications and be free from any defects in materials or workmanship; (iii) will be delivered to Lumara free and clear of all liens and encumbrances; and (iv) will be in compliance with all Applicable Laws and regulations.

13.2 **Lumara Representations.** Lumara hereby represents and warrants to Antares as follows:

(a) Intellectual Property. That Lumara has the requisite legal title and ownership under its Intellectual Property Rights necessary for it to fulfill its obligations under this Agreement, including, without limitation, the granting of the non-exclusive licenses in Article 5. There is no pending or threatened litigation, arbitration, government proceeding, or government investigation (and Lumara has not received any communication relating thereto) which alleges that Lumara's past activities relating to the Drug, or activities proposed under this Agreement, including, without limitation activities with respect to the Antares Patent Rights, infringe or misappropriate any of the Intellectual Property Rights of any Third Person. To the best knowledge of Lumara, there is no Patent Right or other Intellectual Property Right of any Third Person that would be infringed or misappropriated by Antares fulfilling any of its obligations or exercising any of its rights under this Agreement.

(b) Employee Obligations. That all of its employees, officers, independent contractors and consultants have legal obligations requiring, in the case of employees and officers, assignment to Lumara of all inventions made during the course of, and as a result of, their association with Lumara, and obligating the individual to maintain as confidential the confidential information of Lumara, as well as the confidential information of a Third Person which Lumara may receive.

(c) Compliance with Laws. That in carrying out its work under the Product Development Program such work shall be carried out in compliance with any Applicable Laws including, without limitation, federal, state, or local laws, regulations, or guidelines governing the work at the site where such work is being conducted. Moreover, Lumara represents and warrants that in connection with carrying out its work under the Product Development Program, as applicable based on the specific work to be conducted, it will carry out such work under the Product Development Program in accordance with cGLP, cGCP, cGMP. Further, Lumara represents and warrants that it will commercialize Products only in compliance with Applicable Laws, including promotion of the Products only in accordance with its approved label and no off-label promotion of the Product.

(d) No Debarment. That it will comply at all times with the provisions of the Generic Drug Enforcement Act of 1992, and will upon request certify in writing to Antares that neither it, nor its employees, or any person providing services to Lumara in connection with the collaboration contemplated by this Agreement have been debarred under the provisions of such Act.

ARTICLE 14

INFRINGEMENT OF THIRD PERSON RIGHTS

14.1 **Infringement Claims.** If the manufacture, use or sale of Product in the Territory and in the Field results in any claim, suit or proceeding lodged by a Third Person alleging patent infringement against Lumara or Antares (or their respective Affiliates or sublicensees), such Party shall promptly notify the other Party in writing. Subject to the indemnity provisions of Article 16, which shall be controlling, the Party subject to such claim, suit or proceeding shall have the right to defend and control the defense of any such claim, suit or proceeding, using counsel of its own choice; provided that if both Parties are subject to such claim, suit or proceeding, then the Parties shall promptly determine in good faith which Party will defend and control the defense of any such claim, suit or proceeding, using mutually acceptable counsel; and, provided further, that in no event shall any controlling Party enter into any settlement or make any admission that admits or concedes that any Patent Rights or other intellectual property rights of the other Party are invalid or unenforceable, or adversely affects their scope, without the prior written consent of the other Party. If the Parties cannot promptly determine in good faith (and in any event within five (5) business days of initiating discussions with respect thereto) which Party will defend and control the defense of any such claim, suit or proceeding then Antares shall be the controlling Party for the defense if the Device itself is at issue (including selecting counsel), and Lumara shall be the controlling Party for the defense if the Device itself is not at issue and the Drug alone or Product is at issue (including selecting counsel).

ARTICLE 15

INFRINGEMENT BY THIRD PERSONS

15.1 **Notice.** If any of the Licensed Technology licensed under this Agreement is infringed and/or misappropriated by a Third Person ("Infringed Licensed Technology"),

the Party first having knowledge of such infringement/misappropriation shall promptly notify the other in writing. The notice shall set forth the facts of such infringement and/or misappropriation in reasonable detail.

15.2 Prosecution of Actions.

(a) [***].

(b) [***].

(c) [***].

(d) [***].

(e) [***].

15.3 **Infringement of Licensed Technology Outside the Field.**

(a) [***].

(b) [***].

(c) [***].

(d) [***].

(e) [***].

ARTICLE 16

MUTUAL INDEMNIFICATION

16.1 **Responsibility and Control.** Lumara and Antares shall each be solely responsible for the safety of its own employees, agents, licensees or sublicensees with respect to Product development, manufacturing, marketing, selling and detailing the Products, and each shall hold the other harmless with regard to any liability for damages or personal injuries resulting from acts of its respective employees or agents.

16.2 **Antares' Right to Indemnification.** Lumara shall indemnify each of Antares, its successors and assigns, and the directors, officers, employees, and agents thereof (the "Antares Indemnitees"), defend and hold each Antares Indemnitee harmless from and against any and all liabilities, damages, losses, settlements, claims, actions, suits, penalties, fines, costs or expenses (including, without limitation reasonable attorneys' fees) (any of the foregoing, "Damages") incurred by or asserted against any Antares Indemnitee of whatever kind or nature, including, without limitation, any claim or liability based upon negligence, warranty, strict liability, violation of government regulation or infringement of patent or other proprietary rights, but only to the extent arising from or occurring as a result of a claim or demand made by a Third Person (a "Third Person Claim") against any Antares Indemnitee because of (a) breach of any warranty made by Lumara pursuant to Section 13.2 hereof; (b) the Product, unless attributable to an item identified in Section 16.3 below which is under the responsibility of Antares; (c) the distribution or detailing of any Product by or on behalf of Lumara or its sublicensees, except to the extent such claim alleges infringement of any patent, other intellectual property rights or other proprietary rights of a Third Person; (d) any allegation that the manufacture, use, sale, offer for sale or importation of a Product infringes any patent, other intellectual property rights or other proprietary rights of a Third Person, except to the extent such infringement relates to the practice of the Antares Patent Rights or use of the Licensed Technology or the manufacture, use, sale, offer for sale or importation of a Device (including a Device incorporated into a Product) or any delivery system including the Device; or (e) any breach of this Agreement by Lumara, except, in each such case, to the extent that such Damages are finally determined to have resulted from the negligence or misconduct of Antares. Antares shall promptly notify Lumara of any Third Person Claim upon becoming aware thereof, and shall permit Lumara, at Lumara's cost, to defend against such Third Person Claim and to control the defense and disposition (including, without limitation, all decisions to litigate, settle or appeal) of such claim, and shall cooperate in the defense thereof. Antares may, at its option and expense, have its own counsel participate in any proceeding that is under the direction of Lumara and shall cooperate with Lumara and its insurer in the disposition of any such matter.

16.3 **Lumara's Right to Indemnification.** Antares shall indemnify each of Lumara, its successors and assigns, and the directors, officers, employees, and agents thereof (the "Lumara Indemnitees"), defend and hold each Lumara Indemnitee harmless from and against any and all Damages incurred by or asserted against any Lumara Indemnitee of whatever kind or nature, including, without limitation, any claim or liability based upon negligence, warranty, strict liability, violation of government regulation or infringement of patent or other proprietary rights, but only to the extent arising from or occurring as a result of a Third Person Claim against any Lumara Indemnitee because of (a) breach of any warranty made by Antares pursuant to Section 13.1 hereof; (b) any alleged defect in the design or functionality of the Device; (c) the failure of Antares or its agents to manufacture, process, test or package Devices according to specifications; (d) [***]; (e) the [***], warehousing or distribution of a Product by Antares, except to the extent such claim alleges infringement of any patent, other intellectual property rights or other proprietary rights of a Third Person; (f) any allegation

that the practice of the Antares Patent Rights or use of the Licensed Technology or the manufacture, use, sale, offer for sale or importation of a Device (including a Device incorporated into a Product) or any delivery system including the Device, in such cases, infringes any patent, other intellectual property rights or other proprietary rights of a Third Person; or (g) any breach of this Agreement by Antares, except, in each such case, to the extent that such Damages are finally determined to have resulted from the negligence or misconduct of Lumara or a sublicensee of Lumara. Lumara shall promptly notify Antares of any Third Person Claim upon becoming aware thereof, and shall permit Antares at Antares' cost to defend against such Third Person Claim and to control the defense and disposition (including, without limitation, all decisions to litigate, settle or appeal) of such Third Person Claim and shall cooperate in the defense thereof. Lumara may, at its option and expense, have its own counsel participate in any proceeding that is under the direction of Antares and will cooperate wit36h Antares or its insurer in the disposition of any such matter.

16.4 **Insurance**. Each Party shall obtain and maintain insurance reasonably sufficient to cover its potential liability under this Agreement and shall provide evidence of such insurance to the other Party upon request.

16.5 **Limitation of Liability.** [***]**, neither Party shall be liable to the other for any consequential, incidental, special, indirect or similar damages whatsoever, including lost profits, sustained or incurred in connection with the Product or caused by Product defects, regardless of the form of action, whether in contract or tort or otherwise and whether or not such damages were foreseen or unforeseen**.

ARTICLE 17

CONFIDENTIALITY

17.1 **Confidentiality; Exceptions**. Unless otherwise set forth in this Agreement, with respect to all Information disclosed or provided by, or on behalf of, either Party to the other or its designees in connection with this Agreement, whether provided orally, visually, electronically, in writing or in any other form, ("Confidential Information"), the Party receiving such Confidential Information ("Recipient") shall maintain the confidential and proprietary status of such Confidential Information, keep such Confidential Information and each part thereof within its possession or under its control, use all its reasonable efforts to prevent the disclosure of any Confidential Information to any other person, and use all its reasonable efforts to ensure that such Confidential Information is used only for those purposes specifically authorized by this Agreement. These mutual obligations of confidentiality shall apply until [***] following the later of expiration or termination of the Agreement, but such obligations shall not apply to any Information to the extent that such Information is:

(a) independently developed by such Party outside the scope and not in violation of this Agreement, as evidenced by such Party's contemporaneous written records;

(b) in the public domain at the time of its receipt or thereafter becomes part of the public domain through no fault of or breach of this Agreement by the Recipient or by any person to whom the Recipient disclosed such Confidential Information; received without an obligation of confidentiality from a Third Person having the right to disclose such information; or

(c) released from the restrictions of this Section 17.1 by the express written consent of the disclosing Party.

Notwithstanding the provisions of Section 17.1 hereof, the Parties may, to the extent necessary, disclose and use Confidential Information (i) to secure patent protection for an invention developed as a result of the Product Development Program or, to obtain regulatory clearance or institutional or government approval to clinically test or market Product, or (ii) as required by law, statute, rule or court order to be disclosed (the disclosing Party shall, however, use reasonable efforts to obtain confidential treatment of any such disclosure, and consult with the other Party and permit the other Party to participate in seeking an appropriate protective order). Notwithstanding anything to the contrary contained herein, all Confidential Information previously disclosed by the Parties shall continue to be subject to the Confidential Disclosure Agreement, dated [***], between the Parties which shall survive the execution and termination of this Agreement.

17.2 **Authorized Disclosures of Confidential Information.**

(a) Permitted Persons. Each Party may disclose Confidential Information of the other Party, without such Party's prior written consent, to its directors, employees, agents, consultants, permitted suppliers, and other person or entities who need to know such Confidential Information to assist the Party in fulfilling its obligations or exploiting its rights hereunder ("Permitted Person"). As a result of a Party's non-performance of its obligations under this Agreement, the other Party may disclose such Confidential Information to Third Persons as necessary for such Third Person to perform such obligations of that Party, and to Third Persons who are board members or board observers, investors or potential investors, provided the other Party ensures that such Third Person is bound by an appropriate confidentiality agreement prior to disclosure of Confidential Information. The Party making such disclosure shall be responsible for any confidentiality breaches of this Agreement by any Permitted Person to the same extent as if the confidentiality breach was made by the Party.

(b) Legally Required or Necessary. Each Party may also disclose the Confidential Information of the other Party, without such Party's prior written consent, to any person, entity, or government or regulatory authority to the extent that the law requires such disclosure. Notwithstanding the foregoing, prior to disclosing the other Party's Confidential Information under this Subsection, the disclosing Party, to the extent practicable, will give the other Party a copy of the Confidential Information to be disclosed

and provide such Party a reasonable opportunity to comment on the necessity and the text of the proposed disclosure. The disclosing Party agrees to consider such comments in good faith and to reasonably avail itself of available means under the applicable law to minimize the disclosure of such Confidential Information.

(c) Court Orders. Each Party may also disclose the Confidential Information of the other Party, without such Party's prior written consent, pursuant to an order of a Regulatory Authority or court of competent jurisdiction, provided that it promptly notifies the other Party of the required disclosure in order to provide such Party an opportunity to take legal action to prevent or limit such disclosure and, if asked, reasonably assists the other Party in pursuing such action.

(d) Legal Actions. Each Party may also disclose the Confidential Information of the other Party, without such Party's prior written consent, as is necessary to pursue or defend against a legal or regulatory action by one Party against the other with respect to this Agreement. A Party disclosing the other Party's Confidential Information, pursuant to this Subsection, will use reasonable efforts to minimize the disclosure of the other Party's Confidential Information, including, without limitation, by seeking to file pleadings under seal.

17.3 **Return of Confidential Information.** Except as otherwise set forth herein, upon the earlier of the disclosing Party's written request or the expiration or termination of this Agreement, the Recipient shall return or destroy all copies of the disclosing Party's Confidential Information and certify promptly in writing that it has done so, provided that the Recipient shall be entitled to retain one (1) copy of the disclosing Party's Confidential Information in its secured files solely to monitor compliance with its obligations hereunder.

ARTICLE 18

PUBLICITY

18.1 **Disclosure of Agreement.** Neither Party to this Agreement may release any information to any Third Person regarding the terms or existence of this Agreement without the prior written consent of the other Party. This prohibition applies to press releases, educational and scientific conferences, promotional materials, governmental filings and discussions with public officials and the media. Notwithstanding the foregoing, however, this provision does not apply to any internal publications, or disclosures regarding this Agreement or related information to regulatory agencies such as the U.S. Food and Drug Administration, Securities and Exchange Commission, Federal Trade Commission and/or the Department of Justice which may be required by law, including requests for a copy of this Agreement or related information by tax authorities. Subject to the limitation set forth in the immediately preceding sentence, if any Party to this Agreement determines a release of information regarding the existence or terms of this Agreement is required by law, that Party will notify the other Party as soon as practical and give as much detail as possible in relation to the disclosure required. The Parties shall then

cooperate with respect to deciding what information will actually be released. The Parties shall have the right to review and comment on any such information to be included in such governmental filing, including any redactions of Confidential Information required by the governmental agency requiring the release of information. The Parties shall cooperate with respect to any filings under the Hart-Scott-Rodino Antitrust Improvements Act, 15 U.S.C. §18a *et. seq.,* as appropriate. Such press release shall not in any way mention the financial terms or the pharmaceutical compounds governed by this Agreement.

18.2 **Terminations.** Both Parties agree that if this Agreement is terminated, neither Party will disclose its reasons for not proceeding to any Third Person without the express written consent of the other Party.

18.3 **Publications.** Except as otherwise provided in Section 18.1, neither Party shall disclose any information in the Field or derived under this Agreement to any Third Person without the prior written consent of the other Party, and for information outside the Field, neither party shall disclose any information derived under this Agreement to any Third Person without the prior written consent of the other Party, such consent for information outside the Field may not be unreasonably withheld. Furthermore, subject to and in addition to the consent requirement set forth above in this Section 18.3, each Party shall provide the other with an opportunity to review and comment upon, and remove any Confidential Information from, any proposed abstracts, manuscripts or proposed presentations that relate to the Field at least sixty (60) days prior to their intended submission for publication and agrees, upon request, not to submit such an abstract or manuscript for publication until the other Party is given a reasonable period of time to secure patent protection for any material in such publication which it believes to be patentable.

ARTICLE 19

TERM AND TERMINATION

19.1 **Term.** This Agreement shall commence as of the Effective Date and, unless sooner terminated in whole or in part as specifically provided in this Agreement, shall continue in force and effect and will expire upon [***].

19.2 **Termination By Lumara.** This Agreement may be terminated in its entirety by Lumara, upon Lumara's prior written notice to Antares:

(a) [***] from the Effective Date provided that the effective date of such termination shall be at least forty-five (45) days after the date that written notice of such termination is sent to Antares provided, however, [***];

(b) Subject to Section 20.2, if Antares commits a material breach of this Agreement and such breach remains uncured for sixty (60) days following written notice of breach by Antares; or

(c) Subject to Section 20.2, if Antares fails to supply Lumara's requirements of Products pursuant to Article 10 and under the Manufacturing Agreement, and such failure remains uncured for [***] following written notice of such failure to Antares;

(d) If Antares is subject to a petition for relief under any bankruptcy legislation, or makes an assignment for the benefit of creditors, or is subject to the appointment of a receiver for all or a substantial part of Antares' assets, and such petition, assignment or appointment prevents Antares (as a legal or as a practical matter) from performing its obligations under this Agreement, or such petition, assignment or appointment is not otherwise dismissed or vacated within sixty (60) days.

19.3 **Termination by Antares.** This Agreement may be terminated in its entirety by Antares upon Antares' prior written notice to Lumara:

(a) Subject to Section 20.2, if Lumara commits a material breach of this Agreement and such breach remains uncured for sixty (60) days following written notice of breach by Antares; or

(b) If Lumara fails to submit the U.S. Regulatory Submission by [***] and [***], provided that such date shall be extended until [***] (the "First Extension Period") upon Lumara making a date extension payment to Antares of [***], until [***] (the "Second Extension Period") upon Lumara making an additional extension payment to Antares of [***] prior to the end of the First Extension Period for a cumulative total of [***], and until [***] upon Lumara making an additional extension payment to Antares of [***] prior to the end of the Second Extension Period for a cumulative total of [***]; or

(c) If Lumara is subject to a petition for relief under any bankruptcy legislation, or makes an assignment for the benefit of creditors, or is subject to the appointment of a receiver for all or a substantial part of Lumara's assets, and such petition, assignment or appointment prevents Lumara (as a legal or as a practical matter) from performing its obligations under this Agreement, or such petition, assignment or appointment is not otherwise dismissed or vacated within sixty (60) days.

19.4 **Remedies for Material Breach**

(a) Remedies for Lumara. Subject to Sections 16.5 and 20.2, in the event of an uncured material breach by Antares that would entitle Lumara to terminate this Agreement under Section 19.2(b), [***].

(b) Remedies for Antares. Subject to Sections 16.5 and 20.2, in the event of a uncured material breach by Lumara that would entitle Antares to terminate this Agreement under Section 19.3(a), [***].

19.5 **Effect of Termination.**

(a) In the event Lumara terminates this Agreement pursuant to Section 19.2(a), or Antares terminates this Agreement pursuant to Section 19.3, then the licenses granted to Lumara under Section 5.1 shall terminate, and Lumara shall cease all use of the Licensed Technology and the using and selling of Products, provided, however, that Lumara may sell off any remaining inventory of Products existing on the date of termination for a period not to exceed [***] after the termination date.

19.6 **Surviving Rights.** Termination of this Agreement shall not terminate Lumara's obligation to pay all milestone payments, royalties and other payments that shall have accrued hereunder (including any milestone payments then accrued but not yet due under Section 8.3, and in the event this Agreement is terminated by Lumara pursuant to Section 19.2(a), including any milestone payments that would have accrued within [***] of the date of notice of termination). The obligations of the Parties under Article 5 (License), Article 8 (Compensation to Antares, but only with respect to payments accruing prior to and remaining unpaid upon termination or expiration of this Agreement, and in the event this Agreement is terminated by Lumara pursuant to Section 19.2(a), to milestone payments that would have accrued within [***] of the date of notice of termination), Article 11 (Record-Keeping and Audits), Article 12 (Program Intellectual Property), Article 14 (Infringement of Third Person Rights), Article 16 (Mutual Indemnification), Article 17 (Confidentiality), Article 19 (Termination), and Article 20 (Miscellaneous) of this Agreement will survive the termination or expiration of this Agreement.

19.7 **Accrued Rights, Surviving Obligations.** Termination, relinquishment or expiration of the Agreement for any reason shall be without prejudice to any rights which shall have accrued to the benefit of either Party prior to (or as a result of, including, without limitation, rights available under law and equity) such termination, relinquishment or expiration. Such termination, relinquishment or expiration shall not relieve either Party from obligations that are expressly indicated to survive termination or expiration of the Agreement.

ARTICLE 20

MISCELLANEOUS

20.1 **Agency.** Neither Party is, nor shall be deemed to be, an employee, agent, co-venturer or legal representative of the other Party for any purpose. Neither Party shall be entitled to enter into any contracts in the name of, or on behalf of the other Party, nor shall either Party be entitled to pledge the credit of the other Party in any way or hold itself out as having the authority to do so.

20.2 **Dispute Resolution.** The Parties recognize that disputes as to certain matters may from time to time arise which relate to either Party's rights and/or obligations hereunder. The Parties hereby agree that they will attempt in good faith to resolve any controversy, claim or dispute (collectively, a "Dispute") arising out of or relating to this Agreement promptly by negotiations. Any such Dispute which is not settled by the Parties within [***] after notice of such Dispute is given by one Party to the other in writing shall be referred to a senior executive of Lumara and of Antares who are authorized to settle such Disputes on behalf of their respective companies ("Senior Executives") and who, if possible, are not involved in the Dispute. The Senior Executives will meet for negotiations [***] of the end of the [***] negotiation period referred to above, at a time, place and manner mutually acceptable to both Senior Executives. If the Dispute has not been resolved within [***] after the end of the [***] negotiation period referred to above (which period may be extended by mutual agreement), then such Dispute shall be subject to any other remedy available under this Agreement or at law or equity.

20.3 **Assignment.** Except as otherwise provided herein, neither this Agreement nor any interest hereunder shall be assignable by any Party without the prior written consent of the other (which consent shall not be unreasonably withheld, conditioned or delayed); provided, however, that either Party may assign this Agreement to any wholly owned subsidiary or to any successor by merger or sale of substantially all of its business unit to which this Agreement relates. This Agreement shall be binding upon the successors and permitted assignees of the Parties. Any purported assignment in violation of this paragraph shall be void and ineffectual and shall not operate to transfer or assign any interest or title to the purported assignee.

20.4 **Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

20.5 **Force Majeure.** Neither Party shall be liable to the other for loss or damages or shall have any right to terminate this Agreement for any default or delay attributable to any force majeure event, including, but not limited to, acts of God, acts of government, war, fire, flood, earthquake, terrorist acts, strike, labor dispute and the like, if the Party affected shall give prompt notice of any such cause to the other Party. The Party giving such notice shall thereupon be excused from such of its obligations hereunder as it is thereby disabled from performing for so long as it is so disabled and for sixty (60) days

thereafter; provided, however, that such affected Party commences and continues to take reasonable and diligent actions to cure such cause.

20.6 **Notices.** All notices and other communications hereunder shall be in writing and shall be deemed given if delivered personally or by facsimile transmission (receipt verified), telexed, mailed by registered or certified mail (return receipt requested), postage prepaid, or sent by express courier service, to the Parties at the following addresses (or at such other address for a Party as shall be specified by like notice; provided, that notices of a change of address shall be effective only upon receipt thereof):

If to Lumara, addressed to: [***]	Lumara Health Inc. Chesterfield Grove Road Suite 200 Chesterfield, MO 63005 314-645-6600
If to Antares, addressed to: [***]	Antares Pharma, Inc. 100 Princeton South, Suite 300 Ewing, NJ 08628 609-359-3020

20.7 **Amendment.** No amendment, modification or supplement of any provision of the Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

20.8 **Waiver.** No provision of the Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party.

20.9 **Counterparts.** The Agreement may be executed simultaneously in two counterparts, either one of which need not contain the signature of more than one Party but both such counterparts taken together shall constitute one and the same agreement.

20.10 **Descriptive Headings.** The descriptive headings of this Agreement are for convenience only, and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement.

20.11 **Governing Law.** This Agreement shall be governed by and interpreted in accordance with the substantive laws of the State of New York, without regard to its choice of law rules.

20.12 **Severability.** Whenever possible, each provision of the Agreement will be interpreted in such manner as to be effective and valid under Applicable Law, but if any provision of the Agreement is held to be prohibited by or invalid under Applicable Law, such provision will be ineffective only to the extent of such prohibition or invalidity,

without invalidating the remainder of the Agreement. In the event of such invalidity, the Parties shall seek to agree on an alternative enforceable provision that preserves the original purpose of this Agreement.

20.13 **Entire Agreement of the Parties.** This Agreement, including the Exhibits attached hereto, constitutes and contains the complete, final and exclusive understanding and agreement of the Parties hereto, and cancels and supersedes any and all prior negotiations, correspondence, understandings and agreements, whether oral or written, between the Parties respecting the subject matter hereof. In the event there is a discrepancy between the Exhibits and the Agreement, the Agreement shall control.

20.14 **Jointly Prepared.** This Agreement has been prepared jointly by both Parties and shall not be strictly construed against either Party.

20.15 **Limitation of Liability. [***].**

IN WITNESS WHEREOF, the Parties hereto have as of the Effective Date duly executed this Agreement.

LUMARA HEALTH INC.	ANTARES PHARMA, INC.
By: /s/ Thomas S. McHugh	By: /s/ Robert Apple
Name: Thomas S. McHugh Title: Chief Financial Officer	Name: Robert Apple Title: Chief Financial Officer and Chief Commercial Officer

[***] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

EXHIBIT A

INTENTIONALLY LEFT BLANK

[***] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

EXHIBIT B

[***]

[***] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

EXHIBIT C

[***]

[***] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

EXHIBIT D

[***]

[***] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

EXHIBIT E

[***]

[***] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

EXHIBIT F

[***]

[***] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

EXHIBIT G

[***]

Exhibit 21.1

AMAG Pharmaceuticals, Inc.

Subsidiaries of the registrant

AMAG Pharmaceuticals Canada Corporation, a Nova Scotia unlimited liability company

AMAG Europe Limited, a UK private limited company

AMAG Securities Corporation, a Massachusetts corporation

Lumara Health Inc., a Delaware corporation

FP1096, Inc., a Pennsylvania corporation

Lumara Health IP Ltd., a Delaware corporation

Drugtech Sárl, a Swiss company

Lumara Health Services Ltd., a Missouri corporation

CBR Acquisition Holdings Corp., a Delaware corporation

Cbr Systems, Inc., a Delaware corporation

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statements on Forms S-3 (File Nos. 333-192132, 333-202009 and 333-202252) and Forms S-8 (File Nos. 333-82292, 333-131656, 333-148682, 333-159938, 333-168786, 333-182821, 333-190435, 333-197873 and 333-203924) of AMAG Pharmaceuticals, Inc. of our report dated February 24, 2016 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 24, 2016

Exhibit 31.1

CERTIFICATIONS

I, William K. Heiden, certify that:

1. I have reviewed this Annual Report on Form 10-K of AMAG Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 24, 2016

/s/ William K. Heiden
William K. Heiden
Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATIONS

I, Frank E. Thomas, 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 24, 2016

/s/ Frank E. Thomas
Frank E. Thomas
President and Chief Operating Officer
(principal financial officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of AMAG Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, William K. Heiden, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ William K. Heiden
William K. Heiden
Chief Executive Officer
(principal executive officer)
Dated: February 24, 2016

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of AMAG Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Frank E. Thomas, President and Chief Operating 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/ Frank E. Thomas
Frank E. Thomas
President and Chief Operating Officer (principal financial officer)
Dated: February 24, 2016