AMAG PHARMACEUTICALS INC.
Form 10-K
March 01, 2019
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

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FORM 10-K
(Mark One)

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

For the Fiscal Year Ended December 31, 2018
or

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

For the transition period from to
Commission file number 001-10865
AMAG PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	04-2742593
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
1100 Winter Street Waltham, Massachusetts (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 x
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 x
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 x No ¨
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes x No ¨
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.
Large accelerated filer x Accelerated filer ¨ Non-accelerated filer ¨ Smaller reporting company ¨

Emerging growth company¨

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

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

The aggregate market value of the registrant's voting stock held by non-affiliates as of June 29, 2018 was approximately $664.2 million based on the closing price of $19.50 of the Common Stock of the registrant as reported on the NASDAQ Global Select Market on such date. As of February 25, 2019, there were 34,713,130 shares of the registrant's Common Stock, par value $0.01 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

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

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PART I

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

Examples of forward-looking statements contained in this report include, without limitation, statements regarding the following:

- our plans regarding the growth potential of our portfolio and our ability to identify additional product candidates;
- beliefs regarding the expenses, challenges and timing of our preclinical studies and clinical trials, including expectations regarding the clinical trial results for ciraparantag;
- beliefs regarding our commercial strategies, including the impact of our efforts to convert current Makena IM prescribers to the Makena auto-injector and the timing of the commercial launch of Vyleesi;
- our estimates and beliefs regarding the market opportunities for each of our products and product candidates;
- beliefs about and expectations for our commercialization, marketing and manufacturing of our products and product candidates (which may be conducted by third parties), if approved, including plans to raise awareness and education of dyspareunia, VVA and HSDD and the results of such efforts;
- the timing and amounts of milestone and royalty payments;
- expectations and plans as to recent and upcoming regulatory and commercial developments and activities, including requirements and initiatives for clinical trials and post-approval commitments for our products and product candidates, and their impact on our business and competition;
- expectations for our intellectual property rights covering our product candidates and technology and the impact of generics and other competition could have on each of our products and our business generally, including the timing and number of generic entrants;
- developments relating to our competitors and our industry, including the impact of government regulation;
- expectations regarding third-party reimbursement and the behaviors of payers, healthcare providers, patients and other industry participants, including with respect to product price increases and volume-based and other rebates and incentives;
- plans regarding our sales and marketing initiatives, including our contracting, pricing and discounting strategies and efforts to increase patient compliance and access;
- expectations regarding the contribution of revenues from our products to the funding of our on-going operations and costs to be incurred in connection with revenue sources to fund our future operations;
- expectations regarding customer returns and other revenue-related reserves and accruals;
- expectations as to the manufacture of drug substances, drug and biological products and key materials for our products and product candidates;
- the expected impact of recent tax reform legislation and 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;
- expectations regarding our financial performance and our ability to implement our strategic plans for our business;
- estimates and beliefs related to our 2022 Convertible Notes and the manner in which we intend or are required to settle the 2022 Convertible Notes;
- estimates, beliefs and judgments related to the valuation of certain intangible assets, goodwill, contingent consideration, debt and other assets and liabilities, including our impairment analysis and our methodology and assumptions regarding fair value measurements; and
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beliefs regarding the impact of our recent restructuring initiative, including the impact of the combination of our women's and maternal health sales forces and the related reduction in head count.

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.

AMAG Pharmaceuticals® and Feraheme® are registered trademark of AMAG Pharmaceuticals, Inc. Vyleesi™ is a trademark of AMAG Pharmaceuticals, Inc. MuGard® is a registered trademark of Abeona Therapeutics, Inc. Makena® is a registered trademark of AMAG Pharma USA, Inc. Intrarosa® is a registered trademark of Endoceutics, Inc. Other trademarks referred in this report are the property of their respective owners.

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ITEM 1. BUSINESS:

Overview

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a pharmaceutical company focused on bringing innovative products to patients with unmet medical needs by leveraging our development and commercial expertise to invest in and grow our pharmaceutical products across a range of therapeutic areas. Our currently marketed products support the health of patients in the areas of maternal and women's health, anemia management and cancer supportive care, including Feraheme® (ferumoxytol injection) for intravenous ("IV") use, Makena® (hydroxyprogesterone caproate injection), Intrarosa® (prasterone) vaginal inserts and MuGard® Mucoadhesive Oral Wound Rinse. In addition to our marketed products, our portfolio includes three product candidates, Vyleesi™ (bremelanotide), which is being developed for the treatment of hypoactive sexual desire disorder ("HSDD") in pre-menopausal women, AMAG-423 (digoxin immune fab (ovine)), which is being studied for the treatment of severe preeclampsia, and ciraparantag, which is being studied as an anticoagulant reversal agent. On January 16, 2019, we acquired ciraparantag with our acquisition of Perosphere Pharmaceuticals Inc. ("Perosphere"), a privately-held biopharmaceutical company pursuant to an Agreement and Plan of Merger (the "Perosphere Agreement"). Ciraparantag is an anticoagulant reversal agent in development for patients treated with novel oral anticoagulants ("NOACs") or low molecular weight heparin ("LMWH") when reversal of the anticoagulant effect of these products is needed for emergency surgery, urgent procedures or due to life-threatening or uncontrolled bleeding. For additional information, see below under the heading "Collaboration, License and Other Strategic Agreements - Ciraparantag."

On August 6, 2018, we completed the sale of our wholly-owned subsidiary, CBR Acquisition Holdings Corp, and the Cord Blood Registry® ("CBR") business to GI Partners ("GI"), a private equity investment firm, pursuant to the June 14, 2018 Stock Purchase Agreement between us and affiliates of GI. We received $519.3 million in cash at closing and recognized a gain of $87.1 million on the sale during the year ended December 31, 2018. Since August 2015, we had provided services related to the preservation of umbilical cord blood stem cell and cord tissue units operated through CBR. For additional information, see Note C, "Discontinued Operations and Held for Sale", to our consolidated financial statements included in this Annual Report on Form 10-K.

We intend to continue to expand the impact of our current and future products for patients by delivering on our growth strategy, which includes collaborating on and acquiring promising therapies at various stages of development, and advancing them through the clinical and regulatory process to deliver new treatment options to patients. Our primary sources of revenue are from sales of Makena, Feraheme and Intrarosa.

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

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Products and Product Candidates

The following table summarizes the current uses and, subject to regulatory approval, potential uses of the products and product candidates we own or to which we have rights, their current regulatory status and the nature of our rights. Currently, we market and sell our pharmaceutical products solely in the U.S.

Products and Product Candidates	Uses and Potential Uses	Regulatory Status	Nature of Rights
Feraheme® (ferumoxytol injection)	IV iron replacement therapeutic agent for the treatment of iron deficiency anemia ("IDA") in adult patients (a) who have intolerance to oral iron or have had unsatisfactory response to oral iron or (b) who have chronic kidney disease ("CKD").	Approved and marketed.	Own worldwide rights.
Makena® (hydroxyprogesterone caproate injection) (Intramuscular presentations (5 mL multi-dose vial and 1 mL single-dose preservative-free vial) and auto-injector presentation)	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.	Exclusively license rights to auto-injector device for use in the Makena subcutaneous auto-injector presentation (the "Makena auto-injector") from Antares Pharma, Inc. ("Antares"). Granted Prasco, LLC ("Prasco") an exclusive, non-sublicensable, nontranferable license to purchase, distribute and sell a generic version of Makena in the U.S. ("the Makena authorized generic").
Intrarosa®(prasterone) vaginal inserts	A steroid indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy ("VVA"), due to menopause.	Approved and marketed.	Exclusively license rights to develop and commercialize Intrarosa in the U.S. for the treatment of VVA and female sexual dysfunction ("FSD") from Endoceutics, Inc. ("Endoceutics"), subject to certain rights retained by Endoceutics.
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").
Vyleesi™ (bremelanotide)			

(Auto-injector device)	An investigational product designed to be an on demand therapy for the treatment of HSDD in pre-menopausal women.	New Drug Application ("NDA") accepted in June 2018. Prescription Drug User Fee Act ("PDUFA") date is June 23, 2019.	Exclusively license rights to research, develop and sell Vyleesi in North America from Palatin Technologies, Inc. ("Palatin").
AMAG-423 (digoxin immune fab (ovine))	A polyclonal antibody in development for the treatment of severe preeclampsia in pregnant women.	Phase 2b/3a trial ongoing. Received Fast Track and orphan drug designations.	Own worldwide rights.
Ciraparantag	A small molecule anticoagulant in development as a reversal agent for patients treated with NOACs or LMWH when reversal of the anticoagulant effect of these products is needed for emergency surgery, urgent procedures or due to life-threatening or uncontrolled bleeding.	Finalizing Phase 2 trials and plan to initiate Phase 3a trial in the second half of 2019. Received Fast Track designation.	Own worldwide rights.

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Feraheme

Overview

Feraheme received approval from the U.S. Food and Drug Administration (the "FDA") in June 2009 for the treatment of IDA in adult patients with CKD. In February 2018, the FDA approved the supplemental New Drug Application ("sNDA") to expand the label to include all eligible adult IDA patients who have intolerance to oral iron or have had unsatisfactory response to oral iron in addition to patients who have CKD. With the expanded Feraheme label, we have seen and expect to continue to see increased utilization within hematology and oncology clinics and hospitals, and may also see incremental usage within gynecologists and gastroenterologists. In 2018, sales of Feraheme accounted for approximately 28% of our total net revenues.

The expanded Feraheme label was supported by two positive pivotal Phase 3 trials, which evaluated Feraheme versus iron sucrose or placebo in a broad population of patients with IDA and positive results from a third Phase 3 randomized, double-blind non-inferiority trial that evaluated the incidence of moderate-to-severe hypersensitivity reactions (including anaphylaxis) and moderate-to-severe hypotension with Feraheme compared to Injectafer® (ferric carboxymaltose injection) (the "Feraheme comparator trial"). The Feraheme comparator trial demonstrated comparability to Injectafer® based on the primary composite endpoint of the incidence of moderate-to-severe hypersensitivity reactions (including anaphylaxis) and moderate-to-severe hypotension (Feraheme incidence 0.6%; Injectafer® incidence 0.7%). Adverse event rates were similar across both treatment groups; however, the incidence of severe hypophosphatemia (defined by blood phosphorous of <0.2 mg/dl at week 2) was less in the patients receiving Feraheme (0.9% of patients) compared to those receiving Injectafer® (50.8% of patients).

Iron Deficiency Anemia

Currently there are two common methods of iron therapy used to treat IDA: oral iron supplements and IV iron. Oral iron is the first-line iron replacement therapy for most physicians. However, oral iron supplements are poorly absorbed and not well tolerated by some 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 delivered to patients in a shorter time frame while avoiding many of the side effects and treatment compliance issues associated with oral iron, and can result in faster rises in hemoglobin levels. We believe that IV iron is underutilized in IDA patients, and thus a significant opportunity remains to grow the market for IV iron in this patient population.

IDA is prevalent in many different patient populations. For many of these patients, treatment with oral iron is unsatisfactory or is not tolerated. It is estimated that approximately five million people in the U.S. have IDA and we estimate that a small fraction of the patients who are diagnosed with IDA regardless of the underlying cause are currently being treated with IV iron. We estimate that the size of the total 2018 U.S. non-dialysis IV iron replacement therapy market was approximately 1.3 million grams, including patients with IDA due to CKD, gastrointestinal diseases or disorders, inflammatory diseases, chemotherapy-induced anemia and abnormal uterine bleeding ("AUB").

- Chronic Kidney Disease: CKD is a progressive condition that leads to chronic and permanent loss of kidney function. It contributes to the development of many complications, including anemia, hypertension, fluid and electrolyte imbalances, acid/base abnormalities, bone disease and cardiovascular disease. Anemia, a common condition among CKD patients, is associated with cardiovascular complications, decreased quality of life, hospitalizations, and increased mortality. Anemia can develop early during the course of CKD and worsens with advancing kidney disease.

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Gastrointestinal Disease: It is estimated that among IDA patients referred to gastroenterologists, the rate of gastrointestinal pathology was found to be approximately 40% - 80%. IDA in patients with gastrointestinal diseases is likely caused by blood loss and/or the inadequate intake or absorption of iron. Oral iron has been used to treat IDA in patients with gastrointestinal diseases, but its efficacy is variable due to inconsistent bioavailability and absorption, the high incidence of gastrointestinal side effects and patient noncompliance.

Cancer and chemotherapy-induced anemia: IDA is also common in patients with cancer, and it is estimated that 32% - 60% of cancer patients have iron deficiency, most of whom are anemic. Iron supplementation through both oral and IV administration plays an important role in treating anemia in cancer patients. While there may be some differences in the underlying causes of anemia and iron deficiency in cancer patients who are receiving chemotherapy and those who are not, patients in both categories may develop IDA due to blood loss and/or the inadequate intake or absorption of iron. Oral iron has been used to treat IDA in cancer patients, but its efficacy is variable due to inconsistent bioavailability and absorption, a high incidence of gastrointestinal side effects, potential interactions with other

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

- Abnormal Uterine Bleeding: IDA is commonly associated with AUB, which is defined as menstrual flow outside of normal volume, duration, regularity, or frequency. AUB can result from multiple underlying causes, including uterine abnormalities, blood disorders, pregnancy, intrauterine devices, and certain medications. IDA in patients with AUB, regardless of the cause, requires treatment with iron supplementation, either by oral or IV administration.

Post-Approval Commitments for Feraheme

As part of our post-approval Pediatric Research Equity Act ("PREA") requirement to support pediatric labeling of Feraheme for the treatment of CKD, we had initiated a randomized, active-controlled pediatric study of Feraheme for the treatment of IDA in pediatric CKD patients. During 2015, we suspended this trial due to difficulty in enrollment. In December 2016, we met with the FDA to advance the development of a plan in order to satisfy this post-approval commitment for Feraheme and following continued interactions with the FDA regarding the adequacy of our proposed protocol, we amended the protocol and initiated a new pediatric study in 2018. Further, as part of our post-approval PREA requirement to support pediatric labeling of Feraheme for the treatment of IDA for the broader label, we submitted a final protocol to the FDA in mid-2018 with the final report submission due to the FDA in November 2022.

Makena

Overview

Makena is indicated to reduce the risk of preterm birth in women pregnant with a single baby who have a history of singleton spontaneous preterm birth. We acquired the rights to Makena in connection with our acquisition of Lumara Health Inc. ("Lumara Health") in November 2014.

Makena was approved by the FDA in February 2011 as an intramuscular ("IM") injection (the "Makena IM product") packaged in a multi-dose vial and in February 2016 as a single-dose preservative-free vial. The orphan drug exclusivity period that was granted to the Makena IM product in 2011 expired in February 2018. In February 2018, the Makena auto-injector was approved by the FDA for administration via a pre-filled subcutaneous auto-injector, a drug-device combination product. The Makena auto-injector offers an alternative administration option for patients and providers and was designed with features, such as a shorter, thinner, non-visible needle compared to the Makena IM product, to help address some of the known barriers to treatment of recurrent preterm birth, including the lack of patient acceptance and adherence. Our commercial strategy for Makena currently focuses on driving awareness of the availability and attributes of the Makena auto-injector and converting current IM prescribers to the Makena auto-injector.

In July 2018, simultaneously with the launch of the first generic competitor to Makena, we launched our own authorized generic of both the single- and multi-dose vials through our generic partner, Prasco. As a result of this partnership, we are able to provide patients and healthcare providers with access to therapeutically equivalent versions of the branded Makena IM injection. Currently, there are two generic competitors in the market in addition to the Makena authorized generic product, and we expect additional generic entrants to enter the market in 2019 to compete against both the 1ml and 5ml presentations.

Makena is administered weekly by a healthcare professional with treatment beginning between 16 weeks and 20 weeks and six days of gestation and continuing until 36 weeks and six days of gestation or delivery, whichever happens first. The most common side effects of Makena IM product include injection site reactions (pain, swelling, itching, bruising, or a hard bump), hives, itching, nausea, and diarrhea. The most common side effect reported after a single dose of the Makena auto-injector in healthy post-menopausal women was injection site pain. We currently sell Makena primarily to specialty pharmacies, specialty distributors, and pharmacies which, in turn, sell Makena to healthcare providers, hospitals, government agencies and integrated delivery networks. In 2018, sales of Makena, including the Makena authorized generic, accounted for approximately 68% of our total net revenues.

Preterm Birth

Makena is a progestin whose active ingredient is hydroxyprogesterone caproate ("HPC"), which is a synthetic chemical structurally related to progesterone. Progestins, such as HPC, and progesterone belong to a class of drugs called progestogens. Progestogens have been studied to reduce preterm birth and have shown varying results depending upon the subjects enrolled. The Society for Maternal Fetal Medicine (the "SMFM") Publications Committee published clinical guidelines for the use of progestogens to reduce the risk of preterm birth in the American Journal of Obstetrics and Gynecology in May 2012, and which

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

Preterm birth is defined as a birth prior to 37 weeks of pregnancy. According to the Centers of Disease Control and Prevention (the "CDC"), preterm birth affected nearly 400,000 babies born in the U.S. in 2016, or one of every ten infants, with approximately 70% considered late preterm births. In the CDC's September 2017 National Center for Health Statistics Report, it noted that the preterm birth rate rose in 2016 for the second straight year and attributed the rise primarily to an increase in late preterm births, defined as a birth between 34 and 36 weeks of pregnancy. Although the causes of preterm birth are not fully understood, certain women are at a greater risk for preterm birth, including those who have had a previous preterm birth, are pregnant with multiples or have certain uterine or cervical problems. High blood pressure, pregnancy complications (such as placental problems) and certain other health or lifestyle factors may also be contributing factors. Makena is indicated only for use in women who have a history of singleton spontaneous preterm birth who are pregnant with a single baby, which accounts for approximately 140,000 pregnancies annually in the U.S.

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

Post-Approval Commitments for Makena

Makena was approved under the provisions of the FDA's "Subpart H" Accelerated Approval regulations. The Subpart H regulations allow certain drugs, for serious or life-threatening conditions, to be approved on the basis of surrogate endpoints or clinical endpoints other than survival or irreversible morbidity. As a condition of approval under Subpart H, the FDA required that Makena's sponsor perform certain adequate and well-controlled post-approval clinical studies to verify and describe the clinical benefit of Makena as well as fulfill certain other post-approval commitments. We have recently completed enrollment and follow up of the confirmatory clinical study of Makena and expect to release the data by the end of the first quarter of 2019. A follow-up study of the babies born to mothers from the efficacy and safety clinical study is currently ongoing. We expect to complete the follow up study by July 2020.

Intrarosa

Overview

In February 2017, we entered into a license agreement (the "Endoceutics License Agreement") with Endoceutics pursuant to which Endoceutics granted us the U.S. rights to Intrarosa, an FDA-approved product for the treatment of moderate to severe dyspareunia (pain during sexual intercourse), a symptom of VVA, due to menopause. Intrarosa was approved by the FDA in November 2016 and was launched commercially in July 2017.

Intrarosa is the only FDA-approved vaginal non-estrogen treatment indicated for the treatment of moderate to severe dyspareunia, a symptom of VVA, due to menopause. Intrarosa contains prasterone, a synthetic form of dehydroepiandrosterone ("DHEA"), which is an inactive endogenous (i.e. occurring in the body) sex steroid. Prasterone is converted by enzymes in the body into androgens and estrogens to help restore the vaginal tissue as indicated by improvements in the percentage of superficial cells, parabasal cells, and pH. The mechanism of action of Intrarosa is

not fully established. The effectiveness of Intrarosa on moderate to severe dyspareunia in post-menopausal women was examined in two primary 12-week placebo-controlled efficacy trials. Women who used Intrarosa in these trials experienced a significant reduction in moderate to severe dyspareunia, as well as statistically significant improvements in the percentage of vaginal superficial cells, parabasal cells and vaginal pH. In these trials, vaginal discharge and atypical pap smears were the most common adverse reactions. Intrarosa is contraindicated in women with undiagnosed abnormal genital bleeding. The label for Intrarosa contains a precaution that it has not been studied in women with a history of breast cancer.

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Vulvar and Vaginal Atrophy and Dyspareunia

In the U.S., there are an estimated 64 million post-menopausal women, with approximately half, or 32 million, of those women suffering from symptoms of VVA. Of the 32 million women who suffer from symptoms of VVA, we estimate there are approximately 20 million women in the U.S. who suffer from dyspareunia, a symptom of VVA, the majority of which we believe suffer from moderate to severe dyspareunia. We estimate that of those women, only 1.7 million are currently being treated with prescription therapy. The Women's Health Initiative, a long-term national health study, which focused on strategies related to estrogen replacement therapy in post-menopausal women, led to class labeling for all estrogen-containing products, including a boxed safety warning. Intrarosa is not subject to a boxed warning nor any limitations to duration of use as are all other currently approved prescription products to treat VVA.

Vyleesi

Overview

In January 2017, we entered into a license agreement (the "Palatin License Agreement") with Palatin pursuant to which we acquired Vyleesi, an investigational product designed to treat acquired generalized HSDD in pre-menopausal women. In June 2018, the FDA accepted the Vyleesi NDA. The current PDUFA date for completion of FDA review of the Vyleesi NDA is June 23, 2019, and if approved on that date, we expect to launch Vyleesi in the second half of 2019. In November 2018, as part of our discussions with the FDA regarding its review of the NDA submission for Vyleesi, the FDA requested additional data assessing 24-hour ambulatory blood pressure with short-term daily use of Vyleesi. This Phase 1 study is ongoing and is being conducted in premenopausal healthy volunteers. We believe that this study can be conducted and data submitted prior to the June 23, 2019 PDUFA date.

Vyleesi, a melanocortin 4 receptor agonist is designed to be an on demand therapy used in anticipation of sexual activity and self-administered by premenopausal women with HSDD in the thigh or abdomen via a single-use subcutaneous auto-injector. Two identically-designed Phase 3 studies evaluating the safety and efficacy of Vyleesi compared to placebo were conducted by Palatin for the treatment of HSDD in pre-menopausal women. Both trials consisted of a 24-week double-blind, placebo-controlled, randomized parallel group core study phase, comparing a subcutaneous dose of 1.75 mg Vyleesi versus placebo, self-administered via an auto-injector, on demand, and patients were equally randomized (1:1 ratio) to either Vyleesi or placebo. The co-primary endpoints for these trials were evaluated using patient self-reported scores from Question One and Two of the Female Sexual Function Index: Desire Domain ("FSFI-D") and Question 13 from the Female Sexual Distress Scale-Desires/Arousal/Orgasm ("FSDS-DAO"). Women who completed the randomized control core study phase of either study had the option to continue in an ongoing open-label safety extension phase of the study for an additional 52 weeks, which gathered additional data on the safety of long-term and repeated use of Vyleesi. Nearly 80% of patients who completed the randomized portion of the study elected to remain in the open-label portion of the study. All of the patients in the extension study received Vyleesi.

Both studies met the pre-specified co-primary efficacy endpoints of improvement in low sexual desire and decrease in related distress as measured using validated patient-reported outcome instruments. For women taking Vyleesi compared to placebo, the change from baseline in low sexual desire, as measured by the FSFI-D, showed statistically significant improvement with Vyleesi in both median and mean measures of desire in both Phase 3 studies. The median change from baseline was 0.60 vs. 0.00 for both studies, and the mean change from baseline was 0.54 vs. 0.24 ($p=0.0002$) for one study and 0.63 vs. 0.21 ($p<0.0001$) for the other study. Likewise, for women taking Vyleesi compared to placebo, the change from baseline in related distress, as measured by the FSDS-DAO Question 13, also demonstrated statistically significant improvement with Vyleesi in both median and mean measures of desire in both Phase 3 studies. The median change from baseline was -1.0 vs. 0.0 for both studies, and the mean change from baseline was -0.7 vs. -0.4 for both studies, with pValues of <0.0001for one study and 0.0053 for the other study. The

change in the number of satisfying sexual events, a key secondary endpoint, was not significantly different from placebo in either clinical trial.

In the Phase 3 clinical trials, the most frequent adverse events were nausea, flushing, injection site reactions and headache, which were generally mild-to-moderate in severity and were transient. Approximately 18% of patients discontinued participation in the Vyleesi arm due to adverse events in both studies versus 2% in placebo. The adverse events in the extension portion of the study were consistent with that of the controlled studies described above.

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Female Sexual Dysfunction and Hypoactive Sexual Desire Disorder

FSD is defined as persistent or recurring problems during one or more of the stages of a woman's sexual response. It is multi-dimensional and can be caused by physiological, psychological, emotional and/or relational factors. FSD can also have a major impact on a woman's sexual relationships, interpersonal relationships, quality of life, and even their general well-being. HSDD is the most common type of FSD and is characterized by a lack of sexual thoughts and desire for sexual activity, which causes a woman distress or puts a strain on the relationship with her partner, and cannot be accounted for by another medical, physical or psychiatric condition, co-morbidity of another condition or the effects of a medication. Studies suggest that approximately 15 million women in the U.S. are affected by HSDD and approximately 5.8 million of these women are pre-menopausal and have a primary diagnosis of HSDD. Despite one FDA-approved HSDD therapy on the market today for pre-menopausal women, we believe that patient awareness and understanding of the condition is extremely low, and that few women currently seek treatment. HSDD may go undiagnosed due to various factors such as embarrassment or stigma, lack of awareness of low sexual desire as a medical condition or attribution to other external factors, such as stress or fatigue. Market research commissioned by Palatin indicates that 95% of pre-menopausal women suffering from low desire with associated distress are unaware that HSDD is a treatable medical condition. As a result, assuming FDA approval of our NDA for Vyleesi, we expect that the initial focus of our Vyleesi commercialization efforts will be raising awareness and education about the disease for both healthcare professionals and patients with this disorder. During 2018, we launched an unbranded initiative to bring awareness of the HSDD condition to healthcare professionals. We are also working with and funding the Alliance for Advancing Women's Health, an organization seeking to improve outcomes for women's sexual health.

AMAG-423

Overview

In September 2018, we exercised our option to acquire the global rights to AMAG-423 pursuant to an option agreement entered into in July 2015 (the "Velo Agreement") with Velo Bio, LLC, a privately-held life sciences company ("Velo"). AMAG-423 is a polyvalent antibody currently in development for the treatment of severe preeclampsia in pregnant women and has been granted both orphan drug and Fast Track designations by the FDA. AMAG-423 is intended to bind to endogenous digitalis-like factors ("EDLFs") and remove them from the circulation. EDLFs appear to be elevated in preeclampsia and may play an important role in the pathogenesis of preeclampsia. By decreasing EDLFs, AMAG-423 is believed to improve vascular endothelial function and lead to better post-delivery outcomes in affected mothers and their babies.

We have assumed responsibility to complete the Phase 2b/3a clinical study that Velo initiated in the second quarter of 2017 and will incur all of the future clinical, regulatory and other costs required to pursue FDA approval. Approximately 200 antepartum women with severe preeclampsia between 23 and 32 weeks gestation will be enrolled in the multi-center, randomized, double-blind, placebo-controlled, parallel-group Phase 2b/3a study. We have re-initiated the study as the sponsor, and have begun reactivating the current sites, seeking new sites and, as of January 2019, enrolling new patients. Participants in the study receive either AMAG-423 or placebo intravenously four times a day over a maximum of four days. The study's primary endpoint is to demonstrate a reduction in the percentage of babies who develop severe intraventricular hemorrhage (bleeding in the brain), necrotizing enterocolitis (severe inflammation of the infant bowels) or death by 36 weeks corrected gestational age between the AMAG-423 and placebo arms. Secondary endpoints include the change from baseline in maternal creatinine clearance, maternal incidence of pulmonary edema during treatment and the period of time between treatment and delivery. In an effort to accelerate enrollment, we intend to increase the number of trial sites, including potentially initiating sites outside of the U.S., and are targeting to complete enrollment of the Phase 2b/3a study by the end of 2019.

Preeclampsia

Preeclampsia is a multi-system disorder that occurs only during pregnancy and the postpartum period and affects both the mother and baby. Preeclampsia is the leading cause of maternal morbidity and mortality and typically develops in women after 20 weeks of pregnancy and is characterized by elevated blood pressure, as well as vascular abnormalities, that can lead to end organ damage, intrauterine growth restriction and premature delivery. Premature delivery can lead to a number of serious health consequences for the infant, including intraventricular hemorrhage or necrotizing enterocolitis. Approximately 140,000 pregnant women in the U.S. are affected by preeclampsia, with approximately 50,000 impacted by severe preeclampsia, a more serious form of the condition that can be life threatening to both the mother and the baby. Severe preeclampsia can result in acute, as well as long-term, complications and a progressive deterioration in the clinical presentation for both the mother and the baby. There are currently no effective or FDA-approved treatments that address the underlying pathophysiology of preeclampsia or severe preeclampsia. The management of severe preeclampsia is focused on medications to address the symptoms, such as antihypertensives for the urgent control of severe hypertension and magnesium sulfate for the prevention of seizures as well as early delivery of the baby.

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Ciraparantag

In January 2019, we acquired Perosphere, a privately-held biopharmaceutical company focused on developing ciraparantag, a small molecule anticoagulant reversal agent in development as a single dose solution that is delivered intravenously to reverse the effects of certain NOACs (Xarelto®(rivaroxaban), Eliquis®(apixaban), and Savaysa®(edoxaban), as well as Lovenox® (enoxaparin sodium injection), a LMWH), when reversal of the anticoagulant effect of these products is needed for emergency surgery, urgent procedures or due to life-threatening or uncontrolled bleeding. Ciraparantag has been granted Fast Track designation by the FDA and we intend to seek orphan drug designation and Breakthrough Therapy designation in 2019.

Warfarin, a vitamin K antagonist, was the first FDA-approved oral anticoagulant and for over 60 years was the only oral anticoagulant used in the U.S. Although warfarin is effective in the prevention of thromboembolism, its use necessitates frequent blood monitoring, dose adjustments and dietary restrictions. The first FDA-approved NOAC was Pradaxa®(dabigatran), which was introduced to the U.S. market in 2010. Since then Xarelto®, Eliquis® and Savaysa® were approved by the FDA as an alternative mechanism of action to warfarin in inhibiting the body's ability to form blood clots. These NOACs offer similar efficacy to warfarin in reducing thromboembolism but are notably safer with respect to serious bleeding events and do not require monitoring for effectiveness.

The use of NOAC therapy represents the fastest-growing segment of the anticoagulant market in the U.S. with approximately six million patients in the U.S. and nine million patients in certain ex-U.S. countries currently on NOAC and LMWH therapy. In January 2019, the American Heart Association released updated guidelines recommending the use of NOACs over warfarin in the majority of patients with atrial fibrillation. Bleeding is the major complication of anticoagulant treatment, particularly for those patients coming in for emergency surgery or other urgent procedures. Approximately 1.5% to 2.0% of patients on NOACs are at risk for serious bleeding complications each year. Prior to 2015, there were no FDA-approved reversal agents for these anticoagulants. Currently, Praxbind®(idarucizumab) is approved for the reversal of Pradaxa® and AndexXa® (coagulation factor Xa (recombinant), inactivated-zhzo) is approved for the reversal of Eliquis® and Xarelto® and is also in development for the reversal of Savaysa® and Lovenox®.

Ciraparantag has been evaluated in more than 250 healthy volunteers across seven clinical trials. A first in human Phase 1 study evaluated the safety, tolerability, pharmacokinetic, and pharmacodynamic effects of ciraparantag alone and following a single dose of Savaysa®, and another Phase 1 study evaluated the overall metabolism of the drug. Two Phase 1/2 studies evaluated the safety, tolerability, pharmacokinetic, and pharmacodynamic effects related to the reversal of unfractionated heparin and Lovenox® and three Phase 2b randomized, single-blind, placebo-controlled dose-ranging studies evaluated the reversal of Savaysa®, Eliquis®, and Xarelto® to assess the safety and efficacy of ciraparantag, each of which included 12 subjects dosed with ciraparantag. The Phase 2b studies to reverse Xarelto® and Eliquis® are currently ongoing; however, both studies are approximately two-thirds complete, with the low dose cohort expected to finish in the first half of 2019. In these Phase 2b clinical trials, ciraparantag or placebo was administered to healthy volunteers in a blinded fashion after achieving steady blood concentrations of the respective anticoagulant. Pharmacodynamic assessments of whole blood clotting time ("WBCT"), an important laboratory measure of clotting capacity, were sampled frequently for the first hour post study drug dose, and then periodically thereafter out to 24 hours post administration of study drug. Key endpoints in the Phase 2 trials included mean change from baseline in WBCT and the proportion of subjects that returned to within 10% of their baseline WBCT. Subjects in these studies experienced a rapid and statistically significant ($p<0.001$) reduction in WBCT compared to placebo as early as 15 minutes after the administration of ciraparantag in each of the four studies and the effect was sustained for 24 hours. Moreover, in both the Eliquis® and Xarelto® studies, 100% of subjects in the highest dose cohorts (180 mg of ciraparantag) were responders, as defined by a return to within 10% of baseline WBCT within 30 minutes and sustained for at least six hours. Ciraparantag has been well tolerated in clinical trials, with the most common related

adverse events to date being mild sensations of coolness, warmth or tingling, skin flushing, and alterations in taste. There have been no drug-related serious adverse events to date.

Following the completion of the Phase 2b studies, we plan to conduct an End of Phase 2 meeting with the FDA to confirm the design of our Phase 3a trials in healthy volunteers, designed to determine the lowest effective dose of ciraparantag. We expect the Phase 3a program will include one Phase 3a trial for each of the four anticoagulants under investigation for ciraparantag reversal in which healthy volunteers will be brought to steady state on each of the anticoagulant (Xarelto®, Savaysa®, Eliquis®, and Lovenox®), and then administered ciraparantag. We expect the effects will be measured frequently by measuring WBCT using an automated coagulometer. The primary endpoint for the study is expected to be the proportion of subjects who return to within 10% of their baseline WBCT as well as safety outcomes. We intend to initiate the Phase 3a trials in the second half of 2019.

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The Phase 3a trials are expected to be followed by a Phase 3b/4 trial in patients who are currently taking Eliquis®, Xarelto®, Savaysa® or Lovenox® and experience life-threatening or uncontrolled bleeding or require an urgent procedure or surgery that necessitates rapid reversal of their anticoagulant. This trial is expected to evaluate the safety and effectiveness of ciraparantag in the target patient population focusing on the proportion of patients returning to normal WBCT and have evidence of hemostasis as determined by an adjudicated clinical evaluation. Based on previous precedent, we expect the trial to be an open label study with approximately 250 patients and believe that only a portion of the patients in the Phase 3b/4 trial will be required to complete the study at the time of our NDA submission. It is expected that the remainder of the study will be completed as a post-marketing commitment.

In addition, we have contracted with Perosphere Technologies Inc. ("Perosphere Technologies"), an independent company, which is developing an automated coagulometer designed to rapidly and accurately measure WBCT. Due to the variability of measuring WBCT manually, the coagulometer will be used in our Phase 3a and 3b/4 trials to measure WBCT, which is being used as a surrogate marker to demonstrate reversal of anticoagulation following ciraparantag administration. Prior to its use in our Phase 3a trial, Perosphere Technologies will be required to obtain an Investigational Device Exemption ("IDE") approval for its coagulometer, which will require Perosphere Technologies to show that the device is safe and effective to use in our clinical trials.

Perosphere is a party to a clinical trial collaboration agreement with a global pharmaceutical company under which Perosphere agreed to use commercially reasonable efforts to develop and commercialize ciraparantag for use as an anticoagulant reversal agent to reverse the effects of Savaysa®(edoxaban) and LMWH in the U.S. and the European Union ("EU"). Pursuant to this agreement, we have established a joint study management team to oversee studies and regulatory activities under the agreement and we are entitled to receive research and development milestone payments, anticipated in 2019 and 2020, if we complete certain clinical trial deliverables and for so long as we do not prioritize other specified development programs, or otherwise delay or hinder our efforts with Savaysa®. While this pharmaceutical company does not have any current commercial rights to ciraparantag, at its request, we are required to negotiate in good faith for the U.S. or EU. commercialization rights for ciraparantag if we have not otherwise entered into a licensing agreement or other arrangement.

MuGard

MuGard is indicated for the management of oral mucositis/stomatitis (that may be caused by radiotherapy and/or chemotherapy) and all types of oral wounds (mouth sores and injuries), including certain ulcers/canker sores and traumatic ulcers, such as those caused by oral surgery or ill-fitting dentures or braces. We acquired the U.S. commercial rights to MuGard under a June 2013 license agreement with Abeona (the "MuGard Rights"). MuGard was launched in the U.S. by Abeona in 2010 after receiving 510(k) clearance from the FDA.

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 assets in various stages of development. We are currently a party to the following collaborations and other arrangements:

Endoceutics

In February 2017, we entered into the Endoceutics License Agreement with Endoceutics to obtain an exclusive right to commercialize Intrarosa for the treatment of VVA and FSD in the U.S. We have agreed to use commercially reasonable efforts to market, promote and otherwise commercialize Intrarosa for the treatment of VVA and, if approved, FSD in the U.S. Endoceutics has the right to directly conduct additional commercialization activities for Intrarosa for the treatment of VVA and FSD in the U.S. and has the right to conduct activities related generally to the field of intracrinology, in each case, subject to our review and approval and our right to withhold approval in certain

instances. Each party's commercialization activities and budget are described in a commercialization plan, which is updated annually.

Under the terms of the Endoceutics License Agreement, we made an upfront payment of $50.0 million and issued 600,000 shares of unregistered common stock to Endoceutics, which had a value of $13.5 million, as measured on April 3, 2017, the date of closing. In addition, we paid Endoceutics $10.0 million in 2017 upon the delivery by Endoceutics of Intrarosa launch quantities and $10.0 million in 2018 following the first anniversary of the closing. Endoceutics is also eligible to receive certain sales milestone payments, including a first sales milestone payment of $15.0 million, which would be triggered when annual net U.S. sales of Intrarosa exceed $150.0 million, and a second milestone payment of $30.0 million, which would be triggered when annual net U.S. sales of Intrarosa exceed $300.0 million. If annual net U.S. sales of Intrarosa exceed $500.0 million, there are additional sales milestone payments totaling up to $850.0 million, which would be triggered at various sales thresholds. In

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addition, we pay tiered royalties to Endoceutics equal to a percentage of net sales of Intrarosa in the U.S. ranging from mid-teens for calendar year net sales up to $150.0 million to mid twenty percent for any calendar year net sales that exceed $1.0 billion (such royalty rate to be dependent on the aggregate annual net sales of Intrarosa in the U.S.) for the commercial life of Intrarosa, subject to certain deductions.

In the third quarter of 2017, Endoceutics initiated a clinical study with Intrarosa for the treatment of HSDD in post-menopausal women, which is now fully enrolled. Upon review of the full data set, it will be determined whether to continue to pursue an additional clinical trial to support an eventual filing with the FDA for an HSDD indication. We have agreed to share the direct costs related to such studies based upon a negotiated allocation with us funding up to $20.0 million, of which we have paid approximately $6.0 million.

The Endoceutics License Agreement grants us the right to develop and commercialize pharmaceutical products containing DHEA, including Intrarosa, at dosage strengths of 13 mg or less per dose and formulated for intravaginal delivery, excluding any combinations with other active pharmaceutical ingredients, in the U.S. for the treatment of VVA and FSD. Under the Endoceutics License Agreement, except for any compounds or products affecting the melanocortin receptor pathway, including without limitation, Vyleesi (collectively, “Excluded Products”), we are not permitted to research, develop, manufacture, or commercialize (a) DHEA for delivery by any route of administration anywhere in world, (b) any compound (including DHEA) or product for use in VVA anywhere in the world, or (c) commencing on the date of an approval of Intrarosa for the treatment of FSD in the U.S. and continuing for the remainder of the term of the Endoceutics License Agreement, any compound (including DHEA) for use in FSD (each, a “Competing Product”). Any compound or product for use in FSD that would be a Competing Product in the U.S. but that (a) does not contain DHEA and (b) was acquired or licensed or for which the research, development, manufacture or commercialization of such compound or product is initiated by us or our affiliates, in each case, prior to the date of an approval of Intrarosa for the treatment of FSD in the U.S., will be an Excluded Product and will not be subject to the exclusivity obligations under the Endoceutics License Agreement for the treatment of FSD, subject to certain restrictions in the Endoceutics License Agreement. These noncompete restrictions are subject to certain exclusions relating to the acquisition of competing programs.

The Endoceutics License Agreement expires on the date of expiration of all royalty obligations due thereunder unless earlier terminated, including by either party for material breach that is uncured after a 90-day notice period (subject to certain extensions and dispute resolutions provisions). Either party may terminate under certain situations relating to the bankruptcy or insolvency of the other party. We may terminate the Endoceutics License Agreement for a valid business reason upon 365 days prior written notice to Endoceutics; or upon 60 days written notice in the event we reasonably determine in good faith, after due inquiry and after discussions with Endoceutics, that we cannot reasonably continue to develop or commercialize the product as a result of a safety issue regarding the use of Intrarosa. We may also terminate the Endoceutics License Agreement upon 180 days’ notice if there is a change of control of AMAG and the acquiring entity (alone or with its affiliates) is engaged in a competing program (as defined in the Endoceutics License Agreement) in the U.S. or in at least three countries within the EU.

In April 2017, we entered into an exclusive commercial supply agreement with Endoceutics pursuant to which Endoceutics, itself or through affiliates or contract manufacturers, agreed to manufacture and supply Intrarosa to us (the “Endoceutics Supply Agreement”) and is our exclusive supplier of Intrarosa in the U.S., subject to certain rights for us to manufacture and supply Intrarosa in the event of a cessation notice or supply failure (as such terms are defined in the Endoceutics Supply Agreement). Under the Endoceutics Supply Agreement, Endoceutics has agreed to maintain at all times a second source supplier for the manufacture of DHEA and the drug product and to identify, validate and transfer manufacturing intellectual property to the second source supplier by April 2019. The Endoceutics Supply Agreement will generally remain in effect until the termination of the Endoceutics License Agreement.

Palatin

In January 2017, we entered into the Palatin License Agreement with Palatin under which we acquired (a) an exclusive license in all countries of North America (the "Palatin Territory"), with the right to grant sub-licenses, to research, develop and commercialize Vyleesi and any other products containing bremelanotide (collectively, the "Vyleesi Products"), (b) a worldwide non-exclusive license, with the right to grant sub-licenses, to manufacture the Vyleesi Products, and (c) a non-exclusive license in all countries outside the Palatin Territory, with the right to grant sub-licenses, to research and develop (but not commercialize) the Vyleesi Products.

Under the terms of the Palatin License Agreement, we made an upfront payment to Palatin of $60.0 million in February 2017 and subject to agreed-upon deductions, we reimbursed Palatin approximately $25.0 million for reasonable, documented, out-of-pocket expenses incurred by Palatin in connection with the development and regulatory activities necessary to submit an NDA in the U.S. for Vyleesi for the treatment of acquired HSDD in pre-menopausal women. In June 2018, our NDA

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submission to the FDA for Vyleesi was accepted, which triggered a $20.0 million milestone payment, which we paid to Palatin in the second quarter of 2018. In addition, the Palatin License Agreement requires us to make contingent payments of (a) $60.0 million upon FDA approval of Vyleesi, and (b) up to $300.0 million of aggregate sales milestone payments upon the achievement of certain annual net sales milestones over the course of the license. The first sales milestone payment of $25.0 million will be triggered when Vyleesi annual net sales exceed $250.0 million. We are also obligated to pay Palatin tiered royalties on annual net sales in North America of the Vyleesi Products, on a product-by-product basis, in the Palatin Territory ranging from the high-single digits to the low double-digits. The royalties will expire on a product-by-product and country-by-country basis upon the latest to occur of (a) the earliest date on which there are no valid claims of Palatin patent rights covering such Vyleesi Product in such country, (b) the expiration of the regulatory exclusivity period for such Vyleesi Product in such country and (c) ten years following the first commercial sale of such Vyleesi Product in such country. These royalties are subject to reduction in the event that: (x) we must license additional third-party intellectual property in order to develop, manufacture or commercialize a Vyleesi Product or (y) generic competition occurs with respect to a Vyleesi Product in a given country, subject to an aggregate cap on such deductions of royalties otherwise payable to Palatin. After the expiration of the applicable royalties for any Vyleesi Product in a given country, the license for such Vyleesi Product in such country would become a fully paid-up, royalty-free, perpetual and irrevocable license.

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

Velo

In September 2018, we exercised our option to acquire the global rights to AMAG-423 pursuant to an option agreement entered into in July 2015 with Velo, the terms of which were amended at the time of exercise. In connection with the exercise of the option and consummation of the acquisition, we have assumed responsibility to complete the Phase 2b/3a clinical study that Velo initiated in the second quarter of 2017 and will incur all of the clinical, regulatory and other costs required to pursue FDA approval. As part of the acquisition, in September 2018 we paid Velo an upfront option exercise fee of $12.5 million. We are obligated to pay Velo a $30.0 million milestone payment upon FDA approval of AMAG-423. In addition, we are obligated to pay sales milestone payments to Velo of up to $240.0 million in the aggregate, triggered at various annual net sales thresholds between $300.0 million and $900.0 million and low-single digit royalties based on net sales. Further, we have assumed additional obligations under a previous agreement entered into by Velo with a third-party, including a $5.0 million milestone payment upon regulatory approval and $10.0 million following the first commercial sale of AMAG-423, payable in quarterly installments as a percentage of quarterly gross commercial sales until the obligation is met. We are also obligated to pay the third-party low-single digit royalties based on net sales.

Perosphere

On January 16, 2019, we acquired Perosphere, a privately-held biopharmaceutical company focused on developing ciraparantag, a small molecule anticoagulant reversal agent. Pursuant to the Perosphere Agreement, in January 2019, we paid approximately $50.0 million, subject to adjustments for working capital, cash, transaction expenses and specified indebtedness, approximately $40.0 million of which was funded from our available cash and approximately $10.0 million of which was deemed paid in connection with the cancellation of a convertible note in the principal amount of $10.0 million issued to us by Perosphere in October 2018. The purchase price is subject to customary post-closing adjustments under the Perosphere Agreement. In addition, we used available cash to repay $12.0 million

of Perosphere's term loan indebtedness and assumed approximately $6.2 million of Perosphere's other liabilities. We are obligated to pay future contingent consideration of up to an aggregate of $365.0 million (the "Milestone Payments"), including (a) up to an aggregate of $140.0 million that becomes payable upon the achievement of specified regulatory milestones for ciraparantag (the "Regulatory Milestone Payments"), including a $40.0 million milestone payment upon approval of ciraparantag by the European Medicines Agency and (b) up to an aggregate of $225.0 million that becomes payable conditioned upon the achievement of specified sales milestones (the "Sales Milestone Payments"). If the final label approved for ciraparantag in the U.S. includes a boxed warning, the Regulatory Milestone Payments shall no longer be payable, and any previously paid Regulatory Milestone Payments shall be credited against 50% of any future Milestone Payments that otherwise becomes payable. The first Sales Milestone Payment of $20.0 million will be payable upon annual net sales of ciraparantag of at least $100.0 million. Additional details regarding the Perosphere Agreement can be found in Note W, "Subsequent Events," to our consolidated financial statements included in this Annual Report on Form-10-K.

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Prasco

In December 2017, we entered into a Distribution and Supply Agreement (the "Prasco Agreement") with Prasco, under which Prasco was granted an exclusive, non-sublicensable, nontranferable license to purchase, distribute and sell a generic version of Makena in the U.S. In July 2018, Prasco launched the Makena authorized generic of both the single-dose and multi-dose intramuscular injections. Under the Prasco Agreement, we are responsible for the manufacture and supply of the Makena authorized generic to be sold to Prasco at a predetermined supply price. Prasco is also required to pay us a certain percentage of the net distributable profits from the sale of the Makena authorized generic. Pursuant to the terms of the Prasco Agreement, in certain circumstances we have reimbursed and may be required to reimburse additional charges incurred by Prasco if we are unable to supply a certain percentage of product ordered by Prasco in a prespecified timeframe. The Prasco Agreement expires on July 2, 2022, which term will be automatically extended thereafter for additional one year periods, unless canceled by us or Prasco within an agreed-upon notice period. The Prasco Agreement is subject to early termination by us for convenience after a certain period of time or if Prasco is subject to a change of control or by either party for, among other things, uncured breach by or bankruptcy of the other party, lack of commercial viability or FDA notice, or by mutual agreement.

Antares

In connection with a development and license agreement (the "Antares License Agreement") with Antares we have an exclusive, worldwide, royalty-bearing license, with the right to sublicense, to certain intellectual property rights, including know-how, patents and trademarks, to develop, use, sell, offer for sale and import and export the Makena auto-injector. Under the terms of the Antares License Agreement, as amended in March 2018, we are responsible for the clinical development and preparation, submission and maintenance of all regulatory applications in each country where we desire to market and sell the Makena auto-injector, including the U.S. We are required to pay royalties to Antares on net sales of the Makena auto-injector for the Antares Royalty Term. The royalty rates range from high single digit to low double digits and are tiered based on levels of net sales of the Makena auto-injector and decrease after the expiration of licensed patents or where there are generic equivalents to the Makena auto-injector being sold in a particular country. In addition, we are required to pay Antares sales milestone payments upon the achievement of certain annual net sales. The Antares License Agreement terminates at the end of the Antares Royalty Term, but is subject to early termination by us for convenience and by either party upon an uncured breach by or bankruptcy of the other party. See below under "Manufacturing" for a description of the manufacturing agreement entered into with Antares in March 2018.

Abeona

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

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

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

Manufacturing

Overview

We do not own or operate facilities for the manufacture of our commercially distributed products or for our product candidates. We rely solely on third-party contract manufacturers and our licensors (who, in turn, may also rely on third-party contract manufacturers) to manufacture our products for our commercial and clinical use. Our third-party drug product contract manufacturing facilities, and those of our licensors, are subject to current good manufacturing practices (“cGMP”) and

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regulations enforced by the FDA through periodic inspections to confirm such compliance. We target to maintain, where possible, second source suppliers and/or sufficient inventory levels throughout our supply chain to meet our projected near-term demand for all of our products in order to minimize risks of supply disruption. We intend to continue to outsource the manufacture and distribution of our products for the foreseeable future, and we believe this manufacturing strategy will enable us to direct more of our financial resources to the commercialization and development of our products and product candidates.

To support the commercialization and development of our products, 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.

In connection with the acquisition of Perosphere, we assumed the lease on a development facility, which is not currently being utilized.

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 the API for use in the finished drug product of ferumoxytol for commercial sale as well as for use in clinical trials (as amended, the “SAFC Agreement”). Subject to certain conditions, the SAFC Agreement provides that we purchase all of our API from SAFC. The SAFC Agreement has an initial term that ends December 31, 2020, which may be automatically extended thereafter for additional two year periods, unless canceled by us or SAFC within an agreed-upon notice period.

We are party to a Pharmaceutical Manufacturing and Supply Agreement with Patheon, Inc. (“Patheon”) pursuant to which Patheon agreed to manufacture ferumoxytol finished drug product for commercial sale and for use in clinical trials (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.

We have also entered into a manufacturing and supply agreement with a second source supplier to produce ferumoxytol finished drug product in addition to Patheon, which second source supplier was approved by the FDA in 2019.

Makena

The Makena drug product for our commercial and clinical use is currently manufactured by Pfizer Inc. (“Pfizer”) (McPherson facility, formerly Hospira, Inc.) under a Development and Supply Agreement (as amended and restated, the “Pfizer Agreement”). The Pfizer Agreement requires that we satisfy certain minimum purchase requirements and expires on December 31, 2022, which term will be automatically extended thereafter for additional 18 month periods, unless canceled by us or Pfizer within an agreed-upon notice period. Due to continued manufacturing issues at the Pfizer McPherson manufacturing facility, we are currently experiencing a supply disruption of our Makena IM products, which has resulted in both our single-dose and multi-dose branded Makena vials being out-of-stock, as well as periodic supply disruptions and loss of market share for the authorized generic. We also have an agreement with a second source manufacturer for the Makena 1 mL drug product with Piramal Pharma Solutions (formerly Coldstream Laboratories, Inc.).

In June 2018, we entered into a commercial supply agreement with SAFC, Inc. ("SAFC Makena") to supply us with API for use in the finished Makena product (the "SAFC Makena Agreement"). The SAFC Makena Agreement requires that we satisfy certain minimum purchase requirements, but we are not obligated to use SAFC Makena as our sole supplier of Makena API. The SAFC Makena Agreement expires on June 4, 2021, which term will be automatically extended thereafter for additional two year periods, unless canceled by us or SAFC Makena within an agreed-upon notice period. The SAFC Makena Agreement may be terminated by either us or SAFC Makena 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 or insolvency by either party.

In June 2017, we entered into a product supply agreement with Pfizer (Kalamazoo facility) to supply us with the API for use in the finished Makena product (the "Pfizer API Agreement"). The Pfizer API Agreement requires that we satisfy certain minimum purchase requirements. The Pfizer API Agreement expires on June 1, 2020, which term will be automatically extended thereafter for additional one year periods, unless canceled by us or Pfizer within an agreed-upon notice period. The

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Pfizer API Agreement may be terminated by either us or Pfizer in the event of an uncured material breach by or insolvency of the other party.

Antares is the exclusive supplier for the auto-injection devices needed for the Makena auto-injector. In March 2018, we entered into the Antares Manufacturing Agreement that sets forth the terms and conditions pursuant to which Antares agreed to sell to us on an exclusive basis, and we agreed to purchase, the fully packaged Makena auto-injector for commercial distribution. Antares is responsible for the manufacture and supply of the device components and assembly of the Makena auto-injector and we are responsible for the supply of the Makena drug substance in pre-filled syringes to be used in the assembly of the finished auto-injector product. The Antares Manufacturing Agreement terminates at the expiration or earlier termination of the Antares License Agreement, but is subject to early termination by us for certain supply failure situations, and by either party upon an uncured breach by or bankruptcy of the other party or our permanent cessation of commercialization of the Makena auto-injector for efficacy or safety reasons.

In September 2018, we entered into a contract manufacturing agreement with Fresenius Kabi Austria GmbH (“Fresenius”) to manufacture the pre-filled syringes used in the Makena auto-injector product (the “Fresenius Agreement”). The Fresenius Agreement requires that we satisfy certain minimum purchase requirements, but we are not obligated to use Fresenius as our sole supplier of pre-filled syringes. The Fresenius Agreement will continue for a set period of time, including mutually agreed to additional renewals, but may be terminated by either us or Fresenius in the event of an uncured material breach by or insolvency of the other party, by Fresenius if we undergo a change of control to a competitor of Fresenius or by us if Fresenius fails to obtain or maintain any material government licenses or approvals.

Intrarosa

Under the terms of the Endoceutics Supply Agreement, Endoceutics, itself or through affiliates or contract manufacturers, agreed to manufacture and supply Intrarosa to us and is our exclusive supplier of Intrarosa in the U.S., subject to certain rights for us to manufacture and supply Intrarosa in the event of a cessation notice or supply failure. Endoceutics is developing internal manufacturing capabilities for Intrarosa, for which it expects to obtain approval in 2019, which would give them additional manufacturing capacity. The Endoceutics Supply Agreement will generally remain in effect until the termination of the Endoceutics License Agreement.

MuGard

Under the terms of the MuGard License Agreement, Abeona is responsible for all aspects of manufacturing MuGard. We have entered into a supply agreement with Abeona under which we purchase MuGard inventory from Abeona. Our inventory purchases are at the price actually paid by Abeona to purchase it from a third-party plus a mark-up to cover administration, handling and overhead.

Products in Development

Under the Palatin License Agreement, we assumed a long-term commercial supply agreement with Catalent Belgium S.A. for drug product manufacture and packaging services for Vyleesi. In June 2018, we entered into a commercial supply agreement with Lonza Ltd. to supply us with the API for use in the finished Vyleesi product. In addition, in December 2018, we entered into a commercial supply agreement with Ypsomed AG to supply us with the device components of the auto-injector for use in the finished Vyleesi product. All of these agreements have certain minimum purchase requirements.

We have recently entered into an exclusive agreement with Protherics UK Ltd, a subsidiary of BTG plc ("BTG"), for the manufacture of AMAG-423 drug substance for use in the AMAG-423 commercial product (the "BTG Agreement"). BTG has also agreed to supply drug product for our current ongoing clinical trial. BTG owns the rights to digoxin immune fab (ovine), the active ingredient of AMAG-423, which has been marketed in the U.S. for many years as an FDA-approved treatment for patients with life-threatening or potentially life-threatening digoxin toxicity or overdose. Under the terms of the BTG Agreement, we are required to differentiate our product from their product, DigiFab®, including without limitation, via labeling, dosage and/or formulation and if we are unable to show differentiation, we may be in breach of the agreement and be subject to penalties. In addition, the BTG Agreement provides that we satisfy certain minimum purchase requirements. We will need to enter into an additional agreement to manufacture AMAG-423 drug product, especially if it is approved and we need to meet commercial demand.

We have also assumed a commercial supply agreement with PolyPeptide Group for the supply of ciraparantag drug substance. We will need to enter into an additional agreement to manufacture ciraparantag drug product, especially if it is approved and we need to meet commercial demand.

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Raw Materials

We, our licensors and our respective third-party 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. Although certain of our raw or other materials are readily available, others may be obtained only from qualified suppliers. The qualification of an alternative source may require repeated testing of the new materials and generate greater expenses to us or our licensors if materials that we test do not perform in an acceptable manner. In addition, we, our licensors or our respective third-party manufacturers sometimes obtain raw or other materials from one vendor only, even where multiple sources are available, to maintain quality control and enhance working relationships with suppliers, which could make us susceptible to price inflation by the sole supplier, thereby increasing our production costs. As a result of the high-quality standards imposed on our raw or other materials, we, our licensors or our respective third-party manufacturers may not be able to obtain such materials of the quality required to manufacture our products 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 and product candidates. Our success depends, in large part, on our ability, and the ability of our licensors, collaborators and other business partners to maintain the proprietary nature of our technology and other trade secrets. To do so, we must prosecute and maintain existing patents, obtain new patents and ensure trade secret protection. We must also operate without infringing the proprietary rights of third parties or allowing third parties to infringe our rights. Our policy is to aggressively protect our competitive technology position by a variety of means, including applying for or obtaining rights to patents in the U.S. and in foreign countries.

One of our U.S. Feraheme patents received a patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, as amended, (the “Hatch-Waxman Act”) and will expire in June 2023, and the other U.S. patents relating to Feraheme will expire in 2020. In addition, in March 2018, we and Sandoz Inc. (“Sandoz”) entered a stipulation of dismissal pursuant to a settlement agreement that dismissed and resolved a patent infringement suit regarding an ANDA submitted to the FDA by Sandoz. According to the terms of the settlement, if Sandoz receives FDA approval of its ANDA by a certain date, Sandoz may launch its generic version of Feraheme on July 15, 2021, or earlier under certain circumstances customary for settlement agreements of this nature. Sandoz will pay a royalty on the sales of its generic version of Feraheme to us until the expiration of the last Feraheme patent listed in the Orange Book. If Sandoz is unable to secure approval by such date, Sandoz will launch an authorized generic version of Feraheme supplied by us on July 15, 2022 for up to 12 months. Sandoz’s right to distribute, and our obligation to supply, the authorized generic product shall be in accordance with standard commercial terms and profit splits.

Our U.S. patent related to the Makena auto-injector product will expire in 2036, and we have a pending patent application related to the Makena auto-injector product. In addition, we have a license to several U.S. patents and patent applications from Antares related to the Makena auto-injector device and drug-device combination with expiration dates between 2019 and 2034. Our issued patent and Antares’ eligible patents are listed in the Orange Book for the Makena auto-injector product. There are no issued patents covering the Makena IM product.

Under the Palatin License Agreement, we have exclusive rights to a number of U.S. and foreign patents and applications related to Vyleesi that are owned by Palatin. Certain of Palatin’s patents include claims directed to the Vyleesi drug composition of matter and methods of use thereof with terms expiring in 2020, and other patents include

claims directed to methods of treating FSD by subcutaneous administration of compositions that include Vyleesi with terms expiring in 2033. Any one of the issued U.S. patents may be granted up to five years of patent term extension (up to a maximum patent term of 14 years after regulatory approval) pursuant to the Hatch-Waxman Act. Whether any of these U.S. patents will be granted patent term extension under the Hatch-Waxman Act and the length of any such extension cannot be determined until a product covered by such patents receives FDA approval.

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

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extension.

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

Under the terms of the Velo Agreement, we obtained four issued U.S. patents covering methods of using AMAG-423 to treat women exhibiting symptoms of preeclampsia or eclampsia, each of which expires in November 2022, and several corresponding foreign patents that expire in 2023. Digoxin immune fab (ovine), the active ingredient of AMAG-423, has been approved and marketed in the U.S. for many years for a different indication and no longer has composition of matter patent protection. Accordingly, we do not have and will not be able to obtain composition of matter patent protection for AMAG-423. AMAG-423 has been granted orphan drug designation by the FDA and, if approved, we expect it to receive seven years of marketing exclusivity.

Additionally, under the terms of the Perosphere Agreement, we obtained two issued U.S. patents and several foreign patents related to ciraparantag. One U.S. patent includes claims directed to the ciraparantag drug composition of matter with a term that expires in 2034, and the other U.S. patent includes claims directed to methods of using ciraparantag to reverse the anticoagulation effect of certain coagulation inhibitors with a term that expires in 2032. All of the foreign patents expire in 2032. Either of the issued U.S. patents may be granted up to five years of patent term extension (up to a maximum patent term of 14 years after regulatory approval) pursuant to the Hatch-Waxman Act. Whether either of these U.S. patents will be granted patent term extension under the Hatch-Waxman Act and the length of any such extension cannot be determined until a product covered by such patents receives FDA approval.

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

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

Competition

The pharmaceutical industry is intensely competitive and subject to rapid technological change. Our existing or potential competitors for all our products have or may develop products that are more widely accepted than ours, are viewed as more safe, effective, convenient or easier to administer, have been on the market longer and have stronger patient/provider loyalty, have been approved for a larger patient population, are less expensive or offer more attractive insurance coverage, discounts, reimbursements, incentives or rebates and may have or receive patent protection that dominates, blocks, makes obsolete or adversely affects our product development or business.

Feraheme

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.

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

- Venofer®, an iron sucrose complex, which is approved for use in hemodialysis, peritoneal dialysis, non-dialysis dependent CKD patients and pediatric CKD patients and is marketed in the U.S. by Fresenius Medical Care North America and American Regent, Inc. (“American Regent”), a subsidiary of Luitpold Pharmaceuticals, Inc. (a business unit of Daiichi Sankyo Group);

- Injectafer®, a ferric carboxymaltose injection, which is approved to treat IDA in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron. Injectafer® is also indicated for IDA in adult patients with

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

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

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

- 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; and

- Auryxia® (ferric citrate), an oral phosphate binder, which is marketed by Keryx Biopharmaceuticals, Inc. (which recently merged with Akebia Therapeutics, Inc.), and which approved in the U.S. for the treatment of IDA in adult patients with CKD not on dialysis.

In addition to the currently marketed products described above, in the future Feraheme may also compete with Monoferric™ (iron isomaltoside 1000 for injection) (global brand name Monofer®), which is manufactured by Pharmacosmos A/S in over 30 countries outside the U.S., including Canada. Monoferric™ is under development in the U.S. and has completed its Phase III trials in which Monofer® was administered as a single 1,000 mg dose, which, if approved, may offer an alternative for patients. In addition, there are several hypoxia inducible factor stabilizers in various stages of development to treat anemia related to CKD that could potentially compete with Feraheme in the future, a number of which are currently in Phase III trials.

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

Companies that manufacture generic products typically invest far fewer resources in research and development than the manufacturers of branded products and can therefore price their products significantly lower than those branded products already on the market. Therefore, competition from generic IV iron products could limit our sales. Feraheme may face future competition from generic IV iron replacement therapy products. For example, under our settlement agreement with Sandoz, if Sandoz receives FDA approval by a certain date, Sandoz may launch its generic version of Feraheme on July 15, 2021, or earlier under certain circumstances customary for settlement agreements of this nature. If Sandoz is unable to secure approval by such date, Sandoz may launch an authorized generic version of Feraheme on July 15, 2022 for up to twelve months.

Based on sales data provided to us by IQVIA Holdings Inc. ("IQVIA"), we estimate that the size of the total 2018 U.S. non-dialysis IV iron replacement therapy market was approximately 1.3 million grams, which represents an increase of approximately 8.5% over 2017. During 2017 (and until February 2018), Feraheme competed exclusively in the CKD portion of this market, which we estimate is approximately half of the total market. Based on this IQVIA data, the following represents the 2018 and 2017 U.S. market share allocation of the total non-dialysis IV iron market based on the volume of IV iron administered:

2018 U.S. Non-dialysis IV Iron Market	2017 U.S. Non-dialysis IV Iron Market

	(1.3 million grams)	(1.2 million grams)
Venofer®	35%	35%
Injectafer®	33%	26%
Feraheme	15%	12%
INFeD®	6%	15%
Generic sodium ferric gluconate	9%	9%
Ferrlecit®	2%	3%

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

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Makena

Makena competition currently comes mainly from generic formulations of HPC injections as well as from pharmacies that compound a non-FDA approved version of Makena, both of which are sold at a much lower list price than our branded products. In early 2018, Makena's exclusivity period ended and since then two generic competitors have entered the market in addition to the Makena authorized generic product, marketed by Prasco. Currently, American Regent and Slayback Pharma LLC ("Slayback") sell generic versions of the Makena 1ml presentation and 5 ml presentations, respectively, and we expect additional generic entrants to enter the market as early as March 2019 to compete against both the 1ml and 5ml presentations.

The long-term success of the Makena franchise is highly dependent on our ability to maintain and grow the market share for the Makena auto-injector, which was approved for commercialization in February 2018, and which is intended to provide us with an alternative treatment method to the Makena IM product. Although there is no direct competition with the Makena auto-injector, the auto-injector competes for the same patients as generic versions of the Makena IM product, including the Makena authorized generic. We may not be able to continue to convince healthcare providers to use or to switch from using the IM method of administration to the auto-injector, including if healthcare providers are hesitant or apprehensive to use an auto-injector product due to perceptions regarding lack of improvement in safety, efficacy or pain associated with the Makena auto-injector or if the auto-injector is not priced competitively or is not provided comparable insurance coverage to the Makena IM product.

We also expect to continue to face competition for Makena from future generic products as well as products currently in development which offer additional formulations or routes of administration that doctors believe may reduce or prevent preterm birth, such as an oral HPC product, which is currently in development and has completed its End-of-Phase 2 meeting with the FDA.

Based on IQVIA data and internal analytics, we estimate that in the fourth quarter of 2018, the Makena branded products and the Makena authorized generic made up approximately 56% and 22% of the total prescriptions written for all FDA-approved HPC products, respectively. We also estimate that the generic marketed by American Regent generated approximately 22% of the total prescriptions written for all FDA-approved HPC products in the fourth quarter of 2018. In addition to FDA-approved products for the approved indication, other at-risk patients are treated with compounded formulations of HPC or 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.

Intrarosa

Intrarosa faces competition from the following approved products:

- Estrace® Cream (Estradiol vaginal cream, USP 0.01%) ("Estrace"), a vaginal cream for the treatment of VVA marketed by Allergan PLC;

- Estradiol® Vaginal Cream USP, 0.01% (generic version of Estrace®), including a generic marketed by Mylan N.V., which was launched in December 2017, a generic marketed by Teva Pharmaceuticals USA, Inc., a subsidiary of Teva Pharmaceutical Industries Ltd. ("Teva"), which was launched in early 2018, a generic marketed by Impax Laboratories, Inc., which was launched in mid-2018, and a generic marketed by Alvogen Inc., which was launched in mid-2018;

- Vagifem® (estradiol vaginal inserts) ("Vagifem"), a suppository marketed by Novo Nordisk A/S for the treatment of VVA;

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Estradiol vaginal inserts USP (generic versions of Vagifem®), including Yuvafem, which is marketed by Amneal Pharmaceuticals LLC, a generic marketed by Teva and a generic marketed by Glenmark Pharmaceuticals Inc.;

- Premarin Vaginal Cream®, a vaginal cream for the treatment of VVA marketed by Pfizer;

- Estring®(estradiol vaginal ring), a vaginal ring marketed by Pfizer for the treatment of VVA due to menopause;

- Osphena®, an oral therapy marketed by Duchesnay Inc. for the treatment of moderate to severe dyspareunia due to menopause;

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- IMVEXXY® (estradiol vaginal inserts), an estrogen indicated for the treatment of moderate to severe dyspareunia due to menopause, which was launched in mid-2018 and is marketed by TherapeuticsMD, Inc.; and

- Over the counter and compounded remedies that are marketed for dyspareunia and over the counter and compounded products that contain DHEA.

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

In addition, our ability to compete may be affected by the extent and scope of third-party reimbursement for products treating dyspareunia. Some of the products that Intrarosa competes with have a broader indication for VVA and receive reimbursement from governmental healthcare programs. Although we have been able to gain coverage for Intrarosa with commercial health plans, given the increasing number of generic competitors, payers may choose to selectively implement utilization management policies on Intrarosa. Intrarosa is covered as non-preferred and is one of many drugs available. As a result, patients do not receive full reimbursement by third-party commercial payers and may not receive any reimbursement from governmental healthcare programs. Many patients are therefore subject to substantial out-of-pocket costs.

In May 2018, Center for Medicare & Medicaid Services (“CMS”) issued guidelines clarifying the statutory intent of its prior policy to state that drugs for the treatment of moderate to severe dyspareunia due to menopause are not excluded from Medicare Part D coverage when used consistent with this labeling. Medicare formularies are highly cost sensitive, have long decision cycles, and tend to be limited in the number of products that are offered. Therefore, Medicare coverage for Intrarosa may continue to be limited. Less than full reimbursement by governmental and other third-party payers may adversely affect the market acceptance of Intrarosa and put it at a competitive disadvantage to some of the competing products, including generic versions of estrogens and compounded products, which are often priced lower than branded products.

MuGard

There are currently few effective treatments for the treatment or management of oral mucositis. The market for treating oral mucositis is driven primarily by convenience, price and reimbursement and the products in this market remain mostly undifferentiated. There are a number of approaches used to treat or manage oral mucositis that compete with MuGard, including the use of ice chips during chemotherapy treatments, various medicinal mouthwashes, topical anesthetics and 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.

Vyleesi

If Vyleesi is approved for marketing by the FDA and if we are successful in launching and commercializing it, we expect Vyleesi will face competition. Addyi® (flibanserin) was introduced into the market in October 2015 for the treatment of HSDD in pre-menopausal women and is marketed by Sprout2 Inc. (“Sprout”). Addyi® is only available through a risk evaluation and mitigation strategy (“REMS”) program because of an increased risk of severe hypotension

and syncope due to the interaction between Addyi® and alcohol. In addition, Addyi® was approved with a boxed warning to highlight the risks of severe hypotension and syncope in patients who drink alcohol during treatment with Addyi®, in patients who use Addyi® with moderate or strong CYP3A4 inhibitors, or in patients who have liver impairment.

We are not aware of any company actively developing another melanocortin receptor agonist drug for the treatment of HSDD. However, we are aware of several other drugs at various stages of development, most of which are being developed to be taken on a chronic, typically once-daily, basis. Emotional Brain BV, a Netherlands company, is developing two different oral fixed-dose, on-demand combination drugs, one a combination of sildenafil (the active ingredient in Viagra) and testosterone and the other a combination of testosterone and buspirone hydrochloride, and has conducted Phase 2b studies. There may be other companies developing new drugs for FSD indications, some of which may be in clinical trials in the U.S. or elsewhere, or other companies which may sell their products off-label for indications other than FSD.

While we believe that Vyleesi will have competitive advantages for treating HSDD, such as on demand use and length of the therapeutic effect compared to chronic or daily use hormones and other drugs, we may not be able to realize these perceived

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advantages in the market, in part because Vyleesi is administered by subcutaneous auto-injection. While the single-use, disposable auto-injector format is designed to maximize market acceptability, apprehension associated with an injectable drug or certain side effects that were observed in the Phase 3 studies, such as nausea, may impact Vyleesi's ability to achieve significant market acceptance, especially if an oral therapy is available as an alternative.

Ciraparantag

Currently, we expect ciraparantag, if approved, will compete primarily with AndexXa® (coagulation factor Xa (recombinant), inactivated-zhzo) ("Andexxa"), which was approved in 2018 for the reversal of Eliquis® and Xarelto® for patients treated with Eliquis® and Xarelto®, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding. AndexXa® is also in development for the reversal of Savaysa® and Lovenox®. We are seeking approval of ciraparantag to reverse the effects of Eliquis®, Xarelto®, Savaysa® and Lovenox®. Based on clinical data to date, we expect that ciraparantag will be a ready-to-use product with the potential to be stored at room temperature and to be effective at a fixed dose for the NOACs and LMWH being studied.

Sales, Marketing and Distribution

Women's and Maternal Health Products

Following our February 2019 combination of our women's and maternal health sales forces, we will have one integrated sales team, which will now promote Intrarosa, Makena and Vyleesi, if approved, in order to provide healthcare professionals with one commercial point of contact and seeks to maximize efficiency and effectiveness for the promotion of our commercial products. We expect this unified sales force to call on approximately 17,000 obstetricians and gynecologists and other prescribers.

Makena

Makena prescriptions are dispensed via the payer-preferred pharmacy or purchased directly by hospitals, government agencies and integrated delivery networks. Our sales and marketing teams use a variety of strategies and focused, multi-channel methods to promote Makena, including dedicating a managed care team to focus on health plans, including commercial payers, pharmacy benefit managers, and managed Medicaid plans as well as fee-for-service Medicaid programs. In addition, we have partnered with a leading provider of home nursing services (which had previously utilized compounded HPC) pursuant to which the provider performs at-home administration of Makena and co-promotes Makena to certain healthcare providers.

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

Prasco has an exclusive license to purchase, distribute and sell the Makena authorized generic and has agreed to use commercially reasonable efforts to market, distribute and sell the Makena authorized generic during the term of the agreement.

Intrarosa

In July 2017, Intrarosa became available for healthcare provider prescribing and can be ordered through wholesalers and retail pharmacies. As part of our continued launch strategy, and critical to the commercial success of Intrarosa, we are executing an integrated marketing plan designed to drive awareness of dyspareunia and the potential benefits of Intrarosa to increase the likelihood that healthcare providers and patients will view Intrarosa as an accessible and viable treatment option. Despite significant marketing and educational efforts by industry participants intended to spread awareness of the condition and its treatment, studies suggest that women often do not recognize dyspareunia, a symptom of VVA, as a treatable medical condition and are often not aware of treatment options. We have and plan to continue to undertake informational and educational programs such as speaker programs to help spread awareness of dyspareunia and VVA and the benefits of Intrarosa for the conditions indicated. In addition, we have implemented a sampling program, which makes samples of Intrarosa available to healthcare providers through our sales representatives or via our website to areas where we do not have sales representatives.

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We also currently offer a comprehensive copay savings program to patients and have implemented patient-specific marketing programs around the condition of dyspareunia and Intrarosa utilizing digital marketing, print and social media platforms.

Vyleesi

If Vyleesi is approved by the FDA, we expect that it will be distributed nationally through select specialty pharmacies. The initial focus of our Vyleesi commercialization efforts will be to continue to raise awareness and education about HSDD for both healthcare professionals and patients with this disorder, such as our 2018 unbranded condition awareness to healthcare professionals. Additionally, our launch strategy will focus on establishing Vyleesi as the preferred option for women and healthcare providers seeking a treatment for HSDD through media such as direct-to-consumer marketing in lifestyle and social media channels. We also intend to focus our Vyleesi marketing efforts, if approved, towards healthcare professionals, who we expect will play a significant role in increasing HSDD and Vyleesi awareness among their patients, primarily by leveraging our newly combined women's health sales force and through digital media. In order to minimize cost and injection barriers to treatment, we anticipate implementing a competitive copay savings program and injection training to healthcare professionals upon commercial launch of Vyleesi.

Hematology/Oncology Products

Feraheme

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

Our sales and marketing organization uses a variety of common pharmaceutical marketing strategies and methods to promote Feraheme, including sales calls to purchasing entities, such as hospitals and hematology and oncology clinics, in addition to individual physicians or other healthcare professionals, medical education symposia, promotional materials, local and national educational programs, and scientific meetings and conferences. In addition, through AMAG Assist®, we provide customer service and other related programs for Feraheme, including prescription coverage information support services, a patient assistance program for eligible uninsured or functionally under-insured patients and a customer service call center.

The label expansion for Feraheme to include all eligible IDA patients in the U.S. doubled the size of the addressable patient population for Feraheme, which has allowed for increased penetration in existing accounts and has broadened the number of customers utilizing Feraheme within the IV iron marketplace. Additionally, with the expanded label, Feraheme may be promoted as an option for patients who have intolerance to oral iron or have unsatisfactory response to oral iron therapy that are in treatment settings where we already have sales teams, such as obstetricians and gynecologists in connection with AUB. We believe this segment of patients is under-diagnosed and under-treated, and there is a significant opportunity in this market to provide IV iron to such patients. Other categories of potential patients with IDA include those with inflammatory bowel disease treated by gastroenterologists. Our sales teams are working to educate healthcare providers who manage adult IDA patients to expand the IV iron use in physicians' offices, clinics, and hospitals where eligible IDA patients are treated.

MuGard

Our commercial team uses a variety of common pharmaceutical marketing strategies and methods to promote MuGard, including sales calls to providing entities, such as hematology and oncology clinics and hospitals. In addition, other marketing programs may include promotional materials to individual physicians or other healthcare professionals.

We market and sell MuGard to wholesalers and specialty pharmacies. Patients primarily receive MuGard through specialty pharmacies, which receive prescriptions from physicians directly or from AMAG Assist, which acts as our MuGard patient reimbursement and support center. We utilize AMAG Assist as a centralized patient intake and referral management center to process insurance coverage issues and administer our patient assistance program. In order to make MuGard available to patients as soon as possible, we provide a starter kit to clinicians, including a sample bottle and all pertinent information that the patient or caregiver needs to immediately begin MuGard therapy.

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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 2018, 2017 and 2016.

	Years Ended December 31,		
	2018	2017	2016
AmerisourceBergen Drug Corporation	27 %	26 %	27 %
McKesson Corporation	26 %	24 %	14 %
Caremark, LLC	< 10%	< 10%	10 %

The loss of the above customers would have a material adverse effect on our business.

Government Regulation

Overview

Our activities are subject to extensive regulation by numerous governmental authorities in the U.S. The FDC Act and other federal and state statutes and regulations govern, among other things, the research and development, manufacturing, quality control, labeling, recordkeeping, approval, storage, distribution, and advertising, promotion and post-approval monitoring and reporting of pharmaceutical and biological products and medical devices.

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.

Product Development and Approval Process

Clinical Development

Before we may market a new product, we must obtain FDA approval of an NDA for a drug product or a Biologics License Application ("BLA") for a biologic, such as AMAG-423. The FDA may approve an NDA or BLA if, among other requirements, the safety and efficacy of the drug candidate can be established based on the results of preclinical and clinical studies.

Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as in vitro and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including good laboratory practice regulations.

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

Clinical testing typically proceeds in three phases, which may overlap or be combined. Phase 1 trials seek to collect initial data about safety, tolerability, and optimal dosing of the investigational product in healthy human subjects or,

less commonly, in patients with the target disease or condition. The goal of Phase 2 trials is to provide preliminary evidence about the desired therapeutic efficacy of the investigational product in limited studies with small numbers of carefully selected subjects with the target disease or condition. Phase 3 trials generally consist of expanded, large-scale, randomized, double-blind, multi-center

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studies of the safety and efficacy of the product in the target patient population and are used as the primary basis for regulatory approval.

Submission and FDA Review of NDAs, sNDAs and BLAs

Following the successful completion of clinical trials, the sponsor submits the results to the FDA as part of an NDA or BLA. The NDA or BLA must also include the results of preclinical tests and studies, as the FDA requires submission of all relevant data available from pertinent nonclinical studies and clinical trials, as well as, among other required information, information related to the preparation and manufacturing of the drug or biologic candidate, analytical methods, and proposed packaging and labeling. Pursuant to agreements reached during reauthorization of PDUFA, the FDA has a goal of acting on most original NDAs within six months or ten months of the application submission or filing date (the FDA conducts a preliminary review of all NDAs within the first 60 days after submission before accepting them for filing), depending on the nature of the drug. Once the NDA submission has been accepted for filing (60 days post receipt of the application by the FDA, if at all), the FDA typically takes ten months to review the application and respond to the applicant. The review process may be extended by FDA requests for additional information or clarification. The FDA may delay or refuse approval of an NDA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

The FDA may also refer the application to an advisory committee for review, evaluation, and recommendation as to whether the application should be approved. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

If the FDA's evaluations of the NDA or BLA 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 or BLA 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 of BLA. Addressing the deficiencies noted by the FDA could be impractical, and it is possible that the sponsor could withdraw its application or approval may not be obtained or may be costly and may result in significant delays prior to approval.

Where a sponsor wishes to expand the originally approved prescribing information, such as adding a new indication, it must submit and obtain approval of an sNDA. Changes to an indication generally require additional clinical studies, which can be time-consuming and require the expenditure of substantial additional resources. Under PDUFA, the target timeframe for the review of an sNDA to add a new clinical indication is six or ten months from the receipt date, depending on whether or not the sNDA has priority review. As with an NDA or BLA, if the FDA determines that it cannot approve an sNDA in its current form, it will issue a complete response letter as discussed above.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA has a number of programs intended to help expedite testing, review, and approval of drug candidates that meet the applicable eligibility criteria such as Fast Track designation, Breakthrough Designation, priority review and accelerated approval. Specifically, new drugs and biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. For a fast track product, the FDA may consider review of completed sections of an NDA

or BLA on a rolling basis provided the sponsor provides, and the FDA accepts, a schedule for the submission of the completed sections of the NDA or BLA. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the application is submitted. In addition, the Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

A drug may be eligible for Breakthrough Designation if the drug is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies. Breakthrough Designation provides for frequent meetings between the sponsor and the FDA, involving senior and experienced review staff, as appropriate, in a collaborative, cross-functional review and the assignment of an FDA project lead to facilitate efficient review of the development program and serve as a scientific liaison with the sponsor.

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A Fast Track or Breakthrough designated drug candidate may also qualify for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness, under which the FDA reviews the NDA or BLA in a total of six months rather than ten months after it is accepted for filing.

In addition, under the provisions of the FDA's Subpart H Accelerated Approval regulations, accelerated approval may be permitted based on an appropriate surrogate endpoint for a new drug that is intended to treat a serious or life-threatening disease or condition and that provides a meaningful therapeutic benefit over existing treatments.

The 21st Century Cures Act

The 21st Century Cures Act, which was signed into law in December 2016, requires the FDA to establish a process for the qualification of drug development tools that may be used to support or obtain licensure of a biological product or support of the investigational use of a biological product. A drug development tool includes a biomarker, a clinical outcome assessment, and any other method, material, or measure that the FDA determines aids drug development and regulatory review. A biomarker is a characteristic, such as a physiologic, pathologic, or anatomic characteristic or measurement, that is objectively measured and evaluated as an indicator of normal biological processes, pathologic processes, or biological responses to a therapeutic intervention and includes a surrogate endpoint. A clinical outcome assessment is a measurement of a patient's symptoms, overall mental state, or the effects of a disease or condition on how the patient functions and includes a patient-reported outcome.

The 21st Century Cures Act also requires that, for approval of any BLAs submitted after June 12, 2017, the FDA shall make public a brief statement regarding the patient experience data and related information, if any, submitted and reviewed as part of the application. Patient experience data includes data that are collected by any persons, including patients, family members and caregivers of patients, patient advocacy organizations, disease research foundations, researchers and drug manufacturers, and are intended to provide information about patients' experiences with a disease or condition, including the impact of such disease or condition, or a related therapy, on patients' lives and patient preferences with respect to treatment of such disease or condition.

Abbreviated New Drug Application

The Hatch-Waxman Act created the ANDA pathway, which allows companies to seek approval for generic versions of brand-name drugs previously approved under an NDA and listed in the Orange Book. Rather than directly demonstrating the product's safety and efficacy, as is required of an NDA, an ANDA must show that the proposed generic product is the same as the previously approved product in terms of active ingredient(s), strength, dosage form and route of administration. In addition, with certain exceptions, the generic product must have the same labeling as the product to which it refers. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to the previously approved product if, in relevant part, "the rate and extent of absorption of the [generic] drug do not show a significant difference from the rate and extent of absorption of the listed drug."

NDA applicants and holders must provide certain information about patents related to the branded drug for listing in the Orange Book. When an ANDA application is submitted, it must contain one of several possible certifications regarding each of the patents listed in the Orange Book for the branded product that is the reference listed drug. A certification that a listed patent is invalid, unenforceable, or will not be infringed by the sale of the proposed product is called a Paragraph IV certification. If the applicant has provided a Paragraph IV certification to the FDA, the applicant must also send appropriate notice of the Paragraph IV certification to the NDA and patent holders within 20 days of the ANDA or 505(b)(2) application (a marketing application in which sponsors may rely on investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted) being accepted for filing by the FDA. The NDA and patent

holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) application until the earlier of expiration of the patent, a decision in the infringement case that is favorable to the ANDA or 505(b)(2) applicant, or 30 months after the receipt of the Paragraph IV notice (which can be extended if the reference product has 5-year exclusivity and the ANDA or 505(b)(2) application is submitted between four and five years after approval of the reference product).

The Hatch-Watchman Act also provides for a 180-day period of generic product exclusivity for the first generic applicant to submit an ANDA with a paragraph IV certification for a generic version of an NDA-approved drug. Generic pharmaceutical products that are introduced by innovator companies, either directly or through partnering arrangements with other generic companies are known as authorized generics. Authorized generics are equivalent to the innovator companies' brand name drugs but are sold at relatively lower prices than the brand name drugs. An authorized generic product may be marketed during the

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180-day exclusivity period granted to the first manufacturer to submit an ANDA with a Paragraph IV certification for a generic version of the brand product.

Adverse Event Reporting

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

FDA Post-Approval Requirements

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

FDA Regulation of our Products

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

Promotional labeling and advertising materials for all prescription pharmaceutical products must be submitted to the FDA's Office of Promotional Drug Products ("OPDP") at the time of initial dissemination or publication. However, under the Subpart H regulations, until the Makena confirmatory post-approval clinical trial is completed, we are subject to the requirement that all Makena promotional materials be submitted for review to the OPDP at least 30 days prior to the intended time of initial dissemination of the promotional labeling or initial publication of the

advertisement. This extra requirement means that there is a longer lead time before we are able to introduce new promotional material to the market for Makena and we are subject to increased scrutiny prior to using promotional pieces to ensure fair balance.

FDA Regulation of Manufacturing Facilities

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

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approval inspection of the sponsor's manufacturing facility, including its equipment, facilities, laboratories and processes, to determine the facility's compliance with cGMP and other rules and regulations. Vendors that supply finished products or components to the sponsor that are used to manufacture, package, and label products are subject to similar regulation and periodic inspections. If the FDA identifies deficiencies during an inspection, it may issue a formal notice, which may be followed by a warning letter if observations are not addressed satisfactorily. FDA guidelines specify that a warning letter should be issued for violations of "regulatory significance" for which the failure to adequately and promptly achieve correction may result in agency consideration of an enforcement action. Product approval may be delayed or denied due to cGMP non-compliance or other issues at the sponsor's manufacturing facilities or contractor sites or suppliers included in the NDA, sNDA or BLA, 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 drug 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.

Fraud and Abuse Regulation

Our general operations, and the research, development, manufacture, sale, and marketing of our products, are subject to extensive federal and state regulation, including, but not limited to, FDA regulations, the Federal Anti-Kickback Statute ("AKS"), the Federal False Claims Act ("FCA"), and the Foreign Corrupt Practices Act ("FCPA"), and their state analogues, and similar laws in countries outside of the U.S., laws governing sampling and distribution of products and government price reporting laws.

- The AKS makes it illegal for any person, including a prescription drug or medical device manufacturer, to knowingly and willfully solicit, offer, receive, or pay any remuneration, directly or indirectly, in cash or in kind, in exchange for, or to intended to induce, purchasing, ordering, arranging for, or recommending the purchase or order of any item or service, including the purchase or prescription of a particular drug, for which payment may be made by a federal healthcare program. Liability may be established without proving actual knowledge of the statute or specific intent to violate it. In addition, federal law now provides that the government may assert that a claim including items resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA, described below. Violations of the AKS carry potentially significant civil and criminal penalties, including imprisonment, fines, administrative civil monetary penalties and exclusion from participation in federal healthcare programs. Many states

have enacted similar anti-kickback laws, including in laws that prohibit paying or receiving remuneration to induce a referral or recommendation of an item or service reimbursed by any payer, including private payers.

The FCA imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for reimbursement of drugs for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government. The FCA also prohibits knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim or having possession, custody, or control of property or money used, or to be used, by the federal government and knowingly delivering or causing to be delivered, less than all of that money or property. The government may deem manufacturers to have "caused" the submission of false or fraudulent

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claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Claims which include items resulting from a violation of the federal Anti-Kickback Statute are false or fraudulent claims for purposes of the FCA. The FCA permits a private individual acting as a "whistleblower" to bring an action on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. Government enforcement agencies and private whistleblowers have asserted liability under the FCA for, among other things, claims for items not provided as claimed or for medically unnecessary items, kickbacks, promotion of off-label uses, and misreporting of drug prices to federal agencies. Many states have enacted similar false claims laws, including in some cases laws that apply where a claim is submitted to any third-party payer, not just government programs.

- The Health Insurance Portability and Accountability Act of 1996, ("HIPAA") as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, which imposes criminal and civil liability for knowingly and willfully executing a scheme, or attempting to execute a scheme, to defraud any healthcare benefit program, including private payers, or falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

- The Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the "ACA"), which imposed new annual reporting requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, for certain payments and "transfers of value" provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Many states have enacted legislation requiring pharmaceutical companies to, among other things, establish marketing compliance programs, file periodic reports with the state and make periodic public disclosure on sales and marketing activities and prohibiting certain other sales and marketing practices. If we fail to track and report as required by these laws, we could be subject to state and federal penalty provisions.

- The FCPA prohibits U.S. publicly-traded 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 and requires companies to maintain accurate books and records, as well as an adequate system of internal accounting controls. If we violate the FCPA, we could be subject to substantial civil and criminal penalties.

Our activities relating to the sale and marketing of our products may be subject to scrutiny under the above referenced 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.

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

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Other Regulatory Requirements

Several states have enacted legislation requiring manufacturers operating within the state to establish marketing and promotional compliance programs or codes of conduct and/or file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities. In addition, as discussed above, as part of the ACA, certain 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. 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. For example, in June 2018, the State of California enacted the California Consumer Privacy Act of 2018 (the “CCPA”), which will come into effect on January 1, 2020 and provides new data privacy rights for consumers and new operational requirements for companies, which may increase our compliance costs and potential liability. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA could mark the beginning of a trend toward more stringent state privacy legislation in the U.S., which could increase our potential liability and adversely affect our business.

In addition, as discussed above, in the course of our business, we may obtain health information from third parties (i.e., healthcare providers who prescribe our products) that are subject to privacy and security requirements under HIPAA. HIPAA imposes, among other things, specified requirements on covered entities and their business associates relating to the privacy and security of individually identifiable health information including mandatory contractual terms and required implementation of technical safeguards of such information. Although we are not directly subject to HIPAA (other than potentially with respect to providing certain employee benefits) we could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA/HITECH. 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.

Outside the U.S., we are impacted by the privacy and data security requirements at the international, national and regional level, and on an industry specific basis. Legal requirements in the countries in which we do business relating to the collection, storage, handling and transfer of personal data and potentially intellectual property continue to evolve with increasingly strict enforcement regimes. More privacy and security laws and regulations are being adopted, and more are being enforced, with potential for significant financial penalties. In the E.U., the General Data Protection Regulation (“GDPR”) took effect in May 2018 and imposes increasingly stringent data protection and privacy rules. The GDPR extends the geographical scope of EU data protection law to non-EU entities under certain conditions, tightens existing EU data protection principles and creates new obligations for companies and new rights

for individuals. The GDPR is new and therefore guidance, interpretation and enforcement under the GDPR are still developing. The GDPR may increase our responsibility and potential liability in relation to personal data that we process, expose us to substantial potential fines and increase our compliance costs. 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.

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.

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U. S. Healthcare Reform

Our revenue and operations could be affected by changes in healthcare spending and policy in the U.S. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to health care availability, the method of delivery or payment for health care products could negatively impact our business, operations and financial condition. The U.S. Congress and state legislatures from time to time propose and adopt initiatives aimed at cost containment, which could impact our ability to sell our products profitably. For example, the ACA substantially changed the way healthcare is financed by both governmental and private insurers. Since its enactment, however, there have been modifications and challenges to numerous aspects of the ACA. In 2019, litigation, regulation, and legislation related to the ACA are likely to continue, with unpredictable and uncertain results. The full impact of the ACA, any law repealing. replacing, and/or modifying elements of it, and the political uncertainty surrounding any repeal or replacement legislation on our business remains unclear.

Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. In addition, the U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs to limit the growth of government paid healthcare costs. Individual states in the U.S. have passed legislation and implemented regulations requiring reporting related to notification of certain price increases and submissions on justifications for certain price increases. The enforcement of individual state requirements is uncertain, but failure to comply could expose us to substantial financial penalties and the potential for adverse publicity. The number of states establishing requirements to report pricing or otherwise designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing is likely to continue to increase, creating a regulatory landscape of substantial complexity. The pace of change and varying demand of individual state requirements may make it very difficult to comply.

Drug-Device Combination Regulation

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

Medical Device Regulation

All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA’s IDE, regulations that among other things, govern investigational device labeling, prohibit promotion of the investigational device, and specify recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. The IDE application must become effective prior to commencing human clinical trials. The IDE will automatically become effective 30 days after receipt by the FDA, unless the FDA denies the application or notifies the company that the investigation is on hold and may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE that requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

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

Both before and after a device is commercially released, there are ongoing responsibilities under FDA regulations. For example, the FDA requires that device manufacturers maintain particular reviews design and manufacturing practices, labeling and record keeping, and manufacturers' required reports of adverse experiences and other information to identify potential problems with marketed medical devices. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, the FDA could, depending on the FDA's specific findings, require us to notify healthcare professionals and others that the devices present unreasonable risks

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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.

Pharmaceutical Pricing and Reimbursement

Our ability to successfully commercialize our products is dependent, in significant part, on the extent to which coverage and reimbursement for these products and related treatments is available from third-party payers, including state and federal governmental payers, such as Medicare and Medicaid, managed care organizations, private health insurers and other organizations.

Coverage by third-party payers depends on a number of factors, including the third-party's determination that the product is clinically and cost effective both individually and within its therapeutic class. Third-party payers are increasingly challenging the prices charged for pharmaceutical products (including combination products), and continue to institute cost containment measures to control or influence the purchase of pharmaceutical products, such as through the use of prior authorizations and step therapy. There is a continued scrutiny, intensifying criticism and political focus on pharmaceutical pricing practices at both national and regional levels. Especially in the U.S., state legislators are implementing a variety of regulations intended to increase the transparency of bio-pharmaceutical pricing, which may lead to future price control regulations at state levels. Federally, multiple price control mechanisms have been suggested in the recent past, and bi-partisan focus on the issues remains a high priority. Consolidation of pharmacy benefit managers and managed care organizations is also increasing the price pressure in the private sector. If these third-party payers provide an insufficient level of coverage and reimbursement for our products, physicians and other healthcare providers may choose to prescribe alternative products, including generics, which would have an adverse effect on our ability to generate revenues.

Medicaid is a joint federal and state health insurance program that is administered by the states for low-income children, families, pregnant women, and other individuals with disabilities. Under the Medicaid Drug Rebate program established by the ACA, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program. The amount of the rebate is determined by law and will be adjusted upward if average manufacture price ("AMP") increases more than inflation as measured by the Consumer Price Index - Urban. Each quarter, the rebate amount is calculated based on our report of current AMP and best price for each of our products to CMS. The requirements for calculating AMP and best price are complex. We are required to report revisions to AMP or best price previously reported within a certain period, which revisions could affect our rebate liability for prior quarters. Further, changes to the Medicaid Drug Rebate Program, effective as of April 2016, require state Medicaid programs to reimburse certain brand name covered outpatient drugs at actual acquisition cost plus a dispensing fee. If we fail to provide information timely or we are found to have knowingly submitted false information to the government, the statute governing the Medicaid Drug Rebate program provides for civil monetary penalties.

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

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

Effective January 2018, CMS adopted a policy to pay for separately payable, non-pass-through drugs and biologicals other than vaccines purchased through the 340B Drug Pricing Program under the Public Health Services Act (the "340B Program"), with certain exceptions, at the ASP minus 22.5% rather than ASP plus 6%. Drugs not purchased under the 340B Program will

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continue to be paid for at a rate of ASP plus 6%. There has been significant increases in budget pressure, which may adversely impact premium priced agents, such as Feraheme and Makena.

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

Federal law requires that any company participating in the Medicaid Drug Rebate program also participate in the PHS's 340B Program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B Program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the PHS, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on AMP and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program. In addition, we may, but are not required to, offer these covered entities a price lower than the 340B ceiling price. The ACA also obligates the Health Resources and Services Administration (the "HRSA"), the agency which administers the 340B Program, to promulgate various regulations and implement processes to improve the integrity of the 340B Program.

Federal, state and local governments continue to consider legislation to limit the growth of healthcare costs, including the cost of prescription drugs and combination products. In 2017, we saw several states and local government either implement or consider implementing price transparency legislation that may prevent or limit our ability to take price increases at certain rates or frequencies. For example, in 2017, California enacted a new law, that went into effect on January 1, 2018 with initial reporting requirements in effect as of January 1, 2019, to facilitate greater transparency in brand-name and generic drug pricing through the implementation of specific price reporting requirements for pharmaceutical manufacturers. The extent and timing of these changes are not known, but future legislation could limit the price and/or payment for prescription drugs. If adequate reimbursement levels are not maintained by government and other third-party payers for our products, our ability to sell our products may be limited and/or our ability to establish acceptable pricing levels may be impaired, thereby reducing anticipated revenues and profitability.

Success of any products we may ultimately seek approval to commercialize outside of the U.S. will depend largely on obtaining and maintaining governmental coverage, as governmental healthcare programs tend to be the dominant third party payers. Products that are not covered and funded by government entities are unlikely to be used in these markets. We cannot be certain we can obtain coverage and reimbursement for our product in markets outside the U.S. Additionally, ability to market our products on a profitable basis may be limited, given governments control prices of prescription medicines though mechanisms such as, but not limited to, international price referencing, therapeutic price reference, price cuts, rebates, revenue related taxes, and profit controls. In markets outside the U.S., the price of the prescriptions medicines tend to decline over the life of the medicine and/or as the volume increases, making it difficult to achieve expected growth in revenue.

Backlog

We had a $9.1 million and $7.6 million sales backlog as of December 31, 2018 and 2017, respectively. We expect to recognize the $9.1 million in the first quarter of 2019, 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.

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Employees

As of February 25, 2019, we had 467 employees. This number reflects the impact of approximately110 employees who were displaced in our recently completed restructuring effort, which combined our women's health and maternal health sales forces into one integrated sales team. We utilize consultants and independent contractors on a regular basis to assist in the development and commercialization of our products. Our success depends to a significant extent on our ability to continue to attract, retain and motivate qualified sales, technical operations, managerial, scientific and medical personnel of all levels. Although we believe we have been relatively successful to date in obtaining and retaining such personnel, we may not be successful in the future.

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

Foreign Operations

We have no foreign operations. We did not have material revenues from customers outside of the U.S. in 2018 and 2017.

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 on the Internet at http://www. sec.gov. Our internet website address is http://www.amagpharma.com. Through our website, we make available, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy and registration statements, and all of our insider Section 16 reports (and any amendments to such filings), as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. These SEC reports can be accessed through the "Investors" section of our website. The information found on our website is not part of this or any other report we file with, or furnish to, the SEC. Paper copies of our SEC reports are available free of charge upon request in writing to Investor Relations, AMAG Pharmaceuticals, Inc., 1100 Winter Street, Waltham, MA 02451. The content on any website referred to in this Form 10-K is not incorporated by reference into this Form 10-K unless expressly noted.

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ITEM 1A. RISK FACTORS:

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

Risks Related to Our Business and Industry

Our ability to successfully commercialize our products or product candidates, if approved, including our ability to achieve their widespread market acceptance, is critical to the success of our business.

We dedicate a substantial amount of our resources to the commercialization of our products and in preparation for the commercialization of our product candidates, including Vyleesi, which is in development for the treatment of hypoactive sexual desire disorder ("HSDD"). Our ability to generate revenue in the near-term will depend almost entirely on our ability to execute on our commercialization plans and the level of market adoption for, and the continued use of, our products (and, if approved, our product candidates) by physicians, hospitals, patients, and/or healthcare payers, including government payers, consumers, managed care organizations, and retail and specialty pharmacies. If we are not successful in commercializing our products, including achieving and maintaining an adequate level of market adoption, our profitability and our future business prospects will be adversely impacted.

The degree of commercial success and market acceptance of our products and product candidates will depend on a number of factors, including, but not limited to, the following:

- The competitive landscape for our products, including the timing of new competing products (including generics) entering the market, and the level and speed at which competing products (current or new) experience market acceptance;
- The effectiveness of our marketing, sales and distribution strategies and operations and our ability to leverage our established relationships in the medical community and expand our access through contracting strategies;
- Actual or perceived advantages or disadvantages of our products or product candidates as compared to alternative treatments, including their respective safety and efficacy profiles, the potential convenience and ease of administration or cost effectiveness;
- The size of the patient population for our products and our ability to retain or grow our customer base and maintain and efficiently deploy our sales force and commercialization team to compete in the market, especially given the diverse nature of our product portfolio;
- Our ability to supply sufficient inventory of our products for commercial sale, including maintaining commercially viable manufacturing processes that are compliant with applicable laws and regulations (including current good manufacturing practices ("cGMP"));
- The success and timing of regulatory approval and launch for our product candidates, including our ability to obtain regulatory approval for Vyleesi in the U.S. and whether the U.S. Food and Drug Administration (the "FDA") imposes any restrictions on its use or distribution;

- Our ability to engage with and educate healthcare providers and patients to increase awareness and understanding of the underlying disease states that our products treat or the value of the underlying purpose of our products, including moderate to severe dyspareunia and HSDD;

- New safety or drug interaction issues that could arise as our products are used or studied over longer periods of time or used by a wider group of patients, some of whom may be taking other medicines or have additional underlying health problems;

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- Current and future restrictions or limitations on our approved or future indications and patient populations or other adverse regulatory actions;

- The relative price, constraints on pricing and the impact of price increases on our products, including the financial impact of certain programs we may implement such as the Intrarosa comprehensive copay savings program and sample program;

- Our ability to secure and maintain adequate reimbursement from government and third-party payers to optimize patient access and the willingness and ability of patients to pay for our products, including the willingness of healthcare providers to prescribe our products if more economical options are available;

- The performance of our manufacturers, license partners, distributors, providers and other business partners, over which we have limited control;

- Our ability to maintain compliance with all applicable FDA regulations;

- Any significant misestimations of the size of the market and market potential for any of our products or product candidates; and

- Our and our partners' ability to enforce intellectual property rights in and to our products to prohibit a third-party from marketing a competing product (including a generic product) and our ability to avoid third-party patent interference or intellectual property infringement claims.

We have limited experience with development stage products and cannot ensure that we will be successful in gaining approval of our product candidates, including Vyleesi, AMAG-423 and ciraparantag, on a timely basis, or at all, and even if approved, we may not be successful in commercializing such products. Additionally, any approvals that we do obtain may contain unexpected FDA-imposed restrictions on the use or distribution of such products, which could adversely and materially affect our long term success.

Our long-term success and revenue growth depends upon our ability to continue to successfully develop new products. Drug development is inherently risky, time consuming and unpredictable. The FDA imposes substantial requirements on the development of such candidates to become eligible for marketing approval and has substantial discretion in the approval process.

We currently have three product candidates in our pipeline. Vyleesi, an investigational product designed to be an on demand therapy for the treatment of HSDD in pre-menopausal women, for which we were granted a Prescription Drug User Fee Act ("PDUFA") date by the FDA of June 23, 2019. In addition, during 2018 and early 2019, we acquired two development-stage products, AMAG-423, which is in development for the treatment of severe preeclampsia, and ciraparantag, which is in development for patients treated with novel oral anticoagulants or low molecular weight heparin when reversal of the anticoagulant effect of these products is needed for emergency surgery, urgent procedures or due to life-threatening or uncontrolled bleeding.

The approval of our current or future product candidates for commercial sale in the U.S. could be delayed, limited or denied or we may be required to conduct additional studies for a number of reasons, including, but not limited to, that:

- The FDA may determine that our product candidates do not demonstrate safety and efficacy in accordance with regulatory agency standards based on a number of considerations, including adverse medical events that are reported during the trials, such as increases in blood pressure and a serious adverse event of hepatitis of unknown etiology noted in prior Vyleesi clinical trials;

- The FDA could analyze and/or interpret data from clinical trials and preclinical testing in different ways than we or our partners interpret them and determine that our data is insufficient for approval;

- The FDA may require more information, including additional preclinical or clinical data or trials, to support approval, such as the recent request by the FDA for additional data assessing 24-hour ambulatory blood pressure with short-term daily use of Vyleesi;

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- Devices we may use in combination with our products may not be adequate or may not be considered adequate by the FDA, such as the auto-injector device that we plan to use to administer Vyleesi and the coagulometer we intend to use in the Phase 3 clinical program for ciraparantag;

- The FDA could determine that our manufacturing processes are not properly designed, are not conducted in accordance with federal laws or otherwise not properly managed and we may be unable to establish, and obtain FDA approval for, a commercially viable manufacturing process for our product candidates in a timely manner, or at all;

- The supply or quality of our product candidates for our clinical trials may be insufficient, inadequate or delayed, particularly with respect to AMAG-423, which is a biologic and involves a time intensive, complex manufacturing process;

- The size of the patient population required to establish the efficacy of our product candidates to the satisfaction of the FDA may be larger than we anticipated;

- The failure of clinical investigational sites and the records kept at such sites, including the clinical trial data, to be in compliance with the FDA's current good clinical practices regulations ("cGCP"), including the failure to pass FDA inspections of clinical trial sites;

- The FDA may change their approval policies or adopt new regulations;

- The FDA may not be able to undertake reviews or approval processes in a timely fashion, including as a result of government shutdowns, which have become more frequent and lengthy in recent administrations;

- The results of the earlier clinical trials may not be representative of our future, larger trials, particularly since the presumed mechanism of action for certain of our products is not known or understood; for instance ciraparantag has only been studied in a small number of healthy volunteers;

- The FDA may not agree with our regulatory approval strategies or components of our regulatory filings, such as the design or implementation of our clinical trials; for instance, we are relying on precedent to estimate the number of patients required in our Phase 3b ciraparantag trial prior to filing the New Drug Application ("NDA") and the FDA may not agree with our approach and our other expectations for these clinical trials may not ultimately be approved by the FDA; or

- A product may not be approved for the indications that we request.

Further, we have identified the following risks, which are specific to a particular development program:

Vyleesi

- The FDA may determine that the magnitude of efficacy demonstrated in the Vyleesi studies does not amount to a clinically meaningful benefit to pre-menopausal women with HSDD and thus may not approve Vyleesi despite statistically significant efficacy results; and

- Although we believe that the frequent dosing study for Vyleesi can be conducted and with data submitted prior to the June 23, 2019 Vyleesi PDUFA date, if we are not able to submit the results of this study on time or if the study results are unacceptable to the FDA, the FDA may request additional studies and/or we may receive a Complete Response letter to our NDA submission for Vyleesi.

AMAG-423

- AMAG-423 is produced through a time intensive, complex process and there is currently only one third-party that can manufacture it, as further discussed below;

- The Phase 2b/3a trial may produce negative or inconclusive results or may not demonstrate to the FDA's satisfaction that AMAG-423 is safe and effective, particularly in light of the limited amount of data to date demonstrating that AMAG-423 effectively treats severe preeclampsia in this patient population;

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- Patient enrollment may be slower than expected as severe preeclampsia can be a difficult patient population to enroll and enrollment of the study to date has been very slow. For example, although we are in the process of expanding the trial sites to accelerate enrollment, enrollment may be slower for any number of factors, including failure of our third-party vendors (including our CROs) to effectively perform their obligations to us in a timely manner, a lack of patients who meet the enrollment criteria, our inability to establish sufficient trial sites, including outside of the U.S., in a timely manner, or our inability to secure sufficient supply of drug product to meet the accelerated clinical timeline;

- Under our agreement with BTG plc, we are required to differentiate our product from their product DigiFab® including without limitation, via labeling, dosage and/or formulation and if we are unable to show differentiation, we may be in breach of the agreement and be subject to penalties; and

- There is no FDA-approved treatment for severe preeclampsia and accordingly, there is not an established regulatory pathway, which may require us to conduct additional trials or otherwise delay the approval of AMAG-423.

Ciraparantag

- Since the coagulometer that we intend to use in the ciraparantag Phase 3a trials has not yet been fully validated or tested on a large scale, the FDA may (i) determine that the device is not effective in measuring whole blood clotting time, and/or (ii) not grant the Investigational Device Exception, which is necessary prior to the use of the coagulometer in our clinical trials; in such circumstances, ciraparantag may not receive regulatory approval or its approval would be delayed. Moreover, the FDA may only approve ciraparantag in conjunction with the use of the coagulometer (i.e. as a companion diagnostic), which would affect the commercial viability of ciraparantag.

In addition, AMAG-423 has received orphan drug designation from the FDA and we expect to request orphan drug designation for ciraparantag. Under the Orphan Drug Act of 1983, the FDA may designate a product candidate as an orphan drug if it is 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. We cannot guarantee that our clinical data or other information that we generate or submit will be adequate for AMAG-423 or ciraparantag to receive orphan drug exclusivity. Even after an orphan drug is approved, the FDA may subsequently approve another drug for the same condition if the FDA concludes that the latter drug is not the same drug or is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. 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. If we do not receive orphan drug designation, or if the FDA approves another drug for the same indication, we may have limited market exclusivity for our products.

Any failure, delay or setback in obtaining regulatory approval for our product candidates could adversely affect our ability to grow our business and leverage our product portfolio and the future prospects of our business could be materially adversely affected. In addition, share prices have declined significantly in certain instances where companies have failed to obtain FDA approval of a product or where the timing of FDA approval is delayed. If we are required to conduct additional studies, our share price could decline significantly. Further, the market for products that address unmet medical needs is highly speculative and if we have over-estimated the market opportunity for any of our products or product candidates, or if we are unsuccessful in gaining market share, then our business and results of operations could be materially and adversely affected.

Even if regulatory approval is granted by the FDA to market our current or future product candidates, the FDA may impose limitations on the indicated use for which the drug product may be marketed or require additional

post-approval clinical trials or other requirements with which we would need to comply in order to maintain approval of these products. The occurrence of any of these scenarios could materially harm the commercial prospects of our product candidates and our business could be seriously harmed. For additional post-approval risks see Risk Factor below entitled “We are subject to ongoing regulatory obligations and oversight of our products, 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, the incurrence of significant additional expense and other limitations on our ability to commercialize our respective products.”

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Clinical product development involves a lengthy and expensive process, with uncertain timelines and outcomes. Any failure or delay in our clinical development programs could severely harm our business.

Clinical testing is expensive, difficult to design and implement, can take multiple years to complete and is inherently uncertain as to the ultimate timelines and outcomes. The results of preclinical testing or human clinical studies may not be predictive of the results of later-stage clinical trials and failure can occur at any stage of the clinical development process. We are currently conducting a Phase 2b/3a multi-center, randomized, double-blind, placebo-controlled, parallel group study for AMAG-423, for which we are targeting to complete enrollment by the end of 2019. We are also in the process of completing a Phase 2a study for ciraparantag and expect to initiate our Phase 3 clinical development program in the second half of 2019. We may experience delays in these ongoing studies or any future clinical studies we or our partners conduct.

Clinical trials can be delayed, suspended or terminated for a variety of reasons, including, but not limited to, the following:

- Delay or failure to reach agreement with the FDA on a trial design, particularly with product candidates, such as AMAG-423, where there is no current FDA-approved treatment and the endpoints in our ongoing Phase 2b/3a trial have not been used in prior studies;

- Delay or failure to reach agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites, failure by such CROs and trial sites to comply with regulatory requirements or study protocols, or clinical trial sites dropping out of the trial;

- Our inability to manufacture, or obtain from third parties, adequate supply of drug product and substance sufficient to complete our clinical studies;

- Delay or failure in obtaining the necessary approvals from regulators or institutional review boards ("IRBs"), including comparable foreign reviewing entities, in order to commence a clinical trial at a prospective trial site, or their suspension or termination of a clinical trial once commenced;

- Imposition of a clinical hold for safety reasons or following an inspection of our or our partners' clinical trial operations or trial sites by the FDA or other regulatory authorities;

- Slower than expected rate of patient enrollment or difficulty maintaining patients who have initiated participation in a clinical trial or for any post-treatment follow-up;

- Problems with drug product or drug substance storage and distribution;

- Difficultly adding new clinical trial sites on a timely basis, or at all:

- Governmental or regulatory delays and changes in regulatory requirements, policy and guidelines, including guidelines specifically addressing requirements for the development of treatments for our product candidates;

- Ambiguous or negative interim results, or results that are inconsistent with earlier results or that indicate unforeseen safety or efficacy issues; and

- Feedback from the FDA, an IRB or other entity that requires modification of the study protocol.

If we or our partners terminate or experience delays in the completion of any of our ongoing or future clinical trials, our development costs may increase, our regulatory approval process could be delayed and our ability to commercialize and commence sales of our product candidates may be harmed, which could have a material adverse effect on our business. Our inability to successfully complete clinical studies or trials of our product candidates and demonstrate the efficacy and safety necessary to obtain regulatory approval to market any of our product candidates would significantly harm our business prospects, financial condition and results of operations. In addition, many of the reasons that cause or lead to a delay in the commencement or completion of our clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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Our revenues for the Makena franchise may continue to be negatively impacted by recent and future generic entries into the market and the supply disruption of certain of our Makena products.

Our ability to continue to successfully commercialize Makena is dependent upon a number of factors, including our ability to differentiate Makena from other treatment options, especially now that two independent generic competitors have entered the market. Although our partner, Prasco, LLC ("Prasco") markets a generic version of Makena in the U.S. ("the Makena authorized generic") to mitigate the decrease in Makena revenue as generic entrants gain market share, our Makena products will continue to experience pricing and supply chain pressure and as a result, our Makena revenues may fall below expectations which could cause our financial condition and results of operations to be adversely impacted.

The long-term success of the Makena franchise is highly dependent on our ability to successfully commercialize the pre-filled subcutaneous auto-injector (the "Makena auto-injector"), which was approved for commercialization in February 2018, and which provides us with an alternative treatment method to the intramuscular ("IM") formulation of Makena (the "Makena IM product"). Although there is no direct competition with the Makena auto-injector, the auto-injector competes for the same patients as generic versions of the Makena IM product, including Makena authorized generic. We may not be able to convince patients or healthcare providers to use or to switch from using the IM method of administration to the auto-injector, including if patients or healthcare providers are hesitant or apprehensive to use an auto-injector product due to perceptions regarding safety, efficacy or pain associated with the Makena auto-injector, or if the auto-injector is not priced competitively or is not provided comparable insurance coverage.

In addition, we have lost and could lose additional market share if we continue to not be able to deliver sufficient quantities of Makena inventory to meet demand. Due to continued manufacturing issues at our primary third-party manufacturer, we are currently experiencing a supply disruption of our Makena IM products, which has resulted in both our single-dose and multi-dose branded Makena vials being out-of-stock as well as periodic disruptions to our authorized generic supply. Although we are attempting to mitigate this supply issue by manufacturing at our secondary supplier, we can make no guarantees that additional supply will be available in a timely manner and we anticipate that our revenues for the IM products could continue to be adversely impacted. We are currently working with the FDA, healthcare providers, distribution partners and our manufacturers to minimize the impact of the current supply disruption of the IM products, including by encouraging healthcare providers to support new patient starts on the auto-injector. However, due to increased demand of the auto-injector product, we could face supply issues for that product as well. These supply issues have caused and will continue to cause a disruption in our ability to meet commercial demand of Makena more generally, which has and could continue to negatively impact revenues.

Further, we rely on Prasco for our successful commercialization of the Makena authorized generic. We have limited experience working with a generic vendor and selling products under terms customary in the generic marketplace. We are responsible for supplying product to Prasco, and due to the problems with our supply chain, revenues with respect to the Makena authorized generic have been and could continue to be adversely affected and we could be subject to certain charges, which could be substantial. For example, we were required to reimburse Prasco for certain charges it incurred in 2018 due to our inability to supply them with sufficient product to meet their contractual obligations with customers.

If we and Prasco are not able to capture or maintain sufficient market share, if generics are sold at a significant discount to Makena's price, if we continue to experience supply disruptions related to our Makena IM products or if we become unable to meet commercial demand for our Makena auto-injector or Makena authorized generic, our Makena revenues could be materially and adversely affected and, ultimately, could negatively impact our stock price and results of operations.

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

We do not own or operate facilities for the manufacture of our commercially distributed products. We rely solely on third-party contract manufacturing organizations ("CMOs") and our licensors (who, in turn, may also rely on CMOs) to manufacture our products for our commercial and clinical use. We or our licensors may not be able to enter into agreements with manufacturers or second source manufacturers whose facilities and procedures comply with cGMP regulations and other regulatory requirements on a timely basis and with terms that are favorable to us, if at all. Further, our ability to have our products manufactured in sufficient quantities and at acceptable costs to meet our commercial demand and clinical development needs is dependent on the uninterrupted and efficient operation of our CMO's and our licensors' manufacturing facilities. For example, as discussed above, Pfizer, our primary drug product manufacturer of the Makena IM Products, is experiencing manufacturing issues and as a result, we have been and may be unable to meet the demand for both our branded Makena products and the Makena authorized generic. We currently remain out-of-stock of our branded single dose and multi dose vials of Makena product. Any further or other difficulties, disruptions, or delays in the manufacturing process or supply chain could

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result in product defects, shipment delays, suspension of manufacturing of, sale of or clinical development for the product, recall or withdrawal of product previously shipped for commercial or clinical purposes, inventory write-offs, additional supply failure charges to Prasco, or the inability to meet commercial or clinical demand in a timely and cost-effective manner.

In some cases we rely on single source manufacturers without a qualified alternative manufacturer. For example, we only have one manufacturing source for Vyleesi. Securing additional third-party contract manufacturers will require significant time for validating the necessary manufacturing processes, gaining regulatory approval, and implementing the appropriate oversight and may increase the risk of certain problems, including cost overruns, process reproducibility, stability issues, the inability to deliver required quantities of product that conform to specifications in a timely manner, or the inability to manufacture our products in accordance with cGMP. Furthermore, none of our or our licensors' current third-party drug product manufacturers licenses to us exclusively and as such they may exhaust some or all of their resources meeting the demand of other parties or themselves.

Additionally, in early 2018 we received approval for the Makena auto-injector and may encounter difficulties in the production of the Makena auto-injector, including problems involving quality control, assurance and product reliability. For instance, we have received certain complaints regarding auto-injector malfunction. These issues as well as potential issues regarding scale-up, yields, and manufacturing costs, could result in significant delays in production or our inability to meet our demand for the auto-injector product. In addition, we do not currently have back-up suppliers for the Makena auto-injector manufacturers. Establishing an alternative or replacement supplier for the auto-injector device is a long and costly process and may not be successful. While we take precautions to mitigate potential interruptions, any failure at our manufacturers could result in a shortage of our Makena auto-injector inventory.

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

AMAG-423 is a polyclonal antibody that is produced through a time intensive, complex process in which immunogens consisting of an analog of digoxin medication are produced in a laboratory and used to immunize sheep, which sheep then produce certain antibodies. These antibodies are collected, separated, purified, and formulated into digoxin immune fab (ovine). As discussed above, there is only one third-party that can manufacture AMAG-423 and which utilizes its own flock of sheep located entirely in Australia for the production of the antibodies used to produce AMAG-423. We currently have a commercial supply agreement to manufacture AMAG-423 drug substance and since there would only be one source of supply, if there are any disruptions to any part of the supply chain process, including the ability to obtain the ovum serum and other raw materials or any issues with the sheep used to produce the antibodies, such as diseases or natural disasters, our ability to complete the Phase 2b/3a trial or commercialize AMAG-423, if approved, would be adversely affected.

We currently do not have a commercial drug product supply agreement to manufacture ciraparantag and may not be able to enter into such agreement on acceptable terms, if at all. In addition, even if we enter into such agreement, since there would only be one source of supply, if there are any disruptions to any part of the supply chain process, including the ability to obtain certain raw materials, our ability to complete our planned clinical trials or commercialize ciraparantag, if approved, would be adversely affected.

Further, we, our licensors and our respective CMOs currently purchase certain raw and other materials used to manufacture our products from third-party suppliers. At present, we do not have long-term supply contracts with most of these third parties. These third-party suppliers may cease to produce the raw or other materials used in our products or as part of the administration of our products or otherwise fail to supply these materials to us, our licensors or our respective third-party manufacturers, or fail to supply sufficient quantities of these materials or supply materials that do not conform to specifications to us, our licensors or our respective third-party manufacturers in a timely manner for a number of reasons, including, but not limited to, the following:

- Adverse financial developments at or affecting the supplier;

- Unexpected demand for or shortage of raw or other materials;
- Regulatory requirements or action;
- An inability to provide timely scheduling and/or sufficient capacity;
- Manufacturing difficulties;

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- Changes to the specifications of the materials such that they no longer meet our standards;
- Lack of sufficient quantities or profit on the production of materials to interest suppliers;
- Labor disputes or shortages;
- Failure to comply with environmental regulations, such as rules and regulations relating to the handling, storage and discharge of hazardous waste;
- Changes in material hazard classification, which could require changes to our manufacturing processes, which, in turn, could require regulatory approval;
- Disruption due to natural disasters; or
- Import or export problems.

In addition, we, our licensors or our respective third-party manufacturers sometimes obtain raw or other materials from one vendor only, even where multiple sources are available, to maintain quality control and enhance working relationships with suppliers, which could make us susceptible to price inflation by the sole supplier, thereby increasing our production costs. As a result of the high-quality standards imposed on our raw or other materials, we, our licensors or our respective third-party manufacturers may not be able to obtain such materials of the quality required to manufacture our products from an alternative source on commercially reasonable terms, or in a timely manner, if at all.

If, because of the factors discussed above, we are unable to have our products manufactured on a timely or sufficient basis, we may not be able to meet commercial demand or our clinical development needs for our products or product candidates or we may not be able to manufacture our products in a cost-effective manner. As a result, we may lose sales, fail to generate projected revenues or suffer development or regulatory setbacks, any of which could have an adverse impact on our profitability and future business prospects.

Competition in the pharmaceutical and biopharmaceutical industries, including from companies marketing generic products, is intense. If we fail to compete effectively, our business and market position will suffer.

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

Makena competition currently comes mainly from two independent generic formulations of hydroxyprogesterone caproate (“HPC”) injections, which were approved in 2018, as well as from pharmacies that compound a non-FDA approved version of Makena, all of which are sold at much lower list prices than our branded products. We also expect to continue to face competition for Makena from future generic products as well as products currently in development which offer additional formulations or routes of administration that doctors believe may reduce or prevent preterm birth, such as an oral HPC product, which is currently in development and has completed its End-of-Phase 2 meeting with the FDA.

Many of our competitors for Feraheme and Intrarosa are large, well-known pharmaceutical companies and may benefit from significantly greater financial, sales and marketing capabilities, greater technological or competitive advantages, and other resources. Feraheme competes primarily with Injectafer®, a ferric carboxymaltose injection, Venofer®, an iron sucrose complex, and INFeD®, an iron dextran product and there are a number of oral iron replacement therapies either approved, such as Auryxia® (ferric citrate), an oral phosphate binder, or in development, such as Monofer® (iron isomaltoside), and hypoxia inducible factor stabilizers.

Intrarosa faces competition primarily from (a) Estrace® Cream (Estradiol vaginal cream, USP 0.01%), a vaginal cream for the treatment of vulvar and vaginal atrophy ("VVA"), (b) Vagifem®(estradiol vaginal inserts), a suppository for the treatment of VVA, (c) Premarin Vaginal Cream®, a vaginal cream for the treatment of VVA, (d) IMVEXXY® (estradiol vaginal inserts), an estrogen indicated for the treatment of moderate to severe dyspareunia due to menopause, (e) Estring®(estradiol vaginal ring), a

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vaginal ring marketed by Pfizer for the treatment of VVA due to menopause, (f) Osphena®, an oral therapy marketed by Duchesnay Inc. for the treatment of moderate to severe dyspareunia due to menopause, and (g) generic versions of certain of these products and over the counter and compounded remedies to treat VVA and dyspareunia.

We also expect to face competition for Vyleesi, if approved, including from Addyi®, an FDA-approved product for treatment of HSDD in pre-menopausal women as a daily-use oral drug. In addition, we are aware of several other drugs at various stages of development, most of which are being developed to be taken on a chronic, typically once-daily, basis. Emotional Brain BV, a Netherlands company, is developing two different oral fixed-dose, on-demand combination drugs, one a combination of sildenafil (the active ingredient in Viagra) and testosterone and the other a combination of testosterone and buspirone hydrochloride, and has conducted Phase 2b studies. There may be other companies developing new drugs for female sexual dysfunction ("FSD") indications, some of which may be in clinical trials in the U.S. or elsewhere, or other companies which may sell their products off-label for indications other than FSD.

Currently, the primary pharmaceutical competitor we expect ciraparantag, if approved, to compete with is AndexXa® (coagulation factor Xa (recombinant), inactivated-zhzo) ("Andexxa"), which was approved in 2018 for the reversal of Xarelto®(rivaroxaban) and Eliquis®(apixaban), when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding. AndexXa® is also in development for the reversal of Savaysa®(edoxaban) and Lovenox® (enoxaparin sodium injection).

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

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

We rely on a combination of patents, trademarks and trade secrets in the conduct of our business. The patent positions of pharmaceutical and biopharmaceutical firms are generally uncertain and involve complex legal and factual questions. We may not be successful or timely in obtaining any patents for which we submit applications or the breadth of the claims obtained in our patents may not provide sufficient protection for our technology. The degree of protection afforded by patents for proprietary or licensed technologies or for future discoveries may not be adequate to preserve our ability to protect or commercially exploit those technologies or discoveries or to prevent others from doing so. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned or licensed patents may be challenged in the courts or patent offices in the U.S. or abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technologies and products, or limit the duration of the patent protection of our technology and products. In addition, our owned or licensed intellectual property might be subject to liens or encumbrances, which, as a result, may not provide us with sufficient rights to exclude others from developing and commercializing products similar or identical to ours. Therefore, the degree of protection afforded by our intellectual property may provide us with little or no competitive advantage. For example, digoxin immune fab (ovine), the active ingredient of AMAG-423, has been approved and marketed in the U.S. for many years for a different indication and accordingly, no longer has composition of matter patent protection. If possible, we plan to seek additional patent protection for AMAG-423 through patent applications; however, we may not be able to obtain additional patent protection that would provide us with a competitive advantage.

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

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One U.S. patent related to Feraheme that will expire in June 2023 and other U.S. patents related to Feraheme that expire in 2020;

- One U.S. patent related to the Makena auto-injector product that will expire in 2036;
- Four U.S. patents related to AMAG-423 that will expire in 2022, and several foreign patents that will expire in 2023; and
- Two U.S. patents related to ciraparantag that expire in 2032 and 2034, and several foreign patents that will expire in 2032.

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

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- U.S. and foreign patents and applications licensed from Palatin Technologies, Inc. ("Palatin") related to Vyleesi that expire in 2020 and 2033 (one of which may be extended by up to five years under the Hatch-Waxman Act in the U.S);

- U.S. patents licensed from Endoceutics related to Intrarosa that expire in 2028 and 2031 (one of which may be extended by up to five years under the Hatch-Waxman Act);

- U.S. patents licensed from Antares Pharma, Inc. related to the Makena auto-injector product that expire between 2019 and 2034; and

- U.S. patents licensed from Abeona Therapeutics, Inc. related to MuGard that expire in 2022.

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

In addition, although we believe that the patents related to each of our products or product candidates were rightfully issued and the respective portfolios give us sufficient freedom to operate, a third-party could assert that the development, manufacture or commercialization of any of our products or product candidates infringes its patents or other proprietary rights, potentially resulting in harm to our business and financial results. Further, the intellectual property rights that we own or license might be subject to liens or other encumbrances. If we are required to defend against such claims or to protect our own or our licensed proprietary rights against others, it could result in substantial financial and business costs as well as the distraction of our management. An adverse ruling in any litigation or administrative proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly, result in monetary damages, injunctive relief or otherwise harm our competitive position, including by limiting our marketing and selling activities, increasing the risk for generic competition, limiting our development and commercialization activities or requiring us to obtain licenses to use the relevant technology (which licenses may not be available on commercially reasonable terms, if at all).

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. We may become a party to intellectual property litigation or administrative proceedings, including interference or derivation, inter partes review, post grant review or reexamination proceedings before the USPTO. In addition, generic entrants could file an Abbreviated New Drug Application ("ANDA") to seek approval of a generic form of one or more of our products. If an ANDA filer is ultimately successful in patent litigation against us, meets the requirements for a generic version of our branded product to the satisfaction of the FDA under its ANDA, and is able to supply the product in significant commercial quantities, the generic company could introduce a generic version to the market. For example, pursuant to a settlement agreement entered into with Sandoz in March 2018, Sandoz could introduce a generic version of ferumoxytol to the market earlier than the expiration of our patents. Such a market entry would likely limit our Feraheme sales, which would have an adverse impact on our business and results of operations. Further, we may face similar suits in the future, including for our other products, which will be expensive and will consume considerable time and other resources, which could materially and adversely impact our business, especially if we have to divert resources from our commercialization or business development efforts.

We also rely upon unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality

agreements with our corporate licensees, collaborators, contract manufacturers, employees and consultants. However, these agreements may be breached and we may not have adequate remedies for any such breaches, and our trade secrets and other confidential information might become known. In addition, we cannot be certain that others will not independently develop substantially equivalent or superseding proprietary technology, or that an equivalent product will not be marketed in competition with our products, thereby substantially reducing the value of our proprietary rights.

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

Our ability to successfully commercialize our products is dependent, in significant part, on the availability and level of coverage and reimbursement from third-party payers, including governmental payers, private health insurers and other

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organizations. Coverage by third-party payers depends on a number of factors, including the third-party's determination a products' clinical and cost effectiveness, both individually and within their therapeutic class.

There is a continued scrutiny, intensifying criticism and political focus on pharmaceutical pricing practices at both national and regional levels. U.S. state legislators are implementing a variety of regulations intended to increase the transparency of pharmaceutical pricing, which may lead to future price control regulations at state levels. Federally, multiple price control mechanisms have been suggested in the recent past, and bi-partisan focus on the issues remains a high priority. Consolidation of pharmacy benefit managers and managed care organizations is also increasing the price pressure in the private sector. 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 or subject us to criticism and reputational harm in response to any price increases. Congress and the current presidential administration have each indicated that they will continue to pursue new legislative and/or administrative measures to control drug costs. The current presidential administration released a "Blueprint," which contains certain measures that the U.S. Department of Health and Human Services is already working to implement, focusing in part on the cost of drugs. For example, on October 25, 2018, the Centers for Medicare & Medicaid Services ("CMS") issued an Advanced Notice of Proposed Rulemaking ("ANPRM"), indicating it is considering issuing a proposed rule in the spring of 2019 on a model called the International Pricing Index. This model would utilize a basket of other countries' prices as a reference for the Medicare program to use in reimbursing for drugs covered under Part B. The ANPRM also included an updated version of the Competitive Acquisition Program as an alternative to current "buy and bill" payment methods for Part B drugs. If third-party payers provide an insufficient level of coverage and reimbursement for our products, physicians and other healthcare providers may choose to prescribe alternative products, including generics, which would have an adverse effect on our ability to generate revenues.

In addition, federal budgetary concerns could result in the implementation of significant federal spending cuts or regulatory changes, including cuts in Medicare and other health-related spending in the near-term or changes to the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"). For example, the Bipartisan Budget Act of 2018, among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole", which will shift cost for name brand drugs away from Part D participants back to the manufacturers, which could have a negative effect on our profits. Further, on June 14, 2018 the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12.0 billion in ACA risk corridor payments to third-party payors. These efforts could mean that third party payors will not have the levels of funding historically available for coverage and reimbursement of our products, and the effects and risks to our business are not yet fully known. Further, the reimbursement and health care regulatory landscape have continued to evolve rapidly over recent months, including as a result of recent court decisions, making the healthcare landscape (and its impact on third-party payors, providers and our business, and on the viability of the ACA itself) unpredictable. In 2019, litigation, regulation, and legislation related to the ACA are likely to continue, with unpredictable and uncertain results. The extent, timing and details of the changes are not currently known, but the federally funded healthcare landscape could face significant changes during the current presidential administration, including in the near-term, and could impact state and local healthcare programs, including Medicaid and Medicare, which could also have a negative impact on our future operating results. The magnitude of the impact of these laws and developments on our business is uncertain. 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.

The introduction of generic competition in a therapeutic category where our products are used may also affect the reimbursement policies of government authorities and third-party payers. Many generic first regulations, as well as policies and practices promoting use of low cost alternatives, can place significant downward pressure on the use of

our branded products. Additionally, clinical and cost effectiveness reviews of previously established coverage decisions post generic entry, may further limit coverage and the amount of reimbursement for branded medications when there is a generic available. Reimbursement levels or the lack of reimbursement may impact the demand for, or the price of, our branded products. In the U.S, continued increase in patient cost sharing, in the form of higher deductibles, copay and coinsurance levels, have led to patients being burdened with substantial out-of-pocket costs. New measures such as copay aggregators where the manufacturer’s payment assistance, such as copay and insurance cards, no longer count toward a patient’s deductible or out-of-pocket maximum, limit the overall benefit a manufacture can offer the patient. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products, and/or our financial results from the sale of related products could be negatively and materially impacted.

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Intrarosa is dependent on third-party reimbursement to reach its market potential. Payers frequently employ a tiered system in reimbursing end-users for pharmaceutical products, with tier designation affecting copay or deductible amounts. While some of the products that Intrarosa competes with receive reimbursement from governmental healthcare programs, Intrarosa is generally classified as a Tier 3 drug, and therefore patients are unlikely to receive full reimbursement by third-party commercial payers and may not receive any reimbursement from governmental healthcare programs. As a result, patients may be subject to substantial copays or deductible requirements. Less than full reimbursement by governmental and other third-party payers may adversely affect the market acceptance of Intrarosa and put it at a competitive disadvantage to some of the competing products, including generic versions, which are often priced lower than brand name products. In addition, given the increasing number of generic competitors entering the VVA and dyspareunia market, payers may choose to implement step edits or prior authorizations prior to Intrarosa use, which could adversely impact our Intrarosa revenues and profitability. If Intrarosa does not receive adequate reimbursement coverage, the growth in Intrarosa sales may not meet our expectations or receive more favorable third-party reimbursement than its competitors, and our business, financial condition and results of operations may be materially adversely affected.

There is also significant uncertainty concerning the extent and scope of third-party reimbursement for products treating HSDD. Because Addyi® is currently the only FDA-approved therapy to treat HSDD, there is little precedent on which to base expectations as to third-party reimbursement opportunities for Vyleesi, if approved. We believe reimbursement for Vyleesi and other products for the treatment of HSDD will be similar to approved products treating erectile dysfunction and products treating women's health conditions. If this is the case, we expect that commercial payers will likely cover Vyleesi as a non-preferred product, which normally requires a higher copay or deductible than preferred drugs. As a result, patients would be unlikely to receive full reimbursement by third-party commercial payers and may not receive any reimbursement from governmental healthcare programs. Therefore, patients may be subject to substantial copays or deductible requirements. Less than full reimbursement by governmental and other third-party payers may adversely affect the market acceptance of Vyleesi. If Vyleesi does not receive adequate reimbursement coverage, our business, financial condition and results of operations may be materially adversely affected. Further, the market for products for the treatment of HSDD may be particularly vulnerable to unfavorable economic conditions and demand for Vyleesi may be tied to discretionary spending levels of the targeted patient population. Thus, any downturn in the economy could result in weakened demand for Vyleesi.

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

As part of our business strategy to expand our portfolio, we are seeking to in-license or acquire additional pharmaceutical products or companies that leverage our corporate infrastructure and commercial expertise, such as our recent acquisitions of AMAG-423 and Perosphere and our license agreements with Palatin and Endoceutics. There are limited opportunities available that align with our business strategy and there can be no assurance that we will be able to identify or complete any additional transactions in a timely manner, on a cost-effective basis, or at all, or that such transactions will be successfully integrated into our business.

Further, the valuation methods that we use for any acquired or licensed product or business require significant judgment and assumptions. Actual results and performance of the products or businesses that we may acquire, including anticipated synergies, regulatory outcomes, economies of scale and other financial benefits, could differ significantly from our original assumptions, especially during the periods immediately following the closing of the transaction. For example, if the timing of FDA approval for our product candidates, the market for our product candidates or the cost of goods for our product candidates is different from what we predicted in our models, we may not achieve the anticipated financial benefits from our investment in our development products. In addition,

acquisitions may cause significant changes to our current organization and operations, may subject us to more rigid or constraining regulations or government oversight and may have negative tax and accounting consequences. These results could have a negative impact on our financial position or results of operations and result in significant charges in future periods.

In addition, proposing, negotiating and implementing collaborations, in-licensing arrangements or acquisition agreements is a lengthy, complex, time-consuming and expensive process and such transactions are often subject to increasing regulatory oversight. Other companies, including those with substantially greater financial, marketing and sales resources, may compete with us for these arrangements, and we may not be able to enter into such arrangements on acceptable terms or at all. Further, any such strategic transactions by us could result in write-offs or impairments, which may be larger than anticipated or impact our financial statements more quickly than anticipated. Such transactions may also require us to incur additional and significant debt and contingent liabilities, or we may become liable under the target’s contracts, any of which may contain restrictive

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covenants or burdensome obligations that could adversely impact or limit our ability to grow our business, enter into new agreements, undertake our commercialization and development initiatives and adversely affect our operating results.

In addition, our cash and investments may not be sufficient to finance any additional strategic transactions, and we may choose to issue shares of our common or preferred stock as consideration. Alternatively, it may be necessary for us to raise additional funds through public or private financings, and such additional funds may not be available on terms that are favorable to us, if at all. If we are unable to successfully obtain rights to suitable products or if any acquisition or in-license arrangement we make is not successful, our business, financial condition and prospects for growth could suffer. Further, any equity or equity-linked issuance, whether as consideration for a strategic transaction or in a financing transaction, could cause our stockholders to experience significant dilution.

Even if we do acquire or license additional products or businesses, the management of a license arrangement, collaboration, or other strategic arrangement and/or integration of an acquired asset or company may disrupt our ongoing business and require management resources that otherwise would be available for ongoing commercialization efforts and development of our existing enterprise. The integration of the operations of such acquired products or businesses requires significant efforts, including the coordination of information technologies, sales and marketing, operations, manufacturing, safety and pharmacovigilance, medical, finance and business systems and processes. These efforts result in additional expenses and involve significant amounts of management's time. Our future success will significantly depend upon our ability to manage our expanded enterprise and various-staged products, which will pose substantial challenges for management, including challenges related to the management and monitoring of new operations and associated increased costs and complexity.

If we cannot successfully integrate businesses or products we may acquire or in-license into our company, we may experience material negative consequences to our business, financial condition or results of operations. For example, different skills and training are required for the promotion of various therapeutic products. Our revenues and profitability could suffer if we do not successfully expand our sales and commercial expertise into new areas, such as HSDD, preeclampsia and anticoagulant reversal products and our sales force is unable to successfully promote a portfolio of products.

Failure to obtain or maintain regulatory approval in international jurisdictions or to establish a commercialization organization, , or partner with a third party, could prevent us from marketing certain of our products abroad and could limit the growth of our business.

We may attempt to market certain of our existing and future products, product candidates or certain indications outside of the U.S. In order to market our products in the European Union ("EU") and many other foreign jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. Approval by the FDA does not ensure approval by foreign regulatory authorities and the approval procedures in foreign jurisdictions can vary widely and can involve additional clinical trials and data review beyond that required by the FDA. In addition, we have limited experience in preparing, filing and executing the applications necessary to gain foreign regulatory approvals or commercializing products outside of the U.S. and may need to rely on third-parties, including potential collaborators, to assist us with these processes. We may not be able to enter into agreements with third-parties on acceptable terms, if at all. If we pursue regulatory approval outside of the U.S., we may not obtain approval on a timely basis, or at all, and therefore we may be unable to successfully commercialize our products internationally. Additionally, even if we obtain regulatory approval, we will need to establish a commercial organization, or partner with a third party, to commercialize our products in other territories. If we are unable to successfully establish a commercialization infrastructure or enter into an agreement with a third-party on acceptable terms, or at all, the growth of our business would be limited.

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

In recent years, we have considerably expanded our product portfolio with the addition of AMAG-423 and ciraparantag and by obtaining certain development and commercialization rights to Vyleesi and Intrarosa. Management, personnel, systems and facilities that we currently have in place may not be adequate to support this recent growth, and we may not be able to retain or recruit qualified personnel in the future in this competitive environment to adequately support our organization and diversified portfolio. To manage this and any future growth effectively, we will be required to continue to manage the sales and marketing efforts for our existing products and the development of our product candidates while continuing to identify and acquire attractive additions to our portfolio, develop our oversight and collaboration efforts for our licensed products, including development-staged products, enhance our operational, financial and management controls, reporting systems and procedures, maintain benefit plans, and establish and increase our access to commercial supplies of our products, which will be challenging and for which we might not be successful. 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,

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contractors, collaborators, distributors and other third parties. 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 future growth. For example, although we believe the recent combination of our women's and maternal health sales forces will allow us to maximize the efficiency and effectiveness of our commercial organization to promote our products, the resulting reduction of our workforce needed to restructure our commercial organization may not yield the anticipated improvements in our ability to successfully commercialize our products. If we experience difficulties or are unsuccessful in managing our expanded portfolio including the impacts of our restructured commercial organization, our results of operations and business prospects will be negatively impacted.

Further, if we add additional products to our portfolio through licenses or acquisitions, we may face legal, regulatory, and compliance scrutiny or increased expenses as a result of the target's or licensor's pre-acquisition or pre-license business practices, including if such targets or licensors were alleged to have violated any privacy, data security, or other healthcare compliance laws, or failed to comply with all applicable FDA laws and requirements, regardless of whether such allegations have merit. Our recourse for such risks may be limited depending upon the remedies we are able to negotiate in the relevant transaction agreements. If any issues arise, we may not be entitled to sufficient, or any, indemnification or recourse from the licensor or the acquired company, which could have a materially adverse impact on our business and results of operations.

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

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

We may also be the target of claims asserting violations of securities and fraud and abuse laws and derivative actions or other litigation. Any such litigation could result in substantial costs and divert our management's attention and resources, which could cause serious harm to our business, operating results and financial condition. Further, we may not be successful in defending ourselves in a litigation and, as a result, our business could be materially harmed and,

as with any product liability litigation, regardless of the outcome, these claims or suits may generate negative publicity, cause other parties to submit claims or demands, harm our reputation and divert management's time and attention. These lawsuits may also result in large judgments or settlements against us, any of which could have a negative effect on our financial condition and business if in excess of our insurance coverage. Though we maintain liability insurance, if any costs or expenses associated with litigation exceed our insurance coverage or insurance coverage is denied, we may be forced to bear some or all of these costs and expenses directly, which could be substantial.

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

We have limited experience commercializing licensed products, and the addition of Intrarosa and Vyleesi to our product portfolio means that our future revenues are more dependent upon our ability to work effectively and collaboratively with our licensors to develop, market and/or sell the licensed products in our portfolio, including to obtain or maintain regulatory approval. Our arrangements with licensors is critical to successfully bringing our licensed products to market and successfully commercializing them. We rely on our licensors in various respects, including undertaking research and development programs and conducting clinical trials for our licensed products, managing or assisting with the regulatory filings and obtaining approval and maintaining and/or assisting with our commercialization efforts. We do not control our licensors, some of whom may be inexperienced, have a limited operating history, face financial and business hardships (including solvency issues), have limited operations or financial or other resources or have limited or no experience with commercialization activities; therefore, we cannot ensure that these third parties will adequately and timely perform all of their obligations to us. For example, we are dependent upon the contributions of Endoceutics, a small company, to exclusively provide us with all commercial supply and conduct certain clinical and commercialization activities. We cannot guarantee the satisfactory performance of any of our licensors and if any of our licensors breach or terminate their agreements with us, we may not be able to successfully commercialize the licensed product, which could materially and adversely affect our business, financial condition, cash flows and results of operations.

Further, even if contractual safeguards are in place in our licensing arrangements, our licensors may use their own or other technology to develop an alternative product and withdraw their support of the licensed product, or compete with the licensed product. Our licensing arrangements could also limit our activities, including our ability to compete with our licensors in certain geographic or therapeutic areas. For example, Endoceutics' assets, including the intellectual property licensed to us, are subject to a security interest held by a third-party lender, and therefore our rights and remedies under the license agreement may be impaired or inadequate. Disputes may arise between us and a licensor and may involve the ownership of technology developed under a license or other issues arising out of collaborative agreements. In addition, we must work collaboratively with our partners to conduct various activities and if we cannot do so effectively, disagreements could arise. Such disagreements could delay the related program or result in distraction or expensive arbitration or litigation, which may not be resolved in our favor.

Our license and purchase agreements contain complex provisions and impose various milestone payment, royalty, insurance, diligence, reporting and other obligations on us. If we fail to comply with our obligations, our partners may have the right to terminate the license agreement, in which event we would not be able to continue developing or commercializing the licensed products, or we may incur additional costs or may be required to litigate any disputes. If our partners allege that we have breached our obligations under such arrangements, even if such allegations are without merit, defending such allegations, including complying with any audit, reporting or dispute resolution provisions of such agreement, or conducting any investigations, can be expensive and utilize considerable amounts of management's time and efforts. For example, under the terms of our agreement with Lumara Health, the former shareholders of Lumara Health through its shareholder representatives can exercise a right to review our books and records related to the calculation of revenue which trigger the milestone payments owed to Lumara Health. Termination of a license agreement or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms, and, if we lose rights to the licensed products it could materially and adversely affect our business.

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

We rely on and intend to continue to rely on third parties, including licensors, CROs, healthcare providers, third-party logistics providers, packaging, storage and labeling providers, wholesale distributors and certain other important vendors and consultants in the conduct of our business. For example, we or our partners contract with, and plan to continue to contract with, certain CROs to provide clinical trial services for the development of our product candidates or expansion of product indications, 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 or our licensors in a timely and satisfactory manner, if the quality and accuracy of our clinical trial data or our regulatory submissions are compromised due to poor quality or failure to adhere to our protocols or regulatory requirements, or if such third parties otherwise fail to adequately discharge their responsibilities or meet deadlines, our current and future development plans and regulatory submissions, or our commercialization efforts in current indications, may be

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delayed, terminated, limited or subject us to additional expense or regulatory action, which would adversely impact our ability to generate revenues.

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

Additionally, we have limited experience independently commercializing multiple pharmaceutical products and collaborating with partners to commercialize multiple licensed products, including managing and maintaining a supply chain and distribution network for multiple products, and we are placing substantial reliance on licensors and other third parties to perform this expanded network of supply chain and distribution services for us. For example, we rely on may have to rely on other parties with whom we may enter into future agreements, to perform or oversee certain functions, such as supply, research and development, or the regulatory process for the product we license from them, and any failure of such party to perform these functions for any reason, including ceasing doing business, could have a material effect on our ability to commercialize the product.

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

We are a pharmaceutical company focused on marketing our commercial products and developing our product candidates. We plan to continue to expand our portfolio, including through the addition of commercial or development-stage products through acquisitions and in-licensing; thus, the range of skills of our executive officers and management needs to be broad and deep. If we are not able to hire and retain talent to drive commercialization and the expansion of our portfolio, we will be unlikely to maintain or increase our profitability. Because of the specialized and broad nature of our business, including both commercialized and development-stage products (some of which are licensed to us), 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). For example, in February 2019, we implemented a workforce reduction in connection with the combination of our women’s and maternal health sales forces into one integrated sales team. As a result, our workforce was reduced by approximately 110 employees, approximately 100 of whom were part of our field-based commercial organization with the remainder coming from our general and administrative functions. This workforce reduction may be disruptive to our operations, including by distracting management from our core business and affecting employee productivity and moral.

Risks Related to Regulatory Matters

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

We expect that the ACA, as currently enacted or as it may be amended in the future, the 21st Century Cures Act, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our

industry generally and on our ability to maintain or increase our 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 Medicaid Drug Rebate Program, Medicare, the 340B Drug Pricing Program under the Public Health Services Act (the "340B Program"), and fraud and abuse enforcement. For example, beginning April 1, 2013, Medicare payments for all items under Parts A and B, including drugs and biologics, and most payments to plans under Medicare Part D were reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011 (the "BCA") as amended by the American Taxpayer Relief Act of 2012. The BCA requires sequestration for most federal programs, excluding Medicaid, Social Security, and certain other programs. The BCA caps the cuts to Medicare payments for items at 2% and subsequent legislation extended the 2% reduction, on average, to 2027.

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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 the amount of reimbursement rates and terms available from governmental agencies or third-party payers, limiting the profitability of our products, increasing our rebate liability or limiting the commercial opportunities for our products, including acceptance by healthcare payers, or increasing scrutiny for announced price increases.

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

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

In addition to FDA and related regulatory requirements, our general operations, and the research, development, manufacture, sale and marketing of our products, are subject to extensive additional federal and state healthcare regulation, including the Federal Anti-Kickback Statute and the Federal False Claims Act (“FCA”) (and their state analogues), as discussed above in Item 1 under the heading “Government Regulation - Fraud and Abuse Regulation.” If we or our partners, such as licensors, fail to comply with any federal and state laws or regulations governing our industry, we could be subject to criminal and civil penalties and a range of regulatory actions that could adversely affect our ability to commercialize our products, harm or prevent sales of our products, or substantially increase the costs and expenses of commercializing and marketing our products, 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 may be subject to scrutiny under these laws, and private individuals have been active in bringing lawsuits on behalf of the government under the FCA and similar regulations in other countries. In addition, incentives exist under applicable U.S. law that encourage employees and physicians to report violations of rules governing promotional activities for pharmaceutical products. These incentives could lead to so-called whistleblower lawsuits as part of which such persons seek to collect a portion of moneys allegedly overbilled to government agencies as a result of, for example, promotion of pharmaceutical products beyond labeled claims. For example, federal enforcement agencies recently have showed interest in pharmaceutical companies’ product and patient assistance programs, including manufacturer reimbursement support services and relationships with specialty pharmacies. Some of these investigations have resulted in government enforcement authorities intervening in related whistleblower lawsuits and obtaining significant civil and criminal settlements. Such lawsuits, whether with or without merit, are typically time-consuming and costly to defend. Such suits may also result in related shareholder lawsuits, which are also costly to defend.

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

conditions of use.

In recent years, several states have enacted legislation requiring pharmaceutical companies to establish marketing and promotional compliance programs or codes of conduct and/or to file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Several states have also adopted laws that prohibit certain marketing-related activities, including the provision of gifts, meals or other items to certain healthcare providers.

We have developed and implemented a corporate compliance program based on what we believe are current best practices in the pharmaceutical industry; however, relevant compliance laws are broad in scope and there may not be regulations, guidance or court decisions that definitively interpret these laws in the context of particular industry practices. We cannot guarantee that we, our employees, our partners, our consultants or our contractors are or will be in compliance with all federal and state regulations. If we, our partners, or our representatives fail to comply with any of these laws or regulations, a range of fines, penalties and/or other sanctions could be imposed on us, including, but not limited to, restrictions on how we market and sell our products, significant fines, exclusions from government healthcare programs, including Medicare and Medicaid, litigation, or other sanctions. Even if we are not determined to have violated these laws, government investigations into these

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issues typically require the expenditure of significant resources and generate negative publicity, which could also have an adverse effect on our business, financial condition and results of operations. Such investigations or suits may also result in related shareholder lawsuits, which can also have an adverse effect on our business.

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

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

As a condition of reimbursement by various federal and state health insurance programs, we are required to calculate and report certain pricing information to federal and state agencies. Please see our discussion above in Item 1 under the heading, “Pharmaceutical Pricing and Reimbursement” for more information regarding price reporting obligations under the 340B Program and the Department of Veterans Affairs Federal Supply Schedule (the “FSS”) program.

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

Uncertainty exists as new laws, regulations, judicial decisions, or new interpretations of existing laws, or regulations related to our calculations, price reporting or payments obligations increases the chances of a legal challenge, restatement or investigation. If we become subject to investigations, restatements, or other inquiries concerning our compliance with price reporting laws and regulations, we could be required to pay or be subject to additional reimbursements, penalties, sanctions or fines, which could have a material adverse effect on our business, financial condition and results of operations. In addition, it is possible that future healthcare reform measures could be adopted which could result in increased pressure on pricing and reimbursement of our products and thus have an adverse impact on our financial position or business operations.

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

In addition to retroactive rebates and the potential for 340B Program refunds, if we are found to have knowingly submitted any false price information related to the Medicaid Drug Rebate Program to CMS, we may be liable for civil monetary penalties. Such failure could also be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, federal payments may not be available under government programs, including Medicaid or Medicare Part B, for our covered outpatient drugs.

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

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

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We are subject to ongoing regulatory obligations and oversight of our products, 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, the incurrence of significant additional expense and other limitations on our ability to commercialize our respective products.

We are subject to ongoing regulatory requirements and review, including periodic audits pertaining to the development, manufacture, labeling, packaging, adverse event reporting, distribution, storage, marketing, promotion, record keeping and export of our respective products. Failure to comply with such regulatory requirements or the later discovery of previously unknown problems with the manufacture, distributions and storage of our products, or our third-party contract manufacturing facilities or processes by which we manufacture our products may result in restrictions on our ability to manufacture, market, distribute or sell our products, 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;
- Changes to the package insert of our products, such as additional warnings regarding potential side effects or potential limitations on the current dosage or administration;
- Requirements to communicate with physicians and other customers about concerns related to actual or potential safety, efficacy, or other issues involving our products;
- Implementation of risk mitigation programs and post-approval obligations;
- Restrictions on our continued manufacturing, marketing, distribution or sale of our products;
- Temporary or permanent closing of the facilities of our third-party contract manufacturers;
- Interruption or suspension of clinical trials; and
- Refusal by regulators to consider or approve applications for additional indications.

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

In addition, if our products face any safety or efficacy issues, including drug interaction problems, under the FDC Act, the FDA has broad authority to force us to take any number of actions, including, but not limited to, the following:

- Requiring us to conduct post-approval clinical studies to assess known risks or new signals of serious risks, or to evaluate unexpected serious risks;
- Mandating changes to a product’s label;

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

- Removing an already approved product from the market.

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

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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 approval of our product candidates or our commercialization activities.

We are obligated to conduct, and are in the process of conducting, clinical trials for certain of our products and product candidates and certain post-approval clinical trials and we may be required to conduct additional clinical trials, including if we pursue approval of additional indications, new formulations or methods of administration for our products, seek commercialization in other jurisdictions, or in support of our current indications. Similarly, our licensors are conducting certain clinical trials to gain approval in various indications for drug product candidates. The FDA could determine that our clinical trials, or those of our licensors, and/or our or their manufacturing processes were not properly designed, did not include enough patients or appropriate administration, were not conducted in accordance with applicable laws and regulations, or were otherwise not properly managed. In addition, according to cGCP we and/or our licensors are responsible for conducting, recording and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA may conduct inspections of clinical investigator sites which are involved in clinical development programs for our proprietary or licensed products to ensure their compliance with cGCP regulations. If the FDA determines that we, our licensors, our respective CROs or our respective study sites fail to comply with applicable cGCP regulations, the FDA may deem the clinical data generated in such clinical trials to be unreliable and may disqualify certain data generated from those sites or require us and/or our licensors to perform additional clinical trials. For example, many of the clinical trials for our development programs that we have acquired or in-licensed were conducted by small companies that might have had fewer controls or oversight related to their clinical programs. Clinical trials and manufacturing processes are subject to similar risks and uncertainties outside of the U.S. Any such deficiency in the design, implementation or oversight of clinical development programs or post-approval clinical studies could cause us to incur significant additional costs, experience delays or prevent us from commercializing our approved products in their current indications, or obtaining marketing approval for additional indications or for our product candidates, including Vyleesi, AMAG-423 and ciraparantag.

Further, our third-party contract manufacturing facilities and those of our licensors are subject to cGMP regulations enforced by the FDA and equivalent foreign regulations and regulatory agencies through periodic inspections to confirm such compliance. Contract manufacturers must continually expend time, money and effort in production, record-keeping and quality assurance and control to ensure that these manufacturing facilities meet applicable regulatory requirements. Failure to maintain ongoing compliance with cGMP or similar foreign regulations and other applicable manufacturing requirements of various U.S. or foreign regulatory agencies could result in, among other things, the issuance of warning letters, fines, the withdrawal or recall of our products from the marketplace, failure to approve product candidates for commercialization, total or partial suspension of product production, the loss of inventory, suspension of the review of our or our licensors' current or future NDAs or equivalent foreign filings, enforcement actions, injunctions or criminal prosecution and suspension of manufacturing authorizations. For example, in early 2017, our primary third-party manufacturer of Makena received a warning letter from the FDA, which has resulted in supply disruptions of our Makena IM products that led to our current out-of-stock situation for both our single-dose and multi-dose branded Makena vials as well as periodic disruptions to our authorized generic supply. 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 reputational harm, and could have a severe adverse impact on our profitability and the future prospects of our business. If any regulatory agency inspects any of these manufacturing facilities and determines that they are not in compliance with cGMP or similar regulations or our contract manufacturers otherwise determine that they are not in compliance with these regulations, as applicable, such contract manufacturers could experience an inability to manufacture sufficient quantities of product to meet demand or incur unanticipated compliance expenditures.

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

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

Makena was approved by the FDA in February 2011 under Subpart H. As a condition of approval under Subpart H, the FDA required that Makena's sponsor perform certain adequate and well-controlled post-approval clinical studies to verify and describe the clinical benefits of Makena as well as fulfill certain other post-approval commitments. We have recently completed enrollment of the confirmatory clinical study of Makena and expect to release the data by the end of the first quarter of 2019. Furthermore, a follow-up study of the babies born to mothers from the efficacy and safety clinical study is currently ongoing and is expected to be completed by July 2020. If the required post-approval studies fail to verify the clinical benefits of the drug or if we fail to perform the required post-approval studies with due diligence, the FDA has the authority to withdraw approval of the drug following a hearing conducted under the FDA's regulations, which would have a materially adverse impact on our business. We cannot be certain of the results of the confirmatory clinical studies or what action the FDA may take if the results of those studies are not as expected based on clinical data that FDA has already reviewed.

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 complex 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. For example, in June 2018, the State of California enacted the California Consumer Privacy Act of 2018 (the "CCPA"), which will come into effect on January 1, 2020 and provides new data privacy rights for consumers and new operational requirements for companies, which may increase our compliance costs and potential liability. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA could mark the beginning of a trend toward more stringent state privacy legislation in the U.S., which could increase our potential liability and adversely affect our business.

In addition, in the course of our business, we may obtain health information from third parties (e.g., healthcare providers who prescribe our products) that is subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"). 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/HITECH.

We could also be negatively impacted by existing and proposed laws and regulations, as well as government policies and practices related to cybersecurity, data privacy, data localization and data protection outside of the U.S., such as the General Data Protection Regulation ("GDPR"), which took effect in the EU in May 2018. The GDPR extends the geographical scope of EU data protection law to non-EU entities under certain conditions, tightens existing EU data protection principles and creates new obligations for companies and new rights for individuals. Although we believe we are in compliance the applicable provisions of the GDPR, the GDPR is new and therefore guidance, interpretation and enforcement under the GDPR are still developing. The GDPR may increase our responsibility and potential liability in relation to personal data that we process, expose us to substantial potential fines and increase our compliance costs. Notably, on January 21, 2019, Google was fined nearly $57.0 million by French regulators for

violating GDPR. The GDPR could also cause our development costs to increase in connection with clinical trials we are currently conducting and may conduct in the future in the EU for our products and product candidates.

Failure to comply with data protection laws and regulations both within and outside of the U.S. 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.

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

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

Risks Related to our Financial Condition and Results

We may not be able to generate sufficient revenues to achieve and maintain profitability in the future.

In recent years, we have focused on developing a broad product portfolio, including through acquisitions and in-licensing arrangements. The additions to our product portfolio include both commercial products, such as Makena and Intrarosa, which require significant resources to commercialize and product candidates, such as Vyleesi, AMAG-423 and ciraparantag, which require substantial development time and resources before they might generate revenues, if at all. Investment in our development and commercialization efforts often requires significant up-front costs and our products may fail to achieve or maintain commercial success or our product candidates may never receive approval. We expect to continue to incur significant expenses as we continue to commercialize Feraheme, Makena, Intrarosa and Vyleesi, if approved, and develop AMAG-423 and ciraparantag. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. As a result of the substantial expenditures required to support our products and product candidates, we will need to generate sufficient revenues in future periods to achieve and maintain profitability and positive cash flows. In recent years, our profitability was based primarily on our Makena revenues. However, during 2018, we lost market exclusivity for Makena and generic competition commenced in mid-2018. We expect that revenues from sales of Makena will continue to decline in future years due to increased generic competition, including other generic versions of Makena which have been and may be approved by the FDA. There is no guarantee that we will generate sufficient revenues to support our business, or that we will be able to achieve profitability or maintain profitability, if achieved, and there is no guarantee that we will be able to maintain positive cash flow from operations. In the past, we have financed our operations primarily from the issuance of debt and equity, cash from products sales and cash generated by our investing activities. As of December 31, 2018, we incurred an operating loss of $47.0 million, contributing to an accumulated deficit of approximately $542.4 million.

Due to the numerous risks and uncertainties associated with developing and commercializing pharmaceutical products, as well as those related to our expectations for our products and other commercial activities, we are unable

to predict with certainty the extent of any future losses. Our ability to achieve sustained profitability in the future depends, in large part, on our ability to:

- Obtain regulatory approval for our current product candidates, particularly Vyleesi, or any future product candidates;
- Generate revenues from our product candidates, if approved, and continue to grow revenues from our approved products;
- Successfully commercialize our existing products, including the costs of and success of our marketing and awareness campaigns for Intrarosa and Vyleesi, if approved;
- Enter into and maintain agreements to develop our product candidates and commercialize our products;

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- Manufacture our products in sufficient quantities to meet demand;
- Obtain adequate reimbursement coverage for our products from insurance companies, government programs and other third-party payors;
- Progress our clinical development programs in a timely and cost-effective manner, including our ongoing clinical trials for AMAG-423 and ciraparantag; and
- Identify, assess and consummate potential product acquisitions in a cost-effective manner and successfully develop any products we acquire.

If we are not successful in marketing and selling our products, if revenues grow more slowly than we anticipate, if our product candidates are not approved, or if our operating expenses exceed our expectations, or if we are otherwise unable to achieve, maintain or increase profitability on a quarterly or annual basis, our business, results of operations and financial condition could be materially adversely affected and the market price of our common stock may decline.

We may not be able to generate sufficient cash flow to service all of our indebtedness and other obligations.

As of December 31, 2018, we had approximately $341.4 million of total debt outstanding, including $320.0 million aggregate principal amount of our convertible notes due June 1, 2022 bearing interest at 3.25% annually (the “2022 Convertible Notes”) issued in May 2017.

Our ability to make scheduled payments of the principal of, or to pay interest on the 2022 Convertible Notes depends on our future performance, which is subject to economic, financial, competitive and other factors that may be beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and support our growth strategies. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to repay our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations, including under our 2022 Convertible Notes obligations. In addition, if for any reason we are unable to meet our debt service and repayment obligations, we could be in default under the terms of the agreements governing our indebtedness, which could allow our creditors at that time to declare all outstanding indebtedness to be due and payable. Under these circumstances, we may not have sufficient funds to satisfy our debt obligations.

Further, holders of the 2022 Convertible Notes have the right to require us to repurchase their notes upon the occurrence of a fundamental change (which includes certain change of control transactions, stockholder-approved liquidations and dissolutions and certain stock exchange delisting events) at a repurchase price equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest. Upon conversion of the 2022 Convertible Notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we will be required to make cash payments in respect of the notes being converted. We may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of the 2022 Convertible Notes upon an occurrence of a fundamental change. Further, because the indentures governing the 2022 Convertible Notes require that we elect the method by which we will settle conversions significantly in advance of when we are required to deliver the conversion consideration, we may not have sufficient cash available or be able to obtain financing at the time we are ultimately required to settle the 2022 Convertible Notes. Our failure to repurchase the 2022 Convertible Notes at a time when the repurchase is required by the indenture or to pay any cash payable on future conversions of the 2022 Convertible Notes would constitute an event of default.

We may need additional capital to achieve our business objectives and make contingent payments that may become due under our strategic transaction arrangements, which could cause significant dilution to our stockholders.

We may require additional funds or need to establish additional alternative strategic arrangements to execute a business development transaction. We have expended and continue to expend substantial costs associated with the clinical development of our product candidates, including AMAG-423 and ciraparantag, the continued commercialization of our products, our debt obligations and certain milestone payments to our partners. We may at any time seek funding through additional arrangements with collaborators through public or private equity or debt financings, which could result in dilution to our stockholders or increased fix payment obligations. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. The conditions of the credit and capital markets can be volatile, unpredictable and inconsistent and we may not be able to obtain financing or to secure

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alternative strategic arrangements on acceptable terms or within an acceptable timeframe, if at all, which would limit our ability to execute on our strategic plans. Moreover, we may experience a reduction in value or loss of liquidity with respect to our investments, which would put further strain on our cash resources.

Our current level of cash on hand may limit our ability to take advantage of attractive business development opportunities and execute on our strategic plans. In addition, our cash on hand may not be sufficient to make any cash milestone payments to our partners upon the achievement of sales or regulatory milestones. Our ability to make these required payments could be adversely affected if we do not achieve expected revenue and cash flow forecasts, or if we are unable to find other sources of cash in the future. We may also suffer reputational harm and be viewed as an undesirable acquiror or business development partner if we are unable to make the required payments under our strategic transaction arrangements. In addition, if equity or debt investors perceive that our debt levels are too high relative to our profit, our stock price could be negatively affected and/or our ability to raise new equity or debt capital could be limited.

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

Our long-term capital requirements will depend on many other factors, including, but not limited to:

- The commercial success of our products and costs associated with the commercialization of our products, including marketing, sales and distribution costs;
- The outcome, timing and costs associated with development and regulatory approval of our product candidates, including conducting clinical trials;
- Our obligations to make milestone payments, royalty payments or both under our in-licensing arrangements;
- 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 may become a party;
- The costs of manufacturing our products and product candidates, including 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.

Additional funds may not be available to us if and when we need them, on terms that are acceptable to us, or at all. If we are unable to raise additional funds, if needed, we may have to delay, scale back or discontinue the development or commercialization of one or more of our products or product candidates and/or other areas of our business.

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

In general, under Section 382 of the Internal Revenue Code of 1986, as amended (the “Code”), a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change net operating losses and

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

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There can be no assurance that we will not undergo an ownership change and 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.

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.

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

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

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

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

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

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

estimates, there could be a material adverse effect on our financial results and the performance of our stock.

Further, in January 2019, we issued financial guidance, including expected 2019 total revenue and profitability metrics, which is likewise based on estimates and the judgment of management. If, for any reason, we are unable to achieve our projected 2019 revenue or profitability, we may not realize our publicly announced financial guidance. If we fail to realize, or if we change or update any element of, our publicly disclosed financial guidance or other expectations about our business, our stock price could decline in value.

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

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In addition, to determine the required quantities of our products and 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 demand could result in unmet demand or excess inventory, each of which would adversely impact our financial results and results of operations.

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

Goodwill and other intangibles represent a significant portion of our assets. As of December 31, 2018 and 2017, goodwill and other net intangibles comprised approximately 54% and 42%, respectively, of our total assets. Goodwill and other intangible assets are subject to an impairment analysis, which involves judgment and assumptions, at least annually or whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. For example, we recorded intangible asset impairment charges of $319.2 million during 2017. The procedures, judgments and assumptions used in our goodwill and intangible assets impairment testing, and the results of our testing, are discussed in Item 7 of this report “Management’s Discussion and Analysis of Financial Condition and Results of Operations” under the captions “Critical Accounting Policies” and “Results of Operations.” Events giving rise to impairment of goodwill or intangible assets are an inherent risk in the pharmaceutical industry and often cannot be predicted. As a result of the significance of goodwill and other intangible assets, our results of operations and financial position in a future period could be negatively impacted should additional impairments of our goodwill or other intangible assets occur.

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

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

- Product revenues, including the decline in Makena sales and the extent to which sales of the Makena auto-injector and the Makena authorized generic are able to offset the decrease in sales of Makena;
- Regulatory approval of our product candidates, including Vyleesi, AMAG-423 and ciraparantag;
- 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;
- The loss of a key customer or group purchasing organizations (“GPOs”);
- The timing of costs and liabilities incurred in connection with our clinical trials and other product development and commercialization efforts, business development activities or business development transactions into which we may enter;
- Milestone payments we may be required to pay pursuant to contractual obligations;

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

- Any changes to the mix of our business;

- Any adverse impact on our financial results stemming from our recent corporate restructuring;

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

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- The implementation of new or revised accounting or tax rules or policies; and

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

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, specialty pharmacies and physicians ("Customers"). 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 the Customers with whom we do business determine to limit their purchases of our products, our product revenues could be adversely affected. Also, in the event the Customers 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 iron deficiency anemia market. While these contracts are intended to support the use of our products, our competitors could offer better pricing, incentives, higher rebates or exclusive relationships.

Our contracting strategies 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 strategies, 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.

Risks Related to Our Common Stock

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

The market price of our common stock has been, and may continue to be, volatile, and your investment in our stock could decline in value or fluctuate significantly. Our stock price has ranged between $14.35 and $26.10 in the fifty-two week period through February 25, 2019. 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 2022 Convertible Notes, other equity or equity-linked financings, or alternative strategic arrangements that we may pursue.

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.

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Certain provisions in our charter and by-laws, certain provisions of our 2022 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.

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 viewed by a potential acquiror as costly in light of the 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 Fourth 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 2022 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 2022 Convertible Notes may be increased as described in the indenture, in each case, upon the occurrence of certain change of control transactions, which could have the effect of preventing a change of control, whether or not it is desired by, or beneficial to, our stockholders, or may result in the acquisition of us being on terms less favorable to our stockholders than it would otherwise be.

ITEM 1B. UNRESOLVED STAFF COMMENTS:

None.

ITEM 2. PROPERTIES:

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. The initial

term of the lease was five years and two months with one five-year extension term at our option. We have entered into several amendments to the original lease to add additional space and to extend the term of the original lease to April 2021. In addition to base rent, we are also required to pay a proportionate share of the Landlord's operating costs.

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

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

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PART II

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

Market Information

Our common stock trades on the NASDAQ Global Select Market ("NASDAQ") under the trading symbol "AMAG." On February 25, 2019, the closing price of our common stock, as reported on the NASDAQ, was $15.57 per share.

Stockholders

On February 25, 2019, we had approximately 90 stockholders of record of our common stock, and we believe that the number of beneficial holders of our common stock was approximately 8,000 based on responses from brokers to a search conducted by Broadridge Financial Solutions, Inc. on our behalf.

Repurchases of Equity Securities

The following table provides certain information with respect to our purchases of shares of our stock during the three months ended December 31, 2018.

Period	Total Number of Shares Purchased [1]	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs [2]	Maximum Number of Shares (or approximate dollar value) That May Yet Be Purchased Under the Plans or Programs [2]
October 1, 2018 through October 31, 2018	266	$ 21.28	—	953,788
November 1, 2018 through November 30, 2018	263	18.18	—	1,136,091
December 1, 2018 through December 31, 2018	2,264	17.58	—	1,349,996
Total	2,793	$ 17.99	—	

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

(2) We did not repurchase shares of our common stock during the fourth quarter of 2018. We have repurchased and retired $39.5 million cumulatively of our common stock under our share repurchase program to date. These shares were purchased pursuant to a repurchase program authorized by our Board of Directors that was announced in January 2016 to repurchase up to $60.0 million of our common stock, of which $20.5 million remains outstanding as of December 31, 2018. 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, 2018.

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Five Year Comparative Stock Performance

The following graph compares the yearly percentage change in the cumulative total stockholder return on our common stock with the cumulative total return on the NASDAQ Global Select Market Index and the NASDAQ Biotechnology Index over the past five years. The comparisons assume $100 was invested on December 31, 2013 in our common stock, the NASDAQ Global Select Market Index and the NASDAQ Biotechnology Index, and assumes reinvestment of dividends, if any.

	12/31/2013	12/31/2014	12/31/2015	12/31/2016	12/31/2017	12/31/2018
AMAG Pharmaceuticals, Inc.	100.00	175.54	124.34	143.33	54.57	62.56
NASDAQ Global Select Market Index	100.00	116.05	121.	131.51	170.67	163.02
NASDAQ Biotechnology Index	100.00	131.71	140.56	112.25	133.67	121.24

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

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

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ITEM 6. SELECTED FINANCIAL DATA:

The following table sets forth selected financial data as of and for the years ended December 31, 2018, 2017, 2016, 2015 and 2014. 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,				
	2018	2017	2016	2015	2014
	(in thousands, except per share data)				
Statements of Operations Data					
Continuing Operations:					
Revenues:					
Product sales, net	$473,852	$495,645	$432,170	$341,816	$109,998
Other revenues [1]	150	124	317	52,328	14,386
Total revenues	474,002	495,769	432,487	394,144	124,384
Costs and expenses:					
Cost of product sales [2]	215,892	161,349	96,314	78,509	20,306
Research and development expenses	44,846	75,017	65,561	42,710	24,160
Acquired in-process research and development [3]	32,500	65,845	—	—	—
Selling, general and administrative expenses [4]	227,810	178,151	169,468	131,127	72,254
Impairment of intangible assets [5]	—	319,246	15,724	—	—
Acquisition-related costs	—	—	—	11,232	9,478
Restructuring expenses	—	—	341	2,274	2,023
Total costs and expenses	521,048	799,608	347,408	265,852	128,221
Operating (loss) income	(47,046)	(303,839)	85,079	128,292	(3,837)
Other income (expense):					
Interest expense	(51,971)	(68,382)	(73,153)	(53,251)	(14,697)
Loss on debt extinguishment [6]	(35,922)	(10,926)	—	(10,449)	—
Interest and dividend income	5,328	2,810	3,149	1,501	975
Other (expense) income	(74)	(70)	189	(9,173)	217
Total other expense	(82,639)	(76,568)	(69,815)	(71,372)	(13,505)
(Loss) income from continuing operations before income taxes	(129,685)	(380,407)	15,264	56,920	(17,342)
Income tax expense (benefit) [7]	39,654	(175,254)	13,171	12,764	(153,159)
Net (loss) income from continuing operations	$(169,339)	$(205,153)	$2,093	$44,156	$135,817
Discontinued operations:					
Income (loss) from discontinued operations	$18,873	$10,313	$(6,209)	$(17,076)	$—
Gain on sale of CBR business	87,076	—	—	—	—
Income tax expense (benefit)	2,371	4,388	(1,633)	(5,699)	—
Net income (loss) from discontinued operations	103,578	5,925	(4,576)	(11,377)	—
Net (loss) income	$(65,761)	$(199,228)	$(2,483)	$32,779	$135,817
Basic net (loss) income per share:					
(Loss) income from continuing operations	$(4.92)	$(5.88)	$0.06	$1.40	$6.06
Income (loss) from discontinued operations	3.01	0.17	(0.13)	(0.36)	—
Total	$(1.91)	$(5.71)	$(0.07)	$1.04	$6.06

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Diluted net (loss) income per share:					
(Loss) income from continuing operations	$(4.92)	$(5.88)	$0.06	$1.25	$5.45
Income (loss) from discontinued operations	3.01	0.17	(0.13)	(0.32)	—
Total	$(1.91)	$(5.71)	$(0.07)	$0.93	$5.45
Weighted average shares outstanding used to compute net (loss) income per share:					
Basic	34,394	34,907	34,346	31,471	22,416
Diluted	34,394	34,907	34,833	35,308	25,225

	As of December 31,				
	2018	2017	2016	2015	2014
Balance Sheet Data					
Cash, cash equivalents and investments	$394,171	$299,448	$527,130	$456,359	$144,186
Working capital (current assets less current liabilities)	$359,726	$204,150	$405,681	$360,753	$107,548
Total assets [8]	$1,175,459	$1,900,356	$2,478,426	$2,476,210	$1,388,933
Long-term liabilities [9]	$263,360	$832,394	$1,231,160	$1,298,025	$762,492
Stockholders' equity	$746,655	$790,244	$934,389	$932,264	$459,953

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(1) In 2015, we recognized $44.4 million in revenues associated with the amortization of the remaining deferred revenue balance as a result of the termination of a license, development and commercialization agreement (the "Takeda Termination Agreement") with Takeda Pharmaceutical Company Limited ("Takeda") and $6.7 million of additional revenues related to payments made by Takeda upon the final termination date under the terms of the Takeda Termination Agreement.

(2) Cost of product sales in 2018, 2017, 2016, 2015, and 2014 included approximately $158.4 million, $130.4 million, $77.8 million, $63.3 million, and $6.1 million of non-cash expense related to the amortization of intangible assets and the step-up of Lumara Health's inventories at the acquisition date, respectively.

(3) 2018 reflects $12.5 million paid in connection with our acquisition of AMAG-423 and $20.0 million paid to Palatin Technologies, Inc. upon FDA acceptance of the Vyleesi NDA. 2017 reflects $65.8 million related to a $60.0 million one-time upfront payment under the terms of the Palatin License Agreement and $5.8 million, which represented a portion of the consideration recorded in 2017 under the terms of the Endoceutics License Agreement.

(4) 2018 and 2017 reflect increases driven by organizational growth associated with significant launch activities for multiple products and costs related to the commercialization of Intrarosa. 2016 reflects an increase in the Makena-related contingent consideration based on the expected timing of milestone payments. In addition, 2015 reflects a full year recognition of Makena-related selling, general and administrative expenses compared to a partial period in 2014 following our November 2014 acquisition of Lumara Health.

(5) In 2017, we recognized a $319.2 million impairment charge related to the Makena base technology intangible asset. In 2016, we recognized $15.7 million of charges related to the impairment of the remaining net intangible asset for the MuGard Rights.

(6) Reflects $35.9 million, $10.9 million and $10.4 million loss on debt extinguishment in 2018, 2017 and 2015, respectively, due to the early redemption of a $500.0 million aggregate principal amount of 7.875% Senior Notes due 2023 (the "2023 Senior Notes"), the early repayment of a 2015 term loan facility and the early repayment of a 2014 term loan facility, respectively.

(7) The $175.3 million income tax benefit in 2017 was primarily driven by the deferred tax benefit related to the Makena base technology intangible asset impairment and amortization. The $153.2 million income tax benefit in 2014 reflects a $132.9 million decrease in our valuation allowance due to taxable temporary differences available as a source of income to

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realize the benefit of certain of our pre-existing deferred tax assets as a result of the acquisition of Lumara Health.

(8) Reflects the acquisition of CBR during 2015, the recognition of a $319.2 million impairment charge related to the Makena base technology intangible asset in 2017 and the sale of the CBR business in 2018.

(9) Long-term liabilities increased in 2015 as a result of the borrowing against the 2023 Senior Notes and decreased in 2017 and 2018 primarily due to the repayment of our term loan facilities and the 2023 Senior Notes, respectively.

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

Overview

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a pharmaceutical company focused on bringing innovative products to patients with unmet medical needs by leveraging our development and commercial expertise to invest in and grow our pharmaceutical products across a range of therapeutic areas. Our currently marketed products support the health of patients in the areas of maternal and women's health, anemia management and cancer supportive care, including Feraheme® (ferumoxytol injection) for intravenous ("IV") use, Makena® (hydroxyprogesterone caproate injection), Intrarosa® (prasterone) vaginal inserts and MuGard® Mucoadhesive Oral Wound Rinse. In addition to our marketed products, our portfolio includes three product candidates, Vyleesi™ (bremelanotide), which is being developed for the treatment of hypoactive sexual desire disorder ("HSDD") in pre-menopausal women, AMAG-423 (digoxin immune fab (ovine)), which is being studied for the treatment of severe preeclampsia, and ciraparantag, which is being studied as an anticoagulant reversal agent.

On February 7, 2019, we announced that we combined our women's and maternal health sales forces into one integrated sales team. This combined sales force will promote both Intrarosa and Makena and will provide healthcare professionals with one commercial point of contact and seeks to maximize efficiency and effectiveness for the promotion of our commercial products. As a result, we reduced our overall headcount by approximately 110 employees, approximately 100 of whom were part of our field-based commercial organization with the remainder coming from our general and administrative functions. We expect to record a one-time restructuring charge of approximately $6.0 million, primarily related to severance and related benefits, in the first quarter of 2019.

On January 16, 2019, we acquired ciraparantag with our acquisition of Perosphere Pharmaceuticals Inc. ("Perosphere"), a privately-held biopharmaceutical company pursuant to an Agreement and Plan of Merger. Ciraparantag is an anticoagulant reversal agent in development for patients treated with novel oral anticoagulants ("NOACs") or low molecular weight heparin ("LMWH") when reversal of the anticoagulant effect of these products is needed for emergency surgery, urgent procedures or due to life-threatening or uncontrolled bleeding. For additional information on the Perosphere acquisition, see Note W, "Subsequent Events," to our consolidated financial statements included in this Annual Report on Form-10-K.

We intend to continue to expand the impact of our current and future products for patients by delivering on our growth strategy, which includes collaborating on and acquiring promising therapies at various stages of development, and advancing them through the clinical and regulatory process to deliver new treatment options to patients. Our primary sources of revenue are from sales of Makena, Feraheme and Intrarosa. Except as otherwise stated below, the following discussions of our results of operations reflect the results of our continuing operations, excluding the results related to the CBR business, which we sold in August 2018. The CBR business has been separated from continuing operations and reflected as a discontinued operation. See Note C, "Discontinued Operations and Held for Sale," to our consolidated financial statements included in this Annual Report on Form 10-K.

AMAG's Portfolio of Products and Product Candidates

Feraheme

Feraheme received approval from the U.S. Food and Drug Administration (the "FDA") in June 2009 for the treatment of iron deficiency anemia ("IDA") in adult patients with chronic kidney disease ("CKD"). In February 2018, the FDA approved the supplemental New Drug Application to expand the label to include all eligible adult IDA patients who have intolerance to oral iron or have had unsatisfactory response to oral iron in addition to patients who

have CKD. IDA is prevalent in many different patient populations, such as patients with CKD, gastrointestinal diseases or disorders, inflammatory diseases, chemotherapy-induced anemia and abnormal uterine bleeding. For many of these patients, treatment with oral iron is unsatisfactory or is not tolerated. It is estimated that approximately five million people in the U.S. have IDA and we estimate that a small fraction of the patients who are diagnosed with IDA regardless of the underlying cause are currently being treated with IV iron.

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The expanded Feraheme label was supported by two positive pivotal Phase 3 trials, which evaluated Feraheme versus iron sucrose or placebo in a broad population of patients with IDA and positive results from a third Phase 3 randomized, double-blind non-inferiority trial that evaluated the incidence of moderate-to-severe hypersensitivity reactions (including anaphylaxis) and moderate-to-severe hypotension with Feraheme compared to Injectafer® (ferric carboxymaltose injection) (the "Feraheme comparator trial"). The Feraheme comparator trial demonstrated comparability to Injectafer® based on the primary composite endpoint of the incidence of moderate-to-severe hypersensitivity reactions (including anaphylaxis) and moderate-to-severe hypotension (Feraheme incidence 0.6%; Injectafer® incidence 0.7%). Adverse event rates were similar across both treatment groups; however, the incidence of severe hypophosphatemia (defined by blood phosphorous of <0.2 mg/dl at week 2) was less in the patients receiving Feraheme (0.9% of patients) compared to those receiving Injectafer® (50.8% of patients).

Makena

Makena is indicated to reduce the risk of preterm birth in women pregnant with a single baby who have a history of singleton spontaneous preterm birth. We acquired the rights to Makena in connection with our acquisition of Lumara Health Inc. ("Lumara Health") in November 2014.

Makena was approved by the FDA in February 2011 as an intramuscular ("IM") injection (the "Makena IM product") packaged in a multi-dose vial and in February 2016 as a single-dose preservative-free vial. The orphan drug exclusivity period that was granted to the Makena IM product in 2011 expired in February 2018. In February 2018, the Makena auto-injector was approved by the FDA for administration via a pre-filled subcutaneous auto-injector, a drug-device combination product (the "Makena auto-injector"). The Makena auto-injector offers an alternative administration option for patients and providers and was designed with features, such as a shorter, thinner, non-visible needle compared to the Makena IM product, to help address some of the known barriers to treatment of recurrent preterm birth, including the lack of patient acceptance and adherence. Our commercial strategy for Makena currently focuses on driving awareness of the availability and attributes of the Makena auto-injector and converting current IM prescribers to the Makena auto-injector.

In July 2018, simultaneously with the launch of the first generic competitor to Makena, we launched our own authorized generic of both the single- and multi-dose vials through our generic partner, Prasco, LLC (the "Makena authorized generic"). As a result of this partnership, we are able to provide patients and healthcare providers with access to therapeutically equivalent versions of the branded Makena IM injection. Currently, there are two generic competitors in the market in addition to the Makena authorized generic product, and we expect additional generic entrants to enter the market in 2019 to compete against both the 1ml and 5ml presentations.

Intrarosa

In February 2017, we entered into a license agreement (the "Endoceutics License Agreement") with Endoceutics, Inc. ("Endoceutics") pursuant to which Endoceutics granted us the U.S. rights to Intrarosa, an FDA-approved product for the treatment of moderate to severe dyspareunia (pain during sexual intercourse), a symptom of vulvar and vaginal atrophy ("VVA"), due to menopause. Intrarosa was approved by the FDA in November 2016 and was launched commercially in July 2017.

Intrarosa is the only FDA-approved vaginal non-estrogen treatment indicated for the treatment of moderate to severe dyspareunia, a symptom of VVA, due to menopause. Intrarosa contains prasterone, a synthetic form of dehydroepiandrosterone, which is an inactive endogenous (i.e. occurring in the body) sex steroid. Prasterone is converted by enzymes in the body into androgens and estrogens to help restore the vaginal tissue as indicated by improvements in the percentage of superficial cells, parabasal cells, and pH. The mechanism of action of Intrarosa is

not fully established. The effectiveness of Intrarosa on moderate to severe dyspareunia in post-menopausal women was examined in two primary 12-week placebo-controlled efficacy trials. Women who used Intrarosa in these trials experienced a significant reduction in moderate to severe dyspareunia, as well as statistically significant improvements in the percentage of vaginal superficial cells, parabasal cells and vaginal pH. In these trials, vaginal discharge and atypical pap smears were the most common adverse reactions. Intrarosa is contraindicated in women with undiagnosed abnormal genital bleeding. The label for Intrarosa contains a precaution that it has not been studied in women with a history of breast cancer.

In the third quarter of 2017, Endoceutics initiated a clinical study with Intrarosa for the treatment of HSDD in post-menopausal women, which is now fully enrolled. Upon review of the full data set, it will be determined whether to continue to pursue an additional clinical trial to support an eventual filing with the FDA for an HSDD indication. We have agreed to share the direct costs related to such studies based upon a negotiated allocation with us funding up to $20.0 million, of which we have paid approximately $6.0 million. Additional details regarding the Endoceutics License Agreement can be found in Note Q,

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"Collaboration, License and Other Strategic Agreements," to our consolidated financial statements included in this Annual Report on Form 10-K.

Vyleesi

In January 2017, we entered into a license agreement (the "Palatin License Agreement") with Palatin Technologies, Inc. ("Palatin") pursuant to which we acquired Vyleesi, an investigational product designed to treat acquired generalized HSDD in pre-menopausal women. In June 2018, the FDA accepted the Vyleesi NDA. The Prescription Drug User Fee Act ("PDUFA") date for completion of FDA review of the Vyleesi NDA is June 23, 2019, and if approved on that date, we expect to launch Vyleesi in the second half of 2019. In November 2018, as part of our discussions with the FDA regarding its review of the NDA submission for Vyleesi, the FDA requested additional data assessing 24-hour ambulatory blood pressure with short-term daily use of Vyleesi. This Phase 1 study is ongoing and is being conducted in premenopausal healthy volunteers. We believe that this study can be conducted and data submitted prior to the June 23, 2019 PDUFA date.

Vyleesi, a melanocortin 4 receptor agonist is designed to be an on demand therapy used in anticipation of sexual activity and self-administered by premenopausal women with HSDD in the thigh or abdomen via a single-use subcutaneous auto-injector. Two identically-designed Phase 3 studies evaluating the safety and efficacy of Vyleesi compared to placebo were conducted by Palatin for the treatment of HSDD in pre-menopausal women. Both trials consisted of a 24-week double-blind, placebo-controlled, randomized parallel group core study phase, comparing a subcutaneous dose of 1.75 mg Vyleesi versus placebo, self-administered via an auto-injector, on demand, and patients were equally randomized (1:1 ratio) to either Vyleesi or placebo. The co-primary endpoints for these trials were evaluated using patient self-reported scores from Question One and Two of the Female Sexual Function Index: Desire Domain ("FSFI-D") and Question 13 from the Female Sexual Distress Scale-Desires/Arousal/Orgasm ("FSDS-DAO"). Women who completed the randomized control core study phase of either study had the option to continue in an ongoing open-label safety extension phase of the study for an additional 52 weeks, which gathered additional data on the safety of long-term and repeated use of Vyleesi. Nearly 80% of patients who completed the randomized portion of the study elected to remain in the open-label portion of the study. All of the patients in the extension study received Vyleesi.

Both studies met the pre-specified co-primary efficacy endpoints of improvement in low sexual desire and decrease in related distress as measured using validated patient-reported outcome instruments. For women taking Vyleesi compared to placebo, the change from baseline in low sexual desire, as measured by the FSFI-D, showed statistically significant improvement with Vyleesi in both median and mean measures of desire in both Phase 3 studies. The median change from baseline was 0.60 vs. 0.00 for both studies, and the mean change from baseline was 0.54 vs. 0.24 ($p=0.0002$) for one study and 0.63 vs. 0.21 ($p<0.0001$) for the other study. Likewise, for women taking Vyleesi compared to placebo, the change from baseline in related distress, as measured by the FSDS-DAO Question 13, also demonstrated statistically significant improvement with Vyleesi in both median and mean measures of desire in both Phase 3 studies. The median change from baseline was -1.0 vs. 0.0 for both studies, and the mean change from baseline was -0.7 vs. -0.4 for both studies, with pValues of <0.0001for one study and 0.0053 for the other study. The change in the number of satisfying sexual events, a key secondary endpoint, was not significantly different from placebo in either clinical trial.

In the Phase 3 clinical trials, the most frequent adverse events were nausea, flushing, injection site reactions and headache, which were generally mild-to-moderate in severity and were transient. Approximately 18% of patients discontinued participation in the Vyleesi arm due to adverse events in both studies versus 2% in placebo. The adverse events in the extension portion of the study were consistent with that of the controlled studies described above.
AMAG-423

In September 2018, we exercised our option to acquire the global rights to AMAG-423 pursuant to an option agreement entered into in July 2015 with Velo Bio, LLC, a privately-held life sciences company ("Velo"). AMAG-423 is a polyvalent antibody currently in development for the treatment of severe preeclampsia in pregnant women and has been granted both orphan drug and Fast Track designations by the FDA. AMAG-423 is intended to bind to endogenous digitalis-like factors ("EDLFs") and remove them from the circulation. EDLFs appear to be elevated in preeclampsia and may play an important role in the pathogenesis of preeclampsia. By decreasing EDLFs, AMAG-423 is believed to improve vascular endothelial function and lead to better post-delivery outcomes in affected mothers and their babies.

In connection with the exercise of the option and the consummation of the acquisition, we paid Velo an upfront option exercise fee of $12.5 million in September 2018. We are obligated to pay Velo a $30.0 million milestone payment upon FDA approval of the product. In addition, we are obligated to pay sales milestone payments to Velo of up to $240.0 million in the aggregate, triggered at various annual net sales thresholds between $300.0 million and $900.0 million and low-single digit

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royalties based on net sales. Further, we have assumed additional obligations under a previous agreement entered into by Velo with a third-party, including a $5.0 million milestone payment upon regulatory approval and $10.0 million following the first commercial sale of AMAG-423, payable in quarterly installments as a percentage of quarterly gross commercial sales until the obligation is met. We are also obligated to pay the third-party low-single digit royalties based on net sales. See Note P, “Commitments and Contingencies,” to our consolidated financial statements included in this Annual Report on Form 10-K for more information on the AMAG-423 acquisition.

We have assumed responsibility to complete the Phase 2b/3a clinical study that Velo initiated in the second quarter of 2017 and will incur all of the future clinical, regulatory and other costs required to pursue FDA approval. Approximately 200 antepartum women with severe preeclampsia between 23 and 32 weeks gestation will be enrolled in the multi-center, randomized, double-blind, placebo-controlled, parallel-group Phase 2b/3a study. We have re-initiated the study as the sponsor, and have begun reactivating the current sites, seeking new sites and, as of January 2019, enrolling new patients. Participants in the study receive either AMAG-423 or placebo intravenously four times a day over a maximum of four days. The study’s primary endpoint is to demonstrate a reduction in the percentage of babies who develop severe intraventricular hemorrhage (bleeding in the brain), necrotizing enterocolitis (severe inflammation of the infant bowels) or death by 36 weeks corrected gestational age between the AMAG-423 and placebo arms. Secondary endpoints include the change from baseline in maternal creatinine clearance, maternal incidence of pulmonary edema during treatment and the period of time between treatment and delivery. In an effort to accelerate enrollment, we intend to increase the number of trial sites, including potentially initiating sites outside of the U.S., and are targeting to complete enrollment of the Phase 2b/3a study by the end of 2019.

Ciraparantag

In January 2019, we acquired Perosphere, a privately-held biopharmaceutical company focused on developing ciraparantag, a small molecule anticoagulant reversal agent in development as a single dose solution that is delivered intravenously to reverse the effects of certain NOACs (Xarelto®(rivaroxaban), Eliquis®(apixaban), and Savaysa®(edoxaban), as well as Lovenox® (enoxaparin sodium injection), a LMWH), when reversal of the anticoagulant effect of these products is needed for emergency surgery, urgent procedures or due to life-threatening or uncontrolled bleeding. Ciraparantag has been granted Fast Track designation by the FDA and we intend to seek orphan drug designation and Breakthrough Therapy designation in 2019. See Note W, “Subsequent Events,” to our consolidated financial statements included in this Annual Report on Form 10-K for additional information.

Ciraparantag has been evaluated in more than 250 healthy volunteers across seven clinical trials. A first in human Phase 1 study evaluated the safety, tolerability, pharmacokinetic, and pharmacodynamic effects of ciraparantag alone and following a single dose of Savaysa®, and another Phase 1 study evaluated the overall metabolism of the drug. Two Phase 1/2 studies evaluated the safety, tolerability, pharmacokinetic, and pharmacodynamic effects related to the reversal of unfractionated heparin and Lovenox® and three Phase 2b randomized, single-blind, placebo-controlled dose-ranging studies evaluated the reversal of Savaysa®, Eliquis®, and Xarelto® to assess the safety and efficacy of ciraparantag, each of which included 12 subjects dosed with ciraparantag. The Phase 2b studies to reverse Xarelto® and Eliquis® are currently ongoing; however, both studies are approximately two-thirds complete, with the low dose cohort expected to finish in the first half of 2019. In these Phase 2b clinical trials, ciraparantag or placebo was administered to healthy volunteers in a blinded fashion after achieving steady blood concentrations of the respective anticoagulant. Pharmacodynamic assessments of whole blood clotting time (“WBCT”), an important laboratory measure of clotting capacity, were sampled frequently for the first hour post study drug dose, and then periodically thereafter out to 24 hours post administration of study drug. Key endpoints in the Phase 2 trials included mean change from baseline in WBCT and the proportion of subjects that returned to within 10% of their baseline WBCT. Subjects in these studies experienced a rapid and statistically significant ($p<0.001$) reduction in WBCT compared to placebo as early as 15 minutes after the administration of ciraparantag in each of the four studies and the effect was sustained for 24 hours. Moreover, in both the Eliquis® and Xarelto® studies, 100% of subjects in the highest dose cohorts (180 mg

of ciraparantag) were responders, as defined by a return to within 10% of baseline WBCT within 30 minutes and sustained for at least six hours. Ciraparantag has been well tolerated in clinical trials, with the most common related adverse events to date being mild sensations of coolness, warmth or tingling, skin flushing, and alterations in taste. There have been no drug-related serious adverse events to date. Following the completion of the Phase 2b studies, we plan to conduct an End of Phase 2 meeting with the FDA to confirm the design of our Phase 3a trials in healthy volunteers, designed to determine the lowest effective dose of ciraparantag.We intend to initiate the Phase 3a trials in the second half of 2019.

MuGard

MuGard is indicated for the management of oral mucositis/stomatitis (that may be caused by radiotherapy and/or chemotherapy) and all types of oral wounds (mouth sores and injuries), including certain ulcers/canker sores and traumatic ulcers, such as those caused by oral surgery or ill-fitting dentures or braces. We acquired the U.S. commercial rights

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

Critical Accounting Policies

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

Revenue and Allowances

On January 1, 2018, we adopted Accounting Standards Codification (“ASC”) Topic 606, Revenue from Contracts with Customers (“ASC 606”) applying the modified retrospective transition method to all contracts that were not completed as of January 1, 2018. Results for reporting periods beginning after January 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for prior periods. The adoption of ASC 606 did not have an impact on the pattern or timing of recognition of our product revenue, as the majority of our product revenue continues to be recognized when the customer takes control of our product.
Under ASC 606, we recognize revenue when our customer obtains control of promised goods or services in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps:

a.Identify the contract(s) with a customer;
b.Identify the performance obligations in the contract;
c.Determine the transaction price;
d.Allocate the transaction price to the performance obligations in the contract; and
e.Recognize revenue when (or as) the performance obligations are satisfied.

We only apply the five step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, if the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract, determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Our major sources of revenue during the reporting periods were product revenues from Makena (including both our branded and unbranded products), Feraheme and Intrarosa. The adoption of ASC 606 did not have an impact on our product revenue.

We receive payments from customers based upon contractual billing schedules; accounts receivable are recorded when the right to consideration becomes unconditional.

Performance Obligations and Product Revenue

At contract inception, we assess the goods promised in our contracts with customers and identify a performance obligation for each promise to transfer to the customer a good (or bundle of goods) that is distinct. To identify the performance obligations, we consider all of the goods promised in the contract regardless of whether they are explicitly stated or are implied by customary business practices. We determined that the following distinct goods represent separate performance obligations:

•Supply of Makena (branded and unbranded) product
•Supply of Feraheme product
•Supply of Intrarosa product

We principally sell our products to wholesalers, specialty distributors, specialty pharmacies and other customers, including our authorized generic partner (collectively, “Customers”), who purchase products directly from us. Our Customers

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subsequently resell the products to healthcare providers and patients. In addition to distribution agreements with Customers, we enter into arrangements with healthcare providers and payers that provide for government-mandated and/or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of our products.

For the majority of our Customers, we transfer control at the point in time when the goods are delivered. In instances when we perform shipping and handling activities, these are considered fulfillment activities, and accordingly, the costs are accrued when the related revenue is recognized. Taxes collected from Customers and remitted to governmental authorities are excluded from revenues.

Variable Consideration

Under ASC 606, we are required to make estimates of the net sales price, including estimates of variable consideration (such as rebates, chargebacks, discounts, copay assistance and other deductions), and recognize the estimated amount as revenue, when we transfer control of the product to our customers. In addition, we estimate variable consideration related to our share of net distributable profits from our authorized generic partner. Variable consideration must be determined using either an “expected value” or a “most likely amount” method.

We record product revenues net of certain allowances and accruals in our consolidated statements of operations. 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 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. Consideration payable to a Customer, or other parties that purchase goods from a Customer, are considered to be a reduction of the transaction price, and therefore, of revenue.

Product sales allowances and accruals are based on definitive contractual agreements or legal requirements (such as laws and regulations to provide mandatory discounts for sales to government entities) 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 use the expected value method for estimating variable consideration. 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, rebates are typically paid out in arrears, one month to three months months after the sale.

The estimate of variable consideration, which is included in the transaction price, may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved in a future period. Estimating variable consideration and the related constraint requires the use of significant management judgment and actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Discounts

We typically offer a 2% prompt payment discount to certain customers as an incentive to remit payment in accordance with the stated terms of the invoice, generally 30 days. Because we anticipate that those customers who are offered this discount will take advantage of the discount, 100% of the prompt payment discount at the time of sale is accrued for eligible customers, based on the gross amount of each invoice. We adjust the accrual quarterly to reflect actual experience.

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Chargebacks

Chargeback reserves represent the 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. The chargeback estimates are determined 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 adjusted quarterly to reflect actual experience.

Distributor/Wholesaler and Group Purchasing Organization Fees

Fees under 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 the receipt of an invoice from the wholesaler or distributor, as the case may be. Fees under 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. In accordance with ASC 606, since the consideration given to the Customer is not for a distinct good or service, the consideration is a reduction of the transaction price of the vendor’s products or services. We generally pay such amounts within several weeks of the 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 wholesalers, specialty distributors and other customers a limited right to return our products based on the product’s expiration date. The current shelf-lives or time between manufacture and expiration for products in our portfolio range from three years to five years. Product returns are estimated 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. There were no material adjustments to our reserve for product returns during the years ended December 31, 2018, 2017 or 2016. To date, our product returns have been relatively limited; however, returns experience may change over time. We may be required to make future adjustments to our product returns estimate, which would result in a corresponding change to our net product sales in the period of adjustment and could be significant.

Sales Rebates

We contract with various private payer organizations, primarily pharmacy benefit managers, for the payment of rebates with respect to utilization of our products. We determine our estimates for rebates, if applicable, based on actual product sales data and our historical product claims experience. 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 provider. We regularly assess our 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 accumulated reserve estimate, which would affect net product sales in the period of the adjustment and could be

significant.

Governmental Rebates

Governmental rebates relate to our reimbursement arrangements with state Medicaid programs. We determine our estimates for Medicaid rebates, if applicable, based on actual product sales data and our historical product claims experience. In estimating these reserves, we provide for a Medicaid rebate associated with both those expected instances where Medicaid will act as the primary insurer as well as in those instances where we expect Medicaid will act as the secondary insurer. Rebate amounts generally are invoiced quarterly and are paid in arrears, and we expect to pay such amounts within several weeks of notification by the Medicaid or provider entity. 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.

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Other Discounts

Other discounts which we offer include voluntary patient assistance programs, such as copay assistance programs, which are intended to provide financial assistance to qualified commercially insured patients with prescription drug copayments required by payers. The calculation of the accrual for copay assistance is based on an estimate of claims and the cost per claim that we expect to receive associated with product that has been recognized as revenue.

Marketable Securities

We account for and classify our marketable securities as either “available-for-sale,” “held-to-maturity,” or “trading debt securities,” in accordance with the accounting guidance related to the accounting and classification of certain investments in marketable securities. The determination of the appropriate classification by us is based primarily on management’s ability and intent to sell the debt security at the time of purchase. As of December 31, 2018 and 2017, all of our marketable securities were classified as available-for-sale.

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

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

Business Combinations and Asset Acquisitions

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

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

The purchase price allocations are initially prepared on a preliminary basis and are subject to change as additional information becomes available concerning the fair value and tax basis of the assets acquired and liabilities assumed.

Any adjustments to the purchase price allocations are made as soon as practicable but no later than one year from the acquisition date.

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

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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. For asset acquisitions, we record contingent consideration for obligations we consider to be probable and estimable and these liabilities are not adjusted to fair value.

Goodwill

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

In performing our goodwill impairment tests during 2018 and 2017, we utilized the approach prescribed under ASC 350, as amended by ASU 2017-04, Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment, which requires that an entity perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit’s fair value.

When we perform any goodwill impairment test, the estimated fair value of our reporting unit is determined using an income approach that utilizes a discounted cash flow (“DCF”) model or, a market approach, when appropriate, which assesses our market capitalization as adjusted for a control premium, or a combination thereof. The DCF model is based upon expected future after-tax operating cash flows of the reporting unit discounted to a present value using a risk-adjusted discount rate. Estimates of future cash flows require management to make significant assumptions concerning (i) future operating performance, including future sales, long-term growth rates, operating margins, variations in the amount and timing of cash flows and the probability of achieving the estimated cash flows (ii) the probability of regulatory approvals, and (iii) future economic conditions, all of which may differ from actual future cash flows. These assumptions are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy. The discount rate, which is intended to reflect the risks inherent in future cash flow projections, used in the DCF model, is based on estimates of the weighted average cost of capital (“WACC”) of market participants relative to our reporting unit. Financial and credit market volatility can directly impact certain inputs and assumptions used to develop the WACC. Any changes in these assumptions may affect our fair value estimate and the result of an impairment test. We believe the discount rates and other inputs and assumptions are consistent with those that a market participant would use. In addition, in order to assess the reasonableness of the fair value of our reporting unit as calculated under the DCF model, we also compare the reporting unit’s fair value to our market capitalization and calculate an implied control premium (the excess sum of the reporting unit’s fair value over its market capitalization). We evaluate the implied control premium by comparing it to control premiums of recent comparable market transactions, as applicable. Throughout 2017, at points during 2018 and as of December 31, 2018 and 2017, our market capitalization was lower than our stockholders’ equity, or book value. We believe that a market participant buyer would be required to pay a control premium for our business that would cover the difference between our market capitalization and our book value.

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

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Intangible Assets

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

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

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

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

Equity-Based Compensation

Equity-based compensation cost is generally measured at the estimated grant date fair value and recorded to expense over the requisite service period, which is generally the vesting period. Because equity-based compensation expense is

based on awards ultimately expected to vest, we must make certain judgments about whether employees, officers, directors, consultants and advisers will complete the requisite service period, and reduce the compensation expense being recognized for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures are estimated based upon historical experience and adjusted for unusual events such as 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

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the Black-Scholes option pricing model is generally amortized on a straight-line basis over the requisite service period, and is recognized based on the proportionate amount of the requisite service period that has been rendered during each reporting period.

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

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

Income Taxes

We use the asset and liability method of accounting for deferred income taxes. Under this method, deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. A deferred tax asset is established for the expected future benefit of net operating loss ("NOL") and credit carryforwards. Deferred tax assets and liabilities are measured using enacted rates in effect for the year in which those temporary differences are expected to be recovered or settled. A valuation allowance against net deferred tax assets is required if, based on available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. Significant judgments, estimates and assumptions regarding future events, such as the amount, timing and character of income, deductions and tax credits, are required in the determination of our provision for income taxes and whether valuation allowances are required against deferred tax assets. In evaluating our ability to recover our deferred tax assets, we consider all available evidence, both positive and negative, including the existence of taxable temporary differences, our past operating results, the existence of cumulative income in the most recent fiscal years, changes in the business in which we operate and our forecast of future taxable income. In determining future taxable income, we are responsible for assumptions utilized including the amount of state and federal operating income, the reversal of temporary differences and the implementation of feasible and prudent tax planning strategies. These assumptions require significant judgment about the forecasts of future taxable income. As of December 31, 2018, we have established a valuation allowance on our net deferred tax assets other than refundable alternative minimum tax ("AMT") credits to the extent that our existing taxable temporary differences would not be available as a source of income to realize the benefits of those deferred tax assets.

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 U, “Recently Issued and Proposed Accounting Pronouncements,” to our consolidated financial statements included in this Annual Report on Form 10-K for additional information.

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Results of Operations - 2018 as compared to 2017

Revenues

Total revenues for 2018 and 2017 consisted of the following (in thousands except for percentages):

	Years Ended December 31,		2018 to 2017	
	2018	2017	$ Change	% Change
Product sales, net				
Makena	$322,265	$387,158	$(64,893)	(17)%
Feraheme	135,001	105,930	29,071	27 %
Intrarosa	16,218	1,816	14,402	>100 %
MuGard	368	741	(373)	(50)%
Total	473,852	495,645	(21,793)	(4)%
Other revenues	150	124	26	21 %
Total revenues	$474,002	$495,769	$(21,767)	(4)%

Our total revenues for 2018 decreased by $21.8 million as compared to 2017, due primarily to a $64.9 million decrease in Makena net sales, which were impacted by a supply disruption of our IM products and the entry of generic competition in 2018. This decrease was partially offset by an increase of $29.1 million of Feraheme net sales following the approval of its expanded label in February 2018 and an increase of $14.4 million of Intrarosa net sales, which was commercially launched in July 2017.

We expect that sales of Feraheme, Intrarosa and the Makena auto-injector will increase in 2019 as compared to 2018. We expect overall revenues from the Makena IM products to continue to decline due to (i) volume and pricing pressure as a result of current generic competition to Makena, (ii) the expectation of additional generic competitors in the market and (iii) continued manufacturing-related issues. As previously disclosed, we continue to experience delays at our third-party manufacturer of the Makena IM product, which has resulted in our single-dose and multi-dose Makena IM vials being out-of-stock as well as periodic supply disruptions and loss of market share for the authorized generic. We are attempting to mitigate this supply issue by manufacturing at another supplier. The continued impact of generic competition to our Makena sales is dependent on the timing, number and behavior of current and future generic competitors.

In 2019, we expect to recognize revenue related to milestone payments we may receive under the terms of a clinical trial collaboration agreement with a global pharmaceutical company, provided certain clinical obligations are met in connection with our ciraparantag Phase 3 program.

The following table sets forth customers who represented 10% or more of our total revenues for 2018 and 2017:

	Years Ended December 31,	
	2018	2017
AmerisourceBergen Drug Corporation	27%	26%
McKesson Corporation	26%	24%

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Total gross product sales were offset by product sales allowances and accruals for 2018 and 2017 as follows (in thousands except for percentages):

	Years Ended December 31,						2018 to 2017		
	2018	Percent of gross product sales		2017	Percent of gross product sales		$ Change	% Change	
Gross product sales	$974,330			$920,061			$54,269	6	%
Provision for product sales allowances and accruals:									
Contractual adjustments	387,540	40	%	310,588	34	%	76,952	25	%
Governmental rebates	112,938	12	%	113,828	12	%	(890)	—	%
Total	500,478	52	%	424,416	46	%	76,062	18	%
Product sales, net	$473,852			$495,645			$(21,793)	(4)	%

The increase in contractual adjustments as a percentage of gross product sales primarily related to a higher mix of business through commercial reimbursement channels and additional discounts offered to commercial entities.

Product Sales Allowances and Accruals

We record product revenue net of certain allowances and accruals in our consolidated statements of operations. Our contractual adjustments include provisions for returns, pricing and prompt payment discounts, as well as wholesaler distribution fees, rebates to hospitals that qualify for 340B pricing, and volume-based and other commercial rebates and other discounts. Governmental rebates relate to our reimbursement arrangements with state Medicaid programs.

We may refine our estimated revenue reserves as we continue to obtain additional experience or as our customer mix changes. If we determine in future periods that our actual experience is not indicative of our expectations, if our actual experience changes, or if other factors affect our estimates, we may be required to adjust our allowances and accruals estimates, which would affect our net product sales in the period of the adjustment and could be significant.

An analysis of the amount of our product reserves for 2018 and 2017, is as follows (in thousands):

	Contractual Adjustments	Governmental Rebates	Total
Balance at January 1, 2017	$ 47,600	$ 51,399	$98,999
Current provisions relating to sales in current year	314,537	112,167	426,704
Adjustments relating to sales in prior years	(3,949)	1,661	(2,288)
Payments/returns relating to sales in current year	(253,545)	(61,569)	(315,114)
Payments/returns relating to sales in prior years	(42,479)	(53,060)	(95,539)
Balance at December 31, 2017	$ 62,164	$ 50,598	$112,762
Current provisions relating to sales in current year	389,861	105,034	494,895
Adjustments relating to sales in prior years	(2,330)	7,903	5,573
Payments/returns relating to sales in current year	(333,694)	(75,920)	(409,614)
Payments/returns relating to sales in prior years	(58,802)	(58,501)	(117,303)
Balance at December 31, 2018	$ 57,199	$ 29,114	$86,313

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Costs and Expenses

Cost of Product Sales

Cost of product sales for 2018 and 2017 were as follows (in thousands except for percentages):

	Years Ended December 31,		2018 to 2017	
	2018	2017	$ Change	% Change
Cost of product sales	$215,892	$161,349	$54,543	34 %
Percentage of net product sales	46 %	33 %		

Our cost of product sales are primarily comprised of manufacturing costs, costs of managing our contract manufacturers, costs for quality assurance and quality control associated with our product sales, the amortization of product-related intangible assets, the inventory step-up in connection with the November 2014 acquisition of Lumara Health and royalty obligations. Amortization of intangible assets comprised $158.4 million and $130.4 million of the $215.9 million and $161.3 million cost of product sales for the years ended December 31, 2018 and 2017, respectively. The increase of $26.5 million in cost of product sales not related to amortization of intangible assets was due to a larger portion of product sales from higher cost products as well as royalty obligations related to the Makena auto-injector and Intrarosa products.

We expect our cost of product sales, excluding amortization expense, to increase as a percentage of net product sales in 2019 as compared to 2018, due to a shift toward products with higher royalty obligations, such as the Makena auto-injector and Intrarosa.

Research and Development Expenses

Research and development expenses include both external and internal expenses. External expenses primarily include costs of clinical trials and fees paid to contract research organizations (“CROs”), clinical supply and manufacturing expenses, regulatory filing fees, consulting and professional fees as well as other general costs related to the execution of research and development activities. Internal expenses primarily include compensation of employees engaged in research and development activities. Research and development expenses are expensed as incurred. 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 2018 and 2017 consisted of the following (in thousands except for percentages):

	Years Ended December 31,		2018 to 2017	
	2018	2017	$ Change	% Change
External research and development expenses				
Vyleesi-related costs	$11,053	$27,832	$(16,779)	(60)%
Makena-related costs	5,312	12,971	(7,659)	(59)%
Feraheme-related costs	4,143	7,699	(3,556)	(46)%
Intrarosa-related costs	6,267	1,058	5,209	>100 %
AMAG-423-related costs	735	—	735	N/A
Other external costs	388	6,393	(6,005)	(94)%
Total	27,898	55,953	(28,055)	(50)%
Internal research and development expenses	16,948	19,064	(2,116)	(11)%

Total research and development expenses	$44,846	$75,017	$(30,171)	(40)%

Total research and development expenses incurred in 2018 decreased by $30.2 million, or 40%, as compared to 2017. The $16.8 million decrease in Vyleesi-related costs was attributable to costs incurred in 2017 in preparation for the March 2018 NDA submission, partially offset by increased costs in 2018 associated with manufacturing process development and the manufacture of drug product in preparation for potential approval in 2019. Makena-related costs reflected a $7.7 million decrease driven primarily by the completion of the auto-injector program in 2017, partially offset by costs incurred in the Subpart H trials. Feraheme-related costs reflected a $3.6 million decrease driven primarily by the completion of the IDA study in 2017, partially offset by an increase in costs related to the ongoing pediatric studies. The decreased spend for Feraheme,

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Makena, and Vyleesi was partially offset by an increase of $5.2 million related to costs incurred for the Intrarosa HSDD study in post-menopausal women.

We have a number of ongoing research and development programs that we are conducting independently or in collaboration with third parties. We expect our internal research and development expenses to increase substantially in 2019 as compared to 2018 as we expand our internal infrastructure and continue to establish more robust development capabilities. In addition, we expect our external research and development expenses to increase, primarily driven by our investments in AMAG-423 and ciraparantag, including to purchase drug supply needed to support our clinical trials. We cannot determine with certainty the duration and completion costs of our current or future clinical trials of our products or product candidates as the duration, costs and timing of clinical trials depends on a variety of factors including the uncertainties of future clinical and preclinical studies, uncertainties in clinical trial enrollment rates and significant and changing government regulation.

Acquired In-Process Research and Development

During 2018, we recorded $32.5 million for acquired IPR&D related to AMAG-423 and Vyleesi as the respective product candidates had not yet received regulatory approval. Of the $32.5 million, $12.5 million was paid to Velo in September 2018 as an upfront option exercise fee in connection with our acquisition of AMAG-423 and $20.0 million was paid to Palatin in the second quarter of 2018 for the milestone obligation associated with the FDA acceptance of the Vyleesi NDA.

During 2017, we recorded acquired IPR&D expense of $65.8 million primarily related to (a) a $60.0 million one-time upfront payment under the terms of the Palatin License Agreement, which we characterized as acquired IPR&D as the product candidate had not yet received regulatory approval and (b) $5.8 million, which represented a portion of the $83.5 million of consideration recorded to date under the terms of the Endoceutics License Agreement, based on our determination that this portion of the total consideration did not have an alternative future use.

Selling, General and Administrative Expenses

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

Selling, general and administrative expenses for 2018 and 2017 consisted of the following (in thousands except for percentages):

	Years Ended December 31,		2018 to 2017	
	2018	2017	$ Change	% Change
Compensation, payroll taxes and benefits	$126,754	$99,013	$27,741	28 %
Professional, consulting and other outside services	134,049	110,637	23,412	21 %
Fair value of contingent consideration liability	(49,607)	(47,686)	(1,921)	4 %
Equity-based compensation expense	16,614	16,187	427	3 %
Total selling, general and administrative expenses	$227,810	$178,151	$49,659	28 %

Total selling, general and administrative expenses increased by $49.7 million, or approximately 28%, as compared to the same period in 2017. This increase was primarily driven by organizational growth associated with significant launch activities for multiple products in 2018 and costs related to the commercialization of Intrarosa.

In addition, total selling, general and administrative expenses for each of the years ended December 31, 2018 and 2017 included a $49.6 million and $47.7 million reversal, respectively, to the fair value of contingent consideration

liability primarily due to changes in our estimated Makena revenues and the associated milestone payments, as discussed in more detail in Note F, “Fair Value Measurements,” to our consolidated financial statements included in this Annual Report on Form-10-K.

We expect that total selling, general and administrative expenses will increase in 2019 as compared to 2018 as we prepare for the potential launch of Vyleesi, assuming FDA approval in 2019, and as we continue to invest in the growth of our commercial products, including the Makena auto-injector, Intrarosa and Feraheme.

Impairment of Intangible Assets

There were no impairments of intangible assets during the year ended December 31, 2018. During 2017, we recorded an impairment charge of $319.2 million on our Makena base technology intangible asset, which relates solely to the Makena IM product. See Note I, “Goodwill and Intangible Assets, Net,” to our consolidated financial statements included in this Annual Report on Form-10-K for additional information.

Other Expense, Net

Other expense, net for 2018 and 2017 consisted of the following (in thousands except for percentages):

	Years Ended December 31,		2018 to 2017	
	2018	2017	$ Change	% Change
Interest expense	$(51,971)	$(68,382)	$16,411	(24)%
Loss on debt extinguishment	(35,922)	(10,926)	(24,996)	>100 %
Interest and dividend income	5,328	2,810	2,518	90 %
Other expense	(74)	(70)	(4)	6 %
Total other expense, net	$(82,639)	$(76,568)	$(6,071)	8 %

Other expense, net for 2018 increased by $6.1 million as compared to 2017 primarily as the result of the following:

- $35.9 million loss on extinguishment of debt (including a $28.1 million redemption premium) incurred as a result of the early redemption of $500.0 million aggregate principal amount of 7.875% Senior Notes due 2023 (the “2023 Senior Notes”) during 2018 compared to a $10.9 million loss on extinguishment of debt due to the early repayment of a 2015 term loan facility and repurchase of a portion of the 2023 Senior Notes during 2017; and
- $16.4 million decrease in interest expense as compared to 2017 primarily due to the early redemption of the 2023 Senior Notes in 2018 and repayment of a 2015 term loan facility in 2017.

We expect our other expense, net to decrease in 2019 as compared to 2018 due to a reduction in interest expense related to the 2018 redemption of the 2023 Senior Notes.

Income Tax Expense (Benefit)

The following table summarizes our effective tax rate and income tax expense (benefit) for 2018 and 2017 (in thousands except for percentages):

	Years Ended December 31,	
	2018	2017
Effective tax rate	(31)%	46 %
Income tax expense (benefit)	$39,654	$(175,254)

For 2018, we recognized income tax expense of $39.7 million, representing an effective tax rate of (31)%. The difference between the expected statutory federal tax rate of 21% and the (31)% effective tax rate for 2018 was primarily attributable to the establishment of a valuation allowance on net deferred tax assets other than refundable AMT credits, the impact of non-deductible stock compensation and other non-deductible expenses, partially offset by a benefit from contingent consideration associated with Lumara Health, state income taxes and orphan drug tax credits. We have established a valuation allowance on our deferred tax assets other than refundable credits to the extent that our existing taxable temporary differences would not be available as a source of income to realize the benefits of those deferred tax assets. Our valuation allowance on our deferred tax assets, other than refundable AMT credits, increased during the year ended December 31, 2018 primarily because the deferred tax liabilities associated with the CBR business, which was reclassified to discontinued operations and sold during 2018, are no longer available as a source of income to realize the benefits of the net deferred tax assets.

In December 2017, the Tax Cuts and Jobs Act (the “2017 Tax Act”) was enacted. The 2017 Tax Act includes significant changes to the U.S. corporate income tax system, including a reduction of the federal corporate income tax rate from 35% to 21%, effective January 1, 2018. As a result of the reduction in the federal tax rate, we revalued our ending net deferred tax liabilities at December 31, 2017 and recognized a provisional $17.6 million tax benefit. During the year

ended December 31,

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2018, we completed our accounting for the enactment date income tax effects of the 2017 Tax Act in accordance with Staff Accounting Bulletin No. 118 and recorded an immaterial adjustment as a result. See Note K, “Income Taxes,” to our consolidated financial statements included in this Annual Report on Form 10-K for additional information regarding the 2017 Tax Act.

For 2017, we recognized an income tax benefit of $175.3 million, representing an effective tax rate of 46%. The difference between the expected statutory federal tax rate of 35% and the 46% effective tax rate for 2017 was was primarily attributable to the impact of federal tax reform, as discussed above, contingent consideration associated with Lumara Health, federal research and orphan drug tax credits generated during the year, and the impact of state income taxes, partially offset by equity-based compensation expenses and an increase to our valuation allowance.

Net Income from Discontinued Operations

Net income from discontinued operations was $103.6 million in 2018 as compared to $5.9 million in 2017. Of the $103.6 million net income from discontinued operations, $87.1 million represented a gain on the sale of the CBR business, which closed on August 6, 2018. For additional information, see Note C, “Discontinued Operations and Held for Sale,” to our consolidated financial statements included in this Annual Report on Form 10-K.

Results of Operations - 2017 as compared to 2016

Revenues

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

	Years Ended December 31,		2017 to 2016	
	2017	2016	$ Change	% Change
Product sales, net				
Makena	$387,158	$334,050	$53,108	16 %
Feraheme	105,930	97,058	8,872	9 %
Intrarosa	1,816	—	1,816	N/A
MuGard	741	1,062	(321)	(30)%
Total	495,645	432,170	63,475	15 %
Other revenues	124	317	(193)	(61)%
Total revenues	$495,769	$432,487	$63,282	15 %

Our total revenues for 2017 increased by $63.3 million as compared to 2016, due primarily to increases in volume across substantially all of our products.

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

	Years Ended December 31,	
	2017	2016
AmerisourceBergen Drug Corporation	26 %	27 %
McKesson Corporation	24 %	14 %
Caremark, LLC	< 10%	10 %

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

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

Gross product sales increased by $171.2 million, or approximately 23%, during 2017 as compared to 2016 primarily due to increases of $126.1 million and $39.7 million of Makena and Feraheme gross sales, respectively. Of the $126.1 million increase in gross Makena sales, $112.7 million was due to increased volume and $13.4 million was due to price increases. Of the $39.7 million increase in gross Feraheme sales, $27.7 million was due to price increases and $12.1 million was due to increased volume. This total increase in gross product sales was partially offset by $107.7 million of additional allowances and accruals in 2017 as compared to 2016. The increase in contractual adjustments as a percentage of gross product sales primarily related to a change in mix of business to commercial customers.
Net product sales increased by $63.5 million or approximately 15%, during 2017 as compared to 2016 primarily due to a $53.1 million increase in net Makena sales and a $8.9 million increase in net Feraheme sales.

Product Sales Allowances and Accruals
We may refine our estimated revenue reserves as we continue to obtain additional experience or as our customer mix changes. If we determine in future periods that our actual experience is not indicative of our expectations, if our actual experience changes, or if other factors affect our estimates, we may be required to adjust our allowances and accruals estimates, which would affect our net product sales in the period of the adjustment and could be significant.

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

	Contractual Adjustments	Governmental Rebates	Total
Balance at January 1, 2016	$ 30,177	$ 25,767	$55,944
Current provisions relating to sales in current year	224,894	93,035	317,929
Adjustments relating to sales in prior years	(2,348)	(6,052)	(8,400)
Payments/returns relating to sales in current year	(181,150)	(41,636)	(222,786)
Payments/returns relating to sales in prior years	(23,973)	(19,715)	(43,688)
Balance at December 31, 2016	$ 47,600	$ 51,399	$98,999
Current provisions relating to sales in current year	314,537	112,167	426,704
Adjustments relating to sales in prior years	(3,949)	1,661	(2,288)
Payments/returns relating to sales in current year	(253,545)	(61,569)	(315,114)
Payments/returns relating to sales in prior years	(42,479)	(53,060)	(95,539)
Balance at December 31, 2017	$ 62,164	$ 50,598	$112,762

During 2017 and 2016, we implemented gross price increases for Feraheme and Makena, some portion of which were discounted back to customers under volume or market share based contracts. When portions of price increases are discounted back to customers, it can widen the gross to net adjustment percentage while still resulting in a greater net price per unit.

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Costs and Expenses

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

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

The $65.0 million increase in our cost of product sales for 2017 as compared to 2016 was primarily attributable to a $58.2 million net increase in amortization of the Makena base technology intangible asset due to the change in its estimated useful life in 2017 and the Intrarosa developed technology intangible asset, which was placed in service in 2017. Of the remaining $6.8 million increase, $6.6 million was due to increased volume across substantially all of our products and $3.0 million was due to overhead costs and inventory write-offs, partially offset by a $2.9 million decrease in amortization of the inventory step-up.

Research and Development Expenses

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

	Years Ended December 31,		2017 to 2016	
	2017	2016	$ Change	% Change
External research and development expenses				
Vyleesi-related costs	$27,832	$—	$27,832	N/A
Makena-related costs	12,971	19,113	(6,142)	(32)%
Feraheme-related costs	7,699	28,067	(20,368)	(73)%
Other external costs	6,393	2,998	3,395	>100 %
Intrarosa-related costs	1,058	—	1,058	N/A
Total	55,953	50,178	5,775	12 %
Internal research and development expenses	19,064	15,383	3,681	24 %
Total research and development expenses	$75,017	$65,561	$9,456	14 %

Total research and development expenses incurred in 2017 increased by $9.5 million, or 14%, as compared to 2016. The increase was due primarily to $27.8 million incurred in connection with our reimbursement of costs to Palatin associated with the development and regulatory activities for our bremelanotide NDA submission filed in the first quarter of 2018. This increase was partially offset by a $6.1 million decrease related to costs incurred for the Makena auto-injector program and a $20.4 million decrease in Feraheme-related spending as the result of the completion in 2016 of the Phase 3 clinical trial to expand the Feraheme label.

Acquired In-Process Research and Development

During 2017, we recorded acquired IPR&D expense of $65.8 million related to the $60.0 million one-time upfront payment under the terms of the Palatin License Agreement and $5.8 million, which represented a portion of the $83.5 million of consideration recorded to date under the terms of the Endoceutics License Agreement, based on our determination that this portion of total consideration did not have an alternative future use. We did not record any IPR&D expenses during 2016.

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Selling, General and Administrative Expenses

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

	Years Ended December 31,		2017 to 2016	
	2017	2016	$ Change	% Change
Compensation, payroll taxes and benefits	$99,013	$66,592	$32,421	49 %
Professional, consulting and other outside services	110,637	61,603	49,034	80 %
Fair value of contingent consideration liability	(47,686)	25,683	(73,369)	<(100 %)
Equity-based compensation expense	16,187	15,590	597	4 %
Total selling, general and administrative expenses	$178,151	$169,468	$8,683	5 %

Total selling, general and administrative expenses, excluding the $73.4 million decrease to the contingent consideration liability expense, described below, increased by $82.1 million, or approximately 57%, as compared to the same period in 2016 due to the following:

- $32.4 million increase in compensation, payroll taxes and benefits primarily due to increased personnel costs associated with the addition of our women's health commercial team and other organizational growth to support the July 2017 launch of Intrarosa; and

- $49.0 million increase in sales and marketing, consulting, professional fees, and other expenses primarily due to costs related to the July 2017 launch and commercialization of Intrarosa, increased costs associated with the expansion of our women's health sales force and litigation expense related to our ongoing Sandoz patent infringement litigation.

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

Impairment of Intangible Assets

During 2017, we recorded an impairment charge of $319.2 million on our Makena base technology intangible asset, which relates solely to the Makena IM product. During 2016, we recorded an impairment charge of $15.7 million for the MuGard Rights. See Note I, "Goodwill and Intangible Assets, Net," to our consolidated financial statements included in this Annual Report on Form 10-K for additional information.

Other Expense, Net

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

	Years Ended December 31,		2017 to 2016	
	2017	2016	$ Change	% Change
Interest expense	$(68,382)	$(73,153)	$4,771	(7)%
Loss on debt extinguishment	(10,926)	—	(10,926)	N/A
Interest and dividend income	2,810	3,149	(339)	(11)%
Other expense	(70)	189	(259)	>(100%)
Total other expense, net	$(76,568)	$(69,815)	$(6,753)	10 %

Other expense, net for 2017 increased by $6.8 million as compared to 2016 primarily as the result of the following:

- $10.9 million loss on debt extinguishment in 2017 from the early repayment of the outstanding principal amount of a 2015 term loan facility and the repurchase of a portion of the 2023 Senior Notes; and

- $4.8 million decrease in interest expense as compared to 2016 primarily as the result of the repayment of a 2015 term loan facility.

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Income Tax (Benefit) Expense

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

	Years Ended December 31,	
	2017	2016
Effective tax rate	46 %	86 %
Income tax (benefit) expense	$(175,254)	$13,171

For 2017, we recognized an income tax benefit of $175.3 million, representing an effective tax rate of 46%. The difference between the expected statutory federal tax rate of 35% and the 46% effective tax rate for 2017 was primarily attributable to the impact of federal tax reform, as discussed below, contingent consideration associated with Lumara Health, federal research and orphan drug tax credits generated during the year, and the impact of state income taxes, partially offset by equity-based compensation expenses and an increase to our valuation allowance.

In December 2017, the 2017 Tax Act was enacted. The 2017 Tax Act includes significant changes to the U.S. corporate income tax system, including a reduction of the federal corporate income tax rate from 35% to 21%, effective January 1, 2018. As a result of the reduction in the federal tax rate, we revalued our ending net deferred tax liabilities at December 31, 2017 and recognized a provisional $17.6 million tax benefit. See Note K, “Income Taxes,” to our consolidated financial statements included in this Annual Report on Form 10-K for additional information regarding the 2017 Tax Act.

For 2016, we recognized income tax expense of $13.2 million, representing an effective tax rate of 86%. The difference between the expected statutory federal tax rate of 35% and the 86% effective tax rate for 2016 was attributable to the impact of contingent consideration associated with Lumara Health, equity-based compensation expenses and other permanent items, including meals and entertainment expense, officers compensation and Makena-related expenses, partially offset by the benefit of the federal research and development and orphan drug tax credits generated during the year.

Liquidity and Capital Resources

General

We currently finance our operations primarily from cash generated from our operating activities, including sales of our commercialized products. Cash, cash equivalents, investments and certain financial obligations as of December 31, 2018 and 2017 consisted of the following (in thousands except for percentages):

	December 31,			
	2018	2017	$ Change	% Change
Cash and cash equivalents	$253,256	$162,855	$90,401	56 %
Investments	140,915	136,593	4,322	3 %
Total	$394,171	$299,448	$94,723	32 %
Outstanding principal on 2023 Senior Notes	$—	$475,000	$(475,000)	(100)%
Outstanding principal on 2022 Convertible Notes	320,000	320,000	—	— %
Outstanding principal on 2019 Convertible Notes	21,417	21,417	—	— %
Total	$341,417	$816,417	$(475,000)	(58)%

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Cash Flows

The following table presents a summary of the primary sources and uses of cash for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	For the Years Ended December 31			2018 compared to 2017	2017 compared to 2016
(In thousands, except percentages)	2018	2017	2016		
Net cash provided by operating activities	$60,800	$106,596	$246,222	$(45,796)	$(139,626)
Net cash provided by (used in) investing activities	502,155	102,920	(72,704)	399,235	175,624
Net cash used in financing activities	(501,974)	(293,644)	(127,918)	(208,330)	(165,726)
Net increase (decrease) in cash, cash equivalents and restricted cash	$60,981	$(84,128)	$45,600	$145,109	$(129,728)

Operating Activities

Cash flows from operating activities represent the cash receipts and disbursements related to all of our activities other than investing and financing activities. We have historically financed our operating and capital expenditures primarily through cash flows earned through our operations. We expect cash provided by operating activities in addition to our cash, cash equivalents and marketable securities will continue to be a primary source of funds to finance operating needs and capital expenditures.

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

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

For 2018 compared to 2017, net cash flows provided by operations decreased by $45.8 million, driven primarily by a decrease in net income as adjusted for non-cash charges of $34.9 million and a $10.9 million decrease due to changes in operating assets and liabilities. The cash flows from operating activities include cash flows from the operating activities of the CBR business, which is included in discontinued operations. Subsequent to the closing of the CBR transaction on August 6, 2018, we no longer generated cash flows from that business. See Note C, “Discontinued Operations and Held for Sale,” to our consolidated financial statements included in this Annual Report on Form 10-K for further detail regarding our discontinued operations.

For 2017 compared to 2016, net cash flows provided by operations decreased by $139.6 million driven primarily by a decrease in net income as adjusted for non-cash charges of $84.7 million and a $54.9 million increase due to changes in operating assets and liabilities.

Investing Activities

Cash flows provided by investing activities was $502.2 million in 2018 due to $519.3 million in proceeds from the sale of CBR, partially offset by net purchases of marketable securities of $4.6 million and capital expenditures of $2.5 million.

Cash flows provided by investing activities in 2017 was $102.9 million due to net proceeds from the sale of marketable securities of $167.7 million, partially offset by $55.8 million of cash used to purchase the Intrarosa asset

and capital expenditures of $9.0 million.

Cash flows used in investing activities in 2016 was $72.7 million due to net purchases of marketable securities of $67.2 million and capital expenditures of $5.5 million.

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Financing Activities

Cash used in financing activities was $502.0 million in 2018 due to the repayment of the $475.0 million balance of our 2023 Senior Notes and a related redemption premium of $28.1 million.

Cash used in financing activities in 2017 was $293.6 million driven by $353.1 million of principal payments made during 2017, including the full repayment of the remaining balance of a 2015 term loan facility, $191.7 million used for the repurchase of a portion of our 2019 Convertible Notes, $39.8 million of contingent consideration payments and the repurchase of common stock of $19.5 million, partially offset by $320.0 million net proceeds related to the issuance of our 2022 Convertible Notes.

Cash used in financing activities in 2016 was $127.9 million due to $92.1 million of contingent consideration payments, $20.0 million for the repurchase of common stock and $17.5 million in principal debt repayments.

Future Liquidity Considerations

We believe that our cash, cash equivalents and marketable securities as of December 31, 2018, and the cash we expect to receive from sales of our products, will be sufficient to satisfy our cash flow needs for the foreseeable future. As we enter 2019 and look to our significant portfolio investment opportunities, we intend to spend more than our expected revenues in 2019 and will therefore utilize a portion of our $394.2 million of cash and investments to fund our operations. This period of cash outflow is consistent with our evolving business plan to develop and launch innovative products that address unmet medical needs and can deliver long-term, durable revenue growth. Additionally, since December 31, 2018, our actual or expected utilization of cash includes, but is not limited to, the following:

- The $58.2 million of closing consideration for the acquisition of Perosphere, including the assumption of certain liabilities, which we paid in January 2019;
- Repayment of the $21.4 million outstanding principal balance on our 2019 Convertible Notes, which we paid in February 2019;
- Approximately $6.0 million of payments related to the February 2019 restructuring;
- A $60.0 million milestone obligation to Palatin conditioned and payable upon FDA approval of Vyleesi; and
- Approximately $10.0 million of cash interest in connection with our 2022 Convertible Notes.

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.

Borrowings and Other Liabilities

In August 2015, in connection with the CBR acquisition, we completed a private placement of $500.0 million aggregate principal amount of 7.875% Senior Notes due 2023 (the “2023 Senior Notes”). In October 2017, we repurchased $25.0 million principal of the 2023 Senior Notes in a privately negotiated transaction with cash on hand. In September 2018, we repurchased the remaining $475.0 million of the 2023 Senior Notes using the proceeds from the CBR sale.

In the second quarter of 2017, we issued $320.0 million aggregate principal amount of convertible senior notes due 2022 (the “2022 Convertible Notes”). We received net proceeds of $310.4 million from the sale of the 2022 Convertible Notes, after deducting fees and expenses of $9.6 million. The 2022 Convertible Notes are senior unsecured obligations

and bear interest at a rate of 3.25% per year, payable semi-annually in arrears on June 1 and December 1 of each year, beginning on December 1, 2017. The 2022 Convertible Notes will mature on June 1, 2022, unless earlier repurchased or converted. Upon conversion of the 2022 Convertible Notes, such 2022 Convertible Notes will be convertible into, at our election, cash, shares of our common stock, or a combination thereof, at a conversion rate of 36.5464 shares of common stock per $1,000 principal amount of the 2022 Convertible Notes, which corresponds to an initial conversion price of approximately $27.36 per share of our common stock. The conversion rate is subject to adjustment from time to time. The 2022 Convertible Notes were not convertible as of December 31, 2018.

In February 2014, we issued $200.0 million aggregate principal amount of 2.5% convertible senior notes due February 15, 2019 (the “2019 Convertible Notes”). In May 2017 and September 2017, we entered into privately negotiated transactions with certain investors to repurchase approximately $158.9 million and $19.6 million, respectively, aggregate principal amount of the

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2019 Convertible Notes for an aggregate repurchase price of approximately $171.3 million and $21.4 million, respectively, including accrued interest. The remaining $21.4 million of 2019 Convertible Notes matured on February 15, 2019 and were settled with cash.

For additional information, see Note R, “Debt,” 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 of directors had authorized a program to repurchase up to $60.0 million in shares of our common stock. The repurchase program does not have an expiration date and may be suspended for periods or discontinued at any time. Under the program, we may purchase our stock from time to time at the discretion of management in the open market or in privately negotiated transactions. The number of shares repurchased and the timing of the purchases will depend on a number of factors, including share price, trading volume and general market conditions, along with working capital requirements, general business conditions and other factors. We may also from time to time establish a trading plan under Rule 10b5-1 of the Securities and Exchange Act of 1934 to facilitate purchases of our shares under this program. As of December 31, 2018, we repurchased and retired a cumulative total of 2,198,010 shares of common stock under this repurchase program for $39.5 million at an average purchase price of $17.97 per share. As of December 31, 2018, $20.5 million remains available for the repurchase of shares under the program. We did not repurchase any of our common stock during 2018.

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 and vehicle leases, purchases of inventory, debt obligations (including interest payments), and other purchase obligations. Future contractual obligations, as of December 31, 2018, are as follows (in thousands):

	Payment due by period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Lease obligations	$10,228	$5,119	$5,109	$—	$ —
Purchase commitments	88,653	50,353	27,923	7,229	3,148
2019 Convertible Notes	21,484	21,484	—	—	—
2022 Convertible Notes	356,400	10,400	20,800	325,200	—
Total	$476,765	$87,356	$53,832	$332,429	$ 3,148

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. The initial term of the lease was five years and two months with one five-year extension term at our option. We have entered into several amendments to the original lease to add additional space and to extend the term of the original lease to April 2021. In addition to base rent, we are also required to pay a proportionate share of the Landlord’s operating costs.

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

In addition, in connection with our facility lease for the Waltham Premises, the Landlord holds a security deposit in the form of an irrevocable letter of credit, which is classified on our balance sheet as a long-term asset and was $0.5 million as of December 31, 2018 and 2017, respectively.

We also lease vehicles for our sales employees under a Master Agreement with Enterprise FM Trust. Each vehicle is leased for a three year term, commencing on the delivery date.

Rent expense, net of deferred rent amortization, for our leases was $5.1 million, $3.0 million, and $1.6 million for 2018, 2017 and 2016, respectively.

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Purchase Obligations

Purchase obligations primarily represent minimum purchase commitments for inventory. As of December 31, 2018, our minimum purchase commitments totaled $88.7 million.

Contingent Consideration Related to Business Combinations

In connection with our acquisition of Lumara Health in November 2014, we agreed to pay up to $350.0 million in milestone payments based on the achievement of certain sales thresholds. Due to the contingent nature of these milestone payments, we cannot predict the amount or timing of such payments with certainty. During 2018, we were not obligated to make any milestone payments. During 2017 and 2016, we paid $50.0 million and $100.0 million of these milestone payments, respectively. We do not expect to pay any additional milestone payments.

As of December 31, 2018, the contingent consideration related to the Lumara Health and MuGard acquisitions are our only financial liabilities measured and recorded using Level 3 inputs in accordance with accounting guidance for fair value measurements, and represented 100% of the total liabilities measured at fair value. See Note F, “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 September 2018, we exercised our option to acquire the global rights to AMAG-423 pursuant to an option agreement entered into in July 2015 with Velo, the terms of which were amended at the time of exercise. As part of the acquisition, we are be obligated to pay Velo a $30.0 million milestone payment upon FDA approval of AMAG-423. In addition, we are obligated to pay sales milestone payments to Velo of up to $240.0 million in the aggregate, triggered at various annual net sales thresholds between $300.0 million and $900.0 million and low-single digit royalties based on net sales. Further, we have assumed additional obligations under a previous agreement entered into by Velo with a third-party, including a $5.0 million milestone payment upon regulatory approval and $10.0 million following the first commercial sale of AMAG-423, payable in quarterly installments as a percentage of quarterly gross commercial sales until the obligation is met. We are also obligated to pay the third-party low-single digit royalties based on net sales.

Under the terms of the Endoceutics License Agreement, which we entered into with Endoceutics in February 2017, we have agreed to pay tiered royalties to Endoceutics equal to a percentage of net U.S. sales of Intrarosa ranging from the mid-teens (for calendar year net sales up to $150.0 million) to mid twenty percent (for any calendar year net sales that exceed $1.0 billion for the commercial life of Intrarosa). Endoceutics is also eligible to receive certain sales milestone payments, including a first sales milestone payment of $15.0 million, which would be triggered when Intrarosa annual net U.S. sales exceed $150.0 million, and a second milestone payment of $30.0 million, which would be triggered when annual net U.S. sales of Intrarosa exceed $300.0 million. If annual net U.S. sales of Intrarosa exceed $500.0 million, there are additional sales milestone payments totaling up to $850.0 million, which would be triggered at various increasing sales thresholds.

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

In connection with a development and license agreement entered into with Antares Pharma, Inc. (“Antares”), we are required to pay royalties to Antares on net sales of the Makena auto-injector commencing on the launch of the Makena auto-injector in a particular country until the Makena auto-injector is no longer sold or offered for sale in such country or the Antares License Agreement is terminated. The royalty rates range from high single digit to low double digits and are tiered based on levels of net sales of the Makena auto-injector and decrease after the expiration of licensed patents or where there are generic equivalents to the Makena auto-injector being sold in a particular country. Antares is also entitled to sales-based milestone payments upon the achievement of certain annual net sales.

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Other Commitments

Under the terms of the Endoceutics License Agreement, we have committed to an annual minimum marketing spend for Intrarosa and we have agreed to share the direct costs with Endoceutics related to certain clinical studies, based upon a negotiated allocation with us funding up to $20.0 million, of which we have paid approximately $6.0 million.

Employment Arrangements

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

Indemnification Obligations

In the course of operating our business, we have entered into a number of indemnification arrangements under which we may be required to make payments to or on behalf of certain third parties including our directors, officers, and certain employees as well as certain other third parties with whom we enter into agreements. For further discussion of how this may affect our business, see Note 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, 2018, 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, 2018 and 2017, our investments totaled $140.9 million and $136.6 million, respectively, and were invested in corporate debt securities, U.S. treasury and government agency securities, commercial paper, and certificates of deposit. Our investments meet high credit quality and diversification standards, as specified in our investment policy. Our investment policy also limits the amount of our credit exposure to any one issue or issuer, excluding U.S. government entities, and seeks to manage these assets to achieve our goals of preserving principal, maintaining adequate liquidity at all times, and maximizing returns. These investments are subject to interest rate risk. The modeling technique used measures the change in fair values arising from an immediate hypothetical shift in market interest rates and assumes that ending fair values include principal plus accrued interest. If market interest rates for comparable investments were to increase or decrease immediately and uniformly by 50 basis points, or one-half of a percentage point, from levels as of December 31, 2018 and 2017, this would have resulted in a hypothetical change in fair value of our investments of approximately $0.7 million and $0.7 million, respectively. These amounts are determined by considering the impact of the hypothetical interest rate movements on our available-for-sale investment portfolios. This analysis does not consider the effect of credit risk as a result of the changes in overall economic activity that could exist in such an environment.

Equity Price Risk

Our 2022 Convertible Notes include conversion and settlement provisions that are based on the price of our common stock at conversion or at maturity of the 2022 Convertible Notes. The amount of cash we may be required to pay is determined by the price of our common stock. The fair value of our 2022 Convertible Notes is 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.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA:

Index To Consolidated Financial Statements

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MANAGEMENT'S ANNUAL REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

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

Our management, including our principal executive officer and principal financial officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2018 based on the framework in Internal Control -Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in 2013. Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2018.

The effectiveness of our internal control over financial reporting as of December 31, 2018, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included herein.

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Report of Independent Registered Public Accounting Firm

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

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of AMAG Pharmaceuticals, Inc. and its subsidiaries (the “Company”) as of December 31, 2018 and 2017, and the related consolidated statements of operations, comprehensive loss, stockholders’ equity and cash flows for each of the three years in the period ended December 31,2018, including the related notes (collectively referred to as the “consolidated financial statements”). We also have audited the Company’s internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 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, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management’s Annual Report on Internal Control over Financial Reporting. Our responsibility is to express opinions on the Company’s consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company’s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and 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.

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

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
March 1, 2019

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

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

	As of December 31,	
	2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	$253,256	$162,855
Marketable securities	140,915	136,593
Accounts receivable, net	75,347	91,460
Inventories	26,691	34,443
Prepaid and other current assets	18,961	11,009
Note receivable	10,000	—
Assets held for sale	—	45,508
Total current assets	525,170	481,868
Property and equipment, net	7,521	7,904
Goodwill	422,513	422,513
Intangible assets, net	217,033	375,479
Deferred tax assets	1,260	47,120
Restricted cash	495	495
Other long-term assets	1,467	266
Assets held for sale, net of current portion	—	564,711
Total assets	$1,175,459	$1,900,356
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$14,487	$7,717
Accrued expenses	129,537	166,732
Current portion of convertible notes, net	21,276	—
Current portion of acquisition-related contingent consideration	144	49,399
Liabilities held for sale	—	53,870
Total current liabilities	165,444	277,718
Long-term liabilities:		
Long-term debt, net	—	466,291
Convertible notes, net	261,933	268,392
Acquisition-related contingent consideration	215	686
Other long-term liabilities	1,212	1,204
Liabilities held for sale, net of current portion	—	95,821
Total liabilities	428,804	1,110,112
Commitments and Contingencies (Note P)		
Stockholders' equity:		
Preferred stock, par value $0.01 per share, 2,000,000 shares authorized; none issued	—	—
Common stock, par value $0.01 per share, 117,500,000 shares authorized; 34,606,760 and 34,083,112 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	346	341
Additional paid-in capital	1,292,736	1,271,628
Accumulated other comprehensive loss	(3,985)	(3,908)
Accumulated deficit	(542,442)	(477,817)
Total stockholders' equity	746,655	790,244

Total liabilities and stockholders' equity	$1,175,459	$1,900,356

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

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

	Years Ended December 31,		
	2018	2017	2016
Revenues:			
Product sales, net	$473,852	$495,645	$432,170
Other revenues	150	124	317
Total revenues	474,002	495,769	432,487
Costs and expenses:			
Cost of product sales	215,892	161,349	96,314
Research and development expenses	44,846	75,017	65,561
Acquired in-process research and development	32,500	65,845	—
Selling, general and administrative expenses	227,810	178,151	169,468
Impairment of intangible assets	—	319,246	15,724
Restructuring expenses	—	—	341
Total costs and expenses	521,048	799,608	347,408
Operating (loss) income	(47,046)	(303,839)	85,079
Other income (expense):			
Interest expense	(51,971)	(68,382)	(73,153)
Loss on debt extinguishment	(35,922)	(10,926)	—
Interest and dividend income	5,328	2,810	3,149
Other (expense) income	(74)	(70)	189
Total other expense, net	(82,639)	(76,568)	(69,815)
(Loss) income from continuing operations before income taxes	(129,685)	(380,407)	15,264
Income tax expense (benefit)	39,654	(175,254)	13,171
Net (loss) income from continuing operations	$(169,339)	$(205,153)	$2,093
Discontinued operations:			
Income (loss) from discontinued operations	$18,873	$10,313	$(6,209)
Gain on sale of CBR business	87,076	—	—
Income tax expense (benefit)	2,371	4,388	(1,633)
Net income (loss) from discontinued operations	$103,578	$5,925	$(4,576)
Net loss	$(65,761)	$(199,228)	$(2,483)
Basic net (loss) income per share:			
(Loss) income from continuing operations	$(4.92)	$(5.88)	$0.06
Income (loss) from discontinued operations	3.01	0.17	(0.13)
Total	$(1.91)	$(5.71)	$(0.07)
Diluted net (loss) income per share:			
(Loss) income from continuing operations	$(4.92)	$(5.88)	$0.06
Income (loss) from discontinued operations	3.01	0.17	(0.13)
Total	$(1.91)	$(5.71)	$(0.07)
Weighted average shares outstanding used to compute net (loss) income per share:			
Basic	34,394	34,907	34,346
Diluted	34,394	34,907	34,833

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

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

	Years Ended December 31,		
	2018	2017	2016
Net loss	$(65,761)	$(199,228)	$(2,483)
Other comprehensive (loss) income			
Unrealized (losses) gains on marketable securities:			
Holding (losses) gains arising during period, net of tax	(77)	(70)	261
Reclassification adjustment for gains (losses) included in net (loss) income, net of tax	—	—	106
Net unrealized (losses) gains on securities	(77)	(70)	367
Total comprehensive loss	$(65,838)	$(199,298)	$(2,116)

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2015	34,733,117	$ 347	$ 1,233,786	$ (4,205)	$ (297,664)	$ 932,264
Net shares issued in connection with the exercise of stock options and vesting of restricted stock units	355,450	3	227	—	—	230
Repurchase of common stock pursuant to the 2016 share repurchase program	(831,744)	(8)	(19,992)	—	—	(20,000)
Issuance of common stock under employee stock purchase plan	79,324	1	1,467	—	—	1,468
Non-cash equity-based compensation	—	—	22,543	—	—	22,543
Unrealized losses on securities, net of tax	—	—	—	367	—	367
Net loss	—	—	—	—	(2,483)	(2,483)
Balance at December 31, 2016	34,336,147	343	1,238,031	(3,838)	(300,147)	934,389
Settlement of warrants	—	—	323	—	—	323
Equity component of the 2022 Convertible Notes, net of issuance costs and taxes	—	—	43,236	—	—	43,236
Cumulative effect of previously unrecognized excess tax benefits related to stock compensation	—	—	—	—	21,558	21,558
Equity component of debt repurchase	—	—	(27,988)	—	—	(27,988)
Shares issued in connection with Endoceutics License Agreement	600,000	6	13,494	—	—	13,500
Repurchase and retirement of common stock pursuant to the 2016 Share Repurchase Program	(1,366,266)	(14)	(19,453)	—	—	(19,467)
Issuance of common stock under employee stock purchase plan	120,580	1	1,593	—	—	1,594
Net shares issued in connection with the exercise of stock options and vesting of restricted stock units, net of withholdings	392,651	5	(1,272)	—	—	(1,267)
Non-cash equity based compensation	—	—	23,664	—	—	23,664
Unrealized losses on securities, net of tax	—	—	—	(70)	—	(70)
Net loss	—	—	—	—	(199,228)	(199,228)
Balance at December 31, 2017	34,083,112	341	1,271,628	(3,908)	(477,817)	790,244
ASC 606 adoption adjustment, net of tax	—	—	—	—	1,136	1,136
Net shares issued in connection with the exercise of stock options and vesting of restricted stock units, net of	463,776	4	275	—	—	279

withholdings						
Issuance of common stock under employee stock purchase plan	59,872	1	917	—	—	918
Non-cash equity based compensation	—	—	19,916	—	—	19,916
Unrealized losses on securities, net of tax	—	—	—	(77)	—	(77)
Net loss	—	—	—	—	(65,761)	(65,761)
Balance at December 31, 2018	34,606,760	$ 346	$ 1,292,736	$ (3,985)	$ (542,442)	$ 746,655

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

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

	Years Ended December 31,		
	2018	2017	2016
Cash flows from operating activities:			
Net loss	$(65,761)	$(199,228)	$(2,483)
Adjustments to reconcile net loss to net cash provided by operating activities:			
Depreciation and amortization	172,223	155,538	99,886
Impairment of intangible assets	—	319,246	19,663
Provision for bad debt expense	678	3,852	3,209
Amortization of premium/discount on purchased securities	87	302	624
(Gain) loss on disposal of fixed assets	(99)	265	—
Non-cash equity-based compensation expense	19,916	23,664	22,543
Non-cash IPR&D expense	—	945	—
Loss on debt extinguishment	35,922	10,926	—
Amortization of debt discount and debt issuance costs	15,658	14,395	12,105
(Gain) loss on sale of investments, net	(1)	70	38
Change in fair value of contingent consideration	(49,607)	(47,686)	25,683
Deferred income taxes	41,166	(178,421)	7,279
Gain on sale of the CBR business	(87,076)	—	—
Transaction costs	(14,111)	—	—
Changes in operating assets and liabilities:			
Accounts receivable, net	16,995	(14,978)	(9,906)
Inventories	4,722	(2,331)	(2,355)
Receivable from collaboration	—	—	428
Prepaid and other current assets	(6,097)	(2,222)	4,095
Accounts payable and accrued expenses	(32,568)	16,834	49,037
Deferred revenues	8,658	17,080	24,522
Payment of contingent consideration in excess of acquisition date fair value	—	(10,432)	(8,116)
Other assets and liabilities	95	(1,223)	(30)
Net cash provided by operating activities	60,800	106,596	246,222
Cash flows from investing activities:			
Proceeds from sales or maturities of marketable securities	85,342	294,957	127,479
Purchase of marketable securities	(89,956)	(127,249)	(194,723)
Acquisition of Intrarosa intangible asset	—	(55,800)	—
Proceeds from the sale of the CBR business	519,303	—	—
Note receivable	(10,000)	—	—
Capital expenditures	(2,534)	(8,988)	(5,460)
Net cash provided by (used in) investing activities	502,155	102,920	(72,704)

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

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

	Years Ended December 31,		
	2018	2017	2016
Cash flows from financing activities:			
Long-term debt principal payments	(475,000)	(353,125)	(17,502)
Proceeds from 2022 Convertible Notes	—	320,000	—
Payments to repurchase 2019 Convertible Notes	—	(191,730)	—
Payment of premium on debt extinguishment	(28,054)	(625)	—
Proceeds to settle warrants	—	323	—
Payment of convertible debt issuance costs	—	(9,553)	—
Payment of contingent consideration	(119)	(39,793)	(92,130)
Payments for repurchases of common stock	—	(19,466)	(20,000)
Proceeds from the exercise of common stock options	3,881	3,021	3,885
Payments of employee tax withholding related to equity-based compensation	(2,682)	(2,696)	(2,171)
Net cash used in financing activities	(501,974)	(293,644)	(127,918)
Net increase (decrease) in cash, cash equivalents and restricted cash	60,981	(84,128)	45,600
Cash, cash equivalents and restricted cash at beginning of the year	192,770	276,898	231,298
Cash, cash equivalents and restricted cash at end of the year	$253,751	$192,770	$276,898
Supplemental data of cash flow information:			
Cash paid for taxes	$5,345	$5,296	$5,309
Cash paid for interest	$48,757	$56,959	$62,381
Non-cash investing and financing activities:			
Fair value of common stock issued in connection with the acquisition of the Intrarosa intangible asset	$—	$12,555	$—
Contingent consideration accrued for the acquisition of the Intrarosa intangible asset	$—	$9,300	$—

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

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AMAG PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

A. DESCRIPTION OF BUSINESS

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a pharmaceutical company focused on bringing innovative products to patients with unmet medical needs by leveraging our development and commercial expertise to invest in and grow our pharmaceutical products across a range of therapeutic areas. Our currently marketed products support the health of patients in the areas of maternal and women's health, anemia management and cancer supportive care, including Feraheme® (ferumoxytol injection) for intravenous use, Makena® (hydroxyprogesterone caproate injection), Intrarosa® (prasterone) vaginal inserts and MuGard® Mucoadhesive Oral Wound Rinse. In addition to our marketed products, our portfolio includes three product candidates, Vyleesi™ (bremelanotide), which is being developed for the treatment of hypoactive sexual desire disorder ("HSDD") in pre-menopausal women, AMAG-423 (digoxin immune fab (ovine)), which is being studied for the treatment of severe preeclampsia, and ciraparantag, which is being studied as an anticoagulant reversal agent. We acquired ciraparantag through our acquisition of Perosphere Pharmaceuticals Inc ("Perosphere"), which was completed on January 16, 2019. See Note W, "Subsequent Events" for further details on the Perosphere acquisition. On August 6, 2018, we completed the sale of our wholly-owned subsidiary, CBR Acquisition Holdings Corp, and the Cord Blood Registry® ("CBR") business to GI Partners ("GI"), a private equity investment firm, pursuant to the June 14, 2018 Stock Purchase Agreement between us and affiliates of GI. We received $519.3 million in cash at closing and recognized a gain of $87.1 million on the sale during the year ended December 31, 2018. Since August 2015, we had provided services related to the preservation of umbilical cord blood stem cell and cord tissue units operated through CBR. For additional information, see Note C, "Discontinued Operations and Held for Sale".

We are subject to risks common to companies in the pharmaceutical industry including, but not limited to (as such risks pertain to our business) our ability to successfully commercialize our products, intense competition, including from generic products; maintaining and defending the proprietary nature of our technology; our dependence upon third-party manufacturers and our potential inability to obtain raw or other materials and impacts of supply shortages; our reliance on and the extent of reimbursement from third parties for the use of our products, including the impact of generic competitors, Makena's high Medicaid reimbursement concentration and the limited level of reimbursement for Intrarosa; our ability to expand our product portfolio through business development transactions; the approval of our product candidates and our ability to commercialize such products, if approved; employee retention and our ability to manage our expanded product portfolio; potential litigation, including securities and product liability suits; our ability to work effectively and collaboratively with our licensors and partners; our reliance on other third parties in our business, including to conduct our clinical trials and undertake our product and distribution; our ability to attract and retain key employees; our potential failure to comply with federal and state healthcare fraud and abuse laws, marketing disclosure laws, or other federal and state laws and regulations and potential civil or criminal penalties as a result thereof; uncertainties regarding reporting and payment obligations under government pricing programs; post-approval commitments for Makena and Feraheme; our ability to comply with data protection laws and regulations; the impact of disruptions to our information technology systems; our level of and ability to repay our indebtedness; our access to sufficient capital; the availability of net operating loss carryforwards and other tax assets; potential differences between actual future results and the estimates or assumptions used by us in preparation of our consolidated financial statements, including goodwill and intangible assets; the volatility of our stock price; the potential fluctuation of our operating results; and provisions in our charter, by-laws and certain contracts that discourage an acquisition of our company.

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

B. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Principles of Consolidation

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

As of June 30, 2018, our CBR business met all of the conditions to be classified as held for sale and represented a discontinued operation, as we considered the disposal of the CBR business to be a strategic shift that would have a major effect on our operations and financial results. All assets and liabilities associated with CBR were therefore classified as assets and

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liabilities held for sale in our consolidated balance sheets for 2017. Further, all historical operating results for CBR are reflected within discontinued operations in the consolidated statements of operations for all periods presented. For additional information, see Note C, “Discontinued Operations and Held for Sale.”

Use of Estimates and Assumptions

The preparation of consolidated financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities. The most significant estimates and assumptions are used to determine amounts and values of, but are not limited to: revenue recognition related to product sales revenue; product sales allowances and accruals; allowance for doubtful accounts; marketable securities; inventory; acquisition date fair value and subsequent fair value estimates used to assess impairment of long-lived assets, including goodwill, in-process research and development (“IPR&D”) and other intangible assets; contingent consideration; debt obligations; certain accrued liabilities, including clinical trial accruals; income taxes, inclusive of valuation allowances, and equity-based compensation expense. Actual results could differ materially from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents consist principally of cash held in commercial bank accounts, money market funds and U.S. Treasury securities having an original maturity of less than three months at the date of acquisition. We consider all highly liquid marketable securities with a maturity of three months or less as of the acquisition date to be cash equivalents. At December 31, 2018 and 2017, substantially all of our cash and cash equivalents were held in either commercial bank accounts or money market funds.

Marketable Securities

We account for and classify our marketable securities as either “available-for-sale,” “held-to-maturity,” or “trading debt securities,” in accordance with the accounting guidance related to the accounting and classification of certain investments in marketable securities. The determination of the appropriate classification by us is based primarily on management’s ability and intent to sell the debt security at the time of purchase. As of December 31, 2018 and 2017, all of our marketable securities were classified as available-for-sale.

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

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

Inventory

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

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

Restricted Cash

We classified $0.5 million of our cash as restricted cash, a non-current asset on the balance sheet, as of December 31, 2018 and 2017. This amount represented the security deposit delivered to the landlord of our Waltham, Massachusetts headquarters.

Concentrations and Significant Customer Information

Financial instruments which potentially subject us to concentrations of credit risk consist principally of cash and cash equivalents, marketable securities, and accounts receivable. We currently hold our excess cash primarily in institutional money market funds, corporate debt securities, U.S. treasury and government agency securities, commercial paper and certificates of deposit. As of December 31, 2018, we did not have a material concentration in any single investment.

Our operations are located entirely within the U.S. We focus primarily on developing, manufacturing, and commercializing our products and product candidates. The following table sets forth customers who represented 10% or more of our total revenues for 2018, 2017 and 2016:

	Years Ended December 31,		
	2018	2017	2016
AmerisourceBergen Drug Corporation	27%	26%	27%
McKesson Corporation	26%	24%	14%
Caremark, LLC	< 10%	< 10%	10%

Our net accounts receivable primarily represent amounts due for products sold directly to wholesalers, distributors, specialty pharmacies and our authorized generic partner. Accounts receivable for our products are recorded net of reserves for estimated chargeback obligations, prompt payment discounts and any allowance for doubtful accounts. As part of our credit management policy, we perform ongoing credit evaluations of our customers, and we generally do not require collateral. If the financial condition of any of our significant product sales customers was to deteriorate and result in an impairment of its ability to make payments owed to us, an allowance for doubtful accounts may be required which could have a material effect on earnings in the period of any such adjustment. We did not experience any significant bad debts and have not established an allowance for doubtful accounts as of December 31, 2018 and 2017.

At December 31, 2018 and 2017, three and two customers, respectively, accounted for 10% or more of our accounts receivable balance, representing approximately 73% and 57% in the aggregate of our total accounts receivable, respectively.

We are currently dependent on a single supplier for Feraheme drug substance (produced in two separate facilities) as well as for drug substance and final packaging services for Intrarosa. In addition, we currently have a single supplier for our auto-injector product. We have been and may continue to be exposed to a significant loss of revenue from the sale of our products in the event that our suppliers and/or manufacturers are not able to fulfill demand for any reason.

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Property and Equipment, Net

Property 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
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 / 8 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 and equipment, the cost and related depreciation are removed from the accounts and any resulting gain or loss is charged to our consolidated statements of operations. Long-lived assets to be held and used are evaluated for impairment whenever events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their estimated fair values. Assets classified as held for sale are no longer subject to depreciation and are recorded at the lower of carrying value or estimated net realizable value.

Business Combinations and Asset Acquisitions

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

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

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

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

Acquisition-Related Contingent Consideration

Contingent consideration arising from a business combination is included as part of the purchase price and is recognized at its estimated fair value as of the acquisition date. Subsequent to the acquisition date, we measure contingent consideration arrangements at fair value for each period until the contingency is resolved. These changes in fair value are recognized in selling, general and administrative expenses in our consolidated statements of operations. Changes in fair values reflect new information about the likelihood of the payment of the contingent consideration and the passage of time. For asset acquisitions, we record contingent consideration for obligations we consider to be probable and estimable and these liabilities are not adjusted to fair value.

Goodwill

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

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

In performing our goodwill impairment tests during 2018 and 2017, we utilized the approach prescribed under Accounting Standards Codification ("ASC") 350, as amended by ASU 2017-04, Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment ("ASU 2017-04"), which requires that an entity perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value. For additional information, see Note I, "Goodwill and Intangible Assets, Net."

Intangible Assets

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

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

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

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, to the extent we acquire other indefinite-lived intangible assets 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.

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Patents

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

Revenue Recognition

Effective January 1, 2018, we adopted ASC Topic 606, Revenue from Contracts with Customers ("ASC 606"), using the modified retrospective transition method. We recognized the cumulative effect of applying the new revenue standard to all contracts with customers that were not completed as of January 1, 2018 as an adjustment of $1.1 million to the opening balance of stockholders' equity at the beginning of 2018. The adjustment recorded was for incremental contract acquisition costs related to the CBR business. The comparative information has not been restated and continues to be reported under the accounting standards in effect for the periods presented. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, certain collaboration arrangements and financial instruments. ASC 606 also impacts certain other areas, such as the accounting for costs to obtain or fulfill a contract. The standard also requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The adoption of ASC 606 did not have an impact on the amount of reported revenues with respect to our product revenue. See Note D, "Revenue Recognition" for additional information.

Research and Development Expenses

Research and development expenses include both external and internal expenses. External expenses primarily include costs of clinical trials and fees paid to contract research organizations ("CROs"), clinical supply and manufacturing expenses, regulatory filing fees, consulting and professional fees as well as other general costs related to the execution of research and development activities. Internal expenses primarily include compensation of employees engaged in research and development activities. Research and development expenses are expensed as incurred. Manufacturing costs are generally expensed as incurred until a product has received the necessary initial regulatory approval.

Advertising Costs

Advertising costs are expensed as incurred and included in selling, general and administrative expenses in our consolidated statements of operations. Advertising costs, including promotional expenses, costs related to trade shows and print media advertising space were $29.8 million, $9.1 million and $4.9 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Equity-Based Compensation

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

We estimate the fair value of equity-based compensation involving stock options based on the Black-Scholes option pricing model. This model requires the input of several factors such as the expected option term, the expected risk-free

interest rate over the expected option term, the expected volatility of our stock price over the expected option term and the expected dividend yield over the expected option term and are subject to various assumptions. The fair value of awards calculated using the Black-Scholes option pricing model is generally amortized on a straight-line basis over the requisite service period, and is recognized based on the proportionate amount of the requisite service period that has been rendered during each reporting period.

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

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

Income Taxes

We use the asset and liability method of accounting for deferred income taxes. Under this method, deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. A deferred tax asset is established for the expected future benefit of net operating loss ("NOL") and credit carryforwards. Deferred tax assets and liabilities are measured using enacted rates in effect for the year in which those temporary differences are expected to be recovered or settled. A valuation allowance against net deferred tax assets is required if, based on available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. Significant judgments, estimates and assumptions regarding future events, such as the amount, timing and character of income, deductions and tax credits, are required in the determination of our provision for income taxes and whether valuation allowances are required against deferred tax assets. In evaluating our ability to recover our deferred tax assets, we consider all available evidence, both positive and negative, including the existence of taxable temporary differences, our past operating results, the existence of cumulative income in the most recent fiscal years, changes in the business in which we operate and our forecast of future taxable income. In determining future taxable income, we are responsible for assumptions utilized including the amount of state and federal operating income, the reversal of temporary differences and the implementation of feasible and prudent tax planning strategies. These assumptions require significant judgment about the forecasts of future taxable income. As of December 31, 2018, we have established a valuation allowance on our net deferred tax assets other than refundable alternative minimum tax ("AMT") credits to the extent that our existing taxable temporary differences would not be available as a source of income to realize the benefits of those deferred tax assets.

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 Loss

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

Basic and Diluted Net (Loss) Income per Share

We compute basic net (loss) income per share by dividing net (loss) income by the weighted average number of common shares outstanding during the relevant period. Diluted net (loss) income per common share has been

computed by dividing net (loss) income by the diluted number of common shares outstanding during the period. Except where the result would be antidilutive to net income, diluted net income per common share would be computed assuming the impact of the conversion of the 2.5% convertible senior notes due in 2019 (the "2019 Convertible Notes") and the 3.25% convertible senior notes due in 2022 (the "2022 Convertible Notes"), the exercise of outstanding stock options, the vesting of RSUs, and the exercise of warrants.

We have a choice to settle the conversion obligation of our 2022 Convertible Notes and the 2019 Convertible Notes (together, the "Convertible Notes") in cash, shares or any combination of the two. Our policy is to settle the principal balance of the Convertible Notes in cash. As such, we apply the treasury stock method to these securities and the dilution related to the conversion premium, if any, of the Convertible Notes is included in the calculation of diluted weighted-average shares outstanding to the extent each issuance is dilutive based on the average stock price during each reporting period being greater than the conversion price of the respective Convertible Notes.

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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 (loss) income per share for 2018, 2017 and 2016 were as follows (in thousands, except per share data):

	Years Ended December 31,		
	2018	2017	2016
Net (loss) income from continuing operations	$(169,339)	$(205,153)	$2,093
Net income (loss) from discontinued operations	103,578	5,925	(4,576)
Weighted average common shares outstanding	34,394	34,907	34,346
Effect of dilutive securities:			
Stock options and RSUs	—	—	487
Shares used in calculating dilutive net loss per share	34,394	34,907	34,833
Basic net (loss) income per share:			
(Loss) income from continuing operations	$(4.92)	$(5.88)	$0.06
Income (loss) from discontinued operations	3.01	0.17	(0.13)
Total	$(1.91)	$(5.71)	$(0.07)
Diluted net (loss) income per share:			
(Loss) income from continuing operations	$(4.92)	$(5.88)	$0.06
Income (loss) from discontinued operations	3.01	0.17	(0.13)
Total	$(1.91)	$(5.71)	$(0.07)

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

	Years Ended December 31,		
	2018	2017	2016
Options to purchase shares of common stock	3,797	3,531	2,590
Shares of common stock issuable upon the vesting of RSUs	1,129	1,070	613
Warrants	1,008	1,008	7,382
2022 Convertible Notes	11,695	11,695	—
2019 Convertible Notes	790	790	7,382
Shares of common stock under employee stock purchase plan	81	—	36
Total	18,500	18,094	18,003

In connection with the issuance of the 2019 Convertible Notes, in February 2014, we entered into convertible bond hedges with certain financial institutions. The convertible bond hedges are not included for purposes of calculating the number of diluted shares outstanding, as their effect would be anti-dilutive. The convertible bond hedges are generally expected, but not guaranteed, to reduce the potential dilution and/or offset the cash payments we are required to make upon conversion of the remaining 2019 Convertible Notes. During 2018 and 2017, the average common stock price was below the exercise price of the warrants and during 2016, the average common stock price was above the exercise price of the warrants.

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Reclassification

Certain prior period amounts have been reclassified to conform to the current year presentation.

Business Segments

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

C. DISCONTINUED OPERATIONS AND HELD FOR SALE

On August 6, 2018, we completed the sale of our CBR business to GI Partners pursuant to the CBR Purchase Agreement. We received $519.3 million in cash at closing and recognized a gain of $87.1 million on the sale during the year ended December 31, 2018. Although we are providing limited transitional services related to GI for certain agreed-upon sales and marketing, technology, human resources and finance functions for several months post-closing, we do not expect to have any (and have not had any) significant involvement in the operations of the CBR business following the close of the sale.

We determined that the sale of CBR represented a strategic shift that would have a major effect on our business and therefore met the criteria for classification as discontinued operations at June 30, 2018. All historical operating results for CBR were reflected within discontinued operations in the consolidated statements of operations for all periods presented. Further, all assets and liabilities associated with CBR were classified as assets and liabilities held for sale in our consolidated balance sheets for the historical period presented.

Assets and liabilities held for sale were reflected separately in our consolidated balance sheets and were comprised of the following as of December 31, 2018 and 2017 (in thousands):

	December 31, 2018	2017
Assets		
Current assets:		
Cash	$—	$29,259
Accounts receivable, net	—	12,042
Inventories (raw materials)	—	2,913
Prepaid and other current assets	—	1,294
Total current assets held for sale	—	45,508
Property, plant and equipment, net	—	18,092
Intangible assets, net	—	328,991
Goodwill	—	216,971
Other long-term assets	—	496
Restricted cash	—	161
Total long-term assets held for sale	—	564,711
Liabilities		
Current liabilities:		
Accounts payable	—	2,618
Accrued expenses	—	8,758
Deferred revenues, short term	—	42,494
Total current liabilities held for sale	—	53,870
Deferred revenues, long-term	—	24,387
Deferred tax liabilities	—	71,046
Other long-term liabilities	—	388

Total long-term liabilities held for sale	$—	$95,821

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The results of operations of the CBR business were classified as discontinued operations for all periods presented in our consolidated financial statements. The following is a summary of net income (loss) from discontinued operations for the years ended December 31, 2018, 2017 and 2016:

	Years Ended December 31,		
	2018	2017	2016
Service revenues, net	$71,217	$114,177	$99,604
Costs and expenses:			
Cost of services	12,559	21,817	20,575
Research and development expenses	—	—	523
Selling, general and administrative expenses	39,899	81,782	80,402
Impairment of intangible assets	—	—	3,939
Restructuring expenses	—	—	374
Total costs and expenses	52,458	103,599	105,813
Operating income (loss)	18,759	10,578	(6,209)
Other income (expense)	114	(265)	—
Income (loss) from discontinued operations	18,873	10,313	(6,209)
Gain on sale of CBR business	87,076	—	—
Income tax expense (benefit)	2,371	4,388	(1,633)
Net income (loss) from discontinued operations	$103,578	$5,925	$(4,576)

The cash flows related to discontinued operations have not been segregated and are included in the Consolidated Statements of Cash Flows. For the years ended December 31, 2018 and 2017, capital expenditures related to the CBR business were $1.6 million and $4.9 million, respectively. Depreciation and amortization expense related to the CBR business for the same periods was $8.4 million and $21.7 million, respectively. Excluding the gain of $87.1 million recognized on the sale of the CBR business and the related transaction expenses of $14.1 million presented in the Consolidated Statements of Cash Flows for the year ended December 31, 2018, there were no other significant operating or investing non-cash items related to the CBR business for either period presented.

D. REVENUE RECOGNITION

On January 1, 2018, we adopted ASC 606 applying the modified retrospective transition method to all contracts that were not completed as of January 1, 2018. Results for reporting periods beginning after January 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for prior periods. There was no impact to revenue for the year ended December 31, 2018 as a result of adoption.

Under ASC 606, we recognize revenue when our customer obtains control of promised goods or services in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps:

a.Identify the contract(s) with a customer;
b.Identify the performance obligations in the contract;
c.Determine the transaction price;
d.Allocate the transaction price to the performance obligations in the contract; and
e.Recognize revenue when (or as) the performance obligations are satisfied.

We only apply the five step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, if the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract,

determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

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Our major sources of revenue during the reporting periods were product revenues from Makena (including both our branded and unbranded products), Feraheme and Intrarosa. The adoption of ASC 606 did not have an impact on the pattern or timing of recognition of our product revenue, as the majority of our product revenue continues to be recognized when the customer takes control of our product.

Revenue and Allowances

The following table provides information about disaggregated revenue by products for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	Years Ended December 31,		
	2018	2017	2016
Product sales, net			
Makena	$322,265	$387,158	$334,050
Feraheme	135,001	105,930	97,058
Intrarosa	16,218	1,816	—
MuGard	368	741	1,062
Total	$473,852	$495,645	$432,170

Total gross product sales were offset by product sales allowances and accruals for the years ended December 31, 2018, 2017 and 2016 as follows (in thousands):

	Years Ended December 31,		
	2018	2017	2016
Gross product sales	$974,330	$920,061	$748,839
Provision for product sales allowances and accruals:			
Contractual adjustments	387,540	310,588	229,686
Governmental rebates	112,938	113,828	86,983
Total	500,478	424,416	316,669
Product sales, net	$473,852	$495,645	$432,170

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The following table summarizes the product revenue allowance and accrual activity for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	Contractual Adjustments	Governmental Rebates	Total
Balance at January 1, 2016	$ 30,177	$ 25,767	$55,944
Current provisions relating to sales in current year	224,894	93,035	317,929
Adjustments relating to sales in prior years	(2,348)	(6,052)	(8,400)
Payments/returns relating to sales in current year	(181,150)	(41,636)	(222,786)
Payments/returns relating to sales in prior years	(23,973)	(19,715)	(43,688)
Balance at December 31, 2016	47,600	51,399	98,999
Current provisions relating to sales in current year	314,537	112,167	426,704
Adjustments relating to sales in prior years	(3,949)	1,661	(2,288)
Payments/returns relating to sales in current year	(253,545)	(61,569)	(315,114)
Payments/returns relating to sales in prior years	(42,479)	(53,060)	(95,539)
Balance at December 31, 2017	62,164	50,598	112,762
Provisions related to current period sales	389,861	105,034	494,895
Adjustments related to prior period sales	(2,330)	7,903	5,573
Payments/returns relating to current period sales	(333,694)	(75,920)	(409,614)
Payments/returns relating to prior period sales	(58,802)	(58,501)	(117,303)
Balance at December 31, 2018	$ 57,199	$ 29,114	$86,313

We receive payments from customers based upon contractual billing schedules; accounts receivable are recorded when the right to consideration becomes unconditional.

Performance Obligations and Product Revenue

At contract inception, we assess the goods promised in our contracts with customers and identify a performance obligation for each promise to transfer to the customer a good (or bundle of goods) that is distinct. To identify the performance obligations, we consider all of the goods promised in the contract regardless of whether they are explicitly stated or are implied by customary business practices. We determined that the following distinct goods represent separate performance obligations:

•Supply of Makena (branded and unbranded) product
•Supply of Feraheme product
•Supply of Intrarosa product

We principally sell our products to wholesalers, specialty distributors, specialty pharmacies and other customers, including our authorized generic partner (collectively, “Customers”), who purchase products directly from us. Our Customers subsequently resell the products to healthcare providers and patients. In addition to distribution agreements with Customers, we enter into arrangements with healthcare providers and payers that provide for government-mandated and/or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of our products.

For the majority of our Customers, we transfer control at the point in time when the goods are delivered. In instances when we perform shipping and handling activities, these are considered fulfillment activities, and accordingly, the costs are accrued when the related revenue is recognized. Taxes collected from Customers and remitted to governmental authorities are excluded from revenues.

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Variable Consideration

Under ASC 606, we are required to make estimates of the net sales price, including estimates of variable consideration (such as rebates, chargebacks, discounts, copay assistance and other deductions), and recognize the estimated amount as revenue, when we transfer control of the product to our customers. In addition, we estimate variable consideration related to our share of net distributable profits from our authorized generic partner. Variable consideration must be determined using either an "expected value" or a "most likely amount" method.

We record product revenues net of certain allowances and accruals in our consolidated statements of operations. 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 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. Consideration payable to a Customer, or other parties that purchase goods from a Customer, are considered to be a reduction of the transaction price, and therefore, of revenue.

Product sales allowances and accruals are based on definitive contractual agreements or legal requirements (such as laws and regulations to provide mandatory discounts for sales to government entities) 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 use the expected value method for estimating variable consideration. 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, rebates are typically paid out in arrears, one to three months after the sale.

The estimate of variable consideration, which is included in the transaction price, may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved in a future period. Estimating variable consideration and the related constraint requires the use of significant management judgment and actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known. No amounts were constrained as of December 31, 2018.

Discounts

We typically offer a 2% prompt payment discount to certain customers as an incentive to remit payment in accordance with the stated terms of the invoice, generally 30 days. Because we anticipate that those customers who are offered this discount will take advantage of the discount, 100% of the prompt payment discount at the time of sale is accrued for eligible customers, based on the gross amount of each invoice. We adjust the accrual quarterly to reflect actual experience.

Chargebacks

Chargeback reserves represent the 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. The chargeback estimates are determined 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 adjusted quarterly to reflect actual experience.

Distributor/Wholesaler and Group Purchasing Organization Fees

Fees under 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 the receipt of an invoice from the wholesaler or distributor, as the case may be. Fees under 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. In accordance with ASC 606, since the

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consideration given to the Customer is not for a distinct good or service, the consideration is a reduction of the transaction price of the vendor's products or services. We have included these fees in contractual adjustments in the table above. We generally pay such amounts within several weeks of the 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 wholesalers, specialty distributors and other customers a limited right to return our products based on the product's expiration date. The current shelf-lives or time between manufacture and expiration for products in our portfolio range from three to five years. Product returns are estimated 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. There were no material adjustments to our reserve for product returns during the years ended December 31, 2018, 2017 or 2016. To date, our product returns have been relatively limited; however, returns experience may change over time. We may be required to make future adjustments to our product returns estimate, which would result in a corresponding change to our net product sales in the period of adjustment and could be significant.

Sales Rebates

We contract with various private payer organizations, primarily pharmacy benefit managers, for the payment of rebates with respect to utilization of our products. We determine our estimates for rebates, if applicable, based on actual product sales data and our historical product claims experience. 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 provider. We regularly assess our 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 accumulated reserve estimate, which would affect net product sales in the period of the adjustment and could be significant.

Governmental Rebates

Governmental rebates relate to our reimbursement arrangements with state Medicaid programs. We determine our estimates for Medicaid rebates, if applicable, based on actual product sales data and our historical product claims experience. In estimating these reserves, we provide for a Medicaid rebate associated with both those expected instances where Medicaid will act as the primary insurer as well as in those instances where we expect Medicaid will act as the secondary insurer. Rebate amounts generally are invoiced quarterly and are paid in arrears, and we expect to pay such amounts within several weeks of notification by the Medicaid or provider entity. 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.

Other Discounts

Other discounts which we offer include voluntary patient assistance programs, such as copay assistance programs, which are intended to provide financial assistance to qualified commercially insured patients with prescription drug copayments required by payers. The calculation of the accrual for copay assistance is based on an estimate of claims and the cost per claim that we expect to receive associated with product that has been recognized as revenue.

E. MARKETABLE SECURITIES

As of December 31, 2018 and 2017, our marketable securities consisted of securities classified as available-for-sale in accordance with accounting standards which provide guidance related to accounting and classification of certain investments in marketable securities.

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The following is a summary of our marketable securities as of December 31, 2018 and 2017 (in thousands):

	December 31, 2018			
Description of Securities:	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term investments:*				
Corporate debt securities	$51,184	$ —	$ (236)	$50,948
U.S. treasury and government agency securities	7,647	—	(34)	7,613
Commercial paper	3,995	—	—	3,995
Certificates of deposit	12,000	—	—	12,000
Total short-term investments	74,826	—	(270)	74,556
Long-term investments:**				
Corporate debt securities	62,530	52	(433)	62,149
U.S. treasury and government agency securities	2,742	—	(32)	2,710
Certificates of deposit	1,500	—	—	1,500
Total long-term investments	66,772	52	(465)	66,359
Total investments	$141,598	$ 52	$ (735)	$140,915

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

* Represents marketable securities with a remaining maturity of less than one year.
** Represents marketable securities with a remaining maturity of one to three years classified as short-term on our consolidated balance sheets.

Impairments and Unrealized Gains and Losses on Marketable Securities

We did not recognize any other-than-temporary impairment losses in our consolidated statements of operations related to our marketable securities during 2018, 2017 and 2016. We considered various factors, including the length of time that each security was in a realized loss position and our ability and intent to hold these securities until recovery of their amortized cost basis occurs. As of December 31, 2018, we have no material losses in an unrealized loss position for more than one year. Future events may occur, or additional information may become available, which may cause us to identify credit losses where we do not expect to receive cash flows sufficient to recover the entire amortized cost basis of a security and may necessitate the recording of future realized losses on securities in our portfolio. Significant losses in the estimated fair values of our marketable securities could have a material adverse effect on our earnings in future periods.

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F. FAIR VALUE MEASUREMENTS

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

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

The following tables represent the fair value hierarchy as of December 31, 2018 and 2017, for those assets and liabilities that we measure at fair value on a recurring basis (in thousands):

	Fair Value Measurements at December 31, 2018 Using:			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$71,568	$ 71,568	$ —	$ —
Corporate debt securities	113,097	—	113,097	—
U.S. treasury and government agency securities	10,323	—	10,323	—
Commercial paper	3,995	—	3,995	—
Certificates of deposit	13,500	—	13,500	—
Total Assets	$212,483	$ 71,568	$ 140,915	$ —
Liabilities:				
Contingent consideration - Lumara Health	$—	$ —	$ —	$ —
Contingent consideration - MuGard	359	—	—	359
Total Liabilities	$359	$ —	$ —	$ 359

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	Fair Value Measurements at December 31, 2017 Using:			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$4,591	$ 4,591	$ —	$ —
Corporate debt securities	116,152	—	116,152	—
U.S. treasury and government agency securities	9,291	—	9,291	—
Commercial paper	1,999	—	1,999	—
Certificates of deposit	9,151	—	9,151	—
Total Assets	$141,184	$ 4,591	$ 136,593	$ —
Liabilities:				
Contingent consideration - Lumara Health	$49,187	$ —	$ —	$ 49,187
Contingent consideration - MuGard	898	—	—	898
Total Liabilities	$50,085	$ —	$ —	$ 50,085

Marketable securities

Our cash equivalents are classified as Level 1 assets under the fair value hierarchy as these assets have been valued using quoted market prices in active markets and do not have any restrictions on redemption. Our marketable securities are classified as Level 2 assets under the fair value hierarchy as these assets were primarily determined from independent pricing services, which normally derive security prices from recently reported trades for identical or similar securities, making adjustments based upon other significant observable market transactions. At the end of each reporting period, we perform quantitative and qualitative analysis of prices received from third parties to determine whether prices are reasonable estimates of fair value. After completing our analysis, we did not adjust or override any fair value measurements provided by our pricing services as of December 31, 2018 or 2017. In addition, there were no transfers or reclassifications of any securities between Level 1 and Level 2 during 2018 or 2017.

Contingent consideration

In accordance with GAAP, for asset acquisitions, we record contingent consideration for obligations we consider to be probable and estimable and these liabilities are not adjusted to fair value. As of December 31, 2018, no contingent consideration was recorded in accrued expenses. As of December 31, 2017, $10.0 million of contingent consideration was recorded in accrued expenses and was paid to Endoceutics in April 2018 on the first anniversary of the closing of the license agreement between us and Endoceutics.

We recorded contingent consideration related to the November 2014 acquisition of Lumara Health Inc. (“Lumara Health”) for our Makena product and related to our June 2013 license agreement for MuGard® Mucoadhesive Oral Wound Rinse (the “MuGard License Agreement”) with Abeona Therapeutics, Inc. (“Abeona”), under which we acquired the U.S. commercial rights for the management of oral mucositis and stomatitis (the “MuGard Rights”).

The fair value measurements of contingent consideration obligations and the related intangible assets arising from business combinations are classified as Level 3 assets under the fair value hierarchy as these assets have been valued using unobservable inputs. These inputs include: (a) the estimated amount and timing of projected cash flows; (b) the probability of the achievement of the factors on which the contingency is based; and (c) the risk-adjusted discount rate used to present value the probability-weighted cash flows. Significant increases or decreases in any of those inputs in isolation could result in a significantly lower or higher fair value measurement.

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The following table presents a reconciliation of contingent consideration obligations related to the acquisition of Lumara Health and the MuGard Rights (in thousands):

Balance as of January 1, 2017	$147,995
Payments made	(50,224)
Adjustments to fair value of contingent consideration	(47,686)
Balance as of December 31, 2017	$50,085
Payments made	(119)
Adjustments to fair value of contingent consideration	(49,607)
Balance as of December 31, 2018	$359

During 2018, we reduced the fair value of our contingent consideration liability by approximately $49.6 million, primarily based on actual Makena net sales to date and our expectations for future performance, which indicated that achievement of future milestones is not probable. This adjustment was based on our estimates, which are reliant on a number of external factors as well as the exercise of judgment.

The $47.7 million adjustment to the fair value of the contingent consideration liability in 2017 was primarily due to a decrease to the Makena contingent consideration based on a revision of our long-term forecast of total projected net Makena sales, which impacted both the amount and timing of future milestone payments. In addition, during 2017, we paid a $50.0 million sales milestone to the former stockholders of Lumara Health and a $0.2 million royalty payment for MuGard.

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 fair value of the contingent royalty payments payable by us to Abeona under the MuGard License Agreement was determined based on various market factors, including an analysis of estimated sales using a discount rate of approximately 14% as of December 31, 2018. In addition, as of December 31, 2018, we estimated that the undiscounted royalty amounts we could pay under the MuGard License Agreement, based on current projections, may range from $0.3 million to $0.6 million over the remainder of the ten year period, which commenced on June 6, 2013, the acquisition date, which is our best estimate of the period over which we expect the majority of the asset’s cash flows to be derived.

We believe the estimated fair values of the contingent payments associated with 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, 2018, the estimated fair value of the 2022 Convertible Notes and the 2019 Convertible Notes was $294.8 million and $20.9 million, respectively, which differed from their carrying values. As of December 31, 2017, the estimated fair value of our 2023 Senior Notes (as defined below), the 2022 Convertible Notes and the 2019 Convertible Notes was $463.7 million, $282.9 million and $21.6 million, respectively, which differed from their carrying values. See Note R, “Debt,” for additional information on our debt obligations.

G. INVENTORIES

Our major classes of inventories were as follows as of December 31, 2018 and 2017 (in thousands):

	December 31,	
	2018	2017
Raw materials	$9,388	$9,505
Work in process	5,932	4,146

Finished goods	11,371	20,792
Total inventories	$26,691	$34,443

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H. PROPERTY AND EQUIPMENT, NET

Property and equipment, net consisted of the following as of December 31, 2018 and 2017 (in thousands):

	December 31,	
	2018	2017
Computer equipment and software	$1,637	$1,401
Furniture and fixtures	1,737	1,442
Leasehold improvements	2,938	2,938
Laboratory and production equipment	6,000	654
Construction in progress	420	5,068
	12,732	11,503
Less: accumulated depreciation	(5,211)	(3,599)
Property and equipment, net	$7,521	$7,904

During 2018, 2017 and 2016, depreciation expense was $1.6 million, $1.2 million, and $0.9 million, respectively.

I. GOODWILL AND INTANGIBLE ASSETS, NET

Goodwill

Our $422.5 million goodwill balance represents goodwill of the continuing business following the goodwill allocation required by the CBR transaction discussed in Note C, “Discontinued Operations and Held for Sale.” We determined that CBR met the definition of a business and as a result, in accordance with ASC 350 - Intangibles - Goodwill and Other (“ASC 350”), allocated goodwill on a relative fair value basis between CBR and the continuing business for the purposes of determining the carrying value of CBR. As of December 31, 2018, we had no accumulated impairment losses related to goodwill.

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

In performing our goodwill impairment tests during 2018 and 2017, we utilized the approach prescribed under ASC 350, as amended by ASU 2017-04 which requires that an entity perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit’s fair value.

When we perform any goodwill impairment test, the estimated fair value of our reporting unit is determined using an income approach that utilizes a discounted cash flow (“DCF”) model or a market approach, when appropriate, which assesses our market capitalization as adjusted for a control premium, or a combination thereof. The DCF model is based upon expected future after-tax operating cash flows of the reporting unit discounted to a present value using a risk-adjusted discount rate. Estimates of future cash flows require management to make significant assumptions concerning (i) future operating performance, including future sales, long-term growth rates, operating margins, variations in the amount and timing of cash flows and the probability of achieving the estimated cash flows (ii) the probability of regulatory approvals, and (iii) future economic conditions, all of which may differ from actual future cash flows. These assumptions are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy. The discount rate, which is intended to reflect the risks inherent in future cash flow projections, used in the DCF model, is based on estimates of the weighted average cost of capital (“WACC”) of market participants relative to our reporting unit. Financial and credit market volatility can directly impact certain inputs and assumptions used to develop the WACC. Any changes in these assumptions may affect our fair value estimate and the result of an impairment test. We believe the discount rates and other inputs and assumptions are consistent with those that a market participant would use. In addition, in order to assess the reasonableness of the fair

value of our reporting unit as calculated under the DCF model, we also compare the reporting unit's fair value to our market capitalization and calculate an implied control premium (the excess sum of the reporting unit's fair value over its market capitalization). We evaluate the implied control premium by comparing it to control premiums of recent comparable market

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transactions, as applicable. Throughout 2017, at points during 2018 and as of December 31, 2018 and 2017, our market capitalization was lower than our stockholders' equity, or book value. We believe that a market participant buyer would be required to pay a control premium for our business that would cover the difference between our market capitalization and our book value.

As described in the accounting guidance for evaluating long-lived assets for impairment, an entity's fair value may include a control premium in addition to the quoted market price to determine the fair value of a single reporting unit entity, as an acquiring entity is often willing to pay more for equity securities that give it a controlling interest than an investor would pay for a number of equity securities representing less than a controlling interest. This accounting guidance also indicates that the quoted market price of an individual security need not be the sole measurement basis of the fair value of a single reporting unit.

2018 Impairment Testing Results

During the second quarter of 2018, in conjunction with the goodwill allocation required by the CBR transaction and in accordance with ASC 350, we performed a goodwill impairment test to assess whether there were indicators that its fair value was less than its carrying value. As a result of this evaluation, we determined that there was no impairment of goodwill at June 30, 2018.

On October 31, 2018 (the "measurement date"), we conducted our 2018 annual goodwill impairment test using a market approach to estimate the fair value of our reporting unit as of the measurement date. We considered our market capitalization, as adjusted for a control premium, to be one indicator of the fair value of our reporting unit. On October 31, 2018, our stock price closed at $21.50 per share, resulting in a market capitalization of approximately $742 million, which was below the carrying amount of our reporting unit as of the measurement date, resulting in an implied control premium of 2%. In the days following our October 31, 2018 annual testing date, our stock price declined, largely in response to our November 1, 2018 earnings release and Company update. This decline resulted in a market capitalization of approximately $633 million on November 5, 2018, resulting in an implied control premium of 20%. During the third quarter of 2018, we obtained an updated control premium analysis that benchmarked average control premiums paid in prior merger and acquisition transactions among biotechnology and pharmaceutical companies. The analysis indicated that control premiums vary depending on facts and circumstances for each transaction. The range of control premiums observed was between 39% and 96%, with a median of 71%. Management believes that using this market approach of assessing reasonable control premiums provided a sufficient basis to assess whether the fair value of our reporting unit, including a range of reasonable control premiums, was above its carrying amount. Incorporating control premiums in this range to our October 31, 2018 market capitalization of $742 million resulted in a fair value which was at least 36% greater (at the low end of the range) than the carrying amount of our net assets as of October 31, 2018. As a result of this review, we determined that there was no impairment of our goodwill at October 31, 2018.

Between October 31, 2018 and December 31, 2018, our stock price continued to fluctuate, with a median closing stock price of $17.84 per share for the period from November 1, 2018 through December 31, 2018. The median closing stock price of $17.84 per share resulted in a market capitalization of approximately $617 million, which as compared to the $747 million carrying amount of our reporting unit at December 31, 2018 resulted in an implied control premium of 21%. Incorporating the range of control premiums obtained from the control premium study used in our annual goodwill impairment test at October 31, 2018 to the calculated market capitalization of $617 million resulted in a fair value which was at least 15% greater (at the low end of the range) than the carrying amount of our net assets as of December 31, 2018. Using the closing stock price of $15.19 per share on December 31, 2018 results in an implied control premium of 41%. This implied control premium is within the range of control premiums observed. As a result of this review, we determined that there was no impairment of our goodwill between our annual goodwill impairment test date and December 31, 2018. In addition, we determined that there were no other indicators of impairment through December 31, 2018 requiring further assessment.

2017 Impairment Testing Results

During the third quarter of 2017, we determined that the significant reduction in the long-term forecasted cash flows of our largest product, Makena, which led to a $319.2 million impairment of the Makena base technology intangible asset, was an indicator that an interim impairment test of goodwill was necessary at September 30, 2017. We

performed a quantitative goodwill impairment test at September 30, 2017 in accordance with ASU 2017-04, to both assess whether a goodwill impairment existed and if so, the amount of the impairment loss. We considered our market capitalization, as adjusted for a control premium, to be one indicator of the fair value of our reporting unit. On September 30, 2017, our stock price closed at $18.45, resulting in a market capitalization of approximately $653.0 million, which was 18% below the carrying amount of the reporting unit as of September 30, 2017.

During the third quarter of 2017, we obtained a control premium analysis which benchmarked average control premiums paid in prior merger and acquisition transactions among biotechnology and pharmaceutical companies. The analysis indicated

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that control premiums vary depending on facts and circumstances for each transaction. The range of control premiums observed was between 30% and 83%, with a mean of 64%. Management believes that using this market approach of assessing reasonable control premiums provided a sufficient basis to assess whether the fair value of our reporting unit, including a range of reasonable control premiums, was above its carrying amount as of September 30, 2017. Incorporating control premiums in this range to our September 30, 2017 market capitalization of $653.0 million resulted in a fair value which was at least 6% greater (at the low end of the range) than the carrying amount of our net assets as of September 30, 2017. As a result of this review, we determined that there was no impairment of our goodwill at September 30, 2017.

On October 31, 2017 (the “measurement date”), we conducted our 2017 annual goodwill impairment test using an income approach, specifically a DCF model, and a market approach to estimate the fair value of our reporting unit as of the measurement date. We used a range of discount rates between 10.0% and 19.5% across our commercial products and product candidates, which resulted in a weighted average discount rate of 13.6% to determine the fair value of our reporting unit. We believe the discount rate and other inputs and assumptions are consistent with those that a market participant would use. In addition, we believe we utilized reasonable estimates and assumptions about future revenues, cost projections, and cash flows as of the measurement date. As a corroborating step in our 2017 annual impairment assessment, we compared our implied control premium, as determined by the difference between the fair value of our reporting unit as estimated by our DCF analysis and our market capitalization, to control premiums of recent comparable market transactions. The results indicated that the implied control premium was within the range of control premiums observed in prior merger and acquisition transactions among biotechnology and pharmaceutical companies. We believe that using this market approach further corroborated our DCF fair value assessment at October 31, 2017. As a result of our DCF analysis, we determined that the fair value of our reporting unit exceeded its carrying value by 18% and as such, no impairment was recorded as of October 31, 2017. In performing a sensitivity analysis, had we increased the weighted average discount rate by 1%, the fair value of the reporting unit would have still exceeded the carrying value. In addition, we determined that there were no other indicators of impairment through December 31, 2017 requiring further assessment.

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

Intangible Assets

	December 31, 2018				December 31, 2017			
	Cost	Accumulated Amortization	Impairments	Net	Cost	Accumulated Amortization	Impairments	Net
Amortizable intangible assets:								
Makena base technology	$797,100	$ 400,495	$ 319,246	$77,359	$797,100	$ 255,754	$ 319,246	$222,100
Makena auto-injector developed technology	79,100	6,952	—	72,148	—	—	—	—
Intrarosa developed technology	77,655	10,129	—	67,526	77,655	3,376	—	74,279
	953,855	417,576	319,246	217,033	874,755	259,130	319,246	296,379
Indefinite-lived intangible assets:								

Makena IPR&D	—	—	—	—	79,100	—	—	79,100
Total intangible assets	$953,855	$ 417,576	$ 319,246	$217,033	$953,855	$ 259,130	$ 319,246	$375,479

The Makena base technology and IPR&D intangible assets were acquired in November 2014 in connection with our acquisition of Lumara Health. During the first quarter of 2018, following the FDA approval of Makena for administration via a pre-filled subcutaneous auto-injector (the "Makena auto-injector"), we reclassified the Makena IPR&D as the Makena auto-injector developed technology and placed it into service. Amortization of the Makena auto-injector developed technology is being recognized on a straight-line basis over 8.8 years.

During the third quarter of 2017, we received new information from a variety of sources, including from external consulting firms and our authorized generic partner, regarding the potential competitive landscape for the Makena intramuscular ("IM") product (the "Makena IM product") upon loss of orphan drug exclusivity in February 2018. The

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

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

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

Further, during the third and fourth quarters of 2017, we evaluated our Makena IPR&D intangible asset, which is related to the Makena auto-injector, for impairment and concluded that its fair value was greater than its carrying value, and therefore it was not impaired.

The Intrarosa developed technology was acquired in April 2017 from Endoceutics. Amortization of the Intrarosa developed technology is being recognized on a straight line basis over 11.5 years.

The MuGard Rights were acquired from Abeona in June 2013. Amortization of the MuGard Rights was being recognized using an economic consumption model over ten years from the acquisition date, which represented our best estimate of the period over which we expected the majority of the asset's cash flows to be derived. During 2016, based on our determination that the fair value of the net MuGard Rights intangible asset was below its book value, we recorded an impairment charge for the full $15.7 million net intangible asset.

As of December 31, 2018, the weighted average remaining amortization period for our finite-lived intangible assets was approximately 7.5 years. Total amortization expense for 2018, 2017 and 2016, was $158.4 million, $130.4 million and $72.3 million, respectively. Amortization expense for the Makena base technology, Intrarosa developed technology, and the MuGard Rights is recorded in cost of product sales in our consolidated statements of operations. 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, 2019	$ 41,891
Year Ending December 31, 2020	37,123
Year Ending December 31, 2021	31,022
Year Ending December 31, 2022	27,972
Year Ending December 31, 2023	18,207
Thereafter	60,818
Total	$ 217,033

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J. CURRENT AND LONG-TERM LIABILITIES

Accrued Expenses

Accrued expenses consisted of the following as of December 31, 2018 and 2017 (in thousands):

	December 31,	
	2018	2017
Commercial rebates, fees and returns	$80,520	$101,852
Professional, license, and other fees and expenses	23,242	23,657
Salaries, bonuses, and other compensation	22,482	15,882
Interest expense	1,067	13,525
Intrarosa-related license fees	—	10,000
Accrued research and development	2,226	1,816
Total accrued expenses	$129,537	$166,732

K. INCOME TAXES

For the years ended December 31, 2018, 2017, and 2016, 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,		
	2018	2017	2016
Current:			
Federal	$(1,136)	$2,162	$—
State	1,469	5,358	4,169
Total current	$333	$7,520	$4,169
Deferred:			
Federal	$42,886	$(172,048)	$11,208
State	(3,565)	(10,726)	(2,206)
Total deferred	$39,321	$(182,774)	$9,002
Total income tax expense (benefit)	$39,654	$(175,254)	$13,171

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

	Years Ended December 31,		
	2018	2017	2016
Statutory U.S. federal tax rate	21.0 %	35.0 %	35.0 %
State taxes, net of federal benefit	4.7	3.3	5.4
Impact of 2017 tax reform on deferred tax balance	—	4.6	—
Equity-based compensation expense	(1.5)	(0.8)	16.2
Contingent consideration	7.2	4.4	41.5
Other permanent items, net	(1.4)	(0.5)	11.9
Tax credits	6.2	0.7	(19.2)
Write-down of acquired state net operating losses	—	—	67.7
Valuation allowance	(67.4)	(0.8)	(68.3)
Other, net	0.6	0.2	(3.9)
Effective tax rate	(30.6)%	46.1 %	86.3 %

For the year ended December 31, 2018, we recognized income tax expense of $39.7 million, representing an effective tax rate of (30.6)%. The difference between the expected statutory federal tax rate of 21.0% and the effective tax rate of (30.6)% for the year ended December 31, 2018, was primarily attributable to the establishment of a valuation allowance on net deferred

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tax assets other than refundable AMT credits, the impact of non-deductible stock compensation and other non-deductible expenses, partially offset by a benefit from contingent consideration associated with Lumara Health, state income taxes and orphan drug tax credits. We have established a valuation allowance on our deferred tax assets other than refundable credits to the extent that our existing taxable temporary differences would not be available as a source of income to realize the benefits of those deferred tax assets. The valuation allowance on our deferred tax assets, other than refundable AMT credits, increased during the year ended December 31, 2018 primarily because the deferred tax liabilities associated with the CBR business, which was reclassified to discontinued operations and sold during the year ended December 31, 2018, are no longer available as a source of income to realize the benefits of the net deferred tax assets.

On December 22, 2017, the Tax Cuts and Jobs Act (the "2017 Tax Act"), was enacted. The 2017 Tax Act includes significant changes to the U.S. corporate income tax system, including a reduction of the federal corporate income tax rate from 35.0% to 21.0%, effective January 1, 2018. Deferred tax assets and liabilities are measured using enacted rates in effect for the year in which those temporary differences are expected to be recovered or settled. As a result of the reduction in the federal tax rate from 35.0% to 21.0%, we revalued our ending net deferred tax liabilities at December 31, 2017 and recognized a provisional $17.6 million tax benefit.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118"), which allowed us to record provisional amounts for the impact of the 2017 Tax Act during a measurement period which is similar to the measurement period used when accounting for business combinations. During the year ended December 31, 2018, we completed our accounting for the enactment date income tax effects of the 2017 Tax Act in accordance with SAB 118 and recorded immaterial adjustments as a result.

For the year ended December 31, 2017, we recognized an income tax benefit of $175.3 million representing an effective tax rate of 46.1%. The difference between the expected statutory federal tax rate of 35.0% and the 46.1% effective tax rate for 2017 was primarily attributable to the impact of the 2017 federal tax reform legislation, as discussed above, contingent consideration associated with Lumara Health, federal research and orphan drug tax credits generated during the year, and the impact of state income taxes, partially offset by equity-based compensation expenses and an increase to our valuation allowance.

For the year ended December 31, 2016, we recognized income tax expense of $13.2 million representing an effective tax rate of 86.3%. The difference between the statutory tax rate and the effective tax rate was primarily attributable to the impact of contingent consideration associated with Lumara Health, equity-based compensation expenses and other permanent items, including meals and entertainment expense, officer compensation and Makena-related expenses, partially offset by the benefit of the federal research and development and orphan drug tax credits generated during the year. The effective tax rate for the year ended December 31, 2016 reflected the significance of these permanent differences in relation to the pre-tax income for the year ended December 31, 2016. As a result of state tax planning during 2016, we analyzed the acquired state net operating losses ("NOLs") and determined that a significant portion were not utilizable and should be written down. This write-down was offset with a decrease in the valuation allowance as we had previously determined that it was more likely than not that these NOLs would not be utilized.

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

	December 31,	
	2018	2017
Assets		
Net operating loss carryforwards	$46,888	$60,308
Tax credit carryforwards	24,290	15,577
Capital loss carryforwards	20,896	—
Interest expense carryforwards	4,318	—
Equity-based compensation expense	5,931	5,873
Capitalized research & development	4,635	7,872
Intangible assets	12,565	—
Reserves	2,683	3,342
Contingent consideration	87	1,406
Other	5,389	5,971
Valuation allowance	(113,278)	(4,740)
Liabilities		
Property, plant and equipment depreciation	(614)	(198)
Intangible assets and inventory	—	(32,406)
Debt instruments	(12,489)	(15,744)
Other	(41)	(141)
Net deferred tax assets	$1,260	$47,120

The valuation allowance increased by approximately $108.5 million for the year ended December 31, 2018. We have established a valuation allowance on our deferred tax assets other than refundable AMT credits to the extent that our existing taxable temporary differences would not be available as a source of income to realize the benefits of those deferred tax assets. Our valuation allowance on our deferred tax assets, other than refundable AMT credits, increased during the year ended December 31, 2018, primarily because the deferred tax liabilities associated with the CBR business, which was reclassified to discontinued operations and sold during 2018, are no longer available as a source of income to realize the benefits of the net deferred tax assets.

At December 31, 2018, we had federal and state NOL carryforwards of approximately $199.0 million and $92.9 million, respectively, of which $123.1 million and $16.6 million federal and state NOL carryforwards, were acquired as part of the Lumara Health transaction, respectively. The federal and state NOLs expire at various dates through 2038. We have federal tax credits of approximately $23.4 million to offset future tax liabilities of which $2.3 million were acquired as part of the Lumara Health transaction. We have state tax credits of $1.2 million to offset future tax liabilities. These federal and state tax credits will expire periodically through 2038 if not utilized. We have a capital loss carryforward of $90.5 million from the sale of the CBR business that can only be used to offset future capital gains and expires in 2023. Our interest expense carryforward is $17.8 million, which may be carried forward indefinitely.

Utilization of our NOLs, interest expense carryforwards, and research and development (“R&D”) credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future in accordance with Section 382 of the Internal Revenue Code of 1986 (“Section 382”) as well as similar state provisions. These ownership changes may limit the amount of NOLs and interest expense carryforwards that can be utilized annually to offset future taxable income and may limit the amounts of R&D credit carryforwards that can be utilized annually to offset taxes. 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

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December 31, 2018, based upon publicly available information as of December 31, 2018, would limit or otherwise restrict our ability to utilize these NOLs, interest expense, and R&D credit carryforwards. As a result of this analysis, we do not believe there are any significant limitations on our ability to utilize these carryforwards. The NOLs and tax credits acquired from Lumara health are subject to restrictions under Section 382. These restricted NOLs and credits may be utilized subject to an annual limitation. We identified two ownership changes associated with the attributes acquired as part of the Lumara Health transaction and determined these attributes are subject to an annual limitation. Future changes in ownership after December 31, 2018 could affect the limitation in future years and any limitation may result in expiration of a portion of the NOL or R&D credit carryforwards before utilization.

Unrecognized tax benefits represent uncertain tax positions for which reserves have been established. A reconciliation of our changes in unrecognized tax benefits is as follows (in thousands):

	Years Ended December 31,		
	2018	2017	2016
Unrecognized tax benefits at the beginning of the year	$10,560	$13,020	$12,695
Additions based on tax positions related to the current year	12	574	300
Additions for tax positions from prior years	608	340	69
Subtractions for federal tax reform	—	(3,296)	—
Subtractions for tax positions from prior years	—	(78)	(44)
Unrecognized tax benefits at the end of the year	$11,180	$10,560	$13,020

The amount of unrecognized tax benefits that would impact the effective tax rate if recognized is immaterial, as the majority of our uncertain tax positions relate to NOL and credit carryforwards, which, if recognized, are currently expected to require a full valuation allowance.

Our unrecognized tax benefits as of December 31, 2018 increased by $0.6 million as compared to December 31, 2017 primarily due to tax reserves established on R&D tax credits.

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

Our unrecognized tax benefits as of December 31, 2016 increased by $0.3 million as compared to December 31, 2015 primarily due to tax reserves established on R&D tax credits.

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

The statute of limitations for assessment by the Internal Revenue Service (the “IRS”) and most state tax authorities is closed for tax years prior to December 31, 2015, although carryforward attributes that were generated prior to tax year 2015 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 audits in progress. We have two state audits in progress. We do not expect these audits to result in any material impact.

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L. ACCUMULATED OTHER COMPREHENSIVE LOSS

The following table summarizes the changes in the accumulated balances of other comprehensive loss associated with unrealized (losses) gains on securities during 2018, 2017 and 2016 (in thousands):

	December 31,		
	2018	2017	2016
Beginning balance	$(3,908)	$(3,838)	$(4,205)
Other comprehensive loss before reclassifications	(77)	(70)	261
Reclassification adjustment for gains included in net loss	—	—	106
Ending balance	$(3,985)	$(3,908)	$(3,838)

M. EQUITY-BASED COMPENSATION

We currently maintain three equity compensation plans, namely our Fourth Amended and Restated 2007 Equity Incentive Plan, as amended (the "2007 Plan"), the Lumara Health Inc. Amended and Restated 2013 Incentive Compensation Plan (the "Lumara Health 2013 Plan") and our 2015 Employee Stock Purchase Plan ("2015 ESPP"). All outstanding stock options granted under each of our equity compensation plans other than our 2015 ESPP (discussed below) have an exercise price equal to the closing price of a share of our common stock on the grant date. During the fourth quarter of 2017, the then outstanding awards under our Amended and Restated 2000 Stock Plan (the "2000 Plan") expired.

Our 2007 Plan was originally approved by our stockholders in November 2007, and succeeded our 2000 Plan, which has expired and under which no further grants may be made. Any shares that remained available for issuance under the 2000 Plan as of the date of adoption of the 2007 Plan were included in the number of shares that were issued under the 2007 Plan. In addition, any shares subject to outstanding awards granted under the 2000 Plan that expired or terminated for any reason prior to exercise were added to the total number of shares of our stock available for issuance under the 2007 Plan. In June 2018, at our annual meeting of stockholders, our stockholders approved an amendment to our 2007 Plan to, among other things, increase the number of shares of our common stock available for issuance thereunder by 1,043,000 shares. The alloted number of shares available for issuance under the 2007 Plan was 10,537,365 as of December 31, 2018 and there were 2,548,513 shares remaining available for future issuance under the 2007 Plan. As of December 31, 2018, all outstanding options under the 2007 Plan have either a seven or ten-year term.

In November 2014, we assumed the Lumara Health 2013 Plan in connection with the acquisition of Lumara Health. The total number of shares issuable pursuant to awards under this plan as of the effective date of the acquisition and after taking into account any adjustments as a result of the acquisition, was 200,000 shares. As of December 31, 2018, there were 18,242 shares remaining available for issuance under the Lumara Health 2013 Plan, which are available for grants to certain employees, officers, directors, consultants, and advisers of AMAG and our subsidiaries who are newly-hired or who previously performed services for Lumara Health. All outstanding options under the Lumara Health 2013 Plan have a ten-year term.

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

In May 2015, our stockholders approved our 2015 ESPP, which authorizes the issuance of up to 200,000 shares of our common stock to eligible employees. In June 2018, at our annual meeting of stockholders, our stockholders approved an amendment to our 2015 ESPP to increase the maximum number of shares of our common stock that will be made available for sale thereunder by 500,000 shares. 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, 2018, 259,776 shares have been issued under our 2015 ESPP.

During 2018, we also granted equity through inducement grants outside of our equity compensation plans to certain employees to induce them to accept employment with us (collectively, "Inducement Grants"). The options were granted at an exercise price equal to the fair market value of a share of our common stock on the respective grant dates and will be

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exercisable in four equal annual installments beginning on the first anniversary of the respective grant dates. The RSU grants will vest in three equal annual installments beginning on the first anniversary of the respective grant dates. The foregoing grants were made pursuant to inducement grants outside of our stockholder approved equity plans as permitted under the NASDAQ Stock Market listing rules. We assessed the terms of these awards and determined there was no possibility that we would have to settle these awards in cash and therefore, equity accounting was applied.

Stock Options

The following table summarizes stock option activity during 2018:

	2007 Equity Plan	2013 Lumara Equity Plan	Inducement Grants	Total
Outstanding at December 31, 2017	2,590,373	125,536	815,450	3,531,359
Granted	1,047,087	35,400	102,393	1,184,880
Exercised	(150,789)	(2,812)	—	(153,601)
Expired or terminated	(704,885)	(33,674)	(107,500)	(846,059)
Outstanding at December 31, 2018	2,781,786	124,450	810,343	3,716,579

Restricted Stock Units

The following table summarizes RSU activity during 2018:

	2007 Equity Plan	2013 Lumara Equity Plan	Inducement Grants	Total
Outstanding at December 31, 2017	966,623	11,611	91,541	1,069,775
Granted	766,869	1,600	48,418	816,887
Vested	(375,470)	(10,650)	(52,164)	(438,284)
Expired or terminated	(316,881)	(460)	(2,502)	(319,843)
Outstanding at December 31, 2018	1,041,141	2,101	85,293	1,128,535

In March 2018 and February 2017, we granted RSUs under our 2007 Plan to certain members of our senior management covering a maximum of 206,250 and 191,250 shares of common stock, respectively. These performance-based RSUs will vest, if at all, on March 1, 2021 and February 22, 2020, respectively, based on our total shareholder return ("TSR") performance measured against the median TSR of a defined group of companies over a three-year period. As of December 31, 2018, the maximum shares of common stock that may be issued under these awards was 188,250 and 153,750, respectively. The maximum aggregate total fair value of these RSUs is $3.5 million and $3.1 million, respectively, which is being recognized as expense over a period of three years from the date of grant, net of any estimated and actual forfeitures.

Equity-based compensation expense

Equity-based compensation expense for 2018, 2017 and 2016 consisted of the following (in thousands):

	Years Ended December 31,		
	2018	2017	2016
Cost of product sales	$802	$884	$511
Research and development	2,533	3,225	3,475
Selling, general and administrative	16,614	16,187	15,590
Total equity-based compensation expense	19,949	20,296	19,576
Income tax effect	—	(6,188)	(5,696)
After-tax effect of equity-based compensation expense	$19,949	$14,108	$13,880

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.

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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,					
	2018		2017		2016	
	Employees	Non-Employee Directors	Employees	Non-Employee Directors	Employees	Non-Employee Directors
Risk free interest rate (%)	2.75	2.70	1.86	1.61	1.32	1.10
Expected volatility (%)	57	59	53	57	49	54
Expected option term (years)	5.0	4.0	5.0	4.0	5.0	3.0
Dividend yield	none	none	none	none	none	none

Risk free interest rates utilized are based upon published U.S. Treasury yields at the date of the grant for the expected option term. During 2018, 2017 and 2016, 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, 2018:

	December 31, 2018			
	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value ($ in thousands)
Outstanding at beginning of year	3,531,359	$ 28.27	7.2	$ —
Granted	1,184,880	21.14	—	—
Exercised	(153,601)	19.26	—	—
Expired and/or forfeited	(846,059)	35.13	—	—
Outstanding at end of year	3,716,579	$ 24.81	7.3	$ 694
Outstanding at end of year - vested and unvested expected to vest	3,601,519	$ 24.92	7.2	$ 690
Exercisable at end of year	1,928,239	$ 27.26	5.8	$ 515

The weighted average grant date fair value of stock options granted during 2018, 2017 and 2016 was $10.76, $9.52 and $10.63, respectively. A total of 604,886 stock options vested during 2018. The aggregate intrinsic value of options exercised during 2018, 2017 and 2016, excluding purchases made pursuant to our 2015 ESPP, measured as of the exercise date, was approximately $0.6 million, $0.4 million and $1.5 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, 2018:

	December 31, 2018	
	Restricted Stock Units	Weighted Average Grant Date Fair Value
Outstanding at beginning of year	1,069,775	$ 26.07

Granted	816,887	22.32
Vested	(438,284)	28.25
Forfeited	(319,843)	22.86
Outstanding at end of year	1,128,535	$ 23.42
Outstanding at end of year and expected to vest	1,060,647	$ 23.40

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The weighted average grant date fair value of RSUs granted during 2018, 2017 and 2016 was $22.32, $24.18 and $22.28, respectively. The total fair value of RSUs that vested during 2018, 2017 and 2016 was $12.4 million, $12.3 million and $9.1 million, respectively.

At December 31, 2018, the amount of unrecorded equity-based compensation expense for both option and RSU awards, attributable to future periods was approximately $32.7 million. Of this amount, $16.2 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 2.7 years, $12.6 million was associated with RSUs and is expected to be amortized on a straight-line basis to expense over a weighted average period of approximately 1.8 years, and $3.9 million was associated with performance-based RSUs and is expected to be amortized on a straight-line basis to expense over a weighted average period of approximately 1.8 years. Such amounts will be amortized primarily to research and development or selling, general and administrative expense. These future estimates are subject to change based upon a variety of future events, which include, but are not limited to, changes in estimated forfeiture rates, employee turnover, and the issuance of new stock options and other equity-based awards.

N. EMPLOYEE SAVINGS PLAN

We provide a 401(k) Plan to our employees by which they may defer compensation for income tax purposes under Section 401(k) of the Internal Revenue Code. Each employee may elect to defer a percentage of his or her salary up to a specified maximum. As of December 31, 2018 our 401(k) Plan provided, among other things, for a company contribution of 4% of each employee's combined salary and certain other compensation for the plan year. 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 $4.0 million, $2.3 million and $1.6 million for 2018, 2017 and 2016, respectively.

O. STOCKHOLDERS' EQUITY

In January 2016, we announced that our Board authorized a program to repurchase up to $60.0 million in shares of our common stock. The repurchase program does not have an expiration date and may be suspended for periods or discontinued at any time. Under the program, we may purchase our stock from time to time at the discretion of management in the open market or in privately negotiated transactions. The number of shares repurchased and the timing of the purchases will depend on a number of factors, including share price, trading volume and general market conditions, along with working capital requirements, general business conditions and other factors. We may also from time to time establish a trading plan under Rule 10b5-1 of the Securities and Exchange Act of 1934 to facilitate purchases of our shares under this program. During 2018, we did not repurchase shares of common stock under this program. During 2017, we repurchased and retired 1,366,266 shares of common stock under this repurchase program for $19.5 million, at an average purchase price of $14.27 per share. As of December 31, 2018 and 2017, $20.5 million remains available for the repurchase of shares under the program.

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 and vehicle leases, purchases of inventory, debt obligations, and other purchase obligations.

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. The initial term of the lease was five years and two months with one five-year extension term at our option. We have entered into several amendments to the original lease to add additional space and to extend the term of the original lease to April 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.

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In addition, in connection with our facility lease for the Waltham Premises, the Landlord held a security deposit of $0.5 million in the form of an irrevocable letter of credit which is classified on our balance sheet as a long-term asset as of December 31, 2018 and 2017.

We also lease vehicles for our sales employees under a Master Agreement with Enterprise FM Trust. Each vehicle is leased for a three year term, commencing on the delivery date.

Rent expense, net of deferred rent amortization, for our leases was $5.1 million, $3.0 million, and $1.6 million for 2018, 2017 and 2016, respectively.

Future minimum payments under our non-cancelable leases as of December 31, 2018 are as follows (in thousands):

Period	Future Minimum Lease Payments
Year Ending December 31, 2019	$ 5,119
Year Ending December 31, 2020	4,075
Year Ending December 31, 2021	1,034
Year Ending December 31, 2022	—
Year Ending December 31, 2023	—
Total	$ 10,228

Purchase Obligations

Purchase obligations primarily represent minimum purchase commitments for inventory. As of December 31, 2018, our minimum purchase commitments totaled $88.7 million.

Contingent Consideration Related to Business Combinations

In connection with our acquisition of Lumara Health in November 2014, we agreed to pay up to $350.0 million based on the achievement of certain sales milestones, of which $150.0 million has been paid to date. During 2018, we reversed the accrual for a $50.0 million milestone payment based on actual Makena net sales to date and our expectations for future performance, which indicated that achievement of the future milestone was not probable. As we update our analysis in future periods, actual results may vary significantly from the estimated results, which are reliant on a number of external factors as well as the exercise of judgment.

Contingent Regulatory and Commercial Milestone Payments

In connection with the Endoceutics License Agreement, we are required to pay Endoceutics certain sales milestone payments, including a first sales milestone payment of $15.0 million, which would be triggered when Intrarosa annual net U.S. sales exceed $150.0 million and a second milestone payment of $30.0 million, which would be triggered when annual net U.S. sales of Intrarosa exceed $300.0 million. If annual net U.S. sales of Intrarosa exceed $500.0 million, there are additional sales milestone payments totaling up to $850.0 million, which would be triggered at various sales thresholds. We are also obligated to pay tiered royalties to Endoceutics equal to a percentage of net U.S. sales of Intrarosa ranging from mid-teens for calendar year net sales up to $150.0 million to mid twenty percent for any calendar year net sales that exceed $1.0 billion for the commercial life of Intrarosa, with deductions (a) after the later of (i) the expiration date of the last to expire of a licensed patent containing a valid patent claim or (ii) 10 years after the first commercial sale of Intrarosa for the treatment of vulvar and vaginal atrophy (“VVA”) or female sexual dysfunction (“FSD”) in the U.S. (as applicable), (b) for generic competition and (c) for third-party payments, subject to an aggregate cap on such deductions of royalties otherwise payable to Endoceutics.

In connection with the license agreement we entered into with Palatin Technologies, Inc. (“Palatin”) in January 2017 (the “Palatin License Agreement”), we are required to pay Palatin up to $380.0 million in regulatory and commercial milestone payments, of which $20.0 million was paid in 2018 following the acceptance by the FDA of our New Drug Application (“NDA”) for Vyleesi. As of December 31, 2018, the remaining potential milestone payments include $60.0 million upon FDA approval of Vyleesi and up to $300.0 million of aggregate sales milestone payments upon the achievement of certain annual net sales over the course of the license. We are also obligated to pay Palatin tiered royalties on annual net sales of Vyleesi and any other products containing Vyleesi (collectively “the Vyleesi Products”), on a product-by-product basis, in the Palatin Territory, as defined below, ranging from the high-single digits to the low double-digits.

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In September 2018, we exercised our option to acquire the global rights to AMAG-423 pursuant to an option agreement entered into in July 2015 with Velo, the terms of which were amended at the time of exercise. Under the terms of the agreement, we paid Velo an upfront option exercise fee of $12.5 million and are obligated to pay Velo a $30.0 million milestone payment upon FDA approval of AMAG-423. In addition, we are obligated to pay sales milestone payments to Velo of up to $240.0 million in the aggregate, triggered at various annual net sales thresholds between $300.0 million and $900.0 million and low-single digit royalties based on net sales. Further, we have assumed additional obligations under a previous agreement entered into by Velo with a third-party, including a $5.0 million milestone payment upon regulatory approval and $10.0 million following the first commercial sale of AMAG-423, payable in quarterly installments as a percentage of quarterly gross commercial sales until the obligation is met. We are also obligated to pay the third-party low-single digit royalties based on net sales.

In connection with a development and license agreement (the "Antares License Agreement") with Antares Pharma, Inc. ("Antares"), we are required to pay royalties to Antares on net sales of the Makena auto-injector commencing on the launch of the Makena auto-injector in a particular country until the Makena auto-injector is no longer sold or offered for sale in such country or the Antares License Agreement is terminated (the "Antares Royalty Term"). The royalty rates range from high single digit to low double digits and are tiered based on levels of net sales of the Makena auto-injector and decrease after the expiration of licensed patents or where there are generic equivalents to the Makena auto-injector being sold in a particular country. Antares is also entitled to sales-based milestone payments upon the achievement of certain annual net sales.

Employment Arrangements

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

Indemnification Obligations

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

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. We have not incurred any expenses as a result of such indemnification provisions during the years ended December 31, 2018, 2017 or 2016. 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.

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Sandoz Patent Infringement Lawsuit

In March 2016, we initiated a patent infringement suit 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. On March 23, 2018, we and Sandoz entered a stipulation of dismissal in the United States District Court for the District of New Jersey pursuant to a settlement agreement that dismissed and resolved this action. According to the terms of the settlement, if Sandoz receives FDA approval by a certain date, Sandoz may launch its generic version of Feraheme on July 15, 2021, or earlier under certain circumstances customary for settlement agreements of this nature. Sandoz will pay a royalty on the sales of its generic version of Feraheme to us until the expiration of the last Feraheme patent listed in the Orange Book. If Sandoz is unable to secure approval by such date, Sandoz will launch an authorized generic version of Feraheme on July 15, 2022 for up to twelve months. Sandoz's right to distribute, and our obligation to supply, the authorized generic product shall be in accordance with standard commercial terms and profit splits.

Other

On July 20, 2015, the Federal Trade Commission (the "FTC") notified us that it is conducting an investigation into whether Lumara Health or its predecessor engaged in unfair methods of competition with respect to Makena or any hydroxyprogesterone caproate product. The FTC noted in its letter that the existence of the investigation does not indicate that the FTC has concluded that Lumara Health or its predecessor has violated the law and we believe that our contracts and practices comply with relevant law and policy, including the federal Drug Quality and Security Act (the "DQSA"), which was enacted in November 2013, and public statements from and enforcement actions by the FDA regarding its implementation of the DQSA. We have provided the FTC with a response providing a brief overview of the DQSA for context, which we believe was helpful, including: (a) how the statute outlined that large-scale compounding of products that are copies or near-copies of FDA-approved drugs (like Makena) is not in the interests of public safety; (b) our belief that the DQSA has had a significant impact on the compounding of hydroxyprogesterone caproate; and (c) how our contracts with former compounders allow those compounders to continue to serve physicians and patients with respect to supplying medically necessary alternative/altered forms of hydroxyprogesterone caproate. We believe we have fully cooperated with the FTC and we have had no further interactions with the FTC on this matter since we provided our response to the FTC in August 2015.

On or about April 6, 2016, we received Notice of a Lawsuit and Request to Waive Service of a Summons in a case entitled Plumbers' Local Union No. 690 Health Plan v. Actavis Group et. al. ("Plumbers' Union"), which was filed in the Court of Common Pleas of Philadelphia County, First Judicial District of Pennsylvania and, after removal to federal court, is now pending in the United States District Court for the Eastern District of Pennsylvania (Civ. Action No. 16-65-AB). Thereafter, we were also made aware of a related complaint entitled Delaware Valley Health Care Coalition v. Actavis Group et. al. ("Delaware Valley"), which was filed with the Court of Common Pleas of Philadelphia County, First Judicial District of Pennsylvania District Court of Pennsylvania (Case ID: 160200806). The complaints name K-V Pharmaceutical Company ("KV") (Lumara Health's predecessor company), certain of its successor entities, subsidiaries and affiliate entities (the "Subsidiaries"), along with a number of other pharmaceutical companies. We acquired Lumara Health in November 2014, a year after KV emerged from bankruptcy protection, at which time it, along with its then existing subsidiaries, became our wholly-owned subsidiary. We have not been served with process or waived service of summons in either case. The actions are being brought alleging unfair and deceptive trade practices with regard to certain pricing practices that allegedly resulted in certain payers overpaying for certain of KV's generic products. On July 21, 2016, the Plaintiff in the Plumbers' Union case dismissed KV with prejudice to refiling and on October 6, 2016, all claims against the Subsidiaries were dismissed without prejudice. We are in discussions with Plaintiff's counsel to similarly dismiss all claims in the Delaware Valley case. Because the Delaware Valley case is in the earliest stages and we have not been served with process in this case, we are currently unable to predict the outcome or reasonably estimate the range of potential loss associated with this matter, if any.

We may periodically become subject to other legal proceedings and claims arising in connection with ongoing business activities, including claims or disputes related to patents that have been issued or that are pending in the field of research on which we are focused. Other than the above actions, we are not aware of any material claims against us as of December 31, 2018 or 2017.

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 development assets. As of December 31, 2018, we were a party to the following collaborations:

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Velo

As described above in Note P, “Commitments and Contingencies,” in September 2018, we exercised our option to acquire the global rights to the AMAG-423 program, which we accounted for as an asset acquisition under ASU No. 2017-01.

Prasco

In December 2017, we entered into a Distribution and Supply Agreement (the “Prasco Agreement”) with Prasco, LLC (“Prasco”), under which Prasco was granted an exclusive, non-sublicensable, nontranferable license to purchase, distribute and sell a generic version of Makena in the U.S. (the “Makena authorized generic”). In July 2018, Prasco launched the Makena authorized generic of both the single-dose and multi-dose intramuscular injections. Under the Prasco Agreement, we are responsible for the manufacture and supply of the Makena authorized generic to be sold to Prasco at a predetermined supply price. Prasco is also required to pay us a certain percentage of the net distributable profits from the sale of the Makena authorized generic. We account for revenue recognized under the Prasco Agreement in accordance with ASC 606. Pursuant to the terms of the Prasco Agreement, in certain circumstances we have reimbursed and may be required to reimburse Prasco for additional penalties incurred by Prasco if we fail to supply a certain percentage of product ordered by Prasco in a prespecified timeframe. The Prasco Agreement expires on July 2, 2022, which term will be automatically extended thereafter for additional one year periods, unless canceled by us or Prasco within an agreed upon notice period. The Prasco Agreement is subject to early termination by us for convenience after a certain period of time or if Prasco is subject to a change of control or by either party for, among other things, uncured breach by or bankruptcy of the other party, lack of commercial viability or FDA notice, or by mutual agreement.

Antares

We are party to the Antares License Agreement, which grants us an exclusive, worldwide, royalty-bearing license, with the right to sublicense, to certain intellectual property rights, including know-how, patents and trademarks, to develop, use, sell, offer for sale and import and export the Makena auto-injector. Under the terms of the Antares License Agreement, as amended in March 2018, we are responsible for the clinical development and preparation, submission and maintenance of all regulatory applications in each country where we desire to market and sell the Makena auto-injector, including the U.S. We are required to pay royalties to Antares on net sales of the Makena auto-injector for the Antares Royalty Term. The royalty rates range from high single digit to low double digits and are tiered based on levels of net sales of the Makena auto-injector and decrease after the expiration of licensed patents or where there are generic equivalents to the Makena auto-injector being sold in a particular country. In addition, we are required to pay Antares sales milestone payments upon the achievement of certain annual net sales. The Antares License Agreement terminates at the end of the Antares Royalty Term, but is subject to early termination by us for convenience and by either party upon an uncured breach by or bankruptcy of the other party. In March 2018, the Antares License Agreement was amended to, among other things, transfer the agreement to AMAG from our subsidiary, amend certain confidentiality provisions, and to provide for co-termination with the Antares Manufacturing Agreement (described below).

We are also party to a Manufacturing Agreement with Antares (the “Antares Manufacturing Agreement”) that sets forth the terms and conditions pursuant to which Antares agreed to sell to us on an exclusive basis, and we agreed to purchase, the fully packaged Makena auto-injector for commercial distribution. Antares remains responsible for the manufacture and supply of the device components and assembly of the Makena auto-injector. We are responsible for the supply of the drug to be used in the assembly of the finished auto-injector product. The Antares Manufacturing Agreement terminates at the expiration or earlier termination of the Antares License Agreement, but is subject to early termination by us for certain supply failure situations, and by either party upon an uncured breach by or bankruptcy of the other party or our permanent cessation of commercialization of the Makena auto-injector for efficacy or safety

reasons.

Endoceutics

In February 2017, we entered into the Endoceutics License Agreement with Endoceutics. Pursuant to the Endoceutics License Agreement, Endoceutics granted us the right to develop and commercialize pharmaceutical products containing dehydroepiandrosterone ("DHEA"), including Intrarosa, at dosage strengths of 13 mg or less per dose and formulated for intravaginal delivery, excluding any combinations with other active pharmaceutical ingredients, in the U.S. for the treatment of VVA and FSD. The transactions contemplated by the Endoceutics License Agreement closed on April 3, 2017. We accounted for the Endoceutics License Agreement as an asset acquisition under ASU 2017-01. Upon the closing of the Endoceutics License Agreement, we made an upfront payment of $50.0 million and issued 600,000 shares of unregistered common stock to Endoceutics, which had a value of $13.5 million, as measured on April 3, 2017, the date of closing. In addition, we paid Endoceutics $10.0 million in the third quarter of 2017 upon the delivery by

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Endoceutics of Intrarosa launch quantities and $10.0 million in 2018 following the first anniversary of the closing. In the second quarter of 2017, we recorded a total of $83.5 million of consideration, of which $77.7 million was allocated to the Intrarosa developed technology intangible asset and $5.8 million was recorded as IPR&D expense based on their relative fair values.

In addition, we also pay tiered royalties to Endoceutics equal to a percentage of net sales of Intrarosa in the U.S. ranging from mid-teens for calendar year net sales up to $150.0 million to mid twenty percent for any calendar year net sales that exceed $1.0 billion for the commercial life of Intrarosa, with deductions (a) after the later of (i) the expiration date of the last to expire of a licensed patent containing a valid patent claim or (ii) 10 years after the first commercial sale of Intrarosa for the treatment of VVA or FSD in the U.S. (as applicable), (b) for generic competition and (c) for third-party payments, subject to an aggregate cap on such deductions of royalties otherwise payable to Endoceutics. Endoceutics is also eligible to receive certain sales milestone payments, including a first sales milestone payment of $15.0 million, which would be triggered when Intrarosa annual net U.S. sales exceed $150.0 million, and a second milestone payment of $30.0 million, which would be triggered when annual net U.S. sales of Intrarosa exceed $300.0 million. If annual net U.S. sales of Intrarosa exceed $500.0 million, there are additional sales milestone payments totaling up to $850.0 million, which would be triggered at various sales thresholds.

In the third quarter of 2017, Endoceutics initiated a clinical study with Intrarosa for the treatment of HSDD in post-menopausal women, which is now fully enrolled. Upon review of the full data set, it will be determined whether to continue to pursue an additional clinical trial to support an eventual filing with the FDA for an HSDD indication. We have agreed to share the direct costs related to such studies based upon a negotiated allocation with us funding up to $20.0 million, of which we have paid approximately $6.0 million.

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

In April 2017, we entered into an exclusive commercial supply agreement with Endoceutics pursuant to which Endoceutics, itself or through affiliates or contract manufacturers, agreed to manufacture and supply Intrarosa to us (the “Endoceutics Supply Agreement”) and is our exclusive supplier of Intrarosa in the U.S., subject to certain rights for us to manufacture and supply Intrarosa in the event of a cessation notice or supply failure (as such terms are defined in the Endoceutics Supply Agreement). Under the Endoceutics Supply Agreement, Endoceutics has agreed to maintain at all times a second source supplier for the manufacture of DHEA and the drug product and to identify, validate and transfer manufacturing intellectual property to the second source supplier by April 2019. The Endoceutics Supply Agreement will generally remain in effect until the termination of the Endoceutics License Agreement.

The Endoceutics License Agreement expires on the date of expiration of all royalty obligations due thereunder unless earlier terminated in accordance with the Endoceutics License Agreement.

Palatin

In January 2017, we entered into the Palatin License Agreement with Palatin under which we acquired (a) an exclusive license in all countries of North America (the “Palatin Territory”), with the right to grant sub-licenses, to research, develop and commercialize the Vyleesi Products, an investigational product designed to be a treatment for HSDD in pre-menopausal women, (b) a worldwide non-exclusive license, with the right to grant sub-licenses, to manufacture the Vyleesi Products, and (c) a non-exclusive license in all countries outside the Palatin Territory, with the right to grant sub-licenses, to research and develop (but not commercialize) the Vyleesi Products. The transaction closed in February 2017 and was accounted for as an asset acquisition under ASU 2017-01.

Under the terms of the Palatin License Agreement, in February 2017 we paid Palatin $60.0 million as a one-time upfront payment and subject to agreed-upon deductions reimbursed Palatin approximately $25.0 million for reasonable, documented, out-of-pocket expenses incurred by Palatin in connection with the development and

regulatory activities necessary to submit an NDA in the U.S. for Vyleesi for the treatment of HSDD in pre-menopausal women. During 2017, we fulfilled these payment obligations to Palatin. The $60.0 million upfront payment made in February 2017 to Palatin was recorded as IPR&D expense as the product candidate had not received regulatory approval. In June 2018, our NDA submission to the FDA for Vyleesi was accepted, which triggered a $20.0 million milestone payment, which we paid in the second quarter of 2018 and recorded as an IPR&D expense in the first quarter of 2018 when acceptance was deemed probable.

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In addition, the Palatin License Agreement requires us to make contingent payments of (a) $60.0 million upon FDA approval of Vyleesi, and (b) up to $300.0 million of aggregate sales milestone payments upon the achievement of certain annual net sales milestones over the course of the license. The first sales milestone payment of $25.0 million will be triggered when Vyleesi annual net sales exceed $250.0 million. We are also obligated to pay Palatin tiered royalties on annual net sales in North America of the Vyleesi Products, on a product-by-product basis, in the Palatin Territory ranging from the high-single digits to the low double-digits. The royalties will expire on a product-by-product and country-by-country basis upon the latest to occur of (a) the earliest date on which there are no valid claims of Palatin patent rights covering such Vyleesi Product in such country, (b) the expiration of the regulatory exclusivity period for such Vyleesi Product in such country and (c) 10 years following the first commercial sale of such Vyleesi Product in such country. These royalties are subject to reduction in the event that: (x) we must license additional third-party intellectual property in order to develop, manufacture or commercialize a Vyleesi Product or (y) generic competition occurs with respect to a Vyleesi Product in a given country, subject to an aggregate cap on such deductions of royalties otherwise payable to Palatin. After the expiration of the applicable royalties for any Vyleesi Product in a given country, the license for such Vyleesi Product in such country would become a fully paid-up, royalty-free, perpetual and irrevocable license. The Palatin License Agreement expires on the date of expiration of all royalty obligations due thereunder, unless earlier terminated in accordance with the Palatin License Agreement.

Abeona

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

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

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

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

R. DEBT

Our outstanding debt obligations as of December 31, 2018 and December 31, 2017 consisted of the following (in thousands):

	December 31,	
	2018	2017
2023 Senior Notes	$—	$466,291

2022 Convertible Notes	261,933	248,194
2019 Convertible Notes	21,276	20,198
Total long-term debt	283,209	734,683
Less: current maturities	21,276	—
Long-term debt, net of current maturities	$261,933	$734,683

2023 Senior Notes

In August 2015, in connection with the CBR acquisition, we completed a private placement of $500 million aggregate principal amount of 7.875% Senior Notes due 2023 (the “2023 Senior Notes”). The 2023 Senior Notes were issued pursuant to

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an Indenture, dated as of August 17, 2015 (the "Indenture"), by and among us, certain of our subsidiaries acting as guarantors of the 2023 Senior Notes and Wilmington Trust, National Association, as trustee. In October 2017, we repurchased $25.0 million of the 2023 Senior Notes in a privately negotiated transaction, resulting in a loss on extinguishment of debt of $1.1 million. In September 2018, we repurchased the remaining $475.0 million of the 2023 Senior Notes at a premium of $28.1 million using the proceeds from the CBR sale, which resulted in a loss on extinguishment of debt of $35.9 million, inclusive of the premium paid.

Convertible Notes

The outstanding balances of our Convertible Notes as of December 31, 2018 consisted of the following (in thousands):

	2022 Convertible Notes	2019 Convertible Notes	Total
Liability component:			
Principal	$ 320,000	$ 21,417	$341,417
Less: debt discount and issuance costs, net	58,067	141	58,208
Net carrying amount	$ 261,933	$ 21,276	$283,209
Gross equity component	$ 72,576	$ 9,905	$82,481

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

2022 Convertible Notes

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

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

The conversion rate is subject to adjustment from time to time upon the occurrence of certain events, including, but not limited to, the issuance of stock dividends and payment of cash dividends. At any time prior to the close of business on the business day immediately preceding March 1, 2022, holders may convert their 2022 Convertible Notes at their option only under the following circumstances:

1) during any calendar quarter (and only during such calendar quarter) commencing after the calendar quarter ending September 30, 2017, if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day;

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2) during the five business day period after any five consecutive trading day period (the "measurement period") in which the trading price per $1,000 principal amount of the 2022 Convertible Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; or

3) upon the occurrence of specified corporate events.

On or after March 1, 2022, until the close of business on the business day immediately preceding the maturity date, holders may convert all or any portion of their 2022 Convertible Notes, in multiples of $1,000 principal amount, at the option of the holder regardless of the foregoing circumstances. The 2022 Convertible Notes were not convertible as of December 31, 2018.

We determined the expected life of the debt was equal to the five-year term on the 2022 Convertible Notes. The effective interest rate on the liability component was 9.49% for the period from the date of issuance through December 31, 2018. As of December 31, 2018, the "if-converted value" did not exceed the remaining principal amount of the 2022 Convertible Notes.

2019 Convertible Notes

In February 2014, we issued $200.0 million aggregate principal amount of the 2019 Convertible Notes. We received net proceeds of $193.3 million from the sale of the 2019 Convertible Notes, after deducting fees and expenses of $6.7 million. We used $14.1 million of the net proceeds from the sale of the 2019 Convertible Notes to pay the cost of the convertible bond hedges, as described below (after such cost was partially offset by the proceeds to us from the sale of warrants in the warrant transactions described below). In May 2017 and September 2017, we entered into privately negotiated transactions with certain investors to repurchase approximately $158.9 million and $19.6 million, respectively, aggregate principal amount of the 2019 Convertible Notes for an aggregate repurchase price of approximately $171.3 million and $21.4 million, respectively, including accrued interest. Pursuant to ASC Topic 470, Debt ("ASC 470"), the accounting for the May 2017 repurchase of the 2019 Convertible Notes was evaluated on a creditor-by-creditor basis with regard to the 2022 Convertible Notes to determine modification versus extinguishment accounting. We concluded that the May 2017 repurchase of the 2019 Convertible Notes should be accounted for as an extinguishment and we recorded a debt extinguishment gain of $0.2 million related to the difference between the consideration paid, the fair value of the liability component and carrying values at the repurchase date. As a result of the September 2017 repurchase of the 2019 Convertible Notes, we recorded a debt extinguishment loss of $0.3 million related to the difference between the consideration paid, the fair value of the liability component and carrying value at the repurchase date.

The 2019 Convertible Notes are governed by the terms of an indenture between us, as issuer, and Wilmington Trust, National Association, as the trustee. The 2019 Convertible Notes are senior unsecured obligations and bear interest at a rate of 2.5% per year, payable semi-annually in arrears on February 15 and August 15 of each year. The 2019 Convertible Notes will mature on February 15, 2019 unless earlier repurchased or converted. Upon conversion of the remaining 2019 Convertible Notes, such 2019 Convertible Notes will be convertible into, at our election, cash, shares of our common stock, or a combination thereof, at a conversion rate of 36.9079 shares of common stock per $1,000 principal amount of the 2019 Convertible Notes, which corresponds to an initial conversion price of approximately $27.09 per share of our common stock.

The conversion rate is subject to adjustment from time to time upon the occurrence of certain events, including, but not limited to, the issuance of stock dividends and payment of cash dividends. On or after May 15, 2018 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert all or any portion of their 2019 Convertible Notes, in multiples of $1,000 principal amount, at the option of the holder, regardless of the foregoing circumstances. The 2019 Convertible Notes were convertible as of December 31, 2018.

We determined the expected life of the debt was equal to the five-year term of the 2019 Convertible Notes. The effective interest rate on the liability component was 7.79% for the period from the date of issuance through December 31, 2018. As of December 31, 2018, the "if-converted value" did not exceed the remaining principal amount of the 2019 Convertible Notes.

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Convertible Notes Interest Expense

The following table sets forth total interest expense recognized related to the Convertible Notes during 2018, 2017, and 2016 (in thousands):

	Years Ended December 31,		
	2018	2017	2016
Contractual interest expense	$10,935	$8,961	$5,000
Amortization of debt issuance costs	1,403	1,275	1,072
Amortization of debt discount	13,414	11,071	7,544
Total interest expense	$25,752	$21,307	$13,616

Convertible Bond Hedge and Warrant Transactions

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

As of December 31, 2018, the remaining bond hedge transactions covered approximately 0.8 million shares of our common stock underlying the remaining $21.4 million principal amount of the 2019 Convertible Notes. The convertible bond hedges have an exercise price of approximately $27.09 per share, subject to adjustment upon certain events, and are exercisable when and if the 2019 Convertible Notes are converted. If upon conversion of the 2019 Convertible Notes, the price of our common stock is above the exercise price of the convertible bond hedges, the call spread counterparties will deliver shares of our common stock and/or cash with an aggregate value approximately equal to the difference between the price of our common stock at the conversion date and the exercise price, multiplied by the number of shares of our common stock related to the convertible bond hedges being exercised. The convertible bond hedges were separate transactions entered into by us and were not part of the terms of the 2019 Convertible Notes or the warrants, discussed below. Holders of the 2019 Convertible Notes will not have any rights with respect to the convertible bond hedges.

As of December 31, 2018, the remaining warrant transactions covered approximately 1.0 million shares of our common stock underlying the remaining $21.4 million principal amount of the 2019 Convertible Notes. The initial exercise price of the warrants is $34.12 per share, subject to adjustment upon certain events, which was 70% above the last reported sale price of our common stock of $20.07 on February 11, 2014. The warrants would separately have a dilutive effect to the extent that the market value per share of our common stock, as measured under the terms of the warrants, exceeds the applicable exercise price of the warrants. The warrants were issued to the call spread counterparties pursuant to the exemption from registration set forth in Section 4(a)(2) of the Securities Act of 1933, as amended.

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

2015 Term Loan Facility

In August 2015, we entered into a credit agreement with a group of lenders, including Jefferies Finance LLC as administrative and collateral agent, that provided us with, among other things, a six-year $350.0 million term loan facility, under which we borrowed the full amount (the “2015 Term Loan Facility”).

The 2015 Term Loan Facility included an annual mandatory prepayment of the debt in an amount equal to 50% of our excess cash flow (as defined in the 2015 Term Loan Facility) as measured on an annual basis, beginning with the year ended December 31, 2016. We prepaid $3.0 million of the debt in April 2017.

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

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Future Payments

Future annual principal payments on our long-term debt as of December 31, 2018 were as follows (in thousands):

Period	Future Annual Principal Payments
Year Ending December 31, 2019	$21,417
Year Ending December 31, 2020	—
Year Ending December 31, 2021	—
Year Ending December 31, 2022	320,000
Thereafter	—
Total	$341,417

S. CONSOLIDATED QUARTERLY FINANCIAL DATA - UNAUDITED

The following tables provide unaudited consolidated quarterly financial data for 2018 and 2017 (in thousands, except per share data):

	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018
Total revenues	$117,387	$146,254	$ 122,238	$ 88,122
Gross profit	53,475	69,478	75,749	59,406
Operating expenses [2]	104,239	27,591	95,084	78,241
Net loss from continuing operations	$(58,098)	$(25,817)	$ (64,678)	$ (20,746)
Net income (loss) from discontinued operations	$3,856	$5,736	$ 95,517	$ (1,531)
Net (loss) income	$(54,242)	$(20,081)	$ 30,839	$ (22,277)
Basic net (loss) income per share:				
Loss from continuing operations	$(1.70)	$(0.75)	$ (1.88)	$ (0.60)
Income (loss) from discontinued operations	0.11	0.17	2.77	(0.04)
Total	$(1.59)	$(0.58)	$ 0.89	$ (0.64)
Diluted net (loss) income per share:				
Loss from continuing operations	$(1.70)	$(0.75)	$ (1.88)	$ (0.60)
Income (loss) from discontinued operations	0.11	0.17	2.77	(0.04)
Total	$(1.59)	$(0.58)	$ 0.89	$ (0.64)

	March 31, 2017	June 30, 2017	September 30, 2017	December 31, 2017
Total revenues	$112,541	$130,371	$ 124,331	$ 128,525
Gross profit (loss) [1]	84,968	98,270	(226,000)	57,938
Operating expenses [3]	125,112	95,003	28,236	70,663
Net (loss) income from continuing operations	$(35,925)	$(14,252)	$ (155,713)	$ 738
Net (loss) income from discontinued operations	$(635)	$186	$ 3,652	$ 2,722
Net (loss) income	$(36,560)	$(14,066)	$ (152,061)	$ 3,460
Basic net (loss) income per share:				
(Loss) income from continuing operations	$(1.04)	$(0.41)	$ (4.41)	$ 0.02
(Loss) income from discontinued operations	(0.02)	0.01	0.10	0.08
Total	$(1.06)	$(0.40)	$ (4.31)	$ 0.10
Diluted net (loss) income per share:				
(Loss) income from continuing operations	$(1.04)	$(0.41)	$ (4.41)	$ 0.02
(Loss) income from discontinued operations	(0.02)	0.01	0.10	0.08
Total	$(1.06)	$(0.40)	$ (4.31)	$ 0.10

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

(1) Gross profit (loss) for the third quarter of 2017 included an impairment charge of $319.2 million relating to the Makena base technology intangible asset.

(2) Operating expenses for the second quarter of 2018 include the reversal of $49.8 million relating to the fair value of a contingent consideration liability that was no longer expected to be paid.

(3) Operating expenses for the first quarter of 2017 include $60.0 million of acquired IPR&D expense related to the one-time upfront payment under the terms of the Palatin License Agreement. Operating expenses for the third quarter of 2017 include the reversal of $49.9 million relating to the fair value of a contingent consideration liability

that was no longer expected to be paid.

T. VALUATION AND QUALIFYING ACCOUNTS (IN THOUSANDS)

	Balance at Beginning of Period	Additions (2)	Deductions Charged to Reserves	Balance at End of Period
Year ended December 31, 2018:				
Accounts receivable allowances(1)	$ 12,060	$229,509	$(232,026)	$9,543
Rebates, fees and returns reserves(2)	$ 100,702	$270,959	$(294,891)	$76,770
Valuation allowance for deferred tax assets (3)	$ 4,740	$108,562	$(24)	$113,278
Year ended December 31, 2017:				
Accounts receivable allowances(1)	$ 9,533	$168,945	$(166,418)	$12,060
Rebates, fees and returns reserves(2)	$ 89,466	$255,471	$(244,235)	$100,702
Valuation allowance for deferred tax assets (3)	$ 1,429	$3,875	$(564)	$4,740
Year ended December 31, 2016:				
Accounts receivable allowances(1)	$ 10,783	$122,792	$(124,042)	$9,533
Rebates, fees and returns reserves(2)	$ 45,162	$186,941	$(142,637)	$89,466
Valuation allowance for deferred tax assets (3)	$ 11,859	$632	$(11,062)	$1,429

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

(2) Additions to rebates, fees and returns reserves are recorded as a reduction of revenues.

(3) As of December 31, 2018, we have established a valuation allowance on our net deferred tax assets other than refundable AMT credits. At December 31, 2017, our valuation allowance related primarily to certain of our state NOL and credit carryforwards. At December 31, 2016, our valuation allowance related primarily to our federal capital loss carryforward and our state NOL and credit carryforwards acquired from Lumara Health.

U. 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 August 2018, the FASB issued ASU No. 2018-13, Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement (“ASU 2018-13”). This standard eliminates, adds and modifies certain disclosure requirements for fair value measurements as part of its disclosure framework project. ASU 2018-13 is effective for annual reporting periods beginning after December 15, 2019 and interim periods within those annual periods and early adoption is permitted. We are currently evaluating the impact of our adoption of ASU 2018-13 on our consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments (“ASU 2016-13”). This standard requires entities to measure all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions and reasonable and supportable forecasts. ASU 2016-13 is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years and early adoption is permitted. We are currently evaluating the impact of our adoption of ASU 2016-13 in our consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). This statement requires entities to recognize on its balance sheet assets and liabilities associated with the rights and obligations created by leases with terms greater than twelve months. This update is effective for annual reporting periods beginning after December 15, 2018, which for us is the period beginning January 1, 2019. During the fourth quarter of 2018, we finalized our assessments over the impact that these new standards will have on our consolidated results of operations, financial position and disclosures and are finalizing our accounting policies. As of December 31, 2018, we have not identified

any accounting changes that would impact our results of operations or cash flows. However, we expect to recognize material right-of-use assets and lease liabilities related to our operating lease commitments. We currently plan to adopt this standard using the “modified retrospective approach” and follow the related transition option that allows for application of the transition provisions of the standard at the beginning of the period of adoption. In addition, we currently plan to utilize the package of available transition practical expedients. There are also certain considerations related to internal control over financial reporting that are associated with implementing Topic 842. We

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are evaluating our internal control framework over leases to identify any changes that may need to be made in response to the new guidance. In addition, financial statement disclosures under the new guidance in Topic 842 will be expanded in comparison to the disclosure requirements under the current guidance. We will have completed the design and implementation of the appropriate controls to obtain and disclose the information required under Topic 842 in our first quarter of 2019.

V. RECENTLY ADOPTED ACCOUNTING PRONOUNCEMENTS

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which superseded all existing revenue recognition requirements, including most industry specific guidance. The FASB subsequently issued a number of amendments to ASU 2014-09 that have the same effective date and transition date (collectively, "ASC 606"). We adopted ASC 606 on January 1, 2018 using the modified retrospective transition method. See Note D, "Revenue Recognition" for additional information.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash ("ASU 2016-18").which requires amounts generally described as restricted cash and restricted cash equivalents to be included with cash and cash equivalents when reconciling beginning-of-period and end-of-period total amounts shown on the statement of cash flows. We adopted the standard on January 1, 2018 using the retrospective approach and modified the presentation of our consolidated statements of cash flows in accordance with the standard. The adoption of ASU 2016-18 did not have a material impact on our consolidated financial statements.

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

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

W. SUBSEQUENT EVENTS

Acquisition of Perosphere Pharmaceuticals Inc.

On January 16, 2019, we acquired Perosphere through the merger of our wholly-owned subsidiary, Magellan Merger Sub, Inc., a Delaware corporation ("Merger Sub"), with and into Perosphere, with Perosphere continuing as the surviving entity and our wholly-owned subsidiary (the "Merger"). The acquisition enhances our development pipeline

by adding an innovative clinical asset to our portfolio and leveraging our expertise in hematology.

As a result of the acquisition of Perosphere, we acquired the global rights to ciraparantag, an anticoagulant reversal agent, which is being investigated for patients treated with novel oral anticoagulants or low molecular weight heparin when reversal of the anticoagulant effect of these products is needed for emergency surgery, urgent procedures or due to life-threatening or uncontrolled bleeding. In addition, provided certain clinical milestones are met, the Phase 3 program for ciraparantag will be partially funded under an existing clinical trial collaboration agreement, as amended, with a global pharmaceutical company,

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under which we may receive certain payments anticipated in 2019 and 2020 related to ciraparantag for use as an anticoagulant reversal agent to reverse the effects of Savaysa®(edoxaban) and low molecular weight heparin.

The Merger was completed pursuant to the Agreement and Plan of Merger (the "Perosphere Agreement"), dated as of December 12, 2018, by and among, inter alia, AMAG and Perosphere. Pursuant to the Perosphere Agreement, we paid, at closing, an upfront purchase price (the "Upfront Merger Consideration") of approximately $50.0 million, approximately $40.0 million of which was funded from our available cash and approximately $10.0 million of which was deemed paid in connection with the cancellation of a convertible note in the principal amount of $10.0 million issued to us by Perosphere in October 2018. The purchase price is subject to customary post-closing adjustments under the Perosphere Agreement. In addition to the Upfront Merger Consideration, AMAG used available cash to repay $12.0 million of Perosphere's term loan indebtedness and assumed approximately $6.2 million of Perosphere's other liabilities.

Under and subject to the terms and conditions set forth in the Perosphere Agreement, we are obligated to pay future contingent consideration of up to an aggregate of $365.0 million (the "Milestone Payments"), including (a) up to an aggregate of $140.0 million that becomes payable conditioned upon the achievement of specified regulatory milestones for ciraparantag (the "Regulatory Milestone Payments"), including a $40.0 million milestone payment conditioned upon approval by the European Medicines Agency and (b) up to an aggregate of $225.0 million that becomes payable conditioned upon the achievement of specified sales milestones (the "Sales Milestone Payments"). If the final label approved for ciraparantag in the U.S. includes a boxed warning, the Regulatory Milestone Payments shall no longer be payable, and any previously paid Regulatory Milestone Payments shall be credited against 50% of any future Milestone Payment that otherwise becomes payable. The first Sales Milestone Payment of $20.0 million will be payable conditioned upon annual net sales of ciraparantag of at least $100.0 million.

We are unable to provide preliminary estimates of asset and liability values as the valuation of the assets acquired and liabilities assumed is in progress.

2019 Restructuring

In February 2019, we completed a restructuring to combine our women's health and maternal health sales forces into one integrated sales team, which will promote both Intrarosa and Makena. Approximately 110 employees were displaced through this workforce reduction. We expect to record a one-time restructuring charge of approximately $6.0 million primarily related to severance and related benefits in the first quarter of 2019 and expect the activities to be completed by the end of the first quarter of 2019.

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, 2018, 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, 2018 and is incorporated herein by reference.

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Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) that occurred during the three months ended December 31, 2018 that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION:
None.

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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, 2018.

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, 2018.

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, 2018.

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, 2018.

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, 2018.

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PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES:

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

(1) Financial Statements:

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

(2) Financial Statement Schedules:

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

(3) Exhibits:

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

ITEM 16. FORM 10-K SUMMARY:

None.

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EXHIBIT INDEX

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)
3.1, 4.1	Restated Certificate of Incorporation of AMAG Pharmaceuticals, Inc. (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 of Restated Certificate of Incorporation of AMAG Pharmaceuticals, Inc. as filed on May 21, 2015 with the Delaware Secretary of State (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed May 28, 2015, File No. 001-10865)
3.3, 4.3	Amended and Restated By-Laws of AMAG Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed December 17, 2015, File No. 001-10865)
4.5	Specimen certificate representing AMAG Pharmaceuticals, Inc.'s Common Stock (incorporated herein by reference to Exhibit 4.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2009, File No. 001-14732)
4.6	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)
4.7	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)
4.80	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)
4.9	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)
4.1	Form of 7.875% Senior Note due 2023 (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed August 17, 2015, File No. 001-10865)
4.11	Indenture, dated as of May 10, 2017, by and between AMAG Pharmaceuticals, Inc. and Wilmington Trust, National Association (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed May 15, 2017, File No. 001-10865)
4.12	First Supplemental Indenture, dated as of May 10, 2017, by and between AMAG Pharmaceuticals, Inc. and Wilmington Trust, National Association (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed May 15, 2017, File No. 001-10865)
4.13	Form of 3.25% Convertible Senior Note due 2022 (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed May 15, 2017, File No. 001-10865
10.1*	Form of Indemnification Agreement (incorporated herein by reference to Exhibit 10.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2009, File No. 001-14732)
10.2*	AMAG Pharmaceuticals, Inc.'s Amended and Restated Non-Employee Director Compensation Policy (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, File No. 001-10865)
10.3*	AMAG Pharmaceuticals, Inc.'s Fourth Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A filed April 20, 2017, File No. 001-10865)
10.4*	

	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)
10.5*	AMAG Pharmaceuticals, Inc. First Amendment to 2015 Employee Stock Purchase Plan (incorporated herein by reference to Appendix B to the Registrant's Definitive Proxy Statement on Schedule 14A filed April 25, 2018, File No. 001-10865)
10.6*	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)

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10.7*	Form of Incentive Stock Option Agreement for AMAG Pharmaceuticals, Inc. Employees under AMAG Pharmaceuticals, Inc.'s Fourth Amended and Restated 2007 Equity Incentive Plan and the Lumara Health Inc. Amended and Restated 2013 Incentive Compensation Plan (incorporated herein by reference to Exhibit 10.6 to the Company's Annual Report on Form 10-K for the year ended December 31, 2017, File No. 001-10865)
10.8*	Form of Non-Qualified Stock Option Agreement for AMAG Pharmaceuticals, Inc. Employees under AMAG Pharmaceuticals, Inc.'s Fourth Amended and Restated 2017 Equity Incentive Plan and the Lumara Health Inc. Amended and Restated 2013 Incentive Compensation Plan (incorporated herein by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K for the year ended December 31, 2017, File No. 001-10865)
10.9*	Form of Restricted Stock Unit Agreement for AMAG Pharmaceuticals, Inc. Employees under AMAG Pharmaceuticals, Inc.'s Fourth Amended and Restated 2007 Equity Incentive Plan and the Lumara Health Inc. Amended and Restated 2013 Incentive Compensation Plan (incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, File No. 001-10865)
10.10*	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors under AMAG Pharmaceuticals, Inc.'s Fourth Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K for the year ended December 31, 2017, File No. 001-10865)
10.11*	Form of Restricted Stock Unit Agreement for Non-Employee Directors under AMAG Pharmaceuticals, Inc.'s Fourth Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, File No. 001-10865)
10.12*	Form of Non-Plan Stock Option Agreement, by and between AMAG Pharmaceuticals, Inc. and William K. Heiden (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed May 10, 2012, File No. 001-10865)
10.13*	Form of Non-Qualified Stock Option Agreement - Non-Plan Inducement Grant (incorporated herein by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K for the year ended December 31, 2017, File No. 001-10865)
10.14*	Form of Restricted Stock Unit Agreement - Non-Plan Inducement Grant (incorporated herein by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, File No. 001-10865)
10.15*+	AMAG Pharmaceuticals, Inc. Long-Term Incentive Plan (included as Exhibit A to the Form of Award Notice under the AMAG Pharmaceuticals, Inc. Long-term Incentive Plan filed as Exhibit 10.16 to this Quarterly Report on Form 10-Q)
10.16*+	Form of Award Notice under the AMAG Pharmaceuticals, Inc. Long-term Incentive Plan
10.17*	Form of Employment Agreement between AMAG Pharmaceuticals, Inc. and each of its executive officers (other than William K. Heiden) (incorporated herein by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015, File No. 001-10865)
10.18*	Amended and Restated Employment Agreement dated as of February 7, 2014 between AMAG Pharmaceuticals, Inc. and William K. Heiden (incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2014, File No. 001-10865)
10.19*	Amendment to Amended and Restated Employment Agreement, dated as of November 29, 2017, between AMAG Pharmaceuticals, Inc. and William K. Heiden (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed November 30, 2017, File No. 001-10865)
10.20	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)
10.21	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)
10.22	Second Amendment to Lease Agreement, dated June 10, 2013, by and between AMAG Pharmaceuticals, Inc. and BP BAY COLONY LLC, dated December 4, 2015 (incorporated herein by reference to

	Exhibit 10.30 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015, File No. 001-10865)
10.23	Third Amendment to Lease Agreement, dated June 10, 2013, by and between AMAG Pharmaceuticals, Inc. and BP BAY COLONY LLC, dated December 7, 2015 (incorporated herein by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015, File No. 001-10865)

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10.24	Fourth Amendment to Lease Agreement, dated as of June 10, 2013, by and between AMAG Pharmaceuticals, Inc. and BP BAY COLONY, LLC, dated January 1, 2018 (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, File No. 001-10865)
10.25	License Agreement between AMAG Pharmaceuticals, Inc. and Abeona Therapeutics, Inc. (formerly known as PlasmaTech Biopharmaceuticals, Inc. and Access Pharmaceuticals, Inc.) dated as of June 6, 2013 (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, File No. 001-10865) (confidential treatment previously granted)
10.26	Commercial Supply Agreement, dated effective as of August 29, 2012, by and between AMAG Pharmaceuticals, Inc. and Sigma-Aldrich, Inc. (incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012, File No. 001-10865) (confidential treatment previously granted)
10.27	Amendment No.1 to Commercial Supply Agreement, dated October 3, 2013, by and between AMAG Pharmaceuticals, Inc. and Sigma-Aldrich, Inc. (incorporated herein by reference to Exhibit 10.54 to the Company's Annual Report on Form 10-K for the year ended December 31, 2013, File No. 001-10865) (confidential treatment previously granted)
10.28	Amendment No. 2 to Commercial Supply Agreement, dated April 28, 2015, by and between AMAG Pharmaceuticals, Inc. and Sigma-Aldrich, Inc. (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, File No. 001-10865) (confidential treatment previously granted)
10.29	Amendment No. 3 to Commercial Supply Agreement, dated October 19, 2015, by and between the Company and Sigma-Aldrich, Inc. (incorporated herein by reference to Exhibit 10.36 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015, File No. 001-10865) (confidential treatment previously granted)
10.30	Pharmaceutical Manufacturing and Supply Agreement, dated effective as of January 8, 2010, by and between AMAG Pharmaceuticals, Inc. and Patheon Manufacturing Services LLC (as assignee from DSM Pharmaceuticals, Inc.) (incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012, File No. 001-10865) (confidential treatment previously granted)
10.31	Amendment No. 1 to Pharmaceutical Manufacturing and Supply Agreement, dated July 5, 2014, by and between AMAG Pharmaceuticals, Inc. and Patheon Manufacturing Services LLC (as assignee from DSM Pharmaceuticals, Inc.) (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, File No. 001-10865)
10.32	Amendment No. 2 to Pharmaceutical Manufacturing and Supply Agreement, dated June 19, 2015, by and between AMAG Pharmaceuticals, Inc. and Patheon Manufacturing Services LLC (as assignee from DPI Newco LLC as assignee from DSM Pharmaceuticals, Inc.) (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, File No. 001-10865) (confidential treatment previously granted)
10.33	Amended and Restated Technical Transfer and Supply Agreement, dated as of December 19, 2016, by and between AMAG Pharmaceuticals, Inc. and the Pfizer CentreOne Group of Pfizer, Inc. (incorporated herein by reference to Exhibit 10.34 to the Company's Annual Report on Form 10-K for the year ended December 31, 2016) (confidential treatment previously granted)
10.34	Development and License Agreement, dated September 30, 2014, by and between Lumara Health Inc and Antares Pharma, Inc. (incorporated herein by reference to Exhibit 10.42 to the Company's Annual Report on Form 10-K for the year ended December 31, 2015, File No. 001-10865) (confidential treatment previously granted)
10.35	First Amendment to Development and License Agreement, dated March 20, 2018, by and between AMAG Pharma USA, Inc. (f/k/a Lumara Health, Inc.), AMAG Pharmaceuticals, Inc. and Antares Pharma, Inc.(incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, File No. 001-10865) (confidential treatment previously granted)

10.36	Manufacturing Agreement, dated March 20, 2018, by and between AMAG Pharmaceuticals, Inc. and Antares Pharma, Inc. (incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, File No. 001-10865) (confidential treatment previously granted)
10.37	License Agreement, dated January 8, 2017, by and between AMAG Pharmaceuticals, Inc. and Palatin Technologies, Inc., (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed February 3, 2017, File No. 001-10865) (confidential treatment previously granted)
10.38	License Agreement, dated as of February 13, 2017, by and between AMAG Pharmaceuticals, Inc. and Endoceutics Inc. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed April 5, 2017, File No. 001-10865) (confidential treatment previously granted)

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10.39	Manufacturing and Supply Agreement, dated as of April 5, 2017, by and between AMAG Pharmaceuticals, Inc. and Endoceutics Inc. (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed April 5, 2017, File No. 001-10865) (confidential treatment previously granted)
10.40	Distribution and Supply Agreement, dated December 20, 2017, by and between AMAG Pharmaceuticals, Inc. and Prasco, LLC (Confidential treatment previously granted) (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 10-Q/A filed December 21, 2018)
10.41	Commercial Supply Agreement, dated June 4, 2018, by and between AMAG Pharmaceuticals, Inc. and SAFC, Inc. (Confidential treatment previously granted) (incorporated by reference to Exhibit 10.8 to the Company's Current Report on Form 10-Q/A filed December 21, 2018)
10.42	Stock Purchase Agreement, dated June 14, 2018, by and among AMAG Pharmaceuticals, Inc., CBR Acquisition Holdings Corp. and GI Chill Acquisition LLC (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed June 15, 2018 File No. 001-10865)
10.43+	Contract Manufacturing Agreement, dated September 1, 2018, by and between AMAG Pharmaceuticals, Inc. and Fresenius Kabi Austria GmbH (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)
10.44	Agreement and Plan of Merger, dated as of December 12, 2018, by and among AMAG Pharmaceuticals, Inc., Magellan Merger Sub, Inc., Perosphere Pharmaceuticals Inc. and Bryan E. Laulicht, as Perosphere equityholder representative (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed December 13, 2018).
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 and not marked with a "+" or "++" have previously been filed with the SEC and are incorporated herein by reference, as indicated.

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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
President and Chief Executive Officer

Date: March 1, 2019

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

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

Name	Title	Date
/s/ William K. Heiden William K. Heiden	President and Chief Executive Officer (Principal Executive Officer) and Director	March 1, 2019
/s/ Edward Myles Edward Myles	Executive Vice President of Finance, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 1, 2019
/s/ Barbara Deptula Barbara Deptula	Director	March 1, 2019
/s/ John Fallon, M.D. John Fallon, M.D.	Director	March 1, 2019
/s/ Robert J. Perez Robert J. Perez	Director	March 1, 2019
/s/ Lesley Russell, MB. Ch.B., MRCP Lesley Russell, MB. Ch.B., MRCP	Director	March 1, 2019
/s/ Gino Santini Gino Santini	Director	March 1, 2019

/s/ Davey S. Scoon Davey S. Scoon	Director	March 1, 2019
/s/ James Sulat James Sulat	Director	March 1, 2019