AMAG PHARMACEUTICALS INC.
Form 10-K
February 10, 2014

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended December 31, 2013

or

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

For the transition period from to
Commission file number 001-10865

AMAG Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Its Charter)

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

(617) 498-3300
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act: **Common Stock, par value $0.01 per share, 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 o No ý**

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 o No ý**

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 ý No o**

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). **Yes ý No o**

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. ý

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of "accelerated filer," "large accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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

The aggregate market value of the registrant's voting stock held by non-affiliates as of June 30, 2013 was approximately $480,230,000 based on the closing price of $22.25 of the Common Stock of the registrant as reported on the NASDAQ Global Select Market on such date. As of February 3, 2014, there were 21,800,008 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, words such as "may," "will," "expect," "intend," and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements.

Examples of forward-looking statements contained in this report include statements regarding the following: our plan to grow Feraheme in the U.S. chronic kidney disease market and through international expansion, IV iron market expansion and label expansion; the expansion of our portfolio through the in-license or purchase of additional specialty pharmaceutical products and companies; expectations regarding our supplemental New Drug Application for Feraheme and our plans for addressing the complete response letter from the FDA and the path forward for Feraheme in the broad IDA patient population; the timing of the opinion of the European Medicines Agency and the related decision by the European Commission regarding Takeda Pharmaceutical Company Limited's application for Type II variation of the marketing authorization for Rienso in the EU; our expectations regarding the timing for enrollment in and commencement of our pediatric studies and a post-approval trial to assess the safety and efficacy of repeat doses of Feraheme for the treatment of iron deficiency anemia; our expectation of costs to be incurred in connection with and revenue sources to fund our future operations; our expectation for the patient population for Feraheme in the U.S.; our expectations regarding the success of our collaboration with Takeda Pharmaceutical Company Limited, including any potential milestone payments, product sales or royalties we may receive; our expectations regarding the manufacture of all Feraheme/Rienso drug substance and drug product at our third-party manufacturers; our expectations regarding customer returns and other revenue-related reserves and accruals; variations of the labeling and other elements of the marketing authorization for Rienso in the EU that may be expected as a result of the review by the EMA Committee for Medicinal Products for Human Use of IV iron-containing medications used to treat iron deficiency anemia; our expectations regarding the validity of our European ferumoxytol patent and timing of the appeals process; our expectations regarding government regulations, including the Branded Drug Fee under the Health Care Reform Act and the Medicare reimbursement rate for Feraheme and estimates for Medicaid rebates; our expectations regarding our license fee and other collaboration revenues; expected customer mix and utilization rates; the impact of volume rebates and other incentives; provider purchase patterns and use of competitive products; expectations regarding MuGard and our license arrangement with Access Pharmaceuticals, Inc.; the valuation of certain intangible assets, contingent consideration and other assets and liabilities, including our methodology and assumptions regarding fair value measurements; our gross-to-net sales adjustments; our expectations that increasing competitive pressures in 2014 may lead to slowing growth in our products sales; our Citizen Petition; our expectations for product sales and fluctuations in net revenue per gram of Feraheme and our costs of product sales as a percentage of net product sales and royalties, our research and development expenses, external expenses and the timing of our planned research and development projects, and selling, general and administrative expenses; our belief regarding the potential impact of the adoption of newly issued and future accounting guidance on our financial statements; our expectations for our cash, cash equivalents and investments balances and information with respect to any other plans and strategies for our business. Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated or indicated in any forward-looking statements.

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

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ITEM 1. BUSINESS:

Overview

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a specialty pharmaceutical company that markets Feraheme® (ferumoxytol) Injection for Intravenous, or IV, use to treat iron deficiency anemia, or IDA, in adult patients with chronic kidney disease, or CKD, and MuGard® Mucoadhesive Oral Wound Rinse for the management of oral mucositis. Along with driving organic growth of our products, we intend to expand our portfolio with additional commercial-stage specialty products. Our primary goal is to bring to market therapies that provide clear benefits and improve patients' lives.

Currently, our principal source of revenue is from the sale of *Feraheme*, which was approved for marketing in the U.S. in June 2009 by the U.S. Food and Drug Administration, or the FDA, for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. We began selling *Feraheme* in the U.S. in July 2009 through our own commercial organization, including a specialty sales force. We sell *Feraheme* to authorized wholesalers and specialty distributors, who in turn, sell *Feraheme* to healthcare providers who administer *Feraheme* primarily within hospitals, hematology and oncology centers, and nephrology clinics. We are working to continue to grow *Feraheme* in the U.S. CKD market and to drive additional growth of *Feraheme* through international expansion, IV iron market expansion and label expansion. We are also focusing a portion of our efforts on marketing and selling *MuGard* in the U.S.

To further build our business, we intend to continue to expand our portfolio through the in-license or purchase of additional specialty pharmaceutical products or companies. See "*Collaboration, License and Other Material Agreements*" below for discussion of our June 2013 acquisition of the U.S. commercial rights to *MuGard,* or the MuGard Rights. In particular, we are seeking complementary products that will leverage our commercial infrastructure and focus on hematology and oncology centers, hospital infusion centers or other sites of care where IV iron is administered or where IDA patients are diagnosed or treated. We are also evaluating products in other strategic areas of interest, such as gastroenterology or rheumatology. Since patients within these specialties have high rates of co-morbid IDA, these new call points could be synergistic with the potential label expansion of *Feraheme*, if regulatory approval is obtained. In addition, we are contemplating transactions that would be financially beneficial to us, by providing an additional revenue stream from products that are approved for one or more indications, but that would be accretive to earnings and allow us to eliminate duplicative infrastructure, and potentially optimize after-tax cash flows. Finally, we may opportunistically look at commercial products with potential development opportunities in other indications or products that we believe entail lower-risk late stage development.

In addition to expanding our portfolio through the in-license or purchase of additional specialty pharmaceutical products or companies, we believe that a significant opportunity exists in the U.S. for *Feraheme* beyond the treatment of IDA in adult patients with CKD. In December 2012, we submitted a supplemental new drug application, or sNDA, to the FDA seeking approval for *Feraheme* for the treatment of IDA in adult patients who had failed or could not use oral iron. The sNDA included data from two controlled, multi-center Phase III clinical trials, or IDA-301 and IDA-302, including more than 1,400 patients, which served as the primary data supporting the safety and efficacy of ferumoxytol for the treatment of IDA in this broader patient population. In addition, the sNDA included data from an interim analysis of the IDA open-label extension study, or IDA-303, and a previously completed post-approval clinical study evaluating *Feraheme* treatment compared to treatment with another IV iron. On January 21, 2014, we received a complete response letter from the FDA for the sNDA informing us that our sNDA could not be approved in its present form and stating that we have not provided sufficient information to permit labeling of *Feraheme* for safe and effective use for the proposed broader indication. The FDA indicated that its decision was based on the cumulative ferumoxytol data,

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including the global Phase III IDA program and global post-marketing safety reports for the currently indicated CKD patient population. The FDA suggested, among other things, that we submit additional clinical trial data in the proposed broad IDA patient population with a primary composite safety endpoint of serious hypersensitivity/anaphylaxis, cardiovascular events and death, events that are included in the labels of *Feraheme* and other IV irons and that have been reported in the post-marketing environment for *Feraheme*. Additionally, the FDA proposed potentially evaluating alternative dosing and/or administration of *Feraheme*. Our plan for addressing the complete response letter from the FDA includes the following steps: (a) evaluate the FDA's recommendations in the complete response letter; (b) develop a proposal that we believe would be responsive to the points raised in the complete response letter and that we determine would be economically viable; (c) meet with FDA to discuss our proposal and explore the range of possible approaches to the points raised in the complete response letter; and (d) assess the FDA's feedback on our proposal and make a final determination on a possible program that would adequately address the FDA's concerns. Until we have further discussions with the FDA and receive its input, we cannot predict the path forward, if any, for *Feraheme* in the broad IDA patient population, including the related timing and cost of any clinical trials.

Outside of the U.S., ferumoxytol has been granted marketing approval in Canada, Switzerland and the European Union, or EU, for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. The marketing authorization granted in the EU is valid in the 28 EU Member States as well as in Iceland, Liechtenstein and Norway. The trade name for ferumoxytol in Canada is *Feraheme* and in the EU and Switzerland it is Rienso® 30mg/ml solution for Injection. The EU competent authorities and recently Canadian regulatory authorities have implemented class labeling including stronger safety warnings for IV iron products, such as *Feraheme/Rienso*. Under our amended agreement with Takeda Pharmaceutical Company Limited, or Takeda, discussed below in "*Collaboration, License and Other Material Agreements*," Takeda has an exclusive license to market and sell ferumoxytol in Canada, the EU and Switzerland, as well as certain other geographic territories.

In June 2013, Takeda filed an application for Type II Variation of the marketing authorization for *Rienso* in the EU, which is the EU equivalent of a U.S. sNDA, with the European Medicines Agency, or EMA, seeking marketing authorization for an additional therapeutic indication for *Rienso* for the treatment of IDA in adult patients. Takeda is in the process of responding to the Day 90 List of Questions from the EMA and currently expects an opinion from the EMA and a related decision from the European Commission concerning the application for the Type II Variation in mid-2014. If the EMA issues a positive opinion in relation to the inclusion of this additional therapeutic indication, for use in a broad IDA patient population, in the marketing authorization for *Rienso* and the European Commission adopts a decision approving this variation, we expect to receive a significant milestone payment from Takeda. In addition, in October 2013, Takeda filed a Supplemental New Drug Submission, or sNDS, with Health Canada seeking marketing approval for *Feraheme* for the treatment of IDA in a broad range of patients.

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

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Products

The following table summarizes the uses and, subject to regulatory approval, potential uses of our products by us and Takeda, the current U.S. and foreign regulatory status, and the primary markets for our products.

Product	Uses/Potential Uses	Licensees	U.S. Regulatory Status	Ex-U.S. Regulatory Status
Feraheme® (ferumoxytol) Injection	IV iron replacement therapeutic agent for the treatment of IDA in adult patients with CKD.	Takeda (Europe, certain Asia-Pacific countries (excluding Japan, China and Taiwan), Canada, India and Turkey).	Approved and marketed.	Approved and marketed as *Feraheme* in Canada. Approved and marketed as *Rienso* in the European Union. Approved in Switzerland and not currently marketed.
Feraheme® (ferumoxytol) Injection	IV iron replacement therapeutic agent for the treatment of IDA in adult patients with a history of unsatisfactory oral iron therapy or in whom oral iron cannot be used.	Takeda (Europe, certain Asia-Pacific countries (excluding Japan, China and Taiwan), Canada, India and Turkey).	Supplemental New Drug Submission filed December 2012. Complete Response Letter received January 2014.	Application for Type II Variation filed with the EMA by Takeda in 2013. European Commission's decision expected mid-2014. Supplemental New Drug Submission filed with Health Canada by Takeda in 2013.
MuGard® Mucoadhesive Oral Wound Rinse	Management of oral mucocitis/stomatiits and all types of oral wounds.	N/A	Cleared and marketed.	We license only the U.S. commercial rights from Access.

For a discussion of the substantive regulatory requirements applicable to the development and regulatory approval process in the U.S. and other countries, see "*Government Regulation*" below.

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

Overview

In June 2009, *Feraheme* was approved for marketing in the U.S. by the FDA for use as an IV iron replacement therapy for the treatment of IDA in adult patients with all stages of CKD, stage 1 through end-stage renal disease (Stage 5). In July 2009, we began to market and sell *Feraheme* in the U.S. While *Feraheme* is approved for IDA in all stages of CKD, beginning in 2010, due to changes in the way the federal government reimburses providers for the care of dialysis patients, the utilization of *Feraheme* shifted to non-dialysis patients. The non-dialysis CKD IDA market is comprised of a range of health care providers who administer IV iron, including nephrologists, hematologists, oncologists, hospitals and other end-users who treat patients with CKD. We anticipate the majority of all *Feraheme* utilization in the U.S. will continue to be in the non-dialysis CKD patient population until, and if, the Company achieves a broader label to include non-CKD patients.

In December 2011, ferumoxytol was granted marketing approval in Canada, under the trade name *Feraheme*, for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. In June 2012, the European Commission granted marketing authorization for ferumoxytol in the EU, under the trade name *Rienso*, for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. The marketing authorization is valid in the 28 EU Member States as well as in Iceland, Liechtenstein and Norway. In August 2012, ferumoxytol was granted marketing approval

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in Switzerland under the trade name *Rienso* for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. Pursuant to the terms of our License, Development and Commercialization Agreement, as amended in June 2012, or the Amended Takeda Agreement, Takeda has an exclusive license to market and sell ferumoxytol in Canada, the EU and Switzerland, as well as certain other geographic territories.

Chronic kidney disease, anemia, and iron deficiency

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

Currently there are two methods used to treat IDA in CKD patients: oral iron supplements and IV iron. Oral iron is currently the first line iron replacement therapy of choice of most physicians in both the U.S. and abroad. However, oral iron supplements are often not absorbed well by the gastrointestinal tract and frequently cause unpleasant side effects, such as constipation, diarrhea, and cramping, which can lead patients to stop taking their medication. In addition, it can take an extended time for hemoglobin levels to improve following the initiation of oral iron treatment, and even then may not reach the targeted hemoglobin levels. Conversely, iron given intravenously allows larger amounts of iron to be provided to patients while avoiding many of the side effects and treatment compliance issues associated with oral iron, and can result in faster rises in hemoglobin levels. The administration of IV iron has been shown to be effective in treating anemia either when used alone or in combination with an ESA. Current U.S. treatment guidelines indicate that treating first with iron alone may delay or reduce the need for ESA therapy. Iron supplementation is widely used in CKD patients to treat iron deficiency, prevent its development in ESA treated patients, raise hemoglobin levels in the presence or absence of ESA treatment, and reduce ESA doses in patients receiving ESA treatment. We believe that a small fraction of non-dialysis CKD patients in the U.S. who are diagnosed with IDA are currently being treated with IV iron, and thus a significant opportunity remains to grow the market for IV iron in this patient population.

Post-Marketing Commitments of Feraheme in CKD

We have initiated a randomized, active-controlled pediatric study of *Feraheme* for the treatment of IDA in pediatric CKD patients to meet our FDA post-approval Pediatric Research Equity Act requirement to support pediatric labeling of *Feraheme* in the U.S. The study covers both dialysis-

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dependent and non-dialysis dependent CKD pediatric patients and will assess the safety and efficacy of *Feraheme* treatment as compared to oral iron in approximately 288 pediatric patients.

Our pediatric investigation plan, which was a requirement for submission of the Marketing Authorization Application, or MAA, for ferumoxytol, was approved by the EMA in December 2009 and amended in 2012. It includes the pediatric study, as described above, and two additional pediatric studies requested by the EMA. These additional studies include a rollover extension study in pediatric CKD patients and a study in pediatric patients with IDA regardless of the underlying cause. The rollover study is open for enrollment. The pediatric IDA study will commence once the appropriate dose of *Feraheme* is determined from the study data resulting from the pediatric study of *Feraheme*, described above.

As part of our obligations under the Amended Takeda Agreement and as part of our post-approval commitments to the EMA, we initiated a multi-center clinical trial to determine the safety and efficacy of repeat doses of ferumoxytol for the treatment of IDA in patients with hemodialysis-dependent CKD. As part of the commitment we made to the EMA as a condition of the approval of the marketing authorization for ferumoxytol in the EU, this study includes a treatment arm with iron sucrose using a magnetic resonance imaging, or MRI, sub-analysis to evaluate the potential for iron to accumulate in the body following treatment with IV iron, specifically in the heart and liver, and, where possible, other major organs following repeated IV iron administration over a two year period. Enrollment is currently ongoing and we believe enrollment could be completed by the end of 2014. The costs related to the MRI portion of this study are subject to our established cost-sharing arrangement with Takeda.

In addition, certain clinical trials may be necessary to secure desired pricing in the EU Member States and other European markets. If so, the cost of any future trials may be allocated between us and Takeda according to the cost-sharing arrangement under the Amended Takeda Agreement.

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

Overview

IDA not associated with CKD is widely prevalent in many different patient populations. For many of these patients, treatment with oral iron is unsatisfactory. In the U.S., approximately 851,000 grams of IV iron were administered for the treatment of non-dialysis patients with IDA in 2013. We believe that approximately half, or 425,000 grams, of the IV iron administered in the U.S. was for the treatment of non-dialysis patients with CKD and the other half was for non-CKD patients with IDA due to other causes, including patients with gastrointestinal diseases or disorders, abnormal uterine bleeding, or AUB, inflammatory diseases, and chemotherapy-induced anemia. It is estimated that more than 4 million patients in the U.S. have IDA (CKD and non-CKD). We estimate that approximately 5 to 10% of these patients are currently treated with IV iron.

In December 2012, we submitted an sNDA to the FDA for *Feraheme* to expand the approved indication for ferumoxytol beyond the current indication for treatment of IDA in adult patients with CKD to adult IDA patients who have failed or could not use oral iron. The sNDA included data from two controlled, multi-center Phase III clinical trials, IDA-301 and IDA-302, including more than 1,400 patients, which served as the primary data supporting the safety and efficacy of ferumoxytol for the treatment of IDA in this target patient population. In addition, the sNDA included data from an interim analysis of the IDA open-label extension study, IDA-303, and a previously completed post-approval clinical study evaluating *Feraheme* treatment compared to treatment with another IV iron.

Under the guidelines of the Prescription Drug User Fee Act, or PDUFA, the FDA initially set October 21, 2013 as a target date for completion of their review and on October 15, 2013, we received notification from the FDA that our PDUFA date had been extended by three months to January 21, 2014. On January 21, 2014, we received a complete response letter from the FDA for the sNDA

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informing us that our sNDA could not be approved in its present form and stating that we have not provided sufficient information to permit labeling of *Feraheme* for safe and effective use for the proposed broader indication. The FDA indicated that its decision was based on the cumulative ferumoxytol data, including the global Phase III IDA program and global post-marketing safety reports. The FDA suggested, among other things, that we submit additional clinical trial data in the proposed broad IDA patient population with a primary composite safety endpoint of serious hypersensitivity/anaphylaxis, cardiovascular events and death, events that are included in the labels of *Feraheme* and other IV irons and that have been reported in the post-marketing environment for *Feraheme*. Additionally, the FDA proposed potentially evaluating alternative dosing and/or administration of *Feraheme*. Our plan for addressing the complete response letter from the FDA includes the following steps: (a) evaluate the FDA's recommendations in the complete response letter; (b) develop a proposal that we believe would be responsive to the points raised in the complete response letter and that we determine would be economically viable; (c) meet with FDA to discuss our proposal and explore the range of possible approaches to the points raised in the complete response letter; and (d) assess the FDA's feedback on our proposal and make a final determination on a possible program that would adequately address the FDA's concerns. Until we have further discussions with the FDA and receive its input, we cannot predict the path forward, if any, for *Feraheme* in the broad IDA patient population, including the related timing and cost of any clinical trials.

In June 2013, Takeda filed an application for Type II Variation of the marketing authorization for *Rienso* in the EU, which is the EU equivalent of a U.S. sNDA, with the EMA seeking marketing authorization for an additional therapeutic indication for *Rienso* for the treatment of IDA in adult patients. Takeda expects an opinion from the EMA and a related decision from the European Commission concerning this application in mid-2014. If the EMA issues a positive opinion for the inclusion of this additional therapeutic indication, for use in a broad IDA patient population, in the marketing authorization for *Rienso* and the European Commission adopts a decision approving this variation, we expect to receive a significant milestone payment from Takeda.

Currently, INFeD®, Dexferrum®, and as of July 2013, Injectafer® are approved in the U.S. for the treatment of a broader group of patients who are diagnosed with IDA in whom oral iron is unsatisfactory or impossible. All of the other currently marketed IV iron products, including *Feraheme*, are only approved in the U.S. for either the treatment of IDA in CKD patients or CKD patients on hemodialysis. We believe that new competitive entrants into the U.S. IV iron market, such as Injectafer®, could significantly increase the number of patients who will be treated with IV iron.

Underlying conditions in the broad IDA patient population

Multiple underlying conditions are associated with the development of IDA including gastrointestinal diseases or disorders, AUB, inflammatory diseases, and chemotherapy-induced anemia. In addition, a higher than normal incidence of IDA can be found in patients with chronic inflammatory disease (e.g. rheumatoid arthritis) and/or patients with certain cardiovascular diseases (e.g. congestive heart failure).

IDA in patients with gastrointestinal diseases or disorders is likely caused by blood loss and/or the inadequate intake or absorption of iron due primarily to bariatric surgeries, inflammatory bowel disease, chronic gastrointestinal bleeding and certain malabsorption disorders. Based on market research, we estimate that more than 500,000 patients who have gastrointestinal diseases or disorders in the U.S. also have IDA. Oral iron has been used to treat IDA in patients with chronic gastrointestinal diseases or disorders, but its efficacy is variable due to inconsistent bioavailability and absorption, the high incidence of gastrointestinal side effects and patient noncompliance.

AUB is defined as chronic, heavy, or prolonged uterine bleeding that can result from multiple causes, including uterine abnormalities, blood disorders, pregnancy, intrauterine devices, medications,

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and heavy menstrual bleeding. IDA is commonly associated with AUB, and based on market research, we estimate that approximately 1 million women in the U.S. have both IDA and AUB and are treated with a variety of surgical and/or medical management techniques. IDA in patients with AUB, regardless of the cause, requires treatment with iron supplementation, either by oral or IV administration.

IDA is also common in patients with cancer, and based on market research, we estimate that nearly 400,000 cancer patients in the U.S. have IDA. 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 poor absorption, a high incidence of gastrointestinal side effects, potential interactions with other treatments, and patient noncompliance. IV iron has been shown in small clinical trials to be well tolerated in the cancer patient population in both patients who are receiving chemotherapy and those who are not.

MuGard

In June 2013, we entered into a License Agreement with Access Pharmaceuticals, Inc., or Access, under which we acquired the U.S. commercial rights to *MuGard*, or the Access License Agreement, for the management of oral mucositis. *MuGard* is a prescription oral mucoadhesive, which provides a protective coating for the oral cavity and is dispensed in a ready to use form. Mucositis is the painful inflammation and ulceration of the mucous membranes of the mouth and gastrointestinal tract that can be caused by high-dose chemotherapy and/or radiotherapy. Oral mucositis is a common and often debilitating complication of cancer treatment that may impair oral nutritional intake or result in delays, unplanned breaks or decreases in dose for chemotherapy and/or radiation treatments, leading to sub-optimal cancer treatment results. In the U.S., there are approximately 400,000 people per year who experience oral mucositis and approximately 80% of patients with mucositis experience severe oral pain. The incidence rate and severity of symptoms depends on the type of anti-cancer treatment and patient-related risk factors. For example, based on data reported in a 2001 article in *CA: A Cancer Journal for Clinicians*, the incidence of oral mucositis for patients undergoing radiation for the treatment of head and neck cancer could approximate 80%. The incidence of oral mucositis for bone marrow transplant patients undergoing high dose chemotherapy and/or radiation pre-conditioning and patients undergoing conventional chemotherapy is approximately 70% and 40%, respectively.

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

GastroMARK

GastroMARK®, which was marketed and sold under the trade name Lumirem® outside of the U.S, was our oral contrast agent used for delineating the bowel during MRI and was approved for marketing in the U.S., Europe and other countries through our former licensees. In the second quarter of 2012, we terminated our commercial license agreements for *GastroMARK*. Following the completion of our obligations under these agreements in the first quarter of 2013, we ceased commercially manufacturing or selling *GastroMARK*.

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Our Core Proprietary Technology

Our core technology for ferumoxytol is based on coated superparamagnetic iron oxide particles and their characteristic properties. Our core competencies for ferumoxytol include the ability to design such particles for particular applications and to manufacture the particles in controlled sizes. Our technology and expertise enable us to synthesize, sterilize and stabilize these iron oxide particles in a manner necessary for use in pharmaceutical products such as IV iron replacement therapeutics.

Our iron oxide particles are composed of bioavailable iron that is easily utilized by the body and incorporated into the body's iron stores. As a result, our core technology for ferumoxytol is well suited for use as an IV iron replacement therapy product.

Our rights to the technology are derived from and/or protected by license agreements, patents, patent applications and trade secret protections. See "*Patents and Trade Secrets*" below. Our rights to *MuGard* are governed by the Access License Agreement. See Note G to our consolidated financial statements included in this Annual Report on Form 10-K.

Collaboration, License and Other Material Agreements

Takeda

In March 2010, we entered into the Takeda Agreement, under which we granted exclusive rights to Takeda to develop and commercialize *Feraheme/Rienso* as a therapeutic agent in certain agreed-upon territories. In June 2012, we entered into the Amended Takeda Agreement, which removed the Commonwealth of Independent States from the territories under which Takeda has the exclusive rights to develop and commercialize *Feraheme/Rienso.* In addition, the Amended Takeda Agreement modified the timing and pricing arrangements for a supply agreement to be entered into between us and Takeda, the terms related to primary and secondary manufacturing for drug substance and drug product, certain patent related provisions, and the re-allocation of certain of the agreed-upon milestone payments. In February 2014, we entered into the supply agreement with Takeda, which provides the terms under which we will sell *Feraheme* to Takeda in order for Takeda to meet its requirements for commercial use of *Feraheme* in its licensed territories. See "Other Information" in Part II, Item 9B for more information.

In December 2011, ferumoxytol was granted marketing approval in Canada, under the trade name *Feraheme*, for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. In June 2012, the European Commission granted marketing authorization for ferumoxytol under the trade name *Rienso* for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. The marketing authorization is valid in the 28 EU Member States as well as in Iceland, Liechtenstein and Norway. In August 2012, ferumoxytol was granted marketing approval in Switzerland under the trade name *Rienso* for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. During 2012, we received $33.0 million in milestone payments related to grant of marketing authorization for *Rienso* in the EU and the commercial launches of *Feraheme/Rienso* in Canada and the EU.

Under the Amended Takeda Agreement, except under limited circumstances, we have retained the right to manufacture *Feraheme/Rienso* and, accordingly, are responsible for supply of *Feraheme/Rienso* to Takeda at a fixed price per unit, which is capped for a certain period of time. We are also responsible for conducting, and bearing the costs related to, certain pre-defined clinical studies with the costs of future modifications or additional studies to be allocated between the parties according to an agreed-upon cost-sharing mechanism.

In connection with the execution of the original Takeda Agreement, we received a $60.0 million upfront payment from Takeda in April 2010. We have received and may also receive additional regulatory approval and performance-based milestone payments, reimbursement of certain out-of-pocket regulatory and clinical supply costs, defined payments for supply of *Feraheme/Rienso,* and

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tiered double-digit royalties on net product sales in the agreed-upon territories. The remaining milestone payments we may be entitled to receive under the agreement could over time equal up to $186.0 million, including a significant milestone payment if *Rienso* is authorized in the EU by the European Commission for the treatment of a broader population. We can make no assurances as to the amount of milestone payments, if any, we will actually receive under the agreement.

Access

In June 2013, we entered into the Access License Agreement under which Access 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, or the U.S. Territory, for the management of all diseases or conditions of the oropharyngeal cavity, including mucositis.

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

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

Access 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 Access License Agreement terminates at the end of the 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.

Packaging Coordinators, Inc.

In May 2009, we entered into a commercial packaging services agreement with Packaging Coordinators, Inc. (formerly Catalent Pharma Solutions, LLC), or PCI, as amended in January 2013, or the PCI Agreement. Under the provisions of the PCI Agreement, PCI provides certain labeling, packaging and storage services for final U.S. *Feraheme* drug product and storage services for Canadian and Swiss *Feraheme/Rienso* drug product. This agreement will renew automatically for successive established time periods unless either party provides written notice of its desire not to renew within certain time constraints. In addition, either party has the right to immediately terminate the agreement based on certain bankruptcy-related conditions or if the other party materially breaches any provision of this agreement and such breach is not cured within a certain period of time. Further, we may terminate the PCI Agreement for any reason or no reason with ninety days' written notice to PCI. PCI has two qualified facilities in the U.S., which we can utilize for our labeling, packaging and storage needs. *Rienso* labeling and packaging for sale in the EU, Canada and Switzerland is currently conducted in Italy and is the responsibility of Takeda.

Integrated Commercialization Services, Inc.

In October 2008, we entered into a commercial outsourcing services agreement with Integrated Commercialization Services, Inc., or ICS, as amended, or the ICS Agreement. Under the provisions of the ICS Agreement, ICS agreed to be our exclusive third-party logistics provider to perform a variety of functions related to the sale and distribution of *Feraheme* and *MuGard* in the U.S., including services related to warehousing and inventory management, distribution, chargeback processing, accounts

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receivable management, customer service call center management and our sampling program for *MuGard*. This agreement, as amended, will continue in effect until January 31, 2017, unless terminated earlier. The term of the agreement may be extended upon written mutual agreement of the parties six months prior to the expiration of the term. In addition, the ICS Agreement may be terminated under certain conditions such as non-payment of amounts due, failure to perform any material obligations under the agreement, or upon the occurrence of certain bankruptcy-related events.

3SBio

In 2008, we entered into the 3SBio License Agreement and the 3SBio Supply Agreement with 3SBio Inc., or 3SBio, for the development and commercialization of *Feraheme* as an IV iron replacement therapeutic agent in China. In consideration of the grant of the license, we received an upfront payment of $1.0 million. In late January 2014, we mutually terminated the agreement with 3SBio, effective immediately, due to the fact that, despite the best efforts of the parties, regulatory approval in China could not be obtained within the agreed upon time period.

Manufacturing

Feraheme/Rienso

We currently rely solely on third parties for the manufacture of *Feraheme/Rienso* for our commercial and clinical use. Our third-party contract manufacturing facilities are subject to current good manufacturing practices, or cGMP, regulations enforced by the FDA and equivalent foreign regulatory agencies through periodic inspections to confirm such compliance. Although we and Takeda are currently working to establish and qualify alternative manufacturing facilities for both drug substance and finished drug product of *Feraheme/Rienso,* we do not currently have an alternative manufacturer for our *Feraheme/Rienso* drug substance and finished drug product. We target to maintain sufficient inventory levels throughout our supply chain to meet our projected U.S. near-term demand of *Feraheme* drug product in order to minimize risks of supply disruption at points in our single source supply chain. We intend to continue to outsource the manufacture and distribution of *Feraheme/Rienso* for the foreseeable future, and we believe this manufacturing strategy will enable us to direct more of our financial resources to the commercialization of *Feraheme*.

We have also established certain testing and release specifications with the FDA and other foreign regulatory agencies. This release testing must be performed in order to allow the finished product to be used for commercial sale. In addition, variations in the regulatory approval of *Feraheme/Rienso* in the currently approved territories require that our third-party manufacturers follow different manufacturing processes and analytical testing methods.

To support the global commercialization of *Feraheme/Rienso*, 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. We currently have the following contracts in place related to the manufacture of *Feraheme/Rienso*:

Sigma-Aldrich, Inc.

In August 2012, we entered into a Commercial Supply Agreement, or the SAFC Agreement, as amended in October 2013, or the SAFC Amendment, with Sigma-Aldrich, Inc., or SAFC, pursuant to which SAFC agreed to manufacture and we agreed to purchase from SAFC, the active pharmaceutical ingredient, or API, or the drug product intermediate, or DPI, for use in the finished product of ferumoxytol for U.S. commercial sale, for sale outside of the U.S. by Takeda, as well as for use in clinical trials. Subject to certain conditions, the SAFC Agreement provides that we purchase from SAFC certain minimum quantities of API or DPI each year, but we are not obligated to use SAFC as

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our sole supplier of API or DPI. In addition, the prices for each batch will decline as batches are produced in greater quantities throughout each year of the agreement.

The SAFC Amendment provides updated pricing terms beginning on a certain date in the future, which are based on the amount of product produced by SAFC for us and Takeda in a given calendar year. If SAFC is unable to offer these agreed-upon prices, we may terminate our minimum purchase commitments. In addition, if SAFC is unable to meet our actual demand requirements other than due to our acts, omissions or default, our minimum purchase commitment will be suspended for such period. Further, if after a certain date in the future, SAFC is unable to match a *bona fide* offer from a third party to manufacture and supply product to us on better terms than provided by SAFC pursuant to the SAFC Agreement, as amended, then a reduced minimum purchase commitment will apply. In addition, the SAFC Amendment extends the initial term of the SAFC Agreement to December 31, 2020 and may be automatically extended thereafter for additional two year periods, unless cancelled by us or SAFC within an agreed-upon notice period. The SAFC Amendment provides us with the right to terminate the SAFC Agreement, as amended, and any purchase orders under certain conditions and subject to certain notice requirements. The SAFC Amendment also specifies cost-sharing arrangements relating to future process changes or capital improvements to the manufacturing process for *Feraheme/Rienso* under the SAFC Agreement, as amended.

DSM Pharmaceuticals, Inc.

In January 2010, we entered into a Pharmaceutical Manufacturing and Supply Agreement, or the DSM Agreement, with DSM Pharmaceuticals, Inc., or DSM, pursuant to which DSM agreed to manufacture ferumoxytol finished drug product for U.S. commercial sale, for sale outside of the U.S., as well as for use in clinical trials at a fixed price per vial. The DSM Agreement will continue in force until January 13, 2015. The DSM Agreement may be terminated at any time upon mutual written agreement by us and DSM or at any time by us subject to certain notice requirements and early termination fees. In addition, the DSM Agreement may be terminated by either us or DSM in the event of a material breach of the agreement by the other party provided that the breaching party fails to cure such breach within an agreed-upon notice period.

MuGard

Under the terms of the Access License Agreement, Access is responsible for all aspects of manufacturing *MuGard*. We have entered into a quality agreement and plan to enter into a supply agreement with Access under which we will purchase *MuGard* inventory from Access.

Raw Materials

We and our third-party manufacturers currently purchase certain raw and other materials used to manufacture *Feraheme/Rienso* 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. Certain materials used in *Feraheme/Rienso* may from time to time be procured from a single source without a qualified alternative supplier. The qualification of an alternative source may require repeated testing of the new materials and generate greater expenses to us if materials that we or they test do not perform in an acceptable manner. In addition, we 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 and other materials used to manufacture *Feraheme/Rienso*, we may not be able to obtain such materials of the quality required to manufacture *Feraheme/Rienso* from an alternative source on commercially reasonable terms, or in a timely manner, if at all.

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Patents 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 and trade secret protection for our products. Our success depends, in large part, on our ability to maintain the proprietary nature of our technology and other trade secrets. To do so, we must prosecute and maintain existing patents, obtain new patents and ensure trade secret protection. We must also operate without infringing the proprietary rights of third parties or allowing third parties to infringe our rights.

Our policy is to aggressively protect our competitive technology position by a variety of means, including applying for patents in the U.S. and in appropriate foreign countries. We currently hold a number of U.S. and foreign patents, which expire at various times through 2020. Our *Feraheme* patents currently expire in 2020, however, our primary U.S. patent for *Feraheme* may be subject to an extension to 2023 under U.S. patent law and FDA regulations. Our foreign patents may also be eligible for extension in accordance with applicable law in certain countries. We have a license to two U.S. patents relating to *MuGard*, that each expire in 2022.

We also have patent applications pending in the U.S. and have filed counterpart patent applications in certain foreign countries directed to *Feraheme*. Although further patents may be issued on pending applications, we cannot be sure that any such patents will be issued on a timely basis, if at all. In addition, any issued patents may not provide us with competitive advantages or may be challenged by others, and the existing or future patents of third parties may limit our ability to commercialize *Feraheme/Rienso*. For example, in July 2010, Sandoz GmbH, or Sandoz, filed with the European Patent Office, or the EPO, an opposition to our previously issued patent that covers ferumoxytol in the EU. In October 2012, at an oral hearing, the Opposition Division of the EPO revoked our European ferumoxytol patent. In December 2012, our notice of appeal was recorded with the EPO, which suspends the revocation of our patent. We will continue to defend the validity of this patent throughout the appeals process, which we expect to take two to three years. In the event the appeals process is unfavorable to us, it could result in a loss of proprietary rights in the EU and may allow other companies in the EU to use our proprietary technology without a license from us, and may also result in a loss of future royalty or milestone payments to us from Takeda. We cannot predict the outcome of our appeal of the EPO decision. In the event that we do not experience a successful outcome from the appeals process, under EU regulations ferumoxytol would still be entitled to eight years of data protection and ten years of market exclusivity, each from the date of approval, which we believe would create barriers to entry for any generic version of ferumoxytol into the EU market until sometime between 2020 and 2022. Further, our licensed patent rights to *MuGard* may not prevent competitors from independently developing and marketing a competing product that does not infringe our licensed patents or other intellectual property.

We also rely on the benefits of market exclusivity in protecting our intellectual property rights for *Feraheme* in the U.S. The FDA previously determined that ferumoxytol did not qualify as a new chemical entity, or NCE, and instead granted *Feraheme* a three-year "new use" market exclusivity, which expired in June 2012. In March 2010 and December 2012, we formally requested that the FDA reconsider its determination with respect to *Feraheme's* NCE status, which, if granted, would provide *Feraheme* with exclusivity until June 2014, or five years from the date of *Feraheme's* U.S. approval. We cannot give any assurances as to whether the FDA will accept our most recent request for reconsideration, that the FDA will make this reconsideration in a timely manner, or that *Feraheme* will be granted NCE exclusivity. The regulatory approval process for NCE status is discussed in more detail below under the heading "*U.S. Approval Process Marketing Exclusivity"* and the associated risks are discussed in more detail in Part I, Item 1A below under "*Risk Factors*" under the heading, "*Competitors could file applications seeking a path to U.S. approval of a generic ferumoxytol*."

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Frequently, the unpredictable nature and significant costs of patent litigation leads the parties to settle to remove any uncertainty related to the status of their patents. Settlement agreements between branded companies and generic applicants may allow, among other things, a generic product to enter the market prior to the expiration of any or all of the applicable patents covering the branded product, either through the introduction of an authorized generic or by providing a license to the applicant for the patents in suit.

Competition

The pharmaceutical and biopharmaceutical industry is intensely competitive and subject to rapid technological change. We and Takeda compete in the marketing and sale of *Feraheme/Rienso* in various countries around the world, including the U.S., and we compete in the marketing and sale of *MuGard* in the U.S. Many of our competitors 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. Our competitors may develop products that are more widely accepted than ours and may receive patent protection that dominates, blocks or adversely affects our product development or business.

Feraheme

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

There are currently two iron replacement options for treating IDA in CKD patients: oral iron supplements and IV iron. The National Kidney Foundation's Kidney Disease Outcomes Quality Initiative guidelines recommend either oral or IV iron for peritoneal dialysis patients and non-dialysis patients with stages 1 through 5 CKD. Oral iron is currently the first-line iron replacement therapy of choice of most physicians in both the U.S. and abroad. However, oral iron supplements are poorly absorbed by many patients, which may adversely impact their effectiveness, and are associated with certain side effects that may adversely affect patient compliance in using such products. The alternative to oral iron for the treatment of IDA in CKD patients is IV iron.

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

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

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

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

A generic version of Ferrlecit® marketed by Watson Pharmaceuticals, Inc., or Watson;

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

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

As compared to the dosing regimens described above for *Feraheme's* U.S. competitors, *Feraheme* is administered as a 510 milligram injection followed by a second 510 milligram injection three to eight days later, each of which can be administered in less than one minute at a regular office visit.

Pharmacosmos A/S, or Pharmacosmos, the producer of another IV iron, Monofer® (iron isomaltoside 1000), which is approved and marketed in Europe, is also conducting clinical trials in the U.S. and may try to gain regulatory approval in the U.S. for Monofer®.

Outside of the U.S., *Feraheme/Rienso* also competes with a number of branded IV iron replacement products, including Venofer®, Ferrlecit®, Monofer®, Ferinject® (ferric carboxymaltose injection) (the brand name for Injectafer® outside the U.S.) and certain other iron dextran and iron sucrose products. Venofer® and Ferrlecit®, described above, have been marketed in many countries throughout the world, including most of Europe and Canada, for many years. Monofer® is an injectable iron preparation developed by Pharmacosmos, which is currently approved for marketing in approximately 23 countries for the treatment of IDA. Ferinject® is an IV iron replacement therapy developed by Vifor Pharma, the pharmaceuticals business unit of the Galenica Group, and is currently approved for marketing in approximately 46 countries worldwide, for the treatment of iron deficiency where oral iron is ineffective or cannot be used. Currently, all other IV iron products approved and marketed in the EU are approved for marketing to a broader group of patients with IDA. *Feraheme/Rienso* was approved only for use in CKD patients, which could put *Feraheme/Rienso* at a competitive disadvantage unless and until it receives marketing authorization for a broader indication outside of the U.S. In 2013, Takeda filed an application for Type II Variation of the marketing authorization for *Rienso* in the EU with the EMA seeking marketing authorization for an additional therapeutic indication for *Rienso* for the treatment of IDA in adult patients and currently expects an opinion from the EMA and a related decision from the European Commission concerning this application in mid-2014.

The market opportunity for *Feraheme/Rienso* in the U.S. and abroad could also be negatively affected by approved generic IV iron replacement therapy products that achieve commercial success. For example, in 2011, Watson launched a generic version of Ferrlecit® in the U.S. which is approved for marketing in the U.S. for the treatment of IDA in adult patients and in pediatric patients age six years and older undergoing chronic hemodialysis who are receiving supplemental epoetin therapy. Sagent Pharmaceuticals, Inc. has also indicated its intention to introduce a generic iron sucrose in the U.S. in the future. Outside the U.S., there is currently a generic version of Venofer®.

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The Drug Price Competition and Patent Term Restoration Act of 1984, as amended, or the Hatch-Waxman Act, requires an applicant whose subject drug is a drug listed in the FDA's Orange Book to notify the patent-holder of their application and potential infringement of their patent rights. If an applicant for ferumoxytol notifies us of such application, we would have 45 days upon receipt of that notice to bring a patent infringement suit in federal district court against the applicant seeking approval of a product. If such a suit is commenced, the FDA is generally prohibited from granting approval of an application until the earliest of 30 months from the date the FDA accepted the application for filing, the conclusion of litigation in the generic's favor, or expiration of the patent(s). If the litigation is resolved in favor of the applicant or the challenged patent expires during the 30-month stay period, the stay is lifted and the FDA may thereafter approve the application based on the applicable standards for approval.

A generic version of *Feraheme* can be marketed only with the approval of the FDA of the respective application for such generic version. In December 2012, the FDA issued draft guidance making recommendations regarding establishing bioequivalence with *Feraheme*, pursuant to which a party could seek approval of a generic version of that product through an abbreviated new drug application, or ANDA. The FDA generally publishes product-specific bioequivalence guidance after it has received an inquiry from a generic drug manufacturer about submitting an ANDA for the product in question; thus, it is possible that a generic drug manufacturer has approached the FDA requesting guidance about submitting an ANDA for ferumoxytol, the active ingredient in *Feraheme*, and that such an ANDA may be filed in the near future. The ANDA process is discussed in more detail below under the heading "*U.S. Approval Process Marketing Exclusivity."*

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 U.S. sales and any royalties we may receive from Takeda on sales outside of the U.S. See the discussion in Part I, Item 1A below under "*Risk Factors*" under the heading, "*Competitors could file applications seeking a path to U.S. approval of a generic ferumoxytol.*"

We believe that our and Takeda's ability to successfully compete with other IV iron products in the U.S. and internationally depends on a number of factors, including the actual or perceived safety and efficacy profile of *Feraheme/Rienso* as compared to alternative iron replacement therapeutics, our ability to obtain and maintain favorable pricing, insurance coverage and reimbursement rates and terms for *Feraheme/Rienso*, the timing and scope of regulatory approval of *Feraheme/Rienso* for the broad IDA indication and of products or additional indications by our competitors, our ability to implement effective marketing programs, the effectiveness of our sales force, our ability to maintain favorable patent protection for *Feraheme/Rienso*, market acceptance of *Feraheme/Rienso,* and our ability to manufacture sufficient quantities of *Feraheme/Rienso* at commercially acceptable costs. In addition, our ability to effectively compete with these products in the U.S. non-dialysis CKD market depends in part upon our ability to gain formulary access in hospitals and effectively promote *Feraheme* within group purchasing organizations, or GPOs, and to physicians who treat non-dialysis CKD patients.

Based on sales data provided to us in January 2014 by IMS Health Incorporated, or IMS, we estimate that the size of the total 2013 U.S. non-dialysis IV iron replacement therapy market was approximately 851,000 grams, which represented an increase of approximately 6% over 2012. Based on

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this IMS data, the following represents the 2013 and 2012 U.S. market share allocation of the total non-dialysis IV iron market based on the volume of IV iron administered:

	2013 U.S. Non-dialysis IV Iron Market (851,000 grams)	2012 U.S. Non-dialysis IV Iron Market (806,000 grams)
Venofer®	46%	46%
INFeD®	22%	20%
Feraheme	15%	14%
Generic sodium ferric gluconate	10%	10%
Ferrlecit®	6%	7%
Dexferrum®	<1%	3%
Injectafer®	<1%	

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

MuGard

Up to 50% of new cancer patients develop oral mucositis each year for which there are currently few effective treatments. The market for treating oral mucositis is driven primarily by convenience, price and reimbursement and the products in this market remain mostly undifferentiated. There are a number of approaches used to treat or manage oral mucositis, including the use of ice chips during chemotherapy treatments, various medicinal mouthwashes, topical anesthetics and analgesics, and oral gel treatments. For example, many physicians use what is commonly known as "magic mouthwash", which may currently be the most commonly prescribed medication to manage oral mucositis or treat the pain associated with mucositis caused by radiation therapy or chemotherapy. Magic mouthwash is a combination of generic ingredients which are typically compounded in a pharmacy and is preferred by many physicians because of the availability of less expensive generic ingredients used to formulate the mouthwash. However, there is no clinical trial data to support the efficacy or safety of magic mouthwash. The efficacy of *MuGard* has been supported by a randomized, Phase IV multicenter, double-blind, sham-controlled trial.

There are a number of companies in the U.S. commercializing products for the management or treatment of oral mucositis that may compete with *MuGard,* including the following marketed products:

NeutraSal® (supersaturated calcium phosphate rinse), a prescription mouth rinse marketed by Invado Pharmaceuticals, LLC and indicated to treat the painful symptoms associated with oral mucositis;

Caphosol®, a supersaturated calcium phosphate artificial saliva marketed by Jazz Pharmaceuticals, PLC, which is indicated as an adjunct to standard oral care in treating oral mucositis caused by radiation or high dose chemotherapy; and

Kepivance® (palifermin), an IV human growth factor manufactured by Amgen and marketed by Swedish Orphan Biovitrum AB, which is used to reduce the chances of developing severe mucositis and to shorten the time with severe mucositis in patients with cancer who receive high doses of chemotherapy and radiation therapy.

Further, there are several marketed products available which are indicated for the management of pain associated with oral mucositis including the following products:

Episil®, marketed by Cangene BioPharma, Inc., is indicated for the management of pain and relief from pain, by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including oral mucositis/stomatitis that may be caused by chemotherapy or radio therapy;

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Gelclair®, marketed by DARA BioSciences, Inc., is a viscous, concentrated, bio adherent oral gel, indicated for the management of painful symptoms of mucositis of the oropharyngeal cavity caused by chemo-radiotherapy; and

GelX® Oral Gel, marketed by Praelia Pharmaceuticals, Inc., is an oral gel indicated for the relief and management of pain by adhering to the mucosal surface of the mouth and soothing oral lesions of various etiologies, including oral mucositis/stomatitis (may be caused by chemotherapy or radiotherapy), irritation due to oral surgery, aging, and traumatic ulcers caused by braces or ill-fitting dentures, medication, or disease.

Based on data provided to us in January 2014 by IMS we estimate that the total number of prescriptions, or TRx's, filled in the U.S. in 2013 for the treatment or management of oral mucositis was approximately 14,900. The following represents the 2013 market share allocation based on TRx data to treat or manage oral mucositis, which accounts for approximately 75% of the total oral mucositis business. These figures do not include products purchased by hospitals or outpatient clinics, such as Kepivance®:

	2013 Oral Mucositis Market (14,900 TRx)
Neutrasal®	46%
Caphosol®	23%
MuGard	13%
Episil®	11%
GelX®	4%
Gelclair®	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 oral mucositis products.

Sales, Marketing and Distribution

Feraheme

In July 2009, we began U.S. commercial sale of *Feraheme,* which is being marketed and sold in the U.S. through our own commercial organization, including a specialty sales force. We sell *Feraheme* to authorized wholesalers and specialty distributors who, in turn, sell *Feraheme* to healthcare providers who administer *Feraheme* primarily within hospitals, hematology and oncology centers and nephrology clinics. Since many hospitals and hematology, oncology and nephrology practices are members of GPOs, which leverage the purchasing power of a group of entities to obtain discounts based on the collective bargaining power of the group, we also routinely enter into pricing agreements with GPOs in these markets so the members of the GPOs have access to *Feraheme* and the related discounts or rebates. In addition, we outsource a number of our product supply chain services to ICS, our third-party logistics provider, including services related to warehousing and inventory management, distribution, chargeback processing, accounts receivable management and customer service call center management.

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

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Our commercial strategy currently focuses on the non-dialysis dependent CKD market in the U.S. Based on data contained in a 2009 publication in the *Journal of the American Society of Nephrology*, we estimate that there are 1.6 million adults diagnosed in the U.S. with stages 3 through 5 CKD and IDA, and we believe that a small fraction of those patients are currently being treated with IV iron. We believe there is a significant opportunity in this market to provide IV iron to non-dialysis CKD patients, and our sales team has been working to educate physicians who treat CKD patients on the benefits of IV iron and the dosing profile of *Feraheme* in order to change existing treatment paradigms and expand the IV iron use in physicians' offices, clinics, and hospitals where CKD patients are treated for IDA.

Feraheme/Rienso has been granted marketing approval in Canada, the EU, Iceland, Liechtenstein, Norway and Switzerland for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD and was commercially launched in Canada, Switzerland and the EU in 2012. Under the Amended Takeda Agreement, Takeda is solely responsible for *Feraheme/Rienso* commercialization efforts in these areas including the deployment of a specialized sales force, pricing and reimbursement negotiations with national, provincial or local health authorities and customers, and development of market access strategies.

In May 2013, Takeda recalled a single batch of *Rienso* from the Swiss market after becoming aware of four post-marketing adverse event reports relating to potential anaphylaxis/hypersensitivity reactions of varying severity following the administration of *Rienso*. One of these cases included a report of a fatality. The marketing authorization for *Rienso* and other IV iron formulations include, among their special warnings and precautions for use, an indication that the products may cause hypersensitivity reactions including serious and life-threatening anaphylactic/anaphylactoid reactions. The recalled batch was only distributed to and sold in Switzerland and the recall was limited to the specific batch in Switzerland. We and Takeda have completed a quality investigation of the specific Swiss batch of *Rienso*, which we believe did not identify any issues which would have impacted the quality of the recalled batch, and we gathered all available information for the reported adverse events. Takeda has filed a report with SwissMedic, the Swiss Agency for Therapeutic Products, and we and Takeda are awaiting feedback on SwissMedic's review of the findings from the investigation. We and Takeda are currently working with the Swiss authorities and are unable to predict when or if *Rienso* will be reintroduced into the Swiss market.

MuGard

In June 2013, we acquired the U.S. rights to *MuGard* from Access. We began comprehensive promotional activities related to *MuGard* in the third quarter of 2013, including training our sales force and developing new marketing materials, such as health care provider brochures, patient materials, reimbursement information and starter kits. To optimize the sales potential of both of our commercial products, our initial call targets for *MuGard* included current *Feraheme* prescribers as well as other high prescribing clinicians, including radiation oncologists who manage head and neck cancer patients undergoing radiation therapy where the incidence of oral mucositis could approximate 80%. Going forward, our commercial strategy for *MuGard* includes differentiating *MuGard* from other currently used approaches for treating and managing oral mucositis, targeting oral mucositis prescribers and expanding reimbursement coverage for *MuGard*.

Our sales and marketing teams use a variety of common pharmaceutical marketing strategies and methods to promote *MuGard,* including sales calls to providing entities, such as hospitals and hematology and oncology centers. In addition, other tactical programs may include personal and non-personal promotional materials to individual physicians or other healthcare professionals, sponsoring local and national educational programs, participation in scientific meetings and conferences and implementing informational product specific websites.

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We market and sell *MuGard* to wholesalers and specialty pharmacies. Patients primarily receive *MuGard* through specialty pharmacies, which receive prescriptions from either our *MuGard* patient reimbursement and support center, or the HUB, or from physicians directly. We utilize the HUB as a centralized patient intake and referral management center to process insurance coverage issues and administer our patient assistance and copayment programs. In order to provide *MuGard* to patients as soon as possible, we have implemented a robust program that delivers a starter kit to clinicians, including a sample bottle and all pertinent information that the patient or caregiver needs to immediately begin *MuGard* therapy. In addition, we outsource a number of our product supply chain services to ICS, our third-party logistics provider, 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 2013, 2012, and 2011. Revenues from Takeda include collaboration revenue, milestone payments, revenues from product sales to Takeda and royalty payments, in each case in connection with the Amended Takeda Agreement.

	Years Ended December 31,		
	2013	**2012**	**2011**
AmerisourceBergen Drug Corporation	41%	34%	41%
McKesson Corporation	24%	17%	21%
Cardinal Health, Inc.	16%	12%	13%
Takeda Pharmaceuticals Company Limited	11%	31%	13%

Government Regulation

Overview

Our activities are subject to extensive regulation by numerous governmental authorities in the U.S. and abroad. In the U.S., the Federal Food, Drug, and Cosmetic Act, or the FDCA, and other federal and state statutes and regulations govern, among other things, the research and development, manufacturing, quality control, labeling, recordkeeping, approval, storage, distribution, and advertising and promotion of pharmaceutical products and medical devices. Our activities outside of the U.S. are also subject to regulatory requirements governing the testing, approval, safety, effectiveness, manufacturing, labeling, and marketing of *Feraheme/Rienso*.

Failure to comply with any of the applicable U.S. or foreign regulatory 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, withdrawals of approval, clinical holds, warning letters, product recalls, product seizures, total or partial suspension of operations, injunctions, fines, civil penalties, or criminal prosecution.

U.S. Approval Process

Clinical Development

Before we may market a new human drug product in the U.S., we must obtain FDA approval of a New Drug Application, or NDA, for that product. The FDA may approve an NDA if the safety and effectiveness of the drug candidate can be established based on the results of clinical trials.

Clinical testing proceeds in three phases. Phase I trials seek to establish initial data about safety, tolerability, and optimal dosing of the drug candidate in humans. The goal of Phase II trials is to

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provide evidence about the desired therapeutic efficacy of the product candidate in limited studies with small numbers of carefully selected subjects. Phase III trials generally consist of expanded, large-scale, randomized, double-blind, multi-center studies of the safety and effectiveness of the product in the target patient population.

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

Submission and FDA Review of NDAs/sNDAs

Following the successful completion of clinical trials, the sponsor submits the results to the FDA as part of an NDA. The NDA must also include the results of pre-clinical tests and studies, information related to the preparation and manufacturing of the drug candidate, analytical methods, and proposed packaging and labeling. Pursuant to PDUFA, the FDA has a goal of acting on most original NDAs within six months or ten months of the application filing date, depending on the nature of the drug. For drugs candidates intended to treat serious and life-threatening conditions, the FDA has a number of programs intended to help expedite testing, review, and approval.

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

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

Adverse Event Reporting

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

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FDA Post-Approval Requirements

Even if initial approval of an NDA or sNDA is granted, such approval may be subject to post-market regulatory requirements, any or all of which may adversely impact a sponsor's ability to effectively market and sell the approved product. The FDA may require the sponsor to conduct Phase IV clinical trials, also known as post-marketing requirements or post-marketing commitments, to provide additional information on safety and efficacy. The results of such post-market studies may be negative and could lead to limitations on the further marketing of a product. Also, under the Pediatric Research Equity Act, the FDA may require pediatric assessment of certain drugs unless waived or deferred due to the fact that necessary studies are impossible or highly impractical to conduct or where the drug is not likely to be used in a substantial number of pediatric patients, for example. In addition, the FDA may require a sponsor to implement a Risk Evaluation Mitigation Strategy, or REMS, a strategy to manage a known or potential serious risk associated with the product. Failure to comply with REMS requirements may result in civil penalties.

Marketing Exclusivity

Market exclusivity provisions under the FDCA can delay the submission or the approval of certain applications. Under the FDCA, an NCE that is granted regulatory approval may be eligible for five years of U.S. marketing exclusivity. A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety. During the exclusivity period, the FDA may not accept for review an ANDA referencing the NDA.

The FDCA also provides three years of marketing exclusivity for an sNDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application (for example, for new indications, dosages, or strengths of an existing drug). This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent.

FDA Regulation of Product Marketing and Promotion

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

FDA Regulation of Manufacturing Facilities

Manufacturing procedures and quality control for approved drugs must conform to cGMP. Domestic manufacturing establishments must follow cGMP at all times, and are subject to periodic inspections by the FDA in order to assess, among other things, cGMP compliance. In addition, prior to approval of an NDA or sNDA, the FDA will perform a pre-approval inspection of the sponsor's manufacturing facility, including its equipment, facilities, laboratories and processes, to determine the facility's compliance with cGMP and other rules and regulations. Vendors that supply finished products or components to the sponsor that are used to manufacture, package, and label products are subject to similar regulation and periodic inspections. If the FDA identifies deficiencies during an inspection, it may issue a formal notice, which may be followed by a warning letter if observations are not addressed satisfactorily. FDA guidelines specify that a warning letter be issued only for violations of "regulatory

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significance" for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action.

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

To supply products for use outside of the U.S., our third-party manufacturers must comply with cGMP and are subject to periodic inspection by the FDA or by regulatory authorities in certain other countries. In complying with these requirements, manufacturers, including a drug sponsor's third-party contract manufacturers, must continue to expend time, money, and effort in the area of production and quality to ensure compliance. Failure to maintain compliance with cGMP regulations and other applicable manufacturing requirements of various regulatory agencies could result in fines, unanticipated compliance expenditures, recall, total or partial suspension of production, suspension of the FDA's review of future sNDAs, enforcement actions, injunctions, or criminal prosecution.

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, the Federal False Claims Act, and the Foreign Corrupt Practices Act, and their state analogues. Anti-kickback laws make it illegal to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug, that is reimbursed by a state or federal program. False claims laws prohibit anyone from knowingly presenting, or causing to be presented for payment to third-party payers, including Medicare and Medicaid, false or fraudulent claims for reimbursed drugs or services, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. The Foreign Corrupt Practices Act and similar foreign anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. 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 *Feraheme* or *MuGard*, significant fines, exclusions from government healthcare programs, including Medicare and Medicaid, litigation, or other sanctions.

Other U.S. Regulatory Requirements

In recent years, several states have enacted legislation requiring pharmaceutical companies operating within the state to establish marketing and promotional compliance programs or codes of conduct and/or file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities. Similar legislation is being considered by additional states and by Congress. In addition, as part of The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the Health Care Reform Act, the federal government has enacted the Sunshine Act provisions. As of August 2013, manufacturers of drugs are required to publicly report gifts and payments made to physicians and teaching hospitals. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Failure to comply with any of these laws could result in a range of fines, penalties, and/or other sanctions.

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Foreign Regulatory Process

In our efforts to market and sell *Feraheme/Rienso* outside of the U.S., we and our licensees are subject to foreign regulatory requirements. Approval of a drug by applicable regulatory agencies of foreign countries must be secured prior to the marketing of such drug in those countries. The regulatory approval process in countries outside of the U.S. vary widely from country to country and may in some cases be more rigorous than requirements in the U.S. Certain foreign regulatory authorities may require additional studies or studies designed with different clinical endpoints and/or comparators than those which we are conducting or have already completed. In addition, any adverse regulatory action taken by the FDA with respect to an approved product, or a product under review, in the U.S. may affect the regulatory requirements or decisions made by certain foreign regulatory bodies with regard to the regulatory approval of products outside of the U.S.

To obtain regulatory approval of a drug in the EU, application for marketing authorization may be submitted through a centralized, mutual recognition, decentralized procedure, or national procedure (single country). In accordance with the centralized procedure, the applicant can submit a single application for marketing authorization to the EMA. If the EMA issues a positive opinion and the European Commission grants a marketing authorization following this positive opinion, the authorization permits the marketing of a product in all 28 EU Member States and Iceland, Liechtenstein and Norway. According to the mutual recognition procedure, the holder of a marketing authorization in one EU Member States may seek the mutual recognition of this marketing authorization by the competent authorities of other EU Member States and grant by them of related marketing authorizations. According to the decentralized procedure, the applicant for marketing authorization can submit applications simultaneously to several EU Member States, identifying a single reference Member State to act as the primary reviewer of the application. Upon the positive outcome of the assessment by the reference Member State and the acceptance of this assessment by the other EU Member States, a marketing authorization is granted in both the reference Member State and the other EU Member States. The authorization process is essentially the same irrespective of which route is used.

Applicants for marketing authorization in the EU are required to provide a demonstration that studies have been conducted with the medicinal product in the pediatric population as provided by a Pediatric Investigation Plan approved by the Pediatric Committee of the EMA. Alternatively, confirmation that the applicant has been granted a waiver or deferral for the conduct of these studies must be provided.

Once an applicant receives marketing authorization in an EU Member State, through any application route, the applicant is then required to engage in pricing discussions and negotiations with a separate pricing authority in that country. The legislators, policymakers and healthcare insurance funds in the EU Member States continue to propose and implement cost-containing measures to keep healthcare costs down, due in part to the attention being paid to health care cost containment and other austerity measures in the EU. Certain of these changes could impose limitations on the prices pharmaceutical companies are able to charge for their products. The amounts of reimbursement available from governmental agencies or third-party payors for these products may increase the tax obligations on pharmaceutical companies such as ours, or may facilitate the introduction of generic competition with respect to our products. Furthermore, an increasing number of EU Member States and other foreign countries use prices for medicinal products established in other countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere. In addition, the ongoing budgetary difficulties faced by a number of EU Member States, including Greece and Spain, have led and may continue to lead to substantial delays in payment and payment partially with government bonds rather than cash for medicinal products, which could negatively impact our revenues and profitability. Moreover, in order to obtain reimbursement of

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our medicinal products in some countries, including some EU Member States, we may be required to conduct clinical trials that compare the cost-effectiveness of our products to other available therapies. There can be no assurance that our medicinal products will obtain favorable reimbursement status in any country.

In certain countries, commercial sales are only able to commence once pricing approval has been received. In addition, innovative medicinal products are authorized in the EU on the basis of a full marketing authorization application (as opposed to an application for marketing authorization that relies on data in the marketing authorization dossier for another, previously approved medicinal product). Applications for marketing authorization for innovative medicinal products must contain the results of pharmaceutical tests, pre-clinical tests and clinical trials conducted with the medicinal product for which marketing authorization is sought. Innovative medicinal products are entitled to eight years' data exclusivity. During this period, applicants for approval of generics of these innovative products cannot rely on data contained in the marketing authorization dossier submitted for the innovative medicinal product. Innovative medicinal products are entitled to ten years' market exclusivity. During this ten year period no generic medicinal product can be placed on the EU market. The ten-year period of market exclusivity can be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder for the innovative product obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. In June 2012, *Rienso* was granted marketing authorization in the EU for the treatment of IDA in CKD patients and commercially launched in late 2012.

The Canadian pharmaceutical industry is subject to federal regulation by Health Canada, the public health department of the Canadian government charged with overseeing healthcare-related regulatory matters, pursuant to the Canadian federal Food and Drugs Act. Health Canada's criteria for obtaining and maintaining marketing approval is generally similar to that of the FDA. In December 2011, *Feraheme* was granted marketing approval by Health Canada for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD and commercially launched in late 2012.

The pharmaceutical industry in Switzerland is subject to federal regulation by Swissmedic. In August 2012, *Rienso* was granted marketing approval by Swissmedic and commercially launched in late 2012. As discussed above, in May 2013, Takeda recalled a single batch of *Rienso* from the Swiss market and as a result, *Rienso* is not currently being marketed in Switzerland. We are currently unable to predict when or if *Rienso* will be reintroduced into the Swiss market.

Medical Device Regulation

Medical devices, such as *MuGard*, are similarly subject to FDA approval and extensive post-approval regulation under the FDCA. Authorization to commercially distribute a new medical device in the U.S. is generally received in one of two ways. The first, known as premarket notification, or the 510(k) process, requires a sponsor to demonstrate that the new medical device is substantially equivalent to a legally marketed medical device. In this process, the sponsor must submit data that supports the equivalence claim. If human clinical data is required, it must be gathered in compliance with the FDA's investigational device exemption regulations. A sponsor must receive an order from the FDA finding substantial equivalence to another legally marketed medical device before the new medical device can be commercially distributed. Modifications to cleared medical devices can be made without using the 510(k) process if the changes do not significantly affect safety or effectiveness. The second, more rigorous process, known as premarket approval, requires a sponsor to independently demonstrate that the new medical device is safe and effective. A sponsor does this by collecting data regarding design, materials, bench and animal testing, and human clinical data for the medical device. The FDA will authorize commercial distribution if it determines there is reasonable assurance that the medical device is safe and effective. This determination is based on the benefit outweighing the risk for the population intended to be treated with the device.

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

The FDCA provides for a risk-based device classification system for medical devices. Each device is assigned to one of three regulatory classes: Class I, Class II or Class III, based on the level of control necessary to provide reasonable assurance of its safety and effectiveness. As device class increases from Class I, to Class II to Class III, the regulatory controls also increase, with Class I devices subject to the least regulatory control, and Class III devices subject to the most stringent regulatory control.

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

Pharmaceutical Pricing and Reimbursement

In both the U.S. and foreign markets, our and Takeda's ability to successfully commercialize *Feraheme/Rienso* and *MuGard* is dependent, in significant part, on the availability and extent of reimbursement to end-users from third-party payors for the use of *Feraheme/Rienso* and *MuGard*, including governmental payors, managed care organizations, and private health insurers. In the U.S., the federal government provides health insurance for people who are 65 or older, certain younger people with disabilities, and people with End-Stage Renal Disease through the Medicare program, and certain prescription drugs, including *Feraheme*, are covered under Medicare Part B. Medicaid, another program in the U.S., is a health insurance program for low-income children, families, pregnant women, and people with disabilities that is jointly funded by the federal and state governments, but administered by the states. In general, state Medicaid programs are required to cover drugs and biologicals of manufacturers that have entered into a Medicaid Drug Rebate Agreement, as discussed below, although such drugs and biologicals may be subject to prior authorization or other utilization controls. Both Medicare and Medicaid are administered by the Centers for Medicare and Medicaid Services, or CMS.

We participate in and have certain price reporting obligations to the Medicaid program, and we have obligations to report Average Sales Price, or ASP, for the Medicare program. Under the Medicaid program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our products under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to CMS. These data include the average manufacturer price and, in the case of innovator products such as *Feraheme*, the best price for each drug.

Federal law also requires that a company that participates in the Medicaid rebate program report ASP information to CMS for certain categories of drugs that are paid under Part B of the Medicare program, such as *Feraheme*. Manufacturers calculate ASP based on a statutorily defined formula and interpretations of the statute by CMS as to what should or should not be considered in computing ASP.

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An ASP for each National Drug Code for a product that is subject to the ASP reporting requirement must be submitted to CMS no later than 30 days after the end of each calendar quarter. CMS uses these submissions to determine payment rates for drugs under Medicare Part B. Changes affecting the calculation of ASP could affect the ASP calculations for our products and the resulting Medicare payment rate, and could negatively impact our results of operations.

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

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we participate in the Department of Veterans Affairs Federal Supply Schedule, or FSS, pricing program, established by Section 603 of the Veterans Health Care Act of 1992. Under this program, we are obligated to make our product available for procurement on an FSS contract and charge a price to four federal agencies, Department of Veterans Affairs, Department of Defense, Public Health Service and Coast Guard, that is no higher than the statutory Federal Ceiling Price, or FCP. The FCP is based on the non-federal average manufacturer price, which we calculate and report to the Department of Veterans Affairs on a quarterly and annual basis.

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

In addition, U.S. and many foreign governments continue to attempt to curb health care costs through legislation, including legislation aimed at reducing the pricing and reimbursement of pharmaceutical products. The Health Care Reform Act was enacted in the U.S. in March 2010 and includes certain cost containment measures including an increase to the minimum rebates for products covered by Medicaid programs from 15.1% to 23.1% of the average manufacturer price for most innovator products and the expansion of the 340B Drug Discount Program under the Public Health Service Act. Effective March 23, 2010, the Health Care Reform Act expanded manufacturer rebate liability under the Medicaid program from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well. Further, as a result of recent legislation, Medicare payments are subject to a two percent reduction, referred to as sequestration, until 2023. Finally, the Healthcare Reform Act requires pharmaceutical manufacturers of branded prescription drugs to pay a

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branded prescription drug fee to the federal government beginning in 2011. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee of $3.0 billion in 2014 (and set to increase in ensuing years), based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law.

Many of the Healthcare Reform Act's most significant reforms do not take effect until 2014. In 2012, CMS, issued proposed regulations to implement the changes to the drug rebate components of the Medicaid program under the Healthcare Reform Act but has not yet issued final regulations. CMS is currently expected to release the final regulations in 2014.

In addition, the heightened focus on the health care industry by the federal government could result in the implementation of significant federal spending cuts including cuts in Medicare and other health related spending in the near term. In recent years, some states have also passed legislation to control the prices of drugs or devices as well as begun a move toward managed care to relieve some of their Medicaid cost burden. These and any future changes in government regulation or private third-party payors' reimbursement policies may reduce the extent of reimbursement for *Feraheme/Rienso* and *MuGard* and adversely affect our future operating results.

Currently, in U.S. physician clinic and hospital settings, Medicare Part B generally reimburses for physician-administered drugs at a rate of 106% of the drug's ASP. ASP is defined by statute based on certain historical sales and sales incentive data, including rebates and chargebacks, for a defined period of time. As noted above, we submit the required information to CMS on a quarterly basis. In advance of the quarter in which the payment limit for drugs reimbursed under Medicare Part B program will go into effect, CMS calculates and publishes the payment limit. Under this methodology, payment rates change on a quarterly basis, and significant downward fluctuations in ASP, and therefore reimbursement rates, could negatively impact sales of a product. Because ASP is defined by statute, and changes to Medicare payment methodologies require legislative change, it is unclear if and when ASP reimbursement methodology will change for the physician office setting. For hospital outpatient departments, the Medicare payment methodology for many covered Part B drugs also is at 106% of ASP, but CMS could change the payment methodology through regulations, without any intervening legislation. While Medicare is the predominant payor for *Feraheme* for treatment of patients with CKD, Medicare payment policy, in time, can also influence pricing and reimbursement in the non-Medicare markets, as private third-party payors and state Medicaid plans frequently adopt Medicare principles in setting reimbursement methodologies. We cannot predict the impact that any changes in reimbursement policies may have on our ability to compete effectively.

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

In countries outside of the U.S., market acceptance may also depend, in part, upon the availability of reimbursement within existing healthcare payment systems. Generally, in Europe and other countries outside of the U.S., the government sponsored healthcare system is the primary payor of healthcare costs of patients and therefore enjoys significant market power. Some foreign countries also set prices for pharmaceutical products as part of the regulatory process, and we cannot guarantee that the prices set by such governments will be sufficient to generate substantial revenues or allow sales of *Feraheme/Rienso* to be profitable in those countries.

The legislators, policymakers and healthcare insurance funds in the EU Member States continue to propose and implement cost-containing measures to keep healthcare costs down, due in part to the attention being paid to health care cost containment and other austerity measures in the EU. Certain

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of these changes could impose limitations on the prices pharmaceutical companies are able to charge for their products. The amounts of reimbursement available for these products from governmental agencies or third-party payors, may increase the tax obligations on pharmaceutical companies such as ours, or may facilitate the introduction of generic competition with respect to our products. Furthermore, an increasing number of EU Member States and other foreign countries use prices for medicinal products established in other countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere. In addition, the ongoing budgetary difficulties faced by a number of EU Member States, including Greece and Spain, haves led and may continue to lead to substantial delays in payment and payment partially with government bonds rather than cash for medicinal drug products, which could negatively impact our revenues and profitability. Moreover, in order to obtain reimbursement of our medicinal products in some countries, including some EU Member States, we may be required to conduct clinical trials that compare the cost-effectiveness of our products to other available therapies. There can be no assurance that our medicinal products will obtain favorable reimbursement status in any country.

If adequate reimbursement levels are not maintained by government and other third-party payors for *Feraheme/Rienso*, our and Takeda's ability to sell *Feraheme/Rienso* may be limited and/or our and Takeda's ability to establish acceptable pricing levels for *Feraheme/Rienso* may be impaired, thereby reducing anticipated revenues and our prospects of achieving profitability. Similarly, if government and other third-party payor reimbursement levels for *MuGard* are not adequate, our ability to sell the product may be limited, as may our ability to establish acceptable pricing levels, which could reduce anticipated revenues and prospects for achieving profitability for *MuGard*.

Backlog

We had a $0.9 million and $1.7 million product sales backlog as of December 31, 2013 and 2012, respectively. These backlogs were largely due to increased orders of our products from Takeda and to the timing of orders received from our third-party logistics provider. Generally, product orders from our customers are fulfilled within a relatively short time of receipt of a customer order.

Employees

As of February 3, 2014, we had 148 employees. We also utilize consultants and independent contractors on a regular basis to assist in the development and commercialization of *Feraheme* and *MuGard*. 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. During 2013, we expanded our leadership team and strengthened our commercial organization and medical affairs teams. We expect to continue these efforts in 2014, including replacing Greg Madison, our Chief Commercial Officer, who resigned from his position, effective February 7, 2014, in order to pursue another opportunity.

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

Foreign Operations

We have no foreign operations. Revenues from customers outside of the U.S. amounted to approximately 11%, 32% and 14% of our total revenues for 2013, 2012 and 2011, respectively, and were principally related to collaboration revenues recognized in connection with our agreement with Takeda, which is headquartered in Japan. During 2012, our revenues from customers outside of the U.S included approximately $20.0 million related to the recognition of upfront payments and milestones achieved under the Amended Takeda Agreement.

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Research and Development

We have dedicated a significant portion of our resources to our efforts to develop our products and product candidates, particularly *Feraheme*. We incurred research and development expenses of $20.6 million, $33.3 million, and $58.1 million during 2013, 2012 and 2011, respectively. We expect our research and development expenses to increase in 2014 due to the timing of expenses related to our pediatric clinical studies and our clinical trial to determine the safety and efficacy of repeat doses of *Feraheme* for the treatment of IDA in patients with hemodialysis dependent CKD. In addition, research and development expenses could increase further depending on the outcome of discussions with the FDA on the regulatory path forward for *Feraheme* in the broad indication and any resulting clinical trials or development efforts that we may undertake.

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

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 U.S. Securities and Exchange Commission, or 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.

For additional information regarding our segments, refer to Note O of the Notes to Financial Statements included in Part II, Item 8 "Financial Statements and Supplementary Data" of this Annual Report on Form 10-K.

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.

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We are primarily dependent on the success of Feraheme/Rienso.

We currently derive and expect to continue to derive substantially all of our revenue from sales of *Feraheme/Rienso* by us in the U.S. and by our licensees, including Takeda Pharmaceutical Company Limited, or Takeda, outside of the U.S. and, therefore, our ability to become profitable is primarily dependent on our and our licensees' successful commercialization and development of *Feraheme/Rienso.* Accordingly, if we are unable to generate sufficient revenues from sales of *Feraheme/Rienso,* or from milestone payments and royalties we may receive related to *Feraheme/Rienso*, we may never be profitable, our financial condition will be materially adversely affected, and our business prospects will be limited.

We intend to continue to dedicate significant resources to the commercialization of *Feraheme/Rienso*. However, we or Takeda may not be successful in our efforts to successfully commercialize *Feraheme/Rienso* in its current indication for patients with iron deficiency anemia, or IDA, associated with chronic kidney disease, or CKD, or to expand the approved indication of *Feraheme/Rienso* to include additional indications. In December 2012, we filed a supplemental New Drug Application, or sNDA, in the U.S. for *Feraheme* in adult patients with IDA who had failed or could not use oral iron. On January 21, 2014, we received a complete response letter from the U.S. Food and Drug Administration, or the FDA, for the sNDA informing us that our sNDA could not be approved in its present form and stating that we have not provided sufficient information to permit labeling of *Feraheme* for safe and effective use for the proposed broader indication. The FDA indicated that its decision was based on the cumulative ferumoxytol data, including the global Phase III IDA program and global post-marketing safety reports since the launch in 2009. The FDA suggested, among other things, that we submit additional clinical trial data in the proposed broad IDA patient population with a primary composite safety endpoint of serious hypersensitivity/anaphylaxis, cardiovascular events and death, events that are included in the labels of *Feraheme* and other IV irons and that have been reported in the post-marketing environment for *Feraheme*. Additionally, the FDA proposed potentially evaluating alternative dosing and/or administration of *Feraheme*. Our plan for addressing the complete response letter from the FDA includes the following steps: (a) evaluate the FDA's recommendations in the complete response letter; (b) develop a proposal that we believe would be responsive to the points raised in the complete response letter and that we determine would be economically viable; (c) meet with FDA to discuss our proposal and explore the range of possible approaches to the points raised in the complete response letter; and (d) assess the FDA's feedback on our proposal and make a final determination on a possible program that would adequately address the FDA's concerns. Depending upon the outcome of such evaluations and discussions, we may decide not to pursue regulatory approval for the broader indication. Until we have further discussions with the FDA and receive its input, we cannot predict the path forward, if any, for *Feraheme* in the broad IDA patient population, including the related timing and cost of any clinical trials. Generating additional clinical trial data is typically costly and time-consuming. Responding to the issues raised by the FDA in the complete response letter and any other issues or requests for information that may be raised by the FDA will likely cause us to incur significant additional costs, experience further delays and may even prevent us from obtaining U.S. regulatory approval for *Feraheme* in the broader IDA population or narrow our currently approved indications, as discussed in more detail in the following risk factor. Any of these results would, in turn, materially adversely impact our cash position, our ability to increase revenues, our ability to achieve profitability, and the future prospects of our business.

In June 2013, Takeda filed an application for Type II Variation of the marketing authorization for *Rienso* in the EU, which is the European Union, or EU, equivalent of a U.S. sNDA, with the European Medicines Agency, or EMA, seeking marketing authorization for an additional therapeutic indication for *Rienso* for the treatment of IDA in adult patients. In addition, in October 2013, Takeda filed a supplemental New Drug Submission, or sNDS, with Health Canada seeking marketing approval for *Feraheme* for the treatment of IDA in a broad range of patients. However, we have little control over Takeda's interactions with the EU or Canadian regulatory agencies and we cannot be assured when or

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if the EMA will issue a positive opinion for the application for variation of the marketing authorization for *Rienso* in the EU. Neither can we be assured when or if the European Commission will adopt a decision approving this variation or Health Canada will approve the filing. Any failure by Takeda to gain marketing approval for *Feraheme/Rienso* for the treatment of IDA regardless of the underlying cause in a timely manner, or at all, could adversely affect our revenues and cash milestones from Takeda, which in turn would adversely affect results of operations or the future prospects of our business.

We are not currently conducting or sponsoring research to expand our product development pipeline beyond *Feraheme/Rienso.* However, we expect to continue with our efforts to complete additional business development transactions, such as in-licensing, acquisitions or collaborations that would be complementary to our business. For example, in June 2013, we entered into a license agreement with Access Pharmaceuticals, Inc., or Access, pursuant to which we acquired the U.S. commercial rights to market and sell MuGard® Mucoadhesive Oral Wound Rinse for the management of oral mucositis, or the MuGard Rights. Even if we continue to expand our product portfolio, our revenues and operations may not be as diversified as some of our competitors who may have numerous products or product candidates.

Our ability to grow revenues from U.S. sales of Feraheme is limited to the IDA-CKD market given that we have not received regulatory approval to market and sell Feraheme to the broader IDA patient population and may be further limited if we are required to provide additional warnings and/or restrictions related to Feraheme's current or future indications.

As discussed above, in December 2012, we submitted an sNDA to the FDA for *Feraheme* for the treatment of IDA in a broad range of patients and we received a complete response letter from the FDA on January 21, 2014 informing us that our sNDA could not be approved in its present form. In the letter, the FDA stated that we have not provided sufficient information to permit labeling of *Feraheme* for safe and effective use for the proposed indication. This decision by the FDA represents a significant set-back in our efforts to obtain U.S. approval for *Feraheme* for a broader indication as the issues raised and information requested by the FDA may be costly and time-consuming to address. Further, there is no guarantee that any efforts that we decide to undertake will meet the FDA's requirements, and we may not receive approval at all for *Feraheme* in a broader indication.

Evaluation of the content and recommendations of the FDA's complete response letter and further discussions with the FDA may cause us to decide not to pursue regulatory approval for the broader indication. If we continue to pursue approval in the U.S. for the commercial marketing and sale of *Feraheme* for the broad IDA indication, we will have to demonstrate, through the submission of clinical study reports and data sets from one or more prospective, multicenter, randomized controlled trials, or the proposed clinical trials, that the benefit of *Feraheme* use in the proposed population would warrant the risks associated with *Feraheme*, including the potential for adverse events, including anaphylaxis, cardiovascular events, and death. The FDA advised that such trials should address mechanisms to reduce the risk for serious, including fatal, hypersensitivity reactions. Conducting these and other clinical trials is a complex, time-consuming and expensive process that requires adherence to a wide range of regulatory requirements. Depending on the incidence rate of the safety end-point being studied, these studies could require a significant number of patients such that the study cannot be enrolled in a reasonable time or at a reasonable cost to support commercialization. The FDA has substantial discretion in the approval process and may decide that the results of any such additional trials and the information we submit seeking approval in the broader patient population or was otherwise reviewed, including post-marketing safety data, including reports of serious anaphylaxis, cardiovascular events, and death, or any information we provide in response to FDA requests, are insufficient for approval or that *Feraheme* is not effective or safe for the proposed broader indication. For example, in our Phase III clinical trial in the broader patient population, *Feraheme*-treated patients experienced a 0.6% rate of related serious adverse events, or SAEs, as compared to a 0.2% rate of

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related SAEs from our current *Feraheme* label for the treatment of IDA in adult patients with CKD. The FDA indicated that its decision outlined in the complete response letter was based on the cumulative ferumoxytol data, including the global Phase III IDA program and global post-marketing safety reports. In addition, clinical and other data is often susceptible to varying interpretations, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain FDA approval for their products. The clinical trials for the broader patient population included patients with various underlying conditions, or subpopulations, in addition to having IDA, and any additional clinical trials will likely have a similar mix of patients. There is no guarantee that the FDA will determine that the results of our clinical trials of *Feraheme* for the treatment of IDA in adult patients who have failed or could not tolerate oral iron (including any proposed clinical trials) will adequately support approval of *Feraheme* in this broader patient population, or any of the individual subpopulations of IDA patients, to grant approval.

The FDA could also determine that our clinical trials (including any proposed clinical trials) and/or our manufacturing processes were not properly designed, did not include enough patients or appropriate administration, were not conducted in accordance with applicable laws and regulations, or were otherwise not properly managed. In addition, under the FDA's current good clinical practices regulations, or cGCP, we are responsible for conducting, recording and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the trial participants are adequately protected. The FDA may conduct inspections of clinical investigator sites which are involved in our clinical development programs to ensure their compliance with cGCP regulations. If the FDA determines that we, our clinical research organizations, or CROs, or our study sites fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials (including the proposed clinical trials) may be deemed unreliable and the FDA may disqualify certain data generated from those sites or require us to perform additional clinical trials before approving our marketing application, which could further adversely impact our ability to obtain marketing approval in the U.S. for *Feraheme* in the broad IDA indication. Any such deficiency in the design, implementation or oversight of our clinical development programs could cause us to incur significant additional costs, experience further delays or prevent us from obtaining marketing approval for *Feraheme* for the broad IDA indication.

As a result of any information submitted to the FDA in our regulatory filings or in response to any information requests or issues raised by the FDA during the review of our regulatory filings, including the FDA's review of post-marketing safety data in connection with our sNDA and any reevaluation by the FDA of existing data, such as reports of serious anaphylaxis, cardiovascular events, and death, the FDA may request additional information. The additional information may include technical or scientific information, new studies or reanalysis of existing data or risk evaluation and mitigation strategies in the current indication, or we may be required to provide additional warnings and/or restrictions on our current or future *Feraheme* package inserts, notify healthcare providers of changes to the package insert, narrow our currently approved or proposed indications, alter or terminate current or future trials for *Feraheme* or incur significant costs related to post-marketing requirements/commitments, which could put us at a disadvantage to our competitors. Our efforts to obtain approval for the broad IDA indication could adversely affect the commercialization of *Feraheme* in its current indication.

If, for any of these or other reasons, we do not obtain U.S. approval to market and sell *Feraheme* for the treatment of IDA in a broad range of patients, if our current indication is narrowed, if we are required to include additional warnings and/or restrictions on the *Feraheme/Rienso* package insert, including a boxed warning in the U.S. or similar warnings outside of the U.S., or if we experience additional significant delays or setbacks in obtaining approval, or if we receive approval with significant restrictions to our current or proposed package inserts, or are required to incur significant costs as post-marketing commitments, our cash position, our ability to increase revenues, our ability to achieve profitability, and the future prospects of our business could be materially adversely affected.

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Significant safety or drug interaction problems, or the evaluation or reevaluation of existing or future data by the FDA or other regulators, could result in restrictions in the Feraheme/Rienso label, recalls, withdrawal of Feraheme/Rienso from the market, an adverse impact on Feraheme/Rienso sales, our need to alter or terminate current or future Feraheme development programs, and/or a negative impact on the approval and/or timing of our current or future sNDAs, any of which would adversely impact our future business prospects.

Significant safety or drug interaction problems with respect to *Feraheme/Rienso*, including an increase in the severity or frequency of known problems or the discovery of previously unknown problems, or the evaluation or reevaluation of existing or future data by the FDA or other regulators, could result in a variety of adverse regulatory actions. In the U.S., under the Federal Food, Drug and Cosmetic Act, the FDA has broad authority to force drug manufacturers to take any number of actions if safety or drug interaction problems arise, including, but not limited to the following:

Requiring manufacturers to conduct post-approval clinical studies to assess known risks or signals of serious risks, or to identify unexpected serious risks;

Mandating labeling changes to a product based on new safety information; or

Requiring manufacturers to implement a Risk Evaluation Mitigation Strategy where necessary to assure safe use of the drug.

Similar laws and regulations exist in countries outside of the U.S. In addition, unknown safety or drug interaction problems could result in product recalls, restrictions on the product's permissible uses, a negative impact on our current or future sNDAs or withdrawal of the product from the U.S. and/or foreign markets.

For example, in November 2010, following discussions with the FDA, we revised the *Feraheme* package insert, which includes essential information regarding the FDA-approved use of *Feraheme*, including, among other things, the approved indication, side effects, and dosage instructions, to include bolded warnings and precautions that describe events that have been reported during post-marketing review after *Feraheme* administration, including life-threatening hypersensitivity reactions and clinically significant hypotension. We notified healthcare providers of the changes to the *Feraheme* package insert. In June 2011, we made further changes to the *Feraheme* package insert based on additional post-marketing data. These or any future changes to the *Feraheme/Rienso* package insert could adversely impact our or Takeda's ability to successfully compete in the IV iron market and could have an adverse impact on potential sales of *Feraheme* and our future business prospects.

Also, on June 27, 2013 the EMA's Committee for Medicinal Products for Human Use, or CHMP, completed a review of IV iron-containing medications used to treat iron deficiency and anemia. The CHMP concluded that the benefits of these medications are greater than their risks, provided that adequate measures are taken to ensure the early detection and effective management of allergic reactions that may occur. The measures include ensuring that these products be given in an environment where patients who develop an allergic reaction can be treated immediately, ceasing to rely on a lack of allergic reaction to a test dose as an indication of tolerance of larger doses and amendments to the package leaflet. The CHMP recommendation was sent to the European Commission, which on September 13, 2013 endorsed it and adopted a final decision that is legally binding throughout the EU. Although *Rienso* was not included in the evaluation, Takeda is in the process of adopting the recommendations, including updates to the label in the EU to harmonize *Rienso's* label with those of other IV irons included in the review.

The data submitted to both the FDA as part of our NDA and sNDA and to the EMA as part of the Marketing Authorization Application for *Feraheme/Rienso* in the CKD indication was obtained in controlled clinical trials of limited duration. New safety or drug interaction issues may arise as *Feraheme/Rienso* is used over longer periods of time by a wider group of patients, some of whom may be taking other medicines or by patients with additional underlying health problems. As previously discussed, the FDA recently issued a complete response letter for our sNDA that sought expansion of

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the indication for *Feraheme*; the complete response letter concluded that the sNDA could not be approved as submitted because we have not provided sufficient information to permit labeling of *Feraheme* for safe and effective use for the proposed indication. The FDA indicated that its decision was based on the cumulative ferumoxytol data, including the global Phase III IDA program and global post-marketing safety reports. In addition, as we conduct and complete other clinical trials for *Feraheme*, new safety issues may be identified which could negatively impact our ability to successfully complete these studies, the use and/or regulatory status of *Feraheme/Rienso* for the treatment of IDA in patients with CKD in the U.S., EU or other territories, and the prospects for approval if we continue to pursue a broader indication for *Feraheme* for the treatment of IDA regardless of the underlying cause. For example, even if we conduct additional clinical studies, the FDA may determine that any application for *Feraheme* for the treatment of IDA in adult patients who have failed or could not tolerate oral iron does not establish a sufficiently acceptable safety profile for the approval of a broader *Feraheme* label in the U.S.

As more data become available and an increased number of patients are treated with *Feraheme/Rienso*, new or increased safety or drug interaction issues may require us to, among other things, provide additional warnings and/or restrictions on the *Feraheme/Rienso* package insert, including a boxed warning in the U.S., notify healthcare providers of new safety information, narrow our approved indications, alter or terminate current or future trials for additional uses of *Feraheme*, or even remove *Feraheme/Rienso* from the market, any of which could have a significant adverse impact on potential sales of *Feraheme/Rienso* or require us to expend significant additional funds. For example, in May 2013, Takeda recalled a single batch of *Rienso* from the Swiss market after becoming aware of four post-marketing adverse event reports relating to potential anaphylaxis/hypersensitivity reactions of varying severity following the administration of *Rienso*. One of these cases included a report of a fatality. The marketing authorization for *Rienso* and other IV iron formulations include, among their special warnings and precautions for use, an indication that the products may cause hypersensitivity reactions including serious and life-threatening anaphylactic/anaphylactoid reactions. The recalled batch was only distributed to and sold in Switzerland and the recall was limited to the specific batch in Switzerland. We and Takeda have completed an investigation regarding the specific Swiss batch of *Rienso,* which we believe did not identify any issues which would have impacted the quality of the recalled batch, and we gathered all available information for the reported adverse events. Takeda has filed a report with SwissMedic, the Swiss Agency for Therapeutic Products, and we and Takeda are awaiting feedback on SwissMedic's review of the findings from the investigation. We and Takeda are currently working with the Swiss authorities and are unable to predict when or if *Rienso* will be reintroduced into the Swiss market.

Competition in the pharmaceutical and biopharmaceutical industries is intense. If we fail to compete effectively, our business and market position will suffer.

The pharmaceutical and biopharmaceutical industry is intensely competitive and subject to rapid technological change. Many of our competitors 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. Our competitors may develop products that are more widely accepted than ours and may receive patent protection that dominates, blocks or adversely affects our product development or business.

The markets for our current products are highly sensitive to several factors including, but not limited to the following:

- The actual and perceived safety and efficacy profile of the available products;
- The approved indication for each of the available products;
- The ability to obtain appropriate insurance coverage and reimbursement rates and terms;

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Price competitiveness; and

Product characteristics such as convenience of administration and dosing regimens.

The introduction by our competitors of alternatives to *Feraheme/Rienso* or *MuGard* that would be, or are perceived to be, more efficacious, safer, less expensive, easier to administer, available for a broader patient population, or provide more favorable insurance coverage or reimbursement could reduce our revenues and the value of our product development efforts.

Feraheme/Rienso may not receive the same level of market acceptance as competing iron replacement therapy products, in part because most of these products have been on the market longer and are currently widely used by physicians in the U.S. and abroad. In addition, the recent CHMP review of IV iron-containing medications used to treat iron deficiency and anemia (which concluded that the benefits of these medications are greater than their risks, provided that adequate measures are taken to ensure the early detection and effective management of allergic reactions that may occur, including ensuring that these products be given in an environment where patients who develop an allergic reaction can be treated immediately and ceasing to rely on a lack of allergic reaction to a test dose as an indication of tolerance of larger doses) could cause physicians to elect non-IV iron alternatives which may be easier to administer or dose or which may be perceived as less risky.

In addition, *Feraheme* currently competes with several IV iron replacement therapies in the U.S., certain of which are approved for the treatment of IDA in a broader group of patients than *Feraheme.* For example, in July 2013, Injectafer®, which is known as Ferinject® in Europe and is discussed below, was approved by the FDA for the treatment of IDA in adult patients who have an unsatisfactory response to oral iron or who have intolerance to oral iron, which is a broader indication than our current *Feraheme* indication. Injectafer® is approved in the U.S. with a recommended dose of two slow injections or infusion of 750 milligrams each separated by at least seven days apart for a total of 1,500 milligrams. While this dosing regimen is different from *Feraheme*, it does offer similar convenience benefits to *Feraheme* for patients and healthcare providers. Injectafer® is also priced at a significant premium to many other IV irons providing it more opportunity to offer discounts, incentives and rebates to new or existing customers to attract new business. The recent decision by the FDA that we have not provided sufficient information to permit labeling of *Feraheme* for safe and effective use for the proposed indication, will likely make it more difficult for us to compete with Injectafer® in certain customers in the U.S., because Injectafer® has been approved for a broader patient population than *Feraheme*. Even if we continue to seek and eventually obtain labeling of *Feraheme* in a broader population, Injectafer® will have already been available for a considerable period of time. During this period, physicians may increase their use of Injectafer® and gain familiarity with the product making it more difficult for us to cause these physicians to use *Feraheme* in the future. In addition, Injectafer® may enter into commercial contracts with key customers or group purchasing organizations, or GPOs, during this period, which could prevent or make it more difficult for *Feraheme* to retain its existing customers, gain sales to new customers and gain market share in its existing indication with customers or GPOs, if we were to continue to seek and receive approval for the broader patient population in the future. Injectafer®'s U.S. approval or the approval of any other iron replacement product for a broader IDA indication than *Feraheme*, could adversely affect our efforts to market and sell *Feraheme* in the U.S. and our ability to generate additional revenues and achieve profitability.

Feraheme/Rienso also competes with a number of branded IV iron replacement and certain other iron dextran and iron sucrose products outside of the U.S., such as Ferinject® (ferric carboxymaltose injection), which is an IV iron replacement therapy currently approved for marketing in approximately 47 countries worldwide for the treatment of IDA where oral iron is ineffective or cannot be used. If Takeda is unable to convince physicians and other healthcare providers to switch from using the competing IV iron products to *Feraheme/Rienso,* our ability to generate revenues from royalties we may receive from Takeda will be limited and our operating results will be negatively affected. In addition, all other IV iron products currently approved and marketed and sold in the EU are approved for

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marketing to a broader group of patients with IDA. *Feraheme/Rienso* was approved only for use in adult CKD patients, which could put *Feraheme/Rienso* at a competitive disadvantage unless and until it receives approval for a broader indication outside of the U.S. If we or Takeda are not able to differentiate *Feraheme/Rienso* from other marketed IV iron products, our ability to maintain a premium price, our ability to generate revenues and achieve and maintain profitability, and our long-term business prospects could be adversely affected.

There are other companies in the U.S. commercializing products for the management or treatment of oral mucositis that may compete with *MuGard* including (a) NeutraSal® (supersaturated calcium phosphate rinse), a prescription mouth rinse marketed by Invado Pharmaceuticals, LLC; (b) Caphosol® a supersaturated calcium phosphate artificial saliva used as an adjunct to other oral care which is marketed by Jazz Pharmaceuticals, PLC; and (c) Kepivance® (palifermin) an IV human growth factor which is marketed by Swedish Orphan Biovitrum AB. In addition, there are several marketed products available which are indicated for the management of pain associated with oral mucositis including (a) Episil, which is marketed by Cangene BioPharma, Inc.; (b) Gelclair®, which is marketed by DARA BioSciences; and (c) GelX Oral Gel, which is marketed by Praelia Pharmaceuticals, Inc. If we are not able to differentiate *MuGard* from other marketed products for the management or treatment of oral mucositis, our ability to generate additional revenues could be adversely affected.

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

As part of our business strategy to expand our product portfolio and achieve profitability, we are seeking to acquire or in-license other products, or acquire businesses that have a commercialized product or products, that we believe would be complementary to our existing business. For example, in June 2013, we entered into a license agreement with Access, under which we acquired the MuGard Rights. We have limited experience with respect to these business development activities and there can be no assurance that we will be able to identify or complete any such transaction in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated financial benefits of any such transaction, including *MuGard*. The valuation methods that we use for any acquired product or business requires significant judgment and assumptions. Actual results and performance of the product or business that we acquire could differ significantly from our original assumptions, especially during the periods immediately following the closing of the transaction. In addition, acquisitions may cause significant changes to our current structure, 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. We may not be successful in acquiring or in-licensing a product, product candidate or business that will provide us with commercial, development and/or financial synergies with *Feraheme* and our current organization such that we will be able to eliminate expenses either from our existing operations or from the cost structure of the acquired product.

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

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require management resources that otherwise would be available for ongoing development of our existing business and our U.S. commercialization of *Feraheme*. In addition, to finance any such strategic transactions, we may choose to issue shares of our common or preferred stock as consideration, which would result in dilution to our stockholders. Alternatively, it may be necessary for us to raise additional funds through public or private financings, and such additional funds may not be available on terms that are favorable to us, if at all. 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.

We may not realize the anticipated benefits of the acquisition of the MuGard Rights or any future acquisitions or product licenses and the integration of the MuGard Rights or any future acquisitions and any products or product candidates acquired or licensed may disrupt our business and management.

We have and we may in the future acquire or in-license additional specialty pharmaceutical products such as we did with *MuGard*. The integration of the operations of acquired products or businesses, including *MuGard*, requires significant efforts, including the coordination of information technologies, sales and marketing, operations, manufacturing, safety and pharmacovigilance, medical and finance. These efforts result in additional expenses and involve significant amounts of management's time. In addition, we rely on Access, and may in the future have to rely on such other parties with whom we may enter into a future agreement, to perform certain regulatory filings, oversee certain functions, such as pharmacovigilance or the manufacture of the product we license from them, and any failure of Access or any other party to perform these functions for any reason, including ceasing doing business, could have a material effect on our ability to commercialize *MuGard* or any other future product we may acquire. We may not realize the anticipated benefits of the MuGard Rights or any future acquisition, license or collaboration, any of which involves numerous risks including the following:

- Difficulty in integrating the products or product candidates into our business;
- Entry into markets in which we have no or limited direct prior experience, including device markets, and where competitors in such markets have stronger market positions;
- Failure to achieve our strategic objectives, including successfully commercializing and marketing *MuGard* or any other products we may acquire;
- Our ability to train our sales force, and the ability of our sales force, to incorporate successfully new products and devices, including *MuGard*, into their call points;
- Additional legal and/or compliance risk associated with the acquisition of *MuGard* or any other future product;
- The introduction by our competitors of alternatives to *MuGard* that would be, or are perceived to be, more efficacious, safer, less expensive, easier to administer, or provide more favorable insurance coverage or reimbursement could reduce our revenues and the value of our product development efforts;
- Potential write-offs of intangible assets or adjustments to contingent consideration related to estimates we make in the accounting for acquisitions or product licenses, including *MuGard*, and any resulting impact that may have on our quarterly financial results; and
- Disruption of our ongoing business and distraction of our management and employees from other opportunities or our core business functions, including *Feraheme/Rienso*.

If we cannot successfully integrate the *MuGard* business, or other businesses we may acquire, into our company, we may experience material negative consequences to our business, financial condition or results of operations. We cannot assure you that, following any such

acquisitions, including *MuGard*, we will achieve the expected synergies to justify the transaction.

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We are completely dependent on third parties to manufacture our commercial products, including Feraheme/Rienso, and any difficulties, disruptions or delays in the Feraheme/Rienso manufacturing process, including any transition to alternative source manufacturing facilities, could increase our costs, impact our ability to meet our or Takeda's demand forecasts, or adversely affect our profitability and future business prospects.

In 2012, we ceased our manufacturing operations at our Cambridge, Massachusetts manufacturing facility. Consequently, we do not own or operate, and currently do not plan to own or operate, facilities for the manufacture of *Feraheme/Rienso* or our other commercial products, including *MuGard.* We currently rely solely on our third-party contract manufacturers to manufacture *Feraheme/Rienso* for our commercial and clinical use and rely on Access for the manufacture of *MuGard*. We do not currently have an alternative manufacturer for our *Feraheme/Rienso* drug substance and finished drug product and we may not be able to enter into agreements with second source manufacturers whose facilities and procedures comply with current good manufacturing practices, or cGMP, regulations and other regulatory requirements on a timely basis and with terms that are favorable to us, if at all.

Our ability to have our products, including *Feraheme/Rienso* and *MuGard* manufactured in sufficient quantities and at acceptable costs to meet our commercial demand and clinical development needs is dependent on the uninterrupted and efficient operation of our third-party contract manufacturing facilities. Any difficulties, disruptions or delays in the manufacturing process could result in product defects or shipment delays, recall or withdrawal of product previously shipped for commercial or clinical purposes, inventory write-offs or the inability to meet commercial demand in a timely and cost-effective manner. Furthermore, our current third-party manufacturer for *Feraheme/Rienso* does not manufacture for us exclusively and may exhaust some or all of its resources meeting the demand of other customers. Any potential manufacturing delays resulting from insufficient manufacturing capacity due to scheduling conflicts at our third-party manufacturers to produce sufficient quantities of *Feraheme/Rienso* to meet our demand forecasts or any other difficulties in our manufacturing process could result in our inability to meet our commercial demand for *Feraheme/Rienso*.

In addition, securing additional third-party contract manufacturers for *Feraheme/Rienso* will require significant time for transitioning the necessary manufacturing processes, gaining regulatory approval, and for having the appropriate oversight and may increase the risk of certain problems, including cost overruns, process reproducibility, stability issues, the inability to deliver required quantities of product that conform to specifications in a timely manner, or the inability to manufacture *Feraheme/Rienso* in accordance with cGMP. If we are unable to have *Feraheme/Rienso* manufactured on a timely or sufficient basis because of these or other factors, we may not be able to meet commercial demand or our clinical development needs for *Feraheme/Rienso* or may not be able to manufacture *Feraheme/Rienso* in a cost-effective manner, particularly in light of the current fixed price at which we are required to supply *Feraheme/Rienso* to Takeda under our License, Development and Commercialization Agreement, as amended in June 2012, or the Amended Takeda Agreement. As a result, we may lose sales, fail to generate increased revenues, fail to launch the product in markets that cannot support a price in excess of our costs, suffer regulatory setbacks and/or we may lose money on our supply of *Feraheme/Rienso* to Takeda, any of which could have an adverse impact on our potential profitability and future business prospects.

Contract manufacturers may not be able to operate their manufacturing facilities in compliance with cGMP, release specifications and other FDA and equivalent foreign regulations, which could result in a suspension of our contract manufacturers' ability to manufacture Feraheme/Rienso or MuGard, the loss of Feraheme/Rienso or MuGard inventory, an inability to manufacture sufficient quantities of Feraheme/Rienso and MuGard to meet U.S. or foreign demand, as applicable, or other unanticipated compliance costs.

Our third-party contract manufacturing facilities are subject to cGMP regulations enforced by the FDA and equivalent foreign regulatory regulations and agencies through periodic inspections to

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confirm such compliance. Similarly, we rely on Access for the manufacture of *MuGard* and any third-party contract manufacturing facilities engaged by Access are subject to cGMP regulations. 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 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, including *Feraheme/Rienso* and *MuGard* from the marketplace, total or partial suspension of *Feraheme/Rienso* or *MuGard* production, the loss of *Feraheme/Rienso* inventory or the inability of Access to supply sufficient *MuGard* inventory, suspension of the review of our current or any future sNDAs or equivalent foreign filings, enforcement actions, injunctions or criminal prosecution. 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, including *Feraheme/Rienso* and *MuGard*, and could have a severe adverse impact on our potential profitability and the future prospects of our business. If any U.S. or foreign regulatory agency inspects any of these manufacturing facilities and determines that they are not in compliance with cGMP or similar regulations or our or Access's 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 *Feraheme/Rienso* to meet U.S. or foreign demand and of *MuGar*d to meet U.S. demand, or incur unanticipated compliance expenditures.

We have also established certain testing and release specifications with the FDA and other foreign regulatory agencies. This release testing must be performed in order to allow the finished product to be used for commercial sale. If our finished product does not meet these release specifications or if the release testing is variable, we may not be able to supply product to meet our projected demand. We monitor each batch of *Feraheme/Rienso* for ongoing stability after it has been released for commercial sale. If a particular batch 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. In addition, variations in the regulatory approval of *Feraheme/Rienso* in the currently approved territories require that our third-party manufacturers follow different manufacturing processes and analytical testing methods. If we are unable to develop, validate, transfer or gain regulatory approval for the new release test, our ability to supply product to the EU will be adversely affected. Such setbacks could have an adverse impact on *Feraheme/Rienso* sales, our potential profitability and the future prospects of our business.

The success of Feraheme and MuGard in the U.S. depends on our ability to maintain the proprietary nature of our technology.

We rely on a combination of patents, trademarks and copyrights in the conduct of our business. The patent positions of pharmaceutical and biopharmaceutical firms are generally uncertain and involve complex legal and factual questions. We may not be successful or timely in obtaining any patents for which we submit applications. The breadth of the claims obtained in our patents may not provide sufficient protection for our technology. The degree of protection afforded by patents for proprietary or licensed technologies or for future discoveries may not be adequate to preserve our ability to protect or commercially exploit those technologies or discoveries. The patents issued to us may provide us with little or no competitive advantage. In addition, there is a risk that others will independently develop or duplicate similar technology or products or circumvent the patents issued to us.

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Our *Feraheme* patents currently expire in 2020, however, our primary U.S. patent for *Feraheme* may be subject to an extension to 2023 under U.S. patent law and FDA regulations. Our licensed patents relating to *MuGard* expire in 2022. These and any other patents issued to us may be contested or invalidated. There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. We may become a party to patent litigation and other proceedings, including interference and reexamination proceedings declared by the United States Patent and Trademark Office. Further, our licensed patent rights to *MuGard* may not prevent competitors from independently developing and marketing a competing product that does not infringe our licensed patents or other intellectual property.

In addition, claims of infringement or violation of the proprietary rights of others may be asserted against us. If we are required to defend against such claims or to protect our own proprietary rights against others, it could result in substantial financial and business costs, including the business cost attributable to the resulting distraction of our management. An adverse ruling in any litigation or administrative proceeding could prevent us from marketing and selling *Feraheme*, increase the risk that a generic version of *Feraheme* could enter the market to compete with *Feraheme*, limit our development and commercialization of *Feraheme*, or otherwise harm our competitive position and result in additional significant costs. In addition, any successful claim of infringement asserted against us could subject us to monetary damages or an injunction, preventing us from making or selling *Feraheme*. We also may be required to obtain licenses to use the relevant technology. Such licenses may not be available on commercially reasonable terms, if at all. Frequently, the unpredictable nature and significant costs of patent litigation leads the parties to settle to remove this uncertainty. Settlement agreements between branded companies and generic applicants may allow, among other things, a generic product to enter the market prior to the expiration of any or all of the applicable patents covering the branded product, either through the introduction of an authorized generic or by providing a license to the applicant for the patents in suit. Moreover, *MuGard* is subject to many of the same third party infringement risks that *Feraheme* is subject to.

We also rely upon unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our corporate licensees, collaborators, contract manufacturers, employees and consultants. These agreements, however, may be breached. We may not have adequate remedies for any such breaches, and our trade secrets might otherwise become known or might be independently discovered by our competitors. In addition, we cannot be certain that others will not independently develop substantially equivalent or superseding proprietary technology, or that an equivalent product will not be marketed in competition with *Feraheme* or *MuGard*, thereby substantially reducing the value of our proprietary rights. Our inability to protect *Feraheme* or *MuGard* through our patents and other intellectual property rights prior to their expiration could have a material adverse effect on our business, financial condition and prospects.

Competitors could file applications seeking a path to U.S. approval of a generic ferumoxytol.

Under Sections 505(c)(3)(E)(ii) and Section 505(j)(5)(F)(ii) of the Federal Food, Drug, and Cosmetic Act, or FDCA, a new chemical entity, or NCE, may be eligible for five years of marketing exclusivity in the U.S. following regulatory approval. A drug can be classified as an NCE if the FDA has not previously approved any other drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. In 2009, the FDA determined that ferumoxytol did not qualify as an NCE and instead granted *Feraheme* a three-year "new use" market exclusivity, which expired in June 2012. In March 2010 and December 2012, we formally requested that the FDA reconsider its determination with respect to *Feraheme's* NCE status. The FDA may deny our request for reconsideration of NCE status for *Feraheme*, in which case *Feraheme* may be subjected to early

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generic competition. Even if *Feraheme* is granted NCE status, we would only gain marketing exclusivity until June 2014.

Generic ferumoxytol competitors could enter the market through approval of abbreviated new drug applications, or ANDAs, that use *Feraheme* as a reference listed drug, which would allow generic competitors to rely on *Feraheme's* safety and effectiveness trials instead of conducting their own studies. NCE exclusivity, if granted, would preclude approval during the exclusivity period of ANDAs, as well as 505(b)(2) new drug applications, or NDAs, that rely on the FDA's finding of safety and effectiveness for *Feraheme*. An ANDA may be submitted four years after approval of a subject drug with a five-year exclusivity period if the ANDA contains a certification of patent invalidity or non-infringement, known as a "Paragraph IV certification," with respect to patents listed for *Feraheme* in the Orange Book. In recent years, generic manufacturers have used Paragraph IV certifications extensively to challenge the protection of Orange Book-listed patents on a wide array of innovative pharmaceuticals, and we expect this trend to continue. If we are not able to gain or exploit marketing exclusivity beyond the initial three-year exclusivity period that expired in June 2012, we may face significant future competitive threats to our commercialization of *Feraheme* from other manufacturers, including the manufacturers of generic alternatives through the submission of ANDAs. Further, even if *Feraheme* is granted NCE status, another company could challenge that decision and seek to overturn the FDA's determination.

In addition, in December 2012, the FDA published a draft guidance containing product-specific bioequivalence recommendations for drug products containing ferumoxytol. The FDA generally publishes product-specific bioequivalence guidance after it has received an inquiry from a generic drug manufacturer about submitting an ANDA for the product in question; thus, it is possible that a generic drug manufacturer has approached the FDA requesting guidance about submitting an ANDA for ferumoxytol, the active ingredient in *Feraheme*, and that such an ANDA may be filed in the near future. Because the FDA may deny our request for reconsideration of NCE status for *Feraheme,* and because NCE exclusivity would expire in June 2014 even if granted, the published bioequivalence guidance could encourage a generic entrant seeking a path to approval of a generic ferumoxytol to file an ANDA. As a result, we could face generic competition in the near-term or have to engage in extensive litigation with a generic competitor to protect our patent rights, either of which could adversely affect our business and results of operations. In July 2013, we filed a citizen petition requesting that the FDA not approve any ANDAs for a generic ferumoxytol product until FDA completes certain planned studies addressing concerns with other generic IV iron products and imposes additional bioequivalence requirements for sponsors seeking approval of generic ferumoxytol products. However, we cannot predict when or if the FDA will respond or otherwise take any action with respect to the Citizen Petition. 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 U.S. sales and any royalties and milestones we may receive from Takeda, which would have an adverse impact on our business and results of operations.

We are substantially dependent upon our collaboration with Takeda to commercialize Feraheme/Rienso in certain regions outside of the U.S., including Canada, Switzerland and the EU, and if Takeda fails to successfully fulfill its obligations, or is ineffective or unsuccessful in the regulatory approval process or commercialization of Feraheme/Rienso in its licensed territories, or if our collaboration is terminated, our plans to commercialize Feraheme/Rienso outside of the U.S. may be adversely affected.

In March 2010, we entered into our initial agreement with Takeda, which was amended in June 2012, under which we granted exclusive rights to Takeda to develop and commercialize *Feraheme/Rienso* as a therapeutic agent in Europe, certain Asia-Pacific countries (excluding Japan, China and Taiwan), Canada, India and Turkey, or the Licensed Territories. We are highly dependent on Takeda for certain

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regulatory filings outside of the U.S. with respect to *Feraheme/Rienso* and the commercialization of *Feraheme/Rienso* outside of the U.S., including in Canada, Switzerland and the EU. Takeda is in the early stages of the launch of *Feraheme/Rienso* for the treatment of IDA in CKD patients in Canada and the EU, and therefore, revenues from sales of *Feraheme/Rienso* in these territories are not currently a material part of ours or Takeda's business. In June 2013, Takeda filed an application for Type II Variation of the marketing authorization for *Rienso* in the EU with the EMA seeking marketing authorization for an additional therapeutic indication for *Rienso* for the treatment of IDA in adult patients, and in October 2013 Takeda filed a sNDS with Health Canada seeking marketing approval for *Feraheme* for the treatment of IDA in a broad range of patients. It is unclear whether the FDA's January 2014 complete response letter regarding our sNDA for *Feraheme* for the treatment of IDA in a broad range of patients will have any impact on the outcome of Takeda's efforts, but, any regulatory action taken by the FDA with respect to a product under review in the U.S. has the potential to affect the regulatory requirements or decisions made by certain foreign regulatory bodies with regard to the regulatory approval of products outside of the U.S.

To receive regulatory approval outside of the U.S. for the commercial marketing and sale of *Feraheme/Rienso* for the broad IDA indication Takeda will have to demonstrate that *Feraheme/Rienso* is of good quality, safe and effective for use in the broader patient population. The ability to and the extent to which Takeda obtains regulatory approvals for *Feraheme/Rienso* for the treatment of IDA in a broad range of patients in the Licensed Territories and the level of success of Takeda's current and future commercialization efforts outside of the U.S. would be significantly harmed as the result of a number of factors, including but not limited to the following:

If the currently approved CKD indication is narrowed;

If *Feraheme/Rienso* is linked to serious unexpected adverse reaction in patients;

If Takeda experiences significant delays or setbacks in obtaining approval in the broad IDA patient population;

If approval is granted with significant restrictions to the current or proposed package inset;

If Takeda is required to incur significant costs as post-marketing commitments;

If Takeda is ineffective in its commercialization of *Feraheme/Rienso* in the agreed-upon territories;

If revenues fail to materialize due to market, competitive or pricing dynamics in Takeda's territories; and

If we fail to effectively manage our relationship with Takeda.

All of the above factors would have an adverse effect on future royalties or milestone payments we may receive from Takeda, including a significant milestone payment for grant of marketing authorization in the EU for *Rienso* for broader therapeutic indication.

Further, if we fail to fulfill certain of our obligations under the Amended Takeda Agreement, Takeda has the right to assume the responsibility of clinical development and manufacturing of *Feraheme/Rienso* in the agreed-upon territories, which would increase the cost of and potentially delay the *Feraheme/Rienso* development program outside of the U.S.

Takeda has the unilateral right to terminate the Amended Takeda Agreement under certain conditions, including without cause or if it determines in good faith that the continued development of *Rienso* would not be in the best interest of patient welfare. If Takeda terminates the agreement and we chose to continue to commercialize *Feraheme/Rienso* in Takeda's territories, we would be required to either enter into alternative arrangements with third parties to commercialize *Feraheme/Rienso* in Takeda's territories, which we may be unable to do in a timely and cost effective manner, or at all, or

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to increase our internal infrastructure, both of which would likely result in significant additional expense and the disruption or failure of commercial efforts outside of the U.S. In order to continue commercialization efforts, we would also have to assume the full cost of any post-marketing commitments, both currently and in the future, some of which are Takeda's responsibility under a cost-sharing arrangement. In addition, such a termination would prevent us from receiving the milestone payments and royalties we may otherwise receive under the Amended Takeda Agreement.

The success of Feraheme/Rienso abroad depends on our ability to protect our intellectual property rights and the laws of foreign countries may not provide the same level of protection as do the laws of the U.S.

The laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the U.S. and therefore, in addition to similar risks to those described above under the heading "*The success of Feraheme and MuGard in the U.S. depends on our ability to maintain the proprietary nature of our technology,"* our intellectual property rights may be subject to increased risk abroad, including opposition proceedings before the patent offices for other countries, such as the European Patent Office, or the EPO, or similar adversarial proceedings, regarding intellectual property rights with respect to *Feraheme/Rienso*. For example, in July 2010, Sandoz GmbH, or Sandoz, filed with the EPO an opposition to one of our previously issued patents which covers ferumoxytol in the EU. In October 2012, at an oral hearing, the Opposition Division of the EPO revoked our European ferumoxytol patent. In December 2012, our notice of appeal was recorded with the EPO. The appeals process is costly and time-consuming and if it results in an unfavorable outcome to us, it could result in a loss of proprietary rights in the EU and may allow Sandoz or other companies to use our proprietary technology without a license from us, which may also result in a loss of future royalty or milestone payments to us, as well as the possibility that Takeda may determine that the terms of our agreement are no longer viable. We cannot predict the outcome of our appeal of the EPO decision. This or any future patent interference proceedings involving our patents may result in substantial costs to us, distract our management from day-to-day business operations and responsibilities, prevent us or Takeda from marketing and selling *Feraheme/Rienso* or increase the risk that a generic version of *Feraheme/Rienso* could enter the market to compete with *Feraheme/Rienso.* In countries where we do not have or have not applied for patents for ferumoxytol, we may be unable to prevent others from developing or selling similar products. In addition, in jurisdictions outside the U.S. where we have patent rights, we may be unable to prevent unlicensed parties from selling or importing products or technologies derived elsewhere using our proprietary technology. Any such limitation on our intellectual property rights would cause substantial harm to our competitive position and to our ability to develop and commercialize *Feraheme/Rienso.* Our inability to protect *Feraheme/Rienso* through our patents and other intellectual property rights in any territory prior to their expiration could have a material adverse effect on our business, financial condition and prospects.

Wholesaler, distributor and customer buying patterns, particularly those who are members of a GPO, and other factors may cause our quarterly results to fluctuate, and these fluctuations may adversely affect our short-term results.

Our results of operations, including, in particular, product sales, may vary from period to period due to a variety of factors, including the buying patterns of our U.S. wholesalers, distributors, clinics or hospitals, which vary from quarter to quarter. In addition, 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 customers. In the event wholesalers, distributors, clinics or hospitals with whom we do business in the U.S. determine to limit their purchases of our products our product sales could be adversely affected. In addition, these contracts are cancellable at any time by our customers, often without notice, and are non-exclusive

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agreements within the IV iron market. While these contracts are intended to support the use of *Feraheme*, our competitors could offer better pricing, incentives, higher rebates or exclusive relationships. Because *Feraheme* is not indicated for the broad IDA population, the incentives in our contracts for a particular site of care are capped based on our estimate of their patients covered by our current CKD label. Because some of our competitors' products have the broad IDA label, they may provide additional incentives for all of a customer's IV iron usage, essentially becoming an exclusive provider to that particular customer.

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

Our products may not be widely adopted by physicians, hospitals, patients, or healthcare payors, which would adversely impact our potential profitability and future business prospects.

The commercial success of our products depends upon the level of market adoption by physicians, hospitals, patients, and healthcare payors, including managed care organizations and GPOs. If our products do not achieve or maintain an adequate level of market adoption for any reason, our potential profitability and our future business prospects will be adversely impacted. *Feraheme/Rienso* and *MuGard* represent an alternative to other products in their respective markets and might not be adopted if perceived to be no safer, less safe, no more effective, less effective, no more convenient, or less convenient than currently available products. In addition, the pricing and/or reimbursement rates and terms of our products may not be viewed as advantageous to potential prescribers and payors as the pricing and/or reimbursement rates and terms of alternative products.

The degree of market acceptance of *Feraheme/Rienso* in the U.S. and abroad depends on a number of factors, including but not limited to the following:

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

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

The actual or perceived safety and efficacy profile of *Feraheme/Rienso* as compared to alternative iron replacement therapeutic agents, particularly if unanticipated adverse reactions to *Feraheme/Rienso* result in further changes to or restrictions in the *Feraheme/Rienso* package insert, voluntary or involuntary product recalls and/or otherwise create safety concerns among potential prescribers;

The relative price and level of reimbursement in the U.S. for *Feraheme* from payors, including government payors, such as Medicare and Medicaid, and private payors as compared to the price and level of reimbursement for alternative IV iron products;

The relative price and/or level of reimbursement of *Feraheme/Rienso* outside of the U.S. as compared to alternative iron replacement therapeutic agents;

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The actual or perceived convenience and ease of administration of *Feraheme/Rienso* as compared to alternative iron replacement therapeutic agents, including iron administered orally;

The limitation on the approved indications and the patient populations for *Feraheme/Rienso*, especially in light of FDA's decision that we have not provided sufficient information to permit labeling of *Feraheme* for safe and effective use for this population, and the currently approved patient population in Europe; and

The effectiveness of our and Takeda's commercial organizations and distribution networks in marketing, selling and supplying *Feraheme/Rienso*.

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

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

In the U.S., we sell *Feraheme* primarily to wholesalers and specialty distributors and therefore a significant portion of our revenues is generated by a small number of customers. Four customers accounted for 92% of our total revenues during 2013, and three customers accounted for 91% of our accounts receivable balance as of December 31, 2013. We pay these wholesalers and specialty distributors a fee for the services that they provide to us. Because our business is concentrated with such a small number of wholesalers and specialty distributors, we could be forced to accept increases in their fees in order to maintain the current distribution networks through which *Feraheme* is sold. Any increase in fees could have a negative impact on our current and future sales of *Feraheme* in the U.S. and could have a negative impact on the reimbursement rate an individual physician, hospital or clinic would realize upon using *Feraheme*. In addition, a significant portion of our U.S. *Feraheme* sales are generated through a small number of contracts with GPOs. For example, approximately 30% of our end-user demand during 2013 was generated by members of a single GPO with which we have contracted. As a result of the significant percentage of our end-user demand being generated by a single GPO, we may be at a disadvantage in future contract or price negotiations with such GPO and that GPO may be able to influence the demand for *Feraheme* from its members in a particular quarter through communications they make to their customers. In addition, the GPOs can also offer opportunities for competitors to *Feraheme* that provide the ability to quickly gain market share by

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offering a more attractive price or contracts and incentives that encourage the members of the GPO to use or switch to the competing product. The loss of some or all of this demand to a competitor, a material reduction in sales volume, or a significant adverse change in our relationship with any of our key wholesalers, distributors or GPOs could have a material adverse effect on our revenue in any given period and may result in significant annual or quarterly revenue fluctuations.

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

Our ability to successfully commercialize our products is dependent, in significant part, on the availability and extent of reimbursement to end-users from third-party payors for the use of our products, including governmental payors, managed care organizations and private health insurers. Reimbursement by third-party payors depends on a number of factors, including the third-party's determination that the product is competitively priced, safe and effective, appropriate for the specific patient, and cost-effective. Third-party payors are increasingly challenging the prices charged for pharmaceutical products and have instituted and continue to institute cost containment measures to control or significantly influence the purchase of pharmaceutical products. If these entities do not provide coverage and reimbursement for our products or provide an insufficient level of coverage and reimbursement, physicians and other healthcare providers may choose to use alternative products, which would have an adverse effect on our ability to generate revenues.

In addition, U.S. and many foreign governments continue to propose and pass legislation designed to reduce the cost of health care for patients. In the U.S., the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the Health Care Reform Act, was enacted in March 2010 and includes certain cost containment measures including an increase to the minimum rebates for products covered by Medicaid programs, the extension of such rebates to drugs dispensed to Medicaid beneficiaries enrolled in Medicaid managed care organizations and the expansion of the 340B Drug Discount Program under the Public Health Service Act. In addition, the heightened focus on the health care industry by the federal government could result in the implementation of significant federal spending cuts, including cuts in Medicare and other health related spending in the near-term. For example, recent legislation has resulted in Medicare payments being subject to a two percent reduction, referred to as sequestration, until 2023. Because the majority of our *Feraheme* business is through hematology/oncology clinics and outpatient hospital infusions centers, this reduction in the Medicare reimbursement payment for *Feraheme* may adversely impact our future revenues. The magnitude of the impact of these laws on our business is uncertain. Further, in recent years some states have also passed legislation to control the prices of drugs as well as begun a move toward managed care to relieve some of their Medicaid cost burden. While Medicare is the predominant payor for *Feraheme* for treatment of patients with CKD, Medicare payment policy, in time, can also influence pricing and reimbursement in the non-Medicare markets, as private third-party payors and state Medicaid plans frequently adopt Medicare principles in setting reimbursement methodologies. These and any future changes in government regulation or private third-party payors' reimbursement policies may reduce the extent of reimbursement for our products and adversely affect our future operating results.

In January 2011, a prospective payment system for renal dialysis services provided to Medicare beneficiaries who have end-stage renal disease, or ESRD, became effective under which virtually all costs of providing renal dialysis services are reimbursed under a single prospective payment per treatment. This bundled approach to reimbursement has and will likely continue to alter the utilization of physician-administered drugs in the ESRD market as well as put downward pressure on the prices pharmaceutical companies can charge ESRD facilities for such drugs, particularly where alternative products are available. In the U.S., *Feraheme* is sold at a price that is substantially higher than

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

Currently, in U.S. physician clinic and hospital outpatient settings, Medicare Part B generally reimburses for physician-administered drugs at a rate of 106% of the drug's average sales price, or ASP. ASP is defined by statute based on certain historical sales and sales incentive data, including rebates and chargebacks, for a defined period of time. Manufacturers submit the required information to the Centers for Medicare and Medicaid Services, or CMS, on a quarterly basis. In advance of the quarter in which the payment limit for drugs reimbursed under Medicare Part B program will go into effect, CMS calculates and publishes the payment limit. Under this methodology, payment rates change on a quarterly basis, and significant downward fluctuations in ASP, and therefore reimbursement rates, could negatively impact sales of a product. Because ASP is defined by statute, and changes to Medicare payment methodologies require legislative change, it is unclear if and when ASP reimbursement methodology will change for the physician office setting. For hospital outpatient departments, the Medicare payment methodology for many covered Part B drugs also is at 106% of ASP, but CMS could change the payment methodology through regulations, without any intervening legislation. While Medicare is the predominant payor for treatment of patients with CKD, Medicare payment policy, in time, can also influence pricing and reimbursement in the non-Medicare markets, as private third-party payors and state Medicaid plans frequently adopt Medicare principles in setting reimbursement methodologies. We cannot predict the impact that any changes in reimbursement policies may have on our ability to compete effectively.

In addition, it is also possible that a "bundled" payment approach, like for renal dialysis services under Medicare, may be applied to other specific disease states other than ESRD. For example, one large insurer in the U.S has attempted to bundle certain costs related to the treatment of cancer patients. Further changes in the Medicare reimbursement rate, which result in lower payment rates from payors, including Medicare payors, would further limit our ability to successfully market and sell our products in the U.S.

In countries outside of the U.S., market acceptance of *Feraheme/Rienso* may also depend, in part, upon the availability of reimbursement within existing healthcare payment systems. Generally, in Europe and other countries outside of the U.S., the government sponsored healthcare system is the primary payor of healthcare costs of patients and therefore enjoys significant market power. Some foreign countries also set prices for pharmaceutical products as part of the regulatory process, and we cannot guarantee that the prices set by such governments will be sufficient to generate substantial revenues or allow sales of *Feraheme/Rienso* to be profitable in those countries. In addition, Takeda may be unable to obtain favorable pricing in certain countries in Europe making the commercialization impractical and preventing them from launching in those countries. Any such limitations on the reimbursement for *Feraheme/Rienso* in countries outside of the U.S. would have an adverse impact on Takeda's ability to generate product sales of *Feraheme/Rienso* in such territories, which would, in turn, limit the amount of royalties we may receive under our amended agreement with Takeda.

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

In the U.S., there have been, and we expect there will continue to be, a number of legislative and regulatory proposals aimed at changing the U.S. healthcare system. For example, the Patient Protection

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and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, together the Health Care Reform Act, was enacted in the U.S. in March 2010 . The Health Care Reform Act contains a number of provisions that significantly impact the pharmaceutical industry and may negatively affect our potential *Feraheme* revenues. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under the health insurance exchanges, expansion of the 340B program, and fraud and abuse and enforcement. These changes will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

The Healthcare Reform Act made significant changes to the Medicaid program, including an increase to the minimum rebates for products covered by Medicaid programs from 15.1% to 23.1% of the average manufacturer price for most innovator products and the expansion of the 340B Drug Discount Program under the Public Health Service Act. Effective March 23, 2010, the Health Care Reform Act expanded manufacturer rebate liability under the Medicaid program from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well. In addition, the Healthcare Reform Act and subsequent legislation changed the definition of average manufacturer price. Finally, the Healthcare Reform Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government beginning in 2011. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee of $3.0 billion in 2014 (and set to increase in ensuing years), based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. Substantial new provisions affecting compliance have also been added, which may require us to modify our business practices with healthcare providers and potentially incur additional costs. While we are continuing to evaluate this legislation and its potential impact on our business, this legislation may adversely affect the demand for *Feraheme* in the U.S. or cause us to incur additional expenses and therefore adversely affect our financial position and results of operations.

Many of the Healthcare Reform Act's most significant reforms do not take effect until 2014. In 2012, CMS, the federal agency that administers the Medicare and Medicaid program, issued proposed regulations to implement the changes to the drug rebate components of the Medicaid program under the Healthcare Reform Act but has not yet issued final regulations. CMS is currently expected to release the final regulations in 2014.

The Healthcare Reform Act also expanded the Public Health Service's 340B drug pricing discount program. The 340B pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. The Healthcare Reform Act expanded the 340B program to include additional types of covered entities: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the Healthcare Reform Act. For example, the percentage of *Feraheme* business sold to 340B institutions has grown from 11% in 2011 to 15% in 2013. Since these institutions are granted lower prices than those offered to our other customers, any further growth in the 340B business may have a negative impact on our sales price per gram and gross margins.

The Healthcare Reform Act also obligates the Secretary of the HHS to create regulations and processes to improve the integrity of the 340B program and to update the agreement that manufacturers must sign to participate in the 340B program to obligate a manufacturer to offer the 340B price to covered entities if the manufacturer makes the drug available to any other purchaser at any price and to report to the government the ceiling prices for its drugs. HRSA is expected to issue a comprehensive proposed regulation in 2014 that will address many aspects of the 340B program. When that regulation is finalized, it could affect our obligations under the 340B program in ways we cannot anticipate. In addition, legislation may be introduced that, if passed, would further expand the 340B

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program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in the inpatient setting.

Moreover, legislative changes to the Healthcare Reform Act remain possible. We expect that the Healthcare Reform Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase our product sales. In addition, various healthcare reform proposals have emerged at the state level in the U.S. 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 *Feraheme* or the amount of reimbursement rates and terms available from governmental agencies or third-party payors, limiting the profitability of *Feraheme*, increasing our rebate liability or limiting the commercial opportunity for *Feraheme*, including its acceptance by healthcare payors.

Our inability to obtain raw and other materials used in the manufacture of Feraheme/Rienso could adversely impact our ability to manufacture sufficient quantities of Feraheme/Rienso, which would have an adverse impact on our business.

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

Unexpected demand for or shortage of raw or other materials;

Adverse financial developments at or affecting the supplier;

Regulatory requirements or action;

An inability to provide timely scheduling and/or sufficient capacity;

Manufacturing difficulties;

Changes to the specifications of the raw materials such that they no longer meet our standards;

Labor disputes or shortages; or

Import or export problems.

If any of our third-party suppliers cease to supply certain raw or other materials to us or our third-party manufacturers for any reason we could be unable to manufacture *Feraheme/Rienso* in sufficient quantities, on a timely basis, or in a cost-effective manner until we are able to qualify an alternative source. For example, one of the key components in ferumoxytol is produced specifically for us by a third-party supplier and if our third-party supplier is no longer able to supply it to us we will be unable to manufacture *Feraheme/Rienso* until we are able to identify and qualify an alternative supplier. This or any other interruption in our third-party supply chain could adversely affect our ability to satisfy commercial demand and our clinical development needs for *Feraheme/Rienso*.

The qualification of an alternative source may require repeated testing of the new materials and generate greater expenses to us if materials that we test do not perform in an acceptable manner. In addition, we or our third-party manufacturers sometimes obtain raw or other materials

from one vendor only, even where multiple sources are available, to maintain quality control and enhance working relationships with suppliers, which could make us susceptible to price inflation by the sole

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supplier, thereby increasing our production costs. As a result of the high quality standards imposed on our raw or other materials, we or our third-party manufacturers may not be able to obtain such materials of the quality required to manufacture *Feraheme/Rienso* from an alternative source on commercially reasonable terms, or in a timely manner, if at all.

Even if we are able to obtain raw or other materials from an alternative source, if these raw or other materials are not available in a timely manner or on commercially reasonable terms, we would be unable to manufacture *Feraheme/Rienso*, both for commercial sale and for use in our clinical trials, on a timely and cost-effective basis, which could cause us to lose money. Any such difficulty in obtaining raw or other materials could severely hinder our ability to manufacture *Feraheme/Rienso* and could have a material adverse impact on our ability to generate additional revenues and to achieve profitability. Moreover, Access is likely subject to many of the same third party risks regarding the manufacture and supply of *MuGard*, which would impact our ability to generate revenues of *MuGard* in the U.S.

If we or Takeda market or distribute Feraheme/Rienso or if we market or distribute MuGard in a manner that violates federal, state or foreign healthcare fraud and abuse laws, marketing disclosure laws or other federal, state or foreign laws and regulations, we may be subject to civil or criminal penalties.

In addition to FDA and related regulatory requirements in the U.S. and abroad, we are subject to extensive additional federal, state and foreign healthcare regulation, which includes but is not limited to, the Federal False Claims Act, the Federal Anti-Kickback Statute, the Foreign Corrupt Practices Act, 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. False claims laws prohibit anyone from knowingly presenting, or causing to be presented for payment to third-party payors, including Medicare and Medicaid, false or fraudulent claims for reimbursed drugs or services, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Anti-kickback laws make it illegal to solicit, offer, receive or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug, that is reimbursed by a state or federal program. The Foreign Corrupt Practices Act and similar foreign anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Similar laws and regulations exist in many other countries throughout the world in which we intend to commercialize *Feraheme/Rienso* through Takeda. We have developed and implemented a corporate compliance program based on what we believe are current best practices in the pharmaceutical industry, but we cannot guarantee that we, our employees, our consultants or our contractors are or will be in compliance with all federal, state and foreign regulations. If we, our representatives, or Takeda fail to comply with any of these laws or regulations, a range of fines, penalties and/or other sanctions could be imposed on us and/or Takeda, including, but not limited to, restrictions on how we and/or Takeda market and sell *Feraheme/Rienso* and how we market and sell *MuGard*, 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.

In recent years, several U.S. 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. Similar legislation is being considered by additional states and foreign governments. In addition, as part of the Health Care Reform Act, the federal government has enacted the Physician Payment Sunshine Act and related regulations. Beginning in August 2013, manufacturers of drugs are required to capture information to allow for the public reporting of gifts and payments made to physicians and teaching hospitals. Many of these requirements are new and uncertain, and the penalties

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for failure to comply with these requirements are unclear. Compliance with these laws is difficult, time consuming and costly, and if we are found to not 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.

If we fail to comply with any federal, state or foreign laws or regulations governing our industry, we could be subject to a range of regulatory actions that could adversely affect our ability to commercialize our products, 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.

If we fail to comply with our reporting and payment obligations under U.S. 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 U.S. federal and state healthcare programs for *Feraheme*, we are required to calculate and report certain pricing information to U.S. federal and state healthcare agencies. We participate in and have certain price reporting obligations to the Medicaid Drug Rebate program, and we have obligations to report Average Sales Price, or ASP, for the Medicare program. Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient products that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our products under Medicaid and Medicare Part B. Those rebates are based on pricing data reported by us on a monthly and quarterly basis to the CMS. These data include the average manufacturer price and, in the case of innovator products such as *Feraheme*, the best price for each drug.

The Medicaid rebate amount is computed each quarter based on our submission to CMS of our current average manufacturer prices and best prices for the quarter. If we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for a period not to exceed twelve quarters from the quarter in which the data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid program. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. Price recalculations also may affect the ceiling price at which we are required to offer our products to certain covered entities, such as safety-net providers, under the 340B drug discount program. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid rebate program.

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

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Price reporting and payment obligations are highly complex and vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies and the courts. The calculations of average manufacturer price, best price, and ASP include a number of inputs from our contracts with wholesalers, specialty distributors, GPOs and other customers. It also requires us to make an assessment of whether these agreements are deemed to be for *bona fide* services and that the services are deemed to be at fair market value in our industry and for our products. These calculations are very complex and could involve the need for us to unbundle or reallocate discounts or rebates offered over a multiple quarters or across multiple products. Our processes for estimating amounts due under these governmental pricing programs involve subjective decisions and estimates. The unbundling of discounts and rebates across multiple reporting periods can result in a restatement of government price reports and changes to the reimbursement rates for various customers covered under federal programs, such as Medicare, Medicaid or the 340B program.

If we have to restate our calculation of government price reports, we may be forced to refund certain monies back to payers to comply with federal pricing agreements. Such a restatement of our government price reports would also adversely impact our reported financial results of operations in the period of such restatement. As a result, our price reporting calculations remain subject to the risk of errors and our methodologies for calculating these prices could be challenged under the Federal False Claims Act or other laws. In addition, the Health Care Reform Act modified the rules related to certain price reports, among other things. Presently, uncertainty exists as many of the specific determinations necessary to implement this new legislation have yet to be decided and communicated to industry participants. This uncertainty in the interpretation of the legislation increases the chances of an error in price reporting, which could in turn lead to a legal challenge, restatement or investigation. 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.

We are liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted false average manufacturer price, average sales price, or best price information to the government, we may be liable for civil monetary penalties in the amount of $100,000 per item of false information. Our failure to submit monthly/quarterly average manufacturer price, average sales price, and best price data on a timely basis could result in a civil monetary penalty of $10,000 per day for each day the information is late beyond the due date. Such failure also could 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, no federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs.

If we overcharge the government, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We have a history of net losses, and we may not be able to generate sufficient revenues to achieve and maintain profitability in the future.

We have a history of significant operating losses, we may not be profitable in the future, and if we do attain profitability, such profitability may not be sustainable. In the past, we have financed our operations primarily from the sale of our equity securities, cash from sales of *Feraheme/Rienso*, cash generated by our investing activities, and payments from our licensees. As of December 31, 2013, we

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had an accumulated deficit of approximately $466.3 million. Our losses were primarily the result of compensation to employees, commercialization expenses, including marketing and promotion costs, research and development costs, including costs associated with our clinical trials, and general and administrative costs, partially offset by net product sales and collaboration revenues. We expect to continue to incur significant expenses as we continue to market and sell and contract for the manufacture of *Feraheme* as an IV iron replacement therapeutic for use in adult CKD patients in the U.S., market and sell *MuGard* and if we further develop and seek marketing approval for *Feraheme* for the treatment of IDA in a broad range of patients, which would include conducting additional human trials for which we would incur significant research and development costs over a long period of time. As a result, we will need to generate sufficient revenues in future periods to achieve and maintain profitability. There is no guarantee that we will achieve profitability or maintain profitability, if achieved, and there is no guarantee that we will be able to maintain positive cash flow from operations. We anticipate that the majority of any revenue we generate in the next twelve months will be from sales of *Feraheme/Rienso* as an IV iron replacement therapeutic agent for use in adult CKD patients in the U.S., royalties we may receive with respect to sales of *Feraheme/Rienso* in the EU and Canada under the Amended Takeda Agreement, and from sales of *MuGard*. We have never independently marketed or sold any products prior to *Feraheme*, and we may not be successful in marketing or selling *Feraheme* or *MuGard* in the U.S. and Takeda may not be successful in marketing or selling *Feraheme/Rienso* outside of the U.S. If we or Takeda are not successful in marketing and selling *Feraheme/Rienso*, if revenues grow more slowly than we anticipate 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 have limited experience independently commercializing a pharmaceutical product and no experience independently commercializing multiple products, and any failure on our part to effectively execute our Feraheme or MuGard commercial plans in the U.S. would have an adverse impact on our business.

Prior to our commercialization of *Feraheme* in the U.S., we had never independently marketed or sold a product as we had relied on our licensees to market and sell our previously approved products. We have an internal commercial infrastructure to market and sell *Feraheme* and *MuGard* in the U.S. If we are unsuccessful in maintaining an effective commercial function with multiple products, integrating *MuGard* into our existing sales infrastructure, or experience a high level of employee turnover for any reason, our ability to attract and retain qualified personnel, maintain sales levels, and support potential sales growth could be harmed, all of which could prevent us from successfully commercializing *Feraheme* or *MuGard* in the U.S. Any failure by us to successfully commercialize *Feraheme* or *MuGard* in the U.S. could have a material adverse impact on our ability to generate revenues, our ability to achieve profitability, and the future prospects for our business.

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

We are a pharmaceutical company focused on marketing commercial products and we plan to expand our portfolio with additional commercial-stage products through acquisitions and in-licensing; thus, the range of skills of our executive officers needs to be broad and deep. If we are not able to hire and retain talent to drive commercialization and expansion of our portfolio, we will be unlikely to achieve profitability. Further, because of the specialized nature of our business, 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. We have entered into employment agreements with most of our current senior executives, but such agreements do not guarantee that these executives will remain employed by us for any significant period of time, or at all. For example, in February 2014, our chief commercial officer resigned to pursue another opportunity

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after only one year with us, which may lead to increased turnover. There is intense competition for qualified personnel in the areas of our activities, and we may not be able to continue to attract and retain the qualified personnel necessary for the development of our business.

Previously implemented workforce reductions could residually harm our ability to attract and retain qualified personnel. In addition, any restructuring plans we may initiate in the future may be disruptive to our operations and could harm our ability to attract and retain qualified key personnel. For example, cost saving measures may distract management from our core business, harm our reputation, or yield unanticipated consequences, such as attrition beyond planned reductions in workforce, increased difficulties in our day-to-day operations, reduced employee productivity and a deterioration of employee morale. Any workforce reductions could also harm our ability to attract and retain qualified sales, technical operations, managerial, scientific, and medical personnel who are critical to our business. Any future employee turnover, whether occurring as part of a restructuring plan or otherwise, could cause significant disruption if we are unable to implement or maintain a sufficient succession plan for certain personnel or departments. Any failure to attract, retain or replace qualified personnel could prevent us from successfully commercializing and developing our products, impair our ability to maintain sales levels and/or support potential sales growth.

Moreover, although we believe it is necessary to closely manage the cost of our operations to improve our performance, these initiatives may preclude us from making potentially significant expenditures that could improve our competitiveness over the longer term. We cannot guarantee that any cost reduction measures, or other measures we may take in the future, will result in the expected cost savings, or that any cost savings will be unaccompanied by these or other unintended consequences.

We have limited experience independently distributing a pharmaceutical product, and our commercialization plans could suffer if we fail to effectively manage and maintain our supply chain and distribution network.

We do not have significant experience in managing and maintaining a supply chain and distribution network, and we are placing substantial reliance on third parties to perform product supply chain services for us. Such services include packaging, warehousing, inventory management, storage and distribution of *Feraheme/Rienso* and *MuGard*. We have contracted with Packaging Coordinators, Inc. (formerly Catalent Pharma Solutions, LLC) to provide certain labeling, packaging and storage services for final U.S., Canadian and Swiss *Feraheme/Rienso* drug product. In addition, we have contracted with Integrated Commercialization Services, Inc. to be our exclusive third-party logistics provider to perform a variety of functions related to the sale and distribution of *Feraheme* in the U.S., including services related to warehousing and inventory management, distribution, chargeback processing, accounts receivable management and customer service call center management. If these or any future third-parties are unable to provide uninterrupted labeling, packaging and storage services or supply chain services, respectively, we may incur substantial losses of sales to wholesalers or other purchasers of our products.

In addition, the packaging, storage and distribution of our products in the U.S. and abroad requires significant coordination among our, Takeda's, and Access's manufacturing, sales, marketing and finance organizations and multiple third parties including our third-party logistics providers, packaging, labeling and storage provider, distributors, and wholesalers. In most cases, we do not currently have back-up suppliers or service providers to perform these tasks. If any of these third parties experience significant difficulties in their respective processes, fail to maintain compliance with applicable legal or regulatory requirements, fail to meet expected deadlines or otherwise do not carry out their contractual duties to us, or encounter physical or natural damages at their facilities, our ability to deliver our products to meet U.S. or foreign commercial demand could be significantly impaired. The loss of any of our third-party providers, together with 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

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interrupted, which would have an adverse effect on our business, financial condition and results of operations.

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

We rely and intend to continue to rely on third parties, including clinical research organizations , or CROs, third-party manufacturers, third-party logistics providers, packaging and labeling providers, wholesale distributors and certain other important vendors and consultants, including those engaged by Access, in the conduct of our business. In addition, we have contracted and plan to continue to contract with certain third parties to provide certain services, including site selection, enrollment, monitoring, data management and other services, in connection with the conduct of our clinical trials and the preparation and filing of our regulatory applications. We have limited experience conducting clinical trials outside the U.S., and, therefore, we are also largely relying on third parties such as CROs to manage, monitor and carry out these clinical trials. Although we depend heavily on these parties, we do not control them and, therefore, we cannot be assured that these third parties will adequately and timely perform all of their contractual obligations to us. If our third-party service providers cannot adequately fulfill their obligations to us in a timely and satisfactory manner, if the quality and accuracy of our clinical trial data or our regulatory submissions are compromised due to poor quality or failure to adhere to our protocols or regulatory requirements or if such third parties otherwise fail to adequately discharge their responsibilities or meet deadlines, our current and future development plans and regulatory submissions both in and outside of the U.S may be delayed or terminated, which would adversely impact our ability to generate revenues from *Feraheme/Rienso* sales in additional indications and/or outside of the U.S.

Our operating results will likely fluctuate so you should not rely on the results of any single quarter to predict how we will perform over time.

Our future operating results will likely vary from quarter to quarter depending on a number of factors, some of which we cannot control, including but not limited to:

The magnitude of U.S. *Feraheme* and *MuGard* sales;

The loss of a key customer or GPO;

The impact of any pricing or contracting strategies we have implemented or may implement related to our products, including the magnitude of rebates and/or discounts we may offer, or changes in pricing by our competitors or a new entrant into the market;

The introduction of new competitive products, such as Injectafer® or generic versions of new or currently available drug therapies;

Any expansion or contraction of the overall size of the IV iron market, which could result from a number of factors including but not limited to changes in treatment guidelines or practices related to IDA;

Changes in the actual or perceived safety or efficacy profile of our products, especially in light of the recent complete response letter we received from the FDA, that could cause customers to decrease or discontinue their use of our products or could affect the regulatory status of our products in the U.S. or elsewhere;

Changes in the actual or perceived safety or efficacy profile of products that compete with *Feraheme/Rienso* or *MuGard* that could cause our customers to decrease or discontinue their use of our products;

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The timing and magnitude of costs incurred in connection with business development activities or business development transactions into which we may enter;

Any changes to the mix of our business;

Changes in buying patterns, fees and inventory levels of our wholesalers, distributors, clinics or hospitals;

The timing and magnitude of *Feraheme/Rienso* milestone payments, product sales revenues and royalties we may receive from Takeda under the Amended Takeda Agreement;

The initiation or outcome of any material litigation or patent challenges to which we are or become a party and the magnitude of costs associated with such litigation;

The timing and magnitude of costs associated with the commercialization of our products in the U.S., including costs associated with pursuing a broader indication of *Feraheme*, maintaining our commercial infrastructure and executing our promotional and marketing strategies;

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

The timing and magnitude of costs associated with the manufacture of *Feraheme/Rienso*, including costs of raw and other materials and costs associated with maintaining commercial inventory and qualifying additional manufacturing capacities and alternative suppliers;

The timing and magnitude of costs associated with our ongoing and planned clinical studies of *Feraheme/Rienso* in connection with our pediatric program, our current or future post-marketing commitments for the EMA and other regulatory agencies, our pursuit of additional indications and our development of *Feraheme/Rienso* in countries outside of the U.S;

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

Changes in reimbursement practices and laws and regulations affecting our products from federal, state and foreign legislative and regulatory authorities, government health administration authorities, private health insurers and other third-party payors;

The recognition of deferred tax assets during periods in which we generate taxable income; and

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

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

If the estimates we make, or the assumptions on which we rely, in preparing our consolidated financial statements 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 us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges accrued by us, and the related disclosure of contingent assets and liabilities. On an ongoing basis, our management evaluates our critical and other significant estimates and judgments, including among others those associated with revenue recognition related to product sales and collaboration agreements, product sales allowances and accruals, assessing investments for potential other-than-temporary impairment and determining the fair values of our investments, the fair

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value of our assets held for sale, the fair value of assets acquired in a business combination, contingent consideration, the impairment of long-lived assets, including intangible assets, accrued expenses, 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.

As part of our revenue recognition policy, our estimates of product returns, rebates and chargebacks, fees and other discounts require subjective and complex judgments due to the need to make estimates about matters that are inherently uncertain. Any significant differences between our actual results and our estimates could materially affect our financial position and results of operations. For example during each of 2013 and 2012, we revised our estimated Medicaid reserve rate, which resulted in a reduction of our estimated Medicaid rebate reserve and a corresponding increase in revenue related to prior *Feraheme* sales of $0.6 million. Further, during 2012, we reduced our reserve for product returns by approximately $2.2 million due to a lower than expected actual returns rate since the 2009 launch of *Feraheme* as well as a reduction in our expected rate of product returns in the future.

In addition, to determine the required quantities of *Feraheme* and the related manufacturing schedule, we also need to make significant judgments and estimates based on inventory levels, current market trends, anticipated sales, forecasts from Takeda, and other factors. Because of the inherent nature of estimates, there could be significant differences between our and Takeda's estimates and the actual amount of product need. For example, the level of our access to wholesaler and distributor inventory levels and sales data in the U.S., 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.

In connection with our June 2013 acquisition of the MuGard Rights we were and will continue to be required to make estimates related to the fair value of the asset and the related contingent consideration. These estimates require significant judgment and assumptions including but not limited to estimating future cash flows from product sales and developing appropriate discount and probability rates. If these or any other related estimates made in connection with the acquisition of the MuGard Rights or any future acquisitions require adjustment in the future, we could experience significant write-offs or other adjustments and our operating results could be negatively affected.

We and/or Takeda are subject to ongoing U.S. and foreign regulatory obligations and oversight of Feraheme/Rienso and MuGard, 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 products, the incurrence of significant additional expense and other limitations on our ability to commercialize our products.

We and/or Takeda are subject to ongoing regulatory requirements and review both in the U.S. and in foreign jurisdictions pertaining to the manufacture, labeling, packaging, adverse event reporting, storage, marketing, promotion and record keeping related to our products. Failure to comply with such regulatory requirements or the later discovery of previously unknown problems with 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 or sell our products, including potential withdrawal from the market. Any such restrictions could result in a decrease in our product sales, damage to our reputation or the initiation of lawsuits against us, Takeda, or our third-party contract

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manufacturers. We and/or Takeda may also be subject to additional sanctions, including but not limited to:

- Warning letters;
- Civil or criminal penalties;
- Variation, suspension or withdrawal of regulatory approvals;
- Changes to the package insert of our products, such as additional warnings regarding potential side effects or potential limitations on the current dosage and administration of *Feraheme/Rienso* or IV irons as a class;
- 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-marketing obligations;
- Restrictions on our continued manufacturing, marketing or sale of our products;
- Temporary or permanent closing of the facilities of our third-party contract manufacturers; or
- Recalls or a refusal by regulators to consider or approve applications for additional indications.

Any of the above sanctions could have a material adverse impact on our ability to generate revenues and to achieve profitability and cause us to incur significant additional expenses. Moreover, Access is subject to many of the same regulatory requirements and sanctions related to *MuGard*, which would impact our ability to generate revenues of *MuGard* in the U.S.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. If we are found to have improperly promoted off-label uses, we may become subject to significant fines and other liability.

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 or such other regulatory agencies as reflected in the product's approved labeling. If we are found to have promoted such off-label uses, we may become subject to significant government fines and other related liability. For example, the U.S. government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The government has also required companies to enter into complex corporate integrity agreements and/or non-prosecution agreements that can impose significant restrictions and other burdens on the affected companies.

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 due to, for example, promotion of pharmaceutical products beyond labeled claims. 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.

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Our stock price has been and may continue to be volatile, and your investment in our stock could decline in value or fluctuate significantly.

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 $15.90 and $28.42 in the fifty-two week period through February 3, 2014. 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, many of which are beyond our control, may have a significant impact on the market price of our common stock. Factors which may affect the market price of our common stock include, among others:

Our ability to successfully commercialize *Feraheme* in the U.S. and Takeda's ability to successfully commercialize *Feraheme/Rienso* in licensed territories outside of the U.S.;

Our ability to increase or maintain sales and utilization of *Feraheme* in the current indication or the results of our efforts to expand the indications for *Feraheme* for the treatment of IDA in adult patients who have failed or could not use oral iron, especially in light of FDA's recent decision that we have not provided sufficient information to permit labeling of *Feraheme* for safe and effective use for this population;

Fluctuations in our net revenue per unit of *Feraheme* sold in the U.S. in future periods as a result of our pricing and contracting strategy;

Actual or perceived safety concerns related to our products or products or product candidates of our competitors, including as a result of the FDA's recent complete response letter addressing our sNDA and any actions taken by U.S. or foreign regulatory authorities in connection with safety concerns, or any voluntary or involuntary product recalls;

Significant collaboration, product or business acquisitions, joint venture or similar agreements by us or our competitors or the termination of any current or future material collaboration agreements;

The timing and magnitude of product revenue and actual or anticipated fluctuations in our operating results;

Changes in or our failure to meet financial estimates published by securities analysts or our own publicly disclosed financial guidance;

Increases or decreases in our operating expenses or our gross margin on our products;

Developments in patents or other proprietary rights by or for the benefit of us or our competitors, such as the recent decision by the EPO regarding our European ferumoxytol patent or decisions regarding *Feraheme's* NCE status or an ANDA filing by a generic entrant;

Our ability to successfully integrate *MuGard* with our business and market *MuGard* in the U.S.;

The availability of reimbursement coverage for our products or changes in the reimbursement policies of U.S. or foreign governmental or private payors;

Public announcements of U.S. or foreign regulatory actions with respect to our products or products or product candidates of our competitors;

The status or results of clinical trials for *Feraheme* or products or product candidates of our competitors;

The acquisition, development or regulatory approvals of technologies, product candidates or products by us or our competitors;

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Cash milestones earned, if any, under the Amended Takeda Agreement;

The initiation or outcome of any material litigation or patent challenges to which we are or may become a party;

Shareholder activism and attempts to disrupt our strategy by activist investors;

General market conditions; and

Sales of large blocks of our common stock or the dilutive effect of any equity or equity-linked financings or alternative strategic arrangements.

Thus, as a result of events both within and beyond our control, our stock price could fluctuate significantly or lose value rapidly.

If securities analysts downgrade our stock, cease coverage of us, or if our operating results do not meet analysts' forecasts and expectations, our stock price could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us and our business. As of February 3, 2014, seven financial analysts publish reports about us and our business. We do not control these or any other analysts. Furthermore, there are many large, well-established, publicly traded companies active in our industry and market, which may mean that it is less likely that we will receive widespread analyst coverage. In addition, our future operating results are subject to substantial uncertainty, and our stock price could decline significantly if we fail to meet or exceed analysts' forecasts and expectations. If any of the analysts who cover us downgrade our stock, lower their price target or issue commentary or observations about us or our stock that are perceived by the market as negative, our stock price would likely decline rapidly. In addition, if these analysts cease coverage of our company, we could lose visibility in the market, which in turn could also cause our stock price to decline.

If our operating results do not meet our own publicly disclosed financial guidance our stock price could decline.

In February 2014, we publicly provided financial guidance, including expected 2014 net U.S. *Feraheme* and other revenue, including revenue from *MuGard*, ex-U.S. product sales and royalties and milestones, estimated operating expenses, estimated cost of goods sold as a percent of net *Feraheme* products sales, and operating the business to break-even for the full year of 2014. If, for any reason, we are unable to realize our projected 2014 revenue, we may not realize our publicly announced revenue and break-even 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.

We may need additional capital to achieve our business objectives.

We have expended and will continue to expend substantial funds to successfully commercialize and develop *Feraheme*. Our long-term capital requirements will depend on many factors, including, but not limited to:

Our ability to successfully commercialize *Feraheme* in the U.S. and Takeda's ability to successfully commercialize *Feraheme/Rienso* in its licensed territories outside of the U.S.;

Our ability to obtain regulatory approval for *Feraheme/Rienso* to treat IDA regardless of the underlying cause both within the U.S. and outside of the U.S., particularly in the EU, especially in light of FDA's recent decision that we have not provided sufficient information to permit labeling of *Feraheme* for safe and effective use for this population and the need to undertake additional clinical trials in order to pursue the broader indication;

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The magnitude and growth rate of U.S. *Feraheme* sales over prior periods;

The magnitude of *Feraheme/Rienso* sales and royalties we may receive from Takeda outside of the U.S.;

The success, costs and structure of any business or corporate development initiatives to bring additional products into our portfolio;

The outcome of and costs associated with any material litigation or patent challenges to which we are or may become a party;

Our ability to achieve the various milestones and receive the associated payments under the Amended Takeda Agreement;

Costs associated with the U.S. commercialization of our products, including costs associated with maintaining our commercial infrastructure, executing our promotional and marketing strategies, and conducting our required pediatric clinical studies and any post-marketing clinical studies for *Feraheme;*

The timing and magnitude of costs associated with qualifying additional manufacturing capacities and alternative suppliers;

Our ability to maintain successful collaborations with our licensees and/or to enter into additional alternative strategic relationships, if necessary; and

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

We estimate that our cash resources as of December 31, 2013, combined with cash we currently expect to receive from sales of *Feraheme/Rienso* and *MuGard,* earnings on our investments, and royalty and milestone payments we may receive from Takeda will be sufficient to finance our currently planned operations for at least the next twelve months. We may require additional funds or need to establish additional alternative strategic arrangements to execute a business development transaction. We may at any time seek funding through additional arrangements with collaborators through public or private equity or debt financings. We may not be able to obtain financing or to secure alternative strategic arrangements on acceptable terms or within an acceptable timeframe, if at all.

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

The investment of our cash is subject to risks, which may cause losses or adversely affect the liquidity of these investments and our results of operations, liquidity and financial condition.

As of December 31, 2013, we had $27.0 million in cash and cash equivalents and $186.8 million in investments. These investments are subject to general credit, liquidity, market and interest rate risks, which have been and may, in the future, be exacerbated by a U.S. and/or global financial crisis. We may realize losses in the fair value of certain of our investments or a complete loss of these

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investments if the credit markets tighten, which would have an adverse effect on our results of operations, liquidity and financial condition.

The condition of the credit markets can be unpredictable. As a result, we may experience a reduction in value or loss of liquidity with respect to our investments. In addition, should our investments cease paying or reduce the amount of interest paid to us, our interest income would suffer. Further, as part of our determination of the fair value of our investments, we consider credit ratings provided by independent investment rating agencies as of the valuation date. These ratings are subject to change. These market risks associated with our investment portfolio may have an adverse effect on our results of operations, cash position, liquidity and overall financial condition.

We are subject to increasingly complex corporate governance, public disclosure and accounting requirements that could adversely affect our business and financial results.

We are subject to changing rules and regulations of U.S. federal and state government as well as the stock exchange on which our common stock is listed. These entities, including the Public Company Accounting Oversight Board, the NASDAQ Stock Market, or NASDAQ, and the Securities and Exchange Commission, or the SEC, have issued a significant number of new and increasingly complex requirements and regulations over the last several years and continue to develop additional regulations and requirements in response to laws enacted by Congress. Our efforts to comply with these requirements have resulted in, and are likely to continue to result in, an increase in our expenses and a diversion of management's time from other business activities.

Our ability to use net operating loss carryforwards and tax credit carryforwards to offset future taxable income may be limited as a result of future transactions involving our common stock.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, 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." Limitations imposed on the ability to use net operating losses and tax credits to offset future taxable income could require us to pay U.S. federal income taxes earlier than we have estimated would otherwise be required if such limitations were not in effect 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. Similar rules and limitations may apply for state income tax purposes.

Our business could be negatively affected as a result of the actions of activist shareholders.

Proxy contests have been waged against many companies in the biopharmaceutical industry over the last few years. For example, in 2011, MSMB Capital Management LLC, or MSMB Capital, filed a preliminary consent solicitation statement with the SEC seeking to remove and replace most of our then-current directors with MSMB Capital's nominees. The review, consideration and response to efforts by activist shareholders may require the expenditure of significant time and resources by us and may be a significant distraction for our management and employees. The impact of activist shareholders' efforts due to these or other factors may undermine our business and have a material adverse effect on our results of operations. If faced with a proxy contest, we may not be able to successfully defend against the contest, which would be disruptive to our business.

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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 also subject us to sanctions and/or investigations by the SEC, NASDAQ or other regulatory authorities.

An adverse determination in any current or future lawsuits in which we are a defendant, including the class action lawsuit to which we are currently a party, could have a material adverse effect on us.

A purported class action complaint was originally filed on March 18, 2010 in the U.S. District Court for the District of Massachusetts, entitled Silverstrand Investments et. al. v. AMAG Pharm., Inc., et. al., Civil Action No. 1:10-CV-10470-NMG, and was amended on September 15, 2010 and on December 17, 2010. The second amended complaint, or SAC, filed on December 17, 2010 alleged that we and our former President and Chief Executive Officer, former Chief Financial Officer, the then-members of our Board of Directors, or Board, and certain underwriters in our January 2010 offering of common stock violated certain federal securities laws, specifically Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended, and that our former President and Chief Executive Officer and former Chief Financial Officer violated Section 15 of such Act, respectively, by making certain alleged omissions in a registration statement filed in January 2010. The plaintiffs sought unspecified damages on behalf of a purported class of purchasers of our common stock pursuant to our common stock offering on or about January 21, 2010. On August 11 and 15, 2011, respectively, the District Court issued an Opinion and Order dismissing the SAC with prejudice for failure to state a claim upon which relief could be granted. On September 14, 2011, the plaintiffs filed a Notice of Appeal to the U.S. Court of Appeals for the First Circuit, or the Court of Appeals. The Court of Appeals heard oral argument on May 11, 2012. On February 4, 2013, the Court of Appeals affirmed in part and reversed in part the District Court's Opinion and Order and remanded the case to the District Court. On February 19, 2013, we filed a Petition for Panel Rehearing and Rehearing *En Banc*, which was denied on March 15, 2013. On March 22, 2013, we filed a Motion to Stay the Mandate remanding the case to the District Court pending review by the U.S. Supreme Court of the Court of Appeals' February 4, 2013 decision. The Court of Appeals granted the Motion to Stay the Mandate on April 8, 2013. On June 13, 2013, we filed a Petition for a Writ of Certiorari, or the Petition, with the U.S. Supreme Court seeking review of the Court of Appeal's decision and to have that decision overturned. On October 7, 2013 the U.S. Supreme Court denied our Petition, resulting in the case's return to the District Court

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for further proceedings relative to the SAC's surviving claims. On November 6, 2013, we filed a renewed Motion to Dismiss the SAC's surviving claims. On December 6, 2013, the plaintiffs filed a brief in opposition to our Motion to Dismiss and we filed a reply brief in support of our Motion on December 27, 2013. The plaintiffs are seeking leave of court to file a sur-reply in further opposition to our Motion to Dismiss. No hearing on the Motion to Dismiss is currently scheduled. Whether or not the plaintiff's appeal is successful, this type of litigation is often expensive and diverts management's attention and resources, which could adversely affect the operation of our business. If we are ultimately required to pay significant defense costs, damages or settlement amounts, such payments could adversely affect our operations.

We may also be the target of similar litigation in the future. Any future 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. Though we maintain liability insurance, if any costs or expenses associated with this or any other litigation exceed our insurance coverage, we may be forced to bear some or all of these costs and expenses directly, which could be substantial.

Product liability lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our products.

The administration of our products to, or the use of our products by, humans, whether in clinical trials or after approval for commercial use, may expose us to liability claims, whether or not our products are actually at fault for causing an injury. As *Feraheme/Rienso* 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/Rienso*, can cause patients to experience serious hypersensitivity reactions, including anaphylactic-type reactions, some of which have been life-threatening and/or fatal. Although we maintain product liability insurance coverage for claims arising from the use of our products in clinical trials and commercial use, coverage is expensive, and we may not be able to maintain sufficient insurance at a reasonable cost, if at all. Product liability claims, whether or not they have merit, could also decrease demand for our products, subject us to product recalls or harm our reputation, cause us to incur substantial costs, and divert management's time and attention.

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

We have a shareholder rights plan, the provisions of which are intended to deter a hostile takeover by making any proposed hostile acquisition of us more expensive and less desirable to a potential acquirer by enabling our stockholders (other than the potential hostile acquiror) to purchase significant amounts of additional shares of our common stock at dilutive prices. The rights issued pursuant to our shareholder rights plan become exercisable generally upon the earlier of 10 days after a person or group acquires 20% or more of our outstanding common stock or 10 business days after the announcement by a person or group of an intention to acquire 20% of our outstanding common stock via tender offer or similar transaction. The shareholder rights plan could delay or discourage transactions involving an actual or potential change in control of us or our management, including transactions in which stockholders might otherwise receive a premium for their shares over then-current prices.

In addition, certain provisions in our certificate of incorporation and our by-laws may discourage, delay or prevent a change of control or takeover attempt of our company by a third-party as well as

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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, or Section 203, which prevents us from engaging in any business combination with any "interested stockholder," which is defined generally as a person that acquires 15% or more of a corporation's outstanding voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in the manner prescribed in Section 203. These provisions could have the effect of delaying or preventing a change of control, whether or not it is desired by, or beneficial to, our stockholders.

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

ITEM 1B. UNRESOLVED STAFF COMMENTS:

None.

ITEM 2. PROPERTIES:

In June 2013, we entered into a lease agreement with BP Bay Colony LLC, or the Landlord, for the lease of certain real property located at 1100 Winter Street, Waltham, Massachusetts, or the Premises, for use as our principal executive offices. Beginning in September 2013, the initial term of the lease is five years and two months with one five-year extension term at our option. During the extension period, the base rent will be an amount agreed upon by us and the Landlord. In addition to base rent, we are also required to pay a proportionate share of the Landlord's operating costs. The lease requires us to pay base rent during the initial term as follows (in thousands):

Period	Minimum Lease Payments
Year Ended December 31, 2014	$ 1,128
Year Ended December 31, 2015	1,128
Year Ended December 31, 2016	1,128
Year Ended December 31, 2017	1,128
Thereafter	1,034
Total	$ 5,546

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The Landlord agreed to pay for certain agreed-upon improvements 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 new facility lease, in June 2013 we delivered to the Landlord a security deposit of $0.4 million in the form of an irrevocable letter of credit. This security deposit will be reduced to $0.3 million on the second anniversary of the date the lease commenced. The cash securing this letter of credit is classified on our balance sheet as of December 31, 2013 as a long-term asset and is restricted in its use.

In June 2013, we also entered into an Assignment and Assumption of Lease, or the Assignment Agreement, with Shire Human Genetic Therapies, Inc., or Shire, effecting the assignment to Shire of the right to occupy our former office space located at 100 Hayden Avenue, Lexington, Massachusetts, or the Prior Space. Under the Assignment Agreement, the assignment to Shire became effective on September 21, 2013, the date of our departure from the Prior Space, and Shire assumed all of our obligations as the tenant of the Prior Space. The Assignment Agreement also provided for the conveyance of furniture and other personal property by us to Shire.

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 the 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.

A purported class action complaint was originally filed on March 18, 2010 in the U.S. District Court for the District of Massachusetts, entitled Silverstrand Investments et. al. v. AMAG Pharm., Inc., et. al., Civil Action No. 1:10-CV-10470-NMG, and was amended on September 15, 2010 and on December 17, 2010. The second amended complaint, or SAC, filed on December 17, 2010 alleged that we and our former President and Chief Executive Officer, former Chief Financial Officer, the then-members of our Board of Directors, and certain underwriters in our January 2010 offering of common stock violated certain federal securities laws, specifically Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended, and that our former President and Chief Executive Officer and former Chief Financial Officer violated Section 15 of such Act, respectively, by making certain alleged omissions in a registration statement filed in January 2010. The plaintiffs sought unspecified damages on behalf of a purported class of purchasers of our common stock pursuant to our common stock offering on or about January 21, 2010. On August 11 and 15, 2011, respectively, the District Court issued an Opinion and Order dismissing the SAC with prejudice for failure to state a claim upon which relief could be granted. On September 14, 2011, the plaintiffs filed a Notice of Appeal to the U.S. Court of Appeals for the First Circuit, or the Court of Appeals. The Court of Appeals heard oral argument on May 11, 2012. On February 4, 2013, the Court of Appeals affirmed in part and reversed in part the District Court's Opinion and Order and remanded the case to the District Court. On February 19, 2013, we filed a Petition for Panel Rehearing and Rehearing *En Banc*, which was denied on March 15, 2013. On March 22, 2013, we filed a Motion to Stay the Mandate remanding the case to

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the District Court pending review by the U.S. Supreme Court of the Court of Appeals' February 4, 2013 decision. The Court of Appeals granted the Motion to Stay the Mandate on April 8, 2013. On June 13, 2013, we filed a Petition for a Writ of Certiorari, or the Petition, with the U.S. Supreme Court seeking review of the Court of Appeal's decision and to have that decision overturned. On October 7, 2013 the U.S. Supreme Court denied our Petition, resulting in the case's return to the District Court for further proceedings relative to the SAC's surviving claims. On November 6, 2013, we filed a renewed Motion to Dismiss the SAC's surviving claims. On December 6, 2013, the plaintiffs filed a brief in opposition to our Motion to Dismiss and we filed a reply brief in support of our Motion on December 27, 2013. The plaintiffs are seeking leave of court to file a sur-reply in further opposition to our Motion to Dismiss. No hearing on the Motion to Dismiss is currently scheduled. We are currently unable to predict the outcome or reasonably estimate the range of potential loss associated with this matter, if any, and have therefore not recorded any potential estimated liability as we do not believe that such a liability is probable nor do we believe that a range of loss is currently estimable.

In July 2010, Sandoz GmbH, or Sandoz, filed with the European Patent Office, or the EPO, an opposition to a previously issued patent which covers ferumoxytol in EU jurisdictions. In October 2012, at an oral hearing, the Opposition Division of the EPO revoked this patent. In December 2012, our notice of appeal of that decision was recorded with the EPO, which also suspended the revocation of our patent. On May 13, 2013, we filed a statement of grounds of appeal and on September 27, 2013, Sandoz filed a response to that statement. We will continue to defend the validity of this patent throughout the appeals process, which we expect to take two to three years. However, in the event that we do not experience a successful outcome from the appeals process, under EU regulations ferumoxytol would still be entitled to eight years of data protection and ten years of market exclusivity from the date of approval, which we believe would create barriers to entry for any generic version of ferumoxytol into the EU market until sometime between 2020 and 2022. This decision had no impact on our revenues for the year ended December 31, 2013. However, any future unfavorable outcome in this matter could negatively affect the magnitude and timing of future revenues, including royalties and milestone payments we may receive from Takeda pursuant to our collaboration agreement with Takeda. We do not expect to incur any related liability regardless of the outcome of the appeal and therefore have not recorded any liability as of December 31, 2013. We continue to believe the patent is valid and intend to vigorously appeal the decision.

We may periodically become subject to 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, 2013.

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, or NASDAQ, under the trading symbol "AMAG." On February 3, 2014, the closing price of our common stock, as reported on the NASDAQ, was $20.63 per share. The following table sets forth, for the periods indicated, the high and low sale prices per share for our common stock as reported on the NASDAQ.

	High	Low
Year Ended December 31, 2013		
First quarter	$ 23.98	$ 15.00
Second quarter	$ 25.67	$ 18.46
Third quarter	$ 27.00	$ 20.35
Fourth quarter	$ 28.42	$ 18.94
Year Ended December 31, 2012		
First quarter	$ 19.24	$ 14.98
Second quarter	$ 16.45	$ 12.43
Third quarter	$ 17.95	$ 14.11
Fourth quarter	$ 18.50	$ 13.85

Stockholders

On February 3, 2014, 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 26,800 based on responses from brokers to a search conducted by Broadridge Financial Solutions, Inc. on our behalf.

Dividends

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

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Repurchases of Equity Securities

The following table provides certain information with respect to our purchases of shares of our stock during the fourth quarter of 2013.

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 that May Yet Be Purchased Under the Plans or Programs(2)
October 1, 2013 through October 31, 2013				
November 1, 2013 through November 30, 2013				
December 1, 2013 through December 31, 2013	16,034	$ 23.23		
Total	16,034	$ 23.23		

(1) Represents 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 do not currently have any publicly announced repurchase programs or plans.

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, to be filed with the U.S. Securities and Exchange Commission, or the SEC, not later than 120 days after the close of our year ended December 31, 2013.

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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 Market Composite Index and NASDAQ Biotechnology Index over the past five years. The comparisons assume $100 was invested on December 31, 2008 in our common stock, in the NASDAQ Global Market and the NASDAQ Biotechnology Index, and assumes reinvestment of dividends, if any.

	12/31/2008	12/31/2009	12/31/2010	12/31/2011	12/31/2012	12/31/2013
AMAG Pharmaceuticals, Inc.	100.00	106.08	50.49	52.75	41.03	67.73
NASDAQ Global Market Composite Index	100.00	144.83	173.20	150.14	173.45	288.80
NASDAQ Biotechnology Index	100.00	115.96	134.58	150.85	200.25	332.45

The stock price performance shown in this performance graph is not necessarily indicative of future price performance. Information used in the graph was obtained from Zach's Investment Research, Inc., a source we believe is reliable. However, we are not responsible for any errors or omissions in such information.

The material in this section captioned *Five-Year Cumulative 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, 2013, 2012, 2011, 2010 and 2009. 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,				
	2013	2012	2011	2010	2009
	(in thousands, except per share data)				
Statement of Operations Data					
Revenues:					
U.S. *Feraheme* product sales, net	$ 71,362	$ 58,287	$ 52,097	$ 59,339	$ 15,774
License fee and other collaboration revenues	8,385	26,475	8,321	6,132	516
Other product sales and royalties	1,109	616	831	774	888
Total revenues	80,856	85,378	61,249	66,245	17,178
Costs and expenses:					
Cost of product sales	11,960	14,220	10,531	7,606	1,013
Research and development expenses	20,564	33,296	58,140	54,462	36,273
Selling, general and administrative expenses	59,949	53,071	68,863	84,939	77,829
Restructuring expenses		2,215	3,508	2,224	
Total costs and expenses	92,473	102,802	141,042	149,231	115,115
Other income (expense):					
Interest and dividend income, net	1,051	1,286	1,747	1,741	3,154
Gains on sales of assets	924				
Gains (losses) on investments, net	40	(1,466)	(193)	408	942
Fair value adjustment of settlement rights				(788)	(778)
Total other income (expense)	2,015	(180)	1,554	1,361	3,318
Net loss before income taxes	(9,602)	(17,604)	(78,239)	(81,625)	(94,619)
Income tax benefit		854	1,170	472	1,268
Net loss	$ (9,602)	$ (16,750)	$ (77,069)	$ (81,153)	$ (93,351)
Net loss per share basic and diluted:	$ (0.44)	$ (0.78)	$ (3.64)	$ (3.90)	$ (5.46)
Weighted average shares outstanding used to compute net loss per share:					
Basic and diluted	21,703	21,392	21,189	20,806	17,109

	December 31,				
	2013	2012	2011	2010	2009
	(in thousands)				
Balance Sheet Data					
Working capital (current assets less current liabilities)	$ 211,284	$ 221,423	$ 201,037	$ 254,073	$ 85,168
Total assets	$ 265,459	$ 258,137	$ 267,224	$ 336,076	$ 184,619
Long-term liabilities	$ 59,930	$ 52,383	$ 47,634	$ 54,079	$ 4,081
Stockholders' equity	$ 172,408	$ 172,797	$ 180,596	$ 245,286	$ 142,977

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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 specialty pharmaceutical company that markets Feraheme® (ferumoxytol) Injection for Intravenous, or IV, use to treat iron deficiency anemia, or IDA, in adult patients with chronic kidney disease, or CKD, and MuGard® Mucoadhesive Oral Wound Rinse for the management of oral mucositis. Along with driving organic growth of our products, we intend to expand our portfolio with additional commercial-stage specialty products. Our primary goal is to bring to market therapies that provide clear benefits and improve patients' lives.

Currently, our principal source of revenue is from the sale of *Feraheme*, which was approved for marketing in the U.S. in June 2009 by the U.S. Food and Drug Administration, or the FDA, for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. We began selling *Feraheme* in the U.S. in July 2009 through our own commercial organization, including a specialty sales force. We sell *Feraheme* to authorized wholesalers and specialty distributors, who in turn, sell *Feraheme* to healthcare providers who administer *Feraheme* primarily within hospitals, hematology and oncology centers, and nephrology clinics. We are working to continue to grow *Feraheme* in the U.S. CKD market and to drive additional growth of *Feraheme* through international expansion, IV iron market expansion and label expansion. We are also focusing a portion of our efforts on marketing and selling *MuGard* in the U.S.

Portfolio Expansion

To further build our business, we intend to continue to expand our portfolio through the in-license or purchase of additional specialty pharmaceutical products or companies. In particular, we are seeking complementary products that will leverage our commercial infrastructure and focus on hematology and oncology centers, hospital infusion centers or other sites of care where IV iron is administered or where IDA patients are diagnosed or treated. We are also evaluating products in other strategic areas of interest, such as gastroenterology or rheumatology. Since patients within these specialties have high rates of co-morbid IDA, these new call points could be synergistic with the potential label expansion of *Feraheme*, if regulatory approval is obtained. In addition, we are contemplating transactions that would be financially beneficial to us, by providing an additional revenue stream from products that are approved for one or more indications, but that would be accretive to earnings and allow us to eliminate duplicative infrastructure, and potentially optimize after-tax cash flows. Finally, we may opportunistically look at commercialized products in other indications or products that we believe entail lower-risk late stage development.

As an example of a product acquisition with a synergistic call point to *Feraheme*, on June 6, 2013, or the Acquisition Date, we entered into a License Agreement with Access Pharmaceuticals, Inc., or Access, under which we acquired the U.S. commercial rights to *MuGard*, or the Access License Agreement. *MuGard* was launched in the U.S. by Access in 2010 after receiving 510(k) clearance from the FDA. *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 aphthous ulcers/canker sores and traumatic ulcers, such as those caused by oral surgery or ill-fitting dentures or braces. Under the Access License Agreement, we obtained an exclusive, royalty-bearing license, with the right to grant sublicenses, to certain intellectual property rights, including know-how, patents and trademarks, to use, import, offer for sale, sell, manufacture and commercialize *MuGard* in the U.S. and its territories, or the U.S. Territory, for the management of all diseases or conditions of the oropharyngeal cavity, including mucositis, or the MuGard Rights. We sell *MuGard* to wholesalers and specialty and retail pharmacies. See Note G to our consolidated financial statements included in

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this Annual Report on Form 10-K for additional information regarding the Access License Agreement and the MuGard Rights.

Label Expansion of Ferumoxytol

In addition to expanding our portfolio through the in-license or purchase of additional specialty pharmaceutical products or companies, we believe that a significant opportunity exists in the U.S. for *Feraheme* beyond the treatment of IDA in adult patients with CKD. In the U.S., approximately 851,000 grams of IV iron were administered for the treatment of non-dialysis patients with IDA in 2013. We believe that approximately half, or 425,000 grams, of the IV iron administered in the U.S. was for the treatment of non-dialysis patients with CKD and the other half was for non-CKD patients with IDA due to other causes, including patients with gastrointestinal diseases or disorders, abnormal uterine bleeding, inflammatory diseases, and chemotherapy-induced anemia.

In December 2012, we submitted a supplemental new drug application, or sNDA, to the FDA, seeking approval for *Feraheme* for the treatment of IDA in adult patients who had failed or could not use oral iron. The sNDA included data from two controlled, multi-center Phase III clinical trials, or IDA-301 and IDA-302, including more than 1,400 patients, which evaluated the safety and efficacy of ferumoxytol for the treatment of IDA in this broader patient population. Both studies met the primary efficacy endpoints related to improvements in hemoglobin. In these studies no new safety signals were observed with *Feraheme* treatment and the types of reported adverse events were consistent with those seen in previous studies and those contained in the approved U.S. package insert for *Feraheme*. In addition, patients from IDA-301 were eligible to enroll in an open-label extension study, or IDA-303, and receive treatment with *Feraheme,* as defined in the protocol.

On January 21, 2014, we received a complete response letter from the FDA for the sNDA informing us that our sNDA could not be approved in its present form and stating that we have not provided sufficient information to permit labeling of *Feraheme* for safe and effective use for the proposed broader indication. The FDA indicated that its decision was based on the cumulative ferumoxytol data, including the global Phase III IDA program and global post-marketing safety reports for the currently indicated CKD patient population. The FDA suggested, among other things, that we submit additional clinical trial data in the proposed broad IDA patient population with a primary composite safety endpoint of serious hypersensitivity/anaphylaxis, cardiovascular events and death, events that are included in the labels of *Feraheme* and other IV irons and that have been reported in the post-marketing environment for *Feraheme*. Additionally, the FDA proposed potentially evaluating alternative dosing and/or administration of *Feraheme*. Our plan for addressing the complete response letter from the FDA includes the following steps: (a) evaluate the FDA's recommendations in the complete response letter; (b) develop a proposal that we believe would be responsive to the points raised in the complete response letter and that we determine would be economically viable; (c) meet with FDA to discuss our proposal and explore the range of possible approaches to the points raised in the complete response letter; and (d) assess the FDA's feedback on our proposal and make a final determination on a possible program that would adequately address the FDA's concerns. Until we have further discussions with the FDA and receive its input, we cannot predict the path forward, if any, for *Feraheme* in the broad IDA patient population, including the related timing and cost of any clinical trials.

International Expansion of Ferumoxytol

Outside of the U.S., ferumoxytol has been granted marketing approval in Canada, Switzerland and the European Union, or EU, for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. The marketing authorization granted in the EU is valid in the 28 EU Member States as well as in Iceland, Liechtenstein and Norway. The trade name for ferumoxytol in Canada is *Feraheme* and in the EU and Switzerland it is Rienso® 30mg/ml solution for Injection. The

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EU competent authorities and recently Canadian regulatory authorities have implemented class labeling including stronger safety warnings for IV iron products, such as *Feraheme/Rienso*. Under our amended agreement with Takeda Pharmaceutical Company Limited, or Takeda, discussed below, Takeda has an exclusive license to market and sell ferumoxytol in Canada, the EU and Switzerland, as well as certain other geographic territories.

In June 2013, Takeda filed an application for Type II Variation of the marketing authorization for *Rienso* in the EU, which is the EU equivalent of a U.S. sNDA, with the European Medicines Agency, or EMA, seeking marketing authorization for an additional therapeutic indication for *Rienso* for the treatment of IDA in adult patients. Takeda is in the process of responding to the Day 90 List of Questions from the EMA and currently expects an opinion from the EMA and a related decision from the European Commission concerning the application for the Type II Variation in mid-2014. If the EMA issues a positive opinion for the inclusion of this additional therapeutic indication in the marketing authorization for *Rienso* and the European Commission adopts a decision approving this variation, we expect to receive a significant milestone payment from Takeda. In addition, in October 2013, Takeda filed a Supplemental New Drug Submission, or sNDS, with Health Canada seeking marketing approval for *Feraheme* for the treatment of IDA in a broad range of patients.

Takeda Collaboration

In March 2010, we entered into a License, Development and Commercialization Agreement, or the Takeda Agreement, which was amended in June 2012, or the Amended Takeda Agreement, with Takeda under which we granted exclusive rights to Takeda to develop and commercialize *Feraheme/Rienso* as a therapeutic agent in Europe, certain Asia-Pacific countries (excluding Japan, China and Taiwan), Canada, India and Turkey. In February 2014, we entered into the supply agreement with Takeda, which provides the terms under which we will sell *Feraheme* to Takeda in order for Takeda to meet its requirements for commercial use of *Feraheme* in its licensed territories. See "Other Information" in Part II, Item 9B for more information. The Takeda Agreement is discussed in further detail in Note Q to our consolidated financial statements included in this Annual Report on Form 10-K.

Post-Marketing Commitments of Feraheme in CKD

We have initiated a randomized, active-controlled pediatric study of *Feraheme* for the treatment of IDA in pediatric CKD patients to meet our FDA post-approval Pediatric Research Equity Act requirement to support pediatric labeling of *Feraheme* in the U.S. The study covers both dialysis-dependent and non-dialysis dependent CKD pediatric patients and will assess the safety and efficacy of *Feraheme* treatment as compared to oral iron in approximately 288 pediatric patients.

Our pediatric investigation plan, which was a requirement for submission of the Marketing Authorization Application, or MAA, for ferumoxytol, was approved by the EMA in December 2009 and amended in 2012, and includes the pediatric study as described above, and two additional pediatric studies requested by the EMA. These additional studies include a rollover extension study in pediatric CKD patients and a study in pediatric patients with IDA regardless of the underlying cause. The rollover study is open for enrollment. The pediatric IDA study will commence once the appropriate dose of *Feraheme* is determined from the study data resulting from the pediatric study of *Feraheme*, described above.

As part of our obligations under the Amended Takeda Agreement and as part of our post-approval commitments to the EMA, we initiated a multi-center clinical trial to determine the safety and efficacy of repeat doses of ferumoxytol for the treatment of IDA in patients with hemodialysis-dependent CKD. As part of the commitment we made to the EMA as a condition of the marketing authorization for ferumoxytol in the EU, this study includes a treatment arm with iron sucrose using a magnetic

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resonance imaging, or MRI, sub-analysis to evaluate the potential for iron to accumulate in the body following treatment with IV iron, specifically in the heart and liver, and, where possible, other major organs following repeated IV iron administration over a two year period. Enrollment is currently ongoing and we believe enrollment could be completed by the end of 2014. The costs related to the MRI portion of this study are subject to our established cost-sharing arrangement with Takeda.

In addition, certain clinical trials may be necessary to secure desired pricing in the EU Member States and other European markets. If so, the cost of any future trials may be allocated between us and Takeda according to the cost-sharing arrangement under the Amended Takeda Agreement.

Critical Accounting Policies

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. 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. The most significant estimates and assumptions are used in, but are not limited to, revenue recognition related to product sales and collaboration agreements, product sales allowances and accruals, assessing investments for potential other-than-temporary impairment and determining fair values of our investments, the fair value of our assets held for sale, fair value of assets acquired in a business combination, contingent consideration, the impairment of long-lived assets, including intangible assets, accrued expenses and equity-based compensation expense. Actual results could differ materially from those estimates. In making these estimates and assumptions, management employs critical accounting policies. Our critical accounting policies include revenue recognition and related sales allowances and accruals, valuation of investments, equity-based compensation, business combinations and contingent consideration.

1. Revenue Recognition and Related Sales Allowances and Accruals

We recognize revenue from the sale of *Feraheme/Rienso* and *MuGard* as well as license fee and other collaboration revenues, including milestone payments, other product sale revenues, and royalties we receive from our licensees. We recognize revenue in accordance with current accounting guidance related to the recognition, presentation and disclosure of revenue in financial statements, which outlines the basic criteria that must be met to recognize revenue and provides guidance for disclosure of revenue in financial statements. We recognize revenue when:

Persuasive evidence of an arrangement exists;

Delivery of product has occurred or services have been rendered;

The sales price charged is fixed or determinable; and

Collection is reasonably assured.

U.S. Feraheme Product Sales, Net

We record *Feraheme* product sales allowances and accruals related to prompt payment discounts, chargebacks, government and other rebates, distributor, wholesaler and group purchasing organization, or GPO, fees, and product returns as a reduction of revenue in our consolidated statement of operations at the time product sales are recorded. Calculating these gross-to-net sales adjustments involves estimates and judgments based primarily on actual *Feraheme* sales data, forecasted customer buying patterns and market research data related to utilization rates by various end-users. In addition, we also monitor our distribution channel to determine whether additional allowances or accruals are required based on inventory in our sales channel.

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Classification of U.S. Feraheme Product Sales Allowances and Accruals

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

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

Discounts

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

Chargebacks

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

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Government and Other Rebates

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

During 2013, we revised our estimated Medicaid utilization rate based on actual rebate claims received since the 2009 launch of *Feraheme,* our expectations of state level activity, and estimated rebate claims not yet submitted, which resulted in a $0.6 million reduction of our estimated Medicaid rebate reserve related to prior period *Feraheme* sales. This change in estimate was reflected as an increase in our net product sales in 2013. As a result, our gross to net percentage for 2013 was slightly lower than it otherwise would have been had we not reduced our Medicaid rebate reserve. The reduction of our estimated Medicaid rebate reserve had an impact of $0.03 per basic and diluted share for 2013. 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 or if other factors affect estimated claims rates, we may be required to change our estimated Medicaid reserve and/or the current rate at which we estimate our Medicaid claims, which would affect our earnings in the period of the change in estimate and such change could be significant. A 1% increase in our estimate of our Medicaid utilization rate for 2013 would have resulted in approximately a $0.2 million decrease in net product sales.

Distributor/Wholesaler and Group Purchasing Organization Fees

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

Product Returns

Consistent with industry practice, we generally offer our wholesalers, specialty distributors and other customers a limited right to return *Feraheme* purchased directly from us based on the product's expiration date which, once packaged, is currently five years in the U.S. We estimate product returns based on the historical return patterns and known or expected changes in the marketplace. We

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currently have limited actual returns data, and therefore are not able to solely rely on our actual returns experience. 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 consider several additional factors in our product return estimation process, including our internal sales forecasts and inventory levels in the distribution channel. We expect that wholesalers and healthcare providers will not stock significant inventory due to *Feraheme's* cost and expense to store. Based on the level of inventory in the wholesale distribution channel, we determine whether an adjustment to the sales return reserve is appropriate.

We record an estimate of returns at the time of sale. If necessary, our estimated rate of returns may be adjusted for actual return experience as it becomes available and for known or expected changes in the marketplace. During 2012, we reduced our reserve for product returns by approximately $2.2 million, primarily as a result of a lower than expected rate of product returns as well as the lapse of the product return period on certain manufactured *Feraheme* lots that carried a two year expiration. As a result, the product returns provision applied to gross product sales for the year ended December 31, 2012 was a credit of $1.5 million, resulting in an increase to net product sales for the year. The reduction of our estimated product returns reserve had a positive impact of $0.10 per basic and diluted share for year ended December 31, 2012. We did not significantly adjust our reserve for product returns during 2013 or 2011. *Feraheme* is still early in its product lifecycle and returns experience may change over time. A future revision to our product returns estimate would result in a corresponding change to our net product sales in the period in which the change is made and could be significant. A 1% increase in our returns as a percentage of gross sales for the year ended December 31, 2013, would have resulted in approximately a $1.2 million decrease in net product sales.

Other Product Sales and Royalties

Other product sales and royalties include product sales of *Feraheme/Rienso* and GastroMARK® to our licensees, net product sales of *MuGard* and royalties received from our licensees' sales of *Feraheme/Rienso* and *GastroMARK*. We record all product sales for *Feraheme/Rienso* sold to Takeda and the associated cost of product sales in deferred revenues and deferred cost of product sales in our consolidated balance sheet. We recognize these deferred revenues and cost of product sales, in our consolidated statement of operations at the time Takeda reports to us that sales have been made to its customers.

Milestone Payments under Multiple Element Arrangements

From time to time, we may enter into collaborative license and development agreements with biotechnology and pharmaceutical companies for the development and commercialization of our products or product candidates. The terms of the agreements may include non-refundable license fees, payments based on the achievement of certain milestones and performance goals, reimbursement of certain out-of-pocket costs, payments for manufacturing services, and royalties on product sales.

We evaluate revenue from arrangements that have multiple elements to determine whether the components of the arrangement represent separate units of accounting as defined in the accounting guidance related to revenue arrangements with multiple deliverables. Under current accounting guidance, which governs any agreements that contain multiple elements that are either entered into or materially modified subsequent to January 1, 2011, companies are required to establish the selling price of undelivered products and services based on a separate revenue recognition process using management's best estimate of the selling price for an undelivered item when there is no vendor-specific objective evidence or third-party evidence to determine the selling price of that undelivered item. Agreements entered into prior to January 1, 2011, that have not been materially modified,

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including our agreement with Takeda, are accounted for under previous accounting guidance, which provides that an element of a contract can be accounted for separately if the delivered elements have standalone value and the fair value of all undelivered elements is determinable. If an element is considered to have standalone value but the fair value of any of the undelivered items cannot be determined, all elements of the arrangement are recognized as revenue as a single unit of accounting over the period of performance for such undelivered items or services. Significant management judgment is required in determining what elements constitute deliverables and what deliverables or combination of deliverables should be considered units of accounting.

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

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

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

The milestone is related solely to our past performance; and

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

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

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in our consolidated balance sheets. Amounts not expected to be recognized within the next 12 months are classified as long-term deferred revenue.

Takeda Agreement

In March 2010, we entered into the Takeda Agreement which, as discussed above, was amended in June 2012 to, among other things, modify the timing and pricing arrangements for a supply agreement to be entered into between us and Takeda, the terms related to primary and secondary manufacturing for drug substance and drug product, certain patent related provisions, and the re-allocation of certain of the agreed-upon milestone payments. We analyzed the Amended Takeda Agreement and determined that the amended terms did not result in a material modification of the original Takeda Agreement

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(and thus did not require us to change our accounting model) because (a) there were no changes to the deliverables under the original Takeda Agreement as a result of the amendment, and (b) the change in arrangement consideration as a result of the amendment was not quantitatively material in relation to the total arrangement consideration.

Under the Amended Takeda Agreement, except under limited circumstances, we have retained the right to manufacture *Feraheme/Rienso* and, accordingly, are responsible for supply of *Feraheme/Rienso* to Takeda at a fixed price per unit, which is capped for a certain period of time. We are also responsible for conducting, and bearing the costs related to, certain pre-defined clinical studies with the costs of future modifications or additional studies to be allocated between the parties according to an agreed-upon cost-sharing mechanism. We have determined that our obligations under the Amended Takeda Agreement have not changed from those under the original Takeda Agreement and include the following four deliverables: the license, access to future know-how and improvements to the *Feraheme/Rienso* technology, regulatory and clinical research activities, and the manufacturing and supply of product. Pursuant to the accounting guidance in effect in March 2010, when we signed the original Takeda Agreement and which governed revenue recognition on multiple element arrangements, we evaluated the four deliverables under the original Takeda Agreement and determined that our obligation to provide manufacturing supply of product meets the criteria for separation and is therefore treated as a single unit of accounting, which we refer to as the supply unit of accounting. Further, we concluded that the license is not separable from the undelivered future know-how and technological improvements or the undelivered regulatory and clinical research activities. Accordingly, these deliverables are being combined and also treated as a single unit of accounting, which we refer to as the combined unit of accounting.

With respect to the combined unit of accounting, our obligation to provide access to our future know-how and technological improvements is the final deliverable and is an obligation which exists throughout the term of the Amended Takeda Agreement.

In connection with the execution of the original Takeda Agreement, we received a $60.0 million upfront payment from Takeda in April 2010, which we recorded as deferred revenue, as well as approximately $1.0 million reimbursed to us during 2010 for certain expenses incurred prior to entering the agreement, which we considered an additional upfront payment. Because we cannot reasonably estimate the total level of effort required to complete the obligations under the combined deliverable, we are recognizing the entire $60.0 million upfront payment, the $1.0 million reimbursed to us in 2010, as well as any non-substantive milestone payments that are achieved into revenues on a straight-line basis over a period of ten years from March 31, 2010, the date on which we originally entered the Takeda Agreement, which represented the then current patent life of *Feraheme/Rienso* and our best estimate of the period over which we will substantively perform our obligations. We continue to believe that the then current patent life of *Feraheme/Rienso* is our best estimate of the period over which we will substantively perform our obligations under this agreement. Any potential non-substantive milestone payments that may be received in the future will be recognized as revenue on a cumulative catch up basis when they become due and payable.

Under the terms of the Amended Takeda Agreement, Takeda is responsible for reimbursing us for certain out-of-pocket regulatory and clinical trial supply costs associated with carrying out our regulatory and clinical research activities under the collaboration agreement. Because we are acting as the principal in carrying out these services, any reimbursement payments received from Takeda are recorded in license fee and other collaboration revenues in our consolidated statement of operations to match the costs that we incur during the period in which we perform those services.

At the time of shipment, we defer recognition of all revenue for *Feraheme/Rienso* sold to our licensees in our consolidated balance sheets. We recognize revenues from product sales to our licensees, the related cost of goods sold, and any royalty revenues due from our licensees, in our

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consolidated statement of operations at the time our licensees report to us that sales have been made to their customers.

2. Valuation of investments

We generally invest in corporate debt securities U.S. treasury and government agency securities, and commercial paper. All of our investments are classified as "available-for-sale" and are recorded at their estimated fair value. The fair value of our investments is generally determined from quoted market prices received from independent pricing services based upon market transactions. Independent pricing services normally derive security prices from recently reported trades for identical or similar securities, making adjustments based upon other significant observable market transactions. At the end of each reporting period, we perform quantitative and qualitative analyses of prices received from third parties to determine whether prices are reasonable estimates of fair value.

We also analyze when the volume and level of activity for an asset or liability have significantly decreased and when circumstances indicate that a transaction may not be considered orderly. In order to determine whether the volume and level of activity for an asset or liability have significantly decreased, we assess current activity as compared to normal market activity for the asset or liability. We rely on many factors such as trading volume, trading frequency, the levels at which market participants indicate their willingness to buy and sell our securities, as reported by market participants, and current market conditions. Using professional judgment and experience, we evaluate and weigh the relevance and significance of all applicable factors to determine if there has been a significant decrease in the volume and level of activity for an asset, group of similar assets or liabilities. Similarly, in order to identify transactions that are not orderly, we take into consideration the activity in the market which can influence the determination and occurrence of an orderly transaction. Also, we inquire as to whether there may have been restrictions on the marketing of the security to a single or limited number of participants. Where possible, we assess the financial condition of the seller to determine whether observed transactions may have been forced. If there is a significant disparity between the trading price for a security held by us as compared to the trading prices of similar recent transactions, we consider whether this disparity is an indicator of a disorderly trade. Using professional judgment and experience, we evaluate and weigh the relevance and significance of all applicable factors to determine if the evidence suggests that a transaction or group of similar transactions is not orderly. Based upon these procedures, we determined that market activity for our assets appeared normal and that transactions did not appear disorderly as of December 31, 2013 and 2012.

We recognize and report other-than-temporary impairments of our debt securities in accordance with current accounting guidance, which requires that for debt securities with a decline in fair value below amortized cost basis, an other-than-temporary impairment exists if (a) we have the intent to sell the security or (b) it is more likely than not that we will be required to sell the security prior to recovery of its amortized cost basis. If either of these conditions is met, we recognize the difference between the amortized cost of the security and its fair value at the impairment measurement date in our consolidated statement of operations. If neither of these conditions is met, we must perform additional analyses to evaluate whether the unrealized loss is associated with the creditworthiness of the security rather than other factors, such as interest rates or market factors. These factors include evaluation of the security, issuer and other factors such as the duration of the period that, and extent to which, the fair value was less than cost basis, the financial health of and business outlook for the issuer, including industry and sector performance, operational and financing cash flow factors, overall market conditions and trends, underlying collateral, whether we have a favorable history in redeeming similar securities at prices at or above fair value, and credit ratings with respect to our investments provided by investments ratings agencies. 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. In

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this situation, the impairment is considered other-than-temporary and is recognized in our consolidated statement of operations.

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, and the impairment is considered other-than-temporary and is recognized in our consolidated statement of operations. Our assessment of whether unrealized losses are other-than-temporary requires significant judgment.

3. Equity-Based Compensation

Under the fair value recognition guidance of equity-based compensation accounting rules, equity-based compensation cost is generally required to be measured at the grant date (based upon an estimate of the fair value of the compensation granted) and recorded to expense over the requisite service period, which generally is the vesting period. Because equity-based compensation expense is based on awards ultimately expected to vest, we must make certain judgments about whether employees and directors will complete the requisite service period. Accordingly, we have reduced the compensation expense being recognized for estimated 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. Forfeitures are estimated based upon historical experience, adjusted for unusual events such as the corporate restructurings in 2012, 2011 and 2010, which resulted in higher than expected turnover and forfeitures in those years. 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. We estimate the fair value of our restricted stock units whose vesting is contingent upon market conditions using the Monte-Carlo simulation model. These models require 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 whose fair values are calculated using the Black-Scholes option pricing model is generally being 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. The fair value of awards with market conditions is being amortized based upon the estimated derived service period. 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 thus may not be reflective of actual future results or amounts ultimately realized by recipients of these grants. These amounts, and the amounts applicable to future quarters, are also 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. The fair value of restricted stock units granted to our employees and directors is determined based upon the quoted closing market price per share on the date of grant, adjusted for estimated forfeitures. As with any accounting policy that applies judgments and estimates, actual results could significantly differ from those estimates which could result in a material adverse impact to our financial results.

4. Business Combination

In June 2013, we acquired the MuGard Rights and inventory for total consideration of $17.1 million, consisting of a cash payment of $3.4 million and contingent consideration with an estimated acquisition date fair value of $13.7 million. The transaction was accounted for as a business combination under the acquisition method of accounting, which requires, with limited exceptions, that assets acquired and liabilities assumed be recognized at their estimated fair values as of the Acquisition Date. Transaction costs are expensed as incurred. Any excess of the consideration transferred over the estimated values of the net assets acquired is recorded as goodwill.

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The following table summarizes the estimated fair values of the assets acquired related to the MuGard Rights as of the Acquisition Date (in thousands):

Assets Acquired:	
MuGard intangible asset	$ 16,893
Inventory	241
Net identifiable assets acquired	$ 17,134

We recorded $16.9 million of finite-lived intangible assets related to the MuGard Rights, which is being amortized using an economic consumption model over ten years, which represents our best estimate of the period over which we expect the majority of the asset's cash flows to be derived. The fair value of the acquired *MuGard* intangible asset was determined using an income approach, including a discount rate of 19%. This approach begins with a forecast of the net cash flows expected to be generated by the asset over its estimated useful life. These cash flows are then adjusted to present value by applying an appropriate discount rate that reflects the risk factors associated with the cash flow streams. Some of the more significant estimates and assumptions inherent in the income approach include the following:

The amount and timing of projected future cash flows, adjusted for the probability of marketing success;

The discount rate selected to measure the risks inherent in the future cash flows; and

An assessment of the asset's life-cycle and the competitive trends impacting the asset.

Estimating the fair value of assets acquired in a business combination requires significant judgment. We believe the estimated fair values of the assets acquired are based on reasonable assumptions.

5. Intangible Assets and Impairment

Intangible assets represent the fair value of the MuGard Rights. We will amortize these assets using an economic consumption model over ten years. We believe this is the best approximation of the period over which we will derive the majority of value of the MuGard Rights. Intangible assets are reviewed for impairment at least annually and whenever facts or circumstances suggest that the carrying value of these assets may not be recoverable. Our policy is to identify and record impairment losses, if necessary, on intangible assets when events and circumstances indicate that the assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amounts of those assets.

6. Contingent Consideration

The acquisition of the MuGard Rights included contingent consideration to be paid to Access based on the occurrence of future events, in particular the payment of royalties to Access. Acquisition-related contingent consideration is initially recognized at fair value and then remeasured each reporting period, with changes in fair value recorded in our consolidated statements of operations. During 2013, we completed the valuation for the acquisition of the MuGard Rights. Each quarter we will revalue the contingent consideration obligations associated with the acquisition of the MuGard Rights to their then fair value and record increases in the fair value as contingent consideration expense and record decreases in their fair value as a reduction of contingent consideration expense. Changes in contingent consideration expense result from changes in the assumptions regarding probabilities of the estimated timing and amount of royalty payments to Access and the discount rate used to estimate the fair value of the liability. Contingent consideration expense may change significantly as we gain more information related to sales of *MuGard*, impacting our assumptions. Currently, we estimate that the undiscounted

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royalty amounts we could pay under the Access License Agreement may range from $28.0 million to $34.0 million over a ten year period. The assumptions used in estimating fair value require significant judgment. The use of different assumptions and judgments could result in a materially different estimate of fair value.

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.

Results of Operations 2013 as compared to 2012

Revenues

Our total revenues for 2013 and 2012 consisted of the following (in thousands):

	Years Ended December 31,		2013 to 2012 change	
	2013	2012	$ Change	% Change
U.S. *Feraheme* product sales, net	$ 71,362	$ 58,287	$ 13,075	22%
License fee and other collaboration revenues	8,385	26,475	(18,090)	-68%
Other product sales and royalties	1,109	616	493	80%
Total	$ 80,856	$ 85,378	$ (4,522)	-5%

Our total revenues in 2013 decreased by $4.5 million as compared to 2012, primarily as the result of our recognition of approximately $20.0 million in 2012 related to milestone payments we received from Takeda in 2012 as compared to $1.8 million recognized in 2013. The net decrease was partially offset by a $13.1 million increase in U.S. net *Feraheme* product sales and a $0.5 million increase in other product sales and royalties. Our net product sales for each of 2013 and 2012 included a $0.6 million reduction of our estimated Medicaid rebate reserve related to prior *Feraheme* sales, as discussed below. In addition, our net product sales for 2012 included a $2.2 million reduction of our estimated product return reserve, as discussed below.

The following table sets forth customers who represented 10% or more of our total revenues for 2013 and 2012:

	Years Ended December 31,	
	2013	2012
AmerisourceBergen Drug Corporation	41%	34%
McKesson Corporation	24%	17%
Cardinal Health, Inc.	16%	12%
Takeda Pharmaceuticals Company Limited	11%	31%

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U.S. Feraheme Product Sales, Net

U.S. *Feraheme* product sales and product sales allowances and accruals for 2013 and 2012 consisted of the following (in thousands):

	Years Ended December 31,					
	2013	Percent of gross U.S. Feraheme product sales	2012	Percent of gross U.S. Feraheme product sales	$ Change	% Change
Gross U.S. *Feraheme* product sales	$ 119,712		$ 88,725		$ 30,987	35%
Less provision for product sales allowances and accruals:						
Discounts and chargebacks	37,098	31%	26,517	30%		
Government and other rebates	10,868	9%	6,058	7%		
Medicaid rebate reserve adjustment	(568)	0%	(621)	-1%		
Returns	952	1%	(1,516)	-2%		
Total	48,350	40%	30,438	34%		
Net U.S. *Feraheme* product sales	$ 71,362		$ 58,287		$ 13,075	22%

Our gross U.S. *Feraheme* product sales increased by $31.0 million, or 35%, during 2013 as compared to 2012. Of the $31.0 million increase, $21.5 million was due to increased units sold and $9.5 million was due to price increases. This increase was partially offset by $15.7 million of additional allowances and accruals in 2013, excluding a $2.2 million reduction of our estimated product return reserves in 2012 and a $0.6 million reduction of our estimated Medicaid rebate reserve related to prior *Feraheme* sales for each of 2013 and 2012, as described below. As a result of these factors, total net U.S. *Feraheme* product sales increased by $13.1 million, or 22%, during 2013 as compared to 2012. We anticipate increasing competitive pressures in 2014 may lead to slowing growth in product sales as compared to 2013.

Total discounts and chargebacks for 2013 were $37.1 million, or 31% of total gross product sales, as compared to $26.5 million, or 30%, in 2012. The 1% increase in total discounts and chargebacks as a percentage of total gross U.S. *Feraheme* product sales was related primarily to a change in our customer mix.

Total government and other rebates (excluding any changes in estimates related to Medicaid rebate reserves) were $10.9 million, or 9% of total gross U.S. *Feraheme* product sales, in 2013 as compared to $6.1 million, or 7%, in 2012. The 2% increase in total government and other rebates as a percentage of gross U.S. *Feraheme* product sales was related primarily to higher prices charged for *Feraheme* in 2013 as compared to 2012 and increased sales to clinics and hospitals that had volume or market share contracts with us during 2013 as compared to 2012.

We are subject to reimbursement arrangements with state Medicaid programs for which we estimate and record rebate reserves. We determine our estimates for Medicaid rebates based on actual *Feraheme* sales data and our historical *Feraheme* claims experience. During each of 2013 and 2012, we reduced our estimated Medicaid reserve related to prior *Feraheme* sales by approximately $0.6 million based on actual product-specific rebate claims received since the 2009 launch of *Feraheme*, our expectations of state level activity, and estimated rebate claims not yet submitted. These changes in estimates were reflected as an increase of $0.6 million in our net product sales for 2013 and 2012 and resulted in reductions to our gross to net percentage in these respective periods.

We generally offer our wholesalers, specialty distributors and other customers a limited right to return *Feraheme* purchased directly from us, principally based on the product's expiration date which, once packaged, is currently five years in the U.S. Reserves for product returns for U.S. *Feraheme* sales

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are recorded in the period the related revenue is recognized, resulting in a reduction to product sales. Currently, sales to our licensees are recognized as revenue when product is sold to our licensees' customers and therefore no return reserve is required at the time of sale to our licensees. We evaluate our estimated product returns rate each period based on the historical return patterns and known or expected changes in the marketplace. During 2012, we reduced our reserve for product returns by approximately $2.2 million, primarily as a result of a lower than expected rate of product returns as well as the lapse of the product return period on certain manufactured *Feraheme* lots that carried a two year expiration. As a result, the product returns provision applied to gross product sales for 2012 was a credit of $1.5 million, resulting in an increase to product sales, as compared to a $1.0 million charge in 2013, resulting in a decrease to product sales. There was no significant adjustment of our reserve for product returns in 2013.

We regularly assess our Medicaid and product return reserve balances and accrual rates. If we determine in future periods that our actual rebate or returns experience is not indicative of expected claims or returns, if our actual claims or returns experience changes, or if other factors affect estimated claims or returns rates, we may be required to change our Medicaid reserve or product return reserve estimates and/or the current rates at which we estimate Medicaid reserves or returns, which would affect our earnings in the period of the change and could be significant.

An analysis of the amount of, and change in, reserves for 2013 and 2012 is as follows (in thousands):

	Discounts and Chargebacks	Government and Other Rebates	Returns	Total
Balance at January 1, 2012	$ 1,822	$ 3,101	$ 2,842	$ 7,765
Current provisions relating to sales in current year	26,517	6,152	577	33,246
Adjustments relating to sales in prior years		(715)	(2,093)	(2,808)
Payments/returns relating to sales in current year	(24,709)	(4,511)		(29,220)
Payments/returns relating to sales in prior years	(1,859)	(1,597)	(308)	(3,764)
Balance at December 31, 2012	$ 1,771	$ 2,430	$ 1,018	$ 5,219
Current provisions relating to sales in current year	37,098	10,868	952	48,918
Adjustments relating to sales in prior years		(568)		(568)
Payments/returns relating to sales in current year	(34,538)	(8,194)		(42,732)
Payments/returns relating to sales in prior years	(1,648)	(1,699)	(8)	(3,355)
Balance at December 31, 2013	$ 2,683	$ 2,837	$ 1,962	$ 7,482

During 2013 and 2012, we decreased our product sales allowances and accruals by approximately $0.6 million and $2.8 million, respectively, for changes in estimates relating to sales in prior years, as discussed above.

During 2013 and 2012, we implemented gross price increases for *Feraheme,* some portion of which were discounted back to customers under volume or market share based contracts. When portions of price increases are discounted back to customers, it has the effect of widening the gross to net adjustment percentage. In 2014, we expect discounts and rebates to continue to increase as a percentage of gross sales due to increasing pricing pressure caused by the recent approval of Injectafer® in the U.S., our contracting and discounting strategy and the mix of business for *Feraheme*. These discounts and rebates are intended to continue to increase adoption and utilization of *Feraheme*. As a result, we expect the net revenue per gram of *Feraheme* realized in 2014 to sequentially decline from the fourth quarter of 2013; however, we expect the average net revenue per gram for all of 2014 to be relatively consistent with the average net revenue per gram for all of 2013.

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In addition, our results of operations, including, in particular, product sales revenues, fluctuate from quarter to quarter due to the demand patterns of wholesalers, distributors, clinics and hospitals, the reasons for which may vary. We also have limited or no visibility into our customers' buying decisions, which may be affected from time to time by incentives we make available to clinics, hospitals and GPOs including volume rebates. We expect clinics and hospitals to continue to take advantage of such incentives in the future, which may result in uneven purchasing patterns, causing *Feraheme* sales to fluctuate in subsequent quarters.

There are a number of factors that make it difficult to predict the magnitude of future *Feraheme* sales, including but not limited to, the following:

- The magnitude and timing of adoption and utilization of *Feraheme* by physicians, hospitals and other healthcare payors and providers;
- Any expansion or contraction of the overall size of the IV iron market, which could result from a number of factors including but not limited to, changes in treatment guidelines or practices related to IDA;
- The introduction of new competitive products in the iron replacement therapeutic market, such as the July 2013 U.S. approval of Injectafer® for a broad patient population or potential generic versions of new or currently available drug therapies;
- The impact of and any actions taken by us or our competitors to address pricing and reimbursement considerations related to *Feraheme* or products that compete with *Feraheme;*
- The impact of any actual or perceived safety or efficacy issues with *Feraheme* and any related product recalls or potential changes to our current label based on post-marketing safety data;
- The fees charged, and reserves required, related to fees for services provided to wholesalers, distributors, GPOs and others involved in the purchase or distribution of *Feraheme*;
- The effect of federal and other legislation such as The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the Health Care Reform Act, and the Budget Control Act of 2011, including the effect of the recent federal budget sequester on Medicare reimbursement rates which may cause a shift in where patients are treated to sites of care that have a lower mandated price for *Feraheme*, such as 340B institutions;
- The inventory levels maintained by *Feraheme* wholesalers, distributors and clinics or hospitals;
- The frequency of re-orders by existing customers; and
- The impact of any difficulties, disruptions or delays in the manufacturing process for *Feraheme/Rienso*.

As a result of these and other factors, future *Feraheme* sales could vary significantly from quarter to quarter and, accordingly, our *Feraheme* net product revenues in current or previous quarters may not be indicative of future *Feraheme* net product revenues. In addition, we cannot predict whether or when we will be able to satisfactorily address the issues raised in the complete response letter we received from the FDA in January 2014 related to our sNDA for *Feraheme* for the treatment of IDA in a broad range of patients.

Recent Healthcare Reform Legislation

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

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The Health Care Reform Act also requires pharmaceutical manufacturers to pay a prorated share of the overall Branded Drug Fee, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the legislation. The amount of our annual share of the Branded Drug Fee for 2013 and 2012 was less than $0.1 million and these payments were non-deductible for income tax purposes. We have included these amounts in selling, general and administrative expense in our consolidated statements of operations. The amount of this annual payment could increase in future years due to both higher eligible *Feraheme* sales and the increasing amount of the overall fee assessed across manufacturers, but any such increases are not expected to be material to our results of operations or financial condition.

In addition, the number of 340B institutions, which provide drugs at reduced rates, was expanded by the Health Care Reform Act to include additional hospitals. As a result, the volume of *Feraheme* business sold to 340B eligible entities has increased since the implementation of the Health Care Reform Act. Because these institutions are eligible for federal pricing discounts, the revenue realized per unit of *Feraheme* sold to 340B institutions is lower than from our other customers.

Further, under the sequestration required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012, Medicare payments for all items and services under Parts A and B incurred on or after April 1, 2013 have been reduced by up to 2%. Therefore, after adjustment for deductible and co-insurance, the reimbursement rate for physician-administered drugs, including *Feraheme*, under Medicare Part B has been reduced from average selling price, or ASP, plus 6% to ASP plus 4.3%. Because the majority of our business is through hematology/oncology clinics and out-patient hospital infusion centers, this reduction in the Medicare reimbursement payment for *Feraheme* may adversely impact our future revenues. Beginning in April 2013, we amended certain of our customer contracts to try to partially address the impact of sequestration on our customers and their patients. These amendments have led to increased discounts and rebates.

We were not materially impacted by recent healthcare reform legislation during 2013 or 2012. Presently, we have not identified any provisions that could materially impact our business but we will continue to monitor future legislative developments.

License Fee and Other Collaboration Revenues

License fee and other collaboration revenues for 2013 and 2012 consisted of the following (in thousands):

	Years Ended December 31,		2013 to 2012 change	
	2013	2012	$ Change	% Change
Milestone revenues recognized from Takeda	$ 1,800	$ 19,950	$ (18,150)	-91%
Deferred license fee revenues recognized from Takeda	6,096	6,096		0%
Reimbursement revenues from Takeda	489	429	60	14%
Total	$ 8,385	$ 26,475	$ (18,090)	-68%

Our license fee and other collaboration revenues in 2013 decreased by $18.1 million as compared to 2012 primarily due to milestones received in 2012. Our milestone revenues in 2012 included a $15.0 million milestone payment from Takeda associated with the regulatory approval of *Rienso* in the EU, which we deemed a substantive milestone and recorded in its entirety. In addition, our 2012 milestone revenues included the recognition of a portion of an aggregate of $18.0 million of milestone payments related to the commercial launches of *Feraheme/Rienso* in Canada and the EU, which we deemed non-substantive milestones and are amortizing into revenue on a cumulative catch up basis using the proportional performance method extended over the original life of the Takeda Agreement. We did not receive any milestone payments in 2013. In 2013 and 2012, we also recorded $7.9 million

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and $26.1 million, respectively, of revenues associated with the amortization of the upfront payments and the milestone payments we have received since the inception of our agreement with Takeda. As of December 31, 2013, we had approximately $49.3 million remaining in deferred revenues related to the $61.0 million in upfront payments and the $18.0 million in non-substantive milestone payments received from Takeda.

Under the terms of the Amended Takeda Agreement, Takeda is responsible for reimbursing us for certain out-of-pocket development costs we incur in the conduct of certain activities we manage under the agreement. Because we are acting as the principal in carrying out these activities, any reimbursement payments received from Takeda are recorded in license fee and other collaboration revenues and offset the costs that we incur during the period in which we perform those services. During 2013 and 2012, we recorded $0.5 million and $0.4 million, respectively, of revenues associated with certain out-of pocket development costs in connection with the Amended Takeda Agreement.

We anticipate that our license fee and other collaboration revenues will increase in 2014 as compared to 2013 as a result of an increase in out-of-pocket costs associated with certain development activities that we are managing for which Takeda will provide reimbursement. In addition, our license fees and other collaboration revenues would increase significantly if Takeda receives approval of its Type II variation in the EU for Rienso in the broad IDA indication, which would trigger a significant milestone payment. However, there can be no assurances as to whether or when Takeda will receive such approval.

Other Product Sales and Royalties

Other product sales and royalties include product sales and royalties of *Feraheme/Rienso* from Takeda, net product sales of *MuGard* and product sales of *GastroMARK* to our licensees. The $0.5 million increase in other product sales and royalties in 2013 as compared to 2012 was due to increased *MuGard* sales following our June 2013 in-license and increased sales and royalty revenue related to the Amended Takeda Agreement, partially offset by decreased *GastroMARK* sales as a result of our 2012 termination of our agreement with our *GastroMARK* licensees.

As of December 31, 2013, we had approximately $2.4 million in deferred revenue related to product shipped to Takeda, but not yet sold through to Takeda's customers, of which $0.3 million was classified as short-term and $2.1 million was classified as long-term. In addition, we had $2.3 million in deferred cost of product sales, of which $0.3 million was classified as short-term and $2.0 million was classified as long-term. These deferred revenue and deferred cost of product sales are recorded in our consolidated balance sheet as of December 31, 2013.

We expect other product sales and royalties to increase in 2014 as compared to 2013 due to increased *MuGard* sales and increased sales and royalty revenue associated with the Amended Takeda Agreement.

Costs and Expenses

Cost of Product Sales

Cost of product sales for 2013 and 2012 consisted of the following (in thousands):

	Years Ended December 31,		2013 to 2012 change	
	2013	2012	$ Change	% Change
Cost of Product Sales	$ 11,960	$ 14,220	$ (2,260)	-16%
Percentage of Net Product Sales and Royalties	17%	24%		

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Our cost of product sales are primarily comprised of manufacturing costs, costs of managing our contract manufacturers, and costs for quality assurance and quality control associated with our sales of *Feraheme* and *MuGard* in the U.S., sales of *Feraheme/Rienso* to Takeda, and *GastroMARK* sales to our licensees. The $2.3 million decrease in our cost of product sales for 2013 as compared to 2012 was attributable to the following factors:

- $3.6 million decrease due to costs related to the 2012 closure of our Cambridge, Massachusetts manufacturing facility, including $2.3 million in accelerated depreciation and impairment costs related to the 2012 impairment of our manufacturing facility and other related production costs;

- $1.5 million decrease due to a lower average cost per vial sold, partially offset by $1.2 million increase due to a higher volume of *Feraheme* vials sold in 2013;

- $0.8 million increase due to the sale of pre-approval validation lots in 2012, which in accordance with our capitalization policy, excluded costs that had been expensed prior to FDA approval of the manufacturing process;

- $0.5 million increase due to a write-off of inventory that was affected by a voluntary recall of a specific batch of *Rienso* from the Swiss market in May 2013; and

- $0.3 million increase related to sales of *MuGard* and sales to our partners.

We expect our cost of product sales as a percentage of net product sales and royalties to remain relatively consistent in 2014 as compared to 2013.

Research and Development Expenses

Research and development expenses include external expenses, such as costs of clinical trials, contract research and development expenses, certain manufacturing research and development costs, regulatory filing fees, consulting and professional fees and expenses, and internal expenses, such as compensation of employees engaged in research and development activities, the manufacture of product needed to support research and development efforts, related costs of facilities, and other general costs related to research and development. Where possible, we track our external costs by major project. To the extent that external costs are not attributable to a specific project or activity, they are included in other external costs. Prior to the initial regulatory approval of our products or development of new manufacturing processes, costs associated with manufacturing process development and the manufacture of drug product are recorded as research and development expenses. Subsequent to initial regulatory approval, costs associated with the manufacture of our products for commercial sale are capitalized in inventory and recorded as cost of product sales when sold.

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Research and development expenses for 2013 and 2012 consisted of the following (in thousands):

	Years Ended December 31,		2013 to 2012 change	
	2013	2012	$ Change	% Change
External Research and Development Expenses				
Feraheme to treat IDA in CKD patients	$ 4,280	$ 3,226	$ 1,054	33%
Feraheme to treat IDA regardless of the underlying cause	86	12,357	(12,271)	-99%
Feraheme as a therapeutic agent, general	1,615	1,033	582	56%
Feraheme manufacturing process development and materials	2,690	2,297	393	17%
Other external costs	325	152	173	>100%
Total	$ 8,996	$ 19,065	$ (10,069)	-53%
Internal Research and Development Expenses				
Compensation, payroll taxes, benefits and other expenses	9,419	12,237	(2,818)	-23%
Equity-based compensation expense	2,149	1,994	155	8%
Total	$ 11,568	$ 14,231	$ (2,663)	-19%
Total Research and Development Expenses	$ 20,564	$ 33,296	$ (12,732)	-38%

Total research and development expenses incurred in 2013 decreased by $12.7 million, or 38%, as compared to 2012. The decrease was primarily due to reduced external research and development costs of $10.1 million in 2013. In addition, 2013 internal research and development costs decreased by $2.7 million as compared to 2012.

The $10.1 million, or 53%, decrease in our external research and development expenses was due to a $12.3 million decrease in costs incurred in connection with our Phase III clinical development program for *Feraheme* to treat IDA regardless of the underlying cause, which was completed in 2012, partially offset by a $1.1 million increase in our costs associated with our CKD-related trials and a $0.4 million increase in manufacturing process development and materials-related costs.

The $2.7 million, or 19%, decrease in our internal research and development expenses was primarily attributable to the decrease in compensation and related benefit costs in 2013 following our 2012 and 2011 corporate restructurings, which resulted in lower headcount in our research and development departments.

We expect research and development expenses to increase in 2014 as compared to 2013 primarily due to expenses associated with our clinical trial to determine the safety and efficacy of repeat doses of ferumoxytol for the treatment of IDA in patients with hemodialysis-dependent CKD, which began enrollment in the second half of 2013, and increased development costs related to manufacturing process improvement activities. In addition, research and development expenses could increase further depending on the outcome of discussions with the FDA on the regulatory path forward for *Feraheme* in the broad indication and any resulting clinical trials or development efforts that we may undertake.

Research and Development Activities

We do not track our internal costs by project since our research and development personnel work on a number of projects concurrently and much of our fixed costs benefit multiple projects or our operations in general. We track our external costs on a major project basis, in most cases through the later of the completion of the last trial in the project or the last submission of a regulatory filing to the

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FDA or applicable foreign regulatory body. The following major research and development project was ongoing as of December 31, 2013:

Feraheme to treat IDA in CKD patients. This project currently includes: (a) a completed clinical study evaluating *Feraheme* treatment as compared to treatment to another IV iron to support the 2010 MAA submission; (b) a pediatric study that is being conducted as part of our post-approval Pediatric Research Equity Act requirement to support pediatric CKD labeling of *Feraheme*; (c) two additional pediatric studies to be completed in accordance with our approved pediatric investigation plan to support the MAA submission; and (d) an ongoing multi-center clinical trial to be conducted to determine the safety and efficacy of repeat doses of *Feraheme* for the treatment of IDA in patients with hemodialysis dependent CKD, including a treatment arm with iron sucrose using an MRI sub-analysis to evaluate the potential for iron to accumulate in the body following repeated IV iron administration.

Through December 31, 2013, we have incurred aggregate external research and development expenses of approximately $28.2 million related to our current program for the development of *Feraheme* to treat IDA in CKD patients. We currently estimate that the total remaining external costs associated with this development project will be in the range of approximately $20.0 to $30.0 million over the next several years.

In accordance with our policy of tracking external research and development costs through the later of the completion of the last trial in a project or the last submission of a regulatory filing to the FDA, we discontinued tracking our expenses related to *Feraheme* to treat IDA regardless of the underlying cause in the third quarter of 2013, at which point we had incurred $57.8 million of external research and development expenses. In January 2014, we received a complete response letter from the FDA in response to our sNDA submission for *Feraheme* for the treatment of IDA in adult patients who had failed or could not use oral iron. We are currently unable to estimate with any certainty the future costs we will incur, if any, related to our project for *Feraheme* to treat IDA regardless of the cause. In future periods, we may resume the disclosure of such expected future costs as the facts and circumstances warrant.

Conducting clinical trials involves a number of uncertainties, many of which are out of our control. Our estimates of external costs associated with our research and development projects could therefore vary from our current estimates for a variety of reasons including but not limited to the following:

Delays in our clinical trials due to slow enrollment;

Unexpected results from our clinical sites that affect our ability to complete the studies in a timely manner;

Unanticipated adverse reactions to *Feraheme* either in commercial use or in a clinical trial setting;

Inadequate performance or errors by third-party service providers;

Any deficiencies in the design or oversight of these studies by us;

The need to conduct additional clinical trials; or

Any adverse regulatory action or delay in the submission of any applicable regulatory filing.

Selling, General and Administrative Expenses

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

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Selling, general and administrative expenses for 2013 and 2012 consisted of the following (in thousands):

	Years Ended December 31,		2013 to 2012 change	
	2013	2012	$ Change	% Change
Compensation, payroll taxes and benefits	$ 22,819	$ 23,273	$ (454)	-2%
Sales and marketing consulting, professional fees, and other expenses	13,407	12,133	1,274	11%
General and administrative consulting, professional fees and other expenses expenses	17,989	12,860	5,129	40%
Equity-based compensation expense	5,734	4,805	929	19%
Total	$ 59,949	$ 53,071	$ 6,878	13%

Total selling, general and administrative expenses incurred in 2013 increased by $6.9 million, or 13%, as compared to 2012 for the following reasons:

- $0.5 million decrease in compensation, payroll taxes and benefits due to a $0.9 million decrease in one-time retention payments made in 2012, partially offset by an increase of $0.4 million in 2013 due to increased headcount;

- $1.3 million increase in sales and marketing consulting, professional fees, and other expenses primarily due to increased consulting costs related to the acquisition and commercialization of *MuGard*;

- $5.1 million increase in general and administrative consulting, professional fees and other expenses primarily due to $1.9 million of accelerated depreciation expense related to certain leasehold improvements and furniture and fixtures associated with our prior office facility, $1.4 million of increased costs associated with consulting, business development and other legal-related activities, $1.1 million adjustment to the fair value of our contingent consideration liability related to the MuGard Rights, $0.8 million of transaction and other costs related to the acquisition of the MuGard Rights, $0.4 million of costs associated with the relocation of our corporate headquarters, and $0.3 million of costs related to the closure of our Cambridge, Massachusetts manufacturing facility. These increased costs in 2013 were partially offset by $1.6 million in termination fees which we paid in 2012 to our *GastroMARK* licensees in connection with the termination our license agreements with them; and

- $0.9 million increase in equity-based compensation expense due primarily to the expense associated with equity awards to new and existing employees.

We expect total selling, general and administrative expenses will remain relatively constant during 2014 as compared to 2013.

Restructuring Expense

During 2012, we initiated corporate restructurings including a workforce reduction plan. The majority of the workforce reduction plan was associated with our manufacturing and development infrastructure, including our decision to divest our Cambridge, Massachusetts manufacturing facility. The workforce reduction was substantially completed by the end of 2012, and the majority of the related expenses were paid by the end of 2012.

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Other Income (Expense)

Other income (expense) for 2013 and 2012 consisted of the following (in thousands):

	Years Ended December 31,		2013 to 2012 change	
	2013	2012	$ Change	% Change
Interest and dividend income, net	$ 1,051	$ 1,286	$ (235)	-18%
Gains on sale of asset	924		924	N/A
Gains (losses) on investments, net	40	(1,466)	1,506	<(100%)
Total	$ 2,015	$ (180)	$ 2,195	<(100%)

Other income (expense) for 2013 increased by $2.2 million as compared to 2012 primarily as the result of the non-recurring nature of the June 2012 $1.5 million loss realized on the sale of our then-remaining auction rate securities. Additionally, during 2013, we recognized $0.5 million of gains in connection with the sale of Combidex®, a molecular imaging agent which we were not actively pursuing development, and a $0.4 million gains on the sale of fixed assets related to our Cambridge, Massachusetts manufacturing facility. These increases were partially offset by a decrease in interest and dividend income as the result of lower average cash balances during 2013 as compared to 2012.

Income Tax Benefit

We did not recognize any income tax benefit during 2013. We recognized an income tax benefit of $0.9 million during 2012 as the result of our recognition of a corresponding income tax expense associated with the increase in value of certain securities as a result of their redemption at prices higher than the fair market value at which they were recorded. This income tax expense was recorded in other comprehensive loss.

Net Loss

For the reasons stated above, we incurred a net loss of $9.6 million and $16.8 million, or $0.44 and $0.78 per basic and diluted share, for 2013 and 2012, respectively.

Results of Operations 2012 as compared to 2011

Revenues

Our total revenues for 2012 and 2011 consisted of the following (in thousands):

	Years Ended December 31,		2012 to 2011 change	
	2012	2011	$ Change	% Change
U.S. *Feraheme* product sales, net	$ 58,287	$ 52,097	$ 6,190	12%
License fee and other collaboration revenues	26,475	8,321	18,154	>100%
Other product sales and royalties	616	831	(215)	-26%
Total	$ 85,378	$ 61,249	$ 24,129	39%

The $24.1 million increase in our total revenues in 2012 as compared to 2011 was primarily attributable to a $6.2 million increase in U.S. net *Feraheme* product sales and a $18.2 million increase in our license fee and other collaboration revenues associated with our collaboration

agreement with Takeda, as described in further detail below.

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The following table sets forth customers who represented 10% or more of our total revenues for 2012 and 2011:

	Years Ended December 31,	
	2012	2011
AmerisourceBergen Drug Corporation	34%	41%
Takeda Pharmaceuticals Company Limited	31%	13%
McKesson Corporation	17%	21%
Cardinal Health, Inc.	12%	13%

U.S. Feraheme Product Sales, Net

U.S. *Feraheme* product sales and product sales allowances and accruals for 2012 and 2011 consisted of the following (in thousands):

	Years Ended December 31,					
	2012	Percent of gross U.S. Feraheme product sales	2011	Percent of gross U.S. Feraheme product sales	$ Change	% Change
Gross U.S. *Feraheme* product sales	$ 88,725		$ 73,219		$ 15,506	21%
Less provision for product sales allowances and accruals						
Discounts and chargebacks	26,517	30%	13,851	19%		
Government and other rebates	6,058	7%	8,544	12%		
Medicaid rebate reserve adjustment	(621)	-1%	(2,532)	-3%		
Returns	(1,516)	-2%	1,259	2%		
Total	30,438	34%	21,122	29%		
Net U.S. *Feraheme* product sales	$ 58,287		$ 52,097		$ 6,190	12%

Our gross U.S. *Feraheme* product sales increased by $15.5 million, or 21%, in 2012 as compared to 2011. Of the $15.5 million increase, $13.6 million was due to increased units sold and $1.9 million was due to price increases. This increase was partially offset by $9.6 million of additional allowances and accruals in 2012, excluding a $2.2 million reduction of our estimated product return reserves in 2012 and a $0.6 million and $2.5 million reduction of our estimated Medicaid rebate reserve related to prior *Feraheme* sales in 2012 and 2011, respectively. As a result of these factors, total net U.S. *Feraheme* product sales increased by $6.2 million during 2012 as compared to 2011.

Total discounts and chargebacks for 2012 were $26.5 million, or 30% of total gross product sales, as compared to $13.9 million, or 19% of total gross product sales, in 2011. The 11% increase in total discounts and chargebacks as a percentage of total gross product sales in 2012 as compared to 2011 was primarily due to higher discounts offered to customers off the gross sales price as well as a change in pricing strategy from offering rebates for purchases of *Feraheme* above a certain minimum volume threshold to entering into commercial contracts which provide increased upfront discounts on the purchase price of *Feraheme*.

Total government and other rebates (excluding any changes in estimates related to Medicaid rebate reserves) were $6.1 million, or 7% of total gross product sales, in 2012 as compared to $8.5 million, or 12% of gross product sales, in 2011. The decrease in total government and other rebates as a percentage of gross product sales was related primarily to lower volume rebates offered in 2012 as compared to 2011.

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During 2012 and 2011, we revised our estimated Medicaid reserve rate based on actual rebate claims received since the launch of *Feraheme* in July 2009, our expectations of state level activity, and estimated rebate claims not yet submitted, which resulted in a reduction of our estimated Medicaid rebate reserve related to prior period *Feraheme* sales of $0.6 million and $2.5 million, respectively. These changes in estimates were reflected as an increase in our net product sales for, 2012 and 2011 and resulted in reductions to our gross to net percentage in these respective periods.

During 2012, we reduced our reserve for product returns by approximately $2.2 million, primarily as a result of a lower than expected rate of product returns as well as the lapse of the product return period on certain manufactured *Feraheme* lots that carried a two year expiration. As a result, the product returns provision applied to gross product sales for 2012 was a credit of $1.5 million, resulting in an increase to product sales, as compared to a $1.3 million charge in 2011, resulting in decreases to product sales.

An analysis of the amount of, and change in, reserves for 2012 and 2011 is as follows (in thousands):

	Discounts and Chargebacks	Government and Other Rebates	Returns	Total
Balance at January 1, 2011	$ 1,148	$ 8,218	$ 1,797	$ 11,163
Current provisions relating to sales in current year	14,074	8,605	1,259	23,938
Other provisions relating to deferred revenue		(18)		(18)
Adjustments relating to sales in prior years	(223)	(2,593)		(2,816)
Payments/returns relating to sales in current year	(12,251)	(6,195)	(55)	(18,501)
Payments/returns relating to sales in prior years	(926)	(4,916)	(159)	(6,001)
Balance at December 31, 2011	$ 1,822	$ 3,101	$ 2,842	$ 7,765
Current provisions relating to sales in current year	26,517	6,152	577	33,246
Adjustments relating to sales in prior years		(715)	(2,093)	(2,808)
Payments/returns relating to sales in current year	(24,709)	(4,511)		(29,220)
Payments/returns relating to sales in prior years	(1,859)	(1,597)	(308)	(3,764)
Balance at December 31, 2012	$ 1,771	$ 2,430	$ 1,018	$ 5,219

During each of 2012 and 2011, we decreased our product sales allowances and accruals by approximately $2.8 million for changes in estimates relating to sales in prior years, as discussed above.

License Fee and Other Collaboration Revenues

License fee and other collaboration revenues for 2012 and 2011 consisted of the following (in thousands):

	Years Ended December 31,		2012 to 2011 change	
	2012	2011	$ Change	% Change
Milestone revenues recognized from Takeda	$ 19,950	$	$ 19,950	N/A
Deferred license fee revenues recognized from Takeda	6,096	6,096		
Reimbursement revenues primarily from Takeda	429	2,225	(1,796)	-81%
Total	$ 26,475	$ 8,321	$ 18,154	>100%

Our license fee and other collaboration revenues increased by $18.2 million in 2012 as compared to 2011 primarily due to receipt of a $15.0 million substantive milestone payment from Takeda in 2012 as well as the $5.0 million amortized portion of an aggregate $18.0 million in non-substantive milestone payments received from Takeda in 2012. We did not receive any milestone payments in 2011.

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During each of 2012 and 2011 we recorded $6.1 million of revenues associated with the amortization of $61.0 million of deferred revenues recorded in connection with the original Takeda Agreement. In addition, during 2012 and 2011, we recorded $0.4 million and $2.0 million, respectively, of revenues associated with the reimbursement of out-of pocket regulatory and clinical supply costs in connection with the Amended Takeda Agreement.

Other Product Sales and Royalties

The $0.2 million decrease in other product sales and royalties in 2012 as compared to 2011 was due to decreased sales of *GastroMARK*, partially offset by increased sales and royalty revenue related to the Amended Takeda Agreement.

Costs and Expenses

Cost of Product Sales

Cost of product sales for 2012 and 2011 consisted of the following (in thousands):

	Years Ended December 31,		2012 to 2011 change	
	2012	2011	$ Change	% Change
Cost of Product Sales	$ 14,220	$ 10,531	$ 3,689	35%
Percentage of Net Product Sales and Royalties	24%	20%		

The $3.7 million, or 35% increase in our cost of product sales for 2012 as compared to 2011 was attributable to the following factors:

- $2.3 million increase due to the 2012 closure of our Cambridge, Massachusetts manufacturing facility and the related accelerated depreciation and impairment costs;
- $0.9 million increase due to the higher volume of *Feraheme* vials sold; and
- $0.6 million write-off of commercial inventory deemed no longer salable.

Research and Development Expenses

Research and development expenses for 2012 and 2011 consisted of the following (in thousands):

	Years Ended December 31,		2012 to 2011 change	
	2012	2011	$ Change	% Change
External Research and Development Expenses				
Feraheme to treat IDA regardless of the underlying cause	$ 12,357	$ 27,405	$ (15,048)	-55%
Feraheme to treat IDA in CKD patients	3,226	9,385	(6,159)	-66%
Feraheme as a therapeutic agent, general	1,033	917	116	13%
Feraheme manufacturing process development and materials	2,297	2,752	(455)	-17%
Other external costs	152	263	(111)	-42%
Total	$ 19,065	$ 40,722	$ (21,657)	-53%
Internal Research and Development Expenses				
Compensation, payroll taxes, benefits and other expenses	12,237	15,544	(3,307)	-21%
Equity-based compensation expense	1,994	1,874	120	6%
Total	$ 14,231	$ 17,418	$ (3,187)	-18%

Total Research and Development Expenses	$ 33,296	$ 58,140	$ (24,844)	-43%

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Total research and development expenses incurred in 2012 decreased by $24.8 million, or 43%, as compared to 2011. The decrease was primarily due to reduced external research and development costs of $21.7 million in 2012. In addition, 2012 internal research and development costs decreased by $3.2 million as compared to 2011.

The $21.7 million, or 53%, decrease in our external research and development expenses in 2012 was due to the following:

- $15.0 million decrease in costs incurred in connection with our Phase III clinical development program for *Feraheme* to treat IDA regardless of the underlying cause, which was completed in 2012; and

- $6.2 million decrease in costs associated with our global clinical program to support the MAA in the EU for the treatment of IDA in CKD patients, which was completed in 2012, our post-approval clinical study evaluating *Feraheme* treatment as compared to treatment with another IV iron, which was completed in 2011, and the current pace of enrollment in our on-going pediatric studies of *Feraheme.*

The $3.2 million, or 18%, decrease in our internal research and development expenses in 2012 as compared to 2011 was primarily attributable to the decrease in compensation and related benefits following our 2012 and 2011 corporate restructurings, which resulted in lower headcount in our research and development departments.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for 2012 and 2011 consisted of the following (in thousands):

	Years Ended December 31,		2012 to 2011 change	
	2012	2011	$ Change	% Change
Compensation, payroll taxes and benefits	$ 23,273	$ 29,553	$ (6,280)	-21%
Sales and marketing consulting, professional fees, and other expenses	12,133	16,859	(4,726)	-28%
General and administrative consulting, professional fees and other expenses expenses	12,860	14,903	(2,043)	-14%
Equity-based compensation expense	4,805	7,548	(2,743)	-36%
Total	$ 53,071	$ 68,863	$ (15,792)	-23%

Total selling, general and administrative expenses incurred in 2012 decreased by $15.8 million, or 23%, as compared to 2011 for the following reasons:

- A $6.3 million decrease in compensation, payroll taxes and benefits during 2012 as compared to 2011 due primarily to reduced headcount resulting from our 2012 and 2011 corporate restructurings;

- A $4.7 million decrease in sales and marketing consulting, professional fees, and other expenses during 2012 as compared to 2011 primarily due to reduced costs related to advertising and marketing materials, and certain other general marketing costs;

- A $2.0 million decrease in general and administrative consulting, professional fees and other expenses during 2012 as compared to 2011 primarily due to a decrease in our professional fees, specifically $4.5 million of costs incurred in 2011 in connection with our then proposed merger with Allos Therapeutics, Inc., or Allos, including a $2.0 million expense reimbursement fee paid to Allos in connection with the termination of the merger agreement. These increased costs

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were partially offset by $1.6 million in termination fee payments made in 2012 to our *GastroMARK* licensees in connection with the termination of our commercial license agreements with them, costs incurred in 2012 in connection with our intention to expand our product portfolio and the 2012 closure of our Cambridge, Massachusetts manufacturing facility; and

A $2.7 million decrease in equity-based compensation expenses for 2012 due primarily to a $3.3 million reduction of equity-based compensation expense associated with the 2011 departures of certain of our executive officers, and the impact of our 2012 and 2011 corporate workforce reductions, partially offset by the expense associated with equity awards to new executive officers and employees in 2012, and additional equity awards to existing employees.

Restructuring Expense

During 2012, we initiated a corporate restructuring, including a workforce reduction plan. The majority of the workforce reduction plan was associated with our manufacturing and development infrastructure, including our decision to divest our Cambridge, Massachusetts manufacturing facility. The workforce reduction was substantially completed by the end of 2012 and the majority of the related expenses were paid by the end of 2012.

Other Income (Expense)

Other income (expense) for 2012 and 2011 consisted of the following (in thousands):

	Years Ended December 31,		2012 to 2011 change	
	2012	2011	$ Change	% Change
Interest and dividend income, net	$ 1,286	$ 1,747	$ (461)	-26%
Gains (losses) on investments, net	(1,466)	(193)	(1,273)	>100%
Total	$ (180)	$ 1,554	$ (1,734)	<(100%)

Other income (expense) for 2012 decreased by $1.7 million as compared to 2011 primarily due to the $1.5 million loss we realized on the June 2012 sale of our then remaining auction rate security portfolio. In addition, there was a $0.5 million decrease in our interest and dividend income as the result of lower average cash balances in 2012 as compared to 2011.

Income Tax Benefit

We recognized an income tax benefit of $0.9 million and $1.2 million during 2012 and 2011, respectively, as the result of our recognition of a corresponding income tax expense associated with the increase in value of certain securities. This income tax expense was recorded in other comprehensive loss.

Net Loss

For the reasons stated above, we incurred a net loss of $16.8 million and $77.1 million, or $0.78 and $3.64 per basic and diluted share, for 2012 and 2011, respectively.

Liquidity and Capital Resources

General

We finance our operations primarily from the sale of *Feraheme/Rienso* and *MuGard*, including payments from our licensees, cash generated from our investing activities and the sale of our common stock. We expect to continue to incur significant expenses as we continue to manufacture, market and sell *Feraheme/Rienso* as an IV iron replacement therapeutic for use in adult CKD patients in the U.S., Canada,

Switzerland and the EU, as we market and sell *MuGard* in the U.S. and as we further develop and seek regulatory approval for *Feraheme/Rienso* for the treatment of IDA in a broad range of patients in and outside of the U.S.

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

- Our ability to successfully commercialize *Feraheme* in the U.S. and Takeda's ability to successfully commercialize *Feraheme/Rienso* in its licensed territories outside of the U.S.;
- The magnitude of U.S. *Feraheme* and *MuGard* sales;
- Whether we pursue, and our ability to obtain, regulatory approval of *Feraheme* in the U.S. for ferumoxytol to treat IDA regardless of the underlying cause;
- Takeda's ability to obtain EU regulatory approval for ferumoxytol to treat IDA regardless of the underlying cause;
- Our ability to achieve the various milestones and receive the associated payments under the Amended Takeda Agreement;
- The success, costs and structure of any business or corporate development initiatives to bring additional products into our portfolio;
- Our ability to maintain successful collaborations with our licensees and/or to enter into additional strategic relationships or acquisitions, if necessary;
- The magnitude of *Feraheme/Rienso* product sales and royalties we may receive from Takeda outside of the U.S.;
- Costs associated with the U.S. commercialization of *Feraheme* and *MuGard*, including costs associated with maintaining our commercial infrastructure, executing our promotional and marketing strategy for *Feraheme* and *MuGard* and conducting our required pediatric clinical trials and our post-marketing clinical studies for *Feraheme*;
- Costs associated with qualifying additional manufacturing capacities and alternative suppliers;
- The outcome of and costs associated with any material litigation or patent challenges to which we are or may become a party; and
- Our ability to raise additional capital on terms and within a timeframe acceptable to us, if necessary.

As of December 31, 2013, our investments consisted of corporate debt securities and U.S. treasury and government agency securities. We place our cash in instruments that meet high credit quality and diversification standards, as specified in our investment policy. Our investment policy also limits the amount of our credit exposure to any one issue or issuer, excluding U.S. government entities, and seeks to manage these assets to achieve our goals of preserving principal, maintaining adequate liquidity at all times, and maximizing returns.

Cash, cash equivalents and investments as of December 31, 2013 and 2012 consisted of the following (in thousands):

	December 31,			
	2013	2012	$ Change	% Change
Cash and cash equivalents	$ 26,986	$ 46,293	$ (19,307)	-42%

Investments	186,803	180,750	6,053	3%
Total	$ 213,789	$ 227,043	$ (13,254)	-6%

The $13.3 million decrease in cash, cash equivalents and investments as of December 31, 2013, as compared to December 31, 2012, was primarily due to cash expended to fund our operations and

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working capital, cash used to purchase the MuGard Rights, and cash held in escrow as of December 31, 2013 in connection with a business transaction which we did not complete, partially offset by cash received from *Feraheme* sales, other product sales and royalty payments from Takeda and interest income.

We expect that our cash, cash equivalents and investments balances, in the aggregate, may decrease slightly to meet our working capital needs in 2014, excluding any potential milestones we may receive from Takeda. Our expectation assumes our continued investment in the development and commercialization of *Feraheme* and the continued pursuit of business development transactions. We believe that our cash, cash equivalents and investments as of December 31, 2013, and the cash we currently expect to receive from sales of *Feraheme* and *MuGard*, earnings on our investments, and potential product sales and milestone and royalty payments from Takeda will be sufficient to satisfy our cash flow needs for at least the next twelve months.

Year Ended December 31, 2013

Cash flows from operating activities

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

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

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

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

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

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

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

Cash flows from investing activities

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

Cash flows from financing activities

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

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Year Ended December 31, 2012

Cash flows from operating activities

During 2012, our use of $1.2 million in cash in operations was attributable principally to our net loss of approximately $16.8 million, adjusted for the following:

Non-cash operating items of $16.4 million including equity-based compensation expense, depreciation, amortization of premium/discount on purchased securities, a write-down of inventory, net losses (gains) on investments, and other non-cash items;

An increase in deferred revenues and other long-term liabilities of $7.5 million, primarily from the deferral of a portion of the milestones received from Takeda in 2012;

A combined decrease of $3.8 million in accounts receivable, prepaid assets and inventories; and

A decrease of $12.1 million in accounts payable and accrued expenses.

Our net loss of $16.8 million was primarily the result of compensation and other expenses, commercialization expenses, including marketing and promotion costs, research and development costs, including costs associated with our clinical trials and general and administrative costs, partially offset by net product and collaboration revenues, including the recognition of approximately $20.0 million in milestone payments from Takeda.

Cash flows from investing activities

Cash used in investing activities in 2012 was $16.4 million and was primarily attributable to the purchases of investments, partially offset by proceeds from the sales and maturities of our investments, including the June 2012 sale of our remaining auction rate securities portfolio.

Contractual Obligations

We currently have no long-term debt obligations or capital lease obligations. Our contractual obligations primarily consist of our obligations under non-cancellable operating leases and other purchase obligations. Future lease obligations and purchase commitments, as of December 31, 2013, are as follows (in thousands):

	Payment due by period				
	Total	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Facility lease obligations	$ 5,546	$ 1,128	$ 2,256	$ 2,162	$
Purchase commitments	6,780	6,180	600		
Operating lease obligations, excluding facility lease	275	103	172		
Total	$ 12,601	$ 7,411	$ 3,028	$ 2,162	$

Operating and Facility Lease Obligations

We have entered into certain operating leases, including certain office equipment leases, which expire through 2016.

In June 2013, we entered into a lease agreement with BP Bay Colony LLC, or the Landlord, for the lease of certain real property located at 1100 Winter Street, Waltham, Massachusetts, or the Premises, for use as our principal executive offices. The initial term of the lease is five years and two months with one five-year extension term at our option.

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In June 2013, we also entered into an Assignment and Assumption of Lease, or the Assignment Agreement, with Shire Human Genetic Therapies, Inc., or Shire, effecting the assignment to Shire of the right to occupy our prior office space located at 100 Hayden Avenue, Lexington, Massachusetts, or the Prior Space. Under the Assignment Agreement, the assignment to Shire became effective on September 21, 2013, the date of our departure from the Prior Space, and Shire assumed all of our obligations as the tenant of the Prior Space. The Assignment Agreement also provided for the conveyance of furniture and other personal property by us to Shire. As a result, our former lease obligations related to our prior office space are no longer shown in the table above.

Purchase Commitments

During 2013, we entered into various agreements with third parties for which we had remaining purchase commitments of approximately $6.8 million as of December 31, 2013. These agreements principally related to certain purchase orders for the production of *Feraheme/Rienso,* outsourced commercial activities, manufacturing commitments, our information technology infrastructure and other operational activities.

Other Funding Commitments

As of December 31, 2013, we had several ongoing clinical studies in various clinical trial stages. Our most significant clinical trial expenditures were to clinical research organizations, or CROs. The contracts with CROs are generally cancellable, with notice, at our option. We have recorded accrued expenses in our consolidated balance sheet of approximately $0.3 million representing expenses incurred with these organizations as of December 31, 2013, net of any amounts prepaid to these CROs. As a result of our cancellation rights, we have not included these CRO contracts in the contractual obligations table above.

Severance Arrangements

We have entered into employment agreements or other arrangements with most of our executive officers and certain other employees, which provide for salary continuation payments 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 Agreements

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, refer to Note P of the Notes to Financial Statements included in Part II, Item 8 "Financial Statements and Supplementary Data" of this Annual Report on Form 10-K.

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 the matters referenced below, the liability is not probable or the amount cannot be reasonably estimated

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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.

A purported class action complaint was originally filed on March 18, 2010 in the U.S. District Court for the District of Massachusetts, entitled Silverstrand Investments et. al. v. AMAG Pharm., Inc., et. al., Civil Action No. 1:10-CV-10470-NMG, and was amended on September 15, 2010 and on December 17, 2010. The second amended complaint, or SAC, filed on December 17, 2010 alleged that we and our former President and Chief Executive Officer, former Chief Financial Officer, the then-members of our Board of Directors, or Board, and certain underwriters in our January 2010 offering of common stock violated certain federal securities laws, specifically Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended, and that our former President and Chief Executive Officer and former Chief Financial Officer violated Section 15 of such Act, respectively, by making certain alleged omissions in a registration statement filed in January 2010. The plaintiffs sought unspecified damages on behalf of a purported class of purchasers of our common stock pursuant to our common stock offering on or about January 21, 2010. On August 11 and 15, 2011, respectively, the District Court issued an Opinion and Order dismissing the SAC with prejudice for failure to state a claim upon which relief could be granted. On September 14, 2011, the plaintiffs filed a Notice of Appeal to the U.S. Court of Appeals for the First Circuit, or the Court of Appeals. The Court of Appeals heard oral argument on May 11, 2012. On February 4, 2013, the Court of Appeals affirmed in part and reversed in part the District Court's Opinion and Order and remanded the case to the District Court. On February 19, 2013, we filed a Petition for Panel Rehearing and Rehearing *En Banc*, which was denied on March 15, 2013. On March 22, 2013, we filed a Motion to Stay the Mandate remanding the case to the District Court pending review by the U.S. Supreme Court of the Court of Appeals' February 4, 2013 decision. The Court of Appeals granted the Motion to Stay the Mandate on April 8, 2013. On June 13, 2013, we filed a Petition for a Writ of Certiorari, or the Petition, with the U.S. Supreme Court seeking review of the Court of Appeal's decision and to have that decision overturned. On October 7, 2013 the U.S. Supreme Court denied our Petition, resulting in the case's return to the District Court for further proceedings relative to the SAC's surviving claims. On November 6, 2013, we filed a renewed Motion to Dismiss the SAC's surviving claims. On December 6, 2013, the plaintiffs filed a brief in opposition to our Motion to Dismiss and we filed a reply brief in support of our Motion on December 27, 2013. The plaintiffs are seeking leave of court to file a sur-reply in further opposition to our Motion to Dismiss. No hearing on the Motion to Dismiss is currently scheduled.

In July 2010, Sandoz GmbH, or Sandoz, filed with the European Patent Office, or the EPO, an opposition to a previously issued patent which covers ferumoxytol in EU jurisdictions. In October 2012, at an oral hearing, the Opposition Division of the EPO revoked this patent. In December 2012, our notice of appeal of that decision was recorded with the EPO, which also suspended the revocation of our patent. On May 13, 2013, we filed a statement of grounds of appeal and on September 27, 2013, Sandoz filed a response to that statement. We will continue to defend the validity of this patent throughout the appeals process, which we expect to take two to three years. However, in the event that we do not experience a successful outcome from the appeals process, under EU regulations ferumoxytol would still be entitled to eight years of data protection and ten years of market exclusivity from the date of approval, which we believe would create barriers to entry for any generic version of ferumoxytol into the EU market until sometime between 2020 and 2022. This decision had no impact on our revenues for the year ended December 31, 2013. However, any future unfavorable outcome in this matter could negatively affect the magnitude and timing of future revenues, including royalties and milestone payments we may receive from Takeda pursuant to our collaboration agreement with Takeda. We continue to believe the patent is valid and intend to vigorously appeal the decision.

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In July 2013, we submitted a Citizen Petition to the FDA regarding its December 2012 draft guidance providing product-specific bioequivalence recommendations for generic versions of ferumoxytol injection. In the Citizen Petition, we requested that the FDA (a) refrain from approving any abbreviated new drug application referencing *Feraheme* until certain post-market contract studies on Nulecit , the only U.S. approved generic IV iron product, have been completed and have demonstrated that the FDA's proposed pre-market approval standards for generic IV iron formulations are sufficient to ensure therapeutic equivalence, including comparable tissue distribution and no more *in vivo* labile iron leakage than the reference listed drug, or RLD; and (b) require that any sponsors of proposed generic versions of *Feraheme* show that their products are equivalent to the RLD using (a) a comparative study in patients using clinical endpoints and (b) the additional assays that FDA has described for the proposed Nulecit post-market contract studies. We cannot predict when or if the FDA will respond to, or otherwise take any action with respect to, the Citizen Petition.

For additional information on our Legal Proceedings, see the discussion under Part I, Item 3 Legal Proceedings.

Off-Balance Sheet Arrangements

As of December 31, 2013, 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:

As of December 31, 2013 and 2012, our investments equaled $186.8 million and $180.8 million, respectively, and were invested in corporate debt securities, and U.S. treasury and government agency securities and, as of December 31, 2012, the amount also included commercial paper. Our investments meet high credit quality and diversification standards, as specified in our investment policy. Our investment policy also limits the amount of our credit exposure to any one issue or issuer, excluding U.S. government entities, and seeks to manage these assets to achieve our goals of preserving principal, maintaining adequate liquidity at all times, and maximizing returns. These investments are subject to interest rate risk. The modeling technique used measures the change in fair values arising from an immediate hypothetical shift in market interest rates and assumes that ending fair values include principal plus accrued interest. If market interest rates for comparable investments were to increase immediately and uniformly by 50 basis points, or one-half of a percentage point, from levels as of December 31, 2013 and 2012, this would have resulted in a hypothetical decline in fair value of our investments of approximately $1.3 million and $1.0 million, respectively, and if market interest rates for comparable investments were to decrease immediately and uniformly by 50 basis points, or one-half of a percentage point, from levels as of December 31, 2013 and 2012, this would have resulted in a hypothetical increase in fair value of our investments of approximately $1.2 million and $0.9 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.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA:

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MANAGEMENT'S ANNUAL REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

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

Our management, including our principal executive officer and principal financial officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2013 based on the framework in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in 1992. Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2013.

The effectiveness of our internal control over financial reporting as of December 31, 2013, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included below.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows present fairly, in all material respects, the financial position of AMAG Pharmaceuticals, Inc. and its subsidiaries at December 31, 2013 and 2012, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2013 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, 2013, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in 1992. The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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

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

Boston, Massachusetts
February 10, 2014

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AMAG Pharmaceuticals, Inc.

Consolidated Balance Sheets

(in thousands, except share and per share data)

	As of December 31,	
	2013	**2012**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 26,986	$ 46,293
Investments	186,803	180,750
Accounts receivable, net	6,842	6,410
Inventories	17,217	12,451
Receivable from collaboration	278	263
Assets held for sale		2,000
Prepaid and other current assets	3,396	6,213
Restricted cash	2,883	
Total current assets	244,405	254,380
Property and equipment, net	1,846	3,297
Intangible assets, net	16,844	
Restricted cash	400	460
Other long-term assets	1,964	
Total assets	$ 265,459	$ 258,137
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,629	$ 3,515
Accrued expenses	22,266	20,338
Deferred revenues	8,226	9,104
Total current liabilities	33,121	32,957
Long-term liabilities:		
Deferred revenues	44,534	50,350
Acquisition-related contingent consideration, net of current portion	13,609	
Other long-term liabilities	1,787	2,033
Total liabilities	93,051	85,340
Commitments and contingencies (Notes G, P & Q)		
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, 58,750,000 shares authorized; 21,772,571 and 21,506,754 shares issued and outstanding at December 31, 2013 and 2012, respectively	218	215
Additional paid-in capital	641,941	632,487

Accumulated other comprehensive loss	(3,491)	(3,247)
Accumulated deficit	(466,260)	(456,658)
Total stockholders' equity	172,408	172,797
Total liabilities and stockholders' equity	$ 265,459	$ 258,137

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,		
	2013	**2012**	**2011**
Revenues:			
U.S. *Feraheme* product sales, net	$ 71,362	$ 58,287	$ 52,097
License fee and other collaboration revenues	8,385	26,475	8,321
Other product sales and royalties	1,109	616	831
Total revenues	80,856	85,378	61,249
Costs and expenses:			
Cost of product sales	11,960	14,220	10,531
Research and development expenses	20,564	33,296	58,140
Selling, general and administrative expenses	59,949	53,071	68,863
Restructuring expenses		2,215	3,508
Total costs and expenses	92,473	102,802	141,042
Other income (expense):			
Interest and dividend income, net	1,051	1,286	1,747
Gains on sale of assets	924		
Gains (losses) on investments, net	40	(1,466)	(193)
Total other income (expense)	2,015	(180)	1,554
Net loss before income taxes	(9,602)	(17,604)	(78,239)
Income tax benefit		854	1,170
Net loss	$ (9,602)	$ (16,750)	$ (77,069)
Net loss per share:			
Basic and diluted	$ (0.44)	$ (0.78)	$ (3.64)
Weighted average shares outstanding used to compute net loss per share:			
Basic and diluted	21,703	21,392	21,189

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,		
	2013	**2012**	**2011**
Net loss	$ (9,602)	$ (16,750)	$ (77,069)
Other comprehensive income (loss):			
Unrealized gains (losses) on securities:			
Holding gains (losses) arising during period, net of tax	(268)	129	1,980
Reclassification adjustment for (gains) losses included in net loss	24	1,466	206
Net unrealized gains (losses) on securities	(244)	1,595	2,186
Total comprehensive loss	$ (9,846)	$ (15,155)	$ (74,883)

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

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AMAG Pharmaceuticals, Inc.

Consolidated Statements of Stockholders' Equity

(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2010	21,137	$ 211	$ 614,942	$ (7,028)	$ (362,839)	$ 245,286
Net shares issued in connection with the exercise of stock options and restricted stock units	132	1	120			121
Shares issued in connection with employee stock purchase plan	37	1	507			508
Non-cash equity-based compensation			9,564			9,564
Unrealized gains on securities, net of tax of $1.2 million				2,186		2,186
Net loss					(77,069)	(77,069)
Balance at December 31, 2011	21,306	213	625,133	(4,842)	(439,908)	180,596
Net shares issued in connection with the exercise of stock options and restricted stock units	178	2	98			100
Shares issued in connection with employee stock purchase plan	23		270			270
Non-cash equity-based compensation			6,986			6,986
Unrealized gains on securities, net of tax of $0.9 million				1,595		1,595
Net loss					(16,750)	(16,750)
Balance at December 31, 2012	21,507	215	632,487	(3,247)	(456,658)	172,797
Net shares issued in connection with the exercise of stock options and restricted stock units	252	3	1,274			1,277
Shares issued in connection with employee stock purchase plan	14		176			176
Non-cash equity-based compensation			8,004			8,004
Unrealized losses on securities				(244)		(244)
Net loss					(9,602)	(9,602)
Balance at December 31, 2013	21,773	$ 218	$ 641,941	$ (3,491)	$ (466,260)	$ 172,408

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,		
	2013	**2012**	**2011**
Cash flows from operating activities:			
Net loss	$ (9,602)	$ (16,750)	$ (77,069)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,085	3,084	2,536
Impairment loss on assets held for sale		1,100	
Amortization of premium/discount on purchased securities	2,758	2,808	3,639
Write-down of inventory to net realizable value	2,175	1,822	685
Non-cash equity-based compensation expense	8,004	7,024	10,038
Non-cash income tax benefit		(854)	(1,170)
Gains on sale of assets	(924)		
(Gains) losses on investments, net	(40)	1,466	193
Change in fair value of contingent consideration	1,074		
Changes in operating assets and liabilities:			
Accounts receivable, net	(432)	(478)	(147)
Inventories	(1,040)	4,069	821
Receivable from collaboration	(15)	165	13
Prepaid and other current assets	2,817	75	1,661
Other long-term assets	(1,964)		
Accounts payable and accrued expenses	(5,730)	(12,195)	1,698
Deferred revenues	(6,694)	7,912	(6,353)
Other long-term liabilities	(246)	(405)	(349)
Total adjustments	2,828	15,593	13,265
Net cash used in operating activities	(6,774)	(1,157)	(63,804)
Cash flows from investing activities:			
Proceeds from sales or maturities of investments	106,030	133,061	141,095
Purchase of investments	(115,046)	(149,406)	(126,585)
Acquisition of MuGard Rights and inventory	(3,434)		
Proceeds from sale of assets	2,970		
Change in restricted cash	(2,823)		
Capital expenditures	(1,632)	(47)	(507)
Net cash (used in) provided by investing activities	(13,935)	(16,392)	14,003
Cash flows from financing activities:			
Payment of contingent consideration	(51)		
Proceeds from the exercise of stock options	1,277	98	121
Proceeds from the issuance of common stock under ESPP	176	270	508

Net cash provided by financing activities	1,402	368	629
Net decrease in cash and cash equivalents	(19,307)	(17,181)	(49,172)
Cash and cash equivalents at beginning of the year	46,293	63,474	112,646
Cash and cash equivalents at end of the year	$ 26,986	$ 46,293	$ 63,474
Supplemental data:			
Non-cash investing activities:			
Accrued construction in progress	$	$ 228	$

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

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Notes to Consolidated Financial Statements

A. Description of Business

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a specialty pharmaceutical company that markets Feraheme® (ferumoxytol) Injection for Intravenous, or IV, use to treat iron deficiency anemia, or IDA, and MuGard® Mucoadhesive Oral Wound Rinse for the management of oral mucositis.

Currently, our principal source of revenue is from the sale of *Feraheme*, which was approved for marketing in the U.S. in June 2009 by the U.S. Food and Drug Administration, or the FDA, for use as an IV iron replacement therapy for the treatment of IDA in adult patients with chronic kidney disease, or CKD. We began selling *Feraheme* in the U.S. in July 2009 through our own commercial organization, including a specialty sales force. We sell *Feraheme* to authorized wholesalers and specialty distributors, who in turn, sell *Feraheme* to healthcare providers who administer *Feraheme* primarily within hospitals, hematology and oncology centers, and nephrology clinics.

Outside of the U.S., ferumoxytol has been granted marketing approval in Canada, Switzerland and the European Union, or EU, for use as an IV iron replacement therapy for the treatment of IDA in adult patients with CKD. The marketing authorization for *Rienso* in the EU is valid in the 28 EU Member States as well as in Iceland, Liechtenstein and Norway. Under our amended agreement with Takeda Pharmaceutical Company Limited, or Takeda, Takeda has an exclusive license to market and sell ferumoxytol in Canada, the EU and Switzerland, as well as certain other geographic territories. In Canada, Takeda promotes ferumoxytol under the trade name *Feraheme* and in the EU and Switzerland, Takeda promotes ferumoxytol under the trade name Rienso® 30mg/ml solution for Injection.

On June 6, 2013, or the Acquisition Date, we entered into a License Agreement with Access Pharmaceuticals, Inc., or Access, under which we acquired the U.S. commercial rights to *MuGard*, or the Access License Agreement. *MuGard* was launched in the U.S. by Access in 2010 after receiving 510(k) clearance from the FDA. *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 aphthous ulcers/canker sores and traumatic ulcers, such as those caused by oral surgery or ill-fitting dentures or braces. Under the Access License Agreement, we obtained an exclusive, royalty-bearing license, with the right to grant sublicenses, to certain intellectual property rights, including know-how, patents and trademarks, to use, import, offer for sale, sell, manufacture and commercialize *MuGard* in the U.S. and its territories, or the U.S. Territory, for the management of all diseases or conditions of the oropharyngeal cavity, including mucositis, or the MuGard Rights. Additional details regarding the Access License Agreement and the MuGard Rights can be found in Note G.

We are subject to risks common to companies in the pharmaceutical industry including, but not limited to, our primary dependence on the success of *Feraheme/Rienso*, uncertainties related to the regulatory approval process for the broader *Feraheme/Rienso* indication, including limitations to our future revenues, the potential development of significant safety or drug interaction problems with respect to *Feraheme/Rienso*, competition in our industry, uncertainties related to potential collaborations, in-licensing arrangements or acquisition agreements, our dependence on third parties to manufacture *Feraheme/Rienso* and *MuGard*, the potential inability of our or Access' third-party manufacturers to operate their facilities in compliance with current good manufacturing practices and manufacture sufficient quantities of *Feraheme/Rienso* or *MuGard*, uncertainties related to the protection of our proprietary technology related to *Feraheme*, our reliance on Takeda to commercialize *Feraheme/Rienso* in certain territories outside of the U.S., uncertainties regarding market acceptance of *Feraheme/Rienso* or *MuGard*, our reliance on a limited number of customers for *Feraheme*, uncertainties related to patient insurance coverage and third-party reimbursement rates and terms for *Feraheme/Rienso* or *MuGard*, uncertainties related to the impact of current and future healthcare initiatives and legislation,

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our third-party manufacturers, or Access' potential inability to obtain raw or other materials, our potential inadvertent failure to comply with reporting and payment obligations under government pricing programs, our potential inability to become profitable in the future, our limited experience commercializing and distributing a pharmaceutical product, our dependence on key personnel, the potential fluctuation of our operating results, potential differences between actual future results and the estimates or assumptions used by us in preparation of our consolidated financial statements, our potential inadvertent failure to comply with the regulations of the FDA or other federal, state or foreign government agencies, the volatility of our stock price, uncertainties related to the actions of activist stockholders, potential product liability, potential legislative and regulatory changes, and potential costs and liabilities associated with pending or future litigation or patent challenges.

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

B. Summary of Significant Accounting Policies

Use of Estimates and Assumptions

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America 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 in, but are not limited to, revenue recognition related to product sales and collaboration agreements, product sales allowances and accruals, assessing investments for potential other-than-temporary impairment and determining fair values of our investments, the fair value of our assets held for sale, fair value of assets acquired in a business combination, contingent consideration, the impairment of long-lived assets, including intangible assets, accrued expenses, and equity-based compensation expense. Actual results could differ materially from those estimates.

Principles of Consolidation

The accompanying consolidated financial statements include our accounts and the accounts of our wholly-owned subsidiaries, AMAG Europe Limited, AMAG Securities Corporation and Snowbird, Inc. AMAG Europe Limited was incorporated in October 2009 in London, England. AMAG Securities Corporation is a Massachusetts corporation which was incorporated in August 2007. Snowbird, Inc. is a Delaware corporation which was incorporated in December 2013. All intercompany account balances and transactions between the companies have been eliminated.

Cash and Cash Equivalents

Cash and cash equivalents consists 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. We consider all highly liquid investments with a maturity of three months or less at acquisition date to be cash equivalents. At December 31, 2013, substantially all of our cash and cash equivalents were held in either commercial bank accounts or money market funds.

Investments

We account for and classify our investments as either "available-for-sale," "trading," or "held-to-maturity," in accordance with current guidance related to the accounting and classification of certain investments in debt and equity securities. The determination of the appropriate classification by us is based on a variety of factors, including management's intent at the time of purchase. During the years ended December 31, 2013 and 2012, all of our investments were classified as available-for-sale securities.

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

We recognize and report other-than-temporary impairments of our debt securities in accordance with current accounting guidance, which requires that for debt securities with a decline in fair value below amortized cost basis, an other-than-temporary impairment exists if (a) we have the intent to sell the security or (b) it is more likely than not that we will be required to sell the security prior to recovery of its amortized cost basis. If either of these conditions is met, we recognize the difference between the amortized cost of the security and its fair value at the impairment measurement date in our consolidated statement of operations. If neither of these conditions is met, we must perform additional analyses to evaluate whether the unrealized loss is associated with the creditworthiness of the security rather than other factors, such as interest rates or market factors. These factors include evaluation of the security, issuer and other factors such as the duration of the period that, and extent to which, the fair value was less than cost basis, the financial health of and business outlook for the issuer, including industry and sector performance, operational and financing cash flow factors, overall market conditions and trends, underlying collateral, whether we have a favorable history in redeeming similar securities at prices at or above fair value, and credit ratings with respect to our investments provided by investments ratings agencies. 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. In this situation, the impairment is considered other-than-temporary and is recognized in our consolidated statement of operations.

Fair Value Measurements

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

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

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

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

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

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

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represent the fair value hierarchy as of December 31, 2013 and 2012, for those assets and liabilities that we measure at fair value on a recurring basis (in thousands):

	Fair Value Measurements at December 31, 2013 Using:			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market funds	$ 18,767	$ 18,767	$	$
Corporate debt securities	134,123		134,123	
U.S. treasury and government agency securities	52,680		52,680	
Total Assets	$ 205,570	$ 18,767	$ 186,803	$
Liabilities:				
Acquisition-related contingent consideration	$ 14,550	$	$	$ 14,550
Total Liabilities	$ 14,550	$	$	$ 14,550

	Fair Value Measurements at December 31, 2012 Using:			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	$ 24,058	$ 24,058	$	$
Corporate debt securities	111,690		111,690	
U.S. treasury and government agency securities	59,569		59,569	
Commercial paper	9,491		9,491	
	$ 204,808	$ 24,058	$ 180,750	$

With the exception of our money market funds and our acquisition-related contingent consideration, the fair value of our investments is primarily determined from independent pricing services. Independent pricing services normally derive security prices from recently reported trades for identical or similar securities, making adjustments based upon other significant observable market transactions. At the end of each reporting period, we perform quantitative and qualitative analyses of prices received from third parties to determine whether prices are reasonable estimates of fair value. After completing our analyses, we did not adjust or override any fair value measurements provided by our pricing services as of either December 31, 2013 or 2012. In addition, there were no transfers or reclassifications of any securities between Level 1 and Level 2 during either 2013 or 2012.

We also analyze when the volume and level of activity for an asset or liability have significantly decreased and when circumstances indicate that a transaction may not be considered orderly. In order to determine whether the volume and level of activity for an asset or liability have significantly decreased, we assess current activity as compared to normal market activity for the asset or liability. We rely on many factors such as trading volume, trading frequency, the levels at which market participants indicate their willingness to buy and sell our securities, as

reported by market participants, and current market conditions. Using professional judgment and experience, we evaluate and weigh the relevance and significance of all applicable factors to determine if there has been a significant decrease in the volume and level of activity for an asset, group of similar assets or liabilities. Similarly, in order to identify transactions that are not orderly, we take into consideration the activity in the market which

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can influence the determination and occurrence of an orderly transaction. Also, we inquire as to whether there may have been restrictions on the marketing of the security to a single or limited number of participants. Where possible, we assess the financial condition of the seller to determine whether observed transactions may have been forced. If there is a significant disparity between the trading price for a security held by us as compared to the trading prices of similar recent transactions, we consider whether this disparity is an indicator of a disorderly trade. Using professional judgment and experience, we evaluate and weigh the relevance and significance of all applicable factors to determine if the evidence suggests that a transaction or group of similar transactions is not orderly. Based upon these procedures, we determined that market activity for our assets appeared normal and that transactions did not appear disorderly as of December 31, 2013 and 2012.

In 2012, our Level 3 assets consisted solely of auction rate securities, which we sold in mid-2012. The following table provides a rollforward of these Level 3 assets for 2012 (in thousands):

	December 31, 2012
Balance at beginning of period	$ 17,527
Transfers to Level 3	
Total gains (losses) (realized or unrealized):	
Included in earnings	(1,471)
Included in other comprehensive income (loss)	2,373
Purchases, issuances, sales and settlements:	
Purchases	
Issuances	
Sales	(18,329)
Settlements	(100)
Balance at end of period	$
The amount of total gains (losses) for the period included in earnings attributable to the change in unrealized gains (losses) relating to assets still held at end of period	$

We are accounting for the acquisition of the MuGard Rights as a business combination under the acquisition method of accounting. Additional details regarding the Access License Agreement and the MuGard Rights can be found in Note G. The fair value measurements of contingent consideration obligations and the related intangible asset arising from business combinations are determined using unobservable, or Level 3, 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 (decreases) in any of those inputs in isolation could result in a significantly lower or higher fair value measurement.

The following table presents a reconciliation of contingent consideration obligations related to our acquisition of the MuGard Rights measured on a recurring basis using Level 3 inputs as of December 31, 2013 (in thousands):

Balance as of June 6, 2013	$
Acquisition date fair value of contingent consideration	13,700
Balance as of June 30, 2013	$ 13,700
Payments made	(51)
Adjustments to fair value of contingent consideration	1,074
Other adjustments	(173)

Balance as of December 31, 2013	$ 14,550

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During 2013, we recorded $1.1 million in expense related to the increase in fair value of the contingent consideration liability. This expense represents the time value of money impact of the contingent consideration fair value assessment as of December 31, 2013 and is included in selling, general and administrative expenses in our consolidated statements of operations. As of December 31, 2013, we estimate that the undiscounted royalty amounts we could pay under the Access License Agreement may range from $28.0 million to $34.0 million over a ten year period, which is our best estimate of the period over which we expect the majority of the asset's cash flows to be derived. This measure is based on significant Level 3 inputs not observable in the market. Key assumptions include a discount rate of approximately 15%. As of December 31, 2013, the assumptions used for determining fair value of the contingent consideration have not changed significantly from those used at the Acquisition Date. We have classified $0.9 million of the contingent consideration as a short-term liability, which was included in accrued expenses in our consolidated balance sheet as of December 31, 2013.

In addition, in connection with the acquisition of the MuGard Rights, we acquired an intangible asset of $16.9 million, which was originally determined based on fair value measurements. These measures were based on significant Level 3 inputs not observable in the market. Key assumptions include a discount rate of 19%. We believe the estimated fair values of the MuGard Rights are based on reasonable assumptions, however, we cannot provide assurance that the underlying assumptions used to forecast the cash flows will materialize as we estimated and thus, our actual results may vary significantly from the estimated results.

Inventories

Inventories are stated at the lower of cost or market (net realizable value), with approximate cost being determined on a first-in, first-out basis.

Prior to initial approval from the FDA or other regulatory agencies, we expense costs relating to the production of inventory in the period incurred. After such time as the product receives initial regulatory approval, we begin to capitalize the inventory costs related to the product. Prior to the June 2009 FDA approval of *Feraheme* for commercial sale in the U.S., all production costs related to *Feraheme* were expensed to research and development. Subsequent to receiving FDA approval, costs related to the production of *Feraheme* are capitalized to inventory, including the costs of converting previously existing raw or other materials to inventory and vialing, labeling, and packaging inventory manufactured prior to approval whose costs had already been recorded as research and development expense. We continue to expense costs associated with clinical trial material as research and development expense.

Property and Equipment

Property and equipment are recorded at cost and depreciated when placed into service using the straight-line method based on their estimated useful lives. Our laboratory and production equipment and furniture and fixtures are being depreciated over five years. Furniture, fixtures, and leasehold improvements associated with our facility lease are being depreciated over the shorter of their useful lives or the remaining life of the original lease (excluding optional lease renewal terms).

Costs for capital assets not yet placed in service are capitalized on our balance sheets, and the cost of maintenance and repairs is 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 statement 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 (asset group) and its eventual

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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.

Restricted Cash

As of December 31, 2013 and 2012, we classified $3.3 million and $0.5 million as restricted cash, respectively. Included in the $3.3 million restricted cash balance as of December 31, 2013 was a $2.9 million escrow payment related to a business development transaction that we did not complete. The escrow payment was returned to us in January 2014 and as such was classified as short-term as of December 31, 2013. We also included $0.4 million and $0.5 million in our December 31, 2013 and 2012 restricted cash balances, respectively, related to security deposits delivered to the landlord of our then current locations in the form of irrevocable letters of credits.

Patents

We expense all patent-related costs as incurred.

Research and Development Expenses

Research and development expenses include external expenses, such as costs of clinical trials, contract research and development expenses, certain manufacturing research and development costs, regulatory filing fees, consulting and professional fees and expenses, and internal expenses, such as compensation of employees engaged in research and development activities, the manufacture of product needed to support research and development efforts, related costs of facilities, and other general costs related to research and development. Manufacturing costs are expensed as incurred until a product has received the necessary initial regulatory approval.

Advertising Costs

Advertising costs are expensed as incurred and are included in selling, general and administrative expenses in our consolidated statement of operations. Advertising costs, including promotional expenses and costs related to trade shows were $1.9 million, $1.8 million and $3.1 million for the years ended December 31, 2013, 2012 and 2011, respectively.

Revenue Recognition and Related Sales Allowances and Accruals

We recognize revenue from the sale of *Feraheme/Rienso* and *MuGard* as well as license fee and other collaboration revenues, including milestone payments, other product sale revenues, and royalties we receive from our licensees. We recognize revenue in accordance with current accounting guidance related to the recognition, presentation and disclosure of revenue in financial statements, which outlines the basic criteria that must be met to recognize revenue and provides guidance for disclosure of revenue in financial statements. We recognize revenue when:

Persuasive evidence of an arrangement exists;

Delivery of product has occurred or services have been rendered;

The sales price charged is fixed or determinable; and

Collection is reasonably assured.

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U.S. Feraheme Product Sales, Net

We record *Feraheme* product sales allowances and accruals related to prompt payment discounts, chargebacks, government and other rebates, distributor, wholesaler and group purchasing organization, or GPO, fees, and product returns as a reduction of revenue in our consolidated statement of operations at the time product sales are recorded. Calculating these gross-to-net sales adjustments involves estimates and judgments based primarily on actual *Feraheme* sales data, forecasted customer buying patterns, and market research data related to utilization rates by various end-users. In addition, we also monitor our distribution channel to determine whether additional allowances or accruals are required based on inventory in our sales channel. An analysis of our U.S. *Feraheme* product sales allowances and accruals for the years ended December 31, 2013, 2012 and 2011 is as follows (in thousands):

	2013	2012	2011
Provision for U.S. product sales allowances and accruals			
Discounts and chargebacks	$ 37,098	$ 26,517	$ 13,851
Government and other rebates	10,868	6,058	8,544
Medicaid rebate reserve adjustment	(568)	(621)	(2,532)
Returns	952	(1,516)	1,259
Total provision for U.S. product sales allowances and accruals	$ 48,350	$ 30,438	$ 21,122
Total gross U.S. product sales	$ 119,712	$ 88,725	$ 73,219
Total provision for U.S. product sales allowances and accruals as a percent of total gross U.S. product sales	40%	34%	29%

Classification of U.S. Feraheme Product Sales Allowances and Accruals

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

Allowances against receivable balances primarily relate to prompt payment discounts, provider chargebacks and certain government agency rebates and are recorded at the time of sale, resulting in a reduction in product sales revenue and the reporting of product sales receivables net of allowances.

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Accruals related to Medicaid and provider volume rebates, wholesaler and distributor fees, GPO fees, other discounts to healthcare providers and product returns are recorded at the time of sale, resulting in a reduction in product sales revenue and the recording of an increase in accrued expenses.

Discounts

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

Chargebacks

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

Government and Other Rebates

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

During 2013, 2012 and 2011, we revised our estimated Medicaid utilization rate based on actual rebate claims received since the 2009 launch of *Feraheme*, our expectations of state level activity, and estimated rebate claims not yet submitted, which resulted in a reduction of our estimated Medicaid rebate reserve related to prior period *Feraheme* sales of $0.6 million, $0.6 million and $2.5 million, respectively. These changes in estimates were reflected as an increase in our net product sales for 2013, 2012 and 2011. As a result, our gross to net percentages for 2013, 2012 and 2011 were lower than they otherwise would have been had we not reduced our Medicaid rebate reserve. The reduction of our estimated Medicaid rebate reserve had an impact of $0.03, $0.03 and $0.12 per basic and diluted share for 2013, 2012 and 2011, respectively. We regularly assess our Medicaid reserve balance and the rate at which we accrue for claims against product sales. If we determine in future periods that our actual rebate experience is not indicative of expected claims, or if other factors affect estimated claims rates, we may be required to change our estimated Medicaid reserve and/or the current rate at which we estimate our Medicaid claims, which would affect our earnings in the period of the change in estimate and such change could be significant.

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Distributor/Wholesaler and Group Purchasing Organization Fees

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

Product Returns

Consistent with industry practice, we generally offer our wholesalers, specialty distributors and other customers a limited right to return *Feraheme* purchased directly from us based on the product's expiration date which, once packaged, is currently five years in the U.S. We estimate product returns based on the historical return patterns and known or expected changes in the marketplace. We currently have limited actual returns data, and therefore are not able to solely rely on our actual returns experience. 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 consider several additional factors in our product return estimation process, including our internal sales forecasts and inventory levels in the distribution channel. We expect that wholesalers and healthcare providers will not stock significant inventory due to *Feraheme's* cost and expense to store. Based on the level of inventory in the wholesale distribution channel, we determine whether an adjustment to the sales return reserve is appropriate.

We record an estimate of returns at the time of sale. If necessary, our estimated rate of returns may be adjusted for actual return experience as it becomes available and for known or expected changes in the marketplace. During 2012, we reduced our reserve for product returns by approximately $2.2 million primarily as a result of a lower than expected rate of product returns as well as the lapse of the product return period on certain manufactured *Feraheme* lots that carried a two year expiration. As a result, the product returns provision applied to gross product sales for the year ended December 31, 2012 was a credit of $1.5 million, resulting in an increase to net product sales for the year. The reduction of our estimated product returns reserve had a positive impact of $0.10 per basic and diluted share for year ended December 31, 2012. We did not significantly adjust our reserve for product returns during 2013 or 2011. *Feraheme* is still early in its product lifecycle and returns experience may change over time. A future revision to our product returns estimate would result in a corresponding change to our net product sales in the period in which the change is made and could be significant.

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Other Product Sales and Royalties

Other product sales and royalties include product sales of *Feraheme/Rienso* and GastroMARK® to our licensees, net product sales of *MuGard* and royalties received from our licensees' sales of *Feraheme/Rienso* and *GastroMARK*. We record all product sales for *Feraheme/Rienso* sold to Takeda in deferred revenues in our consolidated balance sheet. We recognize these deferred revenues, and the associated cost of product sales, in our consolidated statement of operations at the time Takeda reports to us that sales have been made to its customers.

License Fee and Other Collaboration Revenues

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

Multiple Element Arrangements and Milestone Payments

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

When multiple deliverables are combined and accounted for as a single unit of accounting, we base our revenue recognition pattern on the last to be delivered element. Revenue is recognized using either a proportional performance or straight-line method, depending on whether we can reasonably estimate the level of effort required to complete our performance obligations under an arrangement and whether such performance obligations are provided on a best-efforts basis. To the extent we cannot

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reasonably estimate our performance obligations, we recognize revenue on a straight-line basis over the period we expect to complete our performance obligations. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which we are expected to complete our performance obligations under an arrangement. We may have to revise our estimates based on changes in the expected level of effort or the period we expect to complete our performance obligations.

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

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

The milestone is related solely to our past performance; and

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

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

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in our consolidated balance sheets. Amounts not expected to be recognized within the next 12 months are classified as long-term deferred revenue.

Acquisitions

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

Intangible Assets

Intangible assets with definite useful lives are amortized to their estimated residual values over their estimated useful lives and reviewed for impairment if certain events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

Contingent Consideration

Contingent consideration arising from a business combination is included as part of the acquisition cost and is recognized at fair value as of the acquisition date. Any liability resulting from contingent consideration is remeasured to its fair value at each reporting date until the contingency is resolved. These changes in fair value are recognized in our consolidated statements of operations.

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Shipping and Handling Costs

We utilize a third-party logistics provider, which is a subsidiary of one of our distribution customers, to provide us with various shipping and handling services related to sales of *Feraheme*. As we receive an identifiable benefit and we can reasonably estimate the fair value of this benefit, we have recorded $0.3 million, $0.2 million and $0.1 million as a selling, general and administrative expense during 2013, 2012 and 2011, respectively.

Equity-Based Compensation

Under the fair value recognition guidance of equity-based compensation accounting rules, equity-based compensation cost is generally required to be measured at the grant date (based upon an estimate of the fair value of the compensation granted) and recorded to expense over the requisite service period, which generally is the vesting period. Because equity-based compensation expense is based on awards ultimately expected to vest, we must make certain judgments about whether employees and directors will complete the requisite service period. Accordingly, we have reduced the compensation expense being recognized for estimated 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. Forfeitures are estimated based upon historical experience, adjusted for unusual events such as the corporate restructurings in 2012 and 2011, which resulted in higher than expected turnover and forfeitures in those years. 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. We estimate the fair value of our restricted stock units whose vesting is contingent upon market conditions using the Monte-Carlo simulation model. These models require 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 whose fair values are calculated using the Black-Scholes option pricing model is generally being 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. The fair value of awards with market conditions is being amortized based upon the estimated derived service period. 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 thus may not be reflective of actual future results or amounts ultimately realized by recipients of these grants. These amounts, and the amounts applicable to future quarters, are also 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. The fair value of restricted stock units granted to our employees and directors is determined based upon the quoted closing market price per share on the date of grant, adjusted for estimated forfeitures.

Income Taxes

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

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Concentrations and Significant Customer Information

Financial instruments which potentially subject us to concentrations of credit risk consist principally of cash, investments, and accounts receivable. As of December 31, 2013, our cash, cash equivalents and investments amounted to approximately $213.8 million. We currently invest our excess cash primarily in U.S. government and agency money market funds, and investments in corporate debt securities and U.S. treasury and government agency securities. As of December 31, 2013, we had approximately $18.8 million of our total $27.0 million cash and cash equivalents balance invested in institutional money market funds, of which $12.2 million was invested in a single fund, which is collateralized solely by U.S. treasury and government agency securities.

Our operations are located solely within the U.S. We are focused principally on developing, manufacturing, and commercializing *Feraheme/Rienso* and commercializing *MuGard*. We perform ongoing credit evaluations of our customers and generally do not require collateral. The following table sets forth customers who represented 10% or more of our total revenues for 2013, 2012 and 2011:

	Years Ended December 31,		
	2013	**2012**	**2011**
AmerisourceBergen Drug Corporation	41%	34%	41%
McKesson Corporation	24%	17%	21%
Cardinal Health, Inc.	16%	12%	13%
Takeda Pharmaceuticals Company Limited	11%	31%	13%

In addition, approximately 30%, 32% and 35% of our end-user demand in 2013, 2012 and 2011, respectively, was generated by members of a single GPO with which we have contracted. Revenues from customers outside of the U.S. amounted to approximately 11%, 32% and 14% of our total revenues for 2013, 2012 and 2011, respectively, and were principally related to collaboration revenue recognized in connection with our collaboration agreement with Takeda, which is headquartered in Japan.

We are currently solely dependent on a single supply chain for our *Feraheme/Rienso* drug substance and finished drug product. We are exposed to a significant loss of revenue from the sale of *Feraheme/Rienso* if our suppliers and/or manufacturers cannot fulfill demand for any reason.

Comprehensive Income (Loss)

The current accounting guidance related to comprehensive income (loss) requires us to display comprehensive loss and its components as part of our consolidated financial statements. Our comprehensive loss consists of net loss and other comprehensive income (loss). Other comprehensive income (loss) includes changes in equity that are excluded from net loss, which for all periods presented related to unrealized holding gains and losses on available-for-sale investments, net of tax.

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Net Loss per Share

We compute basic net loss per share by dividing net loss by the weighted average number of common shares outstanding during the relevant period. The components of basic and diluted net loss per share were as follows (in thousands, except per share data):

	Years Ended December 31,		
	2013	2012	2011
Net loss	$ (9,602)	$ (16,750)	$ (77,069)
Weighted average common shares outstanding	21,703	21,392	21,189
Net loss per share:			
Basic and diluted	$ (0.44)	$ (0.78)	$ (3.64)

The following table sets forth the potential common shares issuable upon the exercise of outstanding options and the vesting of restricted stock units (prior to consideration of the treasury stock method), that were excluded from our computation of diluted net loss per share because such options and restricted stock units were anti-dilutive (in thousands):

	Years Ended December 31,		
	2013	2012	2011
Options to purchase shares of common stock	2,820	2,190	1,817
Shares of common stock issuable upon the vesting of restricted stock units	465	374	669
Total	3,285	2,564	2,486

Reclassifications

Certain amounts in prior periods have been reclassified in order to conform to the current period presentation.

C. Investments

As of December 31, 2013 and 2012, our investments equaled $186.8 million and $180.8 million, respectively, and consisted of securities classified as available-for-sale in accordance with accounting standards which provide guidance related to accounting and classification of certain investments in debt and equity securities.

The following is a summary of our investments as of December 31, 2013 and 2012 (in thousands):

	December 31, 2013			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities				
Due in one year or less	$ 42,609	$ 44	$ (4)	$ 42,649
Due in one to three years	91,443	137	(106)	91,474
U.S. treasury and government agency securities				
Due in one year or less	18,526	19		18,545
Due in one to three years	34,123	37	(25)	34,135
Total investments	$ 186,701	$ 237	$ (135)	$ 186,803

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	December 31, 2012			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities				
Due in one year or less	$ 52,332	$ 88	$ (6)	$ 52,414
Due in one to three years	59,176	137	(37)	59,276
U.S. treasury and government agency securities				
Due in one year or less	24,795	86		24,881
Due in one to three years	34,606	84	(2)	34,688
Commercial paper				
Due in one year or less	9,494	1	(4)	9,491
Total investments	$ 180,403	$ 396	$ (49)	$ 180,750

Impairments and Unrealized Gains and Losses on Investments

We did not recognize any other-than-temporary impairment losses in our consolidated statements of operations related to our securities during either 2013 or 2012. We considered various factors, including the length of time that each security was in an unrealized loss position and our ability and intent to hold these securities until the recovery of their amortized cost basis occurs. As of December 31, 2013, none of our investments has been in an unrealized loss position for more than one year. Future events may occur, or additional information may become available, which may cause us to identify credit losses where we do not expect to receive cash flows sufficient to recover the entire amortized cost basis of a security and which may necessitate the recording of future realized losses on securities in our portfolio. Significant losses in the estimated fair values of our investments could have a material adverse effect on our earnings in future periods.

Realized Gains and Losses on Investments

Gains and losses are determined on the specific identification method. Realized gains were insignificant during 2013. During 2012, we recorded realized losses of $1.5 million to our consolidated statement of operations related to the sale of our then-remaining auction rate securities portfolio.

D. Accounts Receivable, Net

Our net accounts receivable were $6.8 million and $6.4 million as of December 31, 2013 and 2012, respectively, and primarily represented amounts due from wholesalers and distributors to whom we sell *Feraheme* directly. Accounts receivable 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 have not required collateral from any customer. To date, we have not experienced significant bad debts. Accordingly, we have not established an allowance for doubtful accounts at either December 31, 2013 or 2012. If the financial condition of any of our significant 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.

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Customers which represented greater than 10% of our accounts receivable balances as of December 31, 2013 and 2012 were as follows:

	December 31,	
	2013	2012
AmerisourceBergen Drug Corporation	43%	48%
McKesson Corporation	29%	28%
Cardinal Health, Inc.	19%	18%

E. Inventories

Our major classes of inventories were as follows as of December 31, 2013 and 2012 (in thousands):

	December 31,	
	2013	2012
Raw materials	$ 3,157	$ 2,652
Work in process	8,322	2,524
Finished goods	5,738	7,275
Total inventories	$ 17,217	$ 12,451

During 2013, we expensed $1.1 million of commercial inventory deemed no longer saleable, which we recorded in cost of goods sold. In addition, during 2013, we expensed $1.1 million of commercial inventory which we determined would solely be used in manufacturing processes development activities at our third-party suppliers, which we have recorded in research and development expense.

During 2012, we expensed $0.6 million of inventory which was initially produced to validate the manufacturing process at third-party suppliers and which we no longer believed was suitable for sale. We have recorded this $0.6 million in research and development expenses. In addition, during 2012, we expensed $0.6 million of commercial inventory deemed no longer saleable, which we recorded in cost of goods sold. We expensed $0.7 million of additional inventory related to our then-ongoing divestiture of our Cambridge, Massachusetts manufacturing facility and recorded the expense in restructuring costs.

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 goods sold. The determination of whether inventory costs will be realizable requires estimates by management of future expected inventory requirements, based on internal sales forecasts and forecasts received from Takeda. Once packaged, *Feraheme/Rienso* currently has a shelf-life of five years in the U.S. and between two and three years outside of the U.S., and as a result of comparison to internal sales forecasts, we expect to fully realize the carrying value of our current *Feraheme/Rienso* finished goods inventory. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required. Charges for inventory write-downs are not reversed if it is later determined that the product is saleable.

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F. Property and Equipment, Net

Property and equipment consisted of the following as of December 31, 2013 and 2012, respectively (in thousands):

	December 31,	
	2013	2012
Furniture and fixtures	$ 1,536	$ 5,326
Leasehold improvements	430	5,373
Laboratory and production equipment	376	115
Construction in process		228
	2,342	11,042
Less accumulated depreciation	(496)	(7,745)
Property and equipment, net	$ 1,846	$ 3,297

In September 2013, we relocated our corporate offices from Lexington, Massachusetts to Waltham, Massachusetts. In connection with our relocation, we recorded $1.6 million of new leasehold improvements and furniture and fixtures related to our new location. In addition, during 2013, we recorded $3.0 million of depreciation expense, including $1.9 million of accelerated depreciation expense related to fixed assets at our prior office facility.

During 2012, we determined that certain assets related to our Cambridge, Massachusetts manufacturing facility, including the related land, building and certain equipment, met the criteria established by current accounting guidance for classifying assets as held for sale. As a result, we reclassified these assets from property, plant and equipment to assets held for sale in our consolidated balance sheet as of December 31, 2012 and recorded the value of these assets at $2.0 million, their estimated fair market value. In October 2013, we sold our Cambridge, Massachusetts manufacturing facility, including the land and building, to 61 Mooney Street LLC. We received $2.0 million in consideration for the land and building at the time of sale and we did not recognize a material gain or loss on this transaction. In addition, we sold certain equipment previously reclassified as held for sale and recognized a $0.4 million gain during 2013.

G. Business Combination

As part of our strategy to expand our portfolio with additional commercial-stage specialty products, in June 2013, we entered into the Access License Agreement pursuant to which we obtained an exclusive, royalty-bearing license, with the right to grant sublicenses, to certain intellectual property rights, including know-how, patents and trademarks, to use, import, offer for sale, sell, manufacture and commercialize *MuGard* in the U.S. Territory for the management of all diseases or conditions of the oropharyngeal cavity, including mucositis.

MuGard was launched in the U.S. by Access in 2010 after receiving 510(k) clearance from the FDA and is indicated for the management of oral mucositis/stomatitis (that may be caused by radiotherapy and/or chemotherapy) and all types of oral wounds (mouth sores and injuries), including aphthous ulcers/canker sores and traumatic ulcers, such as those caused by oral surgery or ill-fitting dentures or braces.

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

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In consideration for the license, we paid Access an upfront payment of $3.3 million in June 2013. We are required to pay royalties to Access on net sales of *MuGard* until the later of (a) the expiration of the licensed patents or (b) the tenth anniversary of the first commercial sale of *MuGard* under the Access License Agreement in the U.S. Territory, or the Royalty Term. These tiered, double-digit royalty rates decrease for any part of the Royalty Term occurring after the expiration of the licensed patents and are subject to off-set against certain of our expenses. After the expiration of the Royalty Term, the license shall become a fully paid-up, royalty-free and perpetual license in the U.S. Territory. In addition to making an upfront payment of $3.3 million, we also acquired $0.2 million of existing *MuGard* inventory from Access, which was included in our condensed consolidated balance sheet as of the Acquisition Date.

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

We estimated the fair value of the acquired MuGard Rights using the income approach. The income approach uses valuation techniques to convert future amounts to a single present amount (discounted). This approach begins with a forecast of the net cash flows expected to be generated by the asset over its estimated useful life. These cash flows are then adjusted to present value by applying an appropriate discount rate that reflects the risk factors associated with the cash flow streams. Some of the more significant estimates and assumptions inherent in the income approach include the following:

- The amount and timing of projected future cash flows, adjusted for the probability of marketing success;
- The discount rate selected to measure the risks inherent in the future cash flows; and
- An assessment of the asset's life-cycle and the competitive trends impacting the asset.

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

Consideration:	
Cash	$ 3,434
Acquisition-related contingent consideration	13,700
Total consideration	$ 17,134

The $17.1 million total consideration includes the estimated fair value of the contingent consideration at the Acquisition Date. During 2013, we completed the valuation for the acquisition of the MuGard Rights and determined the fair value of the contingent consideration to be $13.7 million as of the Acquisition Date, and the fair value of the intangible asset was determined to be $16.9 million

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as of the Acquisition Date. The Acquisition Date fair value of the contingent consideration was determined based on various market factors, including an analysis of estimated sales using a discount rate of approximately 15%. As of December 31, 2013, we estimated that the undiscounted royalty amounts we could pay under the Access License Agreement may range from $28.0 million to $34.0 million over a ten year period, which is our best estimate of the period over which we expect the majority of the asset's cash flows to be derived. The measurement period adjustments represent updates made to the preliminary valuation based on revisions to estimates in the interim period subsequent to the acquisition and initial accounting date.

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

Assets Acquired:	
MuGard intangible asset	$ 16,893
Inventory	241
Net identifiable assets acquired	$ 17,134

The Acquisition Date fair value of the intangible asset was determined based on various market factors, including an analysis of estimated sales using a discount rate of 19%. This measure is based on significant Level 3 inputs not observable in the market. Such valuations require significant estimates and assumptions including but not limited to: estimating future cash flows from product sales and developing appropriate discount and probability rates. We believe the estimated fair values of the MuGard Rights are based on reasonable assumptions, however, we cannot provide assurance that the underlying assumptions used to forecast the cash flows will materialize as we estimated and thus, our actual results may vary significantly from the estimated results.

Commencing from the Acquisition Date, our consolidated financial statements include the assets, liabilities, operating results and cash flows from the acquired product. Revenues related to *MuGard* sales for 2013 were not material.

Transaction costs are not included as a component of consideration transferred and are expensed as incurred. We incurred approximately $0.8 million of acquisition-related costs in 2013. These costs were primarily related to professional and legal fees and are included in selling, general and administrative expenses in our consolidated statements of operations for 2013.

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

H. Intangible Assets, Net

In June 2013, we acquired the MuGard Rights from Access and recorded $16.9 million to finite-lived intangible assets based on the estimated fair value of the MuGard Rights as of the Acquisition Date.

We will amortize the MuGard Rights using an economic consumption model over ten years, which represents our best estimate of the period over which we expect the majority of the asset's cash flows to be derived. We believe this is the best approximation of the period over which we will derive the majority of value of the MuGard Rights. We recorded less than $0.1 million of amortization related to the MuGard Rights in cost of product sales in our consolidated statements of operations for 2013 and as a result, our intangible asset related to the MuGard Rights was $16.8 million as of December 31, 2013.

Intangible assets are reviewed for impairment at least annually and whenever facts or circumstances suggest that the carrying value of these assets may not be recoverable. Our policy is to identify and record impairment losses, if necessary, on intangible assets when events and circumstances indicate that the assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amounts of those assets.

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We expect future annual amortization expense related to our intangible asset to be as follows (in thousands):

Period	Estimated Amortization Expense
Year Ended December 31, 2014	679
Year Ended December 31, 2015	914
Year Ended December 31, 2016	1,215
Year Ended December 31, 2017	1,616
Year Ended December 31, 2018	2,103
Thereafter	10,317
Total	$ 16,844

I. Current and Long-Term Liabilities

Accrued Expenses

Accrued expenses consisted of the following as of December 31, 2013 and 2012 (in thousands):

	December 31, 2013	December 31, 2012
Clinical, manufacturing and regulatory consulting fees and expenses	$ 7,834	$ 7,737
Salaries, bonuses, and other compensation	5,419	5,236
Commercial rebates, fees and returns	4,839	3,448
Professional, license, and other fees and expenses	1,932	1,719
Commercial consulting fees and expenses	1,301	815
Short-term contingent consideration	941	
Restructuring expense		1,383
Total accrued expenses	$ 22,266	$ 20,338

Deferred Revenues

Deferred revenues consisted of the following as of December 31, 2013 and 2012 (in thousands):

	December 31, 2013	December 31, 2012
Short-term deferred revenues:		
Takeda	$ 8,226	$ 8,854
Other short-term deferred revenues		250
Total	$ 8,226	$ 9,104

Long-term deferred revenues:		
Takeda	$ 43,534	$ 49,350
3SBio	1,000	1,000
Total	$ 44,534	$ 50,350

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Our deferred revenues related to Takeda are recorded in our consolidated balance sheets and include the following as of December 31, 2013:

- $49.3 million related to the amortization of upfront payments and milestone payments recognized under the Amended Takeda Agreement. Included in the $49.3 million was the amortization of upfront payments we received from Takeda in 2010, which we are recognizing on a straight-line basis over a period of 10 years, which represents the current patent life of *Feraheme/Rienso* and our best estimate of the period over which we will substantially perform our obligations. In addition, included in the $49.3 million was the amortization of an aggregate of $18.0 million in milestone payments we received from Takeda in 2012 associated with the commercial launches of *Feraheme/Rienso* in Canada and the EU, which we are amortizing over the original life of the Takeda Agreement. During 2013 and 2012, we recorded $7.9 million and $11.1 million to license fee and other collaboration revenues in our consolidated statement of operations; and

- $2.4 million related to product shipped to Takeda but not yet sold through to Takeda's customers, which are included in our consolidated balance sheet.

In consideration of the grant of the license to 3SBio Inc., or 3SBio, in 2008, we received an upfront payment of $1.0 million, the recognition of which has been deferred. In late January 2014, we mutually terminated the agreement with 3SBio, effective immediately, due to the fact that, despite the best efforts of the parties, regulatory approval in China could not be obtained within the agreed upon time period.

Other Long-Term Liabilities

Other long-term liabilities at both December 31, 2013 and 2012 consisted solely of deferred rent related to the lease of our principal executive offices in Lexington, Massachusetts and after September 2013, Waltham, Massachusetts.

J. Income Taxes

For the years ended December 31, 2012 and 2011, we recognized $0.9 million and $1.2 million in current federal income tax benefits, respectively. We did not recognize any current federal income tax benefit for the year ended December 31, 2013. The 2012 and 2011 federal income tax benefits were the result of the recognition of corresponding income tax expense associated with the decrease in the unrealized loss on our investments, primarily related to our auction rate securities, which we carried at fair market value during 2012 and 2011. The corresponding income tax expense was recorded in other comprehensive loss. Due to the uncertainty surrounding the realization of favorable tax attributes in future tax returns, we have recorded a full valuation allowance against our otherwise recognizable net deferred tax assets. We did not recognize any federal income tax benefits in 2013.

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

	Years Ended December 31,		
	2013	2012	2011
Statutory U.S. federal tax rate	(34.0)%	(34.0)%	(34.0)%
State taxes, net of federal benefit	2.4%	4.2%	(3.4)%
Equity-based compensation expense	9.4%	42.4%	2.4%
Permanent items, net	5.3%	1.2%	0.4%
Tax credits	0.5%	0.8%	(1.6)%
Valuation allowance	16.4%	(19.5)%	34.7%
Total tax (benefit) expense	0.0%	(4.9)%	(1.5)%

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 are as follows (in thousands):

	December 31,	
	2013	2012
Assets		
Net operating loss carryforwards	$ 85,269	$ 75,740
Tax credit carryforwards	12,396	12,403
Deferred revenue	20,368	22,315
Equity-based compensation expense	4,176	3,681
Capitalized research & development	39,214	45,137
Intangibles	680	
Other	4,371	4,239
Property and Equipment Depreciation		1,393
Liabilities		
Property, Plant, and Equipment Depreciation	(58)	
	166,416	164,908
Valuation allowance	(166,416)	(164,908)
Net deferred taxes	$	$

Due to the uncertainty surrounding the realization of favorable tax attributes in future tax returns, we have recorded a full valuation allowance against our otherwise recognizable net deferred tax assets. The valuation allowance increased by approximately $1.5 million for the year ended December 31, 2013 primarily due to an increase in net operating loss, or NOL, carryforwards, partially offset by a decrease in capitalized research and development expense, deferred revenue, and property and equipment. The valuation allowance decreased by approximately $2.8 million for the year ended December 31, 2012 primarily due to an increase in our net operating loss, or NOL, carryforwards, capitalized research and development expense, and equity-based compensation expense. The valuation allowance increased by approximately $26.8 million for the year ended December 31, 2011 primarily due to an increase in our NOL carryforwards, capitalized research and development expense, and equity-based compensation expense.

At December 31, 2013, we had federal NOL carryforwards of approximately $234.5 million and state NOL carryforwards of up to $118.9 million. We also had federal capital loss carryforwards of

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$3.3 million to offset future capital gains and an additional $24.6 million and $4.8 million of federal and state NOLs, respectively, not reflected above which were attributable to deductions from the exercise of equity awards. The benefit from these deductions will be recorded as a credit to additional paid-in capital if and when realized through a reduction of taxes paid in cash. Our federal NOLs and our most significant state NOLs expire at various dates through 2033. Our capital loss carryforwards will expire through 2017. In addition, we have federal and state tax credits of approximately $9.3 million and $4.6 million, respectively, to offset future tax liabilities. Our tax credits will expire periodically through 2032 if not utilized.

Utilization of our NOLs and research and development, or 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, or Section 382, as well as similar state provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and taxes, respectively. In general, an ownership change as defined by Section 382 results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50 percentage points 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, may have resulted in a change of control as defined by Section 382 or could result in a change of control in the future upon subsequent disposition. In May 2011, we conducted an analysis under Section 382 to determine if historical changes in ownership through December 31, 2010 would limit or otherwise restrict our ability to utilize these NOL and R&D credit carryforwards. As a result of this analysis, we do not believe there are any significant limitations on our ability to utilize these carryforwards. However, changes in ownership after December 31, 2010 could affect the limitation in future years. Any limitation may result in expiration of a portion of the NOL or R&D credit carryforwards before utilization.

At December 31, 2013 and 2012, we had no unrecognized tax benefits. We have not, as yet, conducted a study of our R&D credit carryforwards. Such a study could result in an adjustment to our R&D credit carryforwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against our R&D credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the consolidated balance sheet or statement of operations if an adjustment were required.

We would recognize both accrued interest and penalties related to unrecognized benefits in income tax expense. We have not recorded any interest or penalties on any unrecognized benefits since inception.

The statute of limitations for assessment by the Internal Revenue Service, or the IRS, and state tax authorities is closed for tax years prior to December 31, 2010, although carryforward attributes that were generated prior to tax year 2010 may still be adjusted upon examination by the IRS or state tax authorities if they either have been or will be used in a future period. We file income tax returns in the U.S. federal and various state jurisdictions. There are currently no federal or state audits in progress.

K. Accumulated Other Comprehensive Loss

In February 2013, the Financial Accounting Standards Board issued an amendment to the accounting guidance for the reporting of amounts reclassified out of accumulated other comprehensive loss, or AOCI. The amendment expands the existing disclosure by requiring entities to present information about significant items reclassified out of AOCI by component. In addition, an entity is required to provide information about the effects on net income of significant amounts reclassified out of each component of AOCI to net income either on the face of the income statement or as a separate

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disclosure in the notes of the financial statements. The amendment is effective for annual or interim reporting periods beginning after December 31, 2012. The adoption of this accounting pronouncement did not have a material impact on our financial statement disclosures.

The changes in AOCI, net of tax, for 2013 and 2012 consisted of the following (in thousands):

	December 31,	
	2013	2012
Beginning Balance	$ (3,247)	$ (4,842)
Other comprehensive income (loss) before reclassifications	(268)	129
Gain (loss) reclassified from other accumulated comprehensive loss	24	1,466
Ending Balance	$ (3,491)	$ (3,247)

The amounts reclassified from other comprehensive loss for 2013 primarily represented realized gains on investments, which are included in our consolidated statement of operations under "Gains (losses) on investments, net."

L. Equity-Based Compensation

We currently maintain two equity compensation plans, including our Third Amended and Restated 2007 Equity Incentive Plan, or the 2007 Plan, and our Amended and Restated 2000 Stock Plan, or the 2000 Plan. During 2012 and 2013, we also granted equity to certain newly hired executive officers through inducement grants outside of these plans.

Third Amended and Restated 2007 Equity Incentive Plan

Our 2007 Plan was originally approved by our stockholders in November 2007. In each of May 2009, May 2010, and May 2013 our stockholders approved proposals to amend and restate our 2007 Plan to, among other things, increase the number of shares authorized for issuance thereunder by 600,000, 800,000 and 1,100,000 shares, respectively. In addition, the amendment approved by our stockholders in May 2009 replaced a limitation on the number of shares in the aggregate which could be issued under the 2007 Plan with respect to restricted stock units, restricted stock, stock and similar equity interests in our company with a fungible share reserve whereby the number of shares available for issuance under the 2007 Plan is reduced by one share of our common stock issued pursuant to an option or stock appreciation right and by 1.5 shares for each share of our common stock issued pursuant to a restricted stock unit award or other similar equity-based award.

The 2007 Plan provides for the grant of stock options, restricted stock units, restricted stock, stock, and other equity interests in our company to employees, officers, directors, consultants, and advisors of our company and our subsidiaries. We generally issue common stock from previously authorized but unissued shares to satisfy option exercises and restricted stock awards. The terms and conditions of each such grant, including, but not limited to, the number of shares, the exercise price, term of the option/award and vesting requirements, are determined by our Board of Directors, or Board, or the Compensation Committee of our Board. Our Board may award stock options in the form of nonqualified stock options or incentive stock options, or ISOs. Stock options may be granted at an exercise price no less than fair market value of a share of our common stock on the date of grant, as determined by our Board or the Compensation Committee of our Board, subject to certain limitations.

As of December 31, 2013, we have granted options and restricted stock units covering 6,289,350 shares of common stock under our 2007 Plan, of which 2,558,113 stock options and 626,348 restricted stock units have expired or terminated, and of which 139,146 options have been exercised and 475,614 shares of common stock have been issued pursuant to restricted stock units that became fully vested.

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The number of options and restricted stock units outstanding under this plan as of December 31, 2013, was 2,199,735 and 290,394, respectively. The remaining number of shares available for future grants as of December 31, 2013 was 2,024,621, not including shares subject to outstanding awards under the 2000 Plan, which will be added to the total number of shares available for issuance under the 2007 Plan to the extent that such awards expire or terminate for any reason prior to exercise. All outstanding stock options granted under our 2007 Plan have an exercise price equal to the closing price of a share of our common stock on the grant date and have either a seven or ten-year term.

Amended and Restated 2000 Stock Plan

Our 2000 Plan provided for the grant of options and other equity-based awards to our directors, officers, employees and consultants. The terms and conditions of each such grant, including, but not limited to, the number of shares, the exercise price, term of the option/award and vesting requirements, were determined by our Board or the Compensation Committee of our Board. As of December 31, 2013, we have granted stock options and restricted stock units covering 2,182,700 shares of common stock under the 2000 Plan, of which 984,339 stock options and 1,500 restricted stock units have expired or terminated, and of which 1,049,420 stock options have been exercised and 42,500 shares of common stock have been issued pursuant to restricted stock units that became fully vested. The remaining number of shares underlying outstanding stock options which were issued pursuant to our 2000 Plan as of December 31, 2013, was 104,941. There were no remaining restricted stock units which were issued pursuant to our 2000 Plan as of December 31, 2013. All outstanding stock options granted under the 2000 Plan have an exercise price equal to the closing price of our common stock on the grant date and have a ten year term. In November 2007, the 2000 Plan was succeeded by our 2007 Plan and, accordingly, no further grants may be made under this plan. Any shares that remained available for issuance under the 2000 Plan as of the date of adoption of the 2007 Plan are included in the number of shares that may be issued under the 2007 Plan. Any shares subject to outstanding awards granted under the 2000 Plan that expire or terminate for any reason prior to exercise will be added to the total number of shares available for issuance under the 2007 Plan.

Other Equity Compensation Grants

In February 2013, we granted restricted stock units to certain members of our senior management covering a maximum of 82,500 shares of common stock, which are subject to a performance condition tied to the price of our common stock. These restricted stock units vest, if at all, at the end of the three-year period ending December 31, 2015 based on the achievement of a minimum, target or maximum stock price range. In the event that the minimum stock price range is not achieved at the measurement date, none of the restricted stock units will vest. The maximum total fair value of these restricted stock units is $0.7 million, which are being recognized to expense over a period of three years from the date of grant, net of any estimated and actual forfeitures.

During 2013 and 2012, our Board granted options to purchase 270,000 and 300,000 shares of our common stock, respectively, to certain members of our senior management to induce them to accept employment with us. These 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. The options will be exercisable in four equal annual installments beginning on the first anniversary of the respective grant dates. Of the 270,000 options granted in 2013, 45,000 were forfeited during 2013. In addition, during 2013 and 2012, our Board granted 115,000 and 100,000 restricted stock units, respectively, to certain members of our senior management to induce them to accept employment with us. These grants will vest in four equal annual installments beginning on the first anniversary of the respective grant dates. Of the 115,000 restricted stock units granted in 2013, 15,000 were forfeited during 2013. The foregoing grants were made pursuant to inducement grants outside of our 2007 Plan as permitted under the NASDAQ Global Market 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. These shares were registered in August 2013.

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Equity-based compensation expense

Equity-based compensation expense for 2013, 2012 and 2011 consisted of the following (in thousands):

	Years Ended December 31,		
	2013	2012	2011
Cost of product sales	$ 121	$ 225	$ 616
Research and development	2,149	1,994	1,874
Selling, general and administrative	5,734	4,805	7,548
Total equity-based compensation expense	$ 8,004	$ 7,024	$ 10,038

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 the corporate restructurings in 2012 and 2011, which resulted in higher than expected turnover and forfeitures in those years. 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.

Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns associated with operating losses we incurred in the past, we have not recognized any excess tax benefits from the exercise of options. Accordingly, there was no impact recorded in cash flows from financing activities or cash flows from operating activities as reported in the accompanying consolidated statements of cash flows.

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

	Years Ended December 31,					
	2013		2012		2011	
	Employees	Non-Employee Directors	Employees	Non-Employee Directors	Employees	Non-Employee Directors
Risk free interest rate (%)	0.95	0.85	0.66	0.68	1.67	1.36
Expected volatility (%)	59	46	57	56	51	51
Expected option term (years)	5.00	4.00	4.66	4.00	5.50	4.00
Dividend yield	none	none	none	none	none	none

Risk free interest rates utilized are based upon published U.S. Treasury yields at the date of the grant for the expected option term. During 2013, we estimated our expected stock price volatility by basing it on the historical volatility of our own common stock price over the prior period equivalent to our expected option term to better reflect expected future volatility. During 2012 and 2011, we estimated our expected stock price volatility by basing it on a blend of our own common stock price and the historical volatility of other similar companies over the prior period equivalent to our expected option term 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.

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The following table summarizes details regarding stock options granted under our equity incentive plans for the year ended December 31, 2013:

	December 31, 2013			
	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value ($ in millions)
Outstanding at beginning of year	2,190,073	$ 23.07		
Granted	1,120,050	18.73		
Exercised	(123,658)	15.02		
Expired and/or forfeited	(366,789)	26.06		
Outstanding at end of year	2,819,676	$ 21.31	7.1	$ 17.5
Outstanding at end of year vested and unvested expected to vest	2,644,475	$ 21.51	7.1	$ 16.4
Exercisable at end of year	1,003,804	$ 28.75	5.2	$ 4.0

The weighted average grant date fair value of stock options granted during 2013, 2012 and 2011 was $8.60, $6.90 and $7.40, respectively. A total of 521,734 stock options vested during 2013. The total grant date fair value of options that vested during 2013, 2012 and 2011 was $4.5 million, $5.5 million and $9.8 million, respectively. The aggregate intrinsic value of options exercised during 2013, 2012 and 2011, excluding purchases made pursuant to our employee stock purchase plans, measured as of the exercise date, was approximately $1.0 million, $0.1 million and $0.1 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.

In 2013, we issued an aggregate of 270,525 restricted stock units to our employees and directors. In general, these grants vest on an annual basis over a four year period. The estimated fair value of restricted stock units granted was determined at the grant date based upon the quoted market price per share on the date of the grant.

The following table summarizes details regarding restricted stock units granted under our equity incentive plans for the year ended December 31, 2013:

	December 31, 2013	
	Unvested Restricted Stock Units	Weighted Average Grant Date Fair Value
Outstanding at beginning of year	373,676	$ 17.02
Granted	270,525	16.31
Vested	(152,889)	18.44
Forfeited	(25,918)	20.77
Outstanding at end of year	465,394	$ 17.28

Outstanding at end of year and expected to vest	382,897	$	17.26

The weighted average grant date fair value of restricted stock units granted during 2013, 2012 and 2011 was $16.31, $15.64 and $15.99, respectively. The total grant date fair of restricted stock units that vested during 2013, 2012 and 2011 was $2.8 million, $3.5 million and $3.1 million, respectively.

At December 31, 2013, the amount of unrecorded equity-based compensation expense for both option and restricted stock unit awards, net of forfeitures, attributable to future periods was

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approximately $16.0 million. Of this amount, $11.5 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, and $4.5 million was associated with restricted stock units and is expected to be amortized to on a straight-line basis to expense over a weighted average period of approximately 2.1 years. Such amounts will be amortized primarily to research and development or selling, general and administrative expense. These future estimates are subject to change based upon a variety of future events, which include, but are not limited to, changes in estimated forfeiture rates, employee turnover, and the issuance of new stock options and other equity-based awards.

M. Employee Savings Plan

We provide a 401(k) Plan to our employees by which they may defer compensation for income tax purposes under Section 401(k) of the Internal Revenue Code. Each employee may elect to defer a percentage of his or her salary up to a specified maximum. Our 401(k) Plan provides, among other things, for a company contribution of 3% of each employee's combined salary and certain other compensation for the plan year. Salary deferred by employees and contributions by us to the 401(k) Plan are not taxable to employees until withdrawn from the 401(k) Plan and contributions are deductible by us when made. The amount of our company contribution for the 401(k) Plan was $0.7 million, $0.8 million, and $1.0 million for 2013, 2012 and 2011, respectively.

N. Stockholders' Equity

Our certificate of incorporation authorizes our Board to issue preferred stock from time to time in one or more series. The rights, preferences, restrictions, qualifications and limitations of such stock are determined by our Board. In September 2009, our Board adopted a shareholder rights plan, or Rights Plan. The terms of the Rights Plan provide for a dividend distribution of one preferred share purchase right, or Right, for each outstanding share of our common stock, par value $0.01 per share, to shareholders of record as of September 17, 2009, and for one such Right to attach to each newly issued share of common stock thereafter. Each Right entitles shareholders to purchase one one-thousandth of a share of Series A Junior Participating Preferred Stock for each outstanding share of our common stock. The Rights issued pursuant to our Rights Plan become exercisable generally upon the earlier of 10 days after a person or group, or an Acquiring Person, acquires 20% or more of our outstanding common stock or 10 business days after the announcement by a person or group of an intention to acquire 20% of our outstanding common stock via tender offer or similar transaction. In that event, each holder of a Right, other than the Acquiring Person, would for a period of 60 days be entitled to purchase, at the exercise price of the Right, such number of shares of our common stock having a current value of twice the exercise price of the Right. Once a person becomes an Acquiring Person, until such Acquiring Person acquires 50% or more of our common stock, our Board can exchange the Rights, in part or in whole, for our common stock at an exchange ratio of one share of common stock per Right. If we are acquired in a merger or other business combination transaction, each holder of a Right, other than the Acquiring Person, would then be entitled to purchase, at the exercise price of the Right, such number of shares of the acquiring company's common stock having a current value of twice the exercise price of the Right. The Board may redeem the Rights or terminate the Rights Plan at any time before a person or group becomes an Acquiring Person. The Rights will expire on September 17, 2019 unless the Rights are earlier redeemed or exchanged by us.

O. 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 human diseases. Long-lived assets consist entirely of property and equipment and are located in the U.S. for all periods presented.

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P. Commitments and Contingencies

Commitments

Operating and Facility Lease Obligations

We have entered into certain operating leases, including certain office equipment which expire through 2014. Expense associated with these operating leases, including previous leases of certain automobiles, amounted to approximately $(0.3) million, $0.9 million, and $0.8 million for 2013, 2012 and 2011, respectively. The net credit for operating lease expense in 2013 is due to the excess of the sales value of certain automobiles we previously leased over the contracted value in connection with the termination of the automobile leases and the subsequent sales of the automobiles by the leasing companies. Future minimum lease payments associated with all non-cancellable equipment, service and lease agreements, excluding facility-related leases are approximately $0.1 million for 2014.

In June 2013, we entered into a lease agreement with BP Bay Colony LLC, or the Landlord, for the lease of certain real property located at 1100 Winter Street, Waltham, Massachusetts, or the Premises, for use as our principal executive offices. Beginning in September 2013, the initial term of the lease is five years and two months with one five-year extension term at our option. During the extension period, the base rent will be an amount agreed upon by us and the Landlord. In addition to base rent, we are also required to pay a proportionate share of the Landlord's operating costs. The lease requires us to pay base rent during the initial term as follows (in thousands):

Period		Minimum Lease Payments
Year Ended December 31, 2014	$	1,128
Year Ended December 31, 2015		1,128
Year Ended December 31, 2016		1,128
Year Ended December 31, 2017		1,128
Thereafter		1,034
Total	$	5,546

The Landlord agreed to pay for certain agreed-upon improvements 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 new facility lease, in June 2013 we delivered to the Landlord a security deposit of $0.4 million in the form of an irrevocable letter of credit. This security deposit will be reduced to $0.3 million on the second anniversary of the date the lease commenced. The cash securing this letter of credit is classified on our balance sheet as of December 31, 2013 as a long-term asset and is restricted in its use.

In June 2013, we also entered into an Assignment and Assumption of Lease, or the Assignment Agreement, with Shire Human Genetic Therapies, Inc., or Shire, effecting the assignment to Shire of the right to occupy our former office space located at 100 Hayden Avenue, Lexington, Massachusetts, or the Prior Space. Under the Assignment Agreement, the assignment to Shire became effective on September 21, 2013, the date of our departure from the Prior Space, and Shire assumed all of our obligations as the tenant of the Prior Space. The Assignment Agreement also provided for the conveyance of furniture and other personal property by us to Shire.

Facility-related rent expense was $1.5 million, $1.7 million and $1.7 million for 2013, 2012, and 2011.

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Purchase Commitments

During 2013, we entered into various agreements with third parties for which we had remaining purchase commitments of approximately $6.8 million as of December 31, 2013. These agreements principally related to certain purchase orders for the production of *Feraheme/Rienso*, certain outsourced commercial activities, manufacturing commitments, our information technology infrastructure, and other operational activities.

Other Funding Commitments

As of December 31, 2013, we had several ongoing clinical studies in various clinical trial stages. Our most significant clinical trial expenditures were to clinical research organizations, or CROs. The contracts with CROs are generally cancellable, with notice, at our option. We have recorded accrued expenses in our consolidated balance sheet of approximately $0.3 million representing expenses incurred with these organizations as of December 31, 2013, net of any amounts prepaid to these CROs. As a result of our cancellation rights, we have not included these CRO contracts in the contractual obligations table above.

Severance Arrangements

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

Indemnification Obligations

As permitted under Delaware law, pursuant to our certificate of incorporation, by-laws and agreements with all of our current directors, executive officers, and certain of our employees, we are obligated to indemnify such individuals for certain events or occurrences while the officer, director or employee is, or was, serving at our request in such capacity. The maximum potential amount of future payments we could be required to make under these indemnification obligations is not capped. Our director and officer insurance policy limits our initial exposure to $1.0 million and our policy provides significant coverage. As a result, we believe the estimated fair value of these indemnification obligations is likely to be immaterial.

We are also a party to a number of other agreements entered into in the ordinary course of business, which contain typical provisions and which obligate us to indemnify the other parties to such agreements upon the occurrence of certain events. Such indemnification obligations are usually in effect from the date of execution of the applicable agreement for a period equal to the applicable statute of limitations. Our aggregate maximum potential future liability under such indemnification provisions is uncertain. Except for expenses we incurred related to the ongoing class action lawsuit filed against us in March 2010, we have not incurred any expenses as a result of such indemnification provisions. Accordingly, we have determined that the estimated aggregate fair value of our potential liabilities under such indemnification provisions is not significant, and we have not recorded any liability related to such indemnification.

Contingencies

Legal Proceedings

We accrue a liability for legal contingencies when we believe that it is both probable that a liability has been incurred and that we can reasonably estimate the amount of the loss. We review these

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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 the 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.

A purported class action complaint was originally filed on March 18, 2010 in the U.S. District Court for the District of Massachusetts, entitled Silverstrand Investments et. al. v. AMAG Pharm., Inc., et. al., Civil Action No. 1:10-CV-10470-NMG, and was amended on September 15, 2010 and on December 17, 2010. The second amended complaint, or SAC, filed on December 17, 2010 alleged that we and our former President and Chief Executive Officer, former Chief Financial Officer, the then-members of our Board, and certain underwriters in our January 2010 offering of common stock violated certain federal securities laws, specifically Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended, and that our former President and Chief Executive Officer and former Chief Financial Officer violated Section 15 of such Act, respectively, by making certain alleged omissions in a registration statement filed in January 2010. The plaintiffs sought unspecified damages on behalf of a purported class of purchasers of our common stock pursuant to our common stock offering on or about January 21, 2010. On August 11 and 15, 2011, respectively, the District Court issued an Opinion and Order dismissing the SAC with prejudice for failure to state a claim upon which relief could be granted. On September 14, 2011, the plaintiffs filed a Notice of Appeal to the U.S. Court of Appeals for the First Circuit, or the Court of Appeals. The Court of Appeals heard oral argument on May 11, 2012. On February 4, 2013, the Court of Appeals affirmed in part and reversed in part the District Court's Opinion and Order and remanded the case to the District Court. On February 19, 2013, we filed a Petition for Panel Rehearing and Rehearing *En Banc*, which was denied on March 15, 2013. On March 22, 2013, we filed a Motion to Stay the Mandate remanding the case to the District Court pending review by the U.S. Supreme Court of the Court of Appeals' February 4, 2013 decision. The Court of Appeals granted the Motion to Stay the Mandate on April 8, 2013. On June 13, 2013, we filed a Petition for a Writ of Certiorari, or the Petition, with the U.S. Supreme Court seeking review of the Court of Appeal's decision and to have that decision overturned. On October 7, 2013 the U.S. Supreme Court denied our Petition, resulting in the case's return to the District Court for further proceedings relative to the SAC's surviving claims. On November 6, 2013, we filed a renewed Motion to Dismiss the SAC's surviving claims. On December 6, 2013, the plaintiffs filed a brief in opposition to our Motion to Dismiss and we filed a reply brief in support of our Motion on December 27, 2013. The plaintiffs are seeking leave of court to file a sur-reply in further opposition to our Motion to Dismiss. No hearing on the Motion to Dismiss is currently scheduled. We are currently unable to predict the outcome or reasonably estimate the range of potential loss associated with this matter, if any, and have therefore not recorded any potential estimated liability as we do not believe that such a liability is probable nor do we believe that a range of loss is currently estimable.

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In July 2010, Sandoz GmbH, or Sandoz, filed with the European Patent Office, or the EPO, an opposition to a previously issued patent which covers ferumoxytol in EU jurisdictions. In October 2012, at an oral hearing, the Opposition Division of the EPO revoked this patent. In December 2012, our notice of appeal of that decision was recorded with the EPO, which also suspended the revocation of our patent. On May 13, 2013, we filed a statement of grounds of appeal and on September 27, 2013, Sandoz filed a response to that statement. We will continue to defend the validity of this patent throughout the appeals process, which we expect to take two to three years. However, in the event that we do not experience a successful outcome from the appeals process, under EU regulations ferumoxytol would still be entitled to eight years of data protection and ten years of market exclusivity from the date of approval, which we believe would create barriers to entry for any generic version of ferumoxytol into the EU market until sometime between 2020 and 2022. This decision had no impact on our revenues for the year ended December 31, 2013. However, any future unfavorable outcome in this matter could negatively affect the magnitude and timing of future revenues, including royalties and milestone payments we may receive from Takeda pursuant to our collaboration agreement with Takeda. We do not expect to incur any related liability regardless of the outcome of the appeal and therefore have not recorded any liability as of December 31, 2013. We continue to believe the patent is valid and intend to vigorously appeal the decision.

We may periodically become subject to other legal proceedings and claims arising in connection with ongoing business activities, including claims or disputes related to patents that have been issued or that are pending in the field of research on which we are focused. Other than the above actions, we are not aware of any material claims against us at December 31, 2013. We expense legal costs as they are incurred.

Q. Collaborative Agreements

Our commercial strategy includes the formation of collaborations with other pharmaceutical companies to facilitate the sale and distribution of *Feraheme/Rienso*, primarily outside of the U.S., as well as expanding our portfolio through the in-license or purchase of additional specialty pharmaceutical products. As of December 31, 2013, we were a party to the following collaborations:

Takeda

In March 2010, we entered into the Takeda Agreement with Takeda under which we granted exclusive rights to Takeda to develop and commercialize *Feraheme/Rienso* as a therapeutic agent in Europe, certain Asia-Pacific countries (excluding Japan, China and Taiwan), the Commonwealth of Independent States, Canada, India and Turkey. In June 2012, we entered into an amendment to the Takeda Agreement, or the Amended Takeda Agreement, which removed the Commonwealth of Independent States from the territories under which Takeda has the exclusive rights to develop and commercialize *Feraheme/Rienso.* In addition, the Amended Takeda Agreement modified the timing and pricing arrangements for a supply agreement to be entered into between us and Takeda, and which was entered into in February 2014, the terms related to primary and secondary manufacturing for drug substance and drug product, certain patent related provisions, and the re-allocation of certain of the agreed-upon milestone payments. We analyzed the Amended Takeda Agreement and determined that the amended terms did not result in a material modification of the original Takeda Agreement (and thus did not require us to change our accounting model) because (a) there were no changes to the deliverables under the original Takeda Agreement as a result of the amendment, and (b) the change in arrangement consideration as a result of the amendment was not quantitatively material in relation to the total arrangement consideration.

Under the Amended Takeda Agreement, except under limited circumstances, we have retained the right to manufacture *Feraheme/Rienso* and, accordingly, are responsible for supply of *Feraheme/Rienso* to Takeda at a fixed price per unit, which is capped for a certain period of time. We are also

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responsible for conducting, and bearing the costs related to, certain pre-defined clinical studies with the costs of future modifications or additional studies to be allocated between the parties according to an agreed-upon cost-sharing mechanism. We have determined that our obligations under the Amended Takeda Agreement have not changed from those under the original Takeda Agreement and include the following four deliverables: the license, access to future know-how and improvements to the *Feraheme/Rienso* technology, regulatory and clinical research activities, and the manufacturing and supply of product. Pursuant to the accounting guidance in effect in March 2010, when we signed the original Takeda Agreement and which governed revenue recognition on multiple element arrangements, we evaluated the four deliverables under the original Takeda Agreement and determined that our obligation to provide manufacturing supply of product meets the criteria for separation and is therefore treated as a single unit of accounting, which we refer to as the supply unit of accounting. Further, we concluded that the license is not separable from the undelivered future know-how and technological improvements or the undelivered regulatory and clinical research activities. Accordingly, these deliverables are being combined and also treated as a single unit of accounting, which we refer to as the combined unit of accounting. With respect to the combined unit of accounting, our obligation to provide access to our future know-how and technological improvements is the final deliverable and is an obligation which exists throughout the term of the Amended Takeda Agreement.

In connection with the execution of the original Takeda Agreement, we received a $60.0 million upfront payment from Takeda in April 2010, which we recorded as deferred revenue, as well as approximately $1.0 million reimbursed to us during 2010 for certain expenses incurred prior to entering the agreement, which we considered an additional upfront payment. Because we cannot reasonably estimate the total level of effort required to complete the obligations under the combined deliverable, we are recognizing the entire $60.0 million upfront payment, the $1.0 million reimbursed to us in 2010, as well as any non-substantive milestone payments that are achieved into revenues on a straight-line basis over a period of ten years from March 31, 2010, the date on which we originally entered the Takeda Agreement, which represented the then current patent life of *Feraheme/Rienso* and our best estimate of the period over which we will substantively perform our obligations. We continue to believe that the then-current patent life of *Feraheme/Rienso* is our best estimate of the period over which we will substantively perform our obligations under this agreement.

In addition, the remaining milestone payments we may be entitled to receive under the Amended Takeda Agreement could over time equal up to $186.0 million. For any milestone payments we may receive based upon the approval by certain regulatory agencies, we have determined that these will be deemed substantive milestones and, therefore, will be accounted for as revenue in the period in which they are achieved. In June 2012, we earned a $15.0 million milestone payment from Takeda based on the European Commission marketing authorization for ferumoxytol. We deemed the $15.0 million milestone payment as a substantive milestone and therefore recognized the full amount as revenue. We have also determined that any non-substantive milestone payments will be accounted for in accordance with our revenue attribution method for the upfront payment, as described above. During 2012, we received an aggregate of $18.0 million in milestone payments from Takeda associated with the commercial launches of *Feraheme/Rienso* in Canada and the EU, which we deemed to be non-substantive milestone payments. Revenues related to the combined unit of accounting are recorded in license fee and other collaboration revenues in our consolidated statement of operations. During 2013, we recorded $7.9 million in revenues associated with the upfront payments and the $18.0 million in non-substantive milestone payments we received in 2012. Any potential non-substantive milestone payments that may be received in the future will be recognized as revenue on a cumulative catch up basis when they become due and payable.

We have received and may also receive additional regulatory approval and performance-based milestone payments, reimbursement of certain out-of-pocket regulatory and clinical supply costs,

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defined payments for supply of *Feraheme/Rienso,* and tiered double-digit royalties on net product sales in the agreed-upon territories under the Amended Takeda Agreement.

Under the terms of the Amended Takeda Agreement, Takeda is responsible for reimbursing us for certain out-of-pocket regulatory and clinical trial supply costs associated with carrying out our regulatory and clinical research activities under the collaboration agreement. Because we are acting as the principal in carrying out these services, any reimbursement payments received from Takeda are recorded in license fee and other collaboration revenues in our consolidated statement of operations to match the costs that we incur during the period in which we perform those services. We recorded $0.5 million, $0.4 million and $2.0 million for 2013, 2012 and 2011, respectively, associated with other reimbursement revenues received from Takeda.

At the time of shipment, we defer recognition of all revenue for *Feraheme/Rienso* sold to our licensees in our consolidated balance sheets. We recognize revenues from product sales to our licensees, the related cost of goods sold, and any royalty revenues due from our licensees, in our consolidated statement of operations at the time our licensees report to us that sales have been made to their customers. During 2013, we recognized $0.5 million in product sales and royalty revenue related to the Amended Takeda Agreement and we have included this revenue in other product sales and royalties in our consolidated statement of operations. As of December 31, 2013, we had approximately $2.4 million in deferred revenue related to product shipped to Takeda but not yet sold through to Takeda's customers, of which $ 0.3 was classified as short-term and $2.1 was classified as long-term. In addition, we had $2.3 million in deferred cost of product sales, of which $ 0.3 was classified as short-term and $2.0 was classified as long-term. These deferred revenue and deferred cost of product sales are recorded in our consolidated balance sheet as of December 31, 2013.

3SBio

In 2008, we entered into a Collaboration and Exclusive License Agreement, or the 3SBio License Agreement, and a Supply Agreement, or the 3SBio Supply Agreement, with 3SBio Inc., or 3SBio, for the development and commercialization of *Feraheme* as an IV iron replacement therapeutic agent in China. In consideration of the grant of the license, we received an upfront payment of $1.0 million, the recognition of which has been deferred. In late January 2014, we mutually terminated the agreement with 3SBio, effective immediately, due to the fact that, despite the best efforts of the parties, regulatory approval in China could not be obtained within the agreed upon time period.

R. Restructuring

During 2012, we initiated corporate restructurings, including a workforce reduction plan. The majority of the workforce reduction plan was associated with our manufacturing and development infrastructure, including our decision to divest our Cambridge, Massachusetts manufacturing facility. The workforce reductions were substantially completed by the end of 2012 and the majority of the related expenses were paid by the end of 2012.

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The following table outlines the components of our restructuring expenses which were recorded in operating expenses and current liabilities for 2013 and 2012 (in thousands):

	December 31,	
	2013	2012
Accrued restructuring, beginning of period	$ 1,383	$ 2,366
Employee severance, benefits and related costs		1,624
Payments	(1,383)	(2,674)
Inventory and other adjustments		67
Accrued restructuring, end of period	$	$ 1,383

S. Consolidated Quarterly Financial Data Unaudited

The following tables provide unaudited consolidated quarterly financial data for 2013 and 2012 (in thousands, except per share data):

	March 31, 2013	June 30, 2013	September 30, 2013	December 31, 2013
U.S. *Feraheme* product sales, net(a)	$ 15,578	$ 17,456	$ 19,347	$ 18,981
License fee and other collaboration revenues	2,003	2,055	1,998	2,329
Other product sales and royalties	299	138	271	401
Total revenues	17,880	19,649	21,616	21,711
Cost of product sales	2,942	3,145	2,547	3,326
Gross margin	14,938	16,504	19,069	18,385
Operating expenses	19,409	19,260	19,464	22,380
Interest and dividend income, net	271	256	246	278
Gains on assets held for sale	299	566		59
Gains on investments, net	6	26	4	4
Net loss	$ (3,895)	$ (1,908)	$ (145)	$ (3,654)
Net loss per share basic and diluted	$ (0.18)	$ (0.09)	$ (0.01)	$ (0.17)

	March 31, 2012	June 30, 2012	September 30, 2012	December 31, 2012
U.S. product sales, net(a)	$ 13,626	$ 14,094	$ 16,186	$ 14,381
License fee and other collaboration revenues(b)	1,753	16,592	1,566	6,564
Other product sales and royalties	101	326	-10	199
Total revenues	15,480	31,012	17,742	21,144
Cost of product sales	2,646	3,224	4,323	4,027

Gross margin	12,834	27,788	13,419	17,117
Operating expenses	25,643	22,772	17,420	20,532
Restructuring expenses(c)		1,058	562	595
Interest and dividend income, net	393	338	295	260
(Losses) gains on investments, net(d)		(1,471)	2	3
Income tax benefit		494	299	61
Net income (loss)	$ (12,416)	$ 3,319	$ (3,967)	$ (3,686)
Net income (loss) per share basic	$ (0.58)	$ 0.16	$ (0.19)	$ (0.17)
Net income (loss) per share diluted	$ (0.58)	$ 0.15	$ (0.19)	$ (0.17)

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Quarterly loss per share totals differ from annual loss per share totals due to rounding.

(a) In each of the quarters ended September 30, 2013 and 2012, we revised our estimated Medicaid utilization rate, which resulted in a reduction of our estimated Medicaid rebate reserve related to prior year *Feraheme* sales of $0.6 million. In addition, in the first three quarters of 2012 we reduced our reserve for product returns by $2.2 million.

(b) During the quarters ended June 30, 2012 and December 31, 2012, we recognized $15.0 million and $5.0 million related to certain milestone payments we received from Takeda upon the EU marketing authorization of *Rienso* and the commercial launches of *Feraheme/Rienso* in Canada and the EU, respectively.

(c) In 2012 we carried out corporate restructurings pursuant to which we reduced our workforce and incurred charges related to employee severance and other related costs. See Note R.

(d) In June 2012, we sold our then remaining ARS portfolio and recognized a loss of approximately $1.5 million.

T. Valuation and Qualifying Accounts (in thousands)

	Balance at Beginning of Period	Additions(a)	Deductions Charged to Reserves	Balance at End of Period
Year ended December 31, 2013:				
Accounts receivable allowances(b)	$ 1,771	$ 37,098	$ (36,186)	$ 2,683
Rebates, fees and returns reserves	$ 3,448	$ 11,820	$ (10,469)	$ 4,799
Year ended December 31, 2012:				
Accounts receivable allowances(b)	$ 1,822	$ 26,517	$ (26,568)	$ 1,771
Rebates, fees and returns reserves	$ 5,943	$ 6,729	$ (9,224)	$ 3,448
Year ended December 31, 2011:				
Accounts receivable allowances(b)	$ 1,148	$ 14,074	$ (13,400)	$ 1,822
Rebates, fees and returns reserves	$ 10,015	$ 9,864	$ (13,936)	$ 5,943

(a) Additions to sales discounts, rebates, fees and returns reserves are recorded as a reduction of revenues.

(b) We have not recorded an allowance for doubtful accounts in any of the years presented above. These accounts receivable allowances represent discounts and other chargebacks related to the provision for U.S. *Feraheme* product sales.

U. 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.

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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, 2013, 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, 2013 and is incorporated herein by reference.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the fourth quarter of the year ended December 31, 2013 that materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION:

Takeda Supply Agreement

On February 7, 2014, we entered into a Supply Agreement with Takeda Pharmaceuticals International, GMBH A/S, an affiliate of Takeda Pharmaceutical Company Limited, which we refer to collectively as Takeda. Pursuant to the Supply Agreement, we will sell to *Feraheme* to Takeda, to meet Takeda's requirements for commercial use of *Feraheme* in Europe, Asia-Pacific countries (excluding Japan, China and Taiwan), Canada, India and Turkey, or collectively, the Licensed Territory, as contemplated by the License, Development and Commercialization Agreement, by and between the Company and Takeda, dated March 31, 2010, as amended June 22, 2012, or, as amended, the License Agreement.

Under the Supply Agreement, Takeda is obligated to periodically provide us with demand forecasts of Takeda's future *Feraheme* requirements, which will direct the forecasting and ordering process as well as our supply obligations. Takeda may order *Feraheme* for commercial use in excess of the forecasts, which we will use commercially reasonable efforts to supply. In addition, the Supply Agreement provides the minimum quantity of *Feraheme* that shall be ordered in each purchase order for commercial supply. Takeda shall have the right to use the *Feraheme* ordered under the Supply Agreement for clinical use, provided that the product be subject to all of the terms of the Supply Agreement, including commercial specifications. Takeda shall be solely responsible for labeling and

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packaging vials of the product in accordance with the terms of the Supply Agreement and the License Agreement. If we are unable, for any reason beyond our reasonable control (including an unanticipated increase in demand beyond the production capacity of the manufacturing sites), to supply sufficient quantities of *Feraheme*, we agree to promptly establish an allocation procedure with respect to the available supply of *Ferahame* for the Licensed Territory and outside the Licensed Territory. Takeda may obtain *Feraheme* from a designated second source established by us, or a DSS, if necessary to meet increased demand, or upon the occurrence of certain defined insolvency events. If we are unable to perform its supply obligations under the Supply Agreement after a negotiated period of time following an insolvency event, Takeda can seek permanent alternative supply sources and the parties' supply and purchase obligations under the Supply Agreement will terminate. The Supply Agreement provides that it will otherwise remain in place for the duration of the License Agreement.

The Supply Agreement provides pricing terms and also provides that Takeda will reimburse us for certain capital expenditures and shall pay us a per-vial manufacturing fee. In addition, the Supply Agreement specifies cost-sharing arrangements relating to future process changes or improvements to the manufacturing process for *Feraheme*. We generally agree to indemnify Takeda and its affiliates for damages resulting from the willful misconduct or gross negligence by us or a DSS with respect to the manufacture of *Feraheme*, or resulting from our breach of the Supply Agreement. Takeda generally agrees to indemnify us, our affiliates and any DSS for damages resulting with respect to the manufacture of *Feraheme* by Takeda or its affiliates, or resulting from Takeda's breach of the Supply Agreement. The Supply Agreement includes quality control and testing terms, representations and warranties of the parties and other provisions customary for an agreement of this type.

The foregoing description of the Supply Agreement is qualified in its entirety by reference to the available text of the Supply Agreement, a redacted copy of which will be filed on our Quarterly Report on Form 10-Q for the quarter ending March 31, 2014, the License Agreement, previously filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, and the amendment to the License Agreement filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 29, 2012.

Executive Employment Agreements

On February 7, 2014, we entered into an employment agreement with Mr. Holmes and into an amended and restated employment agreement with each of our other named executive officers. Each amended and restated employment agreement generally provides for the continued employment of each such officer on the same terms and conditions of his existing employment agreement, except that, to the extent applicable to such officer, each amended and restated employment agreement:

- Eliminates the automatic acceleration of 50% of such officer's unvested equity awards upon a change in control;
- Adds a noncompetition provision, which prohibits such officer from competing with us for a period of 12 months following termination of employment; and
- Provides that, in the event of a termination of employment without cause or for good reason not in connection with a change in control, each officer would be entitled to receive accelerated vesting of time-based equity awards as if he had completed additional service equal to the length of his severance period.

Mr. Holmes' agreement is in substantially the same form as the amended and restated employment agreement for the other named executive officers (other than Mr. Heiden), as more fully described below.

Each of the employment agreements has a term of three years and will automatically renew for additional three year terms following the initial term and any renewal term thereafter, unless either

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party provides at least 60 days' prior written notice of its desire not to renew the agreement. In addition, each agreement provides that the executive shall receive a base salary (with such base salary to be effective February 17, 2014), subject to adjustment at the discretion of the Board of Directors or the Compensation Committee, and shall be eligible to receive an annual performance bonus of up to a specified percentage of base salary. William K. Heiden will receive a base salary of $538,175; Frank E. Thomas will receive a base salary of $437,800; Scott B. Townsend will receive a base salary of $340,000; Christopher White will receive a base salary of $338,300 and Scott Holmes will receive a base salary of $253,000. The annual performance bonus percentage for these executive officers, which remains unchanged from their prior agreements (or, in the case of Mr. Holmes who does not have a prior agreement, unchanged from his bonus percentage for 2013) is as follows: Mr. Heiden, 75%; Mr. Thomas, 50%; Mr. Townsend and Mr. White, 40% and Mr. Holmes, 35%. The increases to base salary reflect ordinary course increases for 2014 made in accordance with our executive compensation program and will be described more fully in our definitive proxy statement for our 2014 annual meeting of stockholders, including in the compensation discussion and analysis.

Pursuant to the employment agreements, in the event that we terminate the named executive officer's employment, other than for death, disability or cause, or he resigns for good reason, and he has complied with all his obligations under all agreements with us and signs a general release of claims in a form acceptable to us, then (i) we are obligated to pay severance to the executive in an amount equal to 12 months of his then current base salary (or 24 months, in the case of Mr. Heiden), paid in equal installments over the severance period in accordance with our usual payroll schedule and (ii) all time-based equity awards held by the executive that would have vested in the 12-month period (or 24-month period, in the case of Mr. Heiden) following the termination of employment will automatically vest and become exercisable. This provision does not apply during the one-year period following a change of control.

Each named executive officer's employment agreement provides that, in the event that upon a change of control, we or the successor to or acquirer of our business elect not to assume all of the then unvested outstanding stock options, restricted stock units and other equity incentives that were granted to the executive officer prior to the change of control, such securities will become vested in full as of the date of the change of control. In addition, in the event that within one year from the date a change of control of the company occurs, we or our successor terminate the employment of the named executive officer, and other than for death, disability or cause, or he resigns for good reason, and he has complied with all of his obligations under all agreements with us and signs a general release of claims in a form acceptable us or our successor, then we or our successor are obligated to provide the executive with the following benefits post-termination:

12 months (or 24 months, in the case of Mr. Heiden) of base salary, paid in equal installments over the severance period in accordance with our usual payroll schedule;

A lump sum equal to one times (or two times, in the case of Mr. Heiden) the executive's target annual bonus amount for the year in which the change of control occurs;

Payment or reimbursement of the premiums for continued health and dental benefits until the earlier of (i) 24 months (or 12 months, in the case of Mr. Heiden) post termination and (ii) health and dental coverage being provided to the executive under another employer's health and dental plan; and

The full acceleration of vesting of any then-unvested time-based stock options, restricted stock units and other equity incentives that were granted before such change of control.

In addition, the employment agreement with each of the named executive officers contains a provision which provides that any payments otherwise due to the executive in connection with a change of control shall be reduced to the extent necessary so that no excise taxes would be due on any such

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payments, but, in the case of each executive other than Mr. Heiden, only if such reduction would result in the executive retaining a larger portion of such payments on an after-tax basis than if no reduction was made and the excise taxes had been paid.

The employment agreement with each named executive officer also provides that, in the event of the death or permanent disability of the executive, all unvested equity awards then held by him shall become immediately vested in full. In addition, in the event of a named executive officer's death, such named executive officer's estate shall be eligible to receive a pro rata portion of such officer's performance bonus for such year based upon the Board of Director's or Compensation Committee's determination that any individual performance objectives were met as of the time of such officer's death.

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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, to be filed with the Securities and Exchange Commission, or the SEC, not later than 120 days after the close of our year ended December 31, 2013.

ITEM 11. EXECUTIVE COMPENSATION:

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the SEC not later than 120 days after the close of our year ended December 31, 2013.

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, to be filed with the SEC not later than 120 days after the close of our year ended December 31, 2013.

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, to be filed with the SEC not later than 120 days after the close of our year ended December 31, 2013.

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, to be filed with the SEC not later than 120 days after the close of our year ended December 31, 2013.

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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.

Management's Annual Report on Internal Control over Financial Reporting

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2013 and 2012

Consolidated Statements of Operations for the years ended December 31, 2013, 2012 and 2011

Consolidated Statements of Comprehensive Loss for the years ended December 31, 2013, 2012 and 2011

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2013, 2012 and 2011

Consolidated Statements of Cash Flows for the years ended December 31, 2013, 2012 and 2011

Notes to Consolidated Financial Statements

2.

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

3.

Exhibit Index.

Exhibit Number	Description
3.1, 4.1	Certificate of Incorporation of the Company, as restated (incorporated herein by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, File No. 001-10865).
3.2, 4.2	By-Laws of the Company, as amended (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed November 28, 2008, File No. 0-14732).
3.3, 4.3	Certificate of Designation of Series A Junior Participating Preferred Stock (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed September 4, 2009, File No. 0-14732).
4.4	Specimen certificate representing the Company's Common Stock (incorporated herein by reference to Exhibit 4.3 to the Current Quarterly Report on Form 10-Q for the quarter ended September 30, 2009, File No. 0-14732).
4.5	Rights Agreement dated as of September 4, 2009 by and among AMAG Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, LLC (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed September 4, 2009, File No. 0-14732).
4.6	Amendment to Rights Agreement, dated May 10, 2012, by and between the Company and American Stock Transfer & Trust Company LLC (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed May 10, 2012).
4.7	Form of Rights Certificate (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed September 4, 2009, File No. 0-14732).

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Exhibit Number	Description
10.1*	Representative Form of Indemnification Agreement (incorporated herein by reference to Exhibit 10.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2009, File No. 001-10865).
10.2*	Summary of the Company's Change of Control Policy applicable to executive officers (incorporated herein by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed February 13, 2006, File No. 0-14732).
10.3*	AMAG Pharmaceuticals, Inc. 2010 Employee Stock Purchase Plan (incorporated herein by reference to Appendix B to the Company's Definitive Proxy Statement on Schedule 14A, filed April 19, 2010, File No. 001-10865).
10.4*	AMAG Pharmaceuticals, Inc.'s Non-Employee Director Compensation Policy (incorporated herein by reference to Exhibit 10.4 to the Company's Annual Report on Form 10-K for the year ended December 31, 2012, File No. 001-10865).
10.5*	Employment Agreement, dated as of May 6, 2012, by and between the Company and William K. Heiden (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 10, 2012 File No. 001-10865).
10.6*	Employment Agreement dated as of August 1, 2011 between the Company and Frank E. Thomas. (incorporated herein by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011, File No. 001-10865).
10.7*	Second Amendment to Employment Agreement dated as of November 30, 2011 between the Company and Frank E. Thomas (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 2, 2011, File No. 001-10865).
10.8*	Retention Agreement between the Company and Scott A. Holmes dated as of December 2, 2011 (incorporated herein by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011, File No. 001-10865).
10.9*	Second Amended and Restated Employment Agreement dated as of December 15, 2009, as amended February 1, 2011 and November 3, 2011 between the Company and Christopher White (incorporated herein by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K for the year ended December 31, 2012, File No. 001-10865).
10.10*	Employment Agreement dated as of August 15, 2012 between the Company and Scott B. Townsend (incorporated herein by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-K for the year ended December 31, 2012, File No. 001-10865).
10.11*	Employment Agreement dated as of January 1, 2013 between the Company and Greg Madison (incorporated herein by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-K for the year ended December 31, 2012, File No. 001-10865).
10.12*	Employment Agreement dated as of June 20, 2013 between the Company and Steve Caffe (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, File No. 0-10865).
10.13*	Second Amended and Restated Employment Agreement dated as of December 15, 2009, as amended February 1, 2011 and November 3, 2011 between the Company and Lee F. Allen, M.D., Ph.D. (incorporated herein by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K for the year ended December 31, 2012, File No. 001-10865).
10.14*	Retention Agreement dated as of August 27, 2012 between the Company and Lee F. Allen, M.D., Ph.D. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 31, 2012, File No. 001-10865).
10.15*	Separation and Consulting Agreement dated as of March 31, 2013 between the Company and Lee F. Allen, M.D., Ph.D. (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, File No. 0-10865).

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Exhibit Number	Description
10.16*	Advanced Magnetics, Inc. Amended and Restated 2000 Stock Plan (incorporated herein by reference to Appendix A to the Company's definitive proxy statement for the year ended September 30, 2005, File No. 0-14732).
10.17*	Form of Stock Option Grant under the Company's 2000 Stock Plan (employees) (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2005, File No. 0-14732).
10.18*	Form of Stock Option Grant under the Company's 2000 Stock Plan (non-employees) (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2005, File No. 0-14732).
10.19*	AMAG Pharmaceuticals, Inc. Third Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A, filed April 19, 2013, File No. 001-10865).
10.20*	Form of Option Agreement (ISO) under the Company's 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed November 30, 2007, File No. 0-14732).
10.21*	Form of Option Agreement (Nonqualified Option) under the Company's 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed November 30, 2007, File No. 0-14732).
10.22*	Form of Restricted Stock Unit Agreement under the Company's 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed November 30, 2007, File No. 0-14732).
10.23*	Form of Option Agreement (Nonqualified Option) for Annual Director Grants under the Company's Second Amended and Restated 2007 Equity Incentive 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, 2010, File No. 001-10865).
10.24*	Form of Restricted Stock Unit Agreement for Annual Director Grants under the Company's Second 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, 2010, File No. 001-10865).
10.25*	Form of November 2011 Restricted Stock Unit Agreement under the Company's Second Amended and Restated 2007 Equity Incentive Plan between the Company and the Company's executive officers (incorporated herein by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011, File No. 001-10865).
10.26*	Form of November 2011 Restricted Stock Unit Agreement under the Company's Second Amended and Restated 2007 Equity Incentive Plan between the Company and each non-executive employee of the Company (incorporated herein by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011, File No. 001-10865).
10.27*	Form of Non-Plan Restricted Stock Unit Agreement, by and between the Company and William K. Heiden (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed May 10, 2012).
10.28*	Form of Non-Plan Stock Option Agreement, by and between the Company 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).
10.29*	Option Agreement under the Company's Second Amended and Restated 2007 Equity Incentive Plan between the Company and Lee F. Allen, dated as of June 25, 2012 (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed June 29, 2012).

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Exhibit Number	Description
10.30*	Option Agreement under the Company's Second Amended and Restated 2007 Equity Incentive Plan between the Company and Christopher G. White, dated as of June 25, 2012 (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed June 29, 2012).
10.31*	Form of February 2013 Performance-based Restricted Stock Unit Agreement under the Company's Second Amended and Restated Equity Incentive Plan between the Company and the Company's executive officers (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, File No. 0-10865).
10.32*	Form of Incentive Stock Option Agreement for Company Employees under the Company's Third Amended and Restated Equity Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, File No. 0-10865).
10.33*	Form of Non-Qualified Stock Option Agreement for Company Employees under the Company's Third Amended and Restated Equity Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, File No. 0-10865).
10.34*	Form of Restricted Stock Unit Agreement for Company Employees under the Company's Third Amended and Restated Equity Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, File No. 0-10865).
10.35*	Form of Non-Qualified Stock Option Agreement Non-Plan Inducement Grant by and between the Company and Greg Madison (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-8, filed August 7, 2013).
10.36*	Form of Restricted Stock Unit Agreement Non-Plan Inducement Grant by and between the Company and Greg Madison (incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-8, filed August 7, 2013).
10.37*	Form of Non-Qualified Stock Option Agreement Non-Plan Inducement Grant (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-8, filed August 7, 2013).
10.38*	Form of Restricted Stock Unit Agreement Non-Plan Inducement Grant (incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-8, filed August 7, 2013).
10.39*	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors under the Company's Third Amended and Restated Equity Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, File No. 0-10865).
10.40*	Form of Restricted Stock Unit Agreement for Non-Employee Directors under the Company's Third Amended and Restated Equity Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, File No. 0-10865).
10.41	Lease Agreement, dated as of May 27, 2008, by and between AMAG Pharmaceuticals, Inc. and Mortimer B. Zuckerman and Edward H. Linde, trustees of 92 Hayden Avenue Trust under Declaration of Trust dated August 18, 1983 This Lease Agreement was assigned in June 2013. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 29, 2008, File No. 0-14732).

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Exhibit Number	Description
10.42	Assignment and Assumption of Lease, dated as of June 10, 2013, by and among AMAG Pharmaceuticals, Inc., Mortimer B. Zuckerman and Edward H. Linde, Trustees of 92 Hayden Avenue Trust under Declaration of Trust dated August 18, 1983 and Shire Human Genetic Therapies, Inc. (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed June 13, 2013, File No. 001-10865).
10.43	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).
10.44	License Agreement between the Company 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. 0-10865) (confidential treatment previously granted).
10.45	Collaboration and Exclusive License Agreement between the Company and 3SBio Inc., dated as of May 25, 2008 (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, File No. 0-14732) (confidential treatment previously granted).
10.46	Supply Agreement between the Company and 3SBio Inc., dated as of May 25, 2008 (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, File No. 0-14732) (confidential treatment previously granted).
10.47+	Commercial Outsourcing Services Agreement, dated October 2008, by and between the Company and Integrated Commercialization Services, Inc. (Including all amendments thereto as of December 31, 2013) (confidential treatment previously granted).
10.48	Commercial Packaging Services Agreement, dated May 29, 2009, by and between the Company and Packaging Coordinators, LLC (formerly Catalent Pharma Solutions LLC) (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed July 1, 2009, File No. 0-14732) (confidential treatment previously granted).
10.49	Amendment No. 1 to Commercial Packaging Services Agreement, dated January 29, 2013, by and between the Company and Packaging Coordinators, LLC (formerly Catalent Pharma Solutions LLC) (incorporated herein by reference to Exhibit 10.39 to the Company's Annual Report on Form 10-K for the year ended December 31, 2012, File No. 001-10865).
10.50	Quality Agreement between the Company and Packaging Coordinators, Inc. (formerly Catalant Pharma Solutions LLC) dated as of June 5, 2013 (which amends and supersedes the Quality Agreement filed as Exhibit C to the Commercial Packaging Services Agreement, dated May 29, 2009, by and between the Company and Catalent Pharma Solutions LLC), filed as Exhibit 10.2 to the Company's Current Report on Form 8-K filed July 1, 2009, file number 000-14732 (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. 0-10865).
10.51	License, Development and Commercialization Agreement by and between the Company and Takeda Pharmaceutical Company Limited, dated March 31, 2010 (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, File No. 001-10865) (confidential treatment previously granted).
10.52	Amendment to the License, Development and Commercialization Agreement, dated June 25, 2012, by and between the Company and Takeda Pharmaceutical Company Limited (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 29, 2012, File No. 001-10865) (confidential treatment previously granted).

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Exhibit Number	Description
10.53	Commercial Supply Agreement, dated effective as of August 29, 2012, by and between the Company 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).
10.54+	Amendment No.1 to Commercial Supply Agreement, dated October 3, 2013, by and between the Company and Sigma-Aldrich, Inc. (Certain confidential information contained in this exhibit was omitted by means of redacting a portion of the text and replacing it with [***]. This exhibit has been filed separately with the SEC without any redactions pursuant to a Confidential Treatment Request under Rule 24b-2 of the Securities and Exchange Act of 1934, as amended).
10.55	Pharmaceutical Manufacturing and Supply Agreement, dated effective as of January 8, 2010, by and between the Company and 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).
21.1+	Subsidiaries of the Company.
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+	The following materials from AMAG Pharmaceuticals, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2013, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Comprehensive (Income) Loss, (iv) Consolidated Statements of Stockholders' Equity, (v) Consolidated Statements of Cash, and (vi) Notes to Consolidated Financial Statements.

+ Exhibits marked with a plus sign ("+") are filed herewith.

++ Exhibits marked with a double plus sign ("++") are furnished herewith.

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

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

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

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

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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: February 10, 2014

We, the undersigned officers and directors of AMAG Pharmaceuticals, Inc., hereby severally constitute and appoint William K. Heiden and Scott A. Holmes, 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)	February 10, 2014
/s/ SCOTT A. HOLMES Scott A. Holmes	Chief Accounting Officer and Vice President of Finance (Principal Financial and Accounting Officer)	February 10, 2014
/s/ BARBARA DEPTULA Barbara Deptula	Director	February 10, 2014
/s/ MICHAEL NARACHI Michael Narachi	Director	February 10, 2014
/s/ ROBERT J. PEREZ Robert J. Perez	Director	February 10, 2014

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Name	Title	Date
/s/ LESLEY RUSSELL, MB. CH.B., MRCP Lesley Russell, MB. Ch.B., MRCP	Director	February 10, 2014
/s/ GINO SANTINI Gino Santini	Director	February 10, 2014
/s/ DAVEY S. SCOON Davey S. Scoon	Director	February 10, 2014

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Exhibit Number	Description
3.1, 4.1	Certificate of Incorporation of the Company, as restated (incorporated herein by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, File No. 001-10865).
3.2, 4.2	By-Laws of the Company, as amended (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed November 28, 2008, File No. 0-14732).
3.3, 4.3	Certificate of Designation of Series A Junior Participating Preferred Stock (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed September 4, 2009, File No. 0-14732).
4.4	Specimen certificate representing the Company's Common Stock (incorporated herein by reference to Exhibit 4.3 to the Current Quarterly Report on Form 10-Q for the quarter ended September 30, 2009, File No. 0-14732).
4.5	Rights Agreement dated as of September 4, 2009 by and among AMAG Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, LLC (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed September 4, 2009, File No. 0-14732).
4.6	Amendment to Rights Agreement, dated May 10, 2012, by and between the Company and American Stock Transfer & Trust Company LLC (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed May 10, 2012).
4.7	Form of Rights Certificate (incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed September 4, 2009, File No. 0-14732).
10.1*	Representative Form of Indemnification Agreement (incorporated herein by reference to Exhibit 10.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2009, File No. 001-10865).
10.2*	Summary of the Company's Change of Control Policy applicable to executive officers (incorporated herein by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed February 13, 2006, File No. 0-14732).
10.3*	AMAG Pharmaceuticals, Inc. 2010 Employee Stock Purchase Plan (incorporated herein by reference to Appendix B to the Company's Definitive Proxy Statement on Schedule 14A, filed April 19, 2010, File No. 001-10865).
10.4*	AMAG Pharmaceuticals, Inc.'s Non-Employee Director Compensation Policy (incorporated herein by reference to Exhibit 10.4 to the Company's Annual Report on Form 10-K for the year ended December 31, 2012, File No. 001-10865).
10.5*	Employment Agreement, dated as of May 6, 2012, by and between the Company and William K. Heiden (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 10, 2012 File No. 001-10865).
10.6*	Employment Agreement dated as of August 1, 2011 between the Company and Frank E. Thomas. (incorporated herein by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011, File No. 001-10865).
10.7*	Second Amendment to Employment Agreement dated as of November 30, 2011 between the Company and Frank E. Thomas (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 2, 2011, File No. 001-10865).
10.8*	Retention Agreement between the Company and Scott A. Holmes dated as of December 2, 2011 (incorporated herein by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011, File No. 001-10865).
10.9*	Second Amended and Restated Employment Agreement dated as of December 15, 2009, as amended February 1, 2011 and November 3, 2011 between the Company and Christopher White (incorporated herein by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K for the year ended December 31, 2012, File No. 001-10865).

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Exhibit Number	Description
10.10*	Employment Agreement dated as of August 15, 2012 between the Company and Scott B. Townsend (incorporated herein by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-K for the year ended December 31, 2012, File No. 001-10865).
10.11*	Employment Agreement dated as of January 1, 2013 between the Company and Greg Madison (incorporated herein by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-K for the year ended December 31, 2012, File No. 001-10865).
10.12*	Employment Agreement dated as of June 20, 2013 between the Company and Steve Caffe (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, File No. 0-10865).
10.13*	Second Amended and Restated Employment Agreement dated as of December 15, 2009, as amended February 1, 2011 and November 3, 2011 between the Company and Lee F. Allen, M.D., Ph.D. (incorporated herein by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K for the year ended December 31, 2012, File No. 001-10865).
10.14*	Retention Agreement dated as of August 27, 2012 between the Company and Lee F. Allen, M.D., Ph.D. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 31, 2012, File No. 001-10865).
10.15*	Separation and Consulting Agreement dated as of March 31, 2013 between the Company and Lee F. Allen, M.D., Ph.D. (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, File No. 0-10865).
10.16*	Advanced Magnetics, Inc. Amended and Restated 2000 Stock Plan (incorporated herein by reference to Appendix A to the Company's definitive proxy statement for the year ended September 30, 2005, File No. 0-14732).
10.17*	Form of Stock Option Grant under the Company's 2000 Stock Plan (employees) (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2005, File No. 0-14732).
10.18*	Form of Stock Option Grant under the Company's 2000 Stock Plan (non-employees) (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2005, File No. 0-14732).
10.19*	AMAG Pharmaceuticals, Inc. Third Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A, filed April 19, 2013, File No. 001-10865).
10.20*	Form of Option Agreement (ISO) under the Company's 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed November 30, 2007, File No. 0-14732).
10.21*	Form of Option Agreement (Nonqualified Option) under the Company's 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed November 30, 2007, File No. 0-14732).
10.22*	Form of Restricted Stock Unit Agreement under the Company's 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed November 30, 2007, File No. 0-14732).
10.23*	Form of Option Agreement (Nonqualified Option) for Annual Director Grants under the Company's Second Amended and Restated 2007 Equity Incentive 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, 2010, File No. 001-10865).
10.24*	Form of Restricted Stock Unit Agreement for Annual Director Grants under the Company's Second 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, 2010, File No. 001-10865).

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Exhibit Number	Description
10.25*	Form of November 2011 Restricted Stock Unit Agreement under the Company's Second Amended and Restated 2007 Equity Incentive Plan between the Company and the Company's executive officers (incorporated herein by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011, File No. 001-10865).
10.26*	Form of November 2011 Restricted Stock Unit Agreement under the Company's Second Amended and Restated 2007 Equity Incentive Plan between the Company and each non-executive employee of the Company (incorporated herein by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K for the year ended December 31, 2011, File No. 001-10865).
10.27*	Form of Non-Plan Restricted Stock Unit Agreement, by and between the Company and William K. Heiden (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed May 10, 2012).
10.28*	Form of Non-Plan Stock Option Agreement, by and between the Company 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).
10.29*	Option Agreement under the Company's Second Amended and Restated 2007 Equity Incentive Plan between the Company and Lee F. Allen, dated as of June 25, 2012 (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed June 29, 2012).
10.30*	Option Agreement under the Company's Second Amended and Restated 2007 Equity Incentive Plan between the Company and Christopher G. White, dated as of June 25, 2012 (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed June 29, 2012).
10.31*	Form of February 2013 Performance-based Restricted Stock Unit Agreement under the Company's Second Amended and Restated Equity Incentive Plan between the Company and the Company's executive officers (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, File No. 0-10865).
10.32*	Form of Incentive Stock Option Agreement for Company Employees under the Company's Third Amended and Restated Equity Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, File No. 0-10865).
10.33*	Form of Non-Qualified Stock Option Agreement for Company Employees under the Company's Third Amended and Restated Equity Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, File No. 0-10865).
10.34*	Form of Restricted Stock Unit Agreement for Company Employees under the Company's Third Amended and Restated Equity Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, File No. 0-10865).
10.35*	Form of Non-Qualified Stock Option Agreement Non-Plan Inducement Grant by and between the Company and Greg Madison (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-8, filed August 7, 2013).
10.36*	Form of Restricted Stock Unit Agreement Non-Plan Inducement Grant by and between the Company and Greg Madison (incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-8, filed August 7, 2013).

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Exhibit Number	Description
10.37*	Form of Non-Qualified Stock Option Agreement Non-Plan Inducement Grant (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-8, filed August 7, 2013).
10.38*	Form of Restricted Stock Unit Agreement Non-Plan Inducement Grant (incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-8, filed August 7, 2013).
10.39*	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors under the Company's Third Amended and Restated Equity Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, File No. 0-10865).
10.40*	Form of Restricted Stock Unit Agreement for Non-Employee Directors under the Company's Third Amended and Restated Equity Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, File No. 0-10865).
10.41	Lease Agreement, dated as of May 27, 2008, by and between AMAG Pharmaceuticals, Inc. and Mortimer B. Zuckerman and Edward H. Linde, trustees of 92 Hayden Avenue Trust under Declaration of Trust dated August 18, 1983 This Lease Agreement was assigned in June 2013. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed May 29, 2008, File No. 0-14732).
10.42	Assignment and Assumption of Lease, dated as of June 10, 2013, by and among AMAG Pharmaceuticals, Inc., Mortimer B. Zuckerman and Edward H. Linde, Trustees of 92 Hayden Avenue Trust under Declaration of Trust dated August 18, 1983 and Shire Human Genetic Therapies, Inc. (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed June 13, 2013, File No. 001-10865).
10.43	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).
10.44	License Agreement between the Company 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. 0-10865) (confidential treatment previously granted).
10.45	Collaboration and Exclusive License Agreement between the Company and 3SBio Inc., dated as of May 25, 2008 (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, File No. 0-14732) (confidential treatment previously granted).
10.46	Supply Agreement between the Company and 3SBio Inc., dated as of May 25, 2008 (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, File No. 0-14732) (confidential treatment previously granted).
10.47+	Commercial Outsourcing Services Agreement, dated October 2008, by and between the Company and Integrated Commercialization Services, Inc. (Including all amendments thereto as of December 31, 2013) (confidential treatment previously granted).
10.48	Commercial Packaging Services Agreement, dated May 29, 2009, by and between the Company and Packaging Coordinators, LLC (formerly Catalent Pharma Solutions LLC) (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed July 1, 2009, File No. 0-14732) (confidential treatment previously granted).

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Exhibit Number	Description
10.49	Amendment No. 1 to Commercial Packaging Services Agreement, dated January 29, 2013, by and between the Company and Packaging Coordinators, LLC (formerly Catalent Pharma Solutions LLC) (incorporated herein by reference to Exhibit 10.39 to the Company's Annual Report on Form 10-K for the year ended December 31, 2012, File No. 001-10865).
10.50	Quality Agreement between the Company and Packaging Coordinators, Inc. (formerly Catalant Pharma Solutions LLC) dated as of June 5, 2013 (which amends and supersedes the Quality Agreement filed as Exhibit C to the Commercial Packaging Services Agreement, dated May 29, 2009, by and between the Company and Catalent Pharma Solutions LLC), filed as Exhibit 10.2 to the Company's Current Report on Form 8-K filed July 1, 2009, file number 000-14732 (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. 0-10865).
10.51	License, Development and Commercialization Agreement by and between the Company and Takeda Pharmaceutical Company Limited, dated March 31, 2010 (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, File No. 001-10865) (confidential treatment previously granted).
10.52	Amendment to the License, Development and Commercialization Agreement, dated June 25, 2012, by and between the Company and Takeda Pharmaceutical Company Limited (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 29, 2012, File No. 001-10865) (confidential treatment previously granted).
10.53	Commercial Supply Agreement, dated effective as of August 29, 2012, by and between the Company 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).
10.54+	Amendment No.1 to Commercial Supply Agreement, dated October 3, 2013, by and between the Company and Sigma-Aldrich, Inc. (Certain confidential information contained in this exhibit was omitted by means of redacting a portion of the text and replacing it with [***]. This exhibit has been filed separately with the SEC without any redactions pursuant to a Confidential Treatment Request under Rule 24b-2 of the Securities and Exchange Act of 1934, as amended).
10.55	Pharmaceutical Manufacturing and Supply Agreement, dated effective as of January 8, 2010, by and between the Company and 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).
21.1+	Subsidiaries of the Company.
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.

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Exhibit Number	Description
101+	The following materials from AMAG Pharmaceuticals, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2013, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Comprehensive (Income) Loss, (iv) Consolidated Statements of Stockholders' Equity, (v) Consolidated Statements of Cash, and (vi) Notes to Consolidated Financial Statements.

+ Exhibits marked with a plus sign ("+") are filed herewith.

++ Exhibits marked with a double plus sign ("++") are furnished herewith.

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

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