AMAG PHARMACEUTICALS INC.
Form 10-K
February 25, 2011

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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, 2010

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.)
100 Hayden Avenue **Lexington, Massachusetts** (Address of Principal Executive Offices)	**02421** (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 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 ý	Accelerated filer o	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, 2010 was approximately $722,500,000 based on the closing price of $34.35 of the Common Stock of the registrant as reported on the NASDAQ Global Market on such date. As of February 16, 2011, there were 21,137,428 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 to be held on May 24, 2011, 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 expectation regarding our intention to initiate a registry study during 2011, the design and expected timing of our global studies of Feraheme for the treatment of iron deficiency anemia in a broad range of patients, our plan to conduct four pediatric studies and the expected timing and design of these studies, our expectation of the timing of a decision by the European Medicines Agency on our Marketing Authorization Application submission, the design and expected timing of our post-approval trial to assess the safety and efficacy of Feraheme compared to an intravenous iron sucrose product in chronic kidney disease patients, our plan to conduct a post-approval trial to assess the safety and efficacy of repeat, episodic Feraheme administration for the treatment of persistent or recurrent iron deficiency anemia and the design of such trial, our statement that our partner in China, 3SBio Inc., or, 3SBio, plans to conduct a Feraheme clinical study in China, our expectation that sales of GastroMARK® will not materially increase, our expectation that Feraheme sales in the dialysis market will continue to decline and will not be significant in 2011, our belief as to the potential size of the non-dialysis chronic kidney disease market, our expectations regarding the success of our collaboration with Takeda Pharmaceutical Company Limited, or Takeda, including any potential milestone payments we may receive, our expectations regarding our future revenues, including expected Feraheme revenues under the Launch Incentive Program, Takeda collaboration and 3SBio collaboration revenues, our expectation that our reserves as a percentage of gross sales will increase in 2011, our expectation that our net sales as a percentage of gross sales will be negatively affected as a result of recent legislation, our expectations regarding future license fee revenues from 3SBio and Bayer Healthcare Pharmaceuticals, our expectation that our costs of product sales will increase in 2011, our expectation that our research and development expenses will increase in 2011, our expectations regarding the amount of external expenses and the timing of our planned research and development projects, our expectation that selling, general and administrative expenses will be less in 2011, our expectation regarding our dividend and interest income, our expectations regarding our short- and long-term liquidity and capital requirements and our ability to finance our operations, our expectations regarding our future cash flows, our belief that the decline in the value of our auction rate securities is temporary and that we will ultimately be able to liquidate these investments without significant loss, our expectations that the remainder of our workforce reduction and the associated payments will be completed by the end of 2011, our belief that we will receive regulatory approval for our alternative manufacturing facilities, our belief that the estimated fair value of our indemnification obligations will not be material, our belief that the allegations asserted against us in the class action lawsuit are without merit and our expectations regarding the potential cost associated with this litigation, our belief regarding the potential impact of the adoption of newly issued and future accounting guidance on our financial statements, 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 biopharmaceutical company focused on the development and commercialization of a therapeutic iron compound to treat iron deficiency anemia, or IDA. Our principal source of revenue is from the sale of Feraheme® (ferumoxytol) Injection for intravenous, or IV, use, 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 are currently pursuing marketing applications in the European Union, or EU, Canada and Switzerland for *Feraheme* for the treatment of IDA in CKD patients.

We market and sell *Feraheme* in the U.S. through our own commercial organization, including a specialized sales force. We began commercial sale of *Feraheme* in July 2009 and sell *Feraheme* primarily to authorized wholesalers and specialty distributors. *Feraheme* is approved for use in the treatment of both dialysis and non-dialysis dependent CKD patients. During 2010, a new prospective payment system for the reimbursement of dialysis services was adopted and became effective on January 1, 2011, which made it less likely that dialysis providers would choose to use *Feraheme* and caused our sales in the dialysis market to begin to decline. As a result, our strategy is primarily focused on growing the utilization of *Feraheme* in non-dialysis dependent CKD patients with IDA in the U.S., specifically in hematology, oncology, nephrology, and hospital sites of care, where a large number of CKD patients are treated.

In November 2010, following discussions with the FDA, we revised the *Feraheme* package insert to include bolded warnings and precautions that describe events that have been reported after *Feraheme* administration in the post-marketing environment, including life-threatening hypersensitivity reactions and clinically significant hypotension. The revised package insert also reflects adverse reactions from post-marketing spontaneous reports and an increase in the recommended observation period following *Feraheme* administration from thirty to sixty minutes to observe patients for signs and symptoms of hypersensitivity. In addition to the changes to the package insert, we agreed to conduct a post-marketing registry study in order to better understand the frequency and timing of adverse events following *Feraheme* administration in the CKD setting. We intend to initiate the registry study during 2011.

Prior to 2009, we devoted substantially all of our resources to our research and development programs. Since the FDA approval and commercial launch of *Feraheme* in mid-2009, we have incurred substantial costs related to the commercialization and development of *Feraheme*. We expect to continue to incur significant expenses to manufacture, market and sell *Feraheme* as an IV iron replacement therapeutic in CKD patients in the U.S., to further develop *Feraheme* for the treatment of IDA in a broad range of patients, and to obtain regulatory approval to market *Feraheme* in countries outside of the U.S. Prior to the commercial launch of *Feraheme*, we financed our operations primarily from the sale of our equity securities, cash generated by our investing activities, and payments from our strategic partners. Since 2009, our revenues have been primarily attributable to product sales of *Feraheme*. We currently expect to fund our future operations from revenue from sales of *Feraheme* in addition to payments from our strategic partners, cash generated by our investing activities, and the sale of our equity securities, if necessary. As of December 31, 2010, we had an accumulated deficit of approximately $362.8 million and our cash, cash equivalents and investments equaled $293.9 million.

Takeda Collaboration

In March 2010, we entered into a License, Development and Commercialization Agreement, or the Takeda Agreement, with Takeda Pharmaceutical Company Limited, or Takeda, under which we granted exclusive rights to Takeda to develop and commercialize *Feraheme* as a therapeutic agent in

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Europe, Asia-Pacific countries (excluding Japan, China and Taiwan), the Commonwealth of Independent States, Canada, India and Turkey, or collectively, the Licensed Territory.

Clinical Development and Regulatory Status of Feraheme

We continue to advance our *Feraheme* clinical development program in adults by conducting two Phase III multi-center clinical trials to assess *Feraheme* for the treatment of IDA in a broad range of patients for whom treatment with oral iron is unsatisfactory, including women with abnormal uterine bleeding, or AUB, patients with cancer or gastrointestinal diseases and postpartum women. In June 2010, we initiated a double blind, placebo-controlled Phase III study which will assess the efficacy and safety of two doses of 510 milligrams each of *Feraheme* compared to placebo in a total of approximately 800 patients with IDA. We have also initiated an open label, active-controlled Phase III study to assess the efficacy and safety of two doses of 510 milligrams each of *Feraheme* compared to a total dose of 1,000 milligrams of an IV iron sucrose product in a total of approximately 600 patients with IDA. Further, an open label extension study is currently enrolling patients from the placebo-controlled study who will be followed for six months and will be eligible to receive two doses of 510 milligrams each of *Feraheme* whenever they meet treatment criteria. These trials are currently enrolling patients and we expect to complete enrollment in the two Phase III studies by the end of 2011.

To meet our FDA post-approval Pediatric Research Equity Act requirement to support pediatric labeling of *Feraheme,* we intend to initiate two randomized, active-controlled pediatric studies in children with CKD and IDA during 2011. One study will be in dialysis dependent CKD patients, and the other will be in CKD patients not on dialysis. Each study will assess the safety and efficacy of *Feraheme* treatment as compared to oral iron in approximately 144 pediatric patients.

In connection with our responsibilities under the Takeda Agreement, in June 2010 we submitted our Marketing Authorization Application, or MAA, for *Feraheme* for the treatment of IDA in CKD patients with the European Medicines Agency, or EMA. In October 2010, we received a list of questions and requests for information related to the MAA, known as the Day 120 List of Questions, from the EMA's Committee for Medicinal Products for Human Use and have been granted an extension to submit our responses. We expect a decision by the EMA on our MAA submission by the end of 2011. Our Pediatric Investigation Plan, which was approved by the EMA in December 2009, includes two pediatric studies needed to meet the requirements of the Pediatric Research Equity Act in the U.S. and two additional pediatric studies requested by the EMA. To further support our MAA, we have initiated a global, randomized, multi-center, active-controlled post-approval trial with approximately 150 adult CKD patients with IDA, both on dialysis and not on dialysis. This study is currently enrolling patients and will assess the safety and efficacy of two doses of 510 milligrams each of *Feraheme* compared to a total dose of 1,000 milligrams of an IV iron sucrose product. We expect to complete enrollment of this study in 2011.

In addition, as part of our obligations under the Takeda Agreement, we are required to initiate a multi-center post-approval clinical trial to assess the safety and efficacy of repeat, episodic *Feraheme* administration for the treatment of persistent or recurrent IDA over a 12 month period. In this study, subjects would receive an initial course of two doses of 510 milligrams each of *Feraheme* and subsequent courses of two doses of 510 milligrams of *Feraheme* whenever they meet treatment criteria. The study is expected to enroll a total of approximately 300 CKD patients with IDA including hemodialysis and peritoneal dialysis patients and those not on dialysis, including post-kidney transplant recipients.

In January 2011, we received a Notice of Non-Compliance from the Therapeutic Products Directorate of Health Canada, or Health Canada, regarding our New Drug Submission for *Feraheme* for the treatment of IDA in adult CKD patients. The Notice of Non-Compliance outlined Health Canada's concerns, which focused mainly on chemistry, manufacturing, and control and preclinical

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toxicology issues. Among other things, Health Canada has requested additional information on polyglucose sorbitol carboxymethylether, or PSC, a material used in the manufacture of *Feraheme*, including, information related to pre-clinical safety of PSC and the manufacturing processes and controls related to the incorporation of PSC.

In August 2010, Takeda filed an MAA with Swissmedic, the Swiss Agency for Therapeutic Products, for *Feraheme* for the treatment of IDA in CKD patients. Takeda recently received a list of questions from Swissmedic, and we are currently working with Takeda to evaluate the questions and potential responses.

In December 2009, our partner in China, 3SBio Inc., or 3SBio, filed an application with the Chinese State Food and Drug Administration, or the SFDA, to obtain approval to begin a registrational clinical trial necessary to file for marketing approval in China. If approved by the SFDA, 3SBio plans to commence a multi-center randomized efficacy and safety study in China involving approximately 200 CKD patients.

In mid-2010, we completed enrollment of our Phase II study of *Feraheme* in vascular-enhanced magnetic resonance imaging, or MRI, for the detection of clinically significant arterial stenosis or occlusion, or the narrowing or blocking of arteries. After a commercial review of the imaging market opportunity and an assessment of the development costs that would be required to gain U.S. approval for an imaging indication, we decided to discontinue this program and focus all of our resources on developing *Feraheme* as a therapeutic agent.

Other information

GastroMARK®, our oral contrast agent used for delineating the bowel in MRI, is approved and marketed in the U.S., Europe, and other countries through our marketing partners. Sales of *GastroMARK* by our marketing partners have been at approximately their current levels for the last several years, and we do not expect sales of *GastroMARK* to materially increase.

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

Our Core Technology

Our core technology is based on small, coated superparamagnetic iron oxide particles and their characteristic properties. Our core competencies include the ability to design such particles for particular applications, to manufacture the particles in controlled sizes, and to cover the particles with different coatings depending upon the application for which they will be used. 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 and MRI contrast agents.

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 is well suited for use as an IV iron replacement therapy product. Our rights to our technology are derived from and/or protected by license agreements, patents, patent applications and trade secret protections. See "Patents and Trade Secrets."

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Products

The following table summarizes the uses and potential uses of our products, the names of our principal marketing partners, the current U.S. and foreign regulatory status, and the primary markets for our products.

Product	Uses/Potential Uses	Marketing Partners	U.S. Status	Foreign Status
Feraheme® (ferumoxytol) Injection	IV iron replacement therapeutic agent for the treatment of IDA in adult patients with CKD.	3SBio (China) and Takeda (Europe, Asia-Pacific countries (excluding Japan, China and Taiwan), the Commonwealth of Independent States, Canada, India and Turkey).	Approved and marketed.	Filed for registrational trial with the SFDA in China, December 2009. New Drug Submission filed with Health Canada, December 2009. Received Notice of Non-Compliance, January 2011. MAA filed with EMA, June 2010. MAA filed with Swissmedic, August 2010.
	IV iron replacement therapeutic agent in patients with IDA, regardless of the underlying cause.	3SBio (China) (option to extend license into additional therapeutic indications). Takeda (Europe, Asia-Pacific countries (excluding Japan, China and Taiwan), the Commonwealth of Independent States, Canada, India and Turkey).	Global Phase III registrational program ongoing.	No marketing applications filed to date.
GastroMARK®	Delineating the bowel in abdominal imaging.	Covidien, Ltd. (U.S.) and Guerbet, S.A. (various countries in the EU, South America, the Middle East, southeast Asia, Africa and eastern Europe).	Approved and marketed.	Approved and marketed in several EU countries.

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."

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

Overview

On June 30, 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 CKD. In July 2009, we began to market and sell *Feraheme* in both the dialysis and non-dialysis CKD markets, including to nephrologists, hematologists, dialysis organizations, hospitals and other end-users who treat patients with CKD. In 2010, due to an impending change in the way the federal government reimburses providers for the care of dialysis patients, the utilization of *Feraheme* shifted from primarily dialysis

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patients to non-dialysis patients. Accordingly, our commercial efforts in 2011 will focus entirely on building *Feraheme* utilization in non-dialysis CKD patients. We anticipate the vast majority of all *Feraheme* utilization in the U.S. will be in the non-dialysis CKD patient population in 2011.

We are currently pursuing marketing applications in the EU, Canada and Switzerland for *Feraheme* for the treatment of IDA in CKD patients. In January 2011, we received a Notice of Non-Compliance from Health Canada in response to our New Drug Submission filed in December 2009, which we are currently reviewing.

Chronic kidney disease, anemia, and iron deficiency

It has been estimated that approximately 10 to 15% of the U.S. adult population is affected by CKD, a condition generally characterized by damaged kidneys, or a reduction in kidney function below 50% of normal. 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. Iron deficiency is a common cause of anemia in CKD patients and can result from multiple blood draws, hospitalizations and interventional procedures, gastrointestinal bleeding, or poor nutritional intake. Regardless of the cause of anemia, 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. Data contained in a 2002 publication in the *Journal of the American Society of Nephrology* suggests that up to 1.6 million stage 3 and 4 non-dialysis CKD patients, who are patients in the later stages of CKD but not yet on dialysis, with anemia may be iron deficient 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 supplements are often not absorbed well by the gastrointestinal tract and frequently have unpleasant side effects, such as constipation, diarrhea, and cramping, which can cause 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. 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. We believe that a small fraction of non-dialysis CKD patients in the U.S. 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.

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

IDA is widely prevalent in many different patient populations for whom treatment with oral iron is unsatisfactory, including women with AUB, patients with cancer or gastrointestinal diseases, and postpartum women. It is estimated that more than 4 million patients in the U.S. have IDA. Currently, approximately 40% of these patients are treated with oral iron and approximately 5% are treated with IV iron.

Based on our belief that the product characteristics of *Feraheme* support clinical development in these additional patient populations, in mid-2010 we initiated a global clinical development program for *Feraheme* in a broad range of patients with IDA, regardless of the underlying cause. The development program is intended to enable the registration of *Feraheme* for the treatment of IDA regardless of the underlying cause in major markets around the world, including the U.S. This program consists of two Phase III studies and is designed to include all patients with IDA for whom treatment with oral iron is unsatisfactory, including women with AUB, patients with cancer or gastrointestinal diseases and

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post-partum women. One study compares treatment with *Feraheme* to treatment with placebo, and the other study compares treatment with *Feraheme* to treatment with an IV iron sucrose product. Patients from the placebo-controlled study will be eligible to enter an extension study to evaluate treatment with *Feraheme* over a six month period. We are currently enrolling patients in this global IDA development program and plan to complete enrollment in the two Phase III studies by the end of 2011.

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, and heavy menstrual bleeding. IDA is commonly associated with AUB, and it is estimated that more than 3 million women in the U.S. have IDA and AUB. 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 it is estimated 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 absolute IDA due to blood loss and/or the inadequate intake or absorption of iron. Oral iron has been used to treat IDA in cancer patients, but its efficacy is variable due to inconsistent bioavailability and absorption, a high incidence of gastrointestinal side effects, potential interactions with 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.

It is estimated that nearly 800,000 patients who have gastrointestinal diseases in the U.S. also have IDA. IDA in patients with gastrointestinal diseases is likely caused by blood loss and/or the inadequate intake or absorption of iron. Oral iron has been used to treat IDA in patients with gastrointestinal diseases, but its efficacy is variable due to inconsistent bioavailability and absorption, the high incidence of gastrointestinal side effects and patient noncompliance.

Currently, only certain iron dextran IV iron products are approved for the treatment of all patients with IDA, regardless of the underlying cause. 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 a new entrant into the broader IDA market could dramatically increase the number of patients treated with IV iron.

GastroMARK

Images of organs and tissues in the abdomen using MRI without contrast agents can be difficult to read because the abdominal organs and tissues cannot be easily distinguished from the loops of the bowel. *GastroMARK*, our oral contrast agent for delineation of the bowel, flows through and darkens the bowel when ingested. By more clearly identifying the intestinal loops, *GastroMARK* enhances the ability to distinguish the bowel from adjacent tissues and organs in the upper gastrointestinal tract.

GastroMARK was approved by the FDA in 1996. Our marketing partner, Covidien, Ltd., or Covidien, or its predecessors, have been marketing *GastroMARK* in the U.S. since 1997. We initially licensed the marketing rights to *GastroMARK* on an exclusive basis to Guerbet S.A., or Guerbet, in western Europe and Brazil. Guerbet has been marketing *GastroMARK* in several EU countries since 1993 under the tradename Lumirem® and subsequently acquired the rights to market *GastroMARK* in several other countries in South America, the Middle East, southeast Asia, Africa, and eastern Europe. See "Licensing, Marketing and Supply Arrangements."

Sales of *GastroMARK* by our marketing partners have been at approximately their current levels for the last several years, and we do not expect sales of *GastroMARK* to materially increase.

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Licensing, Marketing and Supply Arrangements

Although we are commercializing *Feraheme* in the U.S. through our own commercial organization, our commercial strategy has also included the formation of alliances with other pharmaceutical companies to facilitate the sale and distribution of our products. At present we are parties to the following collaborations:

Takeda

In March 2010, we entered into a collaboration agreement with Takeda, under which we granted exclusive rights to Takeda to develop and commercialize *Feraheme* as a therapeutic agent in Europe, Asia-Pacific countries (excluding Japan, China and Taiwan), the Commonwealth of Independent States, Canada, India and Turkey. Under the Takeda Agreement we were initially responsible for the regulatory application for *Feraheme* in the EU, Switzerland and Canada with Takeda responsible for registrational filings in all other regions covered by the agreement. We have since transferred the *Feraheme* regulatory application in Canada to Takeda and in August 2010 Takeda filed the *Feraheme* regulatory application in Switzerland.

Under the Takeda Agreement, except under limited circumstances, we have retained the right to manufacture *Feraheme* and, accordingly, are responsible for supply of *Feraheme* to Takeda. 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, which provides for a cap on such costs. In connection with the execution of the Takeda Agreement, we received a $60.0 million upfront payment in April 2010 from Takeda. We may also receive a combination of regulatory approval and performance-based milestone payments, reimbursement of certain out-of-pocket regulatory and clinical supply costs, defined payments for supply of *Feraheme,* and tiered double-digit royalties on net product sales in the Licensed Territory under the Takeda Agreement. The milestone payments we may be entitled to receive under the agreement could over time equal approximately $220.0 million.

3SBio

In May 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 with respect to the development and commercialization of *Feraheme* as an IV iron replacement therapeutic agent in China. The 3SBio License Agreement grants 3SBio an exclusive license for an initial term of thirteen years to develop and commercialize *Feraheme* as a therapeutic agent in China for an initial indication for the treatment of IDA in patients with CKD, and an option to expand into additional therapeutic indications. In consideration of the grant of the license, we received an upfront payment of $1.0 million. We are eligible to receive certain other specified milestone payments upon regulatory approval of *Feraheme* in China for CKD and other indications. We are also entitled to receive tiered royalties of up to 25% based on sales of *Feraheme* by 3SBio in China. We retained all manufacturing rights for *Feraheme* under these agreements. In addition, pursuant to the 3SBio Supply Agreement, 3SBio has agreed to purchase from us, and we have agreed to supply to 3SBio, *Feraheme* at a predetermined supply price for clinical and commercial use in connection with 3SBio's development and commercialization obligations described above for so long as the 3SBio License Agreement is in effect.

Guerbet

In 1989, we entered into a supply and distribution agreement with Guerbet granting Guerbet an exclusive right to manufacture and sell *GastroMARK* in western Europe and Brazil (under the tradename Lumirem®). This agreement was subsequently amended to expand Guerbet's exclusive rights

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to manufacture and sell *GastroMARK* in various other areas, including South America, the Middle East, southeast Asia, and eastern Europe. Under the terms of this distribution agreement, Guerbet agreed to pay us, as the purchase price for the active ingredient of the licensed products, royalties and a percentage of net sales of *GastroMARK*. We are required to sell to Guerbet its requirements for the active ingredient used in *GastroMARK*. The agreement is perpetual but terminable upon certain specified events.

Covidien

In 1990, we entered into a manufacturing and distribution agreement with Covidien's predecessor granting it a product license and co-marketing rights to *GastroMARK* in the U.S., Canada and Mexico. Covidien currently has rights to *GastroMARK* in the U.S. only. Under the terms of the agreement, we receive royalties based on *GastroMARK* sales by Covidien as well as a percentage of sales for supplying the active ingredient. The agreement is perpetual but terminable upon certain specified events.

Manufacturing and Raw Materials

Our Cambridge, Massachusetts manufacturing facility is registered with the FDA and is subject to current Good Manufacturing Practices, or cGMP, as prescribed by the FDA. In this facility, we currently manufacture *Feraheme* for commercial sale and for use in human clinical trials as well as *GastroMARK* for commercial sale. To support the commercialization of *Feraheme*, we have developed a fully integrated manufacturing support system, including quality assurance, quality control, regulatory affairs and inventory control policies and procedures. These support systems are intended to enable us to maintain high standards of quality for our products.

In 2009, we began commercial manufacture of *Feraheme* and currently have only one manufacturing facility in Cambridge, Massachusetts at which we produce *Feraheme*. We are currently working to obtain the necessary regulatory approvals for alternative manufacturing facilities for *Feraheme*.

We currently purchase certain raw and other materials used to manufacture *Feraheme* from third-party suppliers and at present do not have any long-term supply contracts with 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* 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 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, we may not be able to obtain such materials of the quality required to manufacture *Feraheme* from an alternative source on commercially reasonable terms, or in a timely manner, if at all.

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.

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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 under FDA regulations. Our foreign patents may also be eligible for extension in accordance with applicable law in certain countries. Our inability to protect our products 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.

We also have patent applications pending in the U.S. and have filed counterpart patent applications in certain foreign countries. Although further patents may be issued on pending applications, we cannot be sure that any such patents will be issued on a timely basis, if at all. In addition, any issued patents may not provide us with competitive advantages or may be challenged by others, and the existing or future patents of third parties may limit our ability to commercialize our products. For example, in July 2010, Sandoz GmbH, or Sandoz, filed an opposition to one of our patents which covers *Feraheme* in the EU with the European Patent Office, or EPO. Although we believe that the subject patent is valid, there is a possibility that the EPO could invalidate or require us to narrow the claims contained in the patent. We believe the Sandoz patent opposition is without merit and intend to defend against the opposition vigorously. However, any limitation on the protection of our technology could hinder our ability to develop and market *Feraheme*.

Competition

The pharmaceutical and biopharmaceutical industries are subject to intense competition and rapid technological change. We have competitors both in the U.S. and internationally, and many have greater financial and other resources and more experienced trade, sales and manufacturing organizations than we do. In addition, many of our competitors have name recognition, established positions in the market and long-standing relationships with customers and distributors. The iron replacement therapy market is highly sensitive to several factors including, but not limited to, the actual or perceived safety profile of the available products, the ability to obtain appropriate insurance coverage, coding and reimbursement, price competitiveness, and product characteristics such as convenience of administration and dosing regimens.

Feraheme is approved in the U.S. for use in both dialysis and non-dialysis CKD patients. However, a new prospective payment system for dialysis services provided to Medicare beneficiaries who have end-stage renal disease, or ESRD, was adopted by the Centers for Medicare & Medicaid Services, or CMS, and became effective on January 1, 2011. Under the new prospective payment system, all costs of providing dialysis services are bundled together into a single prospective payment per treatment and therefore health care providers who treat dialysis patients are incentivized to use the lowest priced drugs in each product class. As a result, it is unlikely that we will realize any significant *Feraheme* product sales in the dialysis market because *Feraheme* is priced higher than the other IV iron products. Our commercial strategy is primarily focused on growing the utilization of *Feraheme* in non-dialysis dependent CKD patients with IDA in the U.S. We believe there is a significant opportunity for *Feraheme* in the treatment of IDA in CKD patients not yet on dialysis. The current non-dialysis IV iron market is comprised primarily of three types of facilities where a substantial number of CKD patients are treated: hematology and oncology clinics, hospitals, and nephrology clinics.

There are currently two 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. 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

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affect patient compliance in using such products. The alternative to oral iron for the treatment of IDA is IV iron.

Feraheme currently competes with four IV iron products in the U.S. for the treatment of IDA in CKD patients. Our primary competitor, Venofer®, is an iron sucrose complex, which is approved for use in hemodialysis, peritoneal dialysis and non-dialysis dependent 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. Ferrlecit®, a sodium ferric gluconate, is marketed by Sanofi-Aventis U.S. LLC and is approved for use only in hemodialysis patients. INFeD® is an iron dextran product marketed by Watson Pharmaceuticals, Inc., or Watson, and Dexferrum®, also an iron dextran product, is marketed by American Regent. Both iron dextran products are approved for use in all patients with documented iron deficiency in whom oral iron administration is unsatisfactory or impossible. To date, we have not completed any head-to-head clinical studies comparing *Feraheme* to any other IV iron replacement products.

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

For IV iron replacement therapy in patients with CKD, the total therapeutic course of iron typically used in clinical practice is 1,000 milligrams, or one gram. Venofer® and Ferrlecit® are typically administered as a slow push or a fifteen to sixty minute infusion in doses of 100 to 200 milligrams, thus requiring five to ten physician visits and repeated IV access for patients to receive a standard one gram therapeutic course. INFeD® and Dexferrum® are typically administered as a slow push in 100 milligram doses and also require up to ten physician visits to receive a standard one gram therapeutic course. *Feraheme* is administered as a 510 milligram injection followed by a second 510 milligram injection three to five days later, each of which can be administered in less than one minute at a regular office visit without the use of infusion equipment or prolonged medical intervention.

Based on sales data provided by IMS Health Incorporated, we estimate that the size of the total 2010 U.S. IV iron replacement therapy market was approximately 1.74 million grams, which represented an increase of approximately 8% over 2009. In 2010, approximately 0.74 million grams of IV iron were utilized in the non-dialysis IV iron market, representing a 12.5% increase over 2009 and approximately 1.0 million grams of IV iron were utilized in the dialysis IV iron market, representing a 4.9% increase over 2009. The following represents the 2010 U.S. market share allocation of the total IV iron market and the breakdown between the dialysis and non-dialysis IV iron markets:

	2010 Total IV Iron Market (1.74 million grams)	**2010 Non-dialysis IV Iron Market (0.74 million grams)**	**2010 Dialysis IV Iron Market (1.0 million grams)**
Venofer®	70%	48%	87%
Ferrlecit®	12%	18%	8%
INFeD®	9%	20%	
Feraheme	7%	9%	5%
Dexferrum®	2%	5%	

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Outside of the U.S., *Feraheme* may also compete with Monofer® (iron isomaltoside 1000), an injectable iron preparation for the treatment of IDA developed by Pharmacosmos A/S, or Pharmacosmos, which is currently approved in approximately 16 countries. Pharmacosmos has completed two Phase III non-comparative open-label studies of Monofer® in CKD patients as well as in congestive heart failure patients. Pharmacosmos is currently recruiting patients for three Phase III studies of Monofer® in comparison to oral iron sulfate in patients with inflammatory bowel disease and IDA, non-myeloid malignancies associated with chemotherapy induced anemia and non-dialysis dependent CKD with renal-related anemia. It is too early to determine whether Monofer® will gain any meaningful share of the IV iron market in any country in which it has been approved.

In addition to the currently marketed products, there are several other iron replacement therapy products in various stages of clinical and commercial development in the U.S. and abroad, including Injectafer®, which is known as Ferinject® in Europe. Galenica, through its subsidiary Vifor (International) Inc., or Vifor, exclusively licenses Injectafer® to Luitpold and American Regent for marketing and sale in the U.S. and Canada. In December 2010, Vifor Pharma, the pharmaceuticals business unit of the Galenica Group, and Fresenius Medical Care announced that they have created a new company which will hold the commercialization rights to Venofer® and Ferinject® outside of the U.S.

Injectafer® is in development for a variety of anemia-related indications, including the treatment of IDA in CKD patients, whether or not on dialysis. In March 2008, Luitpold received a non-approvable letter from the FDA for Injectafer® for the treatment of IDA in postpartum women and women with heavy uterine bleeding. Luitpold has initiated several large clinical trials in an effort to provide additional data to address the concerns of the FDA. In June 2007, the UK Medicines and Healthcare Products Regulatory Agency approved the registration of Ferinject® for the treatment of iron deficiency when oral iron preparations are ineffective and cannot be used. Ferinject® is currently approved for marketing in approximately 30 countries including Switzerland, South Korea, and certain countries with the EU. Vifor has completed a Phase III study of patients with chronic heart failure and iron deficiency as well as a Phase III trial for Ferinject® for the treatment of anemia in patients with inflammatory bowel disease. During 2010, Vifor also initiated a Phase IIIb study to evaluate the long-term efficacy of Ferinject® in non-dialysis dependent CKD patients with IDA.

In addition to competition from other marketed products and products known by us to be currently under development, the market opportunity for *Feraheme* could be negatively affected if generic IV iron replacement therapy products were to be approved and achieve commercial success. For example, in July 2009, Watson announced that it entered into a license agreement with GeneraMedix, Inc. for the exclusive U.S. marketing rights to a generic version of Ferrlecit®, which is indicated for the treatment of IDA in hemodialysis patients receiving supplemental erythropoiesis stimulating agent therapy. GeneraMedix, Inc. has filed an Abbreviated New Drug Application with the FDA, which is under expedited review. Companies that manufacture generic products typically invest far less resources in research and development than the manufacturer of a branded product and can therefore price their products significantly lower than those already on the market. It remains unclear if and when a generic product will enter this market.

Sales, Marketing and Distribution

In July 2009 we began commercial sale of *Feraheme,* which is being marketed and sold in the U.S. through our own commercial organization, including a specialized sales force. We sell *Feraheme* primarily through authorized wholesalers and specialty distributors who, in turn, sell *Feraheme* to nephrologists, hematologists, hospitals, dialysis centers, and CKD clinics who treat patients with CKD. In addition, we outsource a number of our product supply chain services to third-party vendors, including services related to warehousing and inventory management, distribution, chargeback processing, accounts receivable management and customer service call center management.

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Our sales and marketing teams use a variety of common pharmaceutical marketing strategies to promote *Feraheme* including sales calls to individual physicians or other healthcare professionals, sampling programs, medical education symposia, journal advertising, personal and non-personal promotional materials, local and national educational programs, scientific meetings and conferences and informational websites. In addition, we provide customer service and other related programs for *Feraheme* including physician reimbursement support services, a patient assistance program for uninsured or under-insured patients and a customer service call center.

Our sales and marketing strategy currently focuses on the non-dialysis dependent CKD market in the U.S. There are an estimated 1.6 million Americans with stage 3 and 4 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.

The following table sets forth customers who represented 10% or more of our revenues for the years ended December 31, 2010, 2009, and 2008.

	For the Years Ended December 31,		
	2010	**2009**	**2008**
AmerisourceBergen Drug Corporation	36%	46%	
Metro Medical Supply, Inc.	21%	28%	
Bayer Healthcare Pharmaceuticals	<10%	<10%	53%
Guerbet S.A.	<10%	<10%	24%
Covidien, Ltd.	<10%	<10%	17%

A large portion of the revenues attributable to Bayer Healthcare Pharmaceuticals in 2008 represents previously deferred revenues related to upfront license fees in connection with a product that we no longer manufacture or sell.

Government Regulation

Overview

The development, manufacture and commercialization of pharmaceutical products are subject to extensive regulation by numerous governmental authorities in the U.S. and, in some instances, by foreign governments. The Federal Food, Drug, and Cosmetic Act, or the FDC Act, and other federal and state statutes and regulations govern, among other things, the research and development, manufacturing, quality control (testing), labeling, record-keeping, approval, storage, distribution, and advertising and promotion of pharmaceutical products. Failure to comply with any of the applicable regulatory requirements may result in a variety of administrative or judicially imposed sanctions including among other things, the FDA'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. The development and approval of a product candidate requires a significant number of years of work and the expenditure of substantial resources, and is often subject to unanticipated delays and may be subject to new legislation or regulations.

In addition to complying with requirements as they currently exist, a sponsor could be negatively impacted by changes in the regulatory framework. From time to time, legislation is introduced that could significantly alter laws pertaining to the approval, manufacturing and/or marketing of drug products. Even without changes to relevant laws, the FDA could release new guidance or revise its implementation of current regulations in a manner that significantly affects us and our products,

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including our ability to receive approval for new indications for *Feraheme*. It is impossible to predict whether legislative changes will be enacted, or whether FDA regulations or guidance will be amended or supplemented, or the potential impact of such changes.

FDA Approval Process

Clinical Development

Before new human pharmaceutical products may be marketed or sold commercially in the U.S., the FDA requires the following steps: (a) pre-clinical laboratory tests, pre-clinical safety and efficacy studies and formulation studies; (b) the submission to the FDA of an Investigational New Drug Application, or IND, for human clinical testing, which must become effective before human clinical trials may commence; (c) adequate and well-controlled human clinical trials under current good clinical practices to establish the safety and efficacy of the drug for its intended use; (d) submission of a New Drug Application, or NDA, to the FDA; (e) approval and validation of manufacturing facilities used in production of the pharmaceutical product under cGMP; and (f) review and approval of the NDA by the FDA.

Pre-clinical studies include the laboratory evaluation of product chemistry and animal studies to assess the potential safety and efficacy of a product and its formulation. The results of such laboratory tests and animal studies are submitted to the FDA as a part of an IND and are reviewed by the FDA prior to and during human clinical trials. If there are no objections from the FDA within 30 days of filing an IND, a sponsor may proceed with initial studies in human volunteers, also known as clinical trials.

Clinical trials are typically conducted in the following three sequential phases, which may overlap in some instances:

Phase I: Clinical trials which involve the initial administration of the study drug to a small group of healthy human volunteers (or, more rarely, to a group of selected patients with the targeted disease or disorder) under the supervision of a principal investigator selected by the sponsor. These Phase I trials are designed to test for safety, dosage tolerance, absorption, distribution, metabolism, excretion and clinical pharmacology and, if possible, early indications of effectiveness.

Phase II: Clinical trials which involve a small sample of the actual intended patient population and aim to: (a) provide a preliminary assessment of the efficacy of the investigational drug for a specific clinical indication; (b) ascertain dose tolerance and optimal dose range; and (c) collect additional clinical information relating to safety and potential adverse effects.

Phase III: If an investigational drug is found through Phase I and Phase II studies to have some efficacy and an acceptable clinical safety profile in the targeted patient population, Phase III studies can be initiated. Phase III studies are well-controlled comparative studies designed to gather additional information within an expanded patient population in geographically dispersed clinical trial sites in order to further establish safety and efficacy in conditions that the drug will be used if approved for marketing.

The FDA may suspend clinical trials at any point in this process if it concludes that patients are being exposed to an unacceptable health risk. In addition, clinical trial results are frequently susceptible to varying interpretations by scientists, medical personnel, regulatory personnel, statisticians and others, which may delay, limit or prevent further clinical development or regulatory approvals of a product candidate.

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Submission and FDA Review of an NDA

Following the successful completion of Phase I, II, and III clinical trials, the results of the trials, together with the results of pre-clinical tests and studies, are submitted to the FDA as part of an NDA. The NDA must also include information related to the preparation and manufacturing of the new drug, analytical methods, and proposed product packaging and labeling. When the NDA is submitted, the FDA has 60 days from receipt to determine whether the application is sufficiently complete to merit a substantive review and should therefore be "filed." If the FDA determines that the application is incomplete, it must notify the sponsor through a "refusal-to-file" letter, and the sponsor then has the option to resubmit the NDA after addressing the concerns raised by the FDA. If the FDA accepts the NDA for filing, the NDA undergoes a series of reviews intended to confirm and validate the sponsor's conclusion that the drug is safe and effective for its proposed use.

Under the Food and Drug Administration Modernization Act, an NDA is designated for either Standard Review or Priority Review. A Priority Review designation may be given if a new drug offers major advancements in treatment or provides a treatment where no adequate therapy exists. The FDA has, pursuant to the Prescription Drug User Fee Act, set a goal that it review and act upon 90% of NDAs with a Standard Review designation within 10 months of their receipt and 90% of NDAs with a Priority Review designation within 6 months of their receipt. However, whether an NDA is designated for a Standard or Priority Review, there is no guarantee that any single submission will be acted on within these time frames, and the FDA's goals are subject to change from time to time. In addition, FDA review of a drug development program may proceed under its "Fast Track" programs, which are intended for a combination of a product and a claim that addresses an unmet medical need. Fast Track is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life threatening conditions and demonstrate the potential to address unmet medical needs. A Fast Track designation provides the sponsor the benefits of scheduling meetings when needed to receive FDA input into development plans, the option of submitting an NDA in sections rather than all components simultaneously, or a rolling review, and the option of requesting evaluation of studies using surrogate endpoints. Fast Track status does not, however, necessarily lead to a Priority Review or Accelerated Approval designation.

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 certain universal post-approval requirements described further below. The FDA may also impose drug-specific conditions on its approval, such as requirements for additional post-marketing testing or surveillance. If the FDA determines that it cannot approve the NDA in its current form, it will issue a complete response letter to indicate that the review cycle for an application is complete and 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 final approval of the NDA. Addressing the deficiencies noted by the FDA could be impractical or costly and may result in significant delays prior to final approval.

Adverse Event Reporting

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

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labeling changes, or, potentially, could require withdrawal or suspension of the product from the market.

FDA Post-Approval Requirements

Even if initial approval of an NDA is granted, such approval is subject to a wide-range of regulatory requirements, any or all of which may adversely impact a sponsor's ability to effectively market and sell the approved product. Furthermore, 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 there is strong evidence that suggests the drug would be ineffective or unsafe or that the drug does not represent a meaningful therapeutic benefit over existing therapies and is not likely to be used in a substantial number of pediatric patients. In addition, the FDA may require a sponsor to implement a Risk Evaluation Mitigation Strategy, or REMS, a strategy to manage a known or potential serious risk associated with the product. The FDA may, either prior to approval or subsequent to approval if new safety data arises, require a REMS if it determines that a REMS is necessary to ensure that the benefits of the product outweigh its risks. A REMS may include a medication guide, patient package insert, a plan for communication with healthcare providers, elements to ensure safe use of the product, and an implementation system. A REMS must also include a timetable for submission of assessments of the strategy at specified time intervals. Failure to comply with a REMS, including submission of a required assessment, may result in substantial civil penalties.

Where a sponsor wishes to expand the originally approved prescribing information, such as adding a new indication, or otherwise change the product formulation or manufacturing and testing requirements, it must submit and obtain approval of a Supplemental New Drug Application, or SNDA. SNDAs generally require additional clinical studies, which can be time-consuming and require the expenditure of substantial additional resources.

FDA Regulation of Product Marketing and Promotion

The FDA also regulates all advertising and promotional activities for products, both prior to and after approval, including but not limited to direct-to-consumer advertising, sales representative communications to healthcare professionals, promotional programming, and promotional activities involving the internet, publications, radio and TV as well as other media. 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, which practices are described in the FDC Act and FDA guidance. cGMP requirements must be followed at all times, and domestic manufacturing establishments 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, 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

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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 notices on FDA Form 483 followed by Warning Letters listing conditions the FDA investigators believe may violate cGMP or other FDA regulations. FDA guidelines specify that a Warning Letter be issued only for violations of "regulatory significance" for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action.

Product approval may be delayed or denied due to cGMP non-compliance or other issues at the sponsor's manufacturing facilities or contractor sites or suppliers included in the NDA, and the complete resolution of these inspectional findings may be beyond the sponsor's control. If after a successful completion of an FDA inspection of a sponsor's manufacturing facilities, the sponsor makes a material change in manufacturing equipment, location or process, additional regulatory review may be required. Re-inspection of the sponsor's manufacturing facilities or contractor sites or suppliers may also occur. 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 in the U.S., foreign manufacturing establishments must also comply with cGMP and are subject to periodic inspection by the FDA or by regulatory authorities in certain of such countries under reciprocal agreements with the FDA. 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 and the Federal False Claims Act. 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. 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*, significant fines, exclusions from government healthcare programs, including Medicare and Medicaid, litigation, or other sanctions.

Other U.S. Regulatory Requirements

We are also subject to regulation under local, state and federal law regarding occupational safety, laboratory practices, handling of chemicals, environmental protection and hazardous substances control. We possess a Byproduct Materials License from the Commonwealth of Massachusetts for receipt, possession, manufacturing and distribution of radioactive materials and Registration Certificates from the federal Drug Enforcement Agency and the Commonwealth of Massachusetts Department of Public

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Health for handling controlled substances. We are also registered with the federal Environmental Protection Agency, or EPA, as a generator of hazardous waste. All hazardous waste disposals must be made in accordance with EPA and Commonwealth of Massachusetts requirements. We are subject to the regulations of the Occupational Safety and Health Act and have a safety program in effect to assure compliance with all of these regulations. We believe our procedures for handling and disposing of hazardous materials used in our research and development activities comply with all applicable federal, state and local requirements. Nevertheless, the risk of accidental contamination or injury from these materials cannot be completely eliminated and, in the event of an accident or injury, we could be held liable for any damages that result.

Certain states also require that we obtain licenses or permits as an out-of-state distributor or manufacturer in order to market, sell and/or ship our pharmaceutical products into their state. We have obtained licenses and permits in some states and, depending on our future activities, may also need to obtain additional licenses or permits in other areas where we decide to manufacture, market or sell our products. New laws, regulations or judicial decisions, or new interpretations of existing laws and regulations, may require us to modify our development programs, revise the way we manufacture, market and sell our products, require additional clinical trials or post-approval safety studies, or limit coverage or reimbursement for our products.

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 Affordability Reconciliation Act, or the Health Care Reform Act, the federal government has enacted the Physician Sunshine provisions. Beginning in 2013, manufacturers of drugs will be 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.

Foreign Regulatory Process

In our efforts to market and sell *Feraheme* outside of the U.S., we and our marketing partners 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 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, marketing authorizations may be submitted under a centralized, mutual recognition or decentralized procedure or national procedure (single country). Under the centralized procedure, the sponsor can submit a single application to the EMA which, if approved, permits the marketing of a product in all EU Member States. Under the mutual recognition procedure, the sponsor applies for national marketing authorization in one state, and upon approval can then seek simultaneous approval in all other EU Member States. Under the decentralized procedure, the sponsor can file simultaneously to several EU Member States, identifying a single reference member state to act as the primary reviewer of the application. Upon approval, the product will be licensed only in the reference member state and the other countries to which it applied. Once

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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. Commercial sales are only able to commence in a country once pricing approval has been received.

Reimbursement

In both the U.S. and foreign markets, our ability to successfully commercialize *Feraheme* depends in significant part on the availability of adequate insurance coverage and reimbursement from government programs, including Medicare and Medicaid, private health insurers, and other third-party payors. Third-party payors are increasingly challenging prices charged for pharmaceutical products and evaluating their cost effectiveness. 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) step therapy, which is a program used to encourage the use of lower cost alternative treatments; (c) variable co-payments, which may make a certain drug more expensive for patients as compared with a competing drug; and (d) utilization management controls, such as requirements for prior authorization before the payor will cover the drug or other coverage policies that limit access to certain drugs for certain uses based on the payor specific coverage policy.

In addition, the U.S. and many foreign governments have been and 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 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 340(B) Public Health Services drug discount program.

Currently, in the hospital outpatient and physician clinic settings, Medicare Part B generally reimburses for physician-administered drugs at a rate of 106% of the drug's average selling 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 CMS on a quarterly basis. CMS then confirms and publishes the ASP for products in advance of the quarter in which the ASP will go into effect. 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. We cannot predict the impact any changes in reimbursement policies may have on our ability to compete effectively.

In July 2010, as required by the Medicare Improvements for Patients and Providers Act of 2008, or MIPPA, CMS published a final rule establishing a new prospective payment system for dialysis services provided to Medicare beneficiaries who have ESRD. MIPPA required CMS to move from a system in which it paid separately for physician-administered drugs for dialysis patients, such as *Feraheme*, to a system in which all costs of providing dialysis services are bundled together into a single prospective payment per treatment. The phase-in of the ESRD expanded prospective payment system began on January 1, 2011, and must be completed by January 1, 2014. 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. While the prospective payment system provisions apply only to Medicare, Medicare is the predominant payor in the ESRD market, and Medicare payment policy, in time, can also influence pricing and reimbursement in the

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non-Medicare markets, as private third-party payors and state Medicaid plans frequently adopt Medicare principles in setting reimbursement methodologies, particularly in the ESRD setting.

To the extent we sell our products internationally, either directly or through our partners, 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 *Ferahame* to be profitable in those countries.

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

Backlog

Generally, we do not have a significant backlog. Product orders from our customers are typically fulfilled within a relatively short time of receipt of a customer order. We had a $0.2 million and $0.1 million product sales backlog as of December 31, 2010 and 2009, respectively.

Employees

As of February 16, 2011, we had 226 employees. We also utilize consultants and independent contractors on a regular basis to assist in the development and commercialization of *Feraheme*. Our success depends in part on our ability to recruit and retain talented and trained scientific, clinical, regulatory, manufacturing, and sales and marketing personnel, as well as senior management. Although we believe we have been relatively successful to date in obtaining and retaining such personnel, we may not be successful in the future.

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

Foreign Operations

We have no foreign operations. Revenues for the year ended December 31, 2010 from customers outside of the U.S. amounted to approximately 10% of our total revenues and were principally related to collaboration revenues recognized in connection with the Takeda Agreement. Revenues for the years ended December 31, 2009 and 2008 from customers outside of the U.S. amounted to 2% and 29%, respectively, of our total revenues and were principally related to customers in France.

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 $54.5 million, $36.3 million and $31.7 million during the years ended December 31, 2010, 2009 and 2008, respectively. We anticipate that a significant portion of our operating expenses will continue to be related to research and development in 2011 as we seek to obtain marketing approval for *Feraheme* in countries outside of the U.S. and expand the approved indications for *Feraheme* in the U.S.

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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. In addition, subject to NASDAQ regulations, we intend to promptly disclose (1) the nature of any amendment to our code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer, or persons performing similar functions and (2) 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 on our website (or in any other medium required by law or the NASDAQ) in the future.

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, any amendments to those reports, proxy and registration statements, and all of our insider Section 16 reports, 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., 100 Hayden Avenue, Lexington, MA 02421. 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 L 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.

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ITEM 1A. RISK FACTORS:

The following is a summary description of some of the material risks and uncertainties that may affect our business, including our future financial and operational results. In addition to the other information in this Annual Report on Form 10-K, the following statements should be carefully considered in evaluating us.

We are solely dependent on the success of Feraheme.

We currently derive and expect to continue to derive substantially all of our revenue from sales of *Feraheme* and, therefore, our ability to become profitable is solely dependent on our successful commercialization and development of *Feraheme.* We currently sell only one other product, *GastroMARK*, in the U.S. and in certain foreign jurisdictions through our marketing partners. However, sales of *GastroMARK* have been at approximately their current levels for many years, and we do not expect sales of *GastroMARK* to materially increase. Accordingly, if we are unable to generate sufficient revenues from sales of *Feraheme*, 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 our *Feraheme* development efforts; however, we may not be successful in our efforts to expand the *Feraheme* package insert to include additional indications or obtain marketing approval for *Feraheme* in additional geographies. Although we are pursuing or have commenced additional clinical trials for *Feraheme* in indications other than chronic kidney disease, or CKD, we are not currently conducting or sponsoring research to expand our product development pipeline beyond *Feraheme* and therefore our revenues and operations will not be as diversified as some of our competitors which have multiple products or product candidates. Any failure by us to gain approval for *Feraheme* in additional indications, gain approval for *Feraheme* in new geographies, or acquire, develop and commercialize additional products and product candidates, could limit long-term shareholder value and adversely affect the future prospects of our business.

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, and 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 generated by our investing activities, and payments from our strategic partners. As of December 31, 2010, we had an accumulated deficit of approximately $362.8 million. Our losses were primarily the result of costs incurred in research and development, including costs associated with our *Feraheme* and other development programs, costs associated with maintaining our sales and marketing infrastructure, and other selling, general and administrative costs. We expect to continue to incur significant expenses to manufacture, market and sell *Feraheme* as an intravenous, or IV, iron replacement therapeutic in CKD patients in the U.S., to further develop *Feraheme* for the treatment of iron deficiency anemia, or IDA, in a broad range of patients and to obtain regulatory approval for *Feraheme* in countries outside of the U.S. As a result, we will need to generate sufficient revenues in future periods to achieve and maintain profitability. We anticipate that the vast majority of any revenue we generate in the near future will be from sales of *Feraheme* as an IV iron replacement therapeutic agent for CKD patients in the U.S. We have never independently marketed or sold any products prior to *Feraheme*, and we may not be successful in marketing or selling *Feraheme*. If we are not successful in marketing and selling *Feraheme*, if revenues grow more slowly than we anticipate or if our operating expenses exceed our expectations, our business, results of operations and financial condition could be materially adversely affected. In addition, if we are unable to achieve, maintain or increase profitability on a quarterly or annual basis, the market price of our common stock may decline.

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Significant safety or drug interaction problems could arise with respect to Feraheme, which could result in restrictions in Feraheme's label, recalls, withdrawal of Feraheme from the market, an adverse impact on Feraheme sales, or cause us to alter or terminate current or future Feraheme clinical development programs, any of which would adversely impact our future business prospects.

Significant safety or drug interaction problems could arise with respect to *Feraheme*, including an increase in the severity or frequency of known problems or the discovery of previously unknown problems, and may result in a variety of adverse regulatory actions. Under the Food and Drug Administration Amendments Act of 2007, the U.S. Food and Drug Administration, or the FDA, has broad authority to force drug manufacturers to take any number of actions if previously unknown safety or drug interaction problems arise, including, but not limited to: (i) requiring manufacturers to conduct post-approval clinical studies to assess known risks or signals of serious risks, or to identify unexpected serious risks; (ii) mandating labeling changes to a product based on new safety information; or (iii) requiring manufacturers to implement a Risk Evaluation Mitigation Strategy, or REMS, where necessary to assure safe use of the drug. In addition, previously unknown safety or drug interaction problems could result in product recalls, restrictions on the product's permissible uses, or withdrawal of the product from the market.

The data submitted to the FDA as part of our New Drug Application, or NDA, was obtained in controlled clinical trials of limited duration. New safety or drug interaction issues may arise as *Feraheme* is used over longer periods of time by a wider group of patients taking numerous other medicines or by patients with additional underlying health problems. In addition, as we conduct other clinical trials for *Feraheme*, new safety problems may be identified which could negatively impact both our ability to successfully complete these studies and the use and/or regulatory status of *Feraheme* for the treatment of IDA in patients with CKD. New safety or drug interaction issues may require us to, among other things, provide additional warnings and/or restrictions on the *Feraheme* package insert, including a boxed warning, directly alert healthcare providers of new safety information, narrow our approved indications, alter or terminate current or planned trials for additional uses of *Feraheme*, or even remove *Feraheme* from the market, any of which could have a significant adverse impact on potential sales of *Feraheme* or require us to expend significant additional funds.

For example, in November 2010, following discussions with the FDA, we revised the *Feraheme* package insert to include bolded warnings and precautions that describe events that have been reported after *Feraheme* administration in the post-marketing environment, including life-threatening hypersensitivity reactions and clinically significant hypotension. In addition, the revised package insert reflects adverse reactions from post-marketing spontaneous reports and an increase in the recommended observation period following *Feraheme* administration from thirty to sixty minutes to observe patients for signs and symptoms of hypersensitivity. Due to these changes to the *Feraheme* package insert, our ability to successfully compete in the IV iron market and potential sales of *Feraheme* and our future business prospects could be adversely impacted. In addition, as more data become available and an increased number of patients are treated with *Feraheme*, we may be required to make further changes to the *Feraheme* package insert, including the inclusion of a boxed warning, directly alert healthcare providers of new safety information, narrow our approved indications, alter or terminate current or planned trials for additional uses of *Feraheme*, or even remove *Feraheme* from the market.

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

In the U.S., our ability to successfully commercialize *Feraheme* is dependent, in significant part, on the availability and extent of reimbursement to end-users from third-party payors for the use of *Feraheme*, including U.S. governmental payors, managed care organizations, private health insurers and

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other third-party payors. Reimbursement by a third-party payor 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. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, 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 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 340(B) Public Health Services drug discount program. These and any future changes in government regulations or private third-party payors' reimbursement policies may reduce the extent of reimbursement for *Feraheme* and adversely affect our future operating results.

In July 2010, as required by the Medicare Improvements for Patients and Providers Act of 2008, or MIPPA, the Centers for Medicare & Medicaid Services, or CMS, published a final rule establishing a new prospective payment system for dialysis services provided to Medicare beneficiaries who have end stage renal disease, or ESRD. MIPPA required CMS to move from a system in which it paid separately for physician-administered drugs for dialysis patients, such as *Feraheme,* to a system in which all costs of providing dialysis services are bundled together into a single prospective payment per treatment. The phase-in of the ESRD expanded prospective payment system began on January 1, 2011, and must be completed by January 1, 2014. 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. *Feraheme* is sold at a price that is substantially higher than alternative IV iron products in the dialysis setting, and as a result, the demand for *Feraheme* in the dialysis setting has begun to show a significant decline. While the prospective payment system provisions apply only to Medicare, Medicare is the predominant payor in the ESRD market, and 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, particularly in the ESRD setting. Changes in the Medicare reimbursement rate may, therefore, result in changes to payment rates from non-Medicare payors as well, further limiting our ability to successfully market and sell *Feraheme* in the dialysis setting.

To the extent we sell our products internationally, either directly or through our partners, 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* to be profitable in those countries.

In the U.S. there have been, and we expect there will continue to be, a number of federal and state healthcare 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 recently enacted Heath Care Reform Act contains a number of provisions that significantly impact the pharmaceutical industry and may negatively affect our potential *Feraheme* revenues. Among other things, the Health

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Care Reform Act increased the minimum Medicaid drug rebates for pharmaceutical companies, extended the rebate provisions to Medicaid managed care organizations, and expanded the 340(b) Public Health Services drug pricing program. In addition, beginning in 2011, the Health Care Reform Act will impose non-deductible annual flat fees on all branded prescription drug manufacturers and importers based upon relative market share. 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* or cause us to incur additional expenses and therefore adversely affect our financial position and results of operations.

In addition, various healthcare reform proposals have emerged at the state level. 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 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 available from governmental agencies or third-party payors, limiting the profitability of *Feraheme*, increasing our tax obligations, increasing our rebate liability or limiting the commercial opportunity for *Feraheme*.

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

The commercial success of *Feraheme* depends upon its level of market adoption by physicians, hospitals, patients, and healthcare payors. If *Feraheme* does not achieve an adequate level of market adoption for any reason, our potential profitability and our future business prospects will be severely adversely impacted. *Feraheme* represents an alternative to other products and might not be adopted by the medical community if perceived to be no safer, less safe, no more effective, less effective, no more convenient, or less convenient than currently available products. The degree of market acceptance of *Feraheme* depends on a number of factors, including but not limited to the following:

- Our ability to demonstrate to the medical community, particularly hematologists, oncologists, hospitals, nephrologists, and others who may purchase or prescribe *Feraheme*, the clinical efficacy and safety of *Feraheme* as an alternative to current treatments for IDA in CKD patients;

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

- The ability of physicians and other providers to be adequately reimbursed for *Feraheme* from payors, including government payors, such as Medicare and Medicaid, and private payors, particularly in light of the recently enacted prospective payment system for dialysis patients with ESRD;

- The relative price of *Feraheme* as compared to alternative iron replacement therapeutic agents;

- The actual or perceived convenience and ease of administration of *Feraheme* as compared to alternative iron replacement therapeutic agents, particularly in light of the recent extension of the recommended observation period following *Feraheme* administration; and

- The effectiveness of our sales and marketing organizations and our distribution network.

We market and sell *Feraheme* for use in both dialysis and non-dialysis CKD patients. However, sales in the dialysis market have recently declined significantly due, in large part, to implementation of the prospective payment system for ESRD drugs like *Feraheme*. Accordingly, we

expect sales of

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Feraheme in the dialysis market to represent a very small portion of our total sales going forward. As a result, unless we capture a significant share of the non-dialysis CKD market, potential *Feraheme* sales, our potential profitability and our future business prospects will be materially adversely impacted.

The key component of our commercialization strategy is to market and sell *Feraheme* for use in non-dialysis CKD patients. The current non-dialysis CKD market is comprised primarily of three types of facilities where a substantial number of CKD patients are treated: hematology and oncology clinics, hospitals, and nephrology clinics. IV iron therapeutic products are not currently widely used by certain physicians who treat non-dialysis CKD patients, particularly nephrologists, due to safety concerns and the inconvenience and often impracticability of administering 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 hospital market depends in part upon our ability to achieve acceptance of *Feraheme* onto hospital formularies. Since many hospitals are members of group purchasing organizations, 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 the hospital market also depends in part on our ability to effectively promote *Feraheme* within group purchasing organizations. If we are not successful in effectively promoting *Feraheme* to physicians who treat non-dialysis CKD patients or if we are not successful in securing and maintaining formulary coverage for *Feraheme* or are significantly delayed in doing so, we will have difficulty achieving wide-spread market acceptance of *Feraheme* in the non-dialysis CKD market and our ability to generate revenues and achieve and maintain profitability, and our long-term business prospects could be adversely affected.

Competition in the pharmaceutical and biopharmaceutical industries is intense. If our competitors are able to develop and market products that are or are perceived to be more effective, safer, more convenient or have more favorable pricing, insurance coverage, coding and reimbursement than Feraheme, the commercial opportunity for Feraheme will be adversely impacted.

The pharmaceutical and biopharmaceutical industries are subject to intense competition and rapid technological change. We have competitors both in the U.S. and internationally, and many have greater financial and other resources, and more experienced trade, sales, and manufacturing organizations than we do. In addition, many of our competitors have name recognition, established positions in the market and long-standing relationships with customers and distributors. Our *Feraheme* commercial opportunity will be reduced or eliminated if our competitors develop, commercialize or acquire or license technologies and drug products that are or are perceived to be safer, more effective, and/or easier to administer, or have more favorable pricing, insurance coverage, coding and reimbursement than *Feraheme*.

Feraheme competes with several other IV iron replacement therapies in the U.S., including Venofer®, which 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., Ferrlecit®, which is marketed by Sanofi-Aventis U.S. LLC, INFeD®, an iron dextran product marketed by Watson Pharmaceuticals, Inc., and Dexferrum®, an iron dextran product marketed by American Regent. *Feraheme* may not receive the same level of market acceptance as these competing iron replacement therapy products, especially since these products have been on the market longer and are currently widely used by physicians. We may not be able to convince physicians and other healthcare providers or payors to switch from using the other marketed IV iron therapeutic products to *Feraheme*. The iron replacement therapy market is highly sensitive to several factors including, but not limited to, the actual and perceived safety profile of the available products, the ability to obtain appropriate insurance coverage, coding and reimbursement, price competitiveness, and product characteristics such as convenience of administration and dosing regimens. To date, we have not completed any head-to-head clinical studies comparing *Feraheme* to other IV iron replacement products.

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In addition to the foregoing currently marketed products, there are several iron replacement therapy products in various stages of clinical and commercial development in the U.S. and abroad, including Monofer® (iron isomaltoside 1000), an injectable iron preparation, which is currently approved in 16 countries for the treatment of IDA, Injectafer®, which is known as Ferinject® in Europe and is approved for marketing in 30 countries including Switzerland, South Korea, and certain countries within the European Union, or EU.

In addition to competition from other marketed products and products known by us to be currently under development, the market opportunity for *Feraheme* could be negatively affected if generic IV iron replacement therapy products were to be approved and achieve commercial success. For example, in July 2009, Watson Pharmaceuticals, Inc. announced that it entered into a license agreement with GeneraMedix, Inc. for the exclusive U.S. marketing rights to a generic version of Ferrlecit®, which is indicated for the treatment of IDA in hemodialysis patients receiving supplemental erythropoiesis stimulating agent therapy. GeneraMedix, Inc. has filed an Abbreviated New Drug Application with the FDA, which is under expedited review. Companies that manufacture generic products typically invest far less resources in research and development than the manufacturer of a branded product and can therefore price their products significantly lower than those already on the market. It remains unclear if or when a generic product will enter this market.

If any of these product candidates are approved for marketing and sale by the FDA, our efforts to market and sell *Feraheme* in the U.S. and our ability to generate additional revenues and achieve profitability could be adversely affected.

We have limited experience independently commercializing a pharmaceutical product, and any failure on our part to effectively execute our Feraheme commercial plans, particularly in light of our recent restructuring, would have a severe adverse impact on our business.

Prior to our commercialization of *Feraheme*, we had never independently marketed or sold a drug product as we had relied on our corporate partners to market and sell our previously approved products. We have an internal sales and marketing infrastructure to market and sell *Feraheme* in the U.S., and if we are unsuccessful in maintaining an effective sales and marketing function or experience a high level of turnover, then the commercialization of *Feraheme* could be severely impaired. In October 2010, we decided to reduce our workforce by approximately 24% as part of an overall corporate workforce reduction. This workforce reduction, or any future reduction, could harm our ability to attract and retain qualified personnel, which could prevent us from successfully commercializing *Feraheme*, impair our ability to maintain sales levels and/or impair our ability to support potential sales growth and sales of *Feraheme* for any additional indications we may commercialize in the future. Our October 2010 workforce reduction could also result in reduced productivity and/or increased turnover among our personnel and could result in an adverse impact on our revenues and financial condition. Any failure by us to successfully execute our commercialization plans for *Feraheme* 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 October 2010 corporate restructuring may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business, all of which could have a material adverse effect on our business.

As a result of our October 2010 workforce reduction, we recorded restructuring charges of approximately $2.2 million in the fourth quarter of 2010. Our restructuring charges were based on a number of assumptions. Actual results may differ and additional charges not currently expected may be incurred in connection with, or as a result of, these reductions. We may not fully realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays in the implementation of the restructuring plan or

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unexpected costs. If we are unable to achieve the anticipated benefits, savings or improvements in our cost structure in the expected time frame or other unforeseen events occur, our business and results of operations may be adversely affected.

Our restructuring plan may also be disruptive to our operations. 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. Our workforce reduction could also harm our ability to attract and retain qualified management, scientific, manufacturing and sales and marketing personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully commercializing and developing *Feraheme*, impair our ability to maintain sales levels and/or support potential sales growth.

Moreover, although we believe it is necessary to reduce 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 the 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 Feraheme 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*. We have contracted with Integrated Commercialization Services, Inc., or ICS, to be our exclusive third-party logistics provider to perform a variety of functions related to the sale and distribution of *Feraheme*, including services related to warehousing and inventory management, distribution, chargeback processing, accounts receivable management and customer service call center management. As a result, a significant amount of our inventory is stored at a single warehouse maintained by ICS. In addition, we have contracted with Catalent Pharma Solutions, LLC, or Catalent, to provide certain labeling and packaging services for final *Feraheme* drug product. If ICS or Catalent are unable to provide uninterrupted supply chain services or labeling and packaging services, respectively, we may incur substantial losses of sales to wholesalers or other purchasers of *Feraheme*.

In addition, the packaging, storage and distribution of *Feraheme* requires significant coordination among our manufacturing, sales, marketing and finance organizations and multiple third parties including our third-party logistics provider, packaging and labeling 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 *Feraheme* to meet 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 *Feraheme* to be delayed or interrupted, which would have an adverse effect on our business, financial condition and results of operations.

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We may not be able to operate our manufacturing facility in compliance with current good manufacturing practices and other FDA regulations, which could result in a suspension of our ability to manufacture Feraheme, the loss of our Feraheme inventory, our inability to manufacture sufficient quantities of Feraheme to meet demand, or other unanticipated compliance costs.

Our Cambridge, Massachusetts manufacturing facility is subject to current good manufacturing practices, or cGMP, regulations enforced by the FDA through periodic inspections to confirm such compliance. We must continually expend time, money and effort in production, record-keeping and quality assurance and control to ensure that our manufacturing facility meets the FDA's regulatory requirements. Failure to maintain ongoing compliance with cGMP regulations and other applicable manufacturing requirements of various regulatory agencies could result in, among other things, the FDA's issuance of Warning Letters, fines, the withdrawal or recall of *Feraheme* from the marketplace, total or partial suspension of *Feraheme* production, the loss of our *Feraheme* inventory, suspension of the FDA's review of any future supplemental New Drug Applications, 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 *Feraheme*, and could have a severe adverse impact on our potential profitability and the future prospects of our business. In addition, if the FDA inspects our manufacturing facility and determines that we are not in compliance with cGMP regulations or we otherwise determine that we are not in compliance with these regulations, we could experience an inability to manufacture sufficient quantities of *Feraheme* to meet demand or incur unanticipated compliance expenditures, either of which could have an adverse impact on *Feraheme* sales, our potential profitability and the future prospects of our business.

We currently manufacture Feraheme at one manufacturing facility without a qualified alternative manufacturing source, and if we experience any difficulties, disruptions or delays in the manufacturing process, we may not be able to produce sufficient quantities of Feraheme to meet commercial demand or continue our Feraheme development efforts.

We currently manufacture *Feraheme* for commercial use and for use in human clinical trials in our Cambridge, Massachusetts manufacturing facility. Although we are working to establish and qualify alternative manufacturing facilities, we currently have only one facility at which we produce *Feraheme*. Our ability to manufacture *Feraheme* 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 manufacturing facility. If there are any difficulties, disruptions or delays in the *Feraheme* manufacturing process, including quality control problems, we may experience manufacturing failures which could result in product defects or shipment delays, recall or withdrawal of products previously shipped for commercial or clinical purposes, inventory write-offs or the inability to meet commercial demand for *Feraheme* in a timely and cost-effective manner. Furthermore, if we fail to continue to attract and retain key members of our manufacturing or quality departments, we may be unable to manufacture sufficient quantities of *Feraheme* in a timely manner, which could delay or impair our product sales and development efforts.

If we are unable to produce sufficient quantities of *Feraheme* to meet demand or we experience any manufacturing difficulties at our Cambridge, Massachusetts manufacturing facility, we will be required to enter into arrangements with third-party manufacturers. We are currently working to establish and qualify alternative manufacturing facilities for *Feraheme*, however we may not be able to enter into agreements with manufacturers whose facilities and procedures comply with cGMP regulations and other regulatory requirements on terms that are favorable to us, if at all. In the event that we do not receive the requisite regulatory approval to produce *Feraheme* at these third-party manufacturing facilities, we will need to enter into arrangements with alternative third-party manufacturers which we may not be able to do in a timely and cost-effective manner. Even if these

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third-party manufacturers are qualified to be alternative manufacturing facilities for *Feraheme* and we were to reach agreement, the transition of the manufacturing process to a third-party could take a significant amount of time. Furthermore, use of second-source manufacturing facilities 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* in accordance with cGMP. If we are unable to consistently manufacture *Feraheme* on a timely basis because of these or other factors, we may not be able to meet commercial demand or our clinical development needs for *Feraheme*. As a result, we may lose sales and fail to generate increased revenues and our clinical development programs may be delayed, which could have an adverse impact on our potential profitability and future business prospects.

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

We currently purchase certain raw and other materials used to manufacture *Feraheme* from third-party suppliers, with whom we do not currently have any long-term supply contracts. These third-party suppliers may cease to produce the raw or other materials used in *Feraheme* or otherwise fail to supply these materials to us or fail to supply sufficient quantities of these materials to us 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;

Labor disputes or shortages;

Manufacturing difficulties;

Regulatory requirements or action;

Adverse financial developments at or affecting the supplier; or

Import or export problems.

If any of our third-party suppliers cease to supply certain raw or other materials to us for any reason we could be unable to manufacture *Feraheme* in sufficient quantities or on a timely basis until we are able to qualify an alternative source, which could adversely affect our ability to satisfy commercial demand and our clinical development needs for *Feraheme*.

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 sometimes obtain raw or other materials from one vendor only, even where multiple sources are available, to maintain quality control and enhance working relationships with suppliers, which could make us susceptible to price inflation by the sole supplier, thereby increasing our production costs. As a result of the high quality standards imposed on our raw or other materials, we may not be able to obtain these materials of the quality required to manufacture *Feraheme* 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*, both for commercial sale and for use in our clinical trials, on a timely and cost-effective basis. Any such difficulty in obtaining raw or other materials could severely hinder our ability to manufacture *Feraheme* and could have a material adverse impact on our ability to generate additional revenues and to achieve profitability.

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Our ability to grow revenues from sales of Feraheme will be limited if we do not obtain approval, or if we experience significant delays in our efforts to obtain approval in the U.S. to market Feraheme for the treatment of IDA in a broad range of patients.

We are currently conducting clinical trials to support our global registrational program to assess *Feraheme* for the treatment of IDA in a broad range of patients. Before obtaining regulatory approval in the U.S. for the commercial marketing and sale of *Feraheme* for the broad IDA indication, we must demonstrate through extensive human clinical trials that *Feraheme* is safe and efficacious for this new use and in this broader patient population. Conducting clinical trials is a complex, time-consuming and expensive process that requires adherence to a wide range of regulatory requirements. The FDA has substantial discretion in the approval process and may decide that the results of our clinical trials are insufficient for approval or that *Feraheme* is not effective or safe in indications other than CKD. 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. There is no guarantee that we will be successful in completing any clinical trials for the treatment of IDA in a broad range of patients in a timely manner or that, if completed, the results of such clinical trials will demonstrate *Feraheme* to be safe and effective in such use and/or patient population.

The FDA could also determine that our clinical trials and/or our manufacturing processes were not properly designed, were not conducted in accordance with federal 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 our study sites fail to comply with applicable cGCP regulations, the clinical data generated in our 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 applications, which could adversely impact our ability to obtain approval 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 significant delays or prevent us from obtaining regulatory approval for *Feraheme* for the IDA indication. This 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.

Our ability to complete our global registrational program for the broad IDA indication in a timely manner depends on a number of factors, including:

- Our ability to identify and enter into contracts with prospective clinical sites in a timely manner;
- The rate of patient enrollment;
- The ability of our clinical research organizations to perform their oversight responsibilities and meet expected deadlines;
- Any adverse impact of our October 2010 corporate restructuring on our ability to execute our clinical trials effectively;
- Any adverse regulatory action which would preclude our ability to continue to conduct or complete our clinical trials, such as a clinical hold on our clinical trials or any further changes to the *Feraheme* package insert; and
- The discovery of previously unknown safety or drug interaction problems with respect to *Feraheme*.

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Any failure by us to obtain U.S. approval for *Feraheme* for the treatment of IDA in a broad range of patients in a timely manner may limit the commercial success of *Feraheme* and our ability to grow our revenues.

Our ability to grow revenues from sales of Feraheme will be limited if we do not obtain approval, or if we experience significant delays in our efforts to obtain approval, to market Feraheme in countries outside of the U.S.

In order for Takeda Pharmaceutical Company Limited, or Takeda, 3SBio Inc., or us to market and sell *Feraheme* in any country outside of the U.S. for any indication, it will be necessary to obtain regulatory approval from the appropriate regulatory authorities. The requirements and timing for regulatory approval vary widely from country to country and may in some cases be different than or more rigorous than requirements in the U.S. For example, in January 2011, we received a Notice of Non-Compliance from the Therapeutic Products Directorate of Health Canada, or, Health Canada, which contained concerns focused mainly on chemistry, manufacturing, and control and preclinical toxicology issues. Health Canada requested, among other things, additional information on polyglucose sorbitol carboxymethylether, or PSC, a material used in the manufacture of *Feraheme*, including information related to pre-clinical safety of PSC and the manufacturing processes and controls related to the incorporation of PSC. We may not be able to adequately address all of the concerns raised in the Notice of Non-Compliance in a timely manner, which could delay or prevent approval of *Feraheme* in Canada. In addition, our June 2010 Marketing Authorization Application submitted to the European Medicines Agency, or EMA, for the approval of *Feraheme* for the treatment of IDA in CKD patients, is largely supported by data from the clinical trials we conducted to support our U.S. NDA filing for the approval of *Feraheme* for the treatment of IDA in CKD patients. The EMA may require us to perform additional studies or provide additional data in order to obtain regulatory approval for any indication in the EU. In addition, any adverse regulatory action taken by the FDA with respect to *Feraheme* in the U.S. may affect the regulatory requirements or decisions made by certain foreign regulatory bodies with regard to the regulatory approval of *Feraheme* outside of the U.S.

Any failure by us, Takeda or 3SBio Inc. to obtain approval for *Feraheme* in any countries outside of the U.S. in a timely manner may limit the commercial success of *Feraheme* and our ability to grow our revenues.

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

We rely and intend to continue to rely on third-parties, including clinical research organizations, third-party manufacturers, third-party logistics providers, packaging and labeling providers, wholesale distributors and certain other important vendors and consultants in the conduct of our business. As a result of the current volatile and unpredictable global economic situation, there may be a disruption or delay in the performance or satisfaction of commitments to us by our third-party contractors or suppliers. For example, as a result of the current economic climate, our distributors, customers or suppliers may experience difficulty in obtaining the liquidity necessary to purchase inventory or raw or other materials, may begin to maintain lower inventory levels or may become insolvent. If such third-parties are unable to adequately satisfy their contractual commitments to us in a timely manner, our business could be severely adversely affected.

In addition, we have and we plan to continue to contract with certain third-parties to provide certain services, including site selection, enrollment, monitoring and data management services in connection with the conduct of our 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 perform all of their contractual obligations to us. If our third-party service providers cannot adequately fulfill their obligations to us in a timely manner and on a satisfactory basis or if the quality and accuracy of

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our clinical trial data is compromised due to 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 development plans both in the U.S. and outside of the U.S. may be delayed or terminated, which would adversely impact our ability to generate revenues from *Feraheme* sales in additional indications and/or outside of the U.S. Further, in order to increase the number of patients available for enrollment in our clinical trials and to support foreign regulatory approval of *Feraheme*, we are conducting trials in geographies outside the U.S. We have no experience conducting clinical trials outside the U.S., and, therefore, we are largely relying on third-parties such as clinical research organizations to manage, monitor and carry out these clinical trials outside of the U.S.

We are substantially dependent upon our collaboration with Takeda to commercialize Feraheme in certain regions outside of the U.S., and if Takeda fails to successfully fulfill its obligations, or is ineffective in its commercialization of Feraheme in the Licensed Territory, or if our collaboration is terminated, our plans to commercialize Feraheme outside of the U.S. may be adversely affected.

In March 2010, we entered into a License, Development and Commercialization Agreement, or the Takeda Agreement, with Takeda, under which we granted exclusive rights to Takeda to develop and commercialize *Feraheme* as a therapeutic agent in Europe, Asia-Pacific countries (excluding Japan, China and Taiwan), the Commonwealth of Independent States, Canada, India and Turkey, or collectively, the Licensed Territory. We are highly dependent on Takeda for certain regulatory filings outside of the U.S. with respect to *Feraheme* and the commercialization of *Feraheme* outside of the U.S. If Takeda fails to perform its obligations under the Takeda Agreement or is ineffective in its commercialization of *Feraheme* in the Licensed Territory or if we fail to effectively manage our relationship with Takeda, our ability to and the extent to which we commercialize and obtain certain regulatory approvals of *Feraheme* outside of the U.S. would be significantly harmed. Further, if we fail to fulfill certain of our obligations under the Takeda Agreement, Takeda has the right to assume the responsibility of clinical development of *Feraheme* in the Licensed Territory, which would increase the cost of and delay the *Feraheme* development program outside of the U.S.

In addition, Takeda has the right to terminate the agreement under certain conditions. If Takeda terminates the Takeda Agreement, we would be required to either enter into alternative arrangements with third parties to commercialize *Feraheme* in the Licensed Territory, which we may be unable to do, or to increase our internal infrastructure, both of which would likely result in significant additional expense and delay or termination of our *Feraheme* clinical development programs 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 *Feraheme* sales;
- The timing and magnitude of costs associated with the commercialization of *Feraheme* in the U.S., including costs associated with maintaining our commercial infrastructure and executing our promotional and marketing strategy;
- Changes in buying patterns and inventory levels of our wholesalers or distributors;
- Any adverse impact on our financial results stemming from our October 2010 corporate restructuring;
- The timing and magnitude of costs associated with our ongoing and planned clinical studies of *Feraheme* in connection with our pursuit of additional indications and our development of *Feraheme* in countries outside of the U.S;

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The timing and magnitude of milestone payments we may receive under the Takeda Agreement;

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

Changes in laws and regulations affecting *Feraheme* from federal and state legislative and regulatory authorities, government health administration authorities, private health insurers and other third-party payors;

The initiation or outcome of any material litigation to which we are a party; and

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.

Wholesaler and distributor buying patterns 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 revenues, may vary from period to period due to a variety of factors, including the buying patterns of our wholesalers and distributors, which vary from quarter to quarter. In the event wholesalers and distributors with whom we do business determine to limit their purchases of our products, sales of our products could be adversely affected. For example, in advance of an anticipated price increase or a reduction in expected rebates or discounts, customers may order *Feraheme* in larger than normal quantities which could cause sales of *Feraheme* to be lower in subsequent quarters than they would have been otherwise. Further, any changes in purchasing patterns, inventory levels, increases in returns of *Feraheme,* delays in purchasing products or delays in payment for products by one of our distributors could also have a negative impact on our revenue and results of operations.

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 accounting principles generally accepted in the United States. 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 collaboration agreements and product sales, product sales allowances and accruals, our assessment of investments for potential other-than-temporary impairment and our determination of the value of our investments, reserves for doubtful accounts, accrued expenses, reserves for legal matters, income taxes and equity-based compensation expense. We base our estimates on market data, our observance of trends in our industry, and various other assumptions that we believe to be reasonable under the circumstances. If actual results differ from these estimates, there could be a material adverse effect on our financial results and the performance of our stock. In addition, we may fail to realize our publicly disclosed financial guidance or other expectations about our business, which could cause our stock to decline in value.

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

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cash flows. In addition, to determine the required quantities of our products and the related manufacturing schedule, we also need to make significant judgments and estimates based on inventory levels, current market trends, anticipated sales, and other factors. Because of the inherent nature of estimates, there could be significant differences between our estimates and the actual amount of product need. For example, the level of our access to wholesaler and distributor inventory levels and sales data, which varies based on the wholesaler or distributor, 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.

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 $13.75 and $40.00 in the fifty-two week period through February 16, 2011. 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.;

The timing and magnitude of *Feraheme* 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;

The availability of reimbursement coverage for *Feraheme* or changes in the reimbursement policies of governmental or private payors;

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

Actual or perceived safety concerns related to *Feraheme* or products or product candidates of our competitors, including any actions taken by regulatory authorities in connection with such concerns;

General market conditions;

Sales of large blocks of our common stock;

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

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

Developments in patents or other proprietary rights by us or our competitors;

The initiation or outcome of any material litigation to which we are a party; and

Significant collaboration, acquisition, joint venture or similar agreements by us or our competitors.

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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 our own publicly disclosed financial guidance or 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. Currently, thirteen 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 our own publicly disclosed financial guidance or analysts' forecasts and expectations. If any of the analysts who cover us downgrade our stock or issue commentary or observations that are perceived by the market to be adverse to us or our stock, our stock price would likely decline rapidly. 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.

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:

The magnitude of *Feraheme* sales;

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

Costs associated with the U.S. commercialization of *Feraheme*, including costs associated with maintaining our commercial infrastructure and distribution network, costs associated with executing our promotional and marketing strategy for *Feraheme,* and costs associated with conducting post-marketing clinical studies;

Costs associated with our development of the broad IDA indication for *Feraheme* in the U.S.;

Costs associated with our pursuit of approval for *Feraheme* outside of the U.S.;

Costs associated with commercial-scale manufacturing of *Feraheme*, including costs of raw and other materials and costs associated with maintaining commercial inventory and qualifying additional manufacturing capacities and alternative suppliers;

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

Our ability to liquidate our investments in auction rate securities, or ARS, in a timely manner and without significant loss;

The impact of the current state of the credit and capital markets upon the investments in our portfolio;

Our ability to maintain successful collaborations with our partners 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.

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We estimate that our cash resources as of December 31, 2010, combined with cash we currently expect to receive from sales of *Feraheme* and from earnings on our investments, will be sufficient to finance our currently planned operations for at least the next twelve months. Thereafter, we may require additional funds or need to establish additional alternative strategic arrangements to execute our business plans. We may seek needed funding through additional arrangements with collaborative partners or 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 additional equity financings or alternative strategic arrangements would be dilutive to our stockholders. In addition, the terms of any 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 not available to current stockholders. 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, 2010, we had $112.6 million in cash and cash equivalents, $147.6 million in short-term investments, and $33.6 million in long-term investments. These investments are subject to general credit, liquidity, market and interest rate risks, which have been and may continue to be exacerbated by the U.S. and global financial crisis which has been occurring over the past several years. The ongoing disruptions in the credit and financial markets have negatively affected many industries, including those in which we invest, and we may realize losses in the fair value of certain of our investments or a complete loss of these investments, which would have an adverse effect on our results of operations, liquidity and financial condition.

As of December 31, 2010, we held a total of $33.6 million in fair market value of ARS reflecting a decline in value of approximately $6.0 million compared to the par value of these securities of $39.6 million. In February 2008, our ARS began to experience failed auctions and have continued to experience failed auctions. Since that time, the continued uncertainty in the credit markets has caused almost all additional auctions with respect to our ARS to fail and prevented us from liquidating certain of our holdings of ARS because the amount of these securities submitted for sale has exceeded the amount of purchase orders for these securities. These auctions may continue to fail indefinitely, and there could be a further decline in value of these securities or any other securities, which may ultimately be deemed to be other-than-temporary. In the future, should we determine that these declines in value of ARS are other-than-temporary, we will recognize the credit-related portion of the loss to our consolidated statement of operations, which could be material. In addition, failed auctions will adversely impact the liquidity of our investments.

The condition of the credit markets remains dynamic and 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. As the ratings of our ARS change we may be required to adjust our future valuation of our ARS which may adversely affect the value of these investments. 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.

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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 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 Global Market, and the U.S. Securities and Exchange Commission, or 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. For example, in July 2010, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as "say on pay" and proxy access. 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 the sale of shares of our common stock in our January 2010 public offering or other past or 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." It is possible that the issuance of shares of our common stock in our January 2010 public offering, together with certain other transactions involving our common stock within the testing period, will result in an ownership change. Even if the issuance of our common stock in our recent offering does not result in an ownership change, this offering would significantly increase the likelihood that there would be an ownership change in the future (which ownership change could occur as a result of transactions involving our common stock that are outside of our control, such as sales by existing stockholders). 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.

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

As a condition of reimbursement by various federal and state healthcare programs for *Feraheme*, we are required to calculate and report certain pricing information to Federal and state healthcare agencies. For example, we are required to provide average selling price information to CMS on a quarterly basis in order to compute Medicare payment rates. Price reporting and payment obligations are highly complex and vary among products and programs. Our processes for estimating amounts due under these governmental pricing programs involve subjective decisions, and 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

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Care Reform Act modified the rules related to certain price reports and expanded the scope of pharmaceutical product sales to which Medicaid rebates apply, 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 or investigation. If we become subject to investigations 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 subject to ongoing regulatory obligations and oversight of Feraheme, and any failure by us to maintain compliance with applicable regulations may result in penalties up to and including the suspension of the manufacturing, marketing and sale of Feraheme, significant additional expense and may limit our ability to commercialize Feraheme.

We are subject to ongoing regulatory requirements and review both in the U.S. and, in some cases, foreign jurisdictions, pertaining to *Feraheme's* manufacture, labeling, packaging, adverse event reporting, storage, marketing, promotion and record keeping. Failure to comply with such regulatory requirements or the later discovery of previously unknown problems with *Feraheme* or our manufacturing facility may result in restrictions on our ability to manufacture, market or sell *Feraheme*, including its withdrawal from the market. Any such restrictions could result in a decrease in *Feraheme* sales, damage to our reputation or the initiation of lawsuits against us. We may also be subject to additional sanctions, including but not limited to:

Warning Letters;

Civil or criminal penalties;

Suspension or withdrawal of regulatory approvals;

Temporary or permanent closing of our manufacturing facilities;

Requirements to communicate with physicians and other customers about concerns related to actual or potential safety, efficacy, or other issues involving *Feraheme;*

Changes to our package insert;

Implementation of an FDA-mandated REMS;

Restrictions on our continued manufacturing, marketing or sale of *Feraheme;* or

Recalls or a refusal by regulators to consider or approve applications for additional indications.

For example, in October 2010, we received a Warning Letter from the Division of Drug Marketing, Advertising, and Communications alleging violations of certain FDA regulations with respect to the *GastroMARK* and *Feraheme* pages of our corporate web site. Although we have addressed the concerns raised in the Warning Letter, there is no guarantee that we will not receive additional warning letters in the future. 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.

If we market or distribute our products 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, we are subject to extensive additional Federal, state and foreign healthcare regulation, which includes but is not limited to, the Federal False Claims Act and the Federal Anti-Kickback Statute. False claims laws prohibit anyone from knowingly

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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. 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 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*, 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 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 by Congress. In addition, as part of the Health Care Reform Act, the federal government has enacted the Physician Sunshine provisions. Beginning in 2013, manufacturers of drugs will be 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. 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 *Feraheme*, harm or prevent sales of *Feraheme*, or substantially increase the costs and expenses of commercializing and marketing *Feraheme,* all of which could have a material adverse effect on our business, financial condition and results of operations.

Our success depends on our ability to attract and retain key employees.

Because of the specialized nature of our business, our success depends to a significant extent on the continued service of our executive officers and on our ability to continue to attract, retain and motivate qualified sales, manufacturing, managerial, scientific, and medical personnel. We have entered into employment agreements with our 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. In addition, in October 2010, as part of an overall corporate workforce reduction, we will reduce our workforce by approximately 24%. This workforce reduction, or any future reduction, could harm our ability to attract and retain qualified key personnel. If we are unable to attract such personnel, or we lose the services of our key personnel for any reason, our *Feraheme* development and commercialization efforts could be adversely impacted.

Furthermore, our expansion into areas and activities requiring additional expertise, such as commercial-scale manufacturing, marketing and sales, and late-stage development has required the addition of new management personnel and the development of additional expertise by existing management personnel. 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

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for the development of our business. Our failure to attract and retain such personnel or to develop such expertise could impose significant limits on our business operations and hinder our ability to successfully and efficiently commercialize *Feraheme* and complete our development projects.

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

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

Our U.S. *Feraheme* patents are currently scheduled to expire in 2020. These and any other patents issued to us may be contested or invalidated. For example, in July 2010, Sandoz GmbH, or Sandoz, filed an opposition to one of our patents which covers *Feraheme* in the EU with the European Patent Office, or EPO. Although we believe that the subject patent is valid, there is a possibility that the EPO could invalidate or require us to narrow the claims contained in our patent. We believe the Sandoz patent opposition is without merit and intend to defend against the opposition vigorously. This or future patent interference proceedings involving our patents may result in substantial costs to us, distract our management, prevent us from marketing and selling *Feraheme*, limit our development and commercialization of *Feraheme* or otherwise harm our ability to commercialize *Feraheme*.

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 costs to us and the distraction of our management. An adverse ruling in any litigation or administrative proceeding could prevent us from marketing and selling *Feraheme*, limit our development and commercialization of *Feraheme*, or 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 injunction, which could prevent 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.

The laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the U.S. In countries where we do not have or have not applied for patents for *Feraheme*, 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.

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 partners, collaborators, 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*, thereby substantially reducing the value of our proprietary rights.

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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, 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, the NASDAQ Global Market or other regulatory authorities.

An adverse determination, if any, in the securities class action lawsuit against us or any other future lawsuits in which we are a defendant, could have a material adverse affect on us.

A purported class action complaint was originally filed on March 18, 2010 in the United States District Court for the District of Massachusetts, entitled Silverstrand Investments v. AMAG Pharm., Inc., et. al., Civil Action No. 1:10-CV-10470-NMG, and was amended on September 15, 2010. The amended complaint alleges that we and our President and Chief Executive Officer, Executive Vice President and Chief Financial Officer, 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 President and Chief Executive Officer and Executive Vice President and Chief Financial Officer violated Section 15 of such Act, respectively, by making certain alleged false and misleading statements and omissions in a registration statement filed in January 2010. The plaintiff seeks 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. The Court has not set a trial date for this matter. We believe that the allegations contained in the complaint are without merit and intend to defend the case vigorously. However, whether or not the plaintiff's claims are 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 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. We maintain liability insurance, however, 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.

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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 humans, whether in clinical trials or after approved commercial usage, may expose us to liability claims, whether or not our products are actually at fault for causing an injury. As *Feraheme* is used over longer periods of time by a wider group of patients taking numerous other medicines or by patients with additional underlying health problems, the likelihood of adverse drug reactions or unintended side effects, including death, may increase. 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 decrease demand for *Feraheme*, 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 our current members of our Board of Directors.

In 2009 we adopted 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 shareholders (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 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 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

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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 Second 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.

We are subject to environmental laws and potential exposure to environmental liabilities.

Because we use certain hazardous materials in the production of our products, we are subject to various federal, state and local environmental laws and regulations that govern our operations, including the import, handling and disposal of non-hazardous and hazardous wastes, and emissions and discharges into the environment. Failure to comply with these laws and regulations could result in costs for corrective action, penalties or the imposition of other liabilities. We also are subject to laws and regulations that impose liability and clean-up responsibility for releases of hazardous substances into the environment. Under certain of these laws and regulations, a current or previous owner or operator of property may be liable for the costs of remediating the release or spill of hazardous substances or petroleum products on or from its property, without regard to whether the owner or operator knew of, or caused, the contamination, and such owner or operator may incur liability to third parties impacted by such contamination. The presence of, or failure to remediate properly the release or spill of, these substances could adversely affect the value of, and our ability to transfer or encumber, our real property.

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ITEM 1B. UNRESOLVED STAFF COMMENTS:

None.

ITEM 2. PROPERTIES:

In May 2008, we entered into a lease agreement for certain real property located at 100 Hayden Avenue, Lexington, Massachusetts for use as our principal executive offices. The term of the lease began on May 22, 2008 and will continue until August 31, 2016 with two successive five year extension terms at our option. The aggregate size of rentable floor area for the offices is 55,924 square feet, and the rent for the initial term commenced in February 2009.

During any extension term, 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 annual operating costs. On May 20, 2008, in connection with our facility lease, we delivered to the landlord a security deposit of approximately $0.5 million in the form of an irrevocable letter of credit. The cash securing this letter of credit is classified on our balance sheet as a long-term asset and is restricted in its use.

Our manufacturing and quality operations are located in a building we own comprised of approximately 25,000 square feet located at 61 Mooney Street, Cambridge, Massachusetts. If we decide to expand our manufacturing capacity, we might not be able to do so on a timely basis, if at all, because the acquisition of, and required regulatory approvals for, additional pharmaceutical manufacturing space can be time-consuming and expensive.

ITEM 3. LEGAL PROCEEDINGS:

On February 11, 2010, we submitted to FINRA Dispute Resolution, Inc. an arbitration claim against our broker-dealer, Jefferies & Company, Inc., or Jefferies, and two former Jefferies employees, Anthony J. Russo, and Robert A. D'Addario, who managed our cash account with Jefferies. We allege that Jefferies, Russo and D'Addario wrongfully marketed and sold a balance of $54.1 million in unsuitable auction rate securities, or ARS, to us from September 2007 through January 2008. We further allege that Jefferies, Russo and D'Addario misrepresented or omitted material facts concerning the nature and risks of ARS, which were inconsistent with our investment objectives to maintain liquidity and flexibility in our portfolio. We primarily seek damages from Jefferies, Russo and D'Addario in the amount of $52.2 million, the total adjusted par value of the ARS that Jefferies, Russo and D'Addario wrongfully marketed and sold to us, plus interest.

A purported class action complaint was originally filed on March 18, 2010 in the United States District Court for the District of Massachusetts, entitled Silverstrand Investments v. AMAG Pharm., Inc., et. al., Civil Action No. 1:10-CV-10470-NMG, and was amended on September 15, 2010. The amended complaint alleges that we and our President and Chief Executive Officer, Executive Vice President and Chief Financial Officer, 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 President and Chief Executive Officer and Executive Vice President and Chief Financial Officer violated Section 15 of such Act, respectively, by making certain alleged false and misleading statements and omissions in a registration statement filed in January 2010. The plaintiff seeks 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. The Court has not set a trial date for this matter. We believe that the allegations contained in the complaint are without merit and intend to defend the case vigorously. We have not recorded an estimated liability associated with this legal proceeding as we do not believe that such a liability is probable and estimable.

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On November 2, 2010, we received a Civil Investigative Demand, or CID, from the U.S. Department of Justice pursuant to the Federal False Claims Act. The CID required the delivery of documents and testimony to the United States Attorney's Office in Boston, Massachusetts, relating to allegations that we caused the submission of false claims to Federal health care programs. In February 2011, the U.S. Department of Justice informed us that it had closed its investigation, that no further investigation is warranted, and that we need not respond further to the CID.

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, 2010.

ITEM 4. [RESERVED]

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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 Market, or NASDAQ, under the trading symbol "AMAG." On February 16, 2011, the closing price of our common stock, as reported on the NASDAQ, was $17.49 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, 2010		
First quarter	$ 52.49	$ 33.29
Second quarter	$ 37.89	$ 29.78
Third quarter	$ 40.00	$ 16.70
Fourth quarter	$ 21.22	$ 13.75
Year Ended December 31, 2009		
First quarter	$ 39.75	$ 22.20
Second quarter	$ 57.19	$ 36.09
Third quarter	$ 58.23	$ 39.24
Fourth quarter	$ 45.14	$ 33.76

Stockholders

On February 16, 2011, we had approximately 103 stockholders of record of our common stock, and we believe that the number of beneficial holders of our common stock was approximately 24,000 based on responses from brokers to a search conducted by Broadridge Financial Solutions, Inc. on our behalf.

Dividends

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

Repurchases of Equity Securities

There were no purchases by us, or any affiliated purchaser of ours, of our equity securities that are registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, during the three months ended December 31, 2010.

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, 2010.

Five-Year Comparative Stock Performance Graph

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 and the NASDAQ Pharmaceutical Index over the past five years. This year we added to our comparison table the

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NASDAQ Biotechnology Index due to our belief that the companies comprising the NASDAQ Biotechnology Index more closely reflect the business characteristics of our company. We will not include the NASDAQ Pharmaceutical Index in next year's performance graph. All periods through October 1, 2007 represented on the graph are as of September 30; thereafter the periods are as of December 31, as we changed our fiscal year end date from September 30 to December 31 in 2007. The comparisons assume $100 was invested on September 30, 2005 in our common stock, in the NASDAQ, the NASDAQ Pharmaceutical Index and the NASDAQ Biotechnology Index, and assumes reinvestment of dividends, if any.

Comparison of Five-Year Cumulative Total Return
Among AMAG Pharmaceuticals, Inc., NASDAQ Global Market, NASDAQ Pharmaceutical Index
and NASDAQ Biotechnology Index

	9/30/05	9/30/06	9/30/07	12/31/07	12/31/08	12/31/09	12/31/10
AMAG Pharmaceuticals, Inc.	$ 100.00	$ 351.18	$ 589.08	$ 619.26	$ 369.21	$ 391.66	$ 186.41
NASDAQ Market Index	$ 100.00	$ 105.94	$ 127.57	$ 125.46	$ 75.24	$ 109.34	$ 129.05
NASDAQ Pharmaceuticals Index	$ 100.00	$ 101.09	$ 111.14	$ 106.10	$ 94.19	$ 104.43	$ 111.38
NASDAQ Biotechnology Index	$ 100.00	$ 96.15	$ 108.98	$ 106.51	$ 93.41	$ 108.32	$ 124.84

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 Morningstar, 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 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 or the Exchange Act, except as otherwise expressly stated in 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, 2010, 2009, 2008 and 2007, the three months ended December 31, 2006, and the year ended September 30, 2006. The information below includes our transition period for the three months ended December 31, 2006 as a result of a change in fiscal year end date from September 30 to December 31 in 2007. 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, 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, and other financial information included elsewhere in this Annual Report on Form 10-K.

	For the Years Ended December 31,				For the Three Months Ended December 31,	For the Year Ended September 30,
	2010	2009	2008	2007	2006	2006
	(in thousands, except per share data)					
Statement of Operations Data						
Revenues:						
Product sales, net	$ 59,978	$ 16,482	$ 751	$ 1,208	$ 353	$ 1,449
License fee and other collaboration revenues	6,132	516	959	1,096	222	907
Royalties	135	180	228	248	44	317
Total revenues	66,245	17,178	1,938	2,552	619	2,673
Costs and expenses:						
Cost of product sales	7,606	1,013	292	320	287	273
Research and development expenses	54,462	36,273	31,716	24,236	6,393	21,294
Selling, general and administrative expenses	84,939	77,829	49,536	20,396	2,197	8,011
Restructuring expenses	2,224					
Total costs and expenses	149,231	115,115	81,544	44,952	8,877	29,578
Other income (expense):						
Interest and dividend income, net	1,741	3,154	9,139	12,506	818	1,575
Gains (losses) on investments, net	408	942	(3,024)			
Fair value adjustment of settlement rights	(788)	(778)	1,566			
Litigation settlement				(4,000)		
Other expense						(35)
Total other income (expense)	1,361	3,318	7,681	8,506	818	1,540
Net loss before income taxes	(81,625)	(94,619)	(71,925)	(33,894)	(7,440)	(25,365)
Income tax benefit	472	1,268	278			
Net loss	$ (81,153)	$ (93,351)	$ (71,647)	$ (33,894)	$ (7,440)	$ (25,365)
Net loss per share basic and diluted:	$ (3.90)	$ (5.46)	$ (4.22)	$ (2.15)	$ (0.60)	$ (2.31)
Weighted average shares outstanding used to compute net loss per share:						

Basic and diluted	20,806	17,109	16,993	15,777	12,383	10,964

	December 31,				
	2010	2009	2008	2007	2006
	(in thousands)				
Balance Sheet Data					
Working capital (current assets less current liabilities)	$ 254,073	$ 85,168	$ 149,918	$ 282,196	$ 149,474
Total assets	$ 336,076	$ 184,619	$ 231,955	$ 294,851	$ 162,342
Long-term liabilities	$ 54,079	$ 4,081	$ 4,149	$ 879	$ 1,688
Stockholders' equity	$ 245,286	$ 142,977	$ 213,414	$ 285,954	$ 152,277

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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 biopharmaceutical company focused on the development and commercialization of a therapeutic iron compound to treat iron deficiency anemia, or IDA. Our principal source of revenue is from the sale of Feraheme® (ferumoxytol) Injection for intravenous, or IV, use, 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 are currently pursuing marketing applications in the European Union, Canada and Switzerland for *Feraheme* for the treatment of IDA in CKD patients.

We market and sell *Feraheme* in the U.S. through our own commercial organization, including a specialized sales force. We began commercial sale of *Feraheme* in July 2009 and sell *Feraheme* primarily to authorized wholesalers and specialty distributors. *Feraheme* is approved for use in the treatment of both dialysis and non-dialysis dependent CKD patients. During 2010, a new prospective payment system for the reimbursement of dialysis services was adopted and became effective on January 1, 2011, which made it less likely that dialysis providers would choose to use *Feraheme* and caused our sales in the dialysis market to begin to decline. As a result, our strategy is primarily focused on growing the utilization of *Feraheme* in non-dialysis dependent CKD patients with IDA in the U.S., specifically in hematology, oncology, nephrology, and hospital sites of care, where a large number of CKD patients are treated.

In November 2010, following discussions with the FDA, we revised the *Feraheme* package insert to include bolded warnings and precautions that describe events that have been reported after *Feraheme* administration in the post-marketing environment, including life-threatening hypersensitivity reactions and clinically significant hypotension. The revised package insert also reflects adverse reactions from post-marketing spontaneous reports and an increase in the recommended observation period following *Feraheme* administration from thirty to sixty minutes to observe patients for signs and symptoms of hypersensitivity. In addition to the changes to the package insert, we agreed to conduct a post-marketing registry study in order to better understand the frequency and timing of adverse events following *Feraheme* administration in the CKD setting. We intend to initiate the registry study during 2011.

Prior to 2009, we devoted substantially all of our resources to our research and development programs. Since the FDA approval and commercial launch of *Feraheme* in mid-2009, we have incurred substantial costs related to the commercialization and development of *Feraheme*. We expect to continue to incur significant expenses to manufacture, market and sell *Feraheme* as an IV iron replacement therapeutic in CKD patients in the U.S., to further develop *Feraheme* for the treatment of IDA in a broad range of patients, and to obtain regulatory approval to market *Feraheme* in countries outside of the U.S. Prior to the commercial launch of *Feraheme*, we financed our operations primarily from the sale of our equity securities, cash generated by our investing activities, and payments from our strategic partners. Since 2009, our revenues have been primarily attributable to product sales of *Feraheme*. We currently expect to fund our future operations from revenue from sales of *Feraheme* in addition to payments from our strategic partners, cash generated by our investing activities, and the sale of our equity securities, if necessary. As of December 31, 2010, we had an accumulated deficit of approximately $362.8 million and our cash, cash equivalents and investments equaled $293.9 million.

Takeda Collaboration

In March 2010, we entered into a License, Development and Commercialization Agreement, or the Takeda Agreement, with Takeda Pharmaceutical Company Limited, or Takeda, under which we

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granted exclusive rights to Takeda to develop and commercialize *Feraheme* as a therapeutic agent in Europe, Asia-Pacific countries (excluding Japan, China and Taiwan), the Commonwealth of Independent States, Canada, India and Turkey, or collectively, the Licensed Territory. Under the Takeda Agreement we were initially responsible for the regulatory application for *Feraheme* in the EU, Switzerland and Canada with Takeda responsible for registrational filings in all other regions covered by the agreement. We have since transferred the *Feraheme* regulatory application in Canada to Takeda, and in August 2010 Takeda filed the *Feraheme* regulatory application in Switzerland.

Clinical Development and Regulatory Status of Feraheme

We continue to advance our *Feraheme* clinical development program in adults by conducting two Phase III multi-center clinical trials to assess *Feraheme* for the treatment of IDA in a broad range of patients for whom treatment with oral iron is unsatisfactory, including women with abnormal uterine bleeding, or AUB, patients with cancer or gastrointestinal diseases and postpartum women. In June 2010, we initiated a double blind, placebo-controlled Phase III study which will assess the efficacy and safety of two doses of 510 milligrams each of *Feraheme* compared to placebo in a total of approximately 800 patients with IDA. We have also initiated an open label, active-controlled Phase III study to assess the efficacy and safety of two doses of 510 milligrams each of *Feraheme* compared to a total dose of 1,000 milligrams of an IV iron sucrose product in a total of approximately 600 patients with IDA. Further, an open label extension study is currently enrolling patients from the placebo-controlled study who will be followed for six months and will be eligible to receive two doses of 510 milligrams each of *Feraheme* whenever they meet treatment criteria. These trials are currently enrolling patients and we expect to complete enrollment in the two Phase III studies by the end of 2011.

To meet our FDA post-approval Pediatric Research Equity Act requirement to support pediatric labeling of *Feraheme*, we intend to initiate two randomized, active-controlled pediatric studies in children with CKD and IDA during 2011. One study will be in dialysis dependent CKD patients, and the other will be in CKD patients not on dialysis. Each study will assess the safety and efficacy of *Feraheme* treatment as compared to oral iron in approximately 144 pediatric patients.

In connection with our responsibilities under the Takeda Agreement, in June 2010 we submitted our Marketing Authorization Application, or MAA, for *Feraheme* for the treatment of IDA in CKD patients with the European Medicines Agency, or EMA. In October 2010, we received a list of questions and requests for information related to the MAA, known as the Day 120 List of Questions, from the EMA's Committee for Medicinal Products for Human Use and have been granted an extension to submit our responses. We expect a decision by the EMA on our MAA submission by the end of 2011. Our Pediatric Investigation Plan, which was approved by the EMA in December 2009, includes two pediatric studies needed to meet the requirements of the Pediatric Research Equity Act in the U.S. and two additional pediatric studies requested by the EMA. To further support our MAA, we have initiated a global, randomized, multi-center, active-controlled post-approval trial with approximately 150 adult CKD patients with IDA, both on dialysis and not on dialysis. This study is currently enrolling patients and will assess the safety and efficacy of two doses of 510 milligrams each of *Feraheme* compared to a total dose of 1,000 milligrams of an IV iron sucrose product. We expect to complete enrollment of this study in 2011.

In addition, as part of our obligations under the Takeda Agreement, we are required to initiate a multi-center post-approval clinical trial to assess the safety and efficacy of repeat, episodic *Feraheme* administration for the treatment of persistent or recurrent IDA over a 12 month period. In this study, subjects would receive an initial course of two doses of 510 milligrams each of *Feraheme* and subsequent courses of two doses of 510 milligrams of *Feraheme* whenever they meet treatment criteria. The study is expected to enroll a total of approximately 300 CKD patients with IDA including hemodialysis and peritoneal dialysis patients and those not on dialysis, including post-kidney transplant recipients.

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In January 2011, we received a Notice of Non-Compliance from the Therapeutic Products Directorate of Health Canada, or Health Canada, regarding our New Drug Submission for *Feraheme* for the treatment of IDA in adult CKD patients. The Notice of Non-Compliance outlined Health Canada's concerns, which focused mainly on chemistry, manufacturing, and control and preclinical toxicology issues. Among other things, Health Canada has requested additional information on polyglucose sorbitol carboxymethylether, or PSC, a material used in the manufacture of *Feraheme*, including information related to pre-clinical safety of PSC and the manufacturing processes and controls related to the incorporation of PSC.

In August 2010, Takeda filed an MAA with Swissmedic, the Swiss Agency for Therapeutic Products, for *Feraheme* for the treatment of IDA in CKD patients. Takeda recently received a list of questions from Swissmedic, and we are currently working with Takeda to evaluate the questions and potential responses.

In December 2009, our partner in China, 3SBio Inc., or 3SBio, filed an application with the Chinese State Food and Drug Administration, or the SFDA, to obtain approval to begin a registrational clinical trial necessary to file for marketing approval in China. If approved by the SFDA, 3SBio plans to commence a multi-center randomized efficacy and safety study in China involving approximately 200 CKD patients.

In mid-2010, we completed enrollment of our Phase II study of *Feraheme* in vascular-enhanced magnetic resonance imaging, or MRI, for the detection of clinically significant arterial stenosis or occlusion, or the narrowing or blocking of arteries. After a commercial review of the imaging market opportunity and an assessment of the development costs that would be required to gain U.S. approval for an imaging indication, we decided to discontinue this program and focus all of our resources on developing *Feraheme* as a therapeutic agent.

Other information

In October 2010, in order to reduce our operating expenses we initiated a corporate restructuring, including a workforce reduction plan, pursuant to which we will reduce our workforce by approximately 24%. As a result of this reduction in our workforce, we recorded restructuring charges of approximately $2.2 million in the fourth quarter of 2010, which consisted of costs related to employee severance, benefits and other related costs. The majority of the workforce reduction was completed by the end of the fourth quarter of 2010 with any remaining positions expected to be eliminated by the end of 2011.

GastroMARK®, our oral contrast agent used for delineating the bowel in MRI, is approved and marketed in the U.S., Europe, and other countries through our marketing partners. Sales of *GastroMARK* by our marketing partners have been at approximately their current levels for the last several years, and we do not expect sales of *GastroMARK* to materially increase.

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 values of investments, reserves for doubtful accounts, accrued expenses, reserves for legal matters, income taxes 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

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accounting policies include revenue recognition and related sales allowances, valuation of investments and equity-based compensation.

Revenue recognition and related sales allowances. We recognize net product sales 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.

We record product sales allowances and accruals related to prompt payment discounts, chargebacks, governmental and other rebates, distributor, wholesaler and group purchasing organizations, 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 blended with historical experience of products similar to *Feraheme* sold by others and other market research. In addition, we also monitor our distribution channel to determine whether additional allowances or accruals are required based on inventory in our sales channel.

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 dialysis organizations, physicians, clinics, hospitals, and GPOs 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. Allowances and accruals are recorded in the same period that the related revenue is recognized and are estimated 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 other products similar to *Feraheme*, specific known market events and trends such as competitive pricing and new product introductions and current and forecasted customer buying patterns and inventory levels, including 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. Reserve estimates are evaluated quarterly and may require adjustments to better align our estimates with actual results. Although allowances and accruals are recorded at the time of product sale, certain rebates are typically paid out, on average, up to six months or longer after the sale. If actual future results vary from our estimates, we may need to adjust our previous estimates, which would affect our earnings in the period of the adjustment.

Classification of Product Sales Allowance and Accruals

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

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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. 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, based on the gross amount of each invoice, at the time of sale. 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.

Governmental and Other Rebates

Governmental 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 market research data related to utilization rates by various end-users and actual *Feraheme* sales data and forecasted customer buying patterns blended with historical experience of products similar to *Feraheme* sold by others. Due to the extended time period between the sale of *Feraheme* and our receipt of the related Medicaid rebate claim, which can be over a year, we currently have limited actual claims payment data, and therefore are not able to solely rely on our actual *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 paid in arrears, and we expect to pay such amounts within several weeks of notification by the Medicaid or provider entity. We adjust the accrual quarterly to reflect actual experience.

Distributor/Wholesaler and Group Purchasing Organization Fees

Fees under our arrangements with distributors and wholesalers are usually based upon units of *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

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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, based on the gross amount of each invoice to the customer, at the time of sale. We adjust the accrual quarterly to reflect actual experience.

Product Returns

Consistent with industry practice, we generally offer our distributors and wholesaler customers a limited right to return product purchased directly from us which is principally based upon the product's expiration date. We currently estimate product returns based upon historical trends in the pharmaceutical industry and trends for products similar to *Feraheme* sold by others. 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.

In addition to the factors discussed above, we consider several additional factors in our estimation process, including our internal sales forecasts and inventory levels in the distribution channel. We expect that wholesalers will not stock significant inventory due to the product's cost and expense to store. Based on the level of inventory in the distribution channel, we determine whether an adjustment to the sales return reserve is appropriate. For example, if levels of inventory in the distribution channel increase and we believe sales returns will be larger than expected, we would adjust the sales return reserve, taking into account historical experience, our returned goods policy and the shelf life of our product, which, once packaged, is currently four years.

If necessary, our estimated rate of returns may be adjusted for historical return patterns as they become available and for known or expected changes in the marketplace. To date, returns and adjustments to our estimated rate of returns have been minimal. If we were to reduce our product returns estimate in the future, doing so would result in increased product sales at the time the return estimate is reduced. If circumstances change or conditions become more competitive in the iron replacement therapy market, we may increase our product returns estimate, which would result in an incremental reduction of product sales at the time the returns estimate is changed. For example, a 1.0% increase in our returns as a percentage of gross sales for the year ended December 31, 2010 would have resulted in approximately a $0.7 million decrease in net product sales.

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 upon 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. This guidance provides that an element of a contract can be accounted for separately if the delivered elements have standalone value and the fair value of any 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 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.

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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 will be 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. Milestones that involve substantive effort on our part and the achievement of which are not considered probable at the inception of the collaboration are considered substantive milestones. We recognize consideration that is contingent upon achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone meets the following criteria: (1) 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; (2) the milestone is related solely to past performance; and (3) 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 are not considered substantive milestones at the onset of the collaboration agreement, 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 a collaboration agreement with Takeda. Under the Takeda Agreement, except under limited circumstances, we have retained the right to manufacture *Feraheme* and, accordingly, are responsible for supply of *Feraheme* to Takeda. 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, which provides for a cap on such costs. In connection with the execution of the Takeda Agreement, we received a $60.0 million upfront payment from Takeda in April 2010, which we initially recorded as deferred revenue. We may also receive a combination of regulatory approval and performance-based milestone payments, reimbursement of certain out-of-pocket regulatory and clinical supply costs, defined payments for supply of *Feraheme,* and tiered double-digit royalties on net product sales by Takeda in the Licensed Territory under the Takeda Agreement. The milestone payments we may be entitled to receive under the agreement could over time equal approximately $220.0 million.

We have determined that the Takeda Agreement includes four deliverables: the license, access to future know-how and improvements to the *Feraheme* technology, regulatory and clinical research services, and the manufacturing and supply of product. Pursuant to the accounting guidance under Accounting Standards Codification 605-25, or ASC 605-25, which governs revenue recognition on

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multiple element arrangements, we have evaluated the four deliverables under the 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, under ASC 605-25, we have concluded that the license is not separable from the undelivered future know-how and technological improvements or the undelivered regulatory and clinical research services. 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.

We have allocated the consideration to be received under the Takeda Agreement based upon a residual value approach for the combined unit of accounting determined at the date on which we entered into the Takeda Agreement. There is significant judgment involved in assessing whether the consideration being received for the supply of *Feraheme* is fair value. In assessing the consideration to be allocated to the supply unit of accounting, we determined that the amount of the consideration allocated to this unit should be based upon the estimated fair value of manufacturing profit to be earned over the expected term of the performance obligation. Based on an analysis of our estimated costs to supply *Feraheme* as well as profit earned by third-party contract pharmaceutical manufacturers, we have determined that the consideration to be received for product supply in addition to the royalties to be received related to those sales represents fair value in return for our supply of product. Therefore, no other consideration under the contract is being allocated to the supply unit of accounting. Of the $220.0 million in potential milestone payments, we have determined that any payments which may become due upon approval by certain regulatory agencies will be deemed substantive milestones and, therefore, will be accounted for as revenue in the period in which they are achieved. All remaining milestone payments will be accounted for in accordance with our revenue attribution method for the upfront payment as defined below.

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 Takeda Agreement. Because we cannot reasonably estimate the total level of effort required to complete the obligations under the combined deliverable, we are recognizing the $60.0 million upfront payment, the $1.0 million reimbursed to us in the year ended December 31, 2010 for certain expenses incurred prior to entering the agreement, as well as any milestone payments that are achieved and not deemed to be substantive milestones into revenues on a straight-line basis over a period of ten years, which represents the current patent life of *Feraheme* and our best estimate of the period over which we will substantively perform our obligations. The potential milestone payments that may be received in the future will be recognized into revenue on a cumulative catch up basis when they become due and payable.

In addition, under the terms of the Takeda Agreement, Takeda is responsible for reimbursing us for certain out-of-pocket regulatory and clinical trial supply costs we incur in the conduct of certain regulatory and clinical research services we perform under the agreement. Because we are acting as the principal in carrying out these services, any reimbursement payments received from Takeda will be 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.

Valuation of investments. The fair value of our investments is generally determined from quoted market prices received from pricing services based upon market transactions. We also have investments in auction rate securities, or ARS, which consist entirely of municipal debt securities backed by student loans and which, prior to 2008, we recorded at cost, which approximated fair market value due to their variable interest rates. Prior to February 2008, these ARS typically reset through an auction process every 7 or 28 days, which generally allowed existing investors to either roll over their holdings and continue to own their securities or liquidate their holdings by selling their securities at par value. In February 2008, our ARS began to experience failed auctions and have continued to experience failed auctions since that time. As a result of the lack of significant observable ARS market activity since

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February 2008, we use a discounted cash flow methodology to value these securities as opposed to valuing them at their par value. Our valuation analysis considers, among other items, assumptions that market participants would use in their estimates of fair value, such as the collateral underlying the security, the creditworthiness of the issuer and any associated guarantees, credit ratings of the security by the major securities rating agencies, the ability or inability to sell the investment in an active market or to the issuer, the timing of expected future cash flows, and the expectation of the next time the security will have a successful auction or when call features may be exercised by the issuer. We believe there are several significant assumptions that are utilized in our valuation analysis, the two most critical of which are the discount rate and the average expected term.

Holding all other factors constant, if we were to increase the discount rate utilized in our valuation analysis by 50 basis points, or one-half of a percentage point, this change would have had the effect of reducing the fair value of our entire ARS portfolio by approximately $0.7 million as of December 31, 2010. Similarly, holding all other factors constant, if we were to increase the average expected term utilized in our fair value calculation by one year, this change would have had the effect of reducing the fair value of our ARS by approximately $1.1 million as of December 31, 2010. We also consider credit ratings with respect to our investments provided by investment ratings agencies. As of December 31, 2010, the majority of our ARS portfolio was rated AAA by at least one of the major securities ratings agencies and all of our investments conformed to the requirements of our investment policy, which requires that, when purchased, all of our investments meet high credit quality standards as defined by credit ratings of the major securities ratings agencies. These ratings are subject to change.

In order to assess whether our investments in debt securities which experience a decline in fair value below amortized cost basis are other-than-temporarily impaired, we evaluate whether (i) we have the intent to sell the security or (ii) 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 there could be a credit loss associated with the security. Factors we consider in making this judgment include, but are not limited to:

the extent to which the market value is less than the cost basis;

the length of time that the market value has been less than the cost basis;

whether the unrealized loss is event-driven, credit-driven or a result of changes in market interest rates or risk premium;

the investment's rating and whether the investment is investment-grade and/or has been downgraded since its purchase;

whether the issuer is current on all payments in accordance with the contractual terms of the investment and is expected to meet all of its obligations under the terms of the investment;

any underlying collateral and the extent to which the recoverability of the carrying value of our investment may be affected by changes in such collateral;

unfavorable changes in expected cash flows; and

other subjective factors.

If we determine from this analysis that we do not expect to receive cash flows sufficient to recover the entire amortized cost of the security, a credit loss exists, 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.

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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 the 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. 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 are 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 are 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 assumed 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.

Impact of Recently Issued and Proposed Accounting Pronouncements

In December 2010, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2010-027, Fees Paid to the Federal Government by Pharmaceutical Manufacturers, or ASU 2010-027. ASU 2010-027 provides guidance concerning the recognition and classification of the new annual fee payable by branded prescription drug manufacturers and importers on branded prescription drugs which was mandated under the health care reform legislation enacted in the U.S. in March 2010. Under this new accounting standard, the annual fee would be presented as a component of operating expenses and recognized over the calendar year such fees are payable using a straight-line method of allocation unless another method better allocates the fee over the calendar year. This ASU is effective for calendar years beginning on or after December 31, 2010, when the fee initially becomes effective, which for us is fiscal 2011. As this standard relates only to classification, the adoption of this accounting standard will not have an impact on our consolidated financial statements.

In January 2010, FASB issued ASU No. 2010-06, Improving Disclosures About Fair Value Measurements, or ASU 2010-06, which amends ASC 820, Fair Value Measurements and Disclosure. ASU 2010-06 requires additional disclosure related to transfers in and out of Levels 1 and 2 and the

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activity in Level 3. This guidance requires a reporting entity to disclose separately the amounts of significant transfers in and out of Level 1 and Level 2 fair value measurements and describe the reasons for the transfers. In addition, this guidance requires a reporting entity to present separately information about purchases, sales issuances, and settlements in the reconciliation for fair value measurements using significant unobservable inputs (Level 3). This accounting standard was effective for interim and annual reporting periods beginning after December 31, 2009 other than for disclosures about purchases, sales, issuances and settlements in the roll forward of activity in Level 3 fair value measurements. Those disclosures will be effective for fiscal years beginning after December 31, 2010 and for interim periods within those fiscal years. We adopted all provisions of this pronouncement during the first quarter of 2010, except for those related to the disclosure of disaggregated Level 3 activity. Since this guidance only amends required disclosures in our consolidated financial statements, it did not have an effect upon our financial position or results of operations. We do not expect the adoption of the remaining provisions of this amendment to have a significant impact on our consolidated financial statements.

In October 2009, the FASB issued ASU No. 2009-13, Multiple-Deliverable Revenue Arrangements, or ASU 2009-13. ASU 2009-13 amends existing revenue recognition accounting pronouncements that are currently within the scope of ASC 605-25 (previously included within Emerging Issues Task Force, or EITF, No. 00-21, Revenue Arrangements with Multiple Deliverables, or EITF 00-21). ASU 2009-13 provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and how the consideration should be allocated. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management's estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. EITF 00-21 previously required that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. This was difficult to determine when the product was not individually sold because of its unique features. Under EITF 00-21, if the fair value of all of the elements in the arrangement was not determinable, then revenue was generally deferred until all of the items were delivered or fair value was determined. This new approach is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, which was January 1, 2011 for us. We do not currently expect the initial adoption of this guidance to have a significant impact on our consolidated financial statements; however, it will likely impact us in the future if we complete any future transactions or if we enter into any material modifications to any of our existing collaborations.

Results of Operations Years Ended December 31, 2010, 2009 and 2008

Revenues

Our revenues for the years ended December 31, 2010, 2009 and 2008 consisted of the following (in thousands):

	Years Ended December 31,			2010 to 2009 change		2009 to 2008 change	
	2010	2009	2008	$ Change	% Change	$ Change	% Change
Product sales, net	$ 59,978	$ 16,482	$ 751	$ 43,496	>100%	$ 15,731	>100%
License fee and other collaboration revenues	6,132	516	959	5,616	>100%	(443)	-46%
Royalties	135	180	228	(45)	-25%	(48)	-21%
Total	$ 66,245	$ 17,178	$ 1,938	$ 49,067	>100%	$ 15,240	>100%

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The $49.1 million increase in our revenues in 2010 as compared to 2009 was primarily attributable to a $43.5 million increase in net product sales, as well as a $5.6 million increase in our license fee and other collaboration revenues. The increase in net product sales was largely due to the fact that 2010 was the first full year during which we marketed and sold *Feraheme* in the U.S. following its FDA approval in mid-2009. The increase in license fee and other collaboration revenues was largely due to revenues associated with the Takeda Agreement, which we entered into in March 2010.

The $15.2 million increase in our revenues in 2009 as compared to 2008 was primarily attributable to a $15.7 million increase in net product sales following the mid-2009 FDA approval and commercial launch of *Feraheme*.

The following table sets forth customers who represented 10% or more of our revenues for the years ended December 31, 2010, 2009 and 2008.

	For the Years Ended December 31,		
	2010	**2009**	**2008**
AmerisourceBergen Drug Corporation	36%	46%	
Metro Medical Supply, Inc.	21%	28%	
Bayer Healthcare Pharmaceuticals	<10%	<10%	53%
Guerbet S.A.	<10%	<10%	24%
Covidien, Ltd.	<10%	<10%	17%

Net Product Sales

Net product sales for the years ended December 31, 2010, 2009 and 2008 consisted of the following (in thousands):

	Years Ended December 31,			2010 to 2009 change		2009 to 2008 change	
	2010	**2009**	**2008**	**$ Change**	**% Change**	**$ Change**	**% Change**
Feraheme	$ 59,339	$ 15,774	$	$ 43,565	>100%	$ 15,774	N/A
GastroMARK	639	708	398	(69)	-10%	310	78%
Feridex I.V. and other			353			(353)	-100%
Total	$ 59,978	$ 16,482	$ 751	$ 43,496	>100%	$ 15,731	>100%

Our total net product sales increased by $43.5 million during the year ended December 31, 2010 as compared to the year ended December 31, 2009. Our net product sales increased primarily because our gross product sales increased by $60.1 million from $22.1 million in 2009 to $82.2 million in 2010. The increase in gross product sales was due to an increase in the total number of *Feraheme* units sold in 2010 as compared to 2009. Approximately $7.6 million of our 2010 gross product sales was related to previously deferred revenues associated with our Launch Incentive Program.

Gross product sales were reduced by $22.2 million and $5.6 million in 2010 and 2009, respectively to account for allowances for governmental and other rebates, discounts and chargebacks, sales returns and wholesaler management fees. This $16.6 million increase in product sales allowances and accruals from 2009 to 2010 reflects greater unit sales of *Feraheme*, higher customer rebates, chargebacks and pricing discounts, and an increase in Medicaid rebates. Medicaid rebates increased due to changes in the scope and amount of Medicaid rebates under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the Health Care Reform Act, which was enacted in March 2010.

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The $15.7 million increase in net product sales for the year ended December 31, 2009 as compared to December 31, 2008 was primarily due to the FDA approval of *Feraheme* on June 30, 2009 and its subsequent U.S. commercial launch.

Our net product sales may fluctuate from period to period as a result of a number of factors, including but not limited to the following:

- wholesaler demand forecasts and buying decisions as well as end-user demand, which can create uneven purchasing patterns by our customers;
- changes or adjustments to our reserves or changes in the timing or availability of government or customer discounts, rebates and incentives;
- changes in the actual or perceived safety profile of *Feraheme*, which could cause customers to reduce or discontinue their use of *Feraheme*; and
- the expansion or contraction of the overall IV iron market.

Our net product sales may also fluctuate from period to period due to the enactment of or changes in legislation that impact third-party reimbursement coverage and pricing. For example, in July 2010, the Centers for Medicare & Medicaid Services published a final rule establishing a new prospective payment system for dialysis services provided to Medicare beneficiaries who have end stage renal disease, which has and will likely continue to alter the utilization of *Feraheme* in this patient population and consequently adversely affect our *Feraheme* sales in the dialysis setting. We began to see the impact of this legislation during 2010 as our sales in the dialysis setting contracted, a trend that we anticipate will continue in the future. As a result of the implementation of the prospective payment system, we expect our dialysis sales for 2011 and beyond will not be significant.

In addition, in March 2010 the Health Care Reform Act was enacted and contains several provisions which impact our business, some of which became effective during 2010, including, but not limited to, the following:

- an increase from 15.1% to 23.1% in the minimum statutory Medicaid rebate to states participating in the Medicaid program;
- an extension of the Medicaid rebate to drugs dispensed to Medicaid beneficiaries enrolled with managed care organizations; and
- an expansion of the 340(B) Public Health Services drug pricing program, which provides drugs at reduced rates, to include additional hospitals, clinics, and healthcare centers in an outpatient setting.

Under the Health Care Reform Act, beginning in 2011, we will incur our share of a new annual fee to be assessed on all branded prescription drug manufacturers and importers. This fee will be calculated based on *Feraheme's* percentage share of total branded prescription drug sales to U.S. government programs (such as Medicare, Medicaid and other related government agency programs) made during the previous year and adjusted based on the amount of *Feraheme* sales. 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, such as the calculation and allocation of the annual fee on branded prescription drugs.

We expect that during 2011 and into the future, our net sales as a percentage of gross sales will continue to be negatively affected as a result of certain aspects of the Health Care Reform Act, specifically, the increase in the minimum Medicaid rebates and the expansion to whom such rebates may potentially apply. It is likely that the effect of this legislation could further adversely impact our future net revenues, however, we are still assessing the full extent of the future impact of this legislation on our business.

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An analysis of our product sales allowances and accruals for the years ended December 31, 2010 and 2009 is as follows (in thousands):

	December 31, 2010	December 31, 2009
Product sales allowances and accruals *		
Discounts and chargebacks	$ 5,113	$ 804
Government and other rebates	15,775	4,329
Returns	1,334	463
Total product sales allowances and accruals	$ 22,222	$ 5,596
Total gross product sales	$ 82,200	$ 22,078
Total product sales allowances and accruals as a percent of total gross product sales	27%	25%

*

We did not have any product sales allowances and accruals for 2008.

An analysis of the amount of, and change in, reserves for the years ended December 31, 2010 and 2009 is as follows (in thousands):

	Discounts	Rebates and Fees	Returns	Total
Balance at January 1, 2009	$	$	$	$
Current provisions relating to sales in current year	804	4,329	463	5,596
Other provisions relating to deferred revenue		1,119		1,119
Adjustments relating to prior years				
Payments/returns relating to sales in current year	(305)	(254)		(559)
Payments/returns relating to sales in prior years				
Other adjustments				
Balance at December 31, 2009	$ 499	$ 5,194	$ 463	$ 6,156
Current provisions relating to sales in current year	5,113	16,374	1,405	22,892
Other provisions relating to deferred revenue		(1,085)		(1,085)
Adjustments relating to sales in prior year		(599)	(71)	(670)
Payments/returns relating to sales in current year	(3,965)	(8,540)		(12,505)
Payments/returns relating to sales in prior year	(499)	(3,126)		(3,625)
Balance at December 31, 2010	$ 1,148	$ 8,218	$ 1,797	$ 11,163

During the year ended December 31, 2010, our product sales allowances and accruals reflected an increase in statutory minimum rebate rates related to Medicaid allowances from 15.1% to 23.1% pursuant to the Health Care Reform Act. In addition, we reduced our product sales allowances and accruals by $0.7 million for changes in estimates relating to sales in the prior year. These adjustments were primarily caused by reductions in our estimates of 2009 Medicaid utilization across *Feraheme* customer classes based on additional data, including information regarding Medicaid claims experience for comparable products and *Feraheme*. Although allowances and accruals are recorded at the time of product sale, certain rebates are typically paid out, on average, up to six months or longer after the sale. If actual future results vary from our estimates, we may need to adjust our previous estimates, which would affect our earnings in the period of the adjustment.

There are several factors that make it difficult to predict future changes in our sales allowances and accruals as a percentage of gross product sales including, but not limited to, the following:

- variations in, and the success of pricing, fee, rebate and discount structures implemented in our efforts to increase adoption of *Feraheme*;

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variations in our customer mix;

changes in legislation, such as the Health Care Reform Act or any future healthcare legislation; and

adjustments and refinements to our prior estimates and assumptions.

Overall, we expect that our reserves as a percent of gross sales will increase during 2011 due primarily to our efforts to increase adoption and utilization of *Feraheme*, our efforts to address continuing reimbursement and competitive pricing pressures, as well as the expected customer mix and utilization rates, all of which will negatively affect our future average per unit net product sales.

Because *Feraheme* has been commercialized in the U.S. for a relatively short period of time, there are a number of factors that continue to make it difficult to predict the magnitude of future *Feraheme* sales, including but not limited to, the magnitude and timing of adoption of *Feraheme* by physicians, hospitals, and other healthcare payors and providers, the effect of federal and other legislation such as the Health Care Reform Act, the inventory levels maintained by *Feraheme* wholesalers, distributors and other customers, the frequency of re-orders by existing customers, the impact of any actual or perceived safety issues with *Feraheme*, the impact of our recently amended package insert or any potential additional warnings, restrictions, or other changes required to be made to the *Feraheme* package insert, and 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*. 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 previous quarters may not be indicative of future *Feraheme* net product revenues.

Deferred Revenue Launch Incentive Program

During the third quarter of 2009 certain dialysis organizations purchased *Feraheme* from us under our Launch Incentive Program. These purchases were made under agreements which provided these customers with an opportunity to purchase *Feraheme* directly from us through September 30, 2009 at discounted pricing and further provided for extended payment terms and expanded rights of return. As a result, in accordance with current accounting guidance which requires that we defer recognition of revenues until we can reasonably estimate returns related to those purchases, we have deferred the recognition of revenues associated with these purchases until our customers report to us that such inventory has been utilized in their operations.

Any purchases made under the Launch Incentive Program that are returned to us will not be recorded as revenue, and, if necessary, we will issue a refund to the customer. For example, during 2010, one of our Launch Incentive Program customers returned to us the majority of its remaining unused inventory in accordance with the terms of our agreement with the customer. This return had no impact on our net product sales as we reduced the deferred revenues and remaining receivable related to this returned inventory and issued a refund of approximately $1.1 million to this customer.

As of December 31, 2010, we had approximately $0.5 million in remaining deferred revenue related to customers who participated in the Launch Incentive Program and as a result, we do not expect to recognize significant revenues related to this program in 2011. In addition, we are not able to reasonably estimate any additional amounts of inventory that may be returned to us under this program and therefore cannot provide any assurance that any of this remaining deferred revenue will be recorded as product revenues in our future consolidated statements of operations.

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License Fee and Other Collaboration Revenues

License fee and other collaboration revenues for the years ended December 31, 2010, 2009 and 2008 consisted of the following (in thousands):

	Years Ended December 31,			2010 to 2009 change		2009 to 2008 change	
	2010	2009	2008	$ Change	% Change	$ Change	% Change
Deferred license fee revenues recognized in connection with the Takeda Agreement	$ 4,572	$	$	$ 4,572	N/A	$	
Reimbursement revenues recognized in connection with the Takeda Agreement	1,560			1,560	N/A		
Deferred license fee revenues recognized in connection with the Bayer Agreements		516	959	(516)	-100%	(443)	-46%
Total	$ 6,132	$ 516	$ 959	$ 5,616	>100%	$ (443)	-46%

All of our license fee and other collaboration revenues for the year ended December 31, 2010 related to revenue recognized under the Takeda Agreement, which we entered into in March 2010. Under the Takeda Agreement, we granted exclusive rights to Takeda to develop and commercialize *Feraheme* as a therapeutic agent in the Licensed Territory. During the year ended December 31, 2010, we recorded $4.6 million of revenues associated with the amortization of $61.0 million of deferred revenues recorded in connection with the Takeda Agreement. The $61.0 million of deferred revenues was comprised of a $60.0 million upfront payment which we received from Takeda in April 2010, 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.

In addition, under the terms of the Takeda Agreement, Takeda is responsible for reimbursing us for certain out-of-pocket regulatory and clinical trial supply costs we incur in the conduct of certain regulatory and clinical research services we perform under the agreement. Because we are acting as the principal in carrying out these activities, any reimbursement payments received from Takeda will be 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. During the year ended December 31, 2010, we recorded $1.5 million of revenues associated with the reimbursement of certain out-of pocket regulatory and clinical supply costs.

Our license fee revenues of $0.5 million and $1.0 million for the years ended December 31, 2009 and 2008, respectively, consisted solely of deferred license fee revenues that were being amortized through the end of our performance obligations in connection with our agreements with Bayer Healthcare Pharmaceuticals, or Bayer, which were terminated in November 2008, relating to Feridex I.V.®, a product we no longer manufacture or sell. In 1995, we entered into a License and Marketing Agreement and a Supply Agreement, or the Bayer Agreements, with Bayer, granting Bayer a product license and exclusive marketing rights to *Feridex I.V.* in the U.S. and Canada. In connection with our decision to cease manufacturing *Feridex I.V.*, the Bayer Agreements were terminated in November 2008 by mutual agreement. Prior to the termination of the Bayer Agreements, we accounted for the revenues associated with the Bayer Agreements on a straight-line basis over their 15 year contract term. Pursuant to the termination agreement, Bayer could continue to sell any remaining *Feridex I.V.* inventory in its possession through April 1, 2009. As a result of the termination of these agreements, we do not expect any additional license fee revenues from Bayer.

In May 2008, we entered into a Collaboration and Exclusive License Agreement, or the 3SBio License Agreement, with 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 and is being recognized

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under the proportional performance methodology as we supply *Feraheme* to 3SBio over the thirteen year initial term of the agreement. We did not record any revenues associated with our agreement with 3SBio during the years ended December 31, 2010, 2009 or 2008 and we do not expect license fee revenues under this agreement to be significant in 2011.

Costs and Expenses

Cost of Product Sales

We incurred costs of $7.6 million and $1.0 million in cost of product sales, or 13% and 6% of net product sales, during the years ended December 31, 2010 and 2009, respectively, which were comprised primarily of manufacturing costs associated with *Feraheme*. The $6.6 million increase in our cost of product sales was attributable to a number of factors including an increase in the average per unit cost to manufacture *Feraheme* due to higher general production costs, as well as an increase in the total number of units sold during 2010 as compared to 2009. In addition, the increase in cost of product sales was partially due to certain idle capacity costs at our Cambridge, Massachusetts manufacturing facility which resulted from reduced production activity caused by our alignment of production volumes during the second half of 2010 with current and expected *Feraheme* sales levels. Lastly, our per unit production costs were higher in 2010 as compared to 2009 because a larger portion of the costs of *Feraheme* sold during 2009 had been previously expensed to research and development as a result of our policy to expense costs associated with the manufacture of our products prior to the June 2009 FDA approval of *Feraheme*.

For the years ended December 31, 2009 and 2008, we incurred costs of $1.0 million and $0.3 million in cost of product sales, or 6% and 39% of net product sales, respectively. This increase in costs during 2009 was principally related to manufacturing costs associated with *Feraheme* product sales which began in July 2009.

We expect our cost of product sales as a percentage of net product sales to increase in 2011 as we expense certain idle capacity costs resulting from reduced internal production activity and as we transition to a supply chain that includes contract manufacturing capabilities. In addition, decreases in net product sales recognized, on a per unit basis, as well as general increases in manufacturing costs may also result in increases in our cost of product sales as a percentage of net product sales in 2011.

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, 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 June 2009 regulatory approval of *Feraheme*, costs associated with manufacturing process development and the manufacture of drug product were recorded as research and development expenses. Subsequent to FDA approval, costs associated with the manufacture of *Feraheme* for commercial sale in the U.S. are capitalized and recorded as cost of product sales when sold.

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Research and development expenses for the years ended December 31, 2010, 2009 and 2008 consisted of the following (in thousands):

	Years Ended December 31,			2010 to 2009 change		2009 to 2008 change	
	2010	2009	2008	$ Change	% Change	$ Change	% Change
External Research and Development Expenses							
Feraheme to treat IDA regardless of the underlying cause	$ 17,132	$ 797	$	$ 16,335	>100%	$ 797	N/A
Feraheme to treat IDA in CKD patients	11,003	346		10,657	>100%	346	N/A
Feraheme as a therapeutic agent in AUB patients		1,131	2,383	(1,131)	-100%	(1,252)	-53%
Feraheme as a therapeutic agent, general	799	4,331	1,601	(3,532)	-82%	2,730	>100%
Feraheme as an imaging agent	2,483	2,524	1,643	(41)	-2%	881	54%
Feraheme manufacturing process development and materials	3,059	2,929	4,591	130	4%	(1,662)	-36%
Other external costs	763	1,133	1,025	(370)	-33%	108	11%
Total	$ 35,239	$ 13,191	$ 11,243	$ 22,048	>100%	$ 1,948	17%
Internal Research and Development Expenses							
Compensation, payroll taxes, benefits and other expenses	15,715	18,636	16,713	(2,921)	-16%	1,923	12%
Equity-based compensation expense	3,508	4,446	3,760	(938)	-21%	686	18%
Total	$ 19,223	$ 23,082	$ 20,473	$ (3,859)	-17%	$ 2,609	13%
Total Research and Development Expenses	$ 54,462	$ 36,273	$ 31,716	$ 18,189	50%	$ 4,557	14%

2010 as compared to 2009

Total research and development expenses incurred in the year ended December 31, 2010 increased by $18.2 million, or 50%, from the year ended December 31, 2009 due to a significant increase in our external research and development expenses, partially offset by a decrease in our internal research and development expenses.

Our external research and development expenses increased by $22.0 million, or greater than 100%, for the year ended December 31, 2010 as compared to the year ended December 31, 2009. The increase in our external expenses was due primarily to costs incurred in connection with our Phase III clinical development program for *Feraheme* to treat IDA regardless of the underlying cause, which was initiated in June 2010, and costs associated with our global clinical study to support our MAA in Europe for the treatment of IDA in CKD patients, including costs incurred to prepare for certain of our planned pediatric studies. These increases were partially offset by certain costs incurred during 2009, which were not incurred during 2010, including costs associated with our efforts to address the manufacturing observations noted by the FDA during a 2008 inspection of our Cambridge, Massachusetts manufacturing facility and costs associated with our then-planned clinical trial for *Feraheme* in patients with AUB, which was discontinued in 2009.

Our internal research and development expenses decreased by $3.9 million, or 17%, for the year ended December 31, 2010 as compared to the year ended December 31, 2009. The decrease in internal costs was due primarily to reduced compensation-related costs in 2010 resulting from the allocation of internal manufacturing costs to inventory during the full year of 2010, whereas such costs were expensed prior to the June 2009 FDA approval of *Feraheme*, as well as reductions in accrued and other compensation-related costs primarily due to our October 2010 restructuring. The decrease in internal costs was also attributable in part to a reduction of equity-based compensation expense due to the effects of our restructuring as well as our application of a higher forfeiture rate in 2010 as compared to 2009 resulting from our routine annual analysis of our historical forfeiture experience.

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2009 as compared to 2008

Total research and development expenses incurred during the year ended December 31, 2009 increased by $4.6 million, or 14%, from the year ended December 31, 2008 due to increases in both our external and internal research and development expenses.

Our external research and development expenses increased by $1.9 million, or 17%, for the year ended December 31, 2009 as compared to the year ended December 31, 2008. The increase in our external expenses was due primarily to costs incurred in the first half of 2009 in connection with our efforts to address the manufacturing observations noted by the FDA during a 2008 inspection of our Cambridge, Massachusetts manufacturing facility. In addition, during 2009 we began preparations for our Phase III clinical development program for *Feraheme* to treat IDA regardless of the underlying cause and progressed our Phase II study of *Feraheme* as a diagnostic agent for vascular-enhanced MRI for the assessment of peripheral arterial disease. These increased external research and development expenses were partially offset by the capitalization to inventory of certain external *Feraheme* manufacturing and materials costs as well as reduced costs in 2009 related to the development of alternative manufacturing sources. In addition, during 2008, we incurred costs related to our then intended *Feraheme* clinical development program in patients with AUB, which was discontinued in early 2009.

Our internal research and development expenses increased by $2.6 million, or 13%, for the year ended December 31, 2009 as compared to the year ended December 31, 2008. The increase in internal costs was due primarily to higher compensation and benefits costs as a result of additional research and development personnel hired as we expanded our development infrastructure and scaled-up our manufacturing capabilities in preparation for the mid-2009 U.S. commercial launch of *Feraheme,* partially offset by the mid-year commencement of the capitalization to inventory of internal costs associated with the manufacture of *Feraheme*, including certain manufacturing personnel-related compensation, payroll taxes, benefits and other expenses. At December 31, 2009, we had 52 full-time equivalents, or FTEs, in research and development as compared to 86 FTEs at December 31, 2008, a decrease of 40% due primarily to the reallocation of manufacturing personnel out of research and development following FDA approval of *Feraheme* in June 2009. The $0.7 million increase in equity-based compensation expense was primarily attributable to increased equity awards to both new and existing employees.

Research and Development Activities

We expect research and development expenses to continue to increase in 2011 as compared to 2010 primarily due to our continued advancement of our clinical development programs, including studies and activities required under the Takeda Agreement, as well as other miscellaneous research and development related activities in support of our *Feraheme* development programs. Factors which will impact 2011 research and development expenses include the design, timing and pace of enrollment of our clinical trials for *Feraheme,* including our development program for *Feraheme* in a broad range of patients with IDA, the safety and efficacy trial of repeat, episodic *Feraheme* administration for the treatment of persistent or recurrent IDA, and our pediatric studies of *Feraheme,* as well as our proposed registry study.

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 by 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

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regulatory filing to the FDA or applicable foreign regulatory body. The following two major research and development projects are currently ongoing:

Feraheme to treat IDA regardless of the underlying cause. This project currently includes: (1) a Phase III clinical study evaluating *Feraheme* treatment compared to treatment with placebo; (2) a Phase III clinical study evaluating *Feraheme* treatment compared to treatment with another IV iron; and (3) an extension study.

Feraheme to treat IDA in CKD patients. This project currently includes: (1) an on-going post-approval clinical study evaluating *Feraheme* treatment compared to treatment with another IV iron to support our MAA submission; (2) two pediatric studies to be conducted as part of our post-approval Pediatric Research Equity Act requirement to support pediatric CKD labeling of *Feraheme*; (3) two additional pediatric studies to be conducted in accordance with our approved Pediatric Investigation Plan to support our MAA submission; and (4) a multi-center post-approval clinical trial to be conducted to assess the safety and efficacy of repeat, episodic *Feraheme* administration for the treatment of persistent or recurrent IDA over a 12 month period.

Through December 31, 2010, we have incurred aggregate external research and development expenses of approximately $17.9 million related to our current program for the development of *Feraheme* to treat IDA regardless of the underlying cause. We currently estimate that the total remaining external costs associated with the efforts needed to complete this development project will be in the range of approximately $40.0 to $50.0 million over approximately the next two years. This represents a decrease of approximately $5.2 from our expected range at September 30, 2010, which primarily reflects actual expenses incurred during the quarter ended December 31, 2010 in connection with this project.

Through December 31, 2010, we have incurred aggregate external research and development expenses of approximately $11.3 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 $40.0 to $50.0 million over the next several years. This represents a decrease of approximately $3.3 million from our expected range at September 30, 2010, which primarily reflects actual expenses incurred during the quarter ended December 31, 2010 in connection with this project.

We are also planning to conduct a post-marketing registry study in order to better understand the frequency and timing of adverse events following *Feraheme* administration in the CKD setting. We intend to initiate the registry study during 2011. However, until we complete our discussions with the FDA and finalize the design of the proposed registry study, we cannot estimate the cost associated with this study.

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, any adverse regulatory action or any delay in the submission of any applicable regulatory filing. As a result, we are unable to reasonably estimate the specific timing of any expected net cash inflows resulting from these projects.

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Selling, General and Administrative Expenses

Our selling, general and administrative expenses include costs related to our commercial personnel, including our specialized sales force, medical education professionals, and other commercial support personnel, administrative personnel costs, external and facilities costs required to support the marketing and sale of *Feraheme* and other costs associated with our corporate-related activities.

Selling, general and administrative expenses for the years ended December 31, 2010, 2009 and 2008 consisted of the following (in thousands):

	Years Ended December 31,			2010 to 2009 change		2009 to 2008 change	
	2010	2009	2008	$ Change	% Change	$ Change	% Change
Compensation, payroll taxes and benefits	$ 35,274	$ 33,447	$ 17,292	$ 1,827	5%	$ 16,155	93%
Professional and consulting fees and other expenses	39,091	33,450	27,967	5,641	17%	5,483	20%
Equity-based compensation expense	10,574	10,932	4,277	(358)	-3%	6,655	>100%
Total	$ 84,939	$ 77,829	$ 49,536	$ 7,110	9%	$ 28,293	57%

The $7.1 million, or 9%, increase in selling, general and administrative expenses for the year ended December 31, 2010 as compared to the year ended December 31, 2009 was due primarily to increased professional and consulting fees and other expenses in 2010. The increase in professional and consulting fees was primarily driven by increased costs associated with consulting and data acquisition fees in support of our commercialization of *Feraheme*. In addition, during 2010 we incurred significantly higher legal and other consulting and professional fees in connection with the securities class action lawsuit, which was filed against us in March 2010, our Takeda collaboration and a number of other one-time legal matters. The increase in total selling, general and administrative expenses was also due in part to an increase in compensation-related costs incurred to support the commercialization of *Feraheme*, including costs associated with a greater average headcount and annual salary increases, partially offset by a reduction in accrued and other compensation-related costs primarily due to our October 2010 restructuring. At December 31, 2009, we had 178 employees in our selling, general and administrative departments. During the first ten months of 2010, we increased our headcount in these departments by approximately 10%. However, in connection with our October 2010 corporate restructuring, we reduced the headcount to 154 employees in our selling, general and administrative departments at December 31, 2010.

The $0.4 million decrease in equity-based compensation expense was primarily due to the effects of our restructuring as well as the application of a higher forfeiture rate to our equity-based compensation in 2010 as compared to 2009, resulting from our routine annual analysis of our historical forfeiture experience. These decreased equity-based compensation expenses were partially offset by expenses associated with incremental equity awards to both new and existing employees.

The $28.3 million, or 57%, increase in selling, general and administrative expenses for the year ended December 31, 2009 as compared to the year ended December 31, 2008 was due primarily to increased costs associated with the expansion of our commercial operations function and our general administrative infrastructure to support our growth as a commercial entity, including compensation and benefits costs related to increased headcount and increased advertising and promotion costs associated with the July 2009 U.S. commercial launch of *Feraheme*. At December 31, 2009, we had 178 employees in our selling, general and administrative departments as compared to 170 employees at December 31, 2008, a 5% increase. The $16.2 million increase in compensation and benefits costs reflected costs associated with a full scale organization in 2009 as compared to our 2008 compensation and benefits costs, which reflected significantly lower costs associated with, among other things, a lower average headcount. Of the $6.7 million increase in equity-based compensation expense, $4.3 million was due primarily to 2009 grants of equity awards to both new and existing employees. In addition, during 2008

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we reversed approximately $2.4 million of previously recorded expense associated with performance-based stock options granted to certain of our executive officers in 2007 because the underlying performance condition was not met.

We expect total selling, general and administrative expenses will be less in 2011 as compared to 2010.

Restructuring Expense

In October 2010, in order to reduce our operating expenses we initiated a corporate restructuring, including a workforce reduction plan, pursuant to which we will reduce our workforce by approximately 24%. The majority of the workforce reduction was completed during the three months ended December 31, 2010, and we expect the remaining positions to be eliminated by the end of 2011. We recorded restructuring charges of $2.2 million during the year ended December 31, 2010 consisting of approximately $2.1 million related to employee severance benefits and approximately $0.1 million related to other charges. These expenses are expected to be substantially paid by the end of 2011.

Other Income (Expense)

Other income (expense) for the years ended December 31, 2010, 2009 and 2008 consisted of the following (in thousands):

	Years Ended December 31,			2010 to 2009 change		2009 to 2008 change	
	2010	2009	2008	$ Change	% Change	$ Change	% Change
Interest and dividend income, net	$ 1,741	$ 3,154	$ 9,139	$ (1,413)	-45%	$ (5,985)	-65%
Gains (losses) on investments, net	408	942	(3,024)	(534)	-57%	3,966	<(100)%
Fair value adjustment of settlement rights	(788)	(778)	1,566	(10)	1%	(2,344)	<(100)%
Total	$ 1,361	$ 3,318	$ 7,681	$ (1,957)	-59%	$ (4,363)	-57%

Other income (expense) for the year ended December 31, 2010 decreased by $2.0 million, or 59%, as compared to the year ended December 31, 2009. The $2.0 million decrease was primarily attributable to a $1.4 million decrease in interest and dividend income as a result of lower average interest rates earned in 2010 as compared to 2009 due to our maintaining higher average investment balances in high quality but lower interest bearing, and shorter duration, U.S. government backed money market and debt securities. In addition, during 2010, we recognized a $0.4 million realized loss related to one of our ARS investments which we elected to redeem in a tender offer from the issuer in October 2010. Accordingly, during the year ended December 31, 2010, we recorded an other-than-temporary impairment of $0.4 million in our consolidated statement of operations.

Other income (expense) for the year ended December 31, 2009 decreased by $4.4 million, or 57%, compared to the year ended December 31, 2008. The $4.4 million decrease was primarily attributable to a $6.0 million decrease in interest and dividend income as the result of a lower average amount of invested funds and lower interest rates in the year ended December 31, 2009 as compared to the year ended December 31, 2008, partially offset by the recognition of $1.3 million in realized losses during 2008 that did not recur during 2009.

In November 2008, we elected to participate in a rights offering by UBS AG, or UBS, which provided us with rights to sell to UBS $9.3 million in par value of our ARS at par value, at any time during a two-year sale period beginning June 30, 2010, or the Settlement Rights. In accordance with current accounting guidance related to the fair value option for financial assets and financial liabilities, as of December 31, 2009 we recorded an asset of approximately $0.8 million, the estimated fair value of the Settlement Rights, in our consolidated balance sheet. This represented a decrease of approximately $0.8 million from the estimated fair value of our Settlement Rights as of December 31, 2008, which we recorded in other income (expense) in our 2009 consolidated statement of operations.

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These Settlement Rights were exercised during 2010. In addition, with the opportunity provided by the Settlement Rights, we designated the ARS subject to the Settlement Rights with a par value of $9.3 million and an estimated fair value of $8.5 million as of December 31, 2009 as trading securities. Accordingly, as of December 31, 2009, we adjusted our estimated value of these trading securities by approximately $0.9 million from the estimated value as of December 31, 2008, which we recorded as a gain on investments in other income (expense) in our 2009 consolidated statement of operations. In accordance with the terms of the Settlement Rights, in June 2010 UBS redeemed all of our ARS subject to Settlement Rights at their par value. As a result, during the year ended December 31, 2010 we recognized both a realized gain of $0.8 million related to the redemption of our UBS ARS subject to Settlement Rights and a corresponding realized loss of $0.8 million related to the exercise of the Settlement Rights.

We expect interest and dividend income to remain generally consistent with current levels during 2011 as a result of the low interest rate environment and our continued investment of our excess cash balances in high quality U.S. government backed money-market and debt securities.

Income Tax Benefit

We recognized an income tax benefit of $0.5 million and $1.1 million during the years ended December 31, 2010 and 2009, respectively, which were the result of our recognition of a corresponding income tax expense associated with the increase in the value of certain securities that we carried at fair market value during the years ended December 31, 2010 and 2009. This income tax expense was recorded in other comprehensive income. There were no similar income tax benefits or provisions for the year ended December 31, 2008. In addition, during 2009 and 2008, we recognized $0.2 million and $0.3 million in income tax benefits, respectively, associated with U.S. research and development tax credits against which we had previously provided a full valuation allowance, but which became refundable as a result of legislation passed in each year.

Net Loss

For the reasons stated above, we incurred a net loss of $81.2 million, $93.4 million and $71.6 million, or $3.90, $5.46 and $4.22 per basic and diluted share, for the years ended December 31, 2010, 2009 and 2008, respectively.

Liquidity and Capital Resources

General

We finance our operations primarily from the sale of *Feraheme*, payments from our strategic partners, cash generated from our investing activities, and the sale of our common stock. We expect to continue to incur significant expenses to manufacture, market and sell *Feraheme* as an IV iron replacement therapeutic in CKD patients in the U.S., to further develop *Feraheme* for the treatment of IDA in a broad range of patients, and to obtain regulatory approval to market *Feraheme* in countries outside of the U.S. 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.;

The magnitude of *Feraheme* sales;

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

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

Costs associated with our development of *Feraheme* for the treatment of IDA in a broad range of patients in the U.S.;

Costs associated with our pursuit of approval for *Feraheme* outside of the U.S.;

Costs associated with commercial-scale manufacturing of *Feraheme*, including costs of raw or other materials and costs associated with maintaining commercial inventory and qualifying additional manufacturing capacities and alternative suppliers;

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

Our ability to liquidate our investments in ARS in a timely manner and without significant loss;

The impact of the current state of the credit and capital markets on our investments;

Our ability to maintain successful collaborations with our partners 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.

As of December 31, 2010, our investments consisted of corporate debt securities, U.S. treasury and government agency securities, commercial paper and ARS. We place our cash and investments 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 from a domestic non-U.S. government entity 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, 2010 and 2009 consisted of the following (in thousands):

	December 31,			
	2010	2009	$ Change	% Change
Cash and cash equivalents	$ 112,646	$ 50,126	$ 62,520	>100%
Short-term investments	147,619	29,578	118,041	>100%
Long-term investments	33,597	49,013	(15,416)	-31%
Total	$ 293,862	$ 128,717	$ 165,145	>100%

The $165.1 million increase in cash, cash equivalents and investments as of December 31, 2010 as compared to December 31, 2009 is primarily due to our receipt of net proceeds of $165.6 million from our January 2010 public offering, the $60.0 million upfront payment received in April 2010 from Takeda, cash received from *Feraheme* sales, and interest income, partially offset by cash used in operations.

We expect that during 2011 our cash balance will decline as we continue to invest in the development and commercialization of *Feraheme*. We believe that our cash, cash equivalents, and short-term investments as of December 31, 2010 and the cash we currently expect to receive from sales of *Feraheme* and earnings on our investments will be sufficient to satisfy our cash flow needs for at least the next twelve months, including projected operating expenses related to our ongoing development and commercialization programs for *Feraheme*.

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In February 2008, our ARS began to experience failed auctions and have continued to experience failed auctions since that time. As a result of the lack of significant observable ARS market activity since February 2008, we use a discounted cash flow methodology to value these securities as opposed to valuing them at their par value. Our valuation analysis considers, among other items, assumptions that market participants would use in their estimates of fair value, such as the collateral underlying the security, the creditworthiness of the issuer and any associated guarantees, credit ratings of the security by the major securities rating agencies, the ability or inability to sell the investment in an active market or to the issuer, the timing of expected future cash flows, and the expectation of the next time the security will have a successful auction or when call features may be exercised by the issuer. We believe we will ultimately be able to liquidate our investments in ARS without significant loss prior to their maturity dates primarily due to the collateral securing most of our ARS. However, it could take until final maturity of the ARS to realize our investments' par value. In the event that we need to access our investments in these securities, we will not be able to do so until a future auction is successful, the issuer calls the security pursuant to a mandatory tender or redemption prior to maturity, a buyer is found outside the auction process, or the securities mature.

As of December 31, 2010, we held a total of $33.6 million in fair market value of ARS, reflecting a decline of approximately $6.0 million compared to the par value of these securities of $39.6 million. As of December 31, 2010, all of our ARS were municipal bonds with an auction reset feature and were classified as available-for-sale. The majority of our ARS portfolio was rated AAA as of December 31, 2010 by at least one of the major securities rating agencies and was primarily collateralized by student loans substantially guaranteed by the U.S. government under the Federal Family Education Loan Program. As of December 31, 2010, all of our ARS continue to pay interest according to their stated terms.

The ongoing uncertainty in the global financial markets has had an adverse impact on financial market activities world-wide, resulting in, among other things, volatility in security prices, diminished liquidity and credit availability, ratings downgrades of certain investments and declining valuations of others. Although we invest our excess cash in investment grade securities, there can be no assurance that changing circumstances will not affect our future financial position, results of operations or liquidity.

Year Ended December 31, 2010

Cash flows from operating activities

During the year ended December 31, 2010, our use of $1.5 million of cash in operations was attributable principally to our net loss of approximately $81.2 million, adjusted for the following:

The receipt of $60.0 million in upfront payments we received from Takeda during 2010;

A decrease of $9.5 million in accounts receivable, excluding the change in receivables generated from our Launch Incentive Program;

$8.9 million we received in connection with *Feraheme* sales deferred under our Launch Incentive Program;

Additional costs of $6.7 million capitalized to inventory as of December 31, 2010;

An increase of $2.7 million in accounts payable and accrued expenses, including an increase of $4.4 million of reserves for commercial discounts, rebates and returns; and

Non-cash operating items of $18.5 million including equity-based compensation expense, depreciation, income tax benefit, and other non-cash items.

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Our net loss of $81.2 million was primarily the result of commercialization expenses, including marketing and promotion costs, compensation and other expenses, research and development costs, including costs associated with clinical trials, and general and administrative costs, partially offset by net product and collaboration revenues.

Cash flows from investing activities

Cash used in investing activities was $103.7 million during 2010 and was primarily attributable to the net purchase of investments, including the use of proceeds received from our January 2010 public offering of common stock.

Cash flows from financing activities

Cash provided by financing activities was $167.8 million in 2010. In January 2010, we sold 3.6 million shares of our common stock at a public offering price of $48.25 per share, which resulted in net proceeds to us of approximately $165.6 million.

Year Ended December 31, 2009

Cash flows from operating activities

During the year ended December 31, 2009, our use of $90.7 million of cash in operations was due principally to our net loss of approximately $93.4 million adjusted for the following:

Additional costs of $9.1 million capitalized to inventory as of December 31, 2009;

An increase of $14.9 million in accounts receivable, excluding receivables generated from our Launch Incentive Program;

An increase of $13.2 million in accounts payable and accrued expenses, including an increase of $5.7 million of reserves for commercial discounts and rebates; and

Non-cash operating items of $16.6 million including equity-based compensation expense, depreciation, income tax benefit, and other non-cash items.

Cash flows from investing activities

Cash provided by investing activities was $71.5 million in 2009 and was primarily attributable to net proceeds from sales and maturities of our investments.

Cash flows from financing activities

Cash provided by financing activities was $5.2 million in 2009 and was primarily attributable to the proceeds from the exercise of stock options as well as proceeds from the issuance of common stock under our Employee Stock Purchase Plan.

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

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purchase obligations. Future lease obligations and purchase commitments, as of December 31, 2010, are as follows (in thousands):

	Payment due by period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease obligations, excluding facility lease	$ 420	$ 334	$ 86	$	$
Facility lease obligations	12,103	2,043	4,164	4,340	1,556
Purchase commitments	3,200	3,040	160		
Total	$ 15,723	$ 5,417	$ 4,410	$ 4,340	$ 1,556

Operating and Facility Lease Obligations

We have entered into certain operating leases, including leases of certain automobiles and certain laboratory and office equipment which expire through 2012. We lease approximately 100 automobiles for our field-based employees. This lease requires an initial minimum lease term of 12 months per automobile. We are responsible for certain disposal costs in the event of termination of the lease.

In May 2008, we entered into a lease agreement for certain real property located at 100 Hayden Avenue, Lexington, Massachusetts for use as our principal executive offices. The term of the lease began on May 22, 2008 and will continue until August 31, 2016 with two successive five year extension terms at our option. The aggregate size of rentable floor area for the offices is 55,924 square feet, and the rent for the initial term commenced in February 2009. The lease requires us to pay rent as follows (in thousands):

Period	Minimum Lease Payments
Year Ended December 31, 2011	$ 1,959
Year Ended December 31, 2012	2,015
Year Ended December 31, 2013	2,071
Year Ended December 31, 2014	2,127
Year Ended December 31, 2015	2,183
Thereafter	1,556
Total	$ 11,911

During any extension term, 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 annual operating costs.

Purchase Commitments

During 2010, we entered into various agreements with third-parties for which we had remaining purchase commitments of approximately $3.2 million as of December 31, 2010. These agreements principally related to certain purchase orders for materials and testing as well as certain outsourced commercial activities, information technology infrastructure and other operational activities.

Other Funding Commitments

As of December 31, 2010, 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 on our consolidated balance sheet of approximately $1.9 million representing expenses

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incurred with these organizations as of December 31, 2010, 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 with each of our executive officers, which provide for payments to such executives in the event that the executive is terminated other than for cause, as defined in the applicable employment agreements.

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 M 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

On February 11, 2010, we submitted to FINRA Dispute Resolution, Inc. an arbitration claim against our broker-dealer, Jefferies & Company, Inc., or Jefferies, and two former Jefferies employees, Anthony J. Russo, and Robert A. D'Addario, who managed our cash account with Jefferies. We allege that Jefferies, Russo and D'Addario wrongfully marketed and sold a balance of $54.1 million in unsuitable ARS to us from September 2007 through January 2008. We further allege that Jefferies, Russo and D'Addario misrepresented or omitted material facts concerning the nature and risks of ARS, which were inconsistent with our investment objectives to maintain liquidity and flexibility in our portfolio. We primarily seek damages from Jefferies, Russo and D'Addario in the amount of $52.2 million, the total adjusted par value of the ARS that Jefferies, Russo and D'Addario wrongfully marketed and sold to us, plus interest.

A purported class action complaint was originally filed on March 18, 2010 in the United States District Court for the District of Massachusetts, entitled Silverstrand Investments v. AMAG Pharm., Inc., et. al., Civil Action No. 1:10-CV-10470-NMG, and was amended on September 15, 2010. The amended complaint alleges that we and our President and Chief Executive Officer, Executive Vice President and Chief Financial Officer, 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 President and Chief Executive Officer and Executive Vice President and Chief Financial Officer violated Section 15 of such Act, respectively, by making certain alleged false and misleading statements and omissions in a registration statement filed in January 2010. The plaintiff seeks 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. The Court has not set a trial date for this matter. We believe that the allegations contained in the complaint are without merit and intend to defend the case vigorously. We have not recorded an estimated liability associated with this legal proceeding as we do not believe that such a liability is probable and estimable.

On November 2, 2010, we received a Civil Investigative Demand, or CID, from the U.S. Department of Justice pursuant to the Federal False Claims Act. The CID required the delivery of documents and testimony to the United States Attorney's Office in Boston, Massachusetts, relating to allegations that we caused the submission of false claims to Federal health care programs. In February

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2011, the U.S. Department of Justice informed us that it had closed its investigation, that no further investigation is warranted, and that we need not respond further to the CID.

In addition, we recently received correspondence from a supplier with whom we have an agreement related to the supply of a certain material used in the production of certain of our products. This correspondence suggests that we are in violation of the terms of the agreement. We believe we have good and valid arguments against such allegations, and we intend to vigorously defend against any such allegations. We are currently unable to predict the outcome or reasonably estimate the range of potential loss associated with this potential claim, if any, and have therefore not recorded any estimated liability as we do not believe that such a liability is probable and estimable.

Off-Balance Sheet Arrangements

As of December 31, 2010, 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, 2010 and 2009, our short- and long-term investments equaled $181.2 million and $78.6 million, respectively, and were invested in corporate debt securities, U.S. treasury and government agency securities, commercial paper and ARS. These investments are subject to interest rate risk and will fall in value if market interest rates increase. However, even 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 at December 31, 2010 and 2009, this would have resulted in a hypothetical decline in fair value of our investments, excluding ARS, which are described below, of approximately $0.7 million and $0.1 million, respectively.

As of December 31, 2010, we held a total of $33.6 million in fair market value of ARS, reflecting an impairment of approximately $6.0 million compared to the par value of these securities of $39.6 million. For further discussion on the analysis of the sensitivity of assumptions utilized in the valuation of our ARS, please refer to our critical accounting policy on the valuation of investments included in Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Annual Report on Form 10-K.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA:

Our Consolidated Financial Statements, Report of Management, and related Report of Independent Registered Public Accounting Firm are presented in the following pages. The reports and financial statements included in this Part II, Item 8 are as follows:

Management's Annual Report on Internal Control over Financial Reporting

Report of Independent Registered Public Accounting Firm

Financial Statements:

Consolidated Balance Sheets as of December 31, 2010 and 2009

Consolidated Statements of Operations for the years ended December 31, 2010, 2009 and 2008

Consolidated Statements of Comprehensive Loss for the years ended December 31, 2010, 2009 and 2008

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2010, 2009 and 2008

Consolidated Statements of Cash Flows for the years ended December 31, 2010, 2009 and 2008

Notes to Consolidated Financial Statements

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MANAGEMENT'S ANNUAL REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Management is responsible for establishing and maintaining adequate internal controls over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities and Exchange Act of 1934, as amended, or the Exchange Act. All internal controls over financial reporting, no matter how well designed, have inherent limitations. As a result of these inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those internal controls determined to be effective can provide only reasonable assurance with respect to reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission, together with related pronouncements issued by both the Public Company Accounting Oversight Board and the U.S. Securities and Exchange Commission. Based on our evaluation under the framework in *Internal Control Integrated Framework*, management concluded our internal control over financial reporting was effective as of December 31, 2010.

Our internal control over financial reporting as of December 31, 2010 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which is included herein, which expresses an unqualified opinion on the effectiveness of our internal control over financial reporting as of December 31, 2010.

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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, 2010 and 2009, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2010 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, 2010, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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 25, 2011

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AMAG Pharmaceuticals, Inc.

Consolidated Balance Sheets

(in thousands, except share and per share data)

	As of December 31,	
	2010	**2009**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 112,646	$ 50,126
Short-term investments	147,619	29,578
Settlement rights		788
Accounts receivable, net	5,785	27,350
Inventories	16,344	9,415
Receivable from collaboration	441	
Prepaid and other current assets	7,949	5,472
Total current assets	290,784	122,729
Property, plant and equipment, net	11,235	12,417
Long-term investments	33,597	49,013
Restricted cash	460	460
Total assets	$ 336,076	$ 184,619
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,553	$ 5,432
Accrued expenses	25,555	21,931
Deferred revenues	6,603	10,198
Total current liabilities	36,711	37,561
Long-term liabilities:		
Deferred revenues	51,292	1,000
Other long-term liabilities	2,787	3,081
Total liabilities	90,790	41,642
Commitments and contingencies (Notes M & N)		
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; 21,137,428 and 17,362,710 shares issued and outstanding at December 31, 2010 and 2009, respectively	211	174
Additional paid-in capital	614,942	432,414
Accumulated other comprehensive loss	(7,028)	(7,925)
Accumulated deficit	(362,839)	(281,686)
Total stockholders' equity	245,286	142,977
Total liabilities and stockholders' equity	$ 336,076	$ 184,619

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,		
	2010	**2009**	**2008**
Revenues:			
Product sales, net	$ 59,978	$ 16,482	$ 751
License fee and other collaboration revenues	6,132	516	959
Royalties	135	180	228
Total revenues	66,245	17,178	1,938
Costs and expenses:			
Cost of product sales	7,606	1,013	292
Research and development expenses	54,462	36,273	31,716
Selling, general and administrative expenses	84,939	77,829	49,536
Restructuring expenses	2,224		
Total costs and expenses	149,231	115,115	81,544
Other income (expense):			
Interest and dividend income, net	1,741	3,154	9,139
Gains (losses) on investments, net	408	942	(3,024)
Fair value adjustment of settlement rights	(788)	(778)	1,566
Total other income (expense)	1,361	3,318	7,681
Net loss before income taxes	(81,625)	(94,619)	(71,925)
Income tax benefit	472	1,268	278
Net loss	$ (81,153)	$ (93,351)	$ (71,647)
Net loss per share:			
Basic and diluted	$ (3.90)	$ (5.46)	$ (4.22)
Weighted average shares outstanding used to compute net loss per share:			
Basic and diluted	20,806	17,109	16,993

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,		
	2010	**2009**	**2008**
Net loss	$ (81,153)	$ (93,351)	$ (71,647)
Other comprehensive income (loss):			
Unrealized gains (losses) on securities:			
Holding gains (losses) arising during period, net of tax	497	2,029	(13,110)
Reclassification adjustment for (gains) losses included in net loss	400	5	3,024
Net unrealized gains (losses)	897	2,034	(10,086)
Total comprehensive loss	$ (80,256)	$ (91,317)	$ (81,733)

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 Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2007	16,946	$ 169	$ 402,346	$ (116,688)	$ 127	$ 285,954
Net shares issued in connection with the exercise of stock options and restricted stock units	59	1	762			763
Shares issued in connection with employee stock purchase plan	13		393			393
Non-cash equity-based compensation			8,037			8,037
Unrealized losses on securities, net					(10,086)	(10,086)
Net loss				(71,647)		(71,647)
Balance at December 31, 2008	17,018	170	411,538	(188,335)	(9,959)	213,414
Net shares issued in connection with the exercise of stock options and restricted stock units	304	3	4,044			4,047
Shares issued in connection with employee stock purchase plan	41	1	1,155			1,156
Non-cash equity-based compensation			15,677			15,677
Unrealized gains on securities, net of tax of $1,089					2,034	2,034
Net loss				(93,351)		(93,351)
Balance at December 31, 2009	17,363	174	432,414	(281,686)	(7,925)	142,977
Net shares issued in connection with the exercise of stock options and restricted stock units	132	1	1,336			1,337
Shares issued in connection with employee stock purchase plan	42		892			892
Non-cash equity-based compensation			14,777			14,777
Unrealized gains on securities, net of tax of $481					897	897
Shares issued in connection with financing, net of financing costs of $8.1 million	3,600	36	165,523			165,559
Net loss				(81,153)		(81,153)
Balance at December 31, 2010	21,137	$ 211	$ 614,942	$ (362,839)	$ (7,028)	$ 245,286

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,		
	2010	**2009**	**2008**
Net loss	$ (81,153)	$ (93,351)	$ (71,647)
Cash flows from operating activities:			
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	2,405	1,913	1,497
Non-cash equity-based compensation expense	14,523	15,421	8,037
Non-cash income tax benefit	(481)	(1,089)	
Amortization of premium/discount on purchased securities	1,679	490	482
Fair value adjustment of settlement rights	788	778	(1,566)
(Gains) losses on investments, net	(408)	(942)	3,024
Changes in operating assets and liabilities:			
Accounts receivable	21,565	(26,942)	(185)
Inventories	(6,675)	(9,063)	288
Receivable from collaboration	(441)		
Prepaid and other current assets	(2,477)	(762)	(1,910)
Accounts payable and accrued expenses	2,745	13,215	6,596
Deferred revenues	46,697	9,682	42
Other long-term liabilities	(294)	(68)	3,006
Total adjustments	79,626	2,633	19,311
Net cash used in operating activities	(1,527)	(90,718)	(52,336)
Cash flows from investing activities:			
Proceeds from sales or maturities of available-for-sale investments	160,079	74,543	233,194
Purchase of available-for-sale investments	(262,597)	(310)	(137,438)
Capital expenditures	(1,223)	(2,835)	(8,178)
Change in restricted cash		61	(426)
Net cash (used in) provided by investing activities	(103,741)	71,459	87,152
Cash flows from financing activities:			
Proceeds from the issuance of common stock, net of underwriting discount and other expenses	165,559		
Proceeds from the exercise of stock options	1,337	4,047	763
Proceeds from the issuance of common stock under ESPP	892	1,156	393
Net cash provided by financing activities	167,788	5,203	1,156
Net increase (decrease) in cash and cash equivalents	62,520	(14,056)	35,972
Cash and cash equivalents at beginning of the year	50,126	64,182	28,210
Cash and cash equivalents at end of the year	$ 112,646	$ 50,126	$ 64,182
Supplemental data:			
Non-cash investing activities:			

Accrued construction in process	$	$ 272	$
Investments reclassified to trading, at fair value	$	$	$ 7,650

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 biopharmaceutical company focused on the development and commercialization of a therapeutic iron compound to treat iron deficiency anemia, or IDA. Our principal source of revenue is from the sale of Feraheme® (ferumoxytol) Injection for intravenous, or IV, use, 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 market and sell *Feraheme* in the U.S. through our own commercial organization and began shipping *Feraheme* to our customers in July 2009.

GastroMARK®, our oral contrast agent used for delineating the bowel in magnetic resonance imaging is approved and marketed in the U.S., Europe and other countries through our marketing partners.

We are subject to risks common to companies in the pharmaceutical industry including, but not limited to, our sole dependence on the success of *Feraheme*, our potential inability to become profitable in the future, the potential development of significant safety or drug interaction problems with respect to *Feraheme*, competition in our industry, uncertainties regarding market acceptance of *Feraheme*, uncertainties related to patient insurance coverage, coding and third-party reimbursement for *Feraheme*, uncertainties related to the impact of current and future healthcare initiatives and legislation, our limited experience commercializing and distributing a pharmaceutical product, our reliance on our partners to commercialize *Feraheme* in certain territories outside of the U.S., our potential inability to operate our manufacturing facility in compliance with current good manufacturing practices, our potential inability to obtain raw or other materials and manufacture sufficient quantities of *Feraheme*, the potential fluctuation of our operating results, potential differences between actual future results and the estimates or assumptions used by us in preparation of our consolidated financial statements, the volatility of our stock price, our potential inability to obtain additional financing, if necessary, on acceptable terms, our potential inadvertent failure to comply with reporting and payment obligations under government pricing programs, our potential inadvertent failure to comply with the regulations of the FDA or other federal, state or foreign government agencies, uncertainty of the regulatory approval process for our other *Feraheme* indications, for any indications outside of the U.S. or for potential alternative manufacturing facilities, uncertainty of the results of our clinical trials, our dependence on key personnel, and uncertainties related to the protection of proprietary technology, any potential adverse determinations against us in any current or future lawsuits in which we are a defendant, potential product liability, potential legislative and regulatory changes, and potential costs and liabilities associated with pending or future litigation.

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, revenue 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 values of investments, reserves for doubtful

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accounts, accrued expenses, reserves for legal matters, income taxes 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 Securities Corporation and AMAG Europe Limited. AMAG Europe Limited was incorporated in October 2009 in London, England. AMAG Securities Corporation is a Massachusetts corporation that was formed in August 2007. All significant intercompany account balances and transactions between the companies have been eliminated.

Cash and Cash Equivalents

Cash and cash equivalents consist principally of cash held in commercial bank accounts and 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. As of December 31, 2010 and 2009, all of our investments were classified as either available-for-sale or trading securities.

Available-for-sale securities are those securities which we view as available for use in current operations, if needed. We generally classify our available-for-sale securities as short-term investments, even though the stated maturity date may be one year or more beyond the current balance sheet date. Available-for-sale investments are stated at fair value with their unrealized gains and losses included 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. Due to our belief that the market for auction rate securities, or ARS, will likely take in excess of twelve months to fully recover, we have classified our ARS as long-term investments.

Trading securities are securities bought and held principally for the purpose of selling them at a later date and are carried at fair value with unrealized gains and losses reported in other income (expense) in our consolidated statements of operations. In November 2008, we elected to participate in a rights offering, by UBS AG, or UBS, one of our securities brokers, which provided us with rights to sell to UBS $9.3 million in par value of our ARS portfolio, at par value, at any time during a two-year sale period beginning June 30, 2010, or the Settlement Rights. We had designated these ARS as trading securities due to the likelihood of the sale of these securities to UBS, which occurred in June 2010.

We recognize and report other-than-temporary impairments of our debt securities in accordance with current accounting guidance. Current guidance requires that for debt securities with a decline in fair value below amortized cost basis, an other-than-temporary impairment exists if (i) we have the intent to sell the security or (ii) 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

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factors, overall market conditions and trends, underlying collateral, 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 of Financial Instruments

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 last 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, or held during the period, certain assets that are required to be measured at fair value on a recurring basis, including our cash equivalents, short- and long-term investments and our Settlement Rights. The following tables represent the fair value hierarchy for those assets that we measure at fair value on a recurring basis as of December 31, 2010 and 2009 (in thousands):

	Fair Value Measurements at December 31, 2010 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	$ 110,238	$ 110,238	$	$
Corporate debt securities	83,768		83,768	
U.S. treasury and government agency securities	50,925		50,925	
Foreign government securities	2,431		2,431	
Commercial paper	10,495		10,495	
Auction rate securities	33,597			33,597
	$ 291,454	$ 110,238	$ 147,619	$ 33,597

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	Total	Fair Value Measurements at December 31, 2009 Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	$ 46,451	$ 46,451	$	$
Corporate debt securities	9,804		9,804	
U.S. treasury and government agency securities	11,247		11,247	
Auction rate securities	57,540			57,540
Settlement rights	788			788
	$ 125,830	$ 46,451	$ 21,051	$ 58,328

With the exception of our ARS and Settlement Rights, which are valued using Level 3 inputs, as discussed below, the fair value of our non-money market fund investments is primarily determined from independent pricing services which use Level 2 inputs to determine fair value. 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 fair value. At the end of each reporting period, we perform quantitative and qualitative analyses of prices received from third parties to determine whether prices are reasonable estimates of fair value. After completing our analyses, we did not adjust or override any fair value measurements provided by our pricing services as of December 31, 2010 or 2009. In addition, there were no transfers or reclassifications of any securities between Level 1 and Level 2 during either of the years ended December 31, 2010 and 2009.

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 with 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 or group of similar assets. 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 non-ARS assets appeared normal and that transactions did not appear disorderly as of December 31, 2010 and 2009.

In November 2008, we elected the fair value option with respect to our Settlement Rights in accordance with accounting guidance related to the fair value option for financial assets and financial liabilities. Under this guidance, we were required to periodically assess the fair value of both the Settlement Rights and our ARS subject to Settlement Rights and record changes until the date when the Settlement Rights were exercised and our ARS subject to Settlement Rights were redeemed. In accordance with the terms of the Settlement Rights, during June 2010 UBS redeemed all of our ARS subject to Settlement Rights at their par value. As a result, during the year ended December 31, 2010,

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we recognized both a realized gain of $0.8 million related to the redemption of our UBS ARS subject to Settlement Rights and a corresponding realized loss of $0.8 million related to the exercise of the Settlement Rights.

The following table provides a roll forward of our assets measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the years ended December 31, 2010 and 2009 (in thousands):

	December 31, 2010	December 31, 2009
Balance at beginning of period	$ 58,328	$ 55,901
Transfers to Level 3		
Total gains (losses) (realized or unrealized):		
Included in earnings	(390)	99
Included in other comprehensive income (loss)	1,184	3,378
Purchases (settlements), net	(25,525)	(1,050)
Balance at end of period	$ 33,597	$ 58,328
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	$	$

Gains and losses (realized and unrealized) included in earnings in the table above are reported in other income (expense) in our consolidated statement of operations.

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 approval from the FDA or other regulatory agencies, we expense costs relating to the production of inventory in the period incurred until such time as the product receives initial regulatory approval, at which point we begin to capitalize the inventory costs related to the product. Prior to the FDA approval of *Feraheme* for commercial sale in June 2009, 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. Until we sell the inventory for which a portion of the costs were previously expensed, the carrying value of our inventories and our cost of product sales will reflect only incremental costs incurred subsequent to the approval date. We continue to expense costs associated with clinical trial material as research and development expense.

Property, Plant and Equipment

Property, plant and equipment are recorded at cost and depreciated when placed into service using the straight-line method, based on the following estimated useful lives: buildings 40 years; building improvements over the shorter of the remaining useful life of the building or the life of the improvement; laboratory and production equipment 5 years; and furniture and fixtures 5 years. The 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

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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. Currently, our long-lived assets consist entirely of property and equipment. 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 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.

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, 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 $7.4 million, $7.5 million and $3.8 million for the years ended December 31, 2010, 2009 and 2008, respectively.

Revenue Recognition

Net Product Sales

We recognize net product sales 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.

We record product sales allowances and accruals related to prompt payment discounts, chargebacks, governmental 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 blended with historical experience of products similar to *Feraheme* sold by others, and other market research. 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

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analysis of our product sales allowances and accruals for the years ended December 31, 2010 and 2009 is as follows (in thousands):

	December 31, 2010	December 31, 2009
Product sales allowances and accruals*		
Discounts and chargebacks	$ 5,113	$ 804
Government and other rebates	15,775	4,329
Returns	1,334	463
Total product sales allowances and accruals	$ 22,222	$ 5,596
Total gross product sales	$ 82,200	$ 22,078
Total product sales allowances and accruals as a percent of total gross product sales	27%	25%

* We did not have any product sales allowances and accruals for 2008.

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 dialysis organizations, physicians, clinics, hospitals, and GPOs 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 and allowances 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 other products similar to *Feraheme*, specific known market events and trends such as competitive pricing and new product introductions and current and forecasted customer buying patterns and inventory levels, including 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. Reserve estimates are evaluated quarterly and may require adjustments to better align our estimates with actual results. Although allowances and accruals are recorded at the time of product sale, certain rebates are typically paid out, on average, up to six months or longer after the sale. If actual future results vary from our estimates, we may need to adjust our previous estimates, which would affect our earnings in the period of the adjustment.

During the year ended December 31, 2010, our product sales allowances and accruals reflected an increase in statutory minimum rebate rates related to Medicaid allowances from 15.1% to 23.1% pursuant to the Healthcare Reform Act enacted in March 2010. In addition, we reduced our product sales allowances and accruals by $0.7 million in 2010 for changes in estimates relating to sales in the prior year. These adjustments were primarily caused by reductions in our estimates of 2009 Medicaid utilization across *Feraheme* customer classes based on additional data, including information regarding Medicaid claims experience for comparable products and *Feraheme*.

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Classification of Product Sales Allowances and Accruals

Allowances against receivable balances primarily relate to prompt payment discounts, provider chargebacks and certain government agency chargebacks and are recorded at the time of sale, resulting in a reduction in product sales revenue or deferred 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. 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, based on the gross amount of each invoice, at the time of sale. 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.

Governmental and Other Rebates

Governmental 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 market research data related to utilization rates by various end-users and actual *Feraheme* sales data and forecasted customer buying patterns blended with historical experience of products similar to *Feraheme* sold by others. Due to the extended time period between the sale of *Feraheme* and our receipt of the related Medicaid rebate claim, which can be over a year, we currently have limited actual claims payment data, and therefore are not able to solely rely on our actual *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. We adjust the accrual quarterly to reflect actual experience.

Distributor/Wholesaler and Group Purchasing Organization Fees

Fees under our arrangements with distributors and wholesalers are usually based upon units of *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

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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, based on the gross amount of each invoice to the customer, at the time of sale. We adjust the accrual quarterly to reflect actual experience.

Product Returns

Consistent with industry practice, we generally offer our distributors and wholesaler customers a limited right to return product purchased directly from us which is principally based upon the product's expiration date which, once packaged, is currently four years. We currently estimate product returns based upon historical trends in the pharmaceutical industry and trends for products similar to *Feraheme* sold by others. 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.

In addition to the factors discussed above, we consider several additional factors in our estimation process, including our internal sales forecasts and inventory levels in the distribution channel. We expect that wholesalers will not stock significant inventory due to the product's cost and expense to store. Based on the level of inventory in the distribution channel, we determine whether an adjustment to the sales return reserve is appropriate.

If necessary, our estimated rate of returns may be adjusted for historical return patterns as they become available and for known or expected changes in the marketplace. To date, returns and adjustments to our estimated rate of returns have been minimal. If we were to reduce our product returns estimate in the future, doing so would result in increased product sales at the time the return estimate is reduced. If circumstances change or conditions become more competitive in the iron replacement therapy market, we may increase our product returns estimate, which would result in an incremental reduction of product sales at the time the returns estimate is changed.

Deferred Revenue Launch Incentive Program

During the third quarter of 2009, certain dialysis organizations purchased *Feraheme* from us under our Launch Incentive Program. These purchases were made under agreements which provided these customers with an opportunity to purchase *Feraheme* through September 30, 2009 at discounted pricing and further provided for extended payment terms and expanded rights of return. As a result, in accordance with current accounting guidance which requires that we defer recognition of revenues until we can reasonably estimate returns related to those purchases, we have deferred the recognition of revenues associated with these purchases until our customers report to us that such inventory has been utilized in their operations.

Any purchases made under the Launch Incentive Program that are returned to us will not be recorded as revenue, and, if necessary, we will issue a refund to the customer. For example, during 2010, one of our Launch Incentive Program customers returned to us the majority of its remaining unused inventory in accordance with the terms of our agreement with the customer. This return had no impact on our net product sales as we reduced the deferred revenues and the remaining receivable of $2.1 million related to this returned inventory and issued a refund of approximately $1.1 million to this customer.

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As of December 31, 2010, we had approximately $0.5 million in remaining deferred revenue related to customers who participated in the Launch Incentive Program and as a result, we do not expect to recognize significant revenues related to this program in 2011. In addition, we are not able to reasonably estimate any additional amounts of inventory that may be returned to us under this program and therefore cannot provide any assurance that any of this remaining deferred revenue will be recorded as product revenues in our future consolidated statements of operations.

License Fee and Other Collaboration Revenues

The terms of product development agreements entered into between us and our collaborative partners 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. Nonrefundable payments and fees are recorded as deferred revenue upon receipt and may require deferral of revenue recognition to future periods.

Royalty Revenues

We receive royalty revenues under license and marketing agreements with several companies that sell products that we developed. The license agreements provide for the payment of royalties to us based on sales of the licensed product. As we do not have the ability to reliably estimate our royalties in any given period, we recognize royalty revenue when cash payments are received.

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. This guidance provides that an element of a contract can be accounted for separately if the delivered elements have standalone value and the fair value of any 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 over the period of performance for such undelivered items or services.

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 will be 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.

Our collaboration agreements may entitle us to additional payments upon the achievement of performance-based milestones. During 2010, we adopted accounting guidance related to the milestone method of revenue recognition. Under this accounting guidance, milestones that involve substantive effort on our part and the achievement of which are not considered probable at the inception of the collaboration are considered substantive milestones. We recognize consideration that is contingent upon

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achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone meets the following criteria: (1) 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; (2) the milestone is related solely to past performance; and (3) the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement. For milestones that are not considered substantive milestones at the onset of the collaboration agreement, 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. The adoption of this accounting guidance did not have any impact on our results of operations.

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*. 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. However, that presumption is overcome and the consideration should be characterized as a cost incurred if both of the following conditions are met:

- 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.

Since both of the above conditions were met with respect to the costs we incurred for shipping and handling services, we have recorded $0.2 million and $0.1 million as a selling, general and administrative expense during the years ended December 31, 2010 and 2009, 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 the 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. 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

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pricing model are 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 are 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 assumed 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.

Equity-based compensation to certain non-employees is accounted for in accordance with current accounting guidance related to the accounting for equity instruments that are issued to other than employees for acquiring, or in conjunction with selling, goods or services.

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.

Concentrations and Significant Customer Information

Financial instruments which potentially subject us to concentrations of credit risk consist principally of cash, cash equivalents, investments, and accounts receivable. As of December 31, 2010, our cash, cash equivalents and investments amounted to approximately $293.9 million. We currently invest our excess cash primarily in U.S. government and agency money market funds, and investments in corporate debt securities, U.S. treasury and government agency securities, commercial paper and ARS. As of December 31, 2010 we had approximately $58.0 million of our total $112.6 million cash and cash equivalents balance invested in an institutional money market 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*. 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 revenues for the years ended December 31, 2010, 2009 and 2008.

	For the Years Ended December 31,		
	2010	**2009**	**2008**
AmerisourceBergen Drug Corporation	36%	46%	
Metro Medical Supply, Inc.	21%	28%	
Bayer Healthcare Pharmaceuticals	<10%	<10%	53%
Guerbet S.A.	<10%	<10%	24%
Covidien, Ltd.	<10%	<10%	17%

A large portion of the revenue attributable to Bayer Healthcare Pharmaceuticals, or Bayer, during 2008 represents previously deferred revenues related to upfront license fees in connection with a product that we no longer manufacture or sell.

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Revenues for the year ended December 31, 2010 from customers outside of the U.S. amounted to approximately 10% of our total revenues and were principally related to collaboration revenue recognized in connection with our collaboration agreement with Takeda Pharmaceutical Company Limited, or Takeda, which is based in Japan. Revenues for the years ended December 31, 2009 and 2008 from customers outside of the U.S., principally in France, amounted to 2% and 29%, respectively, of our total revenues.

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.

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 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), the total of which was excluded from our computation of diluted net loss per share because such options and restricted stock units were anti-dilutive due to a net loss in the relevant periods (in thousands):

	Years Ended December 31,		
	2010	**2009**	**2008**
Options to purchase shares of common stock	2,411	2,416	1,991
Shares of common stock issuable upon the vesting of restricted stock units	385	216	219
Total	2,796	2,632	2,210

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

	Years Ended December 31,		
	2010	**2009**	**2008**
Net loss	$ (81,153)	$ (93,351)	$ (71,647)
Weighted average common shares outstanding	20,806	17,109	16,993
Net loss per share:			
Basic and diluted	$ (3.90)	$ (5.46)	$ (4.22)

C. Investments

As of December 31, 2010 and 2009, the combined total of our short- and long-term investments equaled $181.2 million and $78.6 million, respectively, and consisted of securities classified as trading and available-for-sale in accordance with accounting standards which provide guidance related to accounting and classification of certain investments in debt and equity securities.

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The following is a summary of our short- and long-term investments at December 31, 2010 and 2009 (in thousands):

	December 31, 2010			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term investments:				
Corporate debt securities				
Due in one year or less	$ 37,660	$ 65	$ (12)	$ 37,713
Due in one to three years	45,883	197	(25)	46,055
U.S. treasury and government agency securities				
Due in one year or less	22,554	39	(1)	22,592
Due in one to three years	28,103	235	(5)	28,333
Foreign government securities				
Due in one year or less	2,431			2,431
Due in one to three years				
Commercial paper				
Due in one year or less	10,493	2		10,495
Due in one to three years				
Total short-term investments	$ 147,124	$ 538	$ (43)	$ 147,619
Long-term investments:				
Auction rate securities available for sale				
Due in one year or less	$	$	$	$
Due after five years	39,550		(5,953)	33,597
Total long-term investments	$ 39,550	$	$ (5,953)	$ 33,597
Total short and long-term investments	$ 186,674	$ 538	$ (5,996)	$ 181,216

	December 31, 2009			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term investments:				
Corporate debt securities				
Due in one year or less	$ 8,580	$ 61	$	$ 8,641
Due in one to three years	1,117	46		1,163
U.S. treasury and government agency securities				
Due in one year or less	8,532	136		8,668
Due in one to three years	2,521	58		2,579
Auction rate securities-trading				
Due in one year or less				
Due after five years	8,527			8,527
Total short-term investments	$ 29,277	$ 301	$	$ 29,578
Long-term investments:				
Auction rate securities available for sale				
Due in one year or less	$	$	$	$

Due after five years	56,150		(7,137)	49,013
Total long-term investments	$ 56,150	$	$ (7,137)	$ 49,013
Total short and long-term investments	$ 85,427	$ 301	$ (7,137)	$ 78,591

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Auction Rate Securities and Settlement Rights

As of December 31, 2010, we held a total of $33.6 million in fair market value of ARS, reflecting a decline of approximately $6.0 million compared to the par value of these securities of $39.6 million. At December 31, 2010, all of our ARS were municipal bonds with an auction reset feature and were classified as available-for-sale. The majority of our ARS portfolio was rated AAA as of December 31, 2010 by at least one of the major securities rating agencies and was primarily collateralized by student loans substantially guaranteed by the U.S. government under the Federal Family Education Loan Program. As of December 31, 2010, all of our ARS continue to pay interest according to their stated terms.

In February 2008, our ARS began to experience failed auctions and have continued to experience failed auctions since that time. As a result of the lack of significant observable ARS market activity since February 2008, we use a discounted cash flow methodology to value these securities as opposed to valuing them at their par value. Our valuation analysis considers, among other items, assumptions that market participants would use in their estimates of fair value, such as the collateral underlying the security, the creditworthiness of the issuer and any associated guarantees, credit ratings of the security by the major securities rating agencies, the ability or inability to sell the investment in an active market or to the issuer, the timing of expected future cash flows, and the expectation of the next time the security will have a successful auction or when call features may be exercised by the issuer. In addition, for all available-for-sale debt securities with unrealized losses, management performs an analysis to assess whether we intend to sell or whether we would more likely than not be required to sell the security before the expected recovery of the amortized cost basis. In the event that we intend to sell a security, or may be required to do so, the decline in fair value of the security would be deemed to be other-than-temporary and the full amount of the unrealized loss would be recorded in our consolidated statement of operations as an impairment loss. For example, we agreed to participate in an October 2010 repurchase offer by one of the issuers of our ARS which resulted in our recording a $0.4 million other-than-temporary impairment in our consolidated statement of operations. Regardless of our intent to sell a security, we perform additional analyses on all securities with unrealized losses to evaluate whether there could be a credit loss associated with the security. Based upon the methodology and the analysis above, we have estimated the fair value of our ARS to be $39.6 million as of December 31, 2010 and have recorded the $6.0 million decline in value as an unrealized loss to accumulated other comprehensive loss as of December 31, 2010.

Due to our belief that the market for ARS will likely take in excess of twelve months to fully recover, we have classified our portfolio of ARS as long-term investments in our consolidated balance sheet as of December 31, 2010. We believe that the impairment related to our ARS is primarily attributable to the lack of liquidity of these investments, coupled with the ongoing uncertainty in the credit and capital markets, and we have no reason to believe that any of the underlying issuers of our ARS are presently at risk of default. For all of our ARS, the underlying maturity date is in excess of one year, and the majority have final maturity dates which occur approximately 30 to 40 years in the future. We believe we will ultimately be able to liquidate our investments in ARS without significant loss prior to their maturity dates primarily due to the collateral securing most of our ARS. However, it could take until final maturity of the ARS to realize our investments' par value. As a result, we believe the decline in value of our ARS is a temporary impairment and similarly, any future fluctuation in fair value related to our ARS that we deem to be temporary, including any recoveries of previous write-downs, would be recorded to accumulated other comprehensive loss. If we determine that any future unrealized loss is other-than-temporary, we will record a charge to our consolidated statement of operations. In the event that we need to access our investments in these securities, we will not be able to do so until a future auction is successful, the issuer calls the security pursuant to a mandatory tender or redemption prior to maturity, a buyer is found outside the auction process, or the securities mature. In addition, as part of our determination of the fair value of our investments, we consider credit ratings

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provided by independent investment rating agencies as of the valuation date. These ratings are subject to change, and we may be required to adjust our future valuation of these ARS which may adversely affect the value of these investments. Based upon the various analyses described above, we did not recognize any credit losses related to our securities during either of the years ended December 31, 2010 and 2009.

Impairments and Unrealized Gains and Losses on Investments

The following is a summary of the fair value of our investments with unrealized losses that are deemed to be temporarily impaired and their respective gross unrealized losses aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position as of December 31, 2010 and 2009 (in thousands):

	December 31, 2010					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Corporate debt securities	$ 31,005	$ (37)	$	$	$ 31,005	$ (37)
U.S. treasury and government agency securities	13,447	(6)			13,447	(6)
Auction rate securities			33,597	(5,953)	33,597	(5,953)
	$ 44,452	$ (43)	$ 33,597	$ (5,953)	$ 78,049	$ (5,996)

	December 31, 2009					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Auction rate securities	$	$	$ 49,013	$ (7,137)	$ 49,013	$ (7,137)
	$	$	$ 49,013	$ (7,137)	$ 49,013	$ (7,137)

As noted above, for available-for-sale debt securities with unrealized losses, we perform an analysis to assess whether we intend to sell or whether we would more likely than not be required to sell the security before the expected recovery of the amortized cost basis. Where we intend to sell a security, or may be required to do so, the security's decline in fair value is deemed to be other-than-temporary, and the full amount of the unrealized loss is recorded in our consolidated statement of operations as an impairment loss. Regardless of our intent to sell a security, we perform additional credit and market analyses on all securities with unrealized losses to evaluate whether there could be a credit loss associated with the security. Our assessment of whether unrealized losses are other-than-temporary requires significant judgment. Based upon our evaluation, we did not consider the unrealized losses on our available-for-sale investments to be other-than-temporary impairments as of December 31, 2010 and 2009. We did not recognize any impairment losses in our consolidated statements of operations related to non-ARS available-for-sale securities during either of the years ended December 31, 2010 or 2009.

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.

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Realized Gains and Losses

Gains and losses are determined on the specific identification method. As noted above, during June 2010, UBS called all of our ARS subject to Settlement Rights at their par value, and consequently, we recognized both a realized gain of $0.8 million related to the redemption of our ARS subject to Settlement Rights and a corresponding realized loss of $0.8 million related to the exercise of the Settlement Rights. In addition, during October 2010 we participated in a purchase offer from an issuer of certain of our ARS which resulted in our recording a $0.4 million realized loss. As a result of these transactions, we recorded net realized losses of approximately $0.4 million to our consolidated statements of operations during the year ended December 31, 2010.

D. Accounts Receivable

Our accounts receivable were $5.8 million and $27.4 million as of December 31, 2010 and 2009, respectively, and primarily represented amounts due from wholesalers and distributors to whom we sell *Feraheme* directly. In addition, accounts receivable at December 31, 2009 included $12.1 million owed to us by customers who purchased *Feraheme* directly from us under our Launch Incentive Program. Accounts receivable are recorded net of reserves for estimated chargeback obligations, prompt payment discounts and any allowance for doubtful accounts. Reserves for other sales-related allowances such as rebates, distribution and other fees, and product returns are included in accrued expenses in our consolidated balance sheets.

During 2010, one of our customers returned a portion of its unused inventory which had been received under our Launch Incentive Program in accordance with the terms of our agreement with the customer. As a result, the remaining $2.1 million accounts receivable balance due from this customer as well as the corresponding deferred revenue and rebate reserve balances were reversed. As of December 31, 2010, there were no remaining balances in accounts receivable from any customers to whom we shipped *Feraheme* under our Launch Incentive Plan.

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, 2010 or 2009. If the financial condition of any of our significant customers was to deteriorate and result in an impairment of their ability to make payments owed to us, an allowance for doubtful accounts may be required which could have a material effect on earnings in the period of any such adjustment. Customers which represented greater than 10% of our accounts receivable balances as of December 31, 2010 and 2009 were as follows:

	As of December 31,	
	2010	**2009**
AmerisourceBergen Drug Corporation	65%	29%
Metro Medical Supply, Inc.	18%	20%
Cardinal Health, Inc.	14%	<10%
McKesson Corporation	10%	<10%
Dialysis Clinics, Inc.		15%
Liberty Dialysis, LLC		10%
Satellite Healthcare, Inc.*		10%

* During 2009, our Chief Executive Officer was a member of the Board of Directors of Satellite Healthcare, Inc. but resigned from that position in March 2010. As of December 31, 2009, we had a receivable of approximately $2.8 million from this customer. In addition, during the three months ended March 31, 2010, we recognized approximately $1.0 million in revenues from this customer.

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E. Inventories

Our major classes of inventories were as follows as of December 31, 2010 and 2009 (in thousands):

	2010	2009
Raw materials	$ 2,332	$ 1,584
Work in process	55	1,169
Finished goods	13,954	6,326
Finished goods held by others	3	336
Total inventories	$ 16,344	$ 9,415

Included in finished goods inventory as of December 31, 2010 is approximately $1.5 million of *Feraheme* produced in third-party manufacturing facilities for which we are awaiting regulatory approval and which approval we believe is probable.

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. A critical input in this determination is future expected inventory requirements, based on internal sales forecasts. Once packaged, *Feraheme* currently has a shelf-life of four years, and as a result of comparison to internal sales forecasts, we expect to fully realize the carrying value of our current *Feraheme* 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.

Equity-based compensation of $0.8 million and $0.3 million was capitalized into inventory for the years ended December 31, 2010 and 2009, respectively.

F. Property, Plant and Equipment

Property, plant and equipment consisted of the following as of December 31, 2010 and 2009, respectively (in thousands):

	December 31,	
	2010	2009
Land	$ 360	$ 360
Buildings and improvements	11,163	10,356
Laboratory and production equipment	7,424	6,839
Furniture and fixtures	4,927	4,345
Construction in process	417	1,294
	24,291	23,194
Less accumulated depreciation	(13,056)	(10,777)
Property, plant and equipment, net	$ 11,235	$ 12,417

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G. Current and Long-Term Liabilities

Accrued Expenses

Accrued expenses consisted of the following as of December 31, 2010 and 2009 (in thousands):

	December 31,	
	2010	2009
Commercial rebates, fees and returns	$ 10,015	$ 5,657
Salaries, bonuses, and other compensation	5,176	8,767
Clinical, manufacturing and regulatory consulting fees and expenses	4,987	2,134
Commercial consulting fees and expenses	2,226	3,471
Professional, license, and other fees and expenses	1,827	1,902
Subtotal	24,231	21,931
Restructuring*	1,324	
Total accrued expenses	$ 25,555	$ 21,931

*

On October 28, 2010, in order to reduce our operating expenses we initiated a corporate restructuring, including a workforce reduction plan, pursuant to which we will reduce our workforce by approximately 24%. The majority of the workforce reduction was completed during the three months ended December 31, 2010, and we expect the remaining positions to be eliminated by the end of 2011. During the three months ended December 31, 2010, we recorded $2.2 million of restructuring related costs in operating expenses, primarily related to employee severance, benefits and related costs. These expenses are expected to be substantially paid by the end of 2011.

The following table outlines the components of our restructuring expenses recorded in operating expenses and in current liabilities for the three months ended December 31, 2010 (in thousands):

	Expenses	Cash payments	Amounts Accrued as of December 31, 2010
Employee severance, benefits and related costs	$ 2,224	$ (900)	$ 1,324
Total restructuring	$ 2,224	$ (900)	$ 1,324

Deferred Revenues

Deferred revenues consisted of the following as of December 31, 2010 and 2009 (in thousands):

	December 31,	
	2010	2009
Short-term deferred revenues:		
Takeda	$ 6,096	$
Sales of *Feraheme* under the Launch Incentive Program	507	10,198

Total	$ 6,603	$ 10,198
Long-term deferred revenues:		
Takeda	$ 50,292	$
3SBio	1,000	1,000
Total	$ 51,292	$ 1,000

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During 2010, under the terms of our collaboration agreement with Takeda, we received certain payments, including a $60.0 million upfront fee. We have recorded such payments as deferred revenue which we are recognizing on a straight-line basis over a period of 10 years, which represents the current patent life of *Feraheme* and our best estimate of the period over which we will substantially perform our obligations.

As of December 31, 2009, our short-term deferred revenues of $10.2 million related to our sales of *Feraheme* under the Launch Incentive Program.

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 and is being recognized under the proportional performance methodology as we supply *Feraheme* to 3SBio over the thirteen year initial term of the agreement.

Other Long-Term Liabilities

Other long-term liabilities at both December 31, 2010 and 2009 consisted solely of deferred rent related to the lease of our principal executive offices in Lexington, Massachusetts.

H. Income Taxes

For the years ended December 31, 2010, 2009 and 2008, we recognized current federal income tax benefits of $0.5 million, $1.3 million and $0.3 million, respectively. During 2010 and 2009, we recognized $0.5 million and $1.1 million in tax benefits, respectively, which were the result of an offsetting benefit to the recognition of a corresponding income tax expense recorded in other comprehensive income associated with the increase in the value of certain securities that we carried at fair market value during the same periods. In addition, during 2009 and 2008, we recognized $0.2 million and $0.3 million in tax benefits, respectively, associated with U.S. research and development tax credits against which we had previously provided a full valuation allowance, but which became refundable as a result of legislation passed in that year.

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

	Years Ended December 31,		
	2010	**2009**	**2008**
Statutory U.S. federal tax rate	(34.0)%	(34.0)%	(34.0)%
State taxes, net of federal benefit	(5.8)%	(2.3)%	(5.9)%
Permanent items, net	2.2%	2.1%	2.1%
Tax credits	(2.2)%	(1.0)%	(2.1)%
Valuation allowance	39.2%	33.9%	39.5%
Total tax (benefit) expense	(0.6)%	(1.3)%	(0.4)%

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

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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,	
	2010	2009
Assets		
Net operating loss carryforwards	$ 61,097	$ 61,674
Tax credit carryforwards	11,279	9,501
Deferred revenue	21,861	369
Equity award expense	9,534	6,565
Capitalized research & development	29,146	26,225
Other	8,257	9,114
Liabilities		
Depreciation	(331)	(528)
	140,843	112,920
Valuation allowance	(140,843)	(112,920)
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 $27.9 million, $28.7 million and $32.2 million for the years ended December 31, 2010, 2009 and 2008, respectively, primarily due to an increase in our net operating loss, or NOL, carryforwards, capitalized research and development expense, and equity-based compensation expense.

At December 31, 2010, we had federal NOL carryforwards of approximately $165.6 million and state NOL carryforwards of up to $121.0 million. We also had federal capital loss carryforwards of $1.7 million to offset future capital gains and an additional $24.4 million and $21.8 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 will begin to expire in 2011, and our most significant state NOLs expire at various dates through 2015. Our capital loss carryforwards will expire in 2014. In addition, we have federal and state tax credits of approximately $8.4 million and $4.4 million, respectively, to offset future tax liabilities. Our tax credits will expire periodically through 2031 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. During 2009, we conducted an analysis under Section 382 to determine if historical changes in ownership through December 31, 2008 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

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ownership after December 31, 2008 could affect the limitation in future years, including but not limited to our sale of 3,600,000 shares of common stock in January 2010 in connection with an underwritten public offering. If, subsequent to the date of this analysis, we have experienced a change of control as defined by Section 382, utilization of our NOL or R&D credit carryforwards would be subject to annual limitation under Section 382, which is determined by first multiplying the value of our stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the NOL or R&D credit carryforwards before utilization.

At December 31, 2010 and 2009, 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 September 30, 2007, although carryforward attributes that were generated prior to tax year 2007 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.

I. Equity-Based Compensation

We currently maintain several equity compensation plans, including our Seconded Amended and Restated 2007 Equity Incentive Plan, or the 2007 Plan, our Amended and Restated 2000 Stock Plan, or the 2000 Plan, and our 2010 Employee Stock Purchase Plan, or the 2010 ESPP.

Second Amended and Restated 2007 Equity Incentive Plan

Our 2007 Plan was originally approved by our stockholders in November 2007. In each of May 2009 and May 2010, 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 and 800,000 shares, respectively.

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. 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. ISOs 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. All stock options granted under the 2007 Plan have a ten year term. Our Board establishes the vesting schedule for stock options and the method of payment for the exercise price. In general, options granted vest at a rate of 25 percent on each of the first four anniversaries of the grant date. Our standard stock option agreement allows for payment of the exercise price for vested stock options either through cash remittance of the exercise price to us in exchange for newly issued shares, or through a non-cash exchange of previously issued shares held by

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the recipient equal in value to the exercise price in exchange for newly issued shares. The latter method results in no cash being received by us, but also results in a lower number of total shares subsequently being outstanding (as compared to a cash exercise), as a direct result of previously issued shares being exchanged in return for the issuance of new shares. Shares returned to us in this manner are retired. We generally issue common stock from previously authorized but unissued shares to satisfy option exercises and restricted stock awards.

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.

As of December 31, 2010, we have granted options and restricted stock units covering 3,171,775 shares of common stock under our 2007 Plan, of which 827,738 stock options and 56,666 restricted stock units have expired or terminated, and of which 35,338 options have been exercised and 59,250 shares of common stock have been issued pursuant to restricted stock units that became fully vested. The number of options and restricted stock units outstanding under this plan as of December 31, 2010 was 1,809,718 and 383,065, respectively. The remaining number of shares available for future grants as of December 31, 2010 was 1,312,530, 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 our common stock on the grant date and a ten-year term.

In May 2010, our Board approved a revised Non-Employee Director Compensation Policy, which establishes compensation to be paid to non-employee directors. Pursuant to this revised policy, in May 2010 the Board granted the Chairman of our Board stock options to purchase 10,000 shares of our common stock and restricted stock units covering 5,000 shares of our common stock under the 2007 Plan. In addition, each of the non-employee members of the Board other than the Chairman were granted stock options to purchase 5,000 shares of our common stock and restricted stock units covering 2,500 shares of our common stock under the 2007 Plan; provided that the foregoing awards were pro-rated for those non-employee directors who had served on the Board for less than one year prior to the date of grant. Each of the foregoing grants vests monthly in twelve equal installments beginning on June 1, 2010, provided that delivery of the shares of common stock underlying the foregoing restricted stock unit grants is deferred until the earlier of the third anniversary of the grant date and the date of the director's separation from service from the Board. Each stock option granted to the non-employee members of the Board has an exercise price per share equal to the fair market value of a share of our common stock on the grant date and has a 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, 2010, we have granted stock options and restricted stock units covering 2,182,700 shares of common stock under the 2000 Plan, of which 520,258 stock options and 1,500 restricted stock units have expired or terminated, and of which 1,017,393 stock options have been exercised and 40,000 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 and restricted stock units pursuant to the 2000

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Plan as of December 31, 2010 was 601,049 and 2,500, respectively. 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. 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.

Equity-based compensation expense

Equity-based compensation expense, excluding amounts that have been capitalized into inventory, as of the years ended December 31, 2010, 2009 and 2008 consisted of the following (in thousands):

	Years Ended December 31,		
	2010	2009	2008
Cost of product sales	$ 441	$ 43	$
Research and development	3,508	4,446	3,760
Selling, general and administrative	10,574	10,932	4,277
Total equity-based compensation expense	$ 14,523	$ 15,421	$ 8,037

We reduce the compensation expense being recognized to account for estimated forfeitures, which are based primarily on historical experience. Under the current accounting guidance, forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. As part of our regular review procedures, in 2010 we updated our analysis of our historical forfeiture experience. Based upon this analysis, we increased our expected forfeiture rate due to our determination that our expected forfeiture rate will be higher than what we had previously estimated, in part due to the impact of our October 2010 corporate restructuring.

Equity-based compensation expense for the years ended December 31, 2010, 2009 and 2008 included approximately $0.4 million, $0.7 million and ($2.1) million, respectively, in equity-based compensation expense associated with grants subject to market or performance conditions.

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,					
	2010		2009		2008	
	Employees	Non-Employee Directors	Employees	Non-Employee Directors	Employees	Non-Employee Directors
Risk free interest rate (%)	2.47	1.61	2.21	1.70	2.90	1.59
Expected volatility (%)	58	53	60	58	60	59
Expected option term (years)	5.50	4.00	5.40	4.13	5.10	4.70
Dividend yield	none	none	none	none	none	none

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Risk free interest rates utilized are based upon published U.S. Treasury yields at the date of the grant for the expected option term. We estimate our expected stock price volatility by basing it on a blend of the historical volatility 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 use the calculated historical term of stock options.

The following table summarizes details regarding our stock option plans for the year ended December 31, 2010 (excluding restricted stock units, which are presented separately below):

	December 31, 2010			
	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value ($ in millions)
Outstanding at beginning of year	2,416,072	$ 39.64		
Granted	767,850	35.00		
Exercised	(64,272)	20.81		
Expired and/or forfeited	(708,883)	41.13		
Outstanding at end of year	2,410,767	$ 38.22	7.4	$ 0.3
Outstanding at end of year vested and unvested expected to vest	2,229,741	$ 38.33	7.3	$ 0.3
Exercisable at end of year	1,018,256	$ 40.09	5.9	$ 0.3

The weighted average grant date fair value of stock options granted during the years ended December 31, 2010, 2009 and 2008 was $18.57, $18.32, and $22.61, respectively. The total fair value of options that vested during the years ended December 31, 2010, 2009 and 2008 was $12.0 million, $9.6 million, and $7.6 million, respectively. The aggregate intrinsic value of options exercised during the years ended December 31, 2010, 2009 and 2008, excluding purchases made pursuant to our employee stock purchase plans, measured as of the exercise date, was approximately $1.1 million, $9.2 million, and $1.6 million, respectively. The intrinsic value of a stock option is the amount by which the fair market value of the underlying stock exceeds the exercise price of the common stock option.

In the year ended December 31, 2010, we issued an aggregate of 289,481 restricted stock units to our employees and directors pursuant to our 2007 Plan. In general, these grants vest on an annual basis over a three or 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 estimated fair value of restricted stock unit awards issued during 2010 was approximately $6.2 million. At December 31, 2010, the amount of unrecorded expense associated with restricted stock units attributable to future periods was approximately $6.6 million. This expense is expected to be amortized primarily on a straight-line basis over a weighted average amortization period of approximately 2.4 years. This estimate is subject to change based upon a variety of future events, which include, but are not limited to, changes in estimated forfeiture rates, achievement of a market condition earlier than expected, and the issuance of new restricted stock awards.

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The following table summarizes details regarding restricted stock units granted under our equity incentive plans for the year ended December 31, 2010:

	December 31, 2010	
	Unvested Restricted Stock Units	Weighted Average Grant Date Fair Value
Outstanding at beginning of year	215,500	$ 40.61
Granted	289,481	21.53
Vested	(68,000)	31.85
Forfeited	(51,416)	36.63
Outstanding at end of year	385,565	$ 27.63
Outstanding at end of year and expected to vest	326,867	$ 27.54

At December 31, 2010, the amount of unrecorded equity-based compensation expense attributable to future periods was approximately $29.9 million, of which $23.3 million was associated with stock options and $6.6 million was associated with restricted stock units. Such amounts will be amortized primarily to research and development or selling, general and administrative expense, generally on a straight-line basis over weighted average amortization periods of approximately 2.2 and 2.4 years, respectively. 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, and the issuance of new stock options and other equity-based awards.

2010 Employee Stock Purchase Plan

In May 2010, our stockholders approved our 2010 ESPP as the successor to and continuation of the 2006 Employee Stock Purchase Plan, or 2006 ESPP. The 2010 ESPP authorizes the issuance of up to 100,000 shares of our common stock to eligible employees. Currently, eligible employees may purchase shares (subject to certain plan and/or income tax limitations) in semi-annual offerings through payroll deductions of up to an annual maximum of 10% of the employee's total compensation, as defined by our Board. The purchase price per share is the lesser of 85% of the fair market value of our common stock on the first or last day of the plan period. During 2010, we issued 42,446 shares under our employee stock purchase plans, of which 18,719 were issued under our 2010 ESPP and 23,727 were issued under 2006 ESPP.

The assumptions used for awards granted under our employee stock purchase plans were as follows:

	Years Ended December 31,		
	2010	2009	2008
Risk free interest rate (%)	0.22	0.21	0.82
Expected volatility (%)	42	52	66
Expected option term (years)	0.5	0.5	0.5
Dividend yield	none	none	none

The weighted average fair value for purchase rights granted under our 2010 ESPP and our 2006 ESPP, during the years ended December 31, 2010, 2009 and 2008 was $13.66, $15.65, and $11.83, respectively, and was estimated using the Black-Scholes option-pricing model.

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J. 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 matching contribution for the 401(k) Plan was $1.3 million, $1.1 million, and $0.6 million for the years ended December 31, 2010, 2009 and 2008, respectively.

K. Stockholders' Equity

Preferred Stock

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

Common Stock Transactions

In January 2010, we sold 3,600,000 shares of our common stock, $0.01 par value per share, in an underwritten public offering at a price to the public of $48.25 per common share, resulting in gross proceeds of approximately $173.7 million. Net proceeds to us after deducting fees, commissions and other expenses related to the offering were approximately $165.6 million. The shares were issued pursuant to a shelf registration statement on Form S-3 which became effective upon filing.

L. Business Segments

We have determined that we conduct our operations in one business segment: the manufacture, development and commercialization of products derived from our proprietary technology for use in

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treating human diseases. Long-lived assets consist entirely of property and equipment and are located in the U.S. for all periods presented.

M. Commitments and Contingencies

Commitments

Operating and Facility Lease Obligations

We have entered into certain operating leases, including leases of certain automobiles, and certain laboratory and office equipment which expire through 2012. Expense associated with these operating leases amounted to approximately $1.0 million, $0.9 million, and $0.5 million for the years ended December 31, 2010, 2009 and 2008, respectively. Future minimum lease payments associated with all noncancellable automobile, equipment, service and lease agreements, excluding facility-related leases are estimated to be approximately $0.3 million for 2011 and less than $0.1 million for 2012. We lease approximately 100 automobiles for our field-based employees. This lease requires an initial minimum lease term of 12 months per automobile. We are responsible for certain disposal costs in the event of termination of the lease.

In May 2008, we entered into a lease agreement for certain real property located at 100 Hayden Avenue, Lexington, Massachusetts for use as our principal executive offices. The term of the lease began on May 22, 2008 and will continue until August 31, 2016 with two successive five year extension terms at our option. In accordance with accounting guidance related to accounting for operating leases with scheduled rent increases, we recognize rent expense on this facility on a straight-line basis over the initial term of the lease. In addition, as provided for under the lease, we received approximately $2.2 million of tenant improvement reimbursements from the landlord. These reimbursements are being recorded as a deferred rent liability in our consolidated balance sheets and are amortized on a straight-line basis as a reduction to rent expense over the term of the lease. We have recorded all tenant improvements as leasehold improvements and are amortizing 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.

The lease requires us to pay rent as follows (in thousands):

Period		Minimum Lease Payments
Year Ended December 31, 2011	$	1,959
Year Ended December 31, 2012		2,015
Year Ended December 31, 2013		2,071
Year Ended December 31, 2014		2,127
Year Ended December 31, 2015		2,183
Thereafter		1,556
Total	$	11,911

During any extension term, 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 annual operating costs.

Facility-related rent expense recorded for the years ended December 31, 2010, 2009, and 2008 was $1.7 million, $1.6 million, and $1.7 million, respectively.

In addition, in connection with our facility lease, in May 2008 we delivered to the landlord a security deposit of approximately $0.5 million in the form of an irrevocable letter of credit. The cash

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securing this letter of credit is classified on our balance sheets as a long-term asset and is restricted in its use.

Purchase Commitments

During 2010 we entered into various agreements with third-parties for which we had remaining purchase commitments of approximately $3.2 million as of December 31, 2010. These agreements principally related to certain outsourced commercial activities, our information technology infrastructure, and other operational activities.

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. Other than with respect to the ongoing class action lawsuit filed against us in March 2010 in which case we are paying legal costs for our Chief Financial Officer, Chief Executive Officer and members of our Board, we have not incurred costs to defend lawsuits or settle claims related to these indemnification obligations. 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.

In addition, pursuant to the terms of the underwriting agreement we entered into with the underwriters in connection with our January 2010 public offering, we agreed to indemnify the underwriters in the event of any legal proceeding filed against them related to the public offering. Because the underwriters have been named as defendants in the securities class action lawsuit filed against us in March 2010, and because the claims contained in the complaint relate to the January 2010 public offering, we are paying legal costs for the underwriters in connection with the lawsuit in accordance with the terms of the underwriting agreement. The maximum potential amount of future payments we could be required to make under these indemnification obligations is not capped; however, we believe the estimated fair value of these indemnification obligations will not be material.

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 as described above, 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

Severance Arrangements

On October 28, 2010, in order to reduce our operating expenses we initiated a corporate restructuring, including a workforce reduction plan, pursuant to which we will reduce our workforce by approximately 24%. The majority of the workforce reduction was completed during the three months ended December 31, 2010, and we expect the remaining positions to be eliminated by the end of 2011. During the three months ended December 31, 2010, we recorded $2.2 million of restructuring related

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costs in operating expenses, primarily related to employee severance, benefits and related costs. Any severance, benefits or other related costs are expected to be substantially paid by the end of 2011.

We have entered into employment agreements with certain executives, which provide for payments to such executives in the event that the executive is terminated other than for cause, as defined in the applicable employment agreements.

Legal Proceedings

A purported class action complaint was originally filed on March 18, 2010 in the United States District Court for the District of Massachusetts, entitled Silverstrand Investments v. AMAG Pharm., Inc., et. al., Civil Action No. 1:10-CV-10470-NMG, and was amended on September 15, 2010. The amended complaint alleges that we and our President and Chief Executive Officer, Executive Vice President and Chief Financial Officer, 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 President and Chief Executive Officer and Executive Vice President and Chief Financial Officer violated Section 15 of such Act, respectively, by making certain alleged false and misleading statements and omissions in a registration statement filed in January 2010. The plaintiff seeks 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. The Court has not set a trial date for this matter. We believe that the allegations contained in the complaint are without merit and intend to defend the case vigorously. As this litigation is in an early stage, we are unable to predict its outcome or its ultimate effect, if any, on our financial condition and accordingly, we have not recorded an estimated liability as we do not believe that such a liability is probable and estimable. However, we expect that the costs and expenses related to this litigation could be significant. Our current director and officer liability insurance policies provide that we are responsible for the first $1.0 million of such costs and expenses. Also, a judgment or settlement of these actions could exceed our insurance coverage.

On November 2, 2010, we received a Civil Investigative Demand, or CID, from the U.S. Department of Justice pursuant to the Federal False Claims Act. The CID required the delivery of documents and testimony to the United States Attorney's Office in Boston, Massachusetts, relating to allegations that we caused the submission of false claims to Federal health care programs. In February 2011, the U.S. Department of Justice informed us that it had closed its investigation, that no further investigation is warranted, and that we need not respond further to the CID.

In addition, we recently received correspondence from a supplier with whom we have an agreement related to the supply of a certain material used in the production of certain of our products. This correspondence suggests that we are in violation of the terms of the agreement. We believe we have good and valid arguments against such allegations, and we intend to vigorously defend against any such allegations. We are currently unable to predict the outcome or reasonably estimate the range of potential loss associated with this potential claim, if any, and have therefore not recorded any estimated liability as we do not believe that such a liability is probable and estimable.

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 at December 31, 2010. We expense legal costs as they are incurred.

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N. Collaborative Agreements

Our commercial strategy includes the formation of alliances with other pharmaceutical companies to facilitate the sale and distribution of our products. At present we are parties to the following collaborations:

Takeda

In March 2010, we entered into a License, Development and Commercialization Agreement, or the Takeda Agreement, with Takeda, under which we granted exclusive rights to Takeda to develop and commercialize *Feraheme* as a therapeutic agent in Europe, Asia-Pacific countries (excluding Japan, China and Taiwan), the Commonwealth of Independent States, Canada, India and Turkey, or collectively, the Licensed Territory.

Under the Takeda Agreement, except under limited circumstances, we have retained the right to manufacture *Feraheme* and, accordingly, are responsible for supply of *Feraheme* to Takeda. 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, which provides for a cap on such costs. In connection with the execution of the Takeda Agreement, we received a $60.0 million upfront payment from Takeda in April 2010. We may also receive a combination of regulatory approval and performance-based milestone payments, reimbursement of certain out-of-pocket regulatory and clinical supply costs, defined payments for supply of *Feraheme,* and tiered double-digit royalties on net product sales in the Licensed Territory under the Takeda Agreement. The milestone payments we may be entitled to receive under the agreement could over time equal approximately $220.0 million. Of the $220.0 million in potential milestone payments, we have determined that any payments which may become due upon approval by certain regulatory agencies will be deemed substantive milestones and, therefore, will be accounted for as revenue in the period in which they are achieved. All remaining milestone payments will be accounted for in accordance with our revenue attribution method for the upfront payment as defined below.

We have determined that the Takeda Agreement includes four deliverables: the license, access to future know-how and improvements to the *Feraheme* technology, regulatory and clinical research services, and the manufacturing and supply of product. Pursuant to the accounting guidance under Accounting Standards Codification 605-25, or ASC 605-25, which governs revenue recognition on multiple element arrangements, we have evaluated the four deliverables under the 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, under ASC 605-25, we have concluded that the license is not separable from the undelivered future know-how and technological improvements or the undelivered regulatory and clinical research services. 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.

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. 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 Takeda Agreement. 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 as well as any milestone payments that are achieved and not deemed to be substantive milestones into revenues on a straight-line basis over a period of ten years, which represents the current patent life of *Feraheme* and our best estimate of the period over which we will substantively

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perform our obligations. The potential milestone payments that may be received in the future will be recognized into revenue on a cumulative catch up basis when they become due and payable.

Under the terms of the 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 services under the collaboration agreement. Because we are acting as the principal in carrying out these services, any reimbursement payments received from Takeda will be 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.

Revenues related to the combined unit of accounting and any reimbursement revenues are recorded in license fee and other collaboration revenues in our consolidated statement of operations. During the year ended December 31, 2010, we recorded $4.6 million associated with the upfront payment and $1.5 million associated with other reimbursement revenues in our consolidated statement of operations. Payments to be received for supply of the drug product and royalties will be recorded in product sales and royalties in our consolidated statement of operations. We did not record any revenue for this accounting unit in our consolidated statement of operations during the year ended December 31, 2010.

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 for the development and commercialization of *Feraheme* as an IV iron replacement therapeutic agent in China. The 3SBio License Agreement grants 3SBio an exclusive license for an initial term of thirteen years to develop and commercialize *Feraheme* as a therapeutic agent in China for an initial indication for the treatment of IDA in patients with CKD, and an option to expand into additional therapeutic indications. In consideration of the grant of the license, we received an upfront payment of $1.0 million, the recognition of which has been deferred and is being recognized under the proportional performance methodology as we supply *Feraheme* to 3SBio over the thirteen year initial term of the agreement. We are eligible to receive certain other specified milestone payments upon regulatory approval of *Feraheme* in China for CKD and other indications. We are also entitled to receive tiered royalties of up to 25% based on sales of *Feraheme* by 3SBio in China. We retained all manufacturing rights for *Feraheme* under these agreements. In addition, pursuant to the 3SBio Supply Agreement, 3SBio has agreed to purchase from us, and we have agreed to supply to 3SBio, *Feraheme* at a predetermined supply price for clinical and commercial use in connection with 3SBio's development and commercialization obligations described above for so long as the 3SBio License Agreement is in effect. To date we have not provided 3SBio with any product under this agreement.

Guerbet

In 1989, we entered into a supply and distribution agreement with Guerbet S.A., or Guerbet, granting Guerbet an exclusive right to manufacture and sell *GastroMARK* in western Europe and Brazil (under the tradename Lumirem®). This agreement was subsequently amended to expand Guerbet's exclusive rights to manufacture and sell *GastroMARK* in various other areas, including South America, the Middle East, southeast Asia, and eastern Europe. Under the terms of this distribution agreement, Guerbet has agreed to pay us, as the purchase price for the active ingredient of the licensed products, royalties and a percentage of net sales of *GastroMARK*. We are required to sell to Guerbet its requirements for the active ingredient used in *GastroMARK*. The agreement is perpetual but terminable upon certain specified events.

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Covidien

In 1990, we entered into a manufacturing and distribution agreement with the predecessor of Covidien Ltd., or Covidien, granting it a product license and co-marketing rights to *GastroMARK* in the U.S., Canada and Mexico. Covidien currently has rights to *GastroMARK* in the U.S. only. Under the terms of the agreement, we receive royalties based on *GastroMARK* sales by Covidien as well as a percentage of sales for supplying the active ingredient. The agreement is perpetual but terminable upon certain specified events.

O. Consolidated Quarterly Financial Data Unaudited

The following tables provide consolidated quarterly financial data for the years ended December 31, 2010 and 2009 (in thousands, except per share data):

	March 31, 2010	June 30, 2010	September 30, 2010	December 31, 2010
Product sales, net	$ 13,295	$ 16,226	$ 15,173	$ 15,284
License fee and other collaboration revenues(a)		2,529	1,684	1,919
Royalties	11	72	35	17
Total revenues	13,306	18,827	16,892	17,220
Cost of product sales	1,010	1,884	2,274	2,438
Operating expenses	35,824	38,788	32,017	32,772
Restructuring expenses(b)				2,224
Interest and dividend income, net	471	404	448	418
Gains (losses) on investments, net	4	794	(396)	6
Fair value adjustment of settlement rights		(788)		
Income tax benefit		111	351	10
Net loss	$ (23,053)	$ (21,324)	$ (16,996)	$ (19,780)
Net loss per share basic and diluted	$ (1.15)	$ (1.01)	$ (0.81)	$ (0.94)

	March 31, 2009	June 30, 2009	September 30, 2009	December 31, 2009
Product sales, net(c)	$ 393	$	$ 3,009	$ 13,080
License fees	516			
Royalties	47	55	12	66
Total revenues	956	55	3,021	13,146
Cost of product sales(c)	61		128	824
Operating expenses	28,822	27,382	25,460	32,438
Interest and dividend income, net	1,256	783	503	612
	992	275	(319)	(6)

Gains (losses) on investments, net				
Fair value adjustment of settlement rights	(923)	(185)	321	9
Income tax benefit	179			1,089(d)
Net loss	$ (26,423)	$ (26,454)	$ (22,062)	$ (18,412)
Net loss per share basic and diluted	$ (1.55)	$ (1.55)	$ (1.29)	$ (1.07)

Quarterly loss per share totals differ from annual loss per share totals due to rounding.

(a) In April 2010, we received a $60.0 million upfront payment in connection with our collaboration agreement with Takeda.

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(b) In October 2010 we carried out a corporate restructuring pursuant to which we will reduce our workforce by approximately 24% and we incurred charges related to employee severance and other related costs.

(c) On June 30, 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 CKD. We began shipping *Feraheme* to our customers in July 2009.

(d) Tax benefit which was the result of our recognition of a corresponding income tax expense, which was recorded in other comprehensive income, associated with the increase in the value of certain securities during the year ended December 31, 2009.

P. Valuation and Qualifying Accounts (in thousands)

	Balance at Beginning of Period	Additions(a)	Other Additions(b)	Deductions Charged to Reserves	Balance at End of Period
Year ended December 31, 2010:					
Accounts receivable allowances(c)	$ 499	$ 5,113	$	$ (4,464)	$ 1,148
Rebates, fees and returns reserves	$ 5,657	$ 17,779	$	$ (13,421)	$ 10,015
Year ended December 31, 2009:					
Accounts receivable allowances(c)	$	$ 804	$	$ (305)	$ 499
Rebates, fees and returns reserves	$	$ 4,792	$ 1,119	$ (254)	$ 5,657
Year ended December 31, 2008:					
Accounts receivable allowances(c)	$	$	$	$	$
Rebates, fees and returns reserves	$	$	$	$	$

(a) Additions to sales discounts, rebates, fees and returns reserves are recorded as a reduction of revenues.

(b) Additions to rebate reserves related to deferred revenues are recorded as a reduction to deferred revenues.

(c) We have not recorded an allowance for doubtful accounts in any of the years presented above.

Q. Recently Issued and Proposed Accounting Pronouncements

In December 2010, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2010-027, Fees Paid to the Federal Government by Pharmaceutical Manufacturers, or ASU 2010-027. ASU 2010-027 provides guidance concerning the recognition and classification of the new annual fee payable by branded prescription drug manufacturers and importers on branded prescription drugs which was mandated under the health care reform legislation enacted in the U.S. in March 2010. Under this new accounting standard, the annual fee would be presented as a component of operating expenses and recognized over the calendar year such fees are payable using a straight-line method of allocation unless another method better allocates the fee over the calendar year. This ASU is effective for calendar years beginning on or after December 31, 2010, when the fee initially becomes effective, which for us is fiscal 2011. As this standard relates only to classification, the adoption of this accounting standard will not have an impact on our consolidated financial statements.

In January 2010, the FASB, issued ASU No. 2010-06, Improving Disclosures About Fair Value Measurements, or ASU 2010-06, which amends ASC 820, Fair Value Measurements and Disclosure. ASU 2010-06 requires additional disclosure related to transfers in and out of Levels 1 and 2 and the activity in Level 3. This guidance requires a reporting entity to disclose separately the amounts of significant transfers in and out of Level 1 and Level 2 fair value measurements and describe the

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reasons for the transfers. In addition, this guidance requires a reporting entity to present separately information about purchases, sales issuances, and settlements in the reconciliation for fair value measurements using significant unobservable inputs (Level 3). This accounting standard was effective for interim and annual reporting periods beginning after December 31, 2009 other than for disclosures about purchases, sales, issuances and settlements in the roll forward of activity in Level 3 fair value measurements. Those disclosures will be effective for fiscal years beginning after December 31, 2010 and for interim periods within those fiscal years. We adopted all provisions of this pronouncement during the first quarter of 2010, except for those related to the disclosure of disaggregated Level 3 activity. Since this guidance only amends required disclosures in our consolidated financial statements, it did not have an effect upon our financial position or results of operations. We do not expect the adoption of the remaining provisions of this amendment to have a significant impact on our consolidated financial statements.

In October 2009, the FASB issued ASU No. 2009-13, Multiple-Deliverable Revenue Arrangements, or ASU 2009-13. ASU 2009-13 amends existing revenue recognition accounting pronouncements that are currently within the scope of FASB ASC Subtopic 605-25 (previously included within Emerging Issues Task Force, or EITF, No. 00-21, Revenue Arrangements with Multiple Deliverables, or EITF 00-21). ASU 2009-13 provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and how the consideration should be allocated. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management's estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. EITF 00-21 previously required that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. This was difficult to determine when the product was not individually sold because of its unique features. Under EITF 00-21, if the fair value of all of the elements in the arrangement was not determinable, then revenue was generally deferred until all of the items were delivered or fair value was determined. This new approach is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, which was January 1, 2011 for us. We do not currently expect the initial adoption of this guidance to have a significant impact on our consolidated financial statements; however, it will likely impact us in the future if we complete any future transactions or if we enter into any material modifications to any of our existing collaborations.

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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 the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures were effective and were designed to ensure 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 accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure, and is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission, or, SEC's, rules and forms. 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. Our principal executive officer and principal financial officer have each concluded that our disclosure controls and procedures as of the end of the period covered by this report are effective at a level that provides such reasonable assurances.

Management's Annual Report on Internal Control Over Financial Reporting

The report of our management on both management's responsibility for financial statements and management's annual 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, 2010.

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, 2010 that materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION:

None.

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE:

The information required under this item is incorporated herein by reference to the proposal related to the election of our directors and the section entitled "Executive Officers and Compensation" in 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, 2010.

ITEM 11. EXECUTIVE COMPENSATION:

The information required under this item is incorporated herein by reference to the section entitled "Executive Officers and Compensation" in 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, 2010.

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 the section entitled "Security Ownership of Certain Beneficial Owners and Management" in 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, 2010.

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

The information required under this item is incorporated herein by reference to the section entitled "Certain Relationships and Related Transactions" and to the proposal related to the election of our directors in 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, 2010.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES:

The information required under this item is incorporated herein by reference to the proposal related to the ratification of appointment of independent auditor in 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, 2010.

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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, 2010 and 2009

Consolidated Statements of Operations for the years ended December 31, 2010, 2009 and 2008

Consolidated Statements of Comprehensive Loss for the years ended December 31, 2010, 2009 and 2008

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2010, 2009 and 2008

Consolidated Statements of Cash Flows for the years ended December 31, 2010, 2009 and 2008

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 and 4.1 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 Report on Form 8-K filed September 4, 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	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*	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).

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Exhibit Number	Description
10.2*	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).
10.3*	Specimen of Stock Option Grant in connection with 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).
10.4*	Specimen of Stock Option Grant in connection with 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).
10.5*	Form of Restricted Stock Unit Agreement in connection with the Company's Amended and Restated 2000 Stock Plan (incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed February 13, 2006, File No. 0-14732).
10.6*	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).
10.7*	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).
10.8*	AMAG Pharmaceuticals, Inc.'s Non-Employee Director Compensation Policy (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010, File No. 001-10865).
10.9*	Second Amended and Restated Employment Agreement dated as of December 15, 2009 between the Company and Brian J.G. Pereira, MD. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 17, 2009, File No. 0-14732).
10.10*	Amendment to Employment Agreement dated as of February 1, 2011 between the Company and Brian J.G. Pereira, MD (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed February 4, 2011, File No. 001-10865).
10.11*	Form of Second Amended and Restated Employment Agreement dated as of December 15, 2009 between the Company and each executive officer of the Company (other than Dr. Pereira) (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed December 17, 2009, File No. 0-14732).
10.12*	Form of Amendment to Employment Agreements dated as of February 1, 2011 between the Company and each executive officer of the Company (other than Dr. Pereira) (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed February 4, 2011, File No. 001-10865).
10.13*	AMAG Pharmaceuticals, Inc. Second Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Appendix B to the Company's Definitive Proxy Statement on Schedule 14A, filed April 19, 2010, File No. 001-10865).
10.14*	Form of Option Agreement (ISO) in connection with 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).
10.15*	Form of Option Agreement (Nonqualified Option) in connection with 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).
10.16*	Form of Restricted Stock Unit Agreement in connection with 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).

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Exhibit Number	Description
10.17*	Form of Option Agreement (Nonqualified Option) for Annual Director Grants in connection with 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).
10.18*	Form of Restricted Stock Unit Agreement for Annual Director Grants in connection with 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).
10.19	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 (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).
10.20	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).
10.21	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).
10.22	Commercial Outsourcing Services Agreement, dated October 2008, by and between the Company and Integrated Commercialization Services, Inc. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed July 1, 2009, File No. 0-14732). (confidential treatment previously granted).
10.23	Commercial Packaging Services Agreement, dated May 29, 2009, by and between the Company and 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).
10.24	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).
21.1+	Subsidiaries of the Company.
23.1+	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
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, 2010, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Comprehensive Loss, (iv) Consolidated Statements of Stockholders' Equity, (v) Consolidated Statements of Cash, and (vi) Notes to Consolidated Financial Statements, tagged as blocks of text.

+ Exhibits marked with a plus sign ("+") are filed herewith.

++ Exhibits marked with a double plus sign ("++") are furnished herewith.

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

* 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.

(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/ BRIAN J.G. PEREIRA

Brian J.G. Pereira,
Chief Executive Officer,
President and Director

Date: February 25, 2011

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/ BRIAN J. G. PEREIRA Brian J. G. Pereira, MD	Chief Executive Officer, President and Director (Principal Executive Officer)	February 25, 2011
/s/ DAVID A. ARKOWITZ David A. Arkowitz	Executive Vice President, Chief Financial Officer and Chief Business Officer (Principal Financial and Accounting Officer)	February 25, 2011
/s/ JOSEPH V. BONVENTRE, MD, PHD Joseph V. Bonventre, MD, PhD	Director	February 25, 2011
/s/ MICHAEL NARACHI Michael Narachi	Director	February 25, 2011
/s/ ROBERT J. PEREZ Robert J. Perez	Director	February 25, 2011
/s/ LESLEY RUSSELL, MB. CH.B., MRCP Lesley Russell, MB. Ch.B., MRCP	Director	February 25, 2011
/s/ DAVEY S. SCOON Davey S. Scoon	Director	February 25, 2011
/s/ RON ZWANZIGER Ron Zwanziger	Director	February 25, 2011

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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 and 4.1 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 Report on Form 8-K filed September 4, 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	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*	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).
10.2*	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).
10.3*	Specimen of Stock Option Grant in connection with 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).
10.4*	Specimen of Stock Option Grant in connection with 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).
10.5*	Form of Restricted Stock Unit Agreement in connection with the Company's Amended and Restated 2000 Stock Plan (incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed February 13, 2006, File No. 0-14732).
10.6*	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).
10.7*	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).
10.8*	AMAG Pharmaceuticals, Inc.'s Non-Employee Director Compensation Policy (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010, File No. 001-10865).
10.9*	Second Amended and Restated Employment Agreement dated as of December 15, 2009 between the Company and Brian J.G. Pereira, MD. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed December 17, 2009, File No. 0-14732).
10.10*	Amendment to Employment Agreement dated as of February 1, 2011 between the Company and Brian J.G. Pereira, MD (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed February 4, 2011, File No. 001-10865).

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Exhibit Number	Description
10.11*	Form of Second Amended and Restated Employment Agreement dated as of December 15, 2009 between the Company and each executive officer of the Company (other than Dr. Pereira) (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed December 17, 2009, File No. 0-14732).
10.12*	Form of Amendment to Employment Agreements dated as of February 1, 2011 between the Company and each executive officer of the Company (other than Dr. Pereira) (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed February 4, 2011, File No. 001-10865).
10.13*	AMAG Pharmaceuticals, Inc. Second Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Appendix B to the Company's Definitive Proxy Statement on Schedule 14A, filed April 19, 2010, File No. 001-10865).
10.14*	Form of Option Agreement (ISO) in connection with 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).
10.15*	Form of Option Agreement (Nonqualified Option) in connection with 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).
10.16*	Form of Restricted Stock Unit Agreement in connection with 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).
10.17*	Form of Option Agreement (Nonqualified Option) for Annual Director Grants in connection with 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).
10.18*	Form of Restricted Stock Unit Agreement for Annual Director Grants in connection with 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).
10.19	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 (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).
10.20	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).
10.21	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).
10.22	Commercial Outsourcing Services Agreement, dated October 2008, by and between the Company and Integrated Commercialization Services, Inc. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed July 1, 2009, File No. 0-14732). (confidential treatment previously granted).
10.23	Commercial Packaging Services Agreement, dated May 29, 2009, by and between the Company and 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
10.24	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).
21.1+	Subsidiaries of the Company.
23.1+	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
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, 2010, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Comprehensive Loss, (iv) Consolidated Statements of Stockholders' Equity, (v) Consolidated Statements of Cash, and (vi) Notes to Consolidated Financial Statements, tagged as blocks of text.

+ Exhibits marked with a plus sign ("+") are filed herewith.

++ Exhibits marked with a double plus sign ("++") are furnished herewith.

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

* 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.