AMAG PHARMACEUTICALS INC.
Form 10-K
February 26, 2010

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, 2009

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 0-14732

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 ý No o**

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 o 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 o

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, 2009 was approximately $930,000,000 based on the closing price of $54.67 of the Common Stock of the registrant as reported on the NASDAQ Global Market on such date. As of February 16, 2010, there were 20,987,794 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 25, 2010, 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 expectations regarding our intended development and commercialization of Feraheme® (ferumoxytol) Injection, our expectation that utilization of previously deferred Feraheme Launch Incentive Program revenues will increase, the expected timing of the filing of our marketing authorization application for Feraheme with the European Medicines Agency, our plan to conduct two pediatric studies and the expected timing and design of these studies, our plan to conduct and the intended timing and design of our planned global studies of Feraheme for the treatment of iron deficiency anemia in a broad range of patients, our belief that all items or information requested in the Screening Deficiency Notice from Health Canada are readily addressable, our statement that our partner in China, 3SBio Inc., plans to conduct a Feraheme clinical study in China, our expectation that sales of GastroMARK will not change materially, our expectation that we will not recognize any Feridex I.V. related revenues in 2010, our belief as to the potential size of the non-dialysis chronic kidney disease market segment and current use of intravenous iron within that market segment, our expectation regarding our future revenues, including expected future Feraheme and 3SBio Inc. revenues and our expectation to partly fund our future operations with Feraheme revenues, our expectation that our costs of product sales will increase, our expectation that research and development expenses will increase, 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 increase, our expectation regarding our dividend and interest income, our expectation regarding our short- and long-term liquidity and capital requirements and our ability to finance our operations, our expectation regarding our future cash flows, our expectation that net cash used in operating activities will decrease in 2010, our belief that the impairment in the value of our auction rate securities not subject to settlement right agreements is temporary and that we will ultimately be able to liquidate these investments without significant loss, our intention to sell our auction rate securities subject to settlement right agreements to UBS AG, 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.

ITEM 1. BUSINESS:

Company Overview

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a biopharmaceutical company that utilizes our proprietary technology for the development and commercialization of a therapeutic iron compound to treat iron deficiency anemia and novel imaging agents to aid in the diagnosis of cancer and cardiovascular disease. We currently manufacture and sell two approved products, Feraheme® (ferumoxytol) Injection for intravenous, or IV, use and GastroMARK®.

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On June 30, 2009, *Feraheme* was approved for marketing in the U.S. by the U.S. Food and Drug Administration, or the FDA, for use as an IV iron replacement therapy for the treatment of iron deficiency anemia, or IDA, in adult patients with chronic kidney disease, or CKD. We market and sell *Feraheme* through our own commercial organization, consisting of approximately 120 professionals, including an 80-person specialized sales force and account management and reimbursement teams. We sell *Feraheme* primarily to authorized wholesalers and specialty distributors and began commercial sale of *Feraheme* in the U.S. in July 2009.

In November 2009, the Centers for Medicare & Medicaid Services, or CMS, assigned *Feraheme* two unique Q-codes, one for the treatment of IDA in end-stage renal disease patients undergoing dialysis and one for the treatment of IDA in non-end-stage renal disease patients. These Q-codes, which are temporary product-specific codes that enable automated processing of *Feraheme*-related claims, became effective on January 1, 2010.

For the year ended December 31, 2009, we recognized net product sales of *Feraheme* of $15.8 million, including approximately $1.3 million of the $11.5 million in deferred product revenues we had recorded in the third quarter of 2009. During the third quarter of 2009, shortly after the launch of *Feraheme*, we implemented a Launch Incentive Program under which certain dialysis organizations purchased *Feraheme* directly from us. This program provided certain customers with, among other things, discounted pricing and expanded rights of return. As a result, we deferred revenues associated with this program which we will recognize as revenues as the participating organizations utilize their *Feraheme* inventory. We expect that utilization of the remaining deferred product revenues from the Launch Incentive Program will increase going forward as each Launch Incentive Program customer has begun to use *Feraheme*.

In December 2009, we submitted draft protocols for two proposed clinical trials to meet our FDA post-approval Pediatric Research Equity Act requirement to support pediatric labeling of *Feraheme.* In 2010, we intend to initiate these two randomized, active controlled pediatric studies in children with IDA. 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 children.

We also plan to advance our *Feraheme* clinical development program in adults by initiating two Phase III multi-center clinical trials in mid-2010 to assess *Feraheme* for the treatment of IDA in a broad range of patients, which may include women with abnormal uterine bleeding, or AUB, patients with cancer and gastrointestinal diseases and postpartum women, for whom oral iron is unsatisfactory. One study 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. A second study will 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, we intend to initiate an open label extension study 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.

We continue to evaluate our strategy for seeking approval for *Feraheme* as an IV iron replacement therapeutic agent in countries outside of the U.S. The commercial opportunity for *Feraheme* as an IV iron replacement therapeutic agent varies from country to country, and in determining which additional markets outside of the U.S. we intend to enter, we are assessing factors such as potential pricing and reimbursement, the role of iron in medical treatment protocols, and the regulatory requirements of each country. We expect to file a Marketing Authorization Application, or MAA, for *Feraheme* for the treatment of IDA in CKD patients with the European Medicines Agency, or EMEA, in mid-2010. In the fourth quarter of 2009, we received approval from the EMEA for our Pediatric Investigation Plan, which is a prerequisite for the submission of our *Feraheme* MAA. Our Pediatric Investigation Plan

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includes the two pediatric studies required to meet our Pediatric Research Equity Act requirement and two additional pediatric studies requested by the EMEA. To further support our MAA, we have initiated a global, randomized, Phase IV multi-center, active controlled trial with approximately 150 adult CKD patients both on dialysis and not on dialysis. This study 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.

In December 2009, we filed a New Drug Submission for *Feraheme* to treat IDA in patients with CKD with the Therapeutic Products Directorate of Health Canada, or Health Canada, the federal authority that regulates pharmaceutical drugs and medical devices for human use in Canada. In February 2010, we received a Screening Deficiency Notice from Health Canada requesting certain clarifications and additional documents. We have submitted our response to Health Canada and believe that all of these items are readily addressable. In addition, 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. Once approved by the SFDA, 3SBio plans to commence a multi-center randomized efficacy and safety study in China involving approximately 200 CKD patients.

In addition to its use for the treatment of IDA, *Feraheme* may also be useful as a vascular enhancing agent in magnetic resonance imaging, or MRI. In August 2008, the FDA granted Fast Track designation to *Feraheme* with respect to its development as a diagnostic agent for vascular-enhanced MRI for the assessment of peripheral arterial disease, or PAD, in patients with CKD. We have enrolled over two-thirds of our 108 patient Phase II study of *Feraheme* in vascular-enhanced MRI for the detection of clinically significant arterial stenosis or occlusion, or narrowing or blocking of the arteries.

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 their current levels for the last several years, and we do not expect sales of *GastroMARK* to change materially.

Feridex I.V.®, our liver contrast agent, had been marketed and sold in the U.S., Europe and other countries for a number of years through our marketing partners. In November 2008, we decided to cease manufacturing *Feridex I.V.* Accordingly, we have terminated all of our agreements with our marketing partners for *Feridex I.V.* throughout the world and do not intend to continue commercializing *Feridex I.V.* We recorded no product sales revenues associated with *Feridex I.V.* in 2009 and do not expect to recognize any *Feridex I.V.* related revenues in 2010.

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.

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 nanoparticles and their characteristic properties. Our core competencies include the ability to design such nanoparticles for particular applications, to manufacture the nanoparticles in controlled sizes, and to cover the nanoparticles 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 nanoparticles in

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a manner necessary for use in pharmaceutical products such as IV iron replacement therapeutics and MRI contrast agents.

Our iron oxide nanoparticles are composed of bioavailable iron that is easily utilized by the body and incorporated into the body's iron stores. As a result, products using our core technology are well suited for use as an IV iron replacement therapy. Additionally, the superparamagnetic characteristic of our products result in nanoparticles that become strongly magnetic when placed in a magnetic field, but lose their magnetism once the field is removed. Therefore, use of our nanoparticles can result in MRIs that provide essential information to the reviewing physician. 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."

Products

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

Product	Applications	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 Inc. (China)	Approved for commercial sale on June 30, 2009; commenced commercial launch in July 2009.	3SBio Inc. filed for registrational trial with the Chinese regulatory agency in December 2009.
				New Drug Submission filed with the Canadian regulatory agency in December 2009. Screening Deficiency Notice received and response filed in February 2010.
				Marketing Authorization Application planned to be filed with the European Medicines Agency in mid-2010.
	IV iron replacement therapeutic agent in patients with IDA, regardless of the underlying cause.	None	Global Phase III program planned to be initiated in mid-2010.	No marketing applications filed to date.
	Vascular-enhanced MRI agent for PAD.	None	Phase II clinical trial in progress.	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 European Union, South America, the Middle East, southeast Asia, Africa and eastern Europe)	Approved and marketed.	Approved and marketed in several European Union 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."

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Feraheme as an IV Iron Replacement Therapeutic

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.

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 60% 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.

According to an estimate by the United States Renal Data System, approximately 400,000 CKD patients are projected to be on dialysis in the U.S. in 2010. Approximately 90% of these dialysis patients will receive IV iron as part of managing their anemia. In addition, data contained in a 2002 publication in the *Journal of the American Society of Nephrology* suggests that up to 1.6 million of stage 3 and 4 non-dialysis CKD patients with anemia may be iron deficient and could therefore benefit from receiving IV iron. We believe that less than 10% of these patients are currently being treated with IV 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 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.

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. Rapid administration of large doses of other IV iron products has been associated with an unfavorable safety profile. As a result, other IV iron products are typically administered as a slow push or a 15 to 60 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, potentially resulting in considerable burden to both providers and patients. *Feraheme* is administered as a 510 milligram injection followed by a second 510 milligram injection three to eight days later, each of which can be administered in as fast as 17 seconds at a regular office visit or during dialysis treatment without the use of infusion equipment or prolonged medical intervention.

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Feraheme in indications other than CKD

IDA is widely prevalent in many different patient populations, including women with AUB, patients with cancer and gastrointestinal diseases, and postpartum women. We believe that the product characteristics of *Feraheme* support clinical development in these additional indications, and we are currently in the process of preparing for a global clinical development program for *Feraheme* in a broad range of patients with IDA, regardless of the underlying cause. We intend to initiate our Phase III program for *Feraheme* in IDA in mid-2010.

Included among the patient populations we are evaluating for additional indications for *Feraheme* are women with AUB and cancer patients.

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. Both iron deficiency and IDA are commonly associated with AUB. The prevalence of anemia in AUB patients has been reported to range from 10% to 67%, and the prevalence of iron deficiency in AUB patients has been reported to range from 20% to 50%, depending on patient age and diagnostic criteria. IDA in patients with AUB, regardless of the cause, requires treatment with iron supplementation, either by oral or IV administration.

Anemia is also common in patients with cancer. Depending on the type of cancer, it has been estimated that between 30% and 90% of patients with cancer have anemia. Iron supplementation through both oral and IV administration has 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, the 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.

Ferumoxytol as a Diagnostic Agent for Vascular Enhancement in MRI

MRI is a non-invasive method used to visualize normal or abnormal anatomy or pathophysiology in patients in order to diagnose disease and injury. Imaging agents or biomarkers play an important role in improving the quality of diagnostic images by increasing the contrast between different internal structures or types of tissues in various disease states.

Ferumoxytol is currently in development as an agent for vascular-enhanced MRI because of its ability to increase the magnetic relaxivity of blood, resulting in MRIs with enhanced vascular contrast. When used with the appropriate pulse sequence, ferumoxytol may provide high-quality diagnostic images. In addition to its superparamagnetic properties, ferumoxytol can be administered rapidly as an IV injection at a rate of up to one milliliter per second. It also has a long blood half-life of approximately 15 hours, which may permit repeated imaging of the same or different body regions. These features of ferumoxytol may make it useful as an MRI biomarker in vascular disorders.

The initial focus of our clinical development of ferumoxytol as an imaging agent has been in patients with PAD for the detection of clinically significant arterial stenosis or occlusion. PAD is a manifestation of atherosclerotic cardiovascular disease and can occur when plaque builds up on the inside wall of the arteries that carry blood from the heart to the head, internal organs and limbs causing the arteries to narrow, which can reduce or block blood flow. Symptomatic PAD is associated with decreased quality of life, and whether symptomatic or asymptomatic, PAD is associated with an increased risk of cardiovascular and cerebrovascular problems, and cardiovascular mortality.

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The prevalence of PAD in the U.S. is estimated to be approximately 8 million adults, affecting up to 20% of individuals 65 years of age and older. The prevalence of PAD increases with age, diabetes, CKD, hypertension and smoking, as does the presence of known atherosclerosis in other parts of the body. In the U.S., cardiovascular disease is a common cause of morbidity and mortality, with a prevalence of approximately one in three adults. Additionally, cardiovascular disease is the leading cause of death, accounting for approximately 35% of all deaths in 2005.

Both the diagnosis and clinical management of PAD and cardiovascular disease often require the accurate assessment of vascular anatomy, and therefore, there is an important medical need for the availability of safe and effective techniques for invasive and/or non-invasive imaging modalities in these patient populations. High-resolution imaging, including digital subtraction angiography, contrast-enhanced computed tomography, and contrast-enhanced magnetic resonance angiography all provide the depiction of vascular anatomy required for consideration of endovascular or surgical intervention. However, there are important side effects of these techniques that seriously impact the appropriate evaluation of patients. There is a well-known risk of kidney damage associated with the administration of certain contrast agents for computed tomography, digital subtraction angiography, and X-ray angiography. Several currently approved contrast agents used for MRI in the U.S. are gadolinium-based and are associated with rare but severe adverse events in patients with CKD. In September 2007, the FDA issued a "Black Box" warning for all gadolinium-based contrast agents in certain patients due to these agents' potential association with Nephrogenic Systemic Fibrosis, or NSF. NSF is a condition that so far has only occurred in patients with kidney disease. NSF can pose a serious and potentially fatal risk to patients with CKD, and the FDA has sought to limit the use of currently available contrast agents in this patient population. Currently there is no effective treatment for NSF.

Ferumoxytol is an iron-based agent with unique superparamagnetic properties that may be visualized by MRI. There are no iron-based PAD contrast agents currently approved for MRI in the U.S. The FDA has granted Fast Track designation to ferumoxytol for its development as a diagnostic agent for vascular-enhanced MRI to improve the assessment of suspected PAD in patients with known or suspected CKD. The Fast Track process is designed to facilitate the development and expedite the FDA's review of products and is intended to bring valuable treatments more quickly to patients in need. We have enrolled approximately two-thirds of our 108 patient Phase II study of ferumoxytol for vascular-enhanced MRI for the detection of clinically significant arterial stenosis or occlusion.

We currently have exclusive world-wide rights to market and sell ferumoxytol as an imaging agent.

Feridex I.V.

Feridex I.V. was approved by the FDA in 1996 and by the Committee for Proprietary Medicinal Products in the European Union, or EU, in 1994. In November 2008, we decided to cease manufacturing *Feridex I.V.,* and we do not intend to continue its commercialization. Accordingly, we have terminated all of our agreements with our marketing partners for *Feridex I.V.* throughout the world. We did not record any product sales revenues associated with *Feridex I.V.* in 2009 and do not expect to recognize any *Feridex I.V.* related revenues in 2010.

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

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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."

Licensing, Marketing and Supply Arrangements

Although we are commercializing *Feraheme* 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:

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 up-front payment of $1 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*. 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®) and the option to acquire rights to any future MRI contrast agents developed by us. This agreement was amended in 2002 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. In 2004, it was determined through binding arbitration that Guerbet failed to meet its contractual obligations with respect to the exercise of its option to acquire certain rights to *Feraheme* in imaging, and, accordingly, all such rights reverted back to us. 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 the licensed products. 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

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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

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 at which we produce *Feraheme*. Our ability to manufacture *Feraheme* in sufficient quantities and at an acceptable cost 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 our manufacturing process, including quality control problems, we may experience manufacturing failures which could result in product defects or shipment delays, recall or withdrawal of *Feraheme* previously shipped for commercial or clinical purposes, inventory write-offs or the inability to meet commercial demand for *Feraheme* in a timely and cost-efficient manner. In addition, if we are unable to produce sufficient quantities of *Feraheme* to meet commercial 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 second source manufacturing facilities for *Feraheme*, however we may not be able to enter into agreements on terms acceptable to us with manufacturers whose facilities and procedures are cGMP compliant. Even if we were to reach agreement, the transition of the manufacturing process to a third-party could take a significant amount of time and may not be successful. Any prolonged interruption in our manufacturing operations could result in cancellations of orders or loss of product in the manufacturing process. In addition, use of second source manufacturing facilities may increase the risk of certain problems, including cost overruns, process reproducibility, stability issues, an inability to deliver required quantities of product that conform to specifications in a timely manner or the ability to manufacture *Feraheme* in accordance with cGMP.

The FDA conducts periodic inspections of our manufacturing facility, procedures, operations and testing of our products to determine whether we are in compliance with cGMP and other FDA regulations. Based on these inspections, the FDA may issue notices that require us to modify our manufacturing operations. cGMP regulations require quality control and quality assurance as well as the corresponding maintenance of records and documentation. Failure to operate in compliance with cGMP regulations and other applicable manufacturing requirements of various regulatory agencies could result in 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, or NDAs, enforcement actions, injunctions or criminal prosecution and could impair our ability to obtain product approvals, generate product sales and continue our development efforts.

Furthermore, we need to continue to recruit, train and retain additional qualified manufacturing and quality control and assurance personnel as we manufacture *Feraheme* on a commercial scale. If we fail to attract and retain key members of our manufacturing, quality control or quality assurance departments, we may be unable to manufacture sufficient quantities of *Feraheme* in a timely manner, which could delay our product sales and development efforts.

If we are unable to consistently manufacture our products on a timely basis because of these or other factors, we will not be able to meet demand for *Feraheme*.

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Raw Materials

We currently purchase certain raw 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 materials are readily available, others may be obtained only from qualified suppliers. Certain raw materials used in *Feraheme* are procured from a single source without a qualified alternative supplier. We are in the process of identifying and qualifying additional third-party suppliers for these raw materials. If any of our third-party suppliers should cease to produce the raw materials used in *Feraheme* or otherwise fail to supply these raw materials to us or fail to supply these raw materials to us in sufficient quantities for any reason, including any unexpected demand for or shortage of the raw materials, labor disputes or shortages, manufacturing difficulties, regulatory requirements or action, adverse financial developments at or affecting the supplier or import or export problems, we would be unable to manufacture *Feraheme* in sufficient quantities until we are able to qualify an alternative source.

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 materials from one vendor only, even where multiple sources are available, in order 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 materials, we may not be able to obtain raw materials of the quality required to manufacture *Feraheme* from an alternative source on commercially reasonable terms, or in a timely manner, if at all.

Any delay in or failure to obtain sufficient quantities of raw materials would prevent us from manufacturing *Feraheme*, both for commercial sale and for use in clinical trials. In addition, even if we are able to obtain raw materials from an alternative source, if these raw 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 clinical trials, on a timely and cost-effective basis. Any such difficulty in obtaining raw materials would severely hinder our ability to manufacture *Feraheme* and would have a material adverse impact on our ability to generate additional revenues and our ability to achieve profitability.

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

Our policy is to aggressively protect our competitive technology position by a variety of means, including applying for patents in the U.S. and in appropriate foreign countries. We currently hold a number of U.S. and foreign patents, which expire at various times through 2020. Our *Feraheme* patents currently expire in 2020, which expiration may be subject to an extension under FDA regulations. Because certain patents that cover our products will begin to expire in the coming years, the protection provided by these patents will also begin to expire. Our inability to protect our products through our patents in any territory and other intellectual property rights prior to their expiration could have a material adverse effect on our business, financial condition and prospects.

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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. Any limitation on the protection of our technology could hinder our ability to develop and market our products and product candidates.

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. *Feraheme's* two primary competitors are Venofer®, which is marketed in the U.S. by Fresenius Medical Care North America, or Fresenius, and American Regent Laboratories, Inc., or American Regent, a subsidiary of Luitpold Pharmaceuticals, Inc., or Luitpold, and Ferrlecit®, which is marketed by Sanofi-Aventis U.S. LLC. Products developed by our competitors may be or may be perceived to be safer, more effective, and/or easier to administer or have more favorable pricing, insurance coverage, coding and reimbursement than *Feraheme*. In addition, further technological and product developments may make other iron replacement therapy products more competitive than *Feraheme*, which would adversely impact sales of *Feraheme* as an iron replacement therapeutic agent if such products are approved by the FDA. We may not be able to compete successfully with these companies.

We believe that our ability to successfully compete depends on a number of factors, including the timing and scope of regulatory approval of additional indications and geographies for *Feraheme* and of products by our competitors, our ability to obtain and maintain favorable pricing, insurance coverage, coding and reimbursement for *Feraheme*, 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.

The iron replacement therapy market is highly sensitive to several factors including, but not limited to, the 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 conducted any head-to-head clinical studies comparing *Feraheme* to other IV iron replacement products.

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 IV iron administration for hemodialysis patients with stage 5 CKD, and 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 affect patient compliance in using such products. The alternative, IV iron, is currently available in the U.S. as ferumoxytol, iron sucrose, sodium ferric gluconate, or iron dextran. The IV iron products comprised of iron sucrose or sodium ferric gluconate 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. The iron dextran products are typically administered as a slow push in 100 milligram doses and also require five 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

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in as fast as 17 seconds at a regular office visit or during dialysis treatment without the use of infusion equipment or prolonged medical intervention.

Feraheme currently competes with four IV iron products in the U.S. for the treatment of IDA in CKD patients. Its two primary competitors are Venofer®, an iron sucrose complex, and Ferrlecit®, a sodium ferric gluconate. Venofer® is currently approved for use in hemodialysis, peritoneal dialysis and non-dialysis dependent CKD patients. Ferrlecit® is approved for use only in hemodialysis patients. Dexferrum® is an iron dextran product marketed by American Regent, and INFeD®, also an iron dextran product, is marketed by Watson Pharmaceuticals, Inc., or Watson. Both iron dextran products are used in patients with documented iron deficiency in whom oral iron administration is unsatisfactory or impossible.

Based on sales data provided by IMS Health Incorporated, or IMS Health, we estimate that the size of the 2009 U.S. IV iron replacement therapy market was approximately 1.6 million grams, which represented an increase of approximately 8% over 2008. Of the estimated 1.6 million grams sold in the U.S. IV iron therapy replacement market in 2009, sales of Venofer® and Ferrlecit® represented approximately 67% and 21%, respectively. Dexferrum® and INFeD® together accounted for approximately 11% of sales of grams of iron in the U.S. market in 2009. *Feraheme* accounted for approximately 1% of sales of grams of iron in the U.S. market in 2009.

We compete primarily in two segments of the iron replacement therapy market: the dialysis market and the non-dialysis market.

The dialysis market is the largest and most established market for IV iron replacement therapies, with two companies serving a significant majority of all dialysis patients in the U.S. Fresenius, and DaVita, Inc., or DaVita, together treat more than two-thirds of the U.S. dialysis population. In September 2008, Fresenius finalized an exclusive sublicense agreement with Luitpold, the U.S. licensing partner of Vifor Pharma, a subsidiary of Galenica Ltd., or Galenica, to manufacture, sell and distribute Venofer® to independent outpatient dialysis clinics in the U.S. Luitpold retains the right to sell Venofer® in the U.S. to any other customer. In addition, Galenica, Vifor Pharma, and Fresenius entered into a strategic joint-venture, which became effective on January 1, 2009, to market and distribute Venofer® and Ferinject® in the dialysis market in Europe, the Middle East, Africa and Latin America. Fresenius has significant experience selling and distributing dialysis equipment and supplies to outpatient dialysis clinics and, as a result of these agreements, it may be more difficult for us to penetrate the dialysis market, in particular at their clinics.

We believe there is a significant opportunity for *Feraheme* in the treatment of IDA in CKD patients not yet on dialysis. The non-dialysis IV iron market is comprised primarily of three segments: hospitals, hematology clinics and nephrology clinics. The only primary competitor currently approved for use in non-dialysis dependent CKD patients is Venofer®. Our ability to effectively compete with Venofer® in the non-dialysis CKD market depends in part upon our ability to gain formulary access in hospitals and effectively promote *Feraheme* to physicians who treat non-dialysis CKD patients.

In December 2009, Pharmacosmos A/S, or Pharmacosmos, received a positive recommendation in 22 European countries and a final marketing authorization in Denmark, Iceland and the Netherlands to market Monofer® (iron isomaltoside 1000), its injectable iron preparation for the treatment of IDA. During 2008, Pharmacosmos completed two Phase III non-comparative open-label studies of IV iron oligosaccharide in CKD patients as well as in congestive heart failure patients. Pharmacosmos is currently recruiting patients for a Phase III comparative open-label study of IV iron oligosaccharide in patients with inflammatory bowel disease and IDA. 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 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,

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including Injectafer®, which is known as Ferinject® in Europe, and soluble ferric pyrophosphate, a form of iron given as part of the hemodialysis procedure.

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. 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 in the U.S. Luitpold initiated five clinical trials during 2008 and 2009 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®, and it was simultaneously registered in a total of 18 EU countries. Ferinject® is currently marketed in at least 12 European countries. In November 2009, Vifor completed a Phase III study of patients with chronic heart failure and iron deficiency. In addition, Vifor is sponsoring ongoing Phase III trials for Ferinject® for the treatment of anemia in patients with inflammatory bowel disease and has stated that it is planning to initiate a Phase IIIb study to evaluate the long-term efficacy of Ferinject® in non-dialysis dependent CKD patients with IDA.

Rockwell Medical, or Rockwell, is developing an iron supplemented dialysate product, a form of iron given as part of the hemodialysis procedure, to be used as a treatment for IDA in dialysis patients. Rockwell has completed a Phase IIb clinical trial and has stated that it intends to initiate Phase III trials in the second half of 2010. We do not know when this product might be submitted to the FDA for approval or marketed. If shown to be safe and effective for the treatment of IDA, this product could compete with *Feraheme* in the dialysis market segment.

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., or GeneraMedix, 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 ESA therapy. GeneraMedix has filed an Abbreviated NDA 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. If any of these product candidates are approved for marketing and sale by the FDA, our efforts to market and sell *Feraheme* and our ability to generate additional revenues and achieve profitability could be adversely affected.

Sales, Marketing and Distribution

In July 2009 we began commercial sale of *Feraheme,* which is being marketed and sold through our own commercial organization of approximately 120 professionals, including an 80-person specialized sales force and account management and reimbursement teams.

We sell *Feraheme* primarily through authorized wholesalers and specialty distributors who, in turn, sell *Feraheme* to nephrologists, hematologists, hospitals, dialysis centers, CKD clinics and infusion centers 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.

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,

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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 focuses on two distinct CKD markets in the U.S.: dialysis dependent and non-dialysis dependent CKD patients. The dialysis market segment is an established market with approximately 400,000 patients currently being treated with a total of approximately 1 million grams of IV iron per year. Two thirds of the IV iron given to dialysis patients in the U.S. takes place at the two largest dialysis organizations with the remaining one third at all other dialysis organizations. Our initial focus in the dialysis market has been to encourage potential *Feraheme* purchases through education, contractual incentives and pilot programs. We believe that the non-dialysis market segment has an annual potential of approximately 2 million grams of IV iron use with less than 15% of non-dialysis CKD patients 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, infusion centers 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, 2009, 2008 and 2007. No other company accounted for more than 10% of our total revenues in any period presented below.

	For the Years Ended December 31,		
	2009	**2008**	**2007**
AmerisourceBergen Drug Corporation	46%		
Metro Medical Supply, Inc.	28%		
Bayer Healthcare Pharmaceuticals	<10%	53%	43%
Guerbet S.A.	<10%	24%	26%
Covidien, Ltd.	<10%	17%	15%
Cytogen Corporation			14%

All of the revenues attributable to Cytogen Corporation and a large portion of the revenues attributable to Bayer Healthcare Pharmaceuticals in all periods presented were previously deferred revenues related to up-front license fees.

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.

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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 or product candidates, including our ability to receive approval for new indications for existing products. It is impossible to predict whether legislative changes will be enacted, or whether FDA regulations or guidances will be amended or supplemented, or the potential impact of such changes.

FDA Approval Process

Clinical Development

Before new human pharmaceutical products, including iron replacement therapy products and contrast imaging agents, 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 an 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.

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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.

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 as 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 the "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.

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Adverse Event Reporting

The FDA requires us to submit reports of certain information on side effects and adverse events associated with our 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 place additional limitations on an approved product's use, such as through labeling changes, and, 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 and 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 NDA. Supplemental NDAs 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.

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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 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 supplemental NDAs, 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, the termination of our clinical trials, restrictions on how we market

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and sell *Feraheme*, restrictions on our manufacturing processes, 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 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, including California, Maine, Massachusetts, Minnesota, Nevada, New Mexico, Vermont and West Virginia, as well as the District of Columbia, have enacted legislation requiring pharmaceutical companies operating within the state to establish marketing and promotional compliance programs and/or file periodic reports with the state with respect to sales, marketing, pricing, and other activities. Similar legislation is being considered in a number of other states, as well as by the federal government. Many of these requirements are new and uncertain, and available guidance is limited. Failure to comply with any of these laws could result in a range of fines, penalties and/or other sanctions.

Foreign Regulatory Process

To the extent we choose to develop, manufacture, market or sell *Feraheme* in foreign countries, we will also be subject to foreign regulatory requirements, which vary widely from country to country. 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. may be more or less rigorous as compared with the U.S., and the time required for approval may differ from that required in the U.S. In addition, obtaining marketing approval in foreign countries may involve additional requirements from what the FDA requires.

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 EMEA which, if approved, permits the marketing of a product in all EU Member States. Under the mutual

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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 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. 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.

Currently, in the hospital outpatient, dialysis center and physician clinic settings, Medicare Part B generally reimburses for physician-administered drugs at 106% of its average sales price, or ASP. When a new product is launched, historical sales data is not available and, until such time as CMS believes it has sufficient data to accurately determine the product's ASP, providers are instead generally reimbursed at 106% of the product's wholesale acquisition cost. Once available, 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 2008, Congress enacted the Medicare Improvements for Patients and Providers Act of 2008, or MIPPA, which created a Medicare-expanded bundled payment system for the treatment of end stage renal disease, or ESRD, to be implemented by January 1, 2011. MIPPA requires CMS to move from a system in which it pays separately for physician-administered drugs for dialysis patients to a system in which all costs of providing care to dialysis patients are bundled together into a single capitated payment. The ESRD expanded bundle is to be phased in beginning on January 1, 2011, and the phase-in must be completed by January 1, 2014. In September 2009, in compliance with the statutory requirements of MIPPA, CMS proposed a new prospective payment system for dialysis services provided to Medicare beneficiaries who have ESRD. CMS intends to issue a final rule on the prospective payment system later in 2010 in order to meet the legislative requirements of implementation by January 1, 2011. Given the uncertainties surrounding bundling, we cannot predict the impact such a system will have on sales of *Feraheme* in the dialysis setting. Bundling initiatives implemented in other healthcare settings, however, have frequently resulted in lower utilization of products and services that were added as a component of a bundled payment. Therefore, it is possible that the implementation of a bundled reimbursement system in the ESRD market could have a

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material negative impact on sales of *Feraheme* in the dialysis market, the price we charge for *Feraheme*, and our overall revenues.

While the MIPPA ESRD provisions apply only to Medicare, Medicare payment policy 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. In addition, when a new product is approved, a failure to demonstrate clear economic value associated with the use of the new product as compared to existing products may result in inadequate or no reimbursement. 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 the 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, for providers to obtain reimbursement for *Feraheme* from Medicare, Medicaid and most third-party payors, specific codes must be submitted by the provider with each claim in order to help the payor identify the product used. These codes are issued to manufacturers at the discretion of CMS. Until a new product obtains a unique drug code, it can only be billed by using a miscellaneous drug code. Inclusion of this miscellaneous drug code will subject each claim to manual review and could delay or prevent reimbursement. In November 2009, CMS assigned *Feraheme* two unique Q-codes, one for the treatment of IDA in ESRD patients undergoing dialysis and one for the treatment of IDA in non-ESRD patients. These Q-codes, which are temporary product-specific codes that enable automated processing of *Feraheme*-related claims, became effective on January 1, 2010. The new codes must be adopted by payors in order to facilitate claims processing.

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. In addition, some foreign countries require that the pricing for new drugs be approved before the drug can be sold and/or marketed in that country, and there is no guarantee that our proposed prices will be approved.

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 $0.1 million and $0.2 million product sales backlog as of December 31, 2009 and 2008, respectively.

Employees

As of February 16, 2010, we had 283 employees. We also utilize consultants and independent contractors on a regular basis to assist in the development and commercialization of our products. 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.

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Foreign Operations

We have no foreign operations. Revenues for the years ended December 31, 2009, 2008 and 2007 from customers outside of the U.S., principally in Europe, amounted to 2%, 29% and 28%, respectively, of our total revenues.

Research and Development

We have dedicated a significant portion of our resources to our efforts to develop our product candidates, particularly *Feraheme*. We incurred research and development expenses of $36.3 million, $31.7 million and $24.2 million during the years ended December 31, 2009, 2008 and 2007, respectively. We anticipate that a significant portion of our operating expenses will continue to be related to research and development in 2010 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.

Code of Ethics

Our Board of Directors, or the Board, has adopted a code of ethics that applies to our officers, directors and employees. In August 2009, the Board approved certain amendments to our code of ethics to clarify and better organize it and to make it more appropriate for a company of our size and stage of development. 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.

Our ability to generate future revenues 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 their current levels for the last several 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 dedicate significant resources to our *Feraheme* development efforts; however, we may not be successful in expanding the potential indications or developing new applications for *Feraheme*. Although we are pursuing or have commenced additional clinical trials for *Feraheme* in indications other than chronic kidney disease, or CKD, and as an imaging agent, 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 acquire, develop and commercialize additional products and product candidates or gain approval for additional indications or uses for *Feraheme* could limit long-term shareholder value and would adversely affect the future prospects of our business.

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*.

There are currently two options for treating iron deficiency anemia, or IDA, in CKD patients: oral iron supplements and intravenous, or IV, iron. *Feraheme* primarily competes with two other IV iron replacement therapies, including Venofer®, which is marketed in the U.S. by Fresenius Medical Care North America, or Fresenius, and American Regent Laboratories, Inc., a subsidiary of Luitpold Pharmaceuticals, Inc., or Luitpold, and Ferrlecit®, which is marketed by Sanofi-Aventis U.S. LLC. *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

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convenience of administration and dosing regimens. To date, we have not conducted any head-to-head clinical studies comparing *Feraheme* to other IV iron replacement products.

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 in December 2009 received a positive recommendation in 22 European countries and a final marketing authorization in Denmark, Iceland and the Netherlands for the treatment of IDA, Injectafer®, which is known as Ferinject® in Europe and is approved for marketing in 18 European Union countries, and soluble ferric pyrophosphate, a form of iron given as part of the hemodialysis procedure.

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, or NDA, with the U.S. Food and Drug Administration, or 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.

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

Feraheme may not be widely adopted by physicians, patients, healthcare payors, and the major operators of dialysis clinics in the U.S.

The commercial success of *Feraheme* depends upon its level of market adoption by physicians, patients, and healthcare payors or providers, including dialysis clinics. If *Feraheme* does not achieve an adequate level of market adoption for any reason, our potential profitability and our future business prospects would 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, no more effective, or no more convenient than currently available products. The degree of market acceptance of *Feraheme* depends on a number of factors, including but not limited to:

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

The ability of physicians and other providers to be adequately reimbursed for *Feraheme* in a timely manner from payors, including government payors, such as Medicare and Medicaid, and private payors, particularly in light of the expected "bundling" of costs of providing care to dialysis patients;

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;

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The effectiveness of our sales and marketing organizations and our distribution network; and

The development of unanticipated adverse reactions to *Feraheme* resulting in safety concerns among prescribers.

We market and sell *Feraheme* for use by both dialysis and non-dialysis CKD patients. The dialysis market is the largest and most established market for IV iron replacement therapies, with two companies serving a significant majority of all dialysis patients in the U.S. Fresenius and DaVita, Inc., or DaVita, together treat approximately two-thirds of the U.S. dialysis population. If we are unable to successfully market and sell *Feraheme* to physicians who treat dialysis dependent CKD patients in clinics controlled by either or both of Fresenius and DaVita, our ability to realize and grow revenues from sales of *Feraheme* could be limited. In addition, if we are unable to successfully market and sell *Feraheme* to a significant number of the dialysis clinics that treat the remaining one-third of the U.S. dialysis population, our potential profitability and our future business prospects could be materially adversely impacted.

In September 2008, Fresenius finalized an exclusive sublicense agreement with Luitpold, the U.S. licensing partner of Vifor Pharma, a subsidiary of Galenica Ltd., to manufacture, sell and distribute Venofer®, an IV iron replacement therapeutic, to independent outpatient dialysis clinics in the U.S. Luitpold retains the right to sell Venofer® in the U.S. to any other customer. In addition, Galenica Ltd., Vifor Pharma and Fresenius entered into a strategic joint-venture, which became effective on January 1, 2009, to market and distribute the IV iron products Venofer® and Ferinject® in the dialysis market in Europe, the Middle East, Africa and Latin America. Fresenius has significant experience selling and distributing dialysis equipment and supplies to outpatient dialysis clinics and, as a result of these agreements, it may be difficult for us to penetrate the dialysis market, particularly at its clinics.

Another key component of our commercialization strategy is to market and sell *Feraheme* for use by non-dialysis CKD patients. The current non-dialysis market is comprised primarily of three segments: hospitals, hematology clinics and nephrology clinics. 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. In addition, 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. In addition, IV iron therapeutic products are not currently widely used by certain physicians who treat non-dialysis CKD patients due to safety concerns and the inconvenience and often impracticability of administering IV iron therapeutic products. It is often difficult to change physicians' existing treatment paradigms even when supportive clinical data is available. If we are not successful in securing and maintaining formulary coverage for *Feraheme* or are significantly delayed in doing so or if we are not successful in effectively promoting *Feraheme* to physicians who treat non-dialysis CKD patients , we will have difficulty achieving market acceptance of *Feraheme* in the non-dialysis market and our ability to generate revenues and achieve and maintain profitability, and our long-term business prospects, could be adversely affected.

Our ability to generate future revenues from Feraheme depends heavily on the ability of end-users to receive adequate reimbursement for the use of Feraheme in a timely manner.

The commercial success of *Feraheme* substantially depends on the availability and extent of reimbursement for *Feraheme* from third-party payors, including governmental payors, such as Medicare and Medicaid, and private payors. *Feraheme* is purchased by hospitals, clinics, dialysis centers, physicians and other users, each of which generally relies on third-party payors to reimburse them or their patients for pharmaceutical products administered in the hospital, clinic, dialysis center and

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physician-office settings. Public and private insurance coverage and reimbursement plans are therefore central to new product acceptance, with customers unlikely to use *Feraheme* if they do not receive adequate reimbursement in a timely manner. If *Feraheme* is not reimbursed at an adequate level, our ability to generate revenues from sales of *Feraheme*, our potential profitability and our future business prospects would be adversely affected.

In the U.S. there have been, and we expect there will continue to be, a number of federal and state proposals to reform the healthcare system in ways that could adversely impact the available reimbursement for, and therefore our ability to sell Feraheme profitably.

In the U.S., both federal and state agencies continue to promote efforts to reduce healthcare costs. For example, one of the proposals included in recently proposed federal healthcare legislation would require pharmaceutical manufacturers to be responsible for higher Medicaid rebates owed to state Medicaid agencies. As a result of reimbursement and legislative proposals, and the trend toward managed health care in the U.S., third-party payors, including government and private payors, are also increasingly attempting to contain health care costs by limiting the coverage and the level of reimbursement of new drugs. These cost-containment methods may include, but are not limited to, using formularies, which are lists of approved or preferred drugs, requiring prior authorization or step therapy, which is a program to encourage using lower cost alternative treatments, basing payment amounts on the least costly alternative treatment, or refusing to provide coverage of approved products for medical indications other than those for which the FDA has granted marketing approval. Cost control initiatives could adversely affect the commercial opportunity or decrease the price of *Feraheme* and may impede the ability of potential *Feraheme* users to obtain reimbursement, any of which could have a material adverse effect on our profitability and future business prospects.

Medicare currently reimburses for physician-administered drugs in the hospital outpatient, dialysis center and physician clinic settings at a rate of 106% of the drug's average selling price, or ASP. If the Centers for Medicare & Medicaid Services, or CMS, or one of its local contractors, believe that *Feraheme*'s ASP is too high, it may attempt to initiate one or more of the cost-containment methods discussed above at either the national or local level. In July 2008, Congress enacted the Medicare Improvements for Patients and Providers Act of 2008, or MIPPA, which created a Medicare-expanded bundled payment system for the treatment of end stage renal disease, or ESRD, to be implemented by January 1, 2011. MIPPA requires CMS to move from a system in which it pays separately for physician-administered drugs for dialysis patients to a system in which all costs of providing care to dialysis patients are bundled together into a single capitated payment. The ESRD expanded bundle is to be phased in beginning on January 1, 2011, and the phase-in must be completed by January 1, 2014. In September 2009, in compliance with the statutory requirements of MIPPA, CMS proposed a new prospective payment system for dialysis services provided to Medicare beneficiaries who have ESRD. CMS has stated that it intends to issue a final rule on the prospective payment system later in 2010 in order to meet the legislative requirements of implementation by January 1, 2011. This bundled approach to reimbursement may lower utilization of physician-administered drugs in the ESRD market. In addition, the bundled approach to reimbursement in the dialysis setting may lower the amount of reimbursement available for *Feraheme* and consequently put downward pressure on the price we can charge for *Feraheme*. Therefore, we may be limited in our ability to successfully market and sell *Feraheme* in the dialysis setting. While the MIPPA ESRD provisions apply only to Medicare, Medicare payment policy 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. Any change in the Medicare reimbursement rate would, therefore, likely result in changes to payment rates from non-Medicare payors as well, further limiting our ability to successfully market and sell *Feraheme*.

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To the extent we sell our products internationally, 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 in those countries.

Significant safety or drug interaction problems could arise with respect to Feraheme, resulting in recalls, restrictions in Feraheme's label, withdrawal of Feraheme from the market, or cause us to alter or terminate future Feraheme clinical development programs.

Discovery of previously unknown problems with an approved product may result in 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 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 and with additional underlying health problems. In addition, as we conduct additional 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. These new safety or drug interaction issues may require us to provide additional warnings on the *Feraheme* label, directly alert healthcare providers of new safety information, narrow our approved indications, or alter or terminate future trials planned for additional uses of *Feraheme*, any of which could reduce the market acceptance of *Feraheme*. In addition, if significant safety or drug interaction issues arise, FDA approval for *Feraheme* could be withdrawn, and the FDA could require the recall of all existing *Feraheme* in the marketplace. The FDA also has the authority to require the recall of our products if there is contamination or other problems with manufacturing, transport or storage of the product. 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.

We may also be required to conduct certain post-approval clinical studies to assess known or suspected significant risks associated with *Feraheme*. The Food and Drug Administration Amendments Act of 2007 expanded the FDA's authority. Under the Food and Drug Administration Amendments Act, the FDA may: (i) require manufacturers to conduct post-approval clinical studies to assess known risks or signals of serious risks, or to identify unexpected serious risks; (ii) mandate labeling changes to a product based on new safety information; or (iii) require sponsors to implement a Risk Evaluation Management Strategy, or REMS, where necessary to assure safe use of the drug. If we are required to conduct post-approval clinical studies or implement a REMS, or if the FDA changes the label for *Feraheme* to include additional discussion of potential safety issues, such requirements or restrictions could have a material adverse impact on our ability to generate revenues from sales of *Feraheme*, or require us to expend significant additional funds on clinical studies.

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

Prior to our commercialization of *Feraheme*, we have never independently marketed or sold a drug product as we had relied on our corporate partners to market and sell our other approved products, *Feridex I.V.* and *GastroMARK*. We have established an internal sales and marketing infrastructure to market and sell *Feraheme*, 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

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severely impaired. 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.

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, most 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 would 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, 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 operation.

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 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 NDAs, enforcement actions, injunctions or criminal prosecution. 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

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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 second source manufacturer, 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 second source manufacturing facilities, we currently have only one facility at which we produce *Feraheme*. Our ability to manufacture *Feraheme* in sufficient quantities to meet commercial demand and our clinical development needs at acceptable costs 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 cannot produce sufficient quantities of Feraheme at our manufacturing facility, we will need to rely on third party manufacturers, which may expose us to a number of risks.

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 second source 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. Even if we were to reach agreement, the transition of the manufacturing process to a third party could take a significant amount of time. Any prolonged interruption in our manufacturing operations could result in cancellations of orders or loss of product in the manufacturing process. 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 our products on a timely basis because of these or other factors, we may not be able to meet anticipated 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 materials and our reliance on sole source suppliers could adversely impact our ability to manufacture sufficient quantities of Feraheme, which would have a severe adverse impact on our business.

We currently purchase certain raw materials used to manufacture *Feraheme* from third-party suppliers. We do not have any long-term supply contracts with these third parties. Some of these raw materials are procured from a single source with no qualified alternative supplier. We are in the process of identifying and qualifying additional third-party suppliers for these raw materials used to manufacture *Feraheme*. Third-party suppliers may cease to produce the raw materials used in *Feraheme*

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or otherwise fail to supply these raw materials to us or fail to supply these raw materials to us in sufficient quantities for a number of reasons, including but not limited to the following:

- Unexpected demand for or shortage of raw 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 our raw materials for any reason, we will be unable to manufacture *Feraheme* or unable to manufacture *Feraheme* in sufficient quantities until we are able to qualify an alternative source, which would 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 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 materials, we may not be able to obtain raw 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 materials from an alternative source, if these raw 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 materials would severely hinder our ability to manufacture *Feraheme* and would have a material adverse impact on our ability to generate additional revenues and to achieve profitability.

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 timing and magnitude of our recognition of revenues from sales of *Feraheme,* including the recognition of net product revenues associated with purchases made under our Launch Incentive Program, which were deferred as of September 30, 2009;
- 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 of our wholesalers or distributors;

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The timing and magnitude of costs associated with our development of additional indications for *Feraheme* and our development of *Feraheme* in countries outside of the U.S;

The timing and magnitude of costs associated with commercial-scale manufacturing of *Feraheme*, including costs associated with maintaining commercial inventory and qualifying additional manufacturing capacities and second source suppliers;

Actual or anticipated difficulties, disruptions or delays associated with our manufacturing facility, packager, or supply chain and distribution network;

Changes in laws and regulations concerning reimbursement for *Feraheme*, from government health administration authorities, private health insurers and other third-party payors;

The initiation of litigation to enforce or defend any of our assets; 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, 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 related to revenue recognition and related sales allowances, investments, reserves for doubtful accounts, equity-based compensation, accrued expenses and income taxes. We base our estimates on market data, our observance of trends in our industry, and on various other assumptions that we believe to be reasonable under the circumstances. If actual results differ from these estimates, there could be a material adverse effect on our financial results and the performance of our stock.

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

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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 operation.

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 $22.20 and $58.23 in the fifty-two week period through February 16, 2010. 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;

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

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

Safety concerns related to *Feraheme* or products or product candidates of our competitors;

General market conditions;

Sales of large blocks of our common stock;

The status or results of clinical trials for *Feraheme* in indications other than CKD 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 of litigation to enforce or defend any of our assets; and

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

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

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

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us and our business. Currently, ten financial analysts publish reports about us and our business. We do not control these or any other analysts. Furthermore, there are many large, well-established, publicly traded companies active in our industry and market, which may mean that it is less likely that we will receive widespread analyst coverage. In addition, our future operating results are subject to substantial uncertainty, and our stock price could decline significantly if we fail to meet or exceed analysts' forecasts and expectations, especially with respect to the timing and magnitude of *Feraheme* revenues, including the recognition of net product revenues associated with purchases made under our Launch Incentive Program, which were initially deferred as of September 30, 2009. 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 cause our stock price to decline.

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 or if we attain profitability, it 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, 2009, we had an accumulated deficit of approximately $281.7 million. Our losses are primarily the result of costs incurred in research and development, including costs associated with our *Feraheme* and other development programs, costs associated with establishing and 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 IV iron replacement therapeutic in CKD patients in the U.S. and to further develop *Feraheme* for additional indications and in additional 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 iron replacement therapeutic agent for CKD patients in the U.S. We have never independently marketed or sold any products, 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.

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*. As a result, we anticipate that our expenses will increase and that our cash-burn rate will continue to increase in the near- and long-term. Our long-term capital requirements will depend on many factors, including, but not limited to:

The magnitude of *Feraheme* sales and the timing of our receipt of cash from such sales;

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

Costs associated with our development of additional indications for *Feraheme*;

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Costs associated with our pursuit of approval for *Feraheme* as an IV iron replacement therapeutic agent outside of the U.S.;

Costs associated with potential business development and in-licensing activities;

Costs associated with commercial-scale manufacturing of *Feraheme*, including costs associated with maintaining commercial inventory and qualifying additional manufacturing capacities and second source suppliers;

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

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

Our ability to establish additional development and marketing arrangements or to enter into alternative strategic relationships, if necessary; and

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

We estimate that our existing cash resources, combined with cash we currently expect to receive from sales of *Feraheme* and 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 alternative strategic arrangements to continue our *Feraheme* commercialization efforts and development activities. We may seek needed funding through 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.

We may enter into collaborations, in-licensing arrangements, or acquisition agreements that could disrupt our business, decrease our profitability, result in dilution to stockholders or cause us to incur debt or significant additional expense.

As part of our business strategy, we intend to pursue collaboration and in-licensing opportunities, acquisitions of products or businesses, and/or strategic alliances that we believe would be complementary to our existing business. We have limited experience with respect to these business development activities. Any such strategic transactions by us could result in large and immediate write-offs or the incurrence of debt and contingent liabilities, any of which would adversely impact our operating results. Management of a license arrangement, collaboration, or other strategic arrangement and/or integration of an acquired asset or company may also disrupt our ongoing business, require management resources that otherwise would be available for ongoing development of our existing business and our U.S. commercialization of *Feraheme*. We may not identify or complete any such transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated financial benefits of any such transaction. In addition, to finance any such strategic transactions, we may choose to issue shares of our common or preferred stock as consideration, which would result in dilution to our stockholders. Alternatively, it may be necessary for us to raise additional

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funds through public or private financings, and such additional funds may not be available on terms that are favorable to us, if at all. In addition, proposing, negotiating and implementing collaborations, in-licensing arrangements or acquisition agreements may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing and sales resources, may compete with us for these arrangements, and we may not be able to enter into such arrangements on acceptable terms or at all.

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

At December 31, 2009, we had $50.1 million in cash and cash equivalents, $29.6 million in short-term investments, $49.0 million in long-term investments, and $0.8 million in Settlement Rights with respect to certain of our auction rate securities, or ARS. 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. sub-prime mortgage defaults and the ensuing fallout. The recent 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.

At December 31, 2009, we held a total of $57.5 million in fair market value of ARS, reflecting an impairment of approximately $7.9 million compared to the par value of these securities of $65.4 million. Of the $7.9 million impairment, approximately $7.1 million is considered a temporary impairment and was reported as an unrealized loss at December 31, 2009. The remaining $0.8 million represents a trading loss which was recognized in our consolidated statements of operations. 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 would 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. Based on our ability to access our cash and other short-term investments, our expected operating cash flows, and our other sources of cash, we do not anticipate that the current lack of liquidity with respect to these securities will materially affect our ability to operate our business in the ordinary course in the short term, however, we are uncertain when the current liquidity issues relating to ARS will improve, if at all.

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. For example, in February 2009 three of our ARS with a total par value of $8.7 million and one of our ARS with a par value of $5.0 million were downgraded by one of the major credit rating agencies to A3 and Baa1, respectively, from their previous rating of Aaa. In contrast, the ARS having a par a value of $5.0 million was re-affirmed as AAA by a different major rating agency in January 2009. 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

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risks associated with our investment portfolio may have an adverse effect on our results of operations, cash position, liquidity and overall financial condition.

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 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. Similar rules and limitations may apply for state income tax purposes.

The current credit and financial market conditions may exacerbate certain risks affecting our business.

Over the past two years, the U.S. and global economies have taken a dramatic downturn as a result of the volatility of the credit markets and related financial crisis, as well as a variety of other factors including, among other things, extreme volatility in security prices, severely diminished liquidity and credit availability, ratings downgrades of certain investments and declining valuations of others. The U.S. and certain foreign governments have taken unprecedented actions in an attempt to address and rectify these extreme market and economic conditions by providing liquidity and stability to the financial markets. If the actions taken by the U.S. and other governments are not successful, the continued economic decline may continue to negatively affect the liquidity of our investments, significantly impact our ability to raise capital, if needed, on a timely basis and on acceptable terms or at all, and cause our investments to substantially decline in value. Any of these could have a material adverse effect on our liquidity, cash position and the potential future prospects of our business.

In addition, 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. 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 and 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 materials, may begin to maintain lower inventory levels or could 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.

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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 be required to pay penalties, sanctions and fines which could have a material adverse effect on our business, financial condition and results of operation.

As a condition of reimbursement by various federal and state healthcare programs, we are required to calculate and report certain pricing information to federal and state healthcare agencies. For example, we are required to provide ASP 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. 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 operation.

We are subject to ongoing regulatory review of Feraheme, and if we fail to comply with such continuing regulations, we could be subject to penalties up to and including the suspension of the manufacturing, marketing and sale of Feraheme.

We are subject to ongoing FDA regulatory requirements and review pertaining to *Feraheme's* manufacture, labeling, packaging, adverse event reporting, storage, advertising, 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 market and sell *Feraheme*, including its withdrawal from the market. We may also be subject to additional sanctions, including but not limited to:

FDA 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;*

FDA-imposed label changes;

Implementation of an FDA-mandated REMS;

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

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

Any of these sanctions would have a material adverse impact on our ability to generate revenues and to achieve profitability.

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

In addition to FDA and related regulatory requirements, we are subject to extensive federal and state healthcare regulation, including but not limited to, the federal false claims act and the federal anti-kickback statute. False claims laws prohibit anyone from knowingly presenting, or causing to be

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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 and state regulations and/or 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. 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 operation.

In recent years, several states and localities have enacted legislation requiring pharmaceutical companies 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. 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 and time consuming, 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 operation.

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

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 for additional indications in the U.S.

We have commenced or are pursuing additional clinical trials and plan to seek regulatory approval to market *Feraheme* in indications other than CKD in the U.S. There is no guarantee that we will be successful in completing any clinical trials for additional indications in a timely manner or that, if completed, the results of such clinical trials will demonstrate *Feraheme* to be safe and effective in such uses and/or patient populations.

The FDA imposes substantial requirements on the development and production of all drug products. Before obtaining regulatory approval for the commercial marketing and sale of *Feraheme* for additional indications, we must demonstrate through extensive human clinical trials that *Feraheme* is safe and efficacious for these new uses and in these new patient populations. 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.

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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 contract 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 indications other than CKD. 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 in our efforts to obtain regulatory approval for *Feraheme* in indications other than CKD, or even prevent us from obtaining regulatory approval for *Feraheme* for additional indications. 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.

In addition, our ability to complete our planned clinical trials in a timely manner depends on a number of factors, including:

Our ability to reach agreement with the FDA on a trial design in a timely manner;

Our ability to identify and enter into contracts with prospective clinical sites in a timely manner;

The rate of patient enrollment; and

The ability of our contract research organizations to perform their oversight responsibilities and meet expected deadlines.

Any failure by us to obtain approval for additional *Feraheme* indications in the U.S. 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.

To the extent we wish to manufacture, market or sell *Feraheme* in foreign countries, we will need to comply with foreign regulatory requirements, which vary widely from country to country and may in some cases be more rigorous than requirements in the U.S. Foreign regulatory agents may require additional studies or studies designed with different clinical endpoints and/or comparators than those which we have already completed. The time required for approval may also be longer or shorter than in the U.S. In addition, in order to increase the number of patients available for enrollment in our clinical trials, we may conduct trials in geographies outside the U.S. We have no experience conducting clinical trials outside the U.S., and, therefore, we will need to expend substantial time and resources to identify and familiarize ourselves with the regulatory requirements of such foreign countries.

Any failure by us to obtain approval for *Feraheme* indications 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 clinical trials, and if they fail to fulfill their obligations, our development plans may be adversely affected.

We rely on independent clinical investigators, contract research organizations and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our clinical trials. We have and we plan to continue to contract with certain third-parties to provide certain services, including

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site selection, enrollment, monitoring and data management services. 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 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 may be delayed or terminated.

If we do not effectively manage our growth, our ability to commercialize Feraheme, pursue opportunities and expand our business could be adversely affected.

We have experienced significant growth, which has placed and may continue to place a substantial strain on our management, employees, facilities and resources. In anticipation of the approval and U.S. commercialization of *Feraheme*, we rapidly expanded our marketing, sales, manufacturing, regulatory, medical affairs, finance, development, and compliance capabilities. As our operations continue to expand, we will also need to manage additional relationships with various collaborative partners, suppliers and other third parties. In addition, we will need to continue to improve our operational and financial systems, train and manage our expanding workforce, and maintain close coordination among our various departments. We may not be able to accomplish these tasks, and our failure to accomplish any one of them could prevent us from successfully commercializing *Feraheme*, pursuing new business opportunities, or expanding our business, any one of which could adversely impact our future business prospects.

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 Chief Executive Officer and President, Brian J.G. Pereira, MD, our other executive officers and on our ability to continue to attract, retain and motivate qualified managerial, scientific, medical and sales 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. If we are unable to retain these 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 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.

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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. Future patent interference proceedings involving our patents may harm our ability to commercialize *Feraheme*. 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 preventing us from making or selling *Feraheme*. We also may be required to obtain licenses to use the relevant technology. Such licenses may not be available on commercially reasonable terms, if at all.

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 on *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.

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 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 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 Securities and Exchange Commission, NASDAQ or other regulatory authorities.

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We are exposed to a number of different potential liability claims, and we may not be able to maintain or obtain sufficient insurance coverage to protect our cash and other assets.

The administration of our products to humans, whether in clinical trials or after approved commercial usage, may expose us to liability claims. 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*, divert the attention of our management and key personnel from our core business, require us to spend significant time and money in litigation or pay significant damages, all of which could prevent or interfere with the commercialization and development of *Feraheme* and adversely affect our business. Claims of this nature could also subject us to product recalls or harm our reputation, which could damage our position in the market.

We could be subject to class action litigation due to stock price volatility, which, if it occurs, will distract our management and could result in substantial costs or large judgments against us.

The stock market in general has recently experienced extreme price and volume fluctuations. In addition, the market prices of securities of companies in the biopharmaceutical industry have been extremely volatile and have experienced fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. These fluctuations could adversely affect the market price of our common stock. In the past, securities class action litigation has often been brought against companies following periods of volatility in the market prices of their securities. We may be the target of similar litigation in the future. Securities 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.

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 board of directors. These provisions include:

The ability of our Board of Directors 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 of Directors and for proposals to be brought before our annual meeting of stockholders;

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The authority of our Board of Directors 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 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 Amended and Restated 2007 Equity Incentive Plan generally permits our Board of Directors 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 $54.1 million, the total par value of the ARS that Jefferies, Russo and D'Addario wrongfully marketed and sold to us.

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. We are not aware of any material claims against us at December 31, 2009.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS:

None.

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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, 2010, the closing price of our common stock, as reported on the NASDAQ, was $37.71 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, 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
Year Ended December 31, 2008		
First quarter	$ 66.94	$ 33.00
Second quarter	$ 43.36	$ 33.91
Third quarter	$ 49.39	$ 33.28
Fourth quarter	$ 42.28	$ 18.33

Stockholders

On February 16, 2010, we had approximately 115 stockholders of record of our common stock, and we believe that the number of beneficial holders of our common stock was approximately 5,000 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, during the three months ended December 31, 2009.

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 not later than 120 days after the close of our year ended December 31, 2009.

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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, 2009, 2008 and 2007, the three months ended December 31, 2006, and the years ended September 30, 2006 and 2005. The information below includes our transition period for the three months ended December 31, 2006 as a result of our Board of Directors voting in May 2007 to change our fiscal year end from September 30 to December 31. 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 Years Ended September 30,	
	2009	2008	2007	2006	2006	2005
	(in thousands, except per share data)					
Statement of Operations Data						
Revenues:						
Product sales, net	$ 16,482	$ 751	$ 1,208	$ 353	$ 1,449	$ 890
License fees	516	959	1,096	222	907	1,281
Royalties	180	228	248	44	317	274
Total revenues	17,178	1,938	2,552	619	2,673	2,445
Costs and Expenses:						
Cost of product sales	1,013	292	320	287	273	204
Research and development expenses*	36,273	31,716	24,236	6,393	21,294	12,037
Selling, general and administrative expenses*	77,829	49,536	20,396	2,197	8,011	3,338
Total costs and expenses	115,115	81,544	44,952	8,877	29,578	15,579
Other Income (Expense):						
Interest and dividend income, net	3,154	9,139	12,506	818	1,575	419
Gains (losses) on investments, net	942	(3,024)				
Fair value adjustment of settlement rights	(778)	1,566				
Litigation settlement			(4,000)			
Other income (expense), net					(35)	
Total other income (expense)	3,318	7,681	8,506	818	1,540	419
Net loss before income taxes	(94,619)	(71,925)	(33,894)	(7,440)	(25,365)	(12,715)
Income tax benefit	1,268	278				
Net loss	$ (93,351)	$ (71,647)	$ (33,894)	$ (7,440)	$ (25,365)	$ (12,715)
Net loss per share basic and diluted:	$ (5.46)	$ (4.22)	$ (2.15)	$ (0.60)	$ (2.31)	$ (1.47)
Weighted average shares outstanding used to compute net loss per share:						

Basic and diluted	17,109	16,993	15,777	12,383	10,964	8,634

	December 31,				September 30,	
	2009	2008	2007	2006	2006	2005
	(in thousands)					
Balance Sheet Data						
Working capital (current assets less current liabilities)	$ 85,168	$ 149,918	$ 282,196	$ 149,474	$ 33,623	$ 21,211
Total assets	$ 184,619	$ 231,955	$ 294,851	$ 162,342	$ 47,371	$ 28,292
Long-term liabilities	$ 4,081	$ 4,149	$ 879	$ 1,688	$ 1,795	$ 2,585
Stockholders' equity	$ 142,977	$ 213,414	$ 285,954	$ 152,277	$ 36,075	$ 22,379

*

We adopted accounting guidance related to equity-based compensation expense effective October 1, 2005. Accordingly, the period ended September 30, 2005 does not reflect equity-based compensation expense related to employee stock awards.

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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 that utilizes our proprietary technology for the development and commercialization of a therapeutic iron compound to treat iron deficiency anemia and novel imaging agents to aid in the diagnosis of cancer and cardiovascular disease. We currently manufacture and sell two approved products, Feraheme® (ferumoxytol) Injection for intravenous, or IV, use and GastroMARK®.

On June 30, 2009, *Feraheme* was approved for marketing in the U.S. by the U.S. Food and Drug Administration, or the FDA, for use as an IV iron replacement therapy for the treatment of iron deficiency anemia, or IDA, in adult patients with chronic kidney disease, or CKD. We market and sell *Feraheme* through our own commercial organization, consisting of approximately 120 professionals, including an 80-person specialized sales force and account management and reimbursement teams. We sell *Feraheme* primarily to authorized wholesalers and specialty distributors and began commercial sale of *Feraheme* in the U.S. in July 2009.

In November 2009, the Centers for Medicare & Medicaid Services assigned *Feraheme* two unique Q-codes, one for the treatment of IDA in end-stage renal disease patients undergoing dialysis and one for the treatment of IDA in non-end-stage renal disease patients. These Q-codes, which are temporary product-specific codes that enable automated processing of *Feraheme*-related claims, became effective on January 1, 2010.

For the year ended December 31, 2009, we recognized net product sales of *Feraheme* of $15.8 million, including approximately $1.3 million of the $11.5 million in deferred product revenues we had recorded in the third quarter of 2009. During the third quarter of 2009, shortly after the launch of *Feraheme*, we implemented a Launch Incentive Program under which certain dialysis organizations purchased *Feraheme* directly from us. This program provided certain customers with, among other things, discounted pricing and expanded rights of return. As a result, we deferred revenues associated with this program which we will recognize as revenues as the participating organizations utilize their *Feraheme* inventory. We expect that utilization of the remaining deferred product revenues from the Launch Incentive Program will increase going forward as each Launch Incentive Program customer has begun to use *Feraheme*.

In December 2009, we submitted draft protocols for two proposed clinical trials to meet our FDA post-approval Pediatric Research Equity Act requirement to support pediatric labeling of *Feraheme.* In 2010, we intend to initiate these two randomized, active controlled pediatric studies in children with IDA. 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 children.

We also plan to advance our *Feraheme* clinical development program in adults by initiating two Phase III multi-center clinical trials in mid-2010 to assess *Feraheme* for the treatment of IDA in a broad range of patients, which may include women with abnormal uterine bleeding, or AUB, patients with cancer and gastrointestinal diseases and postpartum women, for whom oral iron is unsatisfactory. One study 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. A second study will 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, we intend to initiate an open label extension study 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.

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We continue to evaluate our strategy for seeking approval for *Feraheme* as an IV iron replacement therapeutic agent in countries outside of the U.S. The commercial opportunity for *Feraheme* as an IV iron replacement therapeutic agent varies from country to country, and in determining which additional markets outside of the U.S. we intend to enter, we are assessing factors such as potential pricing and reimbursement, the role of iron in medical treatment protocols, and the regulatory requirements of each country. We expect to file a Marketing Authorization Application, or MAA, for *Feraheme* for the treatment of IDA in CKD patients with the European Medicines Agency, or EMEA, in mid-2010. In the fourth quarter of 2009, we received approval from the EMEA for our Pediatric Investigation Plan, which is a prerequisite for the submission of our *Feraheme* MAA. Our Pediatric Investigation Plan includes the two pediatric studies required to meet our Pediatric Research Equity Act requirement and two additional pediatric studies requested by the EMEA. To further support our MAA, we have initiated a global, randomized, Phase IV multi-center, active controlled trial with approximately 150 adult CKD patients both on dialysis and not on dialysis. This study 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.

In December 2009, we filed a New Drug Submission for *Feraheme* to treat IDA in patients with CKD with the Therapeutic Products Directorate of Health Canada, or Health Canada, the federal authority that regulates pharmaceutical drugs and medical devices for human use in Canada. In February 2010, we received a Screening Deficiency Notice from Health Canada requesting certain clarifications and additional documents. We have submitted our response to Health Canada and believe that all of these items are readily addressable. In addition, 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. Once approved by the SFDA, 3SBio plans to commence a multi-center randomized efficacy and safety study in China involving approximately 200 CKD patients.

In addition to its use for the treatment of IDA, *Feraheme* may also be useful as a vascular enhancing agent in magnetic resonance imaging, or MRI. In August 2008, the FDA granted Fast Track designation to *Feraheme* with respect to its development as a diagnostic agent for vascular-enhanced MRI for the assessment of peripheral arterial disease, or PAD, in patients with CKD. We have enrolled over two-thirds of our 108 patient Phase II study of *Feraheme* in vascular-enhanced MRI for the detection of clinically significant arterial stenosis or occlusion, or narrowing or blocking of the arteries.

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 their current levels for the last several years, and we do not expect sales of *GastroMARK* to change materially.

Feridex I.V.®, our liver contrast agent, had been marketed and sold in the U.S., Europe and other countries for a number of years through our marketing partners. In November 2008, we decided to cease manufacturing *Feridex I.V.* Accordingly, we have terminated all of our agreements with our marketing partners for *Feridex I.V.* throughout the world and do not intend to continue commercializing *Feridex I.V.* We recorded no product sales revenues associated with *Feridex I.V.* in 2009 and do not expect to recognize any *Feridex I.V.* related revenues in 2010.

In the past, we have devoted substantially all of our resources to our research and development programs and, more recently, we have also incurred substantial costs related to the commercialization of *Feraheme*. 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. At December 31, 2009, our accumulated deficit was approximately $281.7 million. We expect to continue to incur significant expenses to manufacture, market and sell *Feraheme* as an iron replacement therapeutic in CKD patients in the U.S. and to further develop *Feraheme* for additional indications and in additional countries outside of the U.S. In the second half of 2009, we

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began to derive revenues from product sales of *Feraheme*. We now expect to fund our future operations in part from the sale of *Feraheme* in addition to the sale of our equity securities, cash generated by our investing activities, and payments from our strategic partners.

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.

Results of Operations

Year Ended December 31, 2009 Compared to Year Ended December 31, 2008

Revenues

Total revenues were $17.2 million and $1.9 million for the years ended December 31, 2009 and 2008, respectively, representing an increase of approximately $15.3 million, or greater than 100%. The increase in revenues was primarily due to product sales of *Feraheme* following its FDA approval and commercial launch in mid-2009.

The following table sets forth customers who represented 10% or more of our revenues for the years ended December 31, 2009 and 2008. No other company accounted for more than 10% of our total revenues in either year.

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

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

	Years Ended December 31,			
	2009	2008	$ Change	% Change
Product sales, net	$ 16,482	$ 751	$ 15,731	>100%
License fees	516	959	(443)	-46%
Royalties	180	228	(48)	-21%
Total	$ 17,178	$ 1,938	$ 15,240	>100%

Net Product Sales

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

	Years Ended December 31,			
	2009	2008	$ Change	% Change
Feraheme	$ 15,774	$	$ 15,774	N/A
GastroMARK	708	398	310	78%
Feridex I.V.		333	(333)	-100%
Other		20	(20)	-100%
Total	$ 16,482	$ 751	$ 15,731	>100%

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The $15.7 million increase in net product sales was primarily due to the FDA approval of *Feraheme* on June 30, 2009 and its subsequent U.S. commercial launch. Our product sales may fluctuate from period to period as a result of factors such as wholesaler demand forecasts and buying decisions as well as end user demand, which can create uneven purchasing patterns by our customers. Our product sales may also fluctuate as the result of changes or adjustments to our reserves or changes in government or customer rebates.

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 and forecasted customer buying patterns blended with historical experience of products similar to *Feraheme* sold by others. In addition, we also monitor our distribution channel to determine whether additional allowances or accruals are required based on inventory in our sales channel. There were no product sales allowances or accruals for the year ended December 31, 2008. For further details related to our revenue recognition and related sales allowances policy refer to our critical accounting policies 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. An analysis of our product sales allowances and accruals for the year ended December 31, 2009 is as follows (in thousands):

	December 31, 2009
Product sales allowances and accruals:	
Discounts and chargebacks	$ 804
Government and other rebates	4,329
Returns	463
Total product sales allowances and accruals	$ 5,596
Total net product sales	$ 16,482
Total gross product sales	$ 22,078
Total product sales allowances and accruals as a percent of total gross product sales	25%

An analysis of the amount of, and change in, reserves for 2009 is as follows (in thousands):

	Discounts	Rebates and Fees	Returns	Total
Balance at December 31, 2008	$	$	$	$
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

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Product sales allowances and accruals are comprised of both direct and indirect fees, discounts and rebates. 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 generally 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 similar products 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 our products. As part of this evaluation, we also review changes to federal 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.

Because we only recently launched *Feraheme* in the U.S. there are a number of factors that make it particularly difficult to predict the magnitude of future *Feraheme* sales, including the magnitude and timing of adoption of *Feraheme* by physicians, dialysis clinics, hospitals and other healthcare payors and providers, the inventory levels maintained by *Feraheme* wholesalers, distributors and other customers, the frequency of re-orders by existing customers, and the pricing of products that compete with *Feraheme* and other actions taken by our competitors. Accordingly, our *Feraheme* net product revenues in previous quarters may not be indicative of future *Feraheme* net product revenues. As a result of these and other factors, future *Feraheme* sales could vary significantly from quarter to quarter.

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.

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 shipments, 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 returned to us will not be recorded as revenue. Accordingly,

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as of December 31, 2009, we recorded $10.2 million in deferred revenues, representing all product purchased under the Launch Incentive Program which remained held by the dialysis organizations at December 31, 2009, net of any applicable discounts and estimated rebates, which are included in our commercial rebate accruals as of December 31, 2009. In addition, we have deferred the related cost of product sales of approximately $0.3 million and recorded such amount as finished goods inventory held by others as of December 31, 2009. We expect that utilization of the remaining deferred product revenues from the Launch Incentive Program, which were initially recorded during the third quarter of 2009, will increase going forward as each Launch Incentive Program customer has begun to use *Feraheme*. However, with respect to inventory that remained held by others at December 31, 2009, we are unable to reasonably estimate the amount of inventory that may be returned under this program, and therefore we cannot provide any assurance that amounts reported as deferred revenue and associated with this program will be utilized by our customers and thereby recorded by us as product revenues in our future consolidated statements of operations.

License Fee Revenues

Our license fee revenues of $0.5 million and $1.0 million for the years ended December 31, 2009 and 2008, respectively, consisted of deferred license fee revenues that were being amortized in connection with our agreements with Bayer Healthcare Pharmaceuticals, or Bayer, which were terminated in November 2008.

In 1995, we entered into a License and Marketing Agreement and a Supply Agreement, or the Bayer Agreements, 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 continued to sell any remaining *Feridex I.V.* inventory in its possession through April 1, 2009. As a result of the termination of these agreements, during the year ended December 31, 2009 we recognized the remaining $0.5 million of deferred revenues under the Bayer Agreements. No further significant obligation exists by either party.

In May 2008, we entered into a Collaboration and Exclusive License Agreement with 3SBio with respect to 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 up-front payment of $1 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 do not expect license revenues under our agreement with 3SBio to be significant in 2010.

Costs and Expenses

Cost of Product Sales

We incurred costs of $1.0 million and $0.3 million associated with product sales, or 6% and 39% of net product sales, during the years ended December 31, 2009 and 2008, respectively. Our cost of product sales for the year ended December 31, 2009 was comprised primarily of manufacturing costs associated with *Feraheme*. Based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, certain of the costs of *Feraheme* sold during the year ended December 31, 2009 were expensed prior to the June 2009 FDA approval, and therefore are not included in the cost of product sales during this period. We continue to hold *Feraheme* inventory that has been previously expensed, and once such inventory has been fully depleted, we expect our cost of product sales as a percentage of net product sales will increase, reflecting the full manufacturing cost of our inventory. We cannot predict when such previously expensed materials will be exhausted, as this

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will be dependent on the timing and magnitude *Feraheme* sales in the U.S. We also anticipate that costs of product sales will increase as sales volume increases.

In addition, as of December 31, 2009, we deferred approximately $0.3 million of costs associated with product sales made under our Launch Incentive Program. These costs have been recorded as finished goods inventory held by others on our consolidated balance sheet as of December 31, 2009. We will recognize the cost of product sold under the Launch Incentive Program as, and to the extent that, inventory is utilized by our customers.

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. 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 30, 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* to be made commercially available in the U.S. are capitalized.

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

	Years Ended December 31,			
	2009	**2008**	**$ Change**	**% Change**
External Research and Development Expenses				
Feraheme to treat IDA regardless of the underlying cause	$ 797	$	$ 797	N/A
Feraheme to treat IDA in CKD patients	346		346	N/A
Feraheme as a therapeutic agent in AUB patients	1,131	2,383	(1,252)	-53%
Feraheme as a therapeutic agent, general	4,331	1,601	2,730	>100%
Feraheme as an imaging agent in PAD patients	2,524	1,643	881	54%
Feraheme manufacturing and materials	2,929	4,591	(1,662)	-36%
Other external costs	1,133	1,025	108	11%
Total	$ 13,191	$ 11,243	$ 1,948	17%
Internal Research and Development Expenses				
Compensation, payroll taxes, benefits and other expenses	18,636	16,713	1,923	12%
Equity-based compensation expense	4,446	3,760	686	18%
Total	$ 23,082	$ 20,473	$ 2,609	13%
Total Research and Development Expenses	$ 36,273	$ 31,716	$ 4,557	14%

Total research and development expenses incurred in the year ended December 31, 2009 amounted to $36.3 million, an increase of $4.6 million, or 14%, from the year ended December 31, 2008. The $4.6 million increase was primarily due 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, costs associated with our regulatory plans outside of the U.S., costs associated with increased full-time equivalent headcount and increased spending on our clinical development programs for PAD and IDA. The increase in total research and development expenses was partially offset by costs associated with the manufacture of *Feraheme*, which were expensed in 2008 as research and development costs but, as a result of the June 2009 FDA approval of *Feraheme*, were capitalized into inventory in the second half of 2009 and by a reduction in costs associated with our then intended *Feraheme* clinical development program in patients with AUB.

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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 PAD. 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 second source manufacturing. In addition, during 2008, we incurred costs related to our then intended *Feraheme*clinical development program in patients with AUB. However, during the first quarter of 2009 following discussions with the FDA, we decided to pursue a broad Phase III clinical development program for the treatment of IDA in a wide range of patient populations and disease states rather than pursue individual indications, such as AUB. As a result, we did not begin enrollment in our previously planned Phase III studies of *Feraheme* in women with AUB. Subsequent to the first quarter of 2009, we did not incur any costs associated with the AUB clinical development program and do not expect to incur any significant additional future costs associated with the AUB clinical development program. During 2009, we began to incur costs associated with our broader IDA clinical development program and plan to initiate our Phase III program in mid-2010.

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 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 55 full-time equivalents, or FTEs, in research and development as compared to 86 FTEs at December 31, 2008, a decrease of 36% 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.

We expect research and development expenses in 2010 to be significantly higher than our research and development expenses in 2009 primarily as a result of the advancement and the initiation of our clinical development programs and other research and development related functions and activities in support of *Feraheme*. Factors which will impact 2010 research and development expenses include the timing of initiation and pace of enrollment of our pediatric studies of *Feraheme* and our trial of *Feraheme* to support our MAA filing with the EMEA, and the design, timing and pace of enrollment of our other clinical trials of *Feraheme,* including our planned development program for *Feraheme* in a broad range of patients with IDA.

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 regulatory filing to the FDA or applicable foreign regulatory body. We currently anticipate commencing the following two major research and development projects during 2010:

Feraheme to treat IDA regardless of the underlying cause. This project currently includes a Phase III clinical study evaluating *Feraheme* treatment compared to treatment with placebo, a

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second Phase III clinical study evaluating *Feraheme* treatment compared to treatment with another IV iron, and an extension study.

Feraheme to treat IDA in CKD patients. This project includes: (1) a clinical study evaluating *Feraheme* treatment compared to treatment with another IV iron which will support our planned CKD MAA; (2) two pediatric studies to be conducted as part of our Phase IV Pediatric Research Equity Act requirement to support pediatric CKD labeling of *Feraheme*; and (3) two additional pediatric studies in accordance with our approved Pediatric Investigation Plan to support our planned CKD MAA.

During the year ended December 31, 2009, we incurred aggregate external research and development expenses of approximately $0.8 million related to our preparation for our research and development project for *Feraheme* to treat IDA regardless of the underlying cause. We currently estimate that the external costs associated with the efforts needed to complete the development project of *Feraheme* to treat IDA regardless of the underlying cause will be in the range of approximately $70 to $80 million over the next several years.

During the year ended December 31, 2009, we incurred aggregate external research and development expenses of approximately $0.3 million related to our preparation for our research and development project for *Feraheme* to treat IDA in CKD patients. We currently estimate that the external costs associated with the efforts needed to complete the development project of *Feraheme* to treat IDA in CKD patients will be in the range of approximately $30 to $40 million over the next several years.

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 estimations for a variety of reasons including but not limited to the following: significant 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, inadequate performance or errors by third-party service providers, any deficiencies in the design or oversight of these studies by us, the need to conduct additional clinical trials or a delay in the submission of any applicable regulatory filing.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses include costs related to our commercial personnel, including our 80-person 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, 2009 and 2008 consisted of the following (in thousands):

	Years Ended December 31,			
	2009	**2008**	**$ Change**	**% Change**
Compensation, payroll taxes and benefits	$ 33,447	$ 17,292	$ 16,155	93%
Professional and consulting fees and other expenses	33,450	27,967	5,483	20%
Equity-based compensation expense	10,932	4,277	6,655	>100%
Total	$ 77,829	$ 49,536	$ 28,293	57%

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

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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 grants of equity awards to both new and existing employees. In addition, during 2008 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 in which the underlying performance condition was not met.

We expect selling, general and administrative expenses to continue to increase in 2010 as we continue to expand our U.S. commercialization efforts related to *Feraheme,* execute our marketing and promotional programs, and maintain our commercial and administrative infrastructure to support the commercialization of *Feraheme*.

Other Income (Expense)

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

	Years Ended December 31,			
	2009	**2008**	**$ Change**	**% Change**
Interest and dividend income, net	$ 3,154	$ 9,139	$ (5,985)	-65%
Gains (losses) on investments, net	942	(3,024)	3,966	<(100)%
Fair value adjustment of settlement rights	(778)	1,566	(2,344)	<(100)%
Total	$ 3,318	$ 7,681	$ (4,363)	-57%

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, one of our securities brokers, which provided us with the right to sell to UBS $9.3 million in par value of our auction rate securities, or ARS, at par value, at any time during a two-year sale period beginning June 30, 2010, or the Settlement Rights. As a result of the lack of either quoted market prices or other observable market data, we estimate the value of our ARS and Settlement Rights using discounted cash flow analyses using Level 3 inputs as defined by the accounting guidance related to fair value measurements. We elected the fair value option with respect to the Settlement Rights in accordance with current accounting guidance related to the fair value option for financial assets and financial liabilities and as of December 31, 2009, we have recorded an asset equal to our estimated fair value of the Settlement Rights of approximately $0.8 million in our consolidated balance sheet. This represents a decrease of approximately $0.8 million to the estimated fair value of our Settlement Rights from the estimated fair value at December 31, 2008, which we have recorded in other income (expense) in our consolidated statement of operations. In addition, with the opportunity provided by the Settlement Rights, we have 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,

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as of December 31, 2009, we have adjusted our estimated value of these trading securities by approximately $0.9 million from the estimated value at December 31, 2008, which we have recorded as a gain on investments in other income (expense) in our consolidated statement of operations.

We are required to assess the fair value of both the Settlement Rights and our ARS subject to Settlement Rights and record changes each period until the Settlement Rights are exercised or our ARS subject to Settlement Rights are redeemed. Although the Settlement Rights represent the right to sell the securities back to UBS at par, we are required to periodically assess the ability of UBS to meet that obligation in assessing the fair value of the Settlement Rights.

We expect interest and dividend income to increase in 2010 as a result of our anticipated investment of cash received from our January 2010 sale of 3,600,000 shares of our common stock at a public offering price of $48.25 per share and which resulted in net proceeds to us of approximately $165.6 million.

Income Tax Benefit

We recognized an income tax benefit of $1.3 million and $0.3 million during the years ended December 31, 2009 and 2008, respectively. During 2009, we recognized a $1.1 million tax benefit, which was the result of our recognition of a corresponding $1.1 million income tax expense associated with the increase in the value of certain securities that we carried at fair market value during the year ended December 31, 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 benefit, 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 $93.4 million, or $5.46 per basic and diluted share, for the year ended December 31, 2009 as compared to a net loss of $71.6 million, or $4.22 per basic and diluted share, for the year ended December 31, 2008.

Year Ended December 31, 2008 Compared to Year Ended December 31, 2007

Revenues

Total revenues were $1.9 million and $2.6 million for the years ended December 31, 2008 and 2007, respectively. The decrease in revenues was primarily the result of a decrease in product sales and license fee revenues, as discussed below.

The following table sets forth customers who represented 10% or more of our revenues for the years ended December 31, 2008 and 2007. No other company accounted for more than 10% of our total revenues in either year.

	Years Ended December 31,	
	2008	**2007**
Bayer	53%	43%
Guerbet	24%	26%
Covidien	17%	15%
Cytogen		14%

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Our revenues for the years ended December 31, 2008 and 2007 consisted of the following (in thousands):

	Years Ended December 31,			
	2008	2007	$ Change	% Change
Revenues:				
Product sales, net	$ 751	$ 1,208	$ (457)	-38%
License fees	959	1,096	(137)	-13%
Royalties	228	248	(20)	-8%
Total	$ 1,938	$ 2,552	$ (614)	-24%

License Fee Revenues

All of our license fee revenues for the year ended December 31, 2008 consisted of deferred license fee revenues that were being amortized in connection with our agreements with Bayer, which were terminated in November 2008. Our license fee revenues for the year ended December 31, 2007 included deferred license fee revenues that were being amortized in connection with our agreements with Bayer as well as with a License and Marketing Agreement signed with Cytogen Corporation, or Cytogen, which terminated in February 2007.

In 1995, we entered into the Bayer Agreements 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 continued to sell any remaining *Feridex I.V.* inventory in its possession through April 1, 2009, at which time we also completed the recognition of any remaining deferred revenues.

In 2000, we entered into a License and Marketing Agreement with Cytogen in which, among other things, we granted Cytogen exclusive U.S. marketing rights to Combidex®, a molecular imaging agent which we are not actively pursuing development of in the U.S. At the time of signing that agreement, we received shares of common stock of Cytogen with a market value of approximately $13.5 million as a non-refundable licensing fee. This fee was being recognized as revenue over the development period of the products subject to the License and Marketing Agreement based upon costs incurred and expected remaining expenditures related to the agreement. The entire amount of the license fee was recorded as deferred revenues upon signing the License and Marketing Agreement. In February 2007, as part of the settlement of a lawsuit with Cytogen, we paid Cytogen $4.0 million in cash. In addition, the License and Marketing Agreement was terminated and the remainder of the deferred revenues associated with this agreement, $0.4 million, was recognized in February 2007 as there were no additional performance obligations under the License and Marketing Agreement due to its termination.

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Total license fee revenues for the years ended December 31, 2008 and 2007 were recognized as follows (in thousands):

	Years Ended December 31,			
	2008	2007	$ Change	% Change
License fee revenues recognized in connection with the Cytogen agreement	$	$ 358	$ (358)	-100%
License fee revenues recognized in connection with the Bayer Agreements	959	738	221	30%
Total	$ 959	$ 1,096	$ (137)	-13%

Product Sale Revenues

Product sale revenues for the years ended December 31, 2008 and 2007 consisted of the following (in thousands):

	Years Ended December 31,			
	2008	2007	$ Change	% Change
GastroMARK	$ 398	$ 705	$ (307)	-44%
Feridex I.V.	333	368	(35)	-10%
Other	20	135	(115)	-85%
Total	$ 751	$ 1,208	$ (457)	-38%

The $0.5 million decrease in product sale revenues during the year ended December 31, 2008 as compared to the year ended December 31, 2007 primarily resulted from a decrease in sales of *GastroMARK* to our marketing partners and a decrease in sales of bulk *Combidex* to one of our foreign marketing partners for research and development purposes. Product sales of *GastroMARK* may fluctuate from period to period. Fluctuations in our *GastroMARK* product sales are primarily attributable to unpredictable annual product demand by end users and the batch sizes in which our products are manufactured and shipped, which create uneven purchasing patterns by our marketing partners.

Costs and Expenses

Cost of Product Sales

We incurred costs of $0.3 million associated with product sales during both of the years ended December 31, 2008 and 2007. These costs represented approximately 39% and 26% of product sales during the years ended December 31, 2008 and 2007, respectively. The increase in cost of sales as a percentage of product sales during 2008 was partially due to the write-off of $0.2 million of inventory associated with our decision to cease the manufacture and commercialization of *Feridex I.V.* in November 2008. The cost of product sales and therefore our gross margins are dependent on the mix of customers, prices we charge for our products, product mix, changes in unit volume and production efficiencies, none of which had a material impact during 2008 or 2007.

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Research and Development Expenses

Research and development expenses include external expenses, such as costs of clinical trials, contract research and development expenses, commercial manufacturing preparation and related materials 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. To the extent that external costs are not attributable to a specific major project or activity, they are included in other external costs. Manufacturing costs are expensed as incurred until a product has received the necessary initial regulatory approval.

Research and development expenses for the years ended December 31, 2008 and 2007 consisted of the following (in thousands):

	Years Ended December 31,			
	2008	**2007**	**$ Change**	**% Change**
External Research and Development Expenses				
Feraheme as an IV iron replacement therapeutic agent in CKD patients	$ 1,601	$ 10,043	$ (8,442)	-84%
Feraheme as an IV iron replacement therapeutic agent in AUB patients	2,383		2,383	N/A
Feraheme as an imaging agent in PAD patients	1,643		1,643	N/A
Feraheme manufacturing and materials	4,591		4,591	N/A
Other external costs	1,025	2,373	(1,348)	-57%
Total	$ 11,243	$ 12,416	$ (1,173)	-9%
Internal Research and Development Expenses				
Compensation, payroll taxes, benefits and other expenses	16,713	9,884	6,829	69%
Equity-based compensation expense	3,760	1,936	1,824	94%
Total	$ 20,473	$ 11,820	$ 8,653	73%
Total Research and Development Expenses	$ 31,716	$ 24,236	$ 7,480	31%

Total research and development expenses incurred in the year ended December 31, 2008 amounted to $31.7 million, an increase of $7.5 million, or 31%, from the year ended December 31, 2007. The $7.5 million increase was primarily attributable to costs associated with increased headcount, increased production materials and supply costs, costs associated with our preparation for commercial scale manufacturing of *Feraheme*, costs associated with the commencement of spending on our AUB and PAD clinical trials and increased equity-based compensation expense, partially offset by a decrease in expenditures related to our December 2007 New Drug Application, or NDA, submission for *Feraheme,* which were not present during the year ended December 31, 2008.

Our external research and development expenses decreased by $1.2 million, or 9%, for the year ended December 31, 2008 as compared to the year ended December 31, 2007. The decrease in our external expenses was due primarily to the decrease in expenditures associated with the development program and regulatory submission, including FDA filing fees of $1.2 million incurred during 2007 for *Feraheme* as an IV iron replacement therapeutic agent in CKD patients as we completed our Phase III clinical trials and prepared for the submission of our NDA in 2007. These decreased costs were partially offset by increased costs associated with the commencement of spending on our then planned clinical trials of *Feraheme* for AUB and our clinical trial for PAD and an increase in materials procurement, second-source manufacturing qualification, and other costs associated with our

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preparation for commercial scale manufacturing of *Feraheme* as an IV iron replacement therapeutic agent in CKD patients.

Our internal research and development expenses increased by $8.7 million, or 73%, for the year ended December 31, 2008 as compared to the year ended December 31, 2007. The increase in internal costs was due primarily to higher compensation and benefits costs as a result of hiring additional research and development personnel as we continued to expand our development infrastructure and scaled-up our manufacturing capabilities for the planned commercialization of *Feraheme*. At December 31, 2008, we had 86 employees in research and development as compared to 50 employees at December 31, 2007, an increase of 72%. The $1.8 million increase in equity-based compensation expense was primarily attributable to increased equity awards to both new and existing employees.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the years ended December 31, 2008 and 2007 consisted of the following (in thousands):

	Years Ended December 31,			
	2008	**2007**	**$ Change**	**% Change**
Compensation, payroll taxes and benefits	$ 17,292	$ 4,914	$ 12,378	>100%
Professional and consulting fees and other expenses	27,967	9,236	18,731	>100%
Equity-based compensation expense	4,277	6,246	(1,969)	-32%
Total	$ 49,536	$ 20,396	$ 29,140	>100%

The $29.1 million, or greater than 100%, increase in selling, general and administrative expenses for the year ended December 31, 2008 as compared to the year ended December 31, 2007 was due primarily to increased costs associated with the expansion of our commercial operations function, including compensation and benefits costs related to increased headcount, consulting costs related to preparing for the U.S. commercial launch of *Feraheme*, and the expansion of our general and administrative infrastructure. At December 31, 2008, we had 170 employees in our selling, general and administrative departments as compared to 31 employees at December 31, 2007, a greater than four-fold increase.

The $2.0 million decrease in equity-based compensation expense was primarily attributable to the reversal of expense associated with performance-based stock options granted to certain of our executive officers in 2007, the vesting of which was contingent upon FDA approval of *Feraheme* by December 31, 2008. Our NDA for *Feraheme* was not approved by the FDA at December 31, 2008 and as a result, the performance conditions underlying the 110,000 performance-based stock options issued in 2007 were not met. Accordingly, during 2008 we reversed approximately $2.4 million of compensation cost recorded during 2007 from selling, general and administrative expenses associated with these performance-based grants. This reversal of equity-based compensation expense was partially offset by additional 2008 expense associated with increased equity awards for new and existing employees as well as $0.3 million in incremental expense related to market condition based equity awards granted to our Chief Executive Officer during the year ended December 31, 2008.

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Other Income (Expense)

Other income (expense) for the years ended December 31, 2008 and 2007 consisted of the following (in thousands):

	Years Ended December 31,			
	2008	2007	$ Change	% Change
Interest and dividend income, net	$ 9,139	$ 12,506	$ (3,367)	-27%
Gains (losses) on investments, net	(3,024)		(3,024)	N/A
Fair value adjustment of settlement rights	1,566		1,566	N/A
Litigation settlement		(4,000)	4,000	-100%
Total	$ 7,681	$ 8,506	$ (825)	-10%

The $0.8 million, or 10%, decrease in other income (expense) for the year ended December 31, 2008 as compared to the year ended December 31, 2007 was primarily attributable to a $3.4 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, 2008 as compared to the year ended December 31, 2007. In addition, we also recognized $3.0 million of net losses in connection with impairment charges related to certain securities held by us. Of the total $3.0 million impairment charge, $1.3 million was required in connection with the sale of certain securities and losses on securities whose decline in value we deemed to be other-than-temporarily impaired. The remaining $1.7 million was required as a result of the mark to market and resulting realization of losses on certain ARS redesignated as trading securities under current guidance related to accounting for investments in debt and equity securities. No such losses were recognized in the year ended December 31, 2007. The decrease in other income (expense) was partially offset by our recognition of a $1.6 million gain associated with the Settlement Rights we received from UBS during the year ended December 31, 2008. In addition, we recorded a $4.0 million settlement with Cytogen in the year ended December 31, 2007 that did not recur in 2008.

Income Tax Benefit

During the year ended December 31, 2008, we recognized a tax benefit of $0.3 million 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 July 2008.

Net Loss

For the reasons stated above, we incurred a net loss of $71.6 million, or $4.22 per basic and diluted share, for the year ended December 31, 2008 as compared to a net loss of $33.9 million, or $2.15 per basic and diluted share, for the year ended December 31, 2007.

Liquidity and Capital Resources

General

We finance our operations primarily from the sale of *Feraheme*, the sale of our common stock, cash generated from our investing activities, and payments from our strategic partners. 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. as an IV iron replacement therapeutic agent;

The magnitude of *Feraheme* sales and the timing of the receipt of cash from such sales;

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

Costs associated with our development of additional indications for *Feraheme* in the U.S.;

Costs associated with our pursuit of approval for *Feraheme* as an IV iron replacement therapeutic agent outside of the U.S.;

Costs associated with commercial-scale manufacturing of *Feraheme*, including costs associated with maintaining commercial inventory and qualifying additional manufacturing capacities and second source suppliers;

Costs associated with potential business development and in-licensing activities;

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

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

Our ability to establish additional development and marketing arrangements on favorable terms or to enter into 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, 2009, our investments consisted of corporate debt securities, U.S. treasury and government agency securities, and ARS. We place our cash and investments in instruments that meet high credit quality standards, as specified in our investment policy. Our investment policy also limits the amount of our credit exposure to any one issue or issuer and seeks to manage these assets to achieve our goals of preserving principal, maintaining adequate liquidity at all times, and maximizing returns.

Cash and cash equivalents, which consist principally of cash held in commercial bank accounts, money market funds and U.S. Treasury Bills having an original maturity of less than three months, and investments at December 31, 2009 and December 31, 2008 consisted of the following (in thousands):

	December 31,			
	2009	**2008**	**$ Change**	**% Change**
Cash and cash equivalents	$ 50,126	$ 64,182	$ (14,056)	-22%
Short-term investments	29,578	94,914	(65,336)	-69%
Long-term investments	49,013	54,335	(5,322)	-10%
Total cash, cash equivalents and investments	$ 128,717	$ 213,431	$ (84,714)	-40%

The decrease in cash and cash equivalents and investments as of December 31, 2009 as compared to December 31, 2008 is primarily the result of cash used in operations partially offset by cash received from *Feraheme* sales, the net impact of unrealized and realized gains and losses on our investments, and interest income.

As of December 31, 2009, we believe that our cash, cash equivalents, and short-term investments, combined with the cash we received from our January 2010 public offering, the cash we currently expect to receive from sales of *Feraheme* and earnings on our investments, will be sufficient to satisfy our future cash flow needs for at least the next twelve months, including projected operating expenses related to our ongoing development and commercialization programs for *Feraheme*.

At December 31, 2009, we held a total of $57.5 million in fair market value of ARS, reflecting an impairment of approximately $7.9 million compared to our cost basis of these securities of

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$65.4 million. Of the $7.9 million impairment, approximately $7.1 million was considered a temporary impairment and was reported as an unrealized loss at December 31, 2009. The remaining $0.8 million represents a trading loss associated with our UBS ARS, which are described below and recognized in our consolidated statements of operations. The substantial majority of our ARS portfolio was rated AAA as of December 31, 2009 by at least one of the major securities rating agencies and were primarily collateralized by student loans substantially guaranteed by the U.S. government under the Federal Family Education Loan Program. 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. 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. For all of our ARS, the underlying maturity date is in excess of one year and the majority have final maturity dates of 30 to 40 years in the future. We believe we will ultimately be able to liquidate our investments without significant loss prior to the maturity dates noted above primarily due to the collateral securing most of our ARS. However, it could take until final maturity of our ARS to realize the investments' par value. We are uncertain when the current liquidity issues relating to ARS will improve, if at all, however, we do not anticipate that the current lack of liquidity with respect to our ARS will materially affect our ability to operate our business in the ordinary course over the next twelve months.

In November 2008, we elected to participate in a rights offering by UBS, one of our brokers, which provided us with the right 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. By electing to participate in the rights offering, we granted UBS the right, exercisable at any time prior to June 30, 2010 or during the two-year sale period, to purchase or cause the sale of our ARS at par value, or the Call Right. UBS has stated that it will only exercise the Call Right for the purpose of restructurings, dispositions or other solutions that will provide its clients with par value for their ARS. UBS has agreed to pay its clients the par value of their ARS within one day of settlement of any Call Right transaction. Notwithstanding the Call Right, we are permitted to sell ARS to parties other than UBS, which would extinguish the Settlement Rights. Although the Settlement Rights represent the right to sell the securities back to UBS at par, we will be required to periodically assess the economic ability of UBS to meet that obligation in assessing the fair value of the Settlement Rights.

The ongoing distress in the global financial markets has had an adverse impact on financial market activities world-wide, resulting in, among other things, extreme volatility in security prices, severely 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, 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 sales deferred under our Launch Incentive Program;

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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;

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

Changes in other operating assets and liabilities of ($3.1) million, which reflect timing differences between the receipt and payment of cash associated with certain transactions and when such transactions are recognized in our results of operations.

Our net loss for the year ended December 31, 2009 was primarily the result of pre- and post-approval commercialization costs, including advertising and promotion costs associated with our July 2009 U.S. launch of *Feraheme*, costs incurred to address the manufacturing observations noted by the FDA during the 2008 inspection of our manufacturing facility, compensation and other expenses associated with additional employees hired for research and development and commercial operating activities, and general and administrative costs, partially offset by revenues of approximately $17.2 million and interest income of $3.2 million.

We anticipate our net cash used in operating activities will decrease in 2010 from 2009 as a result of the cash we expect to receive from *Feraheme* sales partially offset by increased costs associated with the development of new indications and geographies for *Feraheme* and costs related to the U.S. commercialization of *Feraheme*.

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.

We anticipate cash flows used in investing activities will increase in 2010 as compared to 2009, primarily as the result of our anticipated investment of the cash we received from our January 2010 sale of 3,600,000 shares of our common stock at a public offering price of $48.25 per share and which resulted in net proceeds to us of approximately $165.6 million.

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. We expect our cash flows from financing activities will increase in 2010 primarily as the result of our anticipated investment of the cash we received from our January 2010 public offering, as discussed above.

Year Ended December 31, 2008

Cash flows from operating activities

During the year ended December 31, 2008, our use of cash in operations of $52.3 million was due principally to our net loss of approximately $71.6 million, partially offset by the impact of $7.8 million of changes in certain assets and liabilities, approximately $10.0 million in equity-based compensation and other non-cash expenses, and $1.5 million of net losses on investments and Settlement Rights. Our net loss included compensation-related expenses associated with the hiring of additional employees for research and development and commercial operating activities, payments for activities in support of the commercialization of *Feraheme* as an IV iron replacement therapeutic agent, and costs associated with clinical trials in indications other than CKD.

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Cash flows from investing activities

Cash used in investing activities was $87.2 million in 2008 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 $1.2 million in 2008 and was primarily attributable to the proceeds from the exercise of stock options.

Contractual Obligations

We currently have no long-term debt obligations, capital lease obligations, long-term purchase obligations or other long-term liabilities. Future lease obligations and purchase commitments, as of December 31, 2009, are summarized in the chart below (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	$ 197	$ 125	$ 70	$ 2	$
Facility lease obligations	14,059	1,985	4,077	4,259	3,738
Purchase commitments	2,425	2,425			
Total	$ 16,681	$ 4,535	$ 4,147	$ 4,261	$ 3,738

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 2011. We lease approximately 110 automobiles for our field-based employees. This lease requires an initial minimum lease term of 12 months per automobile. We expect our monthly expense related to this operating lease to be approximately $60,000, which is included above. 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, 2010	$ 1,903
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
Thereafter	3,738
Total	$ 13,813

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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 2009 we entered into various agreements with third-parties for which we had remaining purchase commitments of approximately $2.4 million as of December 31, 2009. These agreements principally related to certain outsourced commercial activities such as our field nursing staff, our information technology infrastructure, and other operational activities.

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 agreement.

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. 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.

Off-Balance Sheet Arrangements

As of December 31, 2009, we did not have any off-balance sheet arrangements as defined in Regulation S-K, Item 303(a)(4)(ii).

Critical Accounting Policies

The preparation of 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 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 and related sales allowances, assessing investments for potential other-than-temporary impairment and determining values of investments, reserves for doubtful accounts, accrued expenses, 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 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.

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We record product sales allowances and accruals related to prompt payment discounts, chargebacks, governmental and other rebates, distributor, wholesaler and 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 and forecasted customer buying patterns blended with historical experience of products similar to *Feraheme* sold by others. 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 comprised of both direct and indirect fees, discounts and rebates. 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 generally 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 similar products 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 our products. As part of this evaluation, we also review changes to federal 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 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.

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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 blended with historical experience of products similar to *Feraheme* sold by others, supplemented with other market research data related to demand patterns for iron replacement therapies which have been marketed for the past several years. 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 accrual 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. 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 blended with historical experience of products similar to *Feraheme* sold by others. 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 certain GPOs are usually based upon member purchases during the prior quarter and are generally billed by the GPO within 30 days after period end. Current accounting standards related to consideration given by a vendor to a customer, including a reseller of a vendor's products, specify that cash consideration given by a vendor to a customer is presumed to be a reduction of the selling price of the vendor's products or services and therefore should be characterized as a reduction of revenue. Consideration should be characterized as a cost incurred if we receive, or will receive, an identifiable benefit (goods or services) in exchange for the consideration and we can reasonably estimate the fair value of the benefit received. Because the fees we pay to wholesalers do not meet the foregoing conditions to be characterized as a cost, we have characterized these fees as a reduction of revenue. We generally pay such amounts within several weeks of our receipt of an invoice from the distributor, wholesaler, or GPO. Accordingly, we accrue 100% of the 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

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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. When considering 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 24 months.

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, 2009 would have resulted in approximately a $0.2 million decrease in net product sales.

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 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. As a result, we no longer had evidence that the par value of these investments approximated their fair value and were required to seek other alternatives to determine the fair value of these securities, which are not based on observable market transactions. As a result, we began estimating the fair values of these securities utilizing a discounted cash flow analysis as opposed to valuing them at 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, the timing of expected future cash flows, and the expectation of the next time the security may 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. In November 2008, we elected to participate in a rights offering by UBS, one of our brokers, which provided us with the right 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 estimate the fair value of these Settlement Rights utilizing a discounted cash flow analysis. Certain key assumptions used in this valuation are the estimated value of these rights at the future date of settlement, the expected term until that date of settlement, and the risk that UBS will not be able to perform under the agreement.

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 $1.2 million as of December 31, 2009. Similarly, holding all other factors constant, if we were to increase the average expected term

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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 $1.5 million as of December 31, 2009. We also consider credit ratings with respect to our investments provided by investment ratings agencies. As of December 31, 2009, 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 investment 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 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 recognized in our consolidated statement of operations. Our assessment of whether unrealized losses are other-than-temporary requires significant judgment.

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

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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 equity awards we grant to 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 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 and/or adverse impact to our financial results.

Impact of Recently Issued and Proposed Accounting Pronouncements

In January 2010, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2010-6, Improving Disclosures About Fair Value Measurements, or ASU 2010-6, which also amends Accounting Standards Codification, or ASC 820. ASU 2010-6 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 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 is 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 are currently evaluating the potential impact of this standard 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). The consensus to EITF Issue No. 08-1, Revenue Arrangements with Multiple Deliverables, or EITF 08-1, provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration 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 deferred until all of the items were delivered or fair value was determined. This new approach is effective

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prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. We are currently evaluating the potential impact of this standard on our consolidated financial statements.

In December 2009, the FASB issued ASU No. 2009-16, Accounting for Transfers of Financial Assets, or ASU 2009-16. ASU 2009-16 relates to the accounting and disclosure requirements related to the servicing and transfer of financial assets. ASU 2009-16 enhances information reported to users of financial statements by providing greater transparency about transfers of financial assets and an entity's continuing involvement in transferred financial assets, including securitization transactions, where entities have continuing exposure to the risks related to transferred financial assets. It eliminates the concept of a "qualifying special-purpose entity," changes the requirements for de-recognizing financial assets, and requires additional disclosures. This amendment is effective for fiscal years beginning after November 15, 2009. We do not expect the adoption of this amendment to have a significant impact on our consolidated financial statements.

In December 2009, the FASB issued ASU No. 2009-17, Improvements to Financial Reporting by Enterprises Involved with Variable Interest Entities, or ASU 2009-17. ASU 2009-17 relates to the accounting and disclosure requirements related to the consolidation of variable interest entities and changes how a reporting entity determines when an entity that is insufficiently capitalized or is not controlled through voting (or similar rights) should be consolidated. The determination of whether a reporting entity is required to consolidate another entity is based on, among other things, the other entity's purpose and design and the reporting entity's ability to direct the activities of the other entity that most significantly impact the other entity's economic performance. The reporting entity will be required to provide additional disclosures about its involvement and will be required to disclose how its involvement with a variable interest entity affects the reporting entity's financial statements. This amendment is effective for fiscal years beginning after November 15, 2009. Early application is not permitted. We do not expect the adoption of this amendment to have a significant impact on our consolidated financial statements.

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

As of December 31, 2009, our short- and long-term investments totaled $78.6 million and were invested in corporate debt securities, U.S. treasury and government agency securities, 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, 2009 and 2008, this would have resulted in a hypothetical decline in fair value of our investments, excluding ARS, which are described below, of approximately $0.1 million and $0.4 million, respectively.

At December 31, 2009, we held a total of $57.5 million in fair market value of ARS, reflecting an impairment of approximately $7.9 million compared to the par value of these securities of $65.4 million. For further discussion on the analysis of the sensitivity of assumptions utilized in the valuation of our ARS, 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:

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INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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MANAGEMENT'S ANNUAL REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Management is responsible for establishing and maintaining adequate internal 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, 2009.

Our internal control over financial reporting as of December 31, 2009 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, 2009.

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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, 2009 and 2008, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2009 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, 2009, 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.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
February 26, 2010

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AMAG Pharmaceuticals, Inc.

Consolidated Balance Sheets

(in thousands, except share and per share data)

	As of December 31,	
	2009	**2008**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 50,126	$ 64,182
Short-term investments	29,578	94,914
Settlement rights	788	
Accounts receivable, net	27,350	408
Inventories	9,415	96
Prepaid and other current assets	5,472	4,710
Total current assets	122,729	164,310
Property, plant and equipment, net	12,417	11,223
Settlement rights		1,566
Long-term investments	49,013	54,335
Restricted cash	460	521
Total assets	$ 184,619	$ 231,955
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,432	$ 2,305
Accrued expenses	21,931	11,571
Deferred revenues	10,198	516
Total current liabilities	37,561	14,392
Long-term liabilities:		
Deferred revenues	1,000	1,000
Other long-term liabilities	3,081	3,149
Total liabilities	41,642	18,541
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; 17,362,710 and 17,018,159 shares issued and outstanding at December 31, 2009 and December 31, 2008, respectively	174	170
Additional paid-in capital	432,414	411,538
Accumulated other comprehensive loss	(7,925)	(9,959)
Accumulated deficit	(281,686)	(188,335)
Total stockholders' equity	142,977	213,414
Total liabilities and stockholders' equity	$ 184,619	$ 231,955

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,		
	2009	**2008**	**2007**
Revenues:			
Product sales, net	$ 16,482	$ 751	$ 1,208
License fees	516	959	1,096
Royalties	180	228	248
Total revenues	17,178	1,938	2,552
Costs and expenses:			
Cost of product sales	1,013	292	320
Research and development expenses	36,273	31,716	24,236
Selling, general and administrative expenses	77,829	49,536	20,396
Total costs and expenses	115,115	81,544	44,952
Other income (expense):			
Interest and dividend income, net	3,154	9,139	12,506
Gains (losses) on investments, net	942	(3,024)	
Fair value adjustment of settlement rights	(778)	1,566	
Litigation Settlement			(4,000)
Total other income (expense)	3,318	7,681	8,506
Net loss before income taxes	(94,619)	(71,925)	(33,894)
Income tax benefit	1,268	278	
Net loss	$ (93,351)	$ (71,647)	$ (33,894)
Net loss per share:			
Basic and diluted	$ (5.46)	$ (4.22)	$ (2.15)
Weighted average shares outstanding used to compute net loss per share:			
Basic and diluted	17,109	16,993	15,777

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,		
	2009	**2008**	**2007**
Net loss	$ (93,351)	$ (71,647)	$ (33,894)
Other comprehensive income (loss):			
Unrealized gains (losses) on securities:			
Holding gains (losses) arising during period, net of tax	2,029	(13,110)	127
Reclassification adjustment for losses and gains, net, included in net loss	5	3,024	
Net unrealized gains (losses)	2,034	(10,086)	127
Total comprehensive loss	$ (91,317)	$ (81,733)	$ (33,767)

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, 2006	14,066	$ 141	$ 234,930	$ (82,794)	$	$ 152,277
Net shares issued in connection with the exercise of stock options and restricted stock units	372	3	4,520			4,523
Shares issued in connection with a financing, net of financing costs of $0.2 million	2,500	25	154,454			154,479
Shares issued in connection with employee stock purchase plan	8		260			260
Non-cash equity-based compensation			8,182			8,182
Unrealized gains on securities, net					127	127
Net loss				(33,894)		(33,894)
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

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,		
	2009	**2008**	**2007**
Net loss	$ (93,351)	$ (71,647)	$ (33,894)
Cash flows from operating activities:			
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	1,913	1,497	798
Non-cash equity-based compensation expense	15,421	8,037	8,182
Non-cash income tax benefit	(1,089)		
Amortization of premium/discount on purchased securities	490	482	(1,023)
Fair value adjustment on settlement rights	778	(1,566)	
Gains (losses) on investments, net	(942)	3,024	
Changes in operating assets and liabilities:			
Accounts receivable	(26,942)	(185)	126
Inventories	(9,063)	288	(40)
Prepaid and other current assets	(762)	(1,910)	(1,701)
Accounts payable and accrued expenses	13,215	6,596	(121)
Deferred revenues	9,682	42	(1,096)
Other long-term liabilities	(68)	3,006	49
Total adjustments	2,633	19,311	5,174
Net cash used in operating activities	(90,718)	(52,336)	(28,720)
Cash flows from investing activities:			
Proceeds from sales or maturities of available-for-sale investments	74,543	233,194	455,608
Proceeds from maturities of held-to-maturity investments			132,795
Purchase of available-for-sale investments	(310)	(137,438)	(693,463)
Purchase of held-to-maturity investments			(110,787)
Capital expenditures	(2,835)	(8,178)	(884)
Change in restricted cash	61	(426)	(61)
Net cash provided by (used in) investing activities	71,459	87,152	(216,792)
Cash flows from financing activities:			
Proceeds from the exercise of stock options	4,047	763	4,523
Proceeds from the issuance of common stock under ESPP	1,156	393	260
Proceeds from the issuance of common stock, net of underwriting discount and other expenses			154,479
Net cash provided by financing activities	5,203	1,156	159,262
Net (decrease) increase in cash and cash equivalents	(14,056)	35,972	(86,250)
Cash and cash equivalents at beginning of the year	64,182	28,210	114,460
Cash and cash equivalents at end of the year	$ 50,126	$ 64,182	$ 28,210
Supplemental data:			

Non-cash investing and financing activities:

Accrued construction in process	$ 272	$	$
Investments reclassified to trading, at fair value	$	$ 7,650	$
Non-cash stock option exercises	$	$	$ 683

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

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Notes to Consolidated Financial Statements

A. Organization and Business

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a biopharmaceutical company that utilizes our proprietary technology for the development and commercialization of a therapeutic iron compound to treat iron deficiency anemia and novel imaging agents to aid in the diagnosis of cancer and cardiovascular disease. We currently manufacture and sell two approved products, Feraheme® (ferumoxytol) Injection for intravenous, or IV, use and GastroMARK®.

On June 30, 2009, *Feraheme* was approved for marketing in the U.S. by the U.S. Food and Drug Administration, or the FDA, for use as an IV iron replacement therapy for the treatment of iron deficiency anemia, or IDA, in adult patients with chronic kidney disease, or CKD. We market and sell *Feraheme* 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, or MRI, is approved and marketed in the U.S., Europe and other countries through our marketing partners.

Feridex I.V.®, our liver contrast agent, has been marketed and sold in the U.S., Europe and other countries for a number of years through our marketing partners. In November 2008, we ceased manufacturing *Feridex I.V.* Accordingly, we have terminated all of our agreements with our marketing partners for *Feridex I.V.* throughout the world and do not intend to continue commercializing *Feridex I.V.*

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*, development by us or our competitors of new technological and product innovations, uncertainty regarding market acceptance of our products, uncertainties related to insurance coverage, coding and third-party reimbursement for our products, our limited experience commercializing and distributing a pharmaceutical product, our potential inability to operate our manufacturing facility in compliance with current good manufacturing practices, or cGMP, our potential inability to obtain raw materials and manufacture sufficient quantities of our products, 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 become profitable in the future, our potential inability to obtain additional financing, if necessary, on acceptable terms, the current credit and financial market conditions, 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 and other government agencies, uncertainty of the regulatory approval process for our other *Feraheme* indications or outside of the U.S., uncertainty of the results of clinical trials, our ability to manage growth, our ability to enter into favorable collaborations and in-licensing arrangements, our dependence on key personnel, and uncertainties related to the protection of proprietary technology, product liability, and potential legislative and regulatory changes.

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

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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 not limited to, revenue recognition and related sales allowances, assessing investments for potential other-than-temporary impairment and determining values of investments, reserves for doubtful accounts, accrued expenses, 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, money market funds and U.S. Treasury securities having an original maturity of less than three months. At December 31, 2009 and 2008, substantially all of our cash and cash equivalents were held in either commercial banks or money market accounts.

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, 2009 and 2008, 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. However, due to our belief that the market for auction rate securities, or ARS, may take in excess of twelve months to fully recover, we have classified our ARS that are not subject to Settlement Rights as long-term investments. 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.

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. With the opportunity provided by the Settlement Rights, we have designated these ARS as trading securities as we are likely to sell these investments to UBS.

Effective April 1, 2009, we adopted a newly issued accounting standard which amended the existing guidance on the recognition and presentation of other-than-temporary impairments on debt and equity securities. This accounting standard establishes a new method of recognizing and reporting other-than-temporary impairments of debt securities and provides additional disclosure requirements

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related to debt and equity securities. Prior to our adoption of this new accounting standard, our assessment of the impairment of our investments included an evaluation of whether a decline in fair value below amortized cost basis was other-than-temporary considering various factors such as the duration of the period that, and extent to which, the fair value was less than cost basis, the financial health of and business outlook for the issuer, including industry and sector performance, operational and financing cash flow factors, overall market conditions and trends, underlying collateral, credit ratings with respect to our investments provided by investments ratings agencies, as well as whether we had the intent and ability to hold an investment for a sufficient period of time to recover its value. Under the new accounting standard, 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, including evaluation of the security, issuer and environmental factors noted above, to evaluate whether the unrealized loss is associated with the creditworthiness of the security or is associated with other factors, such as interest rates or market factors. If we determine from this analysis that we do not expect to receive cash flows sufficient to recover the entire amortized cost of the security, a credit loss exists, and the impairment is considered other-than-temporary and this amount is recognized in our consolidated statement of operations. There were no impairments previously recognized on securities we owned at March 31, 2009 which would not have been recognized under the new accounting standard and therefore there was no cumulative effect adjustment to accumulated deficit and other comprehensive loss as a result of adopting the accounting standard.

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.

The current accounting guidance also 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 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

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following tables represent the fair value hierarchy for those assets that we measure at fair value on a recurring basis as of December 31, 2009 and December 31, 2008 (in thousands):

	Fair Value Measurements at December 31, 2009 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	$ 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

	Fair Value Measurements at December 31, 2008 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	$ 60,403	$ 60,403	$	$
Corporate debt securities	54,320		54,320	
U.S. treasury and government agency securities	37,094		37,094	
Commercial paper	3,500		3,500	
Auction rate securities	54,335			54,335
Settlement rights	1,566			1,566
	$ 211,218	$ 60,403	$ 94,914	$ 55,901

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 for the determination of 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 each reporting period, we perform quantitative and qualitative analyses on 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, 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

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possible, we assess the financial condition of the seller to determine whether observed transactions may have been forced. If the trading price for a security held by us is significantly out of line when compared to the trading prices of similar recent transactions, we consider whether this disparity is an indicator of a disorderly trade. Using professional judgment and experience, we evaluate and weigh the relevance and significance of all applicable factors to determine if the evidence suggests that a transaction or group of similar transactions is not orderly. Based upon these procedures, we determined that market activity for our assets appeared normal and that transactions did not appear disorderly as of December 31, 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. We are required to assess the fair value of both the Settlement Rights and our ARS subject to Settlement Rights and record changes each period until the Settlement Rights are exercised and our ARS subject to Settlement Rights are redeemed. Although the Settlement Rights represent the right to sell the securities back to UBS at par, we are required to periodically assess the ability of UBS to meet that obligation in assessing the fair value of the Settlement Rights.

The following table presents assets measured at fair value on a recurring basis using significant unobservable inputs (Level 3) as of December 31, 2009 and 2008 (in thousands):

	December 31, 2009	December 31, 2008
Balance at beginning of period	$ 55,901	$
Transfers to Level 3		80,725
Total gains (losses) (realized or unrealized):		
Included in earnings	99	(109)
Included in other comprehensive income (loss)	3,378	(10,515)
Purchases (settlements), net	(1,050)	(14,200)
Balance at end of period	$ 58,328	$ 55,901
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	$	$ (109)

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 we receive approval. Upon approval from the FDA, or other regulatory agencies, we then begin to capitalize the subsequent 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 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.

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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 sheet, and the cost of maintenance and repairs is expensed as incurred. Upon sale or other disposition of property and equipment, the cost and related depreciation are removed from the accounts and any resulting gain or loss is charged to our consolidated statement of operations. 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 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 $7.5 million, $3.8 million and $1.1 million for the years ended December 31, 2009, 2008 and 2007, respectively.

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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. 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 and forecasted customer buying patterns blended with historical experience of products similar to *Feraheme* sold by others. Because we only recently launched *Feraheme* in the U.S. there are a number of factors that make it particularly difficult to predict the magnitude of future *Feraheme* sales, including the magnitude and timing of adoption of *Feraheme* by physicians, dialysis clinics, hospitals and other healthcare payors and providers, the inventory levels maintained by *Feraheme* wholesalers, distributors and other customers, the frequency of re-orders by existing customers, and the pricing of products that compete with *Feraheme* and other actions taken by our competitors. In addition, we also monitor our distribution channel to determine whether additional allowances or accruals are required based on inventory in our sales channel. There were no product sales allowances or accruals for the year ended December 31, 2008. An analysis of our product sales allowances and accruals for the year ended December 31, 2009 is as follows (in thousands):

		December 31, 2009
Product sales allowances and accruals:		
Discounts and chargebacks	$	804
Government and other rebates		4,329
Returns		463
Total product sales allowances and accruals	$	5,596
Total net product sales	$	16,482
Total gross product sales	$	22,078
Total product sales allowances and accruals as a percent of total gross product sales		25%

Product sales allowances and accruals are comprised of both direct and indirect fees, discounts and rebates. 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

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regulations) related to the purchase and/or utilization of the product by these entities. Allowances and accruals are generally 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 similar products 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 our products. As part of this evaluation, we also review changes to federal 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 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 blended with historical experience of products similar to *Feraheme* sold by others, supplemented with other market research data related to demand patterns for iron replacement therapies which have been marketed for the past several years. 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 accrual 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. For rebates associated with

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reaching defined performance goals, we determine our estimates using actual *Feraheme* sales data and forecasted customer buying patterns blended with historical experience of products similar to *Feraheme* sold by others. 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 certain GPOs are usually based upon member purchases during the prior quarter and are generally billed by the GPO within 30 days after period end. Current accounting standards related to consideration given by a vendor to a customer, including a reseller of a vendor's products, specify that cash consideration given by a vendor to a customer is presumed to be a reduction of the selling price of the vendor's products or services and therefore should be characterized as a reduction of revenue. Consideration should be characterized as a cost incurred if we receive, or will receive, an identifiable benefit (goods or services) in exchange for the consideration and we can reasonably estimate the fair value of the benefit received. Because the fees we pay to wholesalers do not meet the foregoing conditions to be characterized as a cost, we have characterized these fees as a reduction of revenue. We generally pay such amounts within several weeks of our receipt of an invoice from the distributor, wholesaler, or GPO. Accordingly, we accrue 100% of the 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. When considering 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 24 months.

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.

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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 shipments, 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 returned to us will not be recorded as revenue. Accordingly, as of December 31, 2009, we recorded $10.2 million in deferred revenues, representing all product purchased under the Launch Incentive Program which remained held by the dialysis organizations at December 31, 2009, net of any applicable discounts and estimated rebates, which are included in our commercial rebate accruals as of December 31, 2009. In addition, we have deferred the related cost of product sales of approximately $0.3 million and recorded such amount as finished goods inventory held by others as of December 31, 2009. Because we are unable to reasonably estimate the amount of inventory that may be returned under this program, if any, we cannot provide any assurance that amounts reported as deferred revenue and associated with this program will be utilized by our customers and thereby recorded by us as product revenues in our future consolidated statements of operations.

License Fee 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 royalties on any product sales derived from those collaborations. We recognize license fee and research and development revenue under collaborative arrangements over the term of the applicable agreements through the application of a proportional performance model where revenue is recognized equal to the lesser of the amount due under the agreements or the amount based on the proportional performance to date. In cases where project costs or other performance metrics are estimable, we recognize nonrefundable payments and fees for the licensing of technology or intellectual property rights over the related performance period or when there are no remaining performance obligations. 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

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 which provides that an element of a contract can be accounted for separately if the delivered elements have stand-alone 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

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arrangement are recognized as revenue over the period of performance for such undelivered items or services.

Shipping and Handling Costs

During 2009, we began to 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 $0.1 million as a selling, general and administrative expense during the year ended December 31, 2009.

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 equity awards we grant to 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

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awards. The fair value of restricted stock units granted to 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 and/or 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 equivalents, investments, accounts receivable and Settlement Rights. As of December 31, 2009, our cash equivalents, investments and Settlement Rights amounted to approximately $125.8 million. We currently invest our excess cash primarily in institutional and U.S. government and agency money market funds and investments in corporate debt securities, U.S. treasury and government agency securities, and ARS.

Our operations are located solely within the U.S. We are focused principally on developing, manufacturing, and commercializing an IV iron replacement therapeutic agent and novel imaging agents. 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, 2009, 2008 and 2007. No other company accounted for more than 10% of our total revenues in any period presented below.

	For the Years Ended December 31,		
	2009	**2008**	**2007**
AmerisourceBergen Drug Corporation	46%		
Metro Medical Supply, Inc.	28%		
Bayer Healthcare Pharmaceuticals	<10%	53%	43%
Guerbet S.A.	<10%	24%	26%
Covidien, Ltd.	<10%	17%	15%
Cytogen Corporation			14%

All of the revenue attributable to Cytogen Corporation and a large portion of the revenue attributable to Bayer Healthcare Pharmaceuticals, or Bayer, in the relevant periods presented was the result of previously deferred revenue related to up-front license fees that were either amortized into revenue on a straight line basis or amortized over the period of the estimated performance obligation.

Revenues from customers outside of the U.S., principally in Europe, amounted to 2%, 29%, and 28%, of our total revenues for the years ended December 31, 2009, 2008 and 2007, respectively.

Certain raw materials used in our products are procured from a single source. We sometimes obtain raw materials from one vendor only, even where multiple sources are available, to maintain quality control and enhance working relationships with suppliers.

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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 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 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,		
	2009	2008	2007
Options to purchase shares of common stock	2,416	1,991	1,327
Shares of common stock issuable upon the vesting of restricted stock units	216	219	36
Total	2,632	2,210	1,363

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

	Years Ended December 31,		
	2009	2008	2007
Net loss	$ (93,351)	$ (71,647)	$ (33,894)
Weighted average common shares outstanding	17,109	16,993	15,777
Net loss per share:			
Basic and diluted	$ (5.46)	$ (4.22)	$ (2.15)

In January 2010, we increased our shares outstanding by selling 3,600,000 shares of our common stock, $0.01 par value per share, in an underwritten public offering.

Reclassifications

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

C. Investments

At December 31, 2009 and December 31, 2008, our total aggregate short-and long-term investments totaled $78.6 million and $149.2 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 available-for-sale and trading securities at December 31, 2009 and 2008 (in thousands):

	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

	December 31, 2008			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term investments:				
Corporate debt securities				
Due in one year or less	$ 42,845	$ 106	$ (263)	$ 42,688
Due in one to three years	11,647	58	(73)	11,632
U.S. treasury and government agency securities				
Due in one year or less	18,184	235		18,419
Due in one to three years	18,183	492		18,675
Commercial paper				
Due in one year or less	3,499	1		3,500
Due in one to three years				
Total short-term investments	$ 94,358	$ 892	$ (336)	$ 94,914
Long-term investments:				
Auction rate securities available for sale				
Due in one year or less	$	$	$	$
Due after five years	57,200		(10,515)	46,685
Auction rate securities trading				
Due in one year or less				

Due after five years	7,650			7,650
Total long-term investments	$ 64,850	$	$ (10,515)	$ 54,335
Total short and long-term investments	$ 159,208	$ 892	$ (10,851)	$ 149,249

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Auction Rate Securities and UBS Settlement Rights

At December 31, 2009, we held a total of $57.5 million in fair market value of ARS, reflecting an impairment of approximately $7.9 million compared to the par value of these securities of $65.4 million. Of the $7.9 million impairment, approximately $7.1 million was considered a temporary impairment and was reported as an unrealized loss at December 31, 2009. The remaining $0.8 million represents a trading loss associated with our UBS ARS, the recording of which is described below. Of our total ARS, $49.0 million in fair market value are not subject to Settlement Rights and are classified as available-for-sale. The remaining $8.5 million are subject to Settlement Rights and are classified as trading securities. At December 31, 2009, all of our ARS were municipal bonds with an auction reset feature. The substantial majority of our ARS portfolio was rated AAA as of December 31, 2009 by at least one of the major securities rating agencies and were primarily collateralized by student loans substantially guaranteed by the U.S. government under the Federal Family Education Loan Program. We had traditionally recorded these investments 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. As a result of the lack of observable ARS market activity, we changed our valuation methodology for these securities to a discounted cash flow analysis as opposed to valuing them at 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, 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. Based upon this methodology, we have estimated the fair value of our ARS subject to Settlement Rights to be $8.5 million at December 31, 2009 and, accordingly, we recorded realized gains of approximately $0.9 million during the year ended December 31, 2009. In addition, based upon this methodology, we have estimated the fair value of our remaining ARS not subject to Settlement Rights to be $49.0 million at December 31, 2009, and have recorded a $7.1 million unrealized loss to accumulated other comprehensive loss as of December 31, 2009. As discussed in greater detail below, 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. 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 condensed consolidated statement of operations as an impairment loss. 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. We did not recognize any credit losses related to our securities during the year ended December 31, 2009. We believe that the temporary impairment related to our ARS not subject to Settlement Rights is primarily attributable to the liquidity of these investments, coupled with the ongoing turmoil in the credit and capital markets. As of December 31, 2009, all of our ARS continue to pay interest according to their stated terms.

In November 2008, we elected to participate in a rights offering by UBS which provided us with the right 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. By electing to participate in the rights offering, we granted UBS the right, exercisable at any time prior to June 30, 2010 or during the two-year sale period, to purchase or cause the sale of our ARS at par value, or the Call Right. UBS has stated that it will only exercise the Call Right for the purpose of restructurings, dispositions or other solutions that will provide its clients with par value for their ARS. UBS has agreed to pay its clients the par value of their ARS within one day of settlement of any Call Right transaction. Notwithstanding the Call Right,

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we are permitted to sell the ARS to parties other than UBS, which would extinguish the Settlement Rights.

In accordance with current accounting guidance related to the fair value option for financial assets and financial liabilities, we have recorded an asset equal to the estimated fair value of the Settlement Rights of approximately $0.8 million in our consolidated balance sheet at December 31, 2009. This represents a decrease of approximately $0.8 million to the estimated fair value of our Settlement Rights from the estimated fair value at December 31, 2008, which we have recorded in other income (expense) in our consolidated statement operations. We estimate the fair value of these Settlement Rights utilizing a discounted cash flow analysis. Certain key assumptions used in this valuation include the estimated value of these rights at the future date of settlement, the expected term until the date of settlement, and the risk that UBS will not be able to perform under the agreement. With the opportunity provided by the Settlement Rights, we have designated the UBS ARS 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 as we are likely to sell these investments to UBS. Accordingly, as of December 31, 2009, we have recognized gains of approximately $0.9 million to other income (expense) in our consolidated statement of operations during the year ended December 31, 2009. We are required to assess the fair value of both the Settlement Rights and our ARS subject to Settlement Rights and record changes each period until the Settlement Rights are exercised or our ARS subject to Settlement Rights are redeemed. Although the Settlement Rights represent the right to sell the securities back to UBS at par, we are required to periodically assess the ability of UBS to meet its obligations in assessing the fair value of the Settlement Rights.

Due to our belief that the market for ARS may take in excess of twelve months to fully recover, we have classified our portfolio of ARS not subject to Settlement Rights as long-term investments in our consolidated balance sheet at December 31, 2009. As discussed in greater detail below, we believe that the temporary impairment related to our ARS not subject to Settlement Rights is primarily attributable to the liquidity of these investments, coupled with the ongoing turmoil 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. Any future fluctuation in fair value related to our ARS not subject to Settlement Rights 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. For all of our ARS, the underlying maturity date is in excess of one year, and the majority have final maturity dates of 30 to 40 years in the future. We believe we will ultimately be able to liquidate our investments without significant loss prior to the maturity dates noted above 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 addition, 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, and we may be required to adjust our future valuation of these ARS which may adversely affect the value of these investments.

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

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investment category and length of time that individual securities have been in a continuous unrealized loss position at December 31, 2009 and 2008 (in thousands):

	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)

	December 31, 2008					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Corporate debt securities	$ 33,996	$ (295)	$ 963	$ (41)	$ 34,959	$ (336)
Auction rate securities	46,685	(10,515)			46,685	(10,515)
	$ 80,681	$ (10,810)	$ 963	$ (41)	$ 81,644	$ (10,851)

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 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. Factors we consider in making this judgment include, but are not limited to:

the extent to which 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;

our intent not to sell an impaired investment before its recovery occurs;

whether it is more likely than not that we will be required to sell the investment before recovery occurs;

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.

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Based upon our evaluation, we did not consider the unrealized losses on our available-for-sale investments at December 31, 2009 and 2008 to be other-than-temporarily impaired. Accordingly, no impairment losses were recognized in our consolidated statements of operations related to available-for-sale securities during the years ended December 31, 2009 or 2008.

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 amortized cost basis of a security and which may necessitate the recording of future realized losses on securities in our portfolio. Significant losses in the estimated fair values of our investments could have a material adverse effect on our earnings in future periods.

Realized Gains and Losses

Gains and losses are determined on the specific identification method and, accordingly, during 2009 we recorded gains of $0.2 million to our consolidated statements of operations principally related to our estimated valuation of ARS subject to Settlement Rights.

D. Accounts Receivable

Our accounts receivable were $27.4 million and $0.4 million at December 31, 2009 and 2008, respectively. At December 31, 2009, our accounts receivable primarily represented amounts due from wholesalers and distributors to whom we sell *Feraheme* directly and customers who participated in the Launch Incentive Program. Our accounts receivable at December 31, 2008 primarily represented amounts due from our *GastroMARK* and *Feridex I.V.* customers. 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 condensed consolidated balance sheet.

Included within our accounts receivable balance at December 31, 2009 are $12.1 million in receivables, which represent amounts due from dialysis organizations to whom we shipped *Feraheme* under the 2009 Launch Incentive Program. These shipments 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, we have recorded deferred revenues of $10.2 million net of any applicable discounts and estimated rebates as of December 31, 2009 in accordance with current revenue recognition standards.

To date, we have not experienced significant bad debts. As part of our credit management policy, we perform ongoing credit evaluations of our customers and as a result have not required collateral from any customer. As a result, we have not established an allowance for doubtful accounts at either December 31, 2009 or 2008. If the financial condition of our 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.

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Customers with amounts that represented greater than 10% of our accounts receivable balance at December 31, 2009 and 2008 were as follows:

	As of December 31,	
	2009	2008
AmerisourceBergen Drug Corporation	29%	
Metro Medical Supply, Inc.	20%	
Dialysis Clinics, Inc.	15%	
Liberty Dialysis, LLC	10%	
Satellite Healthcare, Inc.*	10%	
Covidien, Ltd.		72%
Bayer Healthcare Pharmaceuticals		17%
Taejoon Pharmaceutical Co., Ltd		11%

*

During 2009, we entered into an agreement with Satellite Healthcare, Inc., or Satellite, a dialysis organization, under which Satellite purchased $2.8 million of *Feraheme* pursuant to our Launch Incentive Program. Our Chief Executive Officer is a member of the Board of Directors of Satellite. As of December 31, 2009, we had outstanding receivables from Satellite of $2.8 million which, in accordance with their terms, were paid to us in January 2010.

E. Inventories

Our major classes of inventories were as follows at December 31, 2009 and 2008 (in thousands):

	December 31, 2009	December 31, 2008
Raw materials	$ 1,584	$ 9
Work in process	1,169	57
Finished goods	6,326	30
Finished goods held by others	336	
Total inventories	$ 9,415	$ 96

Finished goods inventory held by others primarily relates to inventories held by dialysis organizations to which we have shipped *Feraheme* under the Launch Incentive Program. Agreements entered into under this program provided certain customers with extended payment terms and expanded rights of return. As a result, in accordance with current accounting and reporting standards related to revenue recognition, we have deferred both the recognition of revenues and the costs of the inventory sold under this program and presented inventories held by others as a separate component of our overall inventory as of December 31, 2009.

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 24 months, 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 $0.3 million was capitalized into inventory for the year ended December 31, 2009. There was no equity-based compensation capitalized into inventory for the year ended December 31, 2008.

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F. Property, Plant and Equipment

Property, plant and equipment consisted of the following at December 31, 2009 and 2008, respectively (in thousands):

	As of December 31,	
	2009	2008
Land	$ 360	$ 360
Buildings and improvements	10,356	9,986
Laboratory and production equipment	6,839	5,994
Furniture and fixtures	4,345	3,474
Construction in process	1,294	298
	23,194	20,112
Less- accumulated depreciation	(10,777)	(8,889)
Property, plant and equipment, net	$ 12,417	$ 11,223

G. Current and Long-Term Liabilities

Accrued Expenses

Accrued expenses consisted of the following at December 31, 2009 and 2008 (in thousands):

	December 31, 2009	December 31, 2008
Clinical, manufacturing and regulatory consulting fees and expenses	$ 2,134	$ 1,338
Commercial consulting fees and expenses	3,471	2,752
Salaries, bonuses, and other compensation	8,767	4,989
Professional, license, and other fees and expenses	1,902	2,492
Commercial rebates, fees and returns	5,657	
Totals	$ 21,931	$ 11,571

Deferred Revenues

At December 31, 2009 and 2008, our short-term deferred revenue of $10.2 million and $0.5 million, respectively, related to our sales of *Feraheme* under the Launch Incentive Program and our collaborative agreement with Bayer, respectively. Our long-term deferred revenue of $1.0 million at both December 31, 2009 and 2008, related entirely to our collaborative agreement with 3SBio Inc., or 3SBio. In consideration of the grant of the license to 3SBio in 2008, we received an up-front payment of $1 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, 2009 and 2008 consist 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, 2009 and 2008, we recognized current federal income tax benefits of $1.3 million and $0.3 million, respectively. During 2009, we recognized a $1.1 million tax benefit, which was the result of our recognition of a corresponding $1.1 million income tax expense

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associated with the increase in the value of certain securities that we carried at fair market value during the year ended December 31, 2009. This income tax expense was recorded in other comprehensive income. There were no similar income tax benefits or provisions for the years ended December 31, 2008 or 2007. 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 each 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,		
	2009	2008	2007
Statutory U.S. federal tax rate	(34.0)%	(34.0)%	(34.0)%
State taxes, net of federal benefit	(2.3)%	(5.9)%	(6.3)%
Permanent items, net	2.1%	2.1%	2.1%
Tax credits	(1.0)%	(2.1)%	(1.4)%
Valuation allowance	33.9%	39.5%	39.6%
Total tax (benefit) expense	(1.3)%	(0.4)%	0.0%

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

	December 31,	
	2009	2008
Assets		
Net operating loss carryforwards	$ 61,674	$ 45,754
Tax credit carryforwards	9,501	8,558
Equity award expense	6,565	3,895
Capitalized research & development	26,225	19,123
Other	9,483	7,188
Liabilities		
Depreciation	(528)	(253)
	112,920	84,265
Valuation allowance	(112,920)	(84,265)
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 $28.7 million and $32.2 million for the years ended December 31, 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, 2009, we had federal and state NOL carryforwards of approximately $162.5 million and $110.8 million, respectively, and federal capital loss carryforwards of $1.3 million to offset future taxable income. We also had 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

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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 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 $6.9 million and $3.9 million, respectively, to offset future tax liabilities. Our tax credits will expire periodically through 2030 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 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.

We adopted accounting guidance for uncertainty in income taxes which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return and provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. At the adoption date of January 1, 2007 and also at December 31, 2009, 2008 and 2007, we had no unrecognized tax benefits. We have not, as yet, conducted a study of our R&D credit carryforwards. This study may 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 the Company's 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, 2006, although carryforward attributes that were generated prior to tax year 2006 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.

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I. Equity-Based Compensation

We maintain several equity compensation plans, including our Amended and Restated 2007 Equity Incentive Plan, or the 2007 Plan, our Amended and Restated 2000 Stock Plan, or the 2000 Plan, and our 2006 Employee Stock Purchase Plan, or 2006 ESPP.

2007 Plan

Our 2007 Plan was originally approved by our stockholders in November 2007. In May 2009, our stockholders approved a proposal to amend and restate our 2007 Plan to, among other things, increase the number of shares of our common stock available for issuance thereunder by 600,000 shares. 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 contractual term of no greater than ten years. 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 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 will now be 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, 2009, we have granted options and restricted stock units covering 2,114,444 shares of common stock under our 2007 Plan, of which 261,313 stock options and 6,000 restricted stock units have expired or terminated, and of which 11,580 options have been exercised and 1,250 shares of common stock were 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, 2009 was 1,632,051 and 202,250, respectively. The remaining number of shares available for future grants as of December 31, 2009 was 943,719, 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 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.

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2000 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, 2009, we have granted options and restricted stock units covering 2,182,700 shares of common stock under the 2000 Plan, of which 377,800 stock options and 750 restricted stock units have expired or terminated, and of which 976,879 stock options have been exercised and 30,000 shares of common stock were issued pursuant to restricted stock units that became fully vested. The remaining number of shares underlying outstanding options and restricted stock units pursuant to the 2000 Plan as of December 31, 2009 was 784,021 and 13,250, respectively. All outstanding 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, net of amounts remaining capitalized into inventory, was as follows (in thousands):

	Years Ended December 31,		
	2009	2008	2007
Cost of product sales	$ 43	$	$
Research and development	4,446	3,760	1,936
Selling, general and administrative	10,932	4,277	6,246
Total equity-based compensation expense	$ 15,421	$ 8,037	$ 8,182

Equity-based compensation expense for the years ended December 31, 2009, 2008 and 2007 included approximately $0.7 million, ($2.1) million and $2.4 million, respectively, in equity-based compensation expense associated with grants subject to market or performance conditions. Equity-based compensation of $0.3 million was capitalized into inventory for the year ended December 31, 2009. Capitalized equity-based compensation is recognized into cost of product sales when the related product is sold. There were no equity-based compensation costs capitalized in 2008 or prior periods.

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 several years, 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 nor cash flows from operating activities as reported in the accompanying consolidated statements of cash flows.

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The following table summarizes the weighted average assumptions we utilized for purposes of valuing grants of options to our employees and non-employee directors:

	Years Ended December 31,					
	2009		2008		2007	
	Employees	Non-Employee Directors	Employees	Non-Employee Directors	Employees	Non-Employee Directors
Risk free interest rate (%)	2.21	1.70	2.90	1.59	4.41	3.44
Expected volatility (%)	60	58	60	59	64	62
Expected option term (years)	5.40	4.13	5.10	4.70	5.29	5.50
Dividend yield	none	none	none	none	none	none

Risk free interest rates utilized are based upon published U.S. Treasury yields at the date of the grant for the expected option term. For stock options issued prior to March 31, 2007, we relied exclusively on historical volatility of our own common stock price over the prior period equivalent to our expected option term. For issuances subsequent to March 31, 2007, 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. For stock options issued prior to March 31, 2007, we used the simplified method as promulgated by accounting guidance for estimating the expected option term. For stock options issued subsequent to March 31, 2007, we use the calculated historical term of stock options in computing the expected option term.

The following table summarizes details regarding our stock option plans for the year ended December 31, 2009 (excluding restricted stock units, which are presented separately below):

	December 31, 2009			
	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value ($ in millions)
Outstanding at beginning of year	1,991,486	$ 39.14		
Granted	966,898	33.78		
Exercised	(291,814)	13.87		
Expired and/or forfeited	(250,498)	43.10		
Outstanding at end of year	2,416,072	$ 39.64	8.1 years	$ 9.9
Outstanding at end of year vested and unvested expected to vest	2,266,877	$ 39.66	8.1 years	$ 9.4
Exercisable at end of year	720,677	$ 40.48	6.7 years	$ 4.2

The weighted average grant date fair value of stock options granted during the years ended December 31, 2009, 2008 and 2007 were $18.32, $22.61, and $34.77, respectively. The total fair value of options that vested during the years ended December 31, 2009, 2008 and 2007 were $9.6 million, $7.6 million, and $4.2 million, respectively. The aggregate intrinsic value of options exercised in the years ended December 31, 2009, 2008 and 2007, excluding purchases made pursuant to our 2003 Employee Stock Purchase Plan, or 2003 ESPP, and our 2006 ESPP, measured as of the exercise date, was approximately $9.2 million, $1.6 million, and $17.2 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.

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In the year ended December 31, 2009, we issued an aggregate of 10,000 restricted stock units to employees pursuant to our 2007 Plan. In general, these grants vest ratably, on an annual basis, over a four year period. The estimated fair value of restricted stock units granted was determined at the grant date based upon the quoted market price per share on the date of the grant. The estimated fair value of restricted stock unit awards issued during 2009 was approximately $0.5 million. At December 31, 2009, the amount of unrecorded expense for all outstanding restricted stock units attributable to future periods was approximately $5.0 million, and with the exception of the restricted stock awards subject to market conditions, which we expect will vest over an initial derived service period of 2.8 years, is expected to be amortized primarily to expense 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.

The following table summarizes details regarding restricted stock units granted under our equity incentive plans for the year ended December 31, 2009:

	December 31, 2009	
	Unvested Restricted Stock Units	Weighted Average Grant Date Fair Value
Outstanding at beginning of year	218,500	$ 39.62
Granted	10,000	53.10
Vested	(12,000)	32.73
Forfeited	(1,000)	45.15
Outstanding at end of year	215,500	$ 40.61
Outstanding at end of year and expected to vest	196,536	$ 40.61

At December 31, 2009, the amount of unrecorded equity-based compensation expense attributable to future periods was approximately $34.7 million, of which $29.7 million was associated with stock options and $5.0 million was associated with restricted stock units. Such amounts will be amortized, in varying amounts, primarily to research and development or selling, general and administrative expense, generally on a straight line basis over weighted average amortization periods of approximately 2.6 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 options and other equity-based awards.

Employee Stock Purchase Plan

Our 2006 ESPP authorizes the issuance of up to 100,000 shares of our common stock to eligible employees. Under the terms of the 2006 ESPP, which began on June 1, 2007 and expires May 31, 2012, eligible employees may purchase shares (subject to certain plan and/or income tax limitations) in ten semi-annual offerings through payroll deductions of up to an annual maximum of 10% of the employee's total compensation, including base pay or salary and any overtime, bonuses or commissions. Plan periods consist of six-month periods commencing June 1 and ending November 30 and commencing December 1 and ending May 31. 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. As of December 31, 2009, 2008 and 2007, 56,642, 15,905 and 3,058 shares, respectively, have been issued under our 2006 ESPP.

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The assumptions used for awards granted during 2009 under our 2006 ESPP were as follows:

	Years Ended December 31,		
	2009	2008	2007
Risk free interest rate (%)	0.21	0.82	4.06
Expected volatility (%)	52	66	33
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 2006 ESPP and our 2003 ESPP during the years ended December 31, 2009, 2008 and 2007 was $15.65, $11.83, and $19.23, respectively, and was estimated using the Black-Scholes option-pricing model.

Stock Options Granted to Consultants

In August 2008, we entered a one-year consulting agreement with a non-employee director. Under the terms of this consulting agreement, the director provided consulting and advisory services related to the commercialization and launch of *Feraheme*. As compensation for these consulting services, we granted this director, in the aggregate, options to purchase 2,000 shares of our common stock under our 2007 Plan, at an exercise price of $41.57. Such options were fully vested on August 6, 2009. This resulted in a non-cash charge of approximately $28,000 and $10,000 in the years ended December 31, 2009 and 2008, respectively, with an offsetting credit to additional paid-in capital.

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 on a pre-tax basis up to a specified maximum percentage. Our 401(k) Plan provides, among other things, for a company contribution of 3% of each employee's combined base 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 $1.1 million, $0.6 million, and $0.2 million for the years ended December 31, 2009, 2008 and 2007, 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. On September 4, 2009, our Board adopted a shareholder rights plan, or Rights Plan. The terms of the Rights Plan provide for a dividend distribution of one 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

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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 research, development and commercialization of products derived from our proprietary technology for use in treating human diseases. Long-lived assets consist entirely of property and equipment and are located in the U.S. for all periods presented.

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 2014. Expense associated with these operating leases for the years ended December 31, 2009, 2008 and 2007, amounted to approximately $0.9 million, $0.5 million, and $0.1 million, respectively. Future minimum lease payments associated with all noncancellable automobile, equipment, service and lease agreements, excluding facility related leases are estimated to be approximately $0.1 million for 2010 and 2011, and less than $0.1 million per year from 2012 through 2014. We lease approximately 110 automobiles for our field-based employees. This lease requires an initial minimum lease term of 12 months per automobile. We expect our monthly expense related to this operating lease to be approximately $60,000. 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.

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

Period	Minimum Lease Payments
Year Ended December 31, 2010	$ 1,903
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
Thereafter	3,738
Total	$ 13,813

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, 2009, 2008 and 2007 was $1.6 million, $1.7 million, and $0.4 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 securing this letter of credit is classified on our balance sheet as a long-term asset and is restricted in its use.

Purchase Commitments

During 2009 we entered into various agreements with third-parties for which we had remaining purchase commitments of approximately $2.4 million as of December 31, 2009. These agreements principally related to certain outsourced commercial activities such as our field nursing staff, 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 and executive officers, we are obligated to indemnify our officers and directors for certain events or occurrences while the officer or director 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. We have not incurred costs to defend lawsuits or settle claims related to these indemnification obligations. As a result, we believe the estimated fair value of these indemnification obligations is immaterial.

We are also a party to a number of 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. Since our inception, 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 minimal, and we have not recorded any liability related to such indemnification.

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Severance Arrangements

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 agreement.

Legal Proceedings

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. We are not aware of any material claims against us at December 31, 2009.

N. Collaborative Agreements and Contracts

Our commercial strategy has 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:

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 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 up-front payment of $1 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*. 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.

Bayer

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. Pursuant to the termination agreement, Bayer could continue to sell any remaining *Feridex I.V.* inventory in its possession through April 1, 2009 and other than royalties owed by Bayer to us on such sales, no further obligation exists by either party. As a result of the termination of these agreements, during 2009 we recognized $0.5 million of deferred revenues, which remained at December 31, 2008.

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

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(under the tradename Lumirem®) and the option to acquire such rights to any future MRI contrast agents developed by us. This agreement was amended in 2002 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. In 2004, it was determined through binding arbitration that Guerbet failed to meet its contractual obligations with respect to the exercise of its option to acquire certain rights to *Feraheme* in imaging, and, accordingly, all such rights reverted back to us. 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 the licensed products. 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 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. Subsequent Events

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.

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P. Consolidated Quarterly Financial Data Unaudited

The following tables provide consolidated quarterly financial data for the years ended December 31, 2009 and 2008 (in thousands, except per share data):

	March 31, 2009	June 30, 2009	September 30, 2009	December 31, 2009
Product sales, net(a)	$ 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(a)	61		128	824
Operating expenses	28,822	27,382	25,460	32,438
Interest and dividend income, net	1,256	783	503	612
Gains (losses) on investments, net	992	275	(319)	(6)
Fair value adjustment of settlement rights	(923)	(185)	321	9
Income tax benefit	179			1,089(c)
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)

	March 31, 2008	June 30, 2008	September 30, 2008	December 31, 2008
Product sales, net	$ 392	$ 212	$ 24	$ 123
License fees	184	185	184	406
Royalties	36	89	52	51
Total revenues	612	486	260	580
Cost of product sales	44	31	3	214
Operating expenses	13,208	19,672	24,812	23,560(b)
Interest and dividend income, net	3,266	2,199	2,021	1,653
Gains (losses) on investments, net	73	11	(1,321)	(1,787)
Fair value adjustment of settlement rights				1,566
Income tax benefit			278	
Net loss	$ (9,301)	$ (17,007)	$ (23,577)	$ (21,762)
Net loss per share basic and diluted	$ (0.55)	$ (1.00)	$ (1.39)	$ (1.28)

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

(a) 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.

(b) In the fourth quarter of 2008 we reversed approximately $4.9 million of compensation expense related to certain performance-based stock options which included amounts recorded in 2007 as well as amounts recorded through the first three quarters of 2008.

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

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Q. 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, 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	$	$	$	$	$
Year ended December 31, 2007:					
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.

R. Recently Issued and Proposed Accounting Pronouncements

In January 2010, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2010-6, Improving Disclosures About Fair Value Measurements, or ASU 2010-6, which also amends Accounting Standards Codification, or ASC, 820. ASU 2010-6 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 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 is 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 do not expect the adoption 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). The consensus to EITF Issue No. 08-1, Revenue Arrangements with Multiple Deliverables, or EITF 08-1, provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration 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

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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 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. We are currently evaluating the potential impact of this standard on our consolidated financial statements.

In December 2009, the FASB issued ASU No. 2009-16, Accounting for Transfers of Financial Assets, or ASU 2009-16. ASU 2009-16 relates to the accounting and disclosure requirements related to the servicing and transfer of financial assets. ASU 2009-16 enhances information reported to users of financial statements by providing greater transparency about transfers of financial assets and an entity's continuing involvement in transferred financial assets, including securitization transactions, where entities have continuing exposure to the risks related to transferred financial assets. It eliminates the concept of a "qualifying special-purpose entity," changes the requirements for de-recognizing financial assets, and requires additional disclosures. This amendment is effective for fiscal years beginning after November 15, 2009. We do not expect the adoption of this amendment to have a significant impact on our consolidated financial statements.

In December 2009, the FASB issued ASU No. 2009-17, Improvements to Financial Reporting by Enterprises Involved with Variable Interest Entities, or ASU 2009-17. ASU 2009-17 relates to the accounting and disclosure requirements related to the consolidation of variable interest entities and changes how a reporting entity determines when an entity that is insufficiently capitalized or is not controlled through voting (or similar rights) should be consolidated. The determination of whether a reporting entity is required to consolidate another entity is based on, among other things, the other entity's purpose and design and the reporting entity's ability to direct the activities of the other entity that most significantly impact the other entity's economic performance. The reporting entity will be required to provide additional disclosures about its involvement and will be required to disclose how its involvement with a variable interest entity affects the reporting entity's financial statements. This amendment is effective for fiscal years beginning after November 15, 2009. Early application is not permitted. We do not expect the adoption of this amendment to have a significant impact on our consolidated financial statements.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE:

None.

ITEM 9A. CONTROLS AND PROCEDURES:

Managements' Evaluation of our Disclosure Controls and Procedures

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our "disclosure controls and procedures" (as defined in the Exchange Act Rule 13a-15(e), or Rule 15d-15(e)), with the participation of our management, have each concluded that, as of 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 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

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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, 2009.

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, 2009 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, 2009.

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, 2009.

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, 2009.

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, 2009.

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, 2009.

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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, 2009 and 2008

Consolidated Statements of Operations for the years ended December 31, 2009, 2008 and 2007

Consolidated Statements of Comprehensive Loss for the years ended December 31, 2009, 2008 and 2007

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2009, 2008 and 2007

Consolidated Statements of Cash Flows for the years ended December 31, 2009, 2008 and 2007

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 amended (incorporated herein by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, File No. 0-14732).
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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2009, File No. 0-14732).
4.5	Rights Agreement dated as of September 4, 2009 by and among AMAG Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, LLC (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed September 4, 2009, File No. 0-14732).
4.6	Form of Right 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.

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Exhibit Number	Description
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*	Advanced Magnetics, Inc. 2006 Employee Stock Purchase Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2007, File No. 0-14732).
10.8*	Summary of the Company's Amended and Restated Non-Employee Director Compensation Policy (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009, File No. 0-14732).
10.14*	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).
10.15*	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).
10.16*	AMAG Pharmaceuticals, Inc. Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009, File No. 0-14732.
10.17*	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).
10.18*	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).
10.19*	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).
10.20*	Form of Option Agreement (Nonqualified Option) for Annual Director Grants in connection with the Company's Amended and Restated 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009, File No. 0-14732).
10.21	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).

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10.22	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).
10.23	Supply 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).
10.24	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 June 30, 2009, File No. 0-14732). (confidential treatment previously granted).
10.25	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 June 30, 2009, File No. 0-14732). (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.

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

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

* Exhibits marked with a single asterisk reference management contracts, compensatory plans or arrangements, filed in response to Item 15(a)(3) of the instructions to Form 10-K.

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

(b) *Exhibits.* We hereby file or furnish as exhibits, as the case may be, to this Form 10-K those exhibits listed in Part IV, Item 15(a)(3) above.

(c) *Financial Statement Schedules.* No financial statement schedules have been submitted because they are not required, not applicable, or because the information required is included in the financial statements or the notes thereto.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AMAG PHARMACEUTICALS, INC.

By: /s/ BRIAN J.G. PEREIRA

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

Date: February 26, 2010

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 and President (Principal Executive Officer)	February 26, 2010
/s/ DAVID A. ARKOWITZ David A. Arkowitz	Executive Vice President, Chief Financial Officer and Chief Business Officer (Principal Financial and Accounting Officer)	February 26, 2010
/s/ JOSEPH V. BONVENTRE, MD, PHD Joseph V. Bonventre, MD, PhD	Director	February 26, 2010
/s/ MICHAEL NARACHI Michael Narachi	Director	February 26, 2010
/s/ ROBERT J. PEREZ Robert J. Perez	Director	February 26, 2010
/s/ LESLEY RUSSELL, MB. CH.B., MRCP Lesley Russell, MB. Ch.B., MRCP	Director	February 26, 2010
/s/ DAVEY S. SCOON Davey S. Scoon		
/s/ RON ZWANZIGER Ron Zwanziger	Director	February 26, 2010

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3.1, 4.1	Certificate of Incorporation of the Company, as amended (incorporated herein by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, File No. 0-14732).
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.
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).
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