AMAG PHARMACEUTICALS INC.
Form 10-K
February 27, 2009

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, 2008

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)	(IRS Employer Identification No.)
100 Hayden Avenue Lexington, MA	**02421**
(Address of Principal Executive Offices)	(Zip Code)
(Registrant's Telephone Number, Including Area Code)	**(617) 498-3300**

Securities registered pursuant to Section 12(b) of the Act: **Common Stock, par value $.01 per share, NASDAQ Global Market**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. **Yes o No ý**

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. **Yes o No ý**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. **Yes ý No o**

Indicate by check mark 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 Form10-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 the definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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, 2008 was approximately $580,000,000 based on the closing price of $34.10 of the Common Stock of the registrant as reported on the NASDAQ Global Market on such date. As of February 16, 2009, there were 17,022,534 shares of the registrant's Common Stock, par value $.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 5, 2009, 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: the potential approval of Feraheme *(ferumoxytol injection) in the U.S. and outside of the U.S., statements regarding our belief that we will not need to conduct any additional clinical trials prior to approval of Feraheme, our plan to launch Feraheme, the progress of our intended development and commercialization of Feraheme, the design and timing of potential clinical trials for Feraheme we may initiate in indications other than CKD such as in patients with AUB, cancer, and PAD, future revenues (including expected future revenues under our agreements with Bayer Healthcare Pharmaceuticals and 3SBio Inc.), expected research and development expenses and selling, general and administrative expenses, our expectations regarding our dividend and interest income, our expectations regarding our short- and long-term liquidity and capital requirements and our ability to finance our operations, our belief that the impairment in the value of our securities, including our auction rate securities not subject to settlement right agreements, is temporary and that we will ultimately be able to liquidate our investments without significant loss, 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, or the SEC, 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 anemia and novel imaging agents to aid in the diagnosis of cancer and cardiovascular disease. We have one product candidate, Feraheme (ferumoxytol injection), and two approved products, Feridex I.V.® and GastroMARK®. Throughout this Annual Report on Form 10-K, AMAG Pharmaceuticals, Inc. and our consolidated subsidiary, AMAG Securities Corporation, are collectively referred to as "the Company," "we," "us," or "our."

Feraheme is being developed for use as an intravenous, or IV, iron replacement therapeutic agent for the treatment of iron deficiency anemia, or IDA, and as a diagnostic agent for vascular enhanced magnetic resonance imaging, or MRI, to assess peripheral arterial disease, or PAD. In December 2007, we submitted a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or the FDA, for marketing approval of *Feraheme* for the treatment of IDA in patients with chronic kidney disease, or CKD. In October 2008, we received a Complete Response letter from the FDA with respect to our NDA for *Feraheme* requesting certain additional clinical information, information regarding certain observations noted during a recent FDA inspection at one of our Phase III clinical sites, and resolution of certain deficiencies noted during a recent FDA inspection of our Cambridge, Massachusetts manufacturing facility. We submitted a response to the Complete Response letter in

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October 2008, and in December 2008 we received a second Complete Response letter from the FDA requesting data to clarify a specific chemistry, manufacturing and controls, or CMC, question, resolution of the deficiencies observed during the recent FDA inspection of our manufacturing facility, and finalization of labeling discussions for *Feraheme*. We will need to address the issues raised by the FDA with respect to our NDA in a timely and satisfactory manner in order to obtain approval to market and sell *Feraheme* in the U.S. We are working with the FDA to address the December 2008 Complete Response letter and believe that we will not need to conduct any additional clinical trials of *Feraheme* prior to FDA approval of *Feraheme*.

We currently intend to initiate two Phase III studies of *Feraheme* in women with IDA and abnormal uterine bleeding, or AUB, in the first half of 2009. We expect that these studies will enroll a total of approximately 1,200 AUB patients combined. In 2009, we also currently plan to initiate a Phase III clinical development program for *Feraheme* in patients with IDA and cancer, whether or not receiving chemotherapy. The study designs and timelines for the initiation of our clinical development programs for *Feraheme* in AUB and cancer patients are currently subject to the completion of protocol discussions with the FDA and may ultimately serve as the basis for a broader Phase III clinical development program of *Feraheme* for the treatment of IDA in a broad range of patient populations and disease states.

In addition to its use for the treatment of IDA, *Feraheme* may also be useful as a vascular enhancing agent in MRI. In August 2008, we announced that the FDA granted Fast Track designation to *Feraheme* for its development as a diagnostic agent for vascular-enhanced MRI for the assessment of PAD. We have initiated a 108 patient Phase II study of *Feraheme* in vascular-enhanced MRI for the detection of clinically significant arterial stenosis or occlusion in subjects with intermittent claudication, or leg pain when walking.

If approved for the treatment of IDA in CKD patients, we will market and sell *Feraheme* in the U.S. through our own commercial organization. We have built an internal sales and marketing function, including a direct sales force, in preparation for the planned U.S. commercial launch of *Feraheme* as an IV iron replacement therapeutic agent in CKD patients.

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, patient access to dialysis, the role of iron in medical treatment protocols in each country, and the regulatory requirements of each country. We are also currently evaluating possible strategic alliances and partnerships to assist us in entering attractive foreign markets. For example, in 2008 we entered into a license agreement and a supply agreement with 3SBio Inc., or 3SBio, with respect to the development and commercialization of *Feraheme* as an IV iron replacement therapeutic agent in China.

Feridex I.V., our liver contrast agent, is approved and has been sold in the U.S., Europe and other countries. 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.*

GastroMARK, our oral contrast agent used for delineating the bowel in MRI, is approved and marketed in the U.S., Europe, and other countries. 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.

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

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In May 2007, we changed our fiscal year end from September 30 to December 31, and therefore information is included in this report for the calendar years ended December 31, 2008 and 2007 and the three month transition period ended December 31, 2006. Unless specifically indicated otherwise, any reference to "2008" relates to December 31, 2008 or the year ended December 31, 2008, and any reference to "2007" relates to December 31, 2007 or the year ended December 31, 2007.

Our Core Technology

Our core technology is based on extremely 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 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 and product candidates results 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 magnetic resonance images 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."

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Products and Product Candidates

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

Product or Product Candidate	Applications	Marketing Partners	U.S. Status	Foreign Status
Feraheme	IV iron replacement therapeutic agent in CKD patients.	3SBio Inc. (China)	NDA pending. Second Complete Response letter received December 2008.	No marketing applications filed to date.
	IV iron replacement therapeutic agent in patients with AUB.	None	Two Phase III trials planned to be initiated in the first half of 2009.*	No marketing applications filed to date.
	IV iron replacement therapeutic agent in cancer patients.	None	Phase III protocol under review by the FDA. Phase III trial planned for 2009.*	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.
Feridex I.V.	Diagnosis of liver lesions.	None**	**	**
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.

*

The study designs and timelines for the initiation of our clinical development programs for *Feraheme* in AUB and cancer patients are currently subject to the completion of protocol discussions with the FDA and may ultimately serve as the basis for a broader Phase III clinical development program of *Feraheme* for the treatment of IDA in a broad range of patient populations and disease states.

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We have terminated agreements with all of our *Feridex I.V.* marketing partners including Bayer Healthcare Pharmaceuticals, or Bayer, and TaeJoon Pharmaceutical Co., Ltd, or TaeJoon. We do not intend to further manufacture or commercialize *Feridex I.V.* in the U.S. or abroad.

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**

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. Anemia is a common condition among CKD patients and 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. Iron deficiency is worse in CKD patients on hemodialysis due to the additional blood loss in the hemodialysis procedure. In addition, the diseased kidney often does not produce enough erythropoietin to stimulate sufficient production of red blood cells to meet the body's needs. Consequently, anemia worsens in people with more advanced CKD. To increase red blood cell production, anemic CKD patients are given treatment with erythropoiesis stimulating agents, or ESAs. ESA therapy stimulates red blood cell production, which increases utilization of existing iron stores. Therefore, long-term use of ESA therapy causes the body to progressively deplete its iron stores, and the consequent iron deficiency lessens the effectiveness of ESA therapy in treating anemia. As a result, the majority of CKD patients eventually develop IDA that can be treated with iron replacement therapy.

For most patients receiving ESAs, oral iron supplements do not adequately replenish the body's iron stores. Oral iron supplements are not absorbed well by the gastrointestinal tract and can often have unpleasant side effects, such as constipation, diarrhea and cramping, which can cause patients to stop taking the oral iron supplements. IV iron replacement therapeutics allow greater amounts of iron to be provided to patients while avoiding the side effects associated with oral iron supplements. For iron replacement therapy in patients with CKD, the total therapeutic course of IV iron typically used in clinical practice is 1,000 milligrams, or one gram. Administering large doses of the currently approved IV iron products in the U.S., including sodium ferric gluconate and iron sucrose, has been associated with an unfavorable safety profile. As a result, the most frequently used IV iron products are typically administered as a slow push or a fifteen to thirty 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 National Kidney Foundation's Kidney Disease Outcomes Quality Initiative, or KDOQI, stages patients with CKD on a scale of less severe, or stage 1, through most severe, or stage 5, based on their level of kidney function, whether or not they are on dialysis, and whether or not they have received a kidney transplant. The KDOQI 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.

According to an estimate by the United States Renal Data System, or USRDS, there will be approximately 393,000 CKD patients on dialysis in the U.S. in 2009. Approximately 90% of these dialysis patients receive IV iron as part of managing their anemia. Additionally, according to estimates contained in a 2007 publication in the *Journal of American Medical Association*, based on the 1999 to 2004 National Health and Nutrition Examination Survey, in 2000 there were over 16 million people in the U.S. suffering from stage 3 or stage 4 CKD who were not on dialysis. If these estimates are applied to the U.S. Census population estimates for 2009, then the number of patients with stage 3 and 4 CKD is approximately 18 million in the U.S. Among these patients, we estimate that approximately 3 million have anemia based on the 2004 USRDS Annual Data Report. Moreover, data contained in a 2009 publication in the *Clinical Journal of American Society of Nephrology*, suggests that greater than 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.

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Feraheme CKD clinical development program

In December 2007, we submitted an NDA to the FDA for marketing approval of *Feraheme* for the treatment of IDA in CKD patients. In October 2008, we received a Complete Response letter from the FDA with respect to our NDA for *Feraheme* requesting certain additional clinical information, information regarding certain observations noted during a recent FDA inspection at one of our Phase III clinical sites, and resolution of certain deficiencies noted during a recent FDA inspection of our Cambridge, Massachusetts manufacturing facility. We submitted a response in October 2008, and in December 2008 we received a second Complete Response letter from the FDA requesting data to clarify a specific CMC question, resolution of the deficiencies observed during the FDA's recent inspection of our manufacturing facility, and finalization of labeling discussions for *Feraheme*. We will need to address the issues raised by the FDA with respect to our NDA in a timely and satisfactory manner in order to obtain approval to market and sell *Feraheme* in the U.S. We are working with the FDA to address the December 2008 Complete Response letter and believe that we will not need to conduct any additional clinical trials of *Feraheme* prior to FDA approval of *Feraheme*.

Our NDA for *Feraheme* is supported by four pivotal Phase III clinical studies for *Feraheme* as an IV iron replacement therapeutic agent in patients with CKD. These trials have included patients with all stages of CKD, including patients with stages 1 through 5 CKD who are not on dialysis, patients with stage 5 CKD who are on hemodialysis or peritoneal dialysis, and kidney transplant recipients.

Two of our four pivotal Phase III studies were identically designed efficacy and safety studies in 304 and 303 non-dialysis patients with stages 1 through 5 CKD, respectively, who were randomized in a 3 to 1 ratio to receive either two rapid IV injections of 510 milligrams of *Feraheme* administered within a week or 200 milligrams of oral iron per day for three weeks. Both studies demonstrated a statistically significant achievement of all primary and secondary efficacy endpoints. The third pivotal Phase III trial was an efficacy and safety trial that included 230 CKD patients on hemodialysis and also demonstrated a statistically significant achievement of all primary and secondary efficacy endpoints.

The fourth pivotal Phase III study was a double-blind, placebo-controlled, crossover safety study in 750 patients with all stages of CKD, comparing a single injection of 510 milligrams of *Feraheme* to normal saline placebo. Adverse events occurred in 21.3% of patients after *Feraheme* administration and in 16.7% of patients after placebo administration. On a blinded basis, meaning the physician was not aware whether the patient had received *Feraheme* or oral iron, these adverse events were deemed to be related to treatment by the investigator in 5.2% of patients after *Feraheme* administration and in 4.5% of patients after placebo administration. Serious adverse events, or SAEs, occurred in 2.9% of patients after *Feraheme* administration and in 1.8% of patients after placebo administration. On a blinded basis, these SAEs were deemed to be related to treatment by the investigator in one patient after *Feraheme* administration and in one patient after placebo administration. In this study, the single SAE attributed to the drug after *Feraheme* administration occurred in an 85 year-old male with non-dialysis dependent CKD, hypertension, coronary artery disease, cerebrovascular disease and a history of multiple drug allergies to ciprofloxacin, levofloxacin, and percocet. The patient experienced an anaphylactoid reaction with severe hypotension a few minutes after *Feraheme* administration, was treated with epinephrine and fully recovered.

Across all phases of the *Feraheme* clinical development program with approximately 2,800 total administered doses of *Feraheme*, there were no cases of anaphylaxis and no deaths determined by the investigator to be drug-related. Drug-related SAEs were reported in three, or 0.17%, of 1,726 patients treated with *Feraheme*, one, or 0.35%, of 289 patients treated with oral iron, and one, or 0.13%, of 781 patients treated with placebo.

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Feraheme in indications other than CKD

Iron deficiency anemia is widely prevalent in many different patient populations, including elderly patients and women, and disease states, including cancer and gastrointestinal diseases, as well as patients undergoing various surgical procedures. In addition, we believe that the product characteristics of *Feraheme* support clinical development in additional indications. As a result, we are currently in the process of developing clinical programs for *Feraheme* in certain of these IDA indications, including AUB and cancer.

We currently intend to initiate two Phase III studies of *Feraheme* in women with IDA and AUB in the first half of 2009. We expect that these studies will enroll a total of approximately 1,200 AUB patients combined. In 2009, we also currently plan to initiate a Phase III clinical development program for *Feraheme* in patients with IDA and cancer, whether or not receiving chemotherapy. The study designs and timelines for the initiation of our clinical development programs for *Feraheme* in AUB and cancer patients are currently subject to the completion of protocol discussions with the FDA and may ultimately serve as the basis for a broader Phase III clinical development program of *Feraheme* for the treatment of IDA in a broad range of patient populations and disease states.

Anemia in women with abnormal uterine bleeding

AUB can be 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. The reported incidence of AUB is variable and ranges from approximately 30% to 50% among women of childbearing age. Symptoms of AUB include headache, pain in the abdomen, breast, joint, or other pain, nausea, dizziness, weakness, feelings of sadness or depression, hot flashes, yeast infection or other discomfort in the vagina, and vaginal bleeding.

AUB may be treated medically or surgically depending on the underlying cause, prior response to therapy, desires regarding future fertility, and individual preference of the patient and/or physician. Surgery continues to be a standard treatment to manage bleeding in many women with AUB.

Iron deficiency occurs in approximately 10% of women of childbearing age in the U.S., and IDA occurs in approximately 2% to 5% of such women. Both iron deficiency and IDA are commonly associated with AUB. The prevalence of anemia in AUB patients ranges from 10% to 67%, and the prevalence of iron deficiency in AUB patients ranges from 20% to 50%, depending on patient age and diagnostic criteria. The severity of the anemia is correlated with the degree of blood loss. Anemia in AUB patients is associated most commonly with fatigue, but it is also associated with decreased exercise capacity, negative perceptions regarding physical functioning and vitality, reduced cognitive abilities, and cardiac issues. In addition, anemia in patients with AUB may pose a further health risk by increasing the risk for transfusion and increasing the risk of death among those who require surgery.

The correction of hemoglobin through iron supplementation may minimize the consequences of anemia and reduce the risk of transfusion. As a result, IDA in patients with AUB, regardless of the cause, is treated with iron supplementation, either by oral or IV administration. Although there is limited data regarding the safety and efficacy of IV iron in treating IDA in women with AUB, given *Feraheme*'s potential tolerability and ability to raise hemoglobin levels, we believe further evaluation in this patient population is warranted.

Anemia in patients with cancer

Anemia is common in patients with cancer. Depending on the type of cancer, between 30% and 90% of patients with cancer have anemia. A 2004 observational study conducted in Europe showed that the prevalence of anemia in cancer patients increased from 39% to 68% within six months from the start of the study.

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Anemia in patients with cancer can be caused by a number of different factors. The National Comprehensive Cancer Network categorizes anemia in cancer patients into two categories: anemia caused by cancer and chemotherapy-induced anemia. Anemia caused by cancer occurs in patients who are not receiving chemotherapy. The administration of iron supplements has been shown to be effective in treating anemia in these patients. Many of these patients also develop absolute IDA due to blood loss or the inadequate intake or absorption of iron. Anemia in cancer patients who are receiving chemotherapy can be further exacerbated by the chemotherapy agents themselves. Certain chemotherapy treatments are well recognized as being the cause of chemotherapy-induced anemia through multiple mechanisms, including damage to kidney and bone marrow function.

The current treatment of anemia in cancer patients includes ESAs and iron supplementation. ESAs, including epoetin alfa and darbepoetin alfa, are indicated for the treatment of patients receiving chemotherapy with mild to moderate chemotherapy-induced anemia. ESAs are not indicated for anemic cancer patients who are not receiving chemotherapy due to a possible increased risk of tumor progression, particularly when ESAs have been dosed to target a high hemoglobin level. An FDA alert in 2007 stated that recent studies indicate that ESAs may be ineffective and harmful to anemic cancer patients who are not receiving chemotherapy. In the U.S., a boxed warning was added in March 2007 to both epoetin alfa and darbepoetin alfa product labeling limiting ESA use. In June 2008, the European Medicines Agency, or EMEA, issued a recommendation to use transfusions rather than ESA therapy to treat anemia in patients with cancer. Given the concerns surrounding the use of ESAs for treating cancer in patients not receiving chemotherapy, the treatment of anemia in this population currently relies on addressing the underlying disease, iron supplementation, and/or blood transfusions. However, transfusions are associated with a number of serious health risks, such as allergic reactions, damage to red blood cells, and transmission of infectious diseases.

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. The administration of iron has been used in treating anemia, either alone in cancer patients not receiving chemotherapy, or alone or in combination with an ESA in cancer patients receiving chemotherapy. An inadequate iron supply to the bone marrow is a common cause of an impaired response to ESA therapy, which may be due to depletion of total body iron stores or functional iron deficiency. In such patients, IV iron supplementation may allow for lower doses of ESAs, which may potentially minimize the risks associated with ESA use. In addition, the use of IV iron has the potential to reduce the cost of anemia management in this patient population.

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, and potential interactions with other treatments. 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. The combination of IV iron and ESA therapy appears to result in fewer treatment failures, resulting in an increased erythropoietic response and lower transfusion requirements when compared to patients receiving only ESAs.

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 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 magnetic resonance images with

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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 will be in patients with PAD for the detection of clinically significant arterial stenosis or occlusion in subjects with intermittent claudication, or leg pain when walking. 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. Intermittent claudication is the most common symptom of PAD and can lead to fatigue, cramping and pain of the gluteal, thigh or calf muscles. 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.

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. The currently approved contrast agents used for MRI in the U.S. are all 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 such agents' observed 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 limit the use of currently available contrast agents in this patient population. Currently there is no effective treatment for NSF.

The prevalence of PAD in the U.S. is 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 an important 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. The direct and indirect medical care costs of cardiovascular disease are estimated to exceed $450 billion in 2009.

Ferumoxytol is an iron-based agent with unique paramagnetic properties that may be visualized by MRI. Currently, there are no iron-based PAD contrast agents approved for MRI in the U.S. In August 2008, we announced that the FDA granted Fast Track designation to ferumoxytol for its development as a diagnostic agent for vascular-enhanced MRI to improve the assessment of PAD in patients. 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 initiated a 108 patient Phase II study of ferumoxytol for vascular-enhanced MRI for the detection of clinically significant arterial stenosis or occlusion in subjects with intermittent claudication, or leg pain when walking.

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

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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. See "Licensing, Marketing and Supply Arrangements."

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.

GastroMARK was approved by the FDA in 1996. Our marketing partner, Covidien, Ltd., or Covidien, formerly Tyco Healthcare, Ltd., or Tyco Healthcare, and Mallinckrodt, Inc., or Mallinckrodt, has 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

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 Inc.

On May 25, 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.

Bayer (formerly Berlex Laboratories, Inc.)

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 1996, the parties agreed to remove Canada from the territories

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subject to the Bayer Agreements. Bayer paid us non-refundable license fees and other fees in connection with the Bayer Agreements. The Bayer Agreements were terminated upon mutual agreement in November 2008. Pursuant to the termination agreement, Bayer may 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.

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 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 (formerly Tyco Healthcare and Mallinckrodt)

In 1990, we entered into a manufacturing and distribution agreement with Covidien granting Covidien 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.

Other

We are the licensee of certain technologies related to certain of our imaging products under cross-license agreements with Amersham Health, which is part of GE Healthcare (formerly Nycomed Imaging A.S.), or Amersham, and Bayer Schering Pharma AG (formerly Schering AG), or Bayer Schering. The license agreement with Amersham requires us to make payments upon the attainment of particular milestones relating to *Feridex I.V.* and *GastroMARK*. We are also required under the agreement with Amersham to pay royalties on a percentage of product sales of *Feridex I.V.* and *GastroMARK*, if any. There were no milestone payments made in 2008, 2007, or 2006. Future milestone payments under the Amersham agreement will not exceed $0.4 million.

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 *GastroMARK* for commercial sale and *Feraheme* for potential commercial use as well as for use in human clinical trials. Our current plan is to use this facility to manufacture *Feraheme* for commercial sale if and when *Feraheme* is approved by the FDA.

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The FDA conducts periodic inspections of our manufacturing facility 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. 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 a Warning Letter, fines, product recalls, total or partial suspension of production, suspension of the FDA's review of an NDA or future supplemental NDAs, enforcement actions, injunctions or criminal prosecution and could impair our ability to obtain product approvals, generate product sales and continue our development efforts.

In October 2008, the FDA completed an on-site inspection of our manufacturing facility. At the completion of the inspection the FDA noted certain deficiencies observed during the inspection with respect to our compliance with cGMP regulations. We will need to address the deficiencies noted by the FDA in a timely and satisfactory manner in order to obtain approval to market and sell *Feraheme*. In November 2008 we submitted a response to each of the FDA's inspectional observations. If our response and our proposed remedial measures do not adequately address the FDA's observations, the FDA may take one or more of the regulatory actions described above, which could result in a substantial delay in the approval of *Feraheme,* a suspension of our ability to manufacture *Feraheme*, or the loss of our existing *Feraheme* inventory, or other unanticipated compliance expenditures, any of which would have an adverse impact on our potential profitability and the future prospects of our business.

We have recently begun to manufacture large scale commercial lots of *Feraheme* but as we continue to manufacture *Feraheme* in larger volumes for commercial sale we could experience a number of difficulties, including higher than anticipated material, labor and overhead costs per unit. Additionally, manufacturing and quality control problems may arise as we increase our level of production. We may not be able to continue to increase our manufacturing capacity in a timely and cost-effective manner to meet demand for *Feraheme* if and when it is approved by the FDA, and we may experience delays in manufacturing *Feraheme*, which could result in a shortage in the supply of *Feraheme.* Furthermore, we will need to continue to recruit, train and retain additional qualified manufacturing and quality control personnel as we prepare for production of *Feraheme* on a commercial scale. If we fail to attract and retain key members of our manufacturing or quality control 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 anticipated demand for *Feraheme*.

Although we are working to establish and qualify second source manufacturing facilities for *Feraheme*, we currently have only one manufacturing facility at which we produce *Feraheme*. 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.

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 additional third-party suppliers for these raw materials. If any of these 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

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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 by us 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 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 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 between the years 2009 and 2020, some of which may be subject to 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 commercialize our products prior to the expiration of our patents could have a material adverse effect on our business, financial condition and prospects.

We also have patent applications pending in the U.S., and have filed counterpart patent applications in several foreign countries. Although we believe that further patents will be issued on pending applications, we cannot be sure that these 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.

We are a party to various license agreements, including nonexclusive cross-licensing arrangements covering MRI technology with Amersham and Bayer Schering. Our proprietary position depends in part on these licenses, and termination of the licenses for any reason could limit or prohibit the commercial sale of our contrast agents.

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Competition

The pharmaceutical and biopharmaceutical industries are subject to intense competition and rapid technological change. Most of our competitors that are developing iron replacement therapeutic products have greater financial resources, experience and expertise in product development, manufacturing, marketing and sales than we do. 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 potential 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 will depend on a number of factors, including our ability to successfully develop safe and efficacious products, the timing and scope of regulatory approval of our products and those of our competitors, our ability to obtain favorable pricing, insurance coverage, coding and reimbursement for our products, our ability to implement effective marketing campaigns, our ability to develop an effective sales force, our ability to maintain favorable patent protection for our products, market acceptance of our products and our ability to manufacture sufficient quantities of our products at commercially acceptable costs.

The iron replacement therapy market is highly sensitive to several factors including, but not limited to, the ability to obtain appropriate insurance coverage, coding and reimbursement, price competitiveness, and product characteristics such as convenience of administration and dosing regimens. In particular, the IV iron replacement market is extremely sensitive to the relative safety profiles of the various IV iron replacement therapeutics, and it will be critical that *Feraheme*'s safety profile is or is perceived to be comparable to that of other products in order to be competitive in the marketplace.

There are currently two options for treating IDA in CKD patients: oral iron supplements and IV iron. The National Kidney Foundation's KDOQI 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 iron sucrose, ferric gluconate, or iron dextran. The most frequently used IV iron products are currently comprised of iron sucrose or sodium ferric gluconate, which are typically administered as a slow push or a fifteen to thirty 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. *Feraheme*, if approved, may be administered as two 510 milligram injections in less than one minute per injection, each of which could be administered at a regular office visit or during dialysis treatment without the use of infusion equipment or prolonged medical intervention.

IMS Health Incorporated, or IMS Health, estimates the 2008 U.S. IV iron replacement therapy market at approximately $745 million in gross sales. Based on the projected growth of the dialysis dependent patient population by the USRDS, and the potential increased use of IV iron in the non-dialysis dependent CKD population, we believe that the IV iron replacement therapy market could grow to approximately $1 billion in gross sales by 2010.

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 Medical Care North America, or Fresenius, and DaVita, Inc., or DaVita, together treat more than 60% 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,

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our ability to realize and grow revenues from sales of *Feraheme* will be severely limited, which would have a material adverse impact on our potential profitability, and our future business prospects. In addition, in September 2008, Fresenius finalized an exclusive sublicense agreement with Luitpold Pharmaceuticals, Inc., or Luitpold, the U.S. licensing partner of Vifor Pharma, a subsidiary of Galenica Ltd, or Galenica, to manufacture, sell and distribute Venofer®, an existing 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 2008, Galenica, Vifor Pharma, and Fresenius also 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 this agreement, it may be more difficult for us to penetrate the dialysis market, in particular at Fresenius clinics in the U.S.

There are currently four IV iron products commercially available in the U.S. for the treatment of IDA. Of those four, we anticipate that *Feraheme*, if approved, will compete primarily with Venofer®, an iron sucrose complex, and Ferrlecit®, a sodium ferric gluconate. Venofer® is marketed by Fresenius and American Regent Laboratories, Inc., or American Regent, a subsidiary of Luitpold. Venofer® is currently approved for use in hemodialysis, peritoneal dialysis and non-dialysis dependent CKD patients. Ferrlecit®, is marketed by Watson Pharmaceuticals, Inc., or Watson, and is approved for use in hemodialysis patients. Dexferrum® is an iron dextran product marketed by American Regent and INFeD®, also an iron dextran product, is marketed by Watson. Both iron dextran products are used in patients with documented iron deficiency in whom oral administration is unsatisfactory or impossible.

IMS Health estimates that sales of Venofer® currently represent approximately 61%, and sales of Ferrlecit® represent approximately 26%, of the total grams of iron sold in the 2008 U.S. IV iron therapy replacement market. Dexferrum® and INFeD® together account for 13% of sales of grams of iron in the market.

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 VIT-45, also known as Ferinject® in Europe or Injectafer® in the U.S., and soluble ferric pyrophosphate, or SFP, a form of iron given as part of the hemodialysis procedure.

Galenica, through its Vifor (International) Inc. subsidiary, exclusively licenses Injectafer® to Luitpold and American Regent for the United States and Canada. Injectafer® is in development for a variety of anemia-related indications, including the treatment of anemia in CKD patients, whether or not on dialysis. In addition, Luitpold is sponsoring ongoing Phase III trials for Ferinject® in cardiology (chronic heart failure), irritable bowel disease, orthopedic surgery and post partum anemia. 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 eight European countries. 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 has expanded ongoing clinical trials and is initiating three further clinical trials to provide additional data addressing the concerns of the FDA. Luitpold expects these trials to take two years to complete prior to filing an NDA in the U.S.

Rockwell Medical Technologies, Inc., or Rockwell, is developing an iron supplemented dialysate product, SFP, a form of iron given as part of the hemodialysis procedure to be used as a treatment for anemia in dialysis patients. Rockwell is currently conducting Phase IIb clinical trials and sponsoring an on-going study funded by the National Institutes of Health. We do not know when SFP might be submitted to the FDA for approval or marketed. SFP, if shown to be safe and effective for the treatment of IDA, could compete with IV iron products, including *Feraheme*.

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Pharmacosmos A/S has also completed a non-comparative open-label Phase III study of IV iron oligosaccharide in CKD patients. No additional studies are known to be on-going and their future development plans have not been publicly disclosed.

In addition to competition from the above branded products or product candidates, the market opportunity for *Feraheme* would be negatively affected if generic IV iron replacement therapy products were to be approved and achieve commercial success. For example, in June 2008, Hospira, Inc., or Hospira, reported opening a bioequivalence study for a generic iron sucrose. As of January 2009 the study was not complete and was not actively recruiting patients. Companies that manufacture generic products typically invest far less resources in research and development than the manufacturers of branded products and can therefore price their products significantly lower than those already on the market. It remains unclear whether a generic product will enter this market.

Sales and Marketing

In order to market and sell our approved products we have historically entered into collaboration agreements with marketing and distribution partners. However, if approved, we intend to market and sell *Feraheme* in the U.S. CKD market through our own dedicated sales organization. In anticipation of the U.S. commercial launch of *Feraheme* in CKD, we have assembled a commercial team, including a specialized sales force, of approximately 120 people, which we believe could also position us to market and sell additional products and/or market and sell *Feraheme* in additional indications as they become available. Our sales force will focus on two distinct CKD markets: dialysis dependent and non-dialysis dependent CKD patients. We plan to market *Feraheme* to nephrologists, hematologists, hospitals, dialysis centers, CKD clinics and infusion centers. The promotional strategy for *Feraheme* will focus on educating physicians on the clinical value that *Feraheme* can provide to patients with IDA and CKD. Because there is a relatively small number of nephrologists and hematologists controlling the majority of the existing and potential iron market, we believe that the size of our sales force is appropriate to reach our target physician accounts. Our specialized sales force consists of approximately 72 full-time sales representatives and 8 front line sales managers. At launch, *Feraheme* will be distributed primarily through wholesalers, distributors and specialty pharmacies.

To support our launch efforts, our commercial team includes seasoned professionals who are responsible for brand management, sales, managed markets and reimbursement and commercial analytics. Our commercial team will develop and implement brand strategies to maximize product uptake and adoption with our target physician audiences in accordance with our labeling, if approved. We also intend to use a variety of marketing strategies to promote our products including journal advertising, personal and non-personal promotional materials, local and national educational programs and conferences and informational websites.

Government Regulation

Overview

The development, manufacture and commercialization of our products and product candidates 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

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of a product candidate requires a significant number of years and the expenditure of substantial resources, and is often subject to unanticipated delays and may be subject to new legislation or regulations.

In addition to complying with requirements as they currently exist, a sponsor could be negatively impacted by changes in the regulatory framework. From time to time, legislation is introduced that could significantly alter laws pertaining to the approval, manufacturing and/or marketing of drug products. Even without changes to relevant laws, the FDA could release new guidances or revise its implementation of current regulations in a manner that significantly affects us and our products or product candidates. It is impossible to predict whether legislative changes will be enacted, whether FDA regulations or guidance will be amended or supplemented, or the potential impact of such changes.

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, or cGCP, 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 three sequential phases, although the phases may overlap in some instances. Phase I clinical trials involve the initial administration of the study drug to a small group of healthy human patients (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 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. 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 designed to gather additional information in a broader sample of the target population in order to further establish safety and efficacy.

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

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Submission and FDA Review of an NDA

Following the successful completion of Phase I, II, and III trials, the results of the clinical 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 complete, meaning the FDA makes a determination that 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 PDUFA, 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, 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.

In addition, in accordance with current FDA rules and regulations, if the FDA considers that no active ingredient of a drug has been approved in any other application, the FDA must refer that drug to an advisory committee for review prior to approval or provide reasons in its final action letter as to why it did not refer it to an advisory committee. The advisory committee is typically a panel of clinicians, statisticians, and other experts who review, evaluate and recommend to the FDA whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee.

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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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 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, or PREA, the FDA may require pediatric assessment for 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.

The FDA also requires all companies with approved products to submit reports on adverse drug experiences that occur 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. As a result of these reports, the FDA could place additional limitations on a product's use, such as labeling changes and, potentially, withdrawal or suspension of the product from the market.

Where a sponsor wishes to expand the originally approved prescribing information, or otherwise change the product formulation or manufacturing and testing requirements, it must submit and obtain approval of a supplemental new drug application. Supplemental new drug applications 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. 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 require corrective advertising or other corrective communications to healthcare professionals.

FDA Regulation of Manufacturing Facilities

Manufacturing procedures and quality control for approved drugs must conform to cGMP, which practices are described in the FDC Act and FDA guidance. cGMP requirements must be followed at all times, and domestic manufacturing establishments are subject to periodic inspections by the FDA in

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order to assess, among other things, cGMP compliance. In addition, prior to approval of an NDA, the FDA will perform a pre-approval inspection, or PAI, 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 control 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 and product candidates, including *Feraheme*, are subject to extensive federal and state regulation, including but not limited to FDA regulations, the federal false claims act, and the federal anti-kickback statute. 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, the failure to approve *Feraheme*, restrictions on how we market and sell *Feraheme*, restrictions on our manufacturing processes, significant fines, exclusions from government healthcare programs, including Medicare and Medicaid, litigation, or other sanctions.

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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 on sales, marketing, pricing, and other activities. Similar legislation is being considered in a number of other states. 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 Regulation

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 where we decide to obtain approval for our products may be more or less rigorous as compared with the U.S., and the time required for approval may be longer or shorter than that required in the U.S. To obtain regulatory approval of a drug in the EU, marketing authorizations may be submitted under a centralized, mutual recognition or decentralized procedure or national procedure (single country). Under the centralized procedure, the sponsor can submit a single application to the EMEA which, if approved, permits the marketing of a product throughout the EU. Under the mutual recognition procedure, the sponsor applies for national marketing authorization in one state, and upon approval can then seek simultaneous approval in all other EU Member States. Under the decentralized procedure, the sponsor can file simultaneously to several EU Member States, identifying a single Reference Member State to act as the primary reviewer of the application. Upon approval, the product will be licensed only in the Reference Member State and the other countries to which it applied.

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Reimbursement

In both the U.S. and foreign markets, our ability to successfully commercialize *Feraheme* depends in significant part on the availability of insurance coverage and the amount of reimbursement available from government programs, including Medicare and Medicaid, from private health insurers, and from other third-party payors with respect to our products and product candidates. Significant uncertainty exists as to the reimbursement status of newly-approved drugs used for indications not previously approved by the FDA and for drugs that have competitors for their approved indications. 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 or practices may result in inadequate or no reimbursement.

Certain other factors may also impact the reimbursement status or profitability of *Feraheme*. The U.S. and many foreign governments are attempting to curb health care costs through legislation, including legislation aimed at reducing the pricing and reimbursement of pharmaceutical products. Currently, in the dialysis center and physician clinic settings, Medicare generally reimburses for physician-administered drugs under a Part B payment methodology that reimburses each product at 106% of its average sales price, or ASP. Each product's ASP is calculated by the manufacturer based on certain historical sales and sales incentive data, such as rebates or chargebacks, which is submitted to Centers for Medicare & Medicaid Services, or CMS. CMS then 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.

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 measure the product's ASP, providers are instead generally reimbursed at 106% of the product's wholesale acquisition cost. CMS typically requires one full quarter of sales data before transitioning a new product to an ASP-based reimbursement methodology.

However, it is uncertain how long the ASP reimbursement methodology will continue to apply if and when *Feraheme* is approved by the FDA, and we cannot predict the impact any changes in reimbursement policies may have on our ability to compete effectively. On July 15, 2008, Congress enacted The Medicare Improvements for Patients and Providers Act of 2008, or MIPPA, which created a bundled payment system for the treatment of ESRD to take effect on January 1, 2011. MIPPA requires CMS to begin a process of moving 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 beginning on January 1, 2011 and to complete the phase-in by January 1, 2014. Given the uncertainties surrounding bundling, we cannot predict the impact such a system would have on sales of our products in the hemodialysis market. Bundling initiatives implemented in other healthcare settings, however, have frequently resulted in lower utilization of 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 material negative impact on sales of *Feraheme*, the price we charge for *Feraheme*, and our overall revenues.

While MIPPA applies only to Medicare, these payments can also influence pricing in the non-Medicare markets, as private third-party payors and state Medicaid plans frequently adopt Medicare principles in setting their own reimbursement methodologies. Many third-party payors also use methods other than those discussed above to reduce costs, including: (a) formularies, which limit coverage for drugs not included on a pre-set list; (b) variable co-payments, which may make a certain drug more expensive for patients as compared with a competing drug; and (c) utilization management controls, such as requirements for prior authorization before the payor will cover the drug.

In addition, for providers to obtain reimbursement for *Feraheme* from Medicare, Medicaid and certain third-party payers, select codes must be submitted by the provider with each claim. These codes

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are issued to manufacturers at the discretion of CMS. Certain codes may also be issued by CMS at the request of a provider or Medicare Administrative Contractor. There is no guarantee that we will be successful in obtaining the appropriate codes for *Feraheme*, and our inability to obtain these codes could complicate provider reimbursement and have a material negative impact on *Feraheme* utilization and sales.

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.

Major Customers

The following table sets forth customers who represented 10% or more of our revenues for the years ended December 31, 2008 and 2007, the three months ended December 31, 2006, and the year ended September 30, 2006. No other company accounted for more than 10% of our total revenues in any period presented below.

	For the Years Ended December 31,		For the Three Months Ended December 31, 2006	For the Year Ended September 30, 2006
	2008	2007		
Bayer	53%	43%	31%	41%
Guerbet	24%	26%	45%	37%
Covidien	17%	15%	15%	11%
Cytogen	0%	14%	<10%	<10%

All of the revenues attributable to Cytogen Corporation, or Cytogen, and a large portion of the revenues attributable to Bayer in all periods presented was previously deferred revenue related to up-front license fees.

Backlog

Generally, we do not have a significant backlog. Product orders from our customers are typically fulfilled within a relatively short time of receipt of a customer order. We had a $0.2 million product sales backlog as of December 31, 2008 as compared to a $0.3 million product sales backlog of as of December 31, 2007.

Employees

As of February 16, 2009, we had 259 employees. We also utilize consultants and independent contractors on a regular basis to assist in the development and potential commercialization of our products and product candidates. Our success depends in part on our ability to recruit and retain talented and trained scientific, clinical, regulatory, manufacturing, and sales and marketing personnel, as well as senior management. Although we believe we have been relatively successful to date in obtaining and retaining such personnel, we may not be successful in the future.

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

Foreign Operations

We have no foreign operations. Revenues for the years ended December 31, 2008 and 2007, the three months ended December 31, 2006, and the year ended September 30, 2006 from customers

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outside of the U.S., principally in Europe and Japan, amounted to 29%, 28%, 47% and 41%, respectively, of our total revenues.

Research and Development

We have dedicated a significant portion of our resources in our efforts to develop our product candidates. We incurred research and development expenses of $31.6 million, $24.2 million, $6.4 million and $21.3 million during the years ended December 31, 2008 and 2007, the three months ended December 31, 2006, and the year ended September 30, 2006, respectively. We anticipate that a significant portion of our operating expenses will continue to be related to research and development in 2009.

Code of Ethics

In 2003, we adopted a code of ethics that applies to our officers, directors and employees. In November 2006, our Board of Directors, or the Board, approved certain amendments to our Code of Ethics to conform to NASDAQ requirements. In March 2008, the Board further revised the Code of Ethics to make certain clarifying changes. 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 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.

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

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ITEM 1A. RISK FACTORS:

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

We are solely dependent on the success of Feraheme.

We are currently investing most of our efforts and financial resources in the development and commercialization of *Feraheme*. Our ability to generate future revenues is solely dependent on our ability to obtain marketing approval for and successfully commercialize *Feraheme* as an IV iron replacement therapeutic agent in the U.S. If we are unable to generate revenues from *Feraheme*, our financial condition will be materially adversely affected and our business prospects will be very limited.

Although we have dedicated significant resources to development efforts in the past, we may not be successful in developing new applications for our existing technology or in expanding the potential indications for *Feraheme*. Although we have commenced additional clinical trials for *Feraheme* in indications other than CKD in an effort to expand the potential indications for *Feraheme*, we are not currently conducting or sponsoring research to expand our product development pipeline beyond *Feraheme*. Any failure by us to acquire, develop and commercialize additional products and product candidates or additional indications for *Feraheme* would limit long-term shareholder value and would adversely affect the future prospects of our business.

We currently have two products, *Feridex I.V.* and *GastroMARK*, approved for marketing and sale in the U.S. and in certain foreign jurisdictions. However, we recently ceased the manufacture of *Feridex I.V.* and have terminated all of our agreements with our marketing partners for *Feridex I.V.* throughout the world. In addition, 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.

We may experience significant delays in our efforts to obtain approval for Feraheme or we may never receive regulatory approval for the marketing and commercial sale of Feraheme in the U.S. or elsewhere.

FDA approval of *Feraheme* may be significantly delayed or may never occur for a variety of reasons, including but not limited to the following:

The FDA may determine that *Feraheme* is not safe or efficacious;

We may not be able to adequately address the issues raised in the December 2008 Complete Response letter received by the FDA in a timely manner, if at all;

The FDA may identify deficiencies in the design, implementation or oversight of our clinical development program or manufacturing operations, which we may not be able to adequately address in a timely manner, if at all; or

The FDA may require additional information which we may not be able to provide in a timely manner, if at all.

The FDA imposes substantial requirements on the development, production and commercial introduction of all drug products. Before obtaining regulatory approval for the commercial marketing and sale of *Feraheme*, we must demonstrate through extensive pre-clinical testing and human clinical trials that *Feraheme* is safe and efficacious. In December 2007, we submitted our NDA to the FDA for marketing approval of *Feraheme* for the treatment of IDA in CKD patients. In October 2008, we received a Complete Response letter from the FDA with respect to our NDA for *Feraheme* requesting certain additional clinical information, information regarding certain observations noted during a recent FDA inspection at one of our Phase III clinical sites, and resolution of certain deficiencies noted

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during a recent FDA inspection of our Cambridge, Massachusetts manufacturing facility. We submitted a response to the Complete Response letter in October 2008, and in December 2008 we received a second Complete Response letter from the FDA requesting data to clarify a specific CMC question, resolution of the deficiencies observed during the recent FDA recent inspection of our manufacturing facility, and finalization of labeling discussions for *Feraheme*. If we are unable to adequately address the issues raised or provide the information requested by the FDA with respect to our NDA in a timely manner, we may experience significant delays in our efforts to obtain approval for *Feraheme* or *Feraheme* may not receive approval at all.

The FDA has substantial discretion in the approval process and may decide that the data in our NDA, including any information we provide in our reply to the December 2008 Complete Response letter, is insufficient for approval. The FDA may review our data and determine that *Feraheme* is not efficacious and/or does not have an acceptable safety profile. Clinical and other data is often susceptible to varying interpretations, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain FDA approval for their products. The FDA could also determine that our pre-clinical studies, 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 cGCP regulations, 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 were 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 failed 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.*

Any such deficiency in the design, implementation or oversight of our clinical development program identified by the FDA could cause us to incur significant additional costs, experience significant delays in our efforts to obtain regulatory approval for *Feraheme*, or even prevent us from obtaining regulatory approval for *Feraheme*. 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.

We may not be able to adequately address the deficiencies identified by the FDA during the recent inspection of our manufacturing facility or operate our manufacturing facility in compliance with current good manufacturing practices and other FDA regulations, which could result in a substantial delay in the approval of Feraheme, a suspension of our ability to manufacture Feraheme, the loss of our existing Feraheme inventory, or other unanticipated compliance costs.

Our Cambridge, Massachusetts manufacturing facility is subject to cGMP regulations enforced by the FDA. The FDA conducts periodic inspections of our manufacturing facility 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. 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 a Warning Letter, fines, product recalls, total or partial suspension of production, suspension of the FDA's review of an NDA or future supplemental NDAs, enforcement actions, injunctions or criminal prosecution and could impair our ability to obtain product approvals, generate product sales and continue our development efforts.

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In October 2008, the FDA completed an on-site inspection of our manufacturing facility. At the completion of the inspection, the FDA noted certain deficiencies observed during the inspection with respect to our compliance with cGMP regulations. We will need to address the deficiencies noted by the FDA in a timely and satisfactory manner in order to obtain approval to market and sell *Feraheme* in the U.S. In November 2008 we submitted a response to each of the FDA's inspectional observations. If our response and our proposed remedial measures do not adequately address the FDA's observations, the FDA may take one or more of the regulatory actions described above, which could result in a substantial delay in the approval of *Feraheme,* a suspension of our ability to manufacture *Feraheme*, or the loss of our existing *Feraheme* inventory, or other unanticipated compliance expenditures, any of which would have an adverse impact on our potential profitability and the future prospects of our business.

In addition, if the FDA decides to re-inspect our manufacturing facility to confirm the remedial measures we have implemented are adequate, the FDA may identify new or additional deficiencies with respect to our compliance with cGMP regulations. If the FDA were to identify additional cGMP deficiencies, the FDA could take one or more of the regulatory actions described above, which could result in a substantial delay in the approval of *Feraheme,* a suspension of our ability to manufacture *Feraheme*, or the loss of our existing *Feraheme* inventory, or other unanticipated compliance expenditures, any of which would have an adverse impact on our potential profitability and the future prospects of our business.

We need to maintain, and possibly increase our manufacturing capabilities or establish and qualify second source manufacturing facilities in order to successfully commercialize Feraheme.

We currently manufacture *GastroMARK* for commercial sale and *Feraheme* for potential commercial use and for use in human clinical trials in our Cambridge, Massachusetts manufacturing facility. We also intend to use this facility to manufacture *Feraheme* for commercial sale if and when it is approved by the FDA. Although we have begun the work to establish and qualify second source manufacturing facilities for *Feraheme*, we currently have only one manufacturing facility at which we produce limited quantities of *Feraheme*. We have been manufacturing large scale commercial lots of *Feraheme* for the last several months, but as we continue to manufacture *Feraheme* in larger volumes for commercial sale, we could experience higher than anticipated material, labor and overhead costs per unit. Additionally, manufacturing and quality control problems may arise as we increase our level of production. We may not be able to continue to increase our manufacturing capacity in a timely and cost-effective manner to meet demand for *Feraheme* if and when it is approved by the FDA, and we may experience delays in manufacturing *Feraheme*, which could result in a shortage in the supply of *Feraheme*. Furthermore, we will need to continue to recruit, train and retain additional qualified manufacturing and quality control personnel as we prepare for production of *Feraheme* on a commercial scale. If we fail to continue to attract and retain key members of our manufacturing or quality control 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.

In determining the required quantities of our products and the related manufacturing schedule, we will also need to make significant judgments and estimates based on inventory levels, current market trends, anticipated sales, and other factors. Because of the inherent nature of estimates there could be significant differences between our estimates and the actual amount of product need. 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 business prospects.

Although we are working to establish and qualify second source manufacturing facilities for *Feraheme*, 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. Furthermore, use of second-source manufacturing facilities may increase the

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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 will not be able to meet anticipated demand for *Feraheme*. As a result, we may lose sales and fail to generate increased revenues, which would have a severe 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 additional third-party suppliers for these raw materials. Third-party suppliers may 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 a number of reasons, including but not limited to the following:

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.

If any of our third-party suppliers cease to supply our raw materials for any reason, we would be unable to manufacture *Feraheme* or 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, 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 our products, including *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.

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The commercial success of Feraheme will depend upon the degree of its market acceptance among physicians, patients, healthcare payors, and the two major operators of dialysis clinics in the U.S.

For a variety of reasons, many of which are beyond our control, *Feraheme* may not achieve market acceptance among physicians, patients, or healthcare payors or providers, including dialysis clinics. If *Feraheme* does not achieve an adequate level of market acceptance for any reason, our potential profitability and our future business prospects would be severely adversely impacted. *Feraheme* will represent an alternative to existing products and might not be adopted by the medical community if perceived to be no safer or more effective than currently available products. The degree of market acceptance of *Feraheme* will depend on a number of factors, including:

- 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 adequacy of third-party coding, insurance coverage and reimbursement for *Feraheme* 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 timing of market entry of *Feraheme* relative to competitive treatments;
- 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 therapeutic agents;
- The actual or perceived safety profile of *Feraheme* relative to alternative iron therapeutic agents;
- The *Feraheme* labeling and product insert required by the FDA;
- The availability of generic iron preparations; and
- The effectiveness of our sales, marketing and distribution organizations.

Currently IV iron therapeutic products are not widely used by physicians who treat non-dialysis CKD patients in the physician's office setting due to safety concerns and the inconvenience and often impracticability of administering currently approved IV iron therapeutic products in that setting. A key component of our commercialization strategy is to develop a market for IV iron replacement therapeutics, specifically *Feraheme*, in the non-dialysis CKD market. Therefore, if approved, it will be critical for us to successfully market and sell *Feraheme* to physicians who treat non-dialysis CKD patients in the physician's office setting. It is often difficult to change physicians' existing treatment paradigms even when supportive clinical data is available. If we are not successful in marketing and selling *Feraheme*, if and when approved, to physicians who treat non-dialysis CKD patients in the physician's office setting, our ability to generate revenues, achieve and maintain profitability, and long-term business prospects would be adversely affected.

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 together treat more than 60% 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* will be severely limited, which would have a material adverse impact on our potential profitability, and our future business prospects. In addition, in September 2008, Fresenius finalized an exclusive sublicense agreement with Luitpold, the U.S. licensing partner of Vifor Pharma, a subsidiary of Galenica, to manufacture, sell and distribute Venofer®, an existing IV iron replacement therapeutic, to independent outpatient dialysis clinics in the U.S. Luitpold retains the right to sell Venofer® in the

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U.S. to any other customer. In 2008, Galenica, Vifor Pharma and Fresenius also 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 this agreement, it may be more difficult for us to penetrate the dialysis market, in particular at Fresenius clinics.

Our ability to generate future revenues from Feraheme will depend heavily on our ability to obtain and maintain satisfactory insurance coverage, coding, and reimbursement for Feraheme.

Our ability to successfully commercialize *Feraheme* will depend on the adequacy of insurance coverage, coding, and reimbursement for *Feraheme* from third-party payors, including governmental payors, such as Medicare and Medicaid, and private payors. Payors generally have discretion whether and how to cover new pharmaceutical products, and there is no guarantee that we will be able to convince payors to cover *Feraheme*. We expect that *Feraheme* will be 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 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. If we fail to demonstrate the clear clinical and/or comparative value of *Feraheme* as compared to existing therapeutics, *Feraheme* may not be adequately reimbursed. This could result in lower sales of *Feraheme*, which would have a material adverse effect on us and the results of our operations.

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 impact our ability to sell *Feraheme* profitably. As a result of these reimbursement and legislative proposals, and the trend toward managed health care in the U.S., third-party payors, including government and private payors, are 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, utilizing variable co-payments, or refusing to provide coverage of approved products for medical indications other than those for which the FDA has granted marketing approval.

With respect to *Feraheme*, Medicare currently reimburses for physician-administered drugs in the dialysis center and physician clinic at a rate of 106% of the drug's average selling price, or ASP. If the Centers for Medicare & Medicaid Services, or CMS, or its local contractor, 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. It is highly uncertain whether the ASP reimbursement methodology will continue to apply if and when *Feraheme* is approved by the FDA, and any changes in reimbursement policies may have a negative impact on the level of reimbursement available for *Feraheme*. On July 15, 2008, Congress enacted MIPPA, which created a bundled payment system for the treatment of ESRD to take effect on January 1, 2011. MIPPA requires CMS to begin a process of moving 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 beginning on January 1, 2011 and to complete the phase-in by January 1, 2014. 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 MIPPA applies only to Medicare, private payors and state Medicaid plans frequently adopt Medicare principles in setting their own reimbursement

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methodologies. 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*.

In addition, for providers to obtain reimbursement for *Feraheme* from Medicare, Medicaid and certain third-party payers, select codes must be submitted by the provider with each claim. These codes are issued to manufacturers at the discretion of CMS. Certain codes may also be issued by CMS at the request of a provider or Medicare Administrative Contractor. There is no guarantee that we will be successful in obtaining the appropriate codes for *Feraheme*, and our inability to obtain these codes could complicate provider reimbursement and have a material negative impact on *Feraheme* utilization and sales.

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 payer 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.

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

We have never marketed or sold a drug product as we have relied on our corporate partners to market and sell our current approved products, *Feridex I.V.* and *GastroMARK*. In preparation for the planned U.S. commercial launch of *Feraheme* as an IV iron replacement therapeutic agent in CKD patients, we have built an internal sales and marketing function, including a direct sales force, in the U.S. Developing an internal marketing team and sales force is expensive and time-consuming. In addition, we have and continue to expend substantial amounts of capital to prepare for the U.S. commercial launch of *Feraheme* before we know whether the FDA has approved the marketing and sale of *Feraheme*. If *Feraheme* is not approved by the FDA or is not approved in a timely manner, we may not have the ability to redeploy the sales force, and we will have no way to recoup the capital expended in building the sales force and commercial organization.

Competition for experienced and skilled marketing and sales personnel is intense, and we cannot guarantee that we will be able to attract and retain a sufficient number of qualified individuals to successfully promote *Feraheme*. If we are unsuccessful in developing an effective sales and marketing function, then our marketing efforts and our planned product launch of *Feraheme* as an IV iron replacement therapeutic agent could be delayed or the commercialization of *Feraheme* could be severely impaired. Furthermore, we may not be successful in marketing and selling *Feraheme*. Factors that may adversely impact our ability to effectively market and sell *Feraheme* include:

- Our inability to recruit, train and retain adequate numbers of qualified sales and marketing personnel;
- The inability of our sales personnel to obtain access to and persuade adequate numbers of physicians to prescribe or use *Feraheme*;
- A lack of complementary products that can be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with larger product lines; and
- Unforeseen costs and expenses associated with maintaining a sales and marketing organization.

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Any delay or failure in our commercial product launch of *Feraheme* would have a material adverse impact on our ability to generate revenues, our ability to achieve profitability, and the future prospects for 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, our commercial opportunity for Feraheme will be adversely impacted.

The pharmaceutical and biopharmaceutical industries are subject to intense competition and rapid technological change. Most of our competitors which are developing iron replacement therapeutic products have greater financial resources, experience and expertise in product development, manufacturing, marketing and sales than we do. Our *Feraheme* commercial opportunity will be reduced or eliminated if our competitors develop and commercialize 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*. In addition, any significant delays in FDA approval or U.S. commercial launch of *Feraheme* could allow our competitors to bring products to market before we do and impair our ability to successfully commercialize *Feraheme*.

There are currently two options for treating IDA in CKD patients: oral iron supplements and IV iron. We anticipate that, if approved, *Feraheme* will primarily compete with existing IV iron replacement therapies, including Venofer®, which is marketed by Fresenius and American Regent, a subsidiary of Luitpold, Ferrlecit®, which is marketed by Watson, and certain oral iron products. These competing iron replacement therapy products may receive greater market acceptance than *Feraheme*, especially since these products are already on the market and are currently widely used by physicians. We may not be able to convince physicians to switch from using the currently approved IV iron therapeutic products to *Feraheme*. The iron replacement therapy market is highly sensitive to several factors including, but not limited to, the ability to obtain appropriate insurance coverage, coding and reimbursement, price competitiveness, and product characteristics such as convenience of administration and dosing regimens. In particular, the IV iron replacement market is extremely sensitive to the perceived relative safety profiles of the various IV iron replacement therapeutics, and it will be critical that *Feraheme*'s safety profile is or is perceived to be comparable to that of other products in order to be competitive in the marketplace. To date, we have not conducted any head-to-head clinical studies comparing the relative safety profiles of *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 VIT-45, also known as Ferinject® in Europe or Injectafer® in the U.S., and SFP, a form of iron given as part of the hemodialysis procedure.

Galenica, through its Vifor (International) Inc. subsidiary, exclusively licenses Injectafer® to Luitpold and American Regent for the United States and Canada. Injectafer® is in development for a variety of anemia-related indications, including the treatment of anemia in CKD patients, whether or not on dialysis. In addition, Luitpold is sponsoring ongoing Phase III trials for Ferinject® in cardiology (chronic heart failure), irritable bowel disease, orthopedic surgery and post partum anemia. 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 eight European countries. 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 has expanded ongoing clinical trials and is initiating three further clinical trials to provide additional data addressing the concerns of the FDA. Luitpold expects these trials to take two years to complete prior to filing an NDA in the U.S.

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Rockwell is developing an iron supplemented dialysate product, SFP, a form of iron given as part of the hemodialysis procedure to be used as a treatment for anemia in dialysis patients. Rockwell is currently conducting Phase IIb clinical trials and sponsoring an on-going study funded by the National Institutes of Health. We do not know when an NDA for SFP might be submitted to the FDA for approval or when SFP may be marketed in the U.S. SFP, if shown to be safe and effective for the treatment of IDA, could compete with IV iron products, including *Feraheme*.

Pharmacosmos A/S has also completed a non-comparative open-label Phase III study of IV iron oligosaccharide in CKD patients. No additional studies are known to be on-going, and their future development plans have not been publicly disclosed.

In addition to competition from currently approved products and products known by us to be currently under development, the market opportunity for *Feraheme* would be negatively affected if generic IV iron replacement therapy products were to be approved and achieve commercial success. For example, in June 2008, Hospira reported opening a bioequivalence study for a generic iron sucrose. As of January 2009, the study was not complete and was not actively recruiting patients. 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 whether 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*, if approved, and our ability to generate additional revenues and achieve profitability would be adversely affected.

Further technological and product developments may also make new iron replacement therapy products more competitive than IV iron products, adversely impacting our ability to successfully commercialize *Feraheme*.

Feraheme, if approved, will remain subject to ongoing regulatory review, 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.

If approved, *Feraheme* will remain subject to FDA regulatory requirements and review pertaining to its manufacture, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping. If we fail to comply with such regulatory requirements, we could be subject to sanctions, including but not limited to Warning Letters, civil or criminal penalties, injunctions, 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*, restrictions on our continued manufacturing, marketing or sale of *Feraheme*, recalls or a refusal by the FDA to consider or approve applications for additional indications, any of which could have a material adverse impact on our ability to generate revenues and to achieve profitability.

Significant safety or drug interaction problems could arise for Feraheme even after FDA approval, resulting in recalls, restrictions in Feraheme's label, or withdrawal of Feraheme from the market.

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. If approved, 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. These new safety or drug interaction issues may require us to provide additional warnings on the *Feraheme* label or narrow our approved indications, each of which could reduce the market acceptance of *Feraheme*. In addition, if significant safety or drug interaction issues arise,

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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 would 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, or the FDAAA, expanded the FDA's authority. Under the FDAAA, 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 REMS where necessary to assure safe use of the drug. If we are required to conduct post-approval clinical studies or implement REMS, or if the FDA changes the label for *Feraheme* to include additional discussion of potential safety issues, such requirements or restrictions would 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.

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 $18.33 and $52.50 in the fifty-two week period through February 16, 2009. 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, among others, include:

General market conditions;

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

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

Actual or anticipated fluctuations in our operating results;

Changes in financial estimates or recommendations by securities analysts;

Sales of large blocks of our common stock;

Loss of any of our key scientific or management personnel;

The results of clinical trials for *Feraheme* or potentially competitive products or product candidates;

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;

Public concern regarding the safety of *Feraheme* or products or product candidates of 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.

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For example, any announcement of any positive or negative developments with respect to our efforts to obtain FDA approval to market and sell *Feraheme*, or our competitors' efforts to obtain FDA approval for competitive product candidates, would likely have a dramatic impact on our stock price. Thus, as a result of events both within and beyond our control, our stock price could fluctuate significantly or lose value rapidly.

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

In recent quarters, the U.S. and global economies have taken a dramatic downturn as a result of the deterioration in 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 recently 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 rely on third-parties, including our clinical research organizations, third-party manufacturers, 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 of our third-party contractors and suppliers. 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.

Our ability to generate and grow revenues from the sale 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. or if we do not obtain approval to market Feraheme in countries outside of the U.S.

The NDA we submitted to the FDA in December 2007 requests approval to market and sell *Feraheme* in the U.S. as an IV iron replacement therapeutic agent for the treatment of IDA in CKD patients, whether or not on dialysis. We are conducting and plan to conduct additional clinical trials and seek regulatory approval to market *Feraheme* in indications other than CKD. Before we can obtain approval to market *Feraheme* for these additional indications, we will need to successfully conduct clinical trials showing that *Feraheme* is safe and effective for these new uses and in these new patient populations and then apply for and obtain appropriate regulatory approvals. Conducting clinical trials is a complex, time-consuming and expensive process that requires adherence to a wide range of regulatory requirements. 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.

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

Protocol design;

Timing of regulatory and institutional review board approval;

Availability of clinical study material; and

The rate of patient enrollment.

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Any delay incurred in our clinical trials for additional indications could result in increased development costs and delays in regulatory approvals and could have an adverse effect on our development strategy. In addition, in order to increase the number of patients available for enrollment in our clinical trials, we plan to conduct trials in geographies outside the U.S., including India. We have no experience conducting clinical trials outside the U.S. and therefore such trials will require substantial time and resources to identify and familiarize ourselves with the regulatory requirements of such foreign countries.

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.

Any failure by us to obtain approval for additional *Feraheme* indications in the U.S. or any failure to obtain approval for any indications outside the U.S. 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 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 on a timely and 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 meet deadlines, our development plans may be delayed or terminated.

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

At December 31, 2008, we had $64.2 million in cash and cash equivalents, $94.9 million in short-term investments, $54.3 million in long-term investments, and $1.6 million in settlement rights. We have historically invested our funds in institutional money market funds, corporate debt securities, commercial paper, U.S. Treasury and government agency securities, municipal debt securities, and auction rate securities, or ARS, in accordance with the criteria set forth in our investment policy. These investments are subject to general credit, liquidity, market and interest rate risks, which may be exacerbated by the U.S. sub-prime mortgage defaults and the ensuing fallout, which have affected various sectors of the financial markets and caused credit and liquidity issues. We may realize losses in the fair value of these 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, 2008, we held a total of $54.3 million in fair market value of ARS, reflecting an impairment of approximately $12.2 million compared to our cost basis of these securities of $66.5 million. Of the $12.2 million impairment, approximately $10.5 million represents a temporary impairment and is reported as an unrealized loss at December 31, 2008. The remaining $1.7 million impairment represents an other-than-temporary impairment which is recognized in our consolidated statement of operations at December 31, 2008. Greater than 90% of these ARS were rated AAA as of

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December 31, 2008 by at least one of the major securities rating agencies, most of which were collateralized by student loans substantially guaranteed by the U.S. government under the Federal Family Education Loan Program. We had traditionally recorded these ARS at cost, which approximated fair market value due to their variable interest rates. Prior to February 2008, these investments 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.

Since February 2008, 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 a loss in 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. As a result, we may experience a reduction in value or loss of liquidity with respect to our investments. For example, during 2008, we recorded an impairment charge of $1.3 million related to certain corporate debt securities held by us. This impairment charge was required after we conducted an analysis of other-than-temporary impairment factors for our securities including the severity of declines and current financial market conditions, which caused us to determine that the $1.3 million impairment was other-than-temporary. In addition, should our investments cease paying or reduce the amount of interest paid to us, our interest income would suffer. 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. For example, in late 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 value of $5.0 million was re-affirmed as AAA by a different major rating agency in January 2009. As the ratings of these ARS have changed we may be required to adjust our future valuation of these ARS which may adversely affect the value of these investments. These market risks associated with our investment portfolio may have an adverse effect on our results of operations, cash position, liquidity and overall financial condition.

Our corporate compliance program cannot ensure that we are in compliance with all applicable laws and regulations, and our failure to comply with such laws and regulations could harm our business.

Our general operations, and the research, development, manufacture, sale and marketing of our products and product candidates are subject to extensive federal and state regulation, including but not limited to FDA regulations, the federal false claims act, and the federal anti-kickback statute. While we are developing and implementing a corporate compliance program based on what we believe are current best practices in the pharmaceuticals industry, we cannot guarantee that we, our employees, our consultants or our contractors are or will be in compliance with all potential federal and state

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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, the termination of our clinical trials, the failure to obtain approval of *Feraheme*, restrictions on how we market and sell *Feraheme*, restrictions on our manufacturing processes, significant fines, exclusions from government healthcare programs, including Medicare and Medicaid, litigation, or other sanctions. If any such actions are instituted against us, and we are not successful in defending ourselves, such actions could have a significant adverse impact on our business.

Legislative or regulatory changes may adversely impact our business.

The U.S. government and other governments have shown significant interest in pursuing healthcare reform. 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 *Feraheme*, require additional clinical trials or post-approval safety studies, or limit coverage or reimbursement for *Feraheme*. Any such new laws, regulations, decisions or interpretations may therefore have a significant adverse impact on our ability to successfully develop and commercialize *Feraheme*, and could have a material adverse impact on our ability to generate and grow our revenues and 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 likelihood of obtaining regulatory approval in the U.S. for *Feraheme* as an IV iron replacement therapeutic agent;
- The timing and magnitude of revenues from product sales of *Feraheme*, if approved;
- The timing and magnitude of costs associated with our preparations for the planned U.S. commercial launch of *Feraheme*, including costs associated with building and maintaining our commercial infrastructure and executing our promotional and marketing strategy for *Feraheme*, if approved;
- The timing and magnitude of costs associated with commercial-scale manufacturing of *Feraheme*, including costs associated with building commercial inventory and qualifying additional manufacturing capacities and second source suppliers;
- The timing and magnitude of costs associated with our development of additional indications for *Feraheme*;
- Changes in laws and regulations concerning reimbursement for *Feraheme*, if approved, from government health administration authorities, private health insurers and other third-party payors; 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.

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

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executive officers and on our ability to continue to attract, retain and motivate qualified personnel. We have entered into employment agreements with the majority of 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 severely 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. The 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.

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 employees, management, facilities and resources. In anticipation of the potential approval and U.S. commercial launch of *Feraheme*, we have rapidly expanded our regulatory, medical affairs, marketing, sales, manufacturing, finance, development, and compliance capabilities. As our operations expand, we will 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.

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 planned U.S. commercial launch 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 stock as consideration, which would result in dilution to our stockholders. Alternatively, it may be necessary for us to raise additional funds through public or private financings, and such additional funds may not be available on terms that are favorable to us. 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

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for these arrangements, and we may not be able to enter into such arrangements on acceptable terms or at all.

We may need additional capital to achieve our business objectives.

We have expended and will continue to expend substantial funds to complete development, clinical trials, commercial launch preparations, and other activities necessary to successfully commercialize *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:

- Our ability to successfully obtain regulatory approval in the U.S. for *Feraheme* as an IV iron replacement therapeutic agent in a timely manner;
- The timing and magnitude of revenues from product sales of *Feraheme*, if approved;
- Costs associated with our preparations for the planned U.S. commercial launch of *Feraheme*, including costs associated with building and maintaining our commercial infrastructure and executing our promotional and marketing strategy for *Feraheme*, if approved;
- Costs associated with commercial-scale manufacturing of *Feraheme*, including costs associated with building commercial inventory and qualifying additional manufacturing capacities and second source suppliers;
- Costs associated with our development of additional indications for *Feraheme*;
- Costs associated with the pursuit of potential business development activities;
- Costs associated with our pursuit of approval for *Feraheme* as an IV iron replacement therapeutic agent outside of the U.S.;
- Our ability to liquidate our ARS investments in a timely manner and without significant loss;
- The impact of the current deterioration in 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 earnings on our investments, will be sufficient to finance our 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 development activities, any of which would have a material adverse effect on our business, financial condition and future business prospects.

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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.

Moreover, 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 products. 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.

We currently hold a number of U.S. and foreign patents, which expire between the years 2009 and 2020, some of which may be subject to 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 commercialize our products prior to the expiration of our patents could have a material adverse effect on our business, financial condition and prospects as the expiration of such patents could permit generic drug manufacturers to manufacture, market and sell lower cost drugs that compete with our products and product candidates. In the future, we may be required to obtain additional licenses to patents or other proprietary rights of others in order to commercialize our products or continue with our development efforts. Such licenses may not be available on acceptable terms, if at all. The failure to obtain such licenses could result in delays in marketing our products or our inability to proceed with the development, manufacture or sale of our products or product candidates requiring such licenses.

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 our products, we will 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 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 our products, thereby substantially reducing the value of our proprietary rights.

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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. These claims might be made by customers, including corporate partners, clinical trial subjects, patients, pharmaceutical companies, or others. We maintain product liability insurance coverage for claims arising from the use of our products and product candidates in clinical trials and commercial use. However, coverage is becoming increasingly expensive, costs may continue to increase significantly, and we may not be able to maintain insurance at a reasonable cost. Furthermore, our insurance may not provide sufficient coverage amounts to protect us against liability, which could deplete our capital resources. We also may not be able to obtain commercially reasonable product liability insurance for any product approved for marketing in the future. Our insurance coverage and our resources may not be sufficient to satisfy any liability or cover costs resulting from product liability claims. A product liability claim or series of claims brought against us could reduce or eliminate our resources, whether or not the plaintiffs in such claims ultimately prevail. In addition, pursuant to our certificate of incorporation, by-laws and contractual agreements with our directors and officers, and in order to attract competent candidates, we are obligated to indemnify our officers and directors against certain claims arising from their service to us. We maintain directors and officers' liability insurance to cover such potential claims against our officers and directors. However, this insurance may not be adequate for certain claims and deductibles apply. As a result of our indemnification obligations and in instances where insurance coverage is not available or insufficient, any liability claim or series of claims brought against our officers or directors could deplete or exhaust our resources, regardless of the ultimate disposition of such claims.

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

Because we use certain hazardous materials in the production of our products and product candidates, 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.

If securities analysts downgrade our stock or cease coverage of us, the price of our stock 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. 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.

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ITEM 1B. UNRESOLVED STAFF COMMENTS:

None.

ITEM 2. PROPERTIES:

On May 27, 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 control 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:

We may periodically become subject to legal proceedings and claims arising in connection with on-going 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, 2008.

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 under the trading symbol "AMAG." On February 16, 2009, the closing price of our common stock, as reported on the NASDAQ Global Market, was $38.60 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 Global Market.

	High	Low
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
Year Ended December 31, 2007		
First quarter	$65.95	$54.28
Second quarter	$72.95	$57.50
Third quarter	$61.52	$51.17
Fourth quarter	$71.45	$53.41

Stockholders

On February 16, 2009, we had approximately 140 stockholders of record of our common stock, and we believe that the number of beneficial holders of our common stock was approximately 3,800 based on responses from brokers to a search conducted by Georgeson, Inc. on our behalf.

Dividends

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

Repurchases of Equity Securities

There were no purchases by us, or any affiliated purchaser of ours, of our equity securities that are registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, during the three months ended December 31, 2008.

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 SEC not later than 120 days after the close of our year ended December 31, 2008.

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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, 2008 and 2007, the three months ended December 31, 2006, and the years ended September 30, 2006 through 2004. The information below includes our transition period for the three months ended December 31, 2006 as a result of our Board 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,		
	2008	2007	2006	2006	2005	2004
	(in thousands, except per share data)					
Statement of Operations Data						
Revenues:						
License fees	$ 959	$ 1,096	$ 222	$ 907	$ 1,281	$ 2,748
Royalties	228	248	44	317	274	240
Product sales	751	1,208	353	1,449	890	768
Total revenues	1,938	2,552	619	2,673	2,445	3,756
Costs and Expenses:						
Cost of product sales	292	320	287	273	204	117
Research and development expenses*	31,716	24,236	6,393	21,294	12,037	6,084
Selling, general and administrative expenses*	49,536	20,396	2,197	8,011	3,338	2,220
Total costs and expenses	81,544	44,952	8,877	29,578	15,579	8,421
Other Income (Expense):						
Interest and dividend income, net	9,139	12,506	818	1,575	419	170
Losses on investments, net	(3,024)					
Fair value adjustment of settlement rights	1,566					
Litigation settlement		(4,000)				
Other income (expense), net				(35)		
Total other income	7,681	8,506	818	1,540	419	170
Net loss before income taxes	(71,925)	(33,894)	(7,440)	(25,365)	(12,715)	(4,495)
Income tax benefit	278					
Net loss	$ (71,647)	$ (33,894)	$ (7,440)	$ (25,365)	$ (12,715)	$ (4,495)
Net loss per share basic and diluted:	$ (4.22)	$ (2.15)	$ (0.60)	$ (2.31)	$ (1.47)	$ (0.57)
Weighted average shares outstanding used to compute net loss per share:						
Basic and diluted	16,993	15,777	12,383	10,964	8,634	7,818

	December 31,			September 30,		
	2008	2007	2006	2006	2005	2004
	(in thousands)					
Balance Sheet Data						

Working capital (current assets less current liabilities)	$149,918	$282,196	$149,474	$33,623	$21,211	$12,314
Total assets	$231,955	$294,851	$162,342	$47,371	$28,292	$23,811
Long-term liabilities	$ 4,149	$ 879	$ 1,688	$ 1,795	$ 2,585	$ 3,134
Stockholders' equity	$213,414	$285,954	$152,277	$36,075	$22,379	$17,546

*

We adopted Statement of Financial Accounting Standards, or SFAS, 123R effective October 1, 2005. Accordingly, periods prior to the date of adoption do 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 anemia and novel imaging agents to aid in the diagnosis of cancer and cardiovascular disease. We have one product candidate, Feraheme (ferumoxytol injection), and two approved products, *Feridex I.V.* and *GastroMARK*.

Feraheme is being developed for use as an intravenous, or IV, iron replacement therapeutic agent for the treatment of iron deficiency anemia, or IDA, and as a diagnostic agent for vascular enhanced magnetic resonance imaging, or MRI, to assess peripheral arterial disease, or PAD. In December 2007, we submitted a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or the FDA, for marketing approval of *Feraheme* for the treatment of IDA in patients with chronic kidney disease, or CKD. In October 2008, we received a Complete Response letter from the FDA with respect to our NDA for *Feraheme* requesting certain additional clinical information, information regarding certain observations noted during a recent FDA inspection at one of our Phase III clinical sites, and resolution of certain deficiencies noted during a recent FDA inspection of our Cambridge, Massachusetts manufacturing facility. We submitted a response to the Complete Response letter in October 2008, and in December 2008 we received a second Complete Response letter from the FDA requesting data to clarify a specific chemistry, manufacturing and controls, or CMC, question, resolution of the deficiencies observed during the recent FDA inspection of our manufacturing facility, and finalization of labeling discussions for *Feraheme*. We will need to address the issues raised by the FDA with respect to our NDA in a timely and satisfactory manner in order to obtain approval to market and sell *Feraheme* in the U.S. We are working with the FDA to address the December 2008 Complete Response letter and believe that we will not need to conduct any additional clinical trials of *Feraheme* prior to FDA approval of *Feraheme*.

We intend to initiate two Phase III studies of *Feraheme* in women with IDA and abnormal uterine bleeding, or AUB, in the first half of 2009. We expect that these studies will enroll a total of approximately 1,200 AUB patients combined. In 2009, we also currently plan to initiate a Phase III clinical development program for *Feraheme* in patients with IDA and cancer, whether or not receiving chemotherapy. The timelines for the initiation of our clinical development programs for *Feraheme* in AUB and cancer patients are currently subject to the completion of protocol discussions with the FDA and may ultimately serve as the basis for a broader Phase III clinical development program of *Feraheme* for the treatment of IDA in a broad range of patient populations and disease states.

In addition to its use for the treatment of IDA, *Feraheme* may also be useful as a vascular enhancing agent in MRI. In August 2008, we announced that the FDA granted Fast Track designation to *Feraheme* for its development as a diagnostic agent for vascular-enhanced MRI for the assessment of PAD. We have initiated a 108 patient Phase II study of *Feraheme* in vascular-enhanced MRI for the detection of clinically significant arterial stenosis or occlusion in subjects with intermittent claudication, or leg pain when walking.

If approved for the treatment of IDA in CKD patients, we will market and sell *Feraheme* in the U.S. through our own commercial organization. We have built an internal sales and marketing function, including a direct sales force, in preparation for the planned U.S. commercial launch of *Feraheme* as an IV iron replacement therapeutic agent in CKD patients.

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

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markets outside of the U.S. we intend to enter, we are assessing factors such as potential pricing and reimbursement, patient access to dialysis, the role of iron in medical treatment protocols in each country, and the regulatory requirements of each country. We are also currently evaluating possible strategic alliances and partnerships to assist us in entering attractive foreign markets. For example, in 2008 we entered into a license agreement and a supply agreement with 3SBio Inc., or 3SBio, with respect to the development and commercialization of *Feraheme* as an IV iron replacement therapeutic agent in China.

Feridex I.V., our liver contrast agent, is approved and has been sold in the U.S., Europe and other countries. 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.*

GastroMARK, our oral contrast agent used for delineating the bowel in MRI, is approved and marketed in the U.S., Europe, and other countries. 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.

Results of Operations

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.

	For the Years Ended December 31,	
	2008	2007
Bayer	53%	43%
Guerbet	24%	26%
Covidien	17%	15%
Cytogen	0%	14%

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:				
License fees	$ 959	$ 1,096	$ (137)	-13%
Royalties	228	248	(20)	-8%
Product sales	751	1,208	(457)	-38%
Total	$ 1,938	$ 2,552	$ (614)	-24%

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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 Healthcare Pharmaceuticals, or 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 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 1996, the parties agreed to remove Canada from the territories subject to the Bayer Agreements. In connection with our decision in November 2008 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 in November 2008, 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 may 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, we are recognizing $0.5 million of deferred revenues, which remained at December 31, 2008, through April 1, 2009.

In August 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,* our investigational functional 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.

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%

As a result of our termination of the Bayer Agreements in November 2008, we expect our 2009 license fee revenues will decline significantly from their 2008 levels. 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

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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 2009.

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%
Combidex	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 may fluctuate from period to period. Fluctuations in our 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. Due to our decision to cease the manufacture and commercialization of *Feridex I.V.* in November 2008, we expect that revenues from our currently approved products will continue to decrease during 2009.

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.

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.

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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 $7.3 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 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, partially offset by costs associated with the commencement of spending on our clinical trials for *Feraheme* for AUB and PAD and an increase in materials procurement, second-source manufacturing qualification, and other costs associated with our 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 benefit 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.

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We expect research and development expenses to increase in 2009 as we advance our PAD, AUB, and potentially other clinical development programs, continue commercial manufacturing preparations, purchase additional *Feraheme* materials and supplies, and continue other research and development related functions and activities in support of *Feraheme.* If *Feraheme* receives approval from the FDA, we will record materials, supplies and other costs associated with manufacturing *Feraheme* as inventory in accordance with our capitalization policies.

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 NDA submission to the FDA. In December 2007, we submitted an NDA for *Feraheme* as an IV iron replacement therapeutic agent in CKD patients and therefore do not intend to track additional external costs related to that project.

During 2008, we began incurring costs related to our PAD and AUB clinical development programs. We currently intend to initiate two Phase III studies of *Feraheme* in women with IDA and AUB in the first half of 2009. We expect that these studies will enroll a total of approximately 1,200 AUB patients combined. In 2009, we also currently plan to initiate a Phase III clinical development program for *Feraheme* in patients with IDA and cancer, whether or not receiving chemotherapy. The study designs and timelines for the initiation of our clinical development programs for *Feraheme* in AUB and cancer patients are currently subject to the completion of protocol discussions with the FDA and may ultimately serve as the basis for a broader Phase III clinical development program of *Feraheme* for the treatment of IDA in a broad range of patient populations and disease states.

At this time, due to the numerous risks and uncertainties inherent in the clinical development and regulatory approval process, including significant and changing government regulation, and given the current stage of our development of our additional indications for *Feraheme*, we are unable to estimate with any certainty the costs we will incur in the development of such other indications. The estimated costs to completion for the various stages of clinical development can also vary significantly depending on the nature of the product candidate, the number of patients enrolled in each trial, the speed at which patients are enrolled, the disease indications being tested and many other factors. For a discussion of the risks and uncertainties associated with the timing and cost of completing development of a product candidate, see Item 1A "Risk Factors" of this Annual Report on Form 10-K. While we are currently focused on obtaining FDA approval of *Feraheme* and the subsequent planned U.S. commercial launch of *Feraheme* as an IV iron replacement therapeutic agent in CKD patients, we anticipate that we will make determinations as to which, if any additional indications to pursue and how much funding to direct to each additional indication on an ongoing basis in response to our ongoing discussions with the FDA regarding our proposed protocols and our proposed study designs, the scientific and clinical progress associated with each indication, as well as an ongoing assessment as to each indication's commercial potential. We cannot forecast with any degree of certainty which indications may be subject to future collaborative or licensing arrangements, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. Similarly, we are currently unable to provide meaningful estimates of the timing of completion of each of our development projects for additional indications for *Feraheme* as an estimation of completion dates would be highly speculative and subject to a number of risks and uncertainties.

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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 planned 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, or CEO, during the year ended December 31, 2008. In addition, in February 2008, we granted 100,000 performance-based stock options to our CEO which will vest only if we achieve a performance target with respect to our commercial sale of *Feraheme* on or prior to March 31, 2009. We have deemed it improbable that the performance target associated with these options will be met by March 31, 2009 and therefore have recognized no expense related to these grants as of December 31, 2008.

We expect selling, general and administrative expenses to continue to increase in 2009 as we continue our efforts to augment our infrastructure and prepare for the planned U.S. commercial launch of *Feraheme*. We continue to incur significant expense related to maintaining our sales force, developing our marketing infrastructure, executing related marketing and promotional programs and hiring consultants in preparation for the planned commercialization of *Feraheme* in the U.S. as an IV iron replacement therapeutic in patients with CKD.

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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%
Loss 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 SFAS 115. 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 as discussed below under "Liquidity and Capital Resources," 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.

We expect interest and dividend income to continue to decrease in 2009 as a result of declining interest rates due to the current economic climate coupled with declining cash and investments balances as a result of the commercial, clinical, and manufacturing activities noted above.

Income Tax Benefit

During the year ended December 31, 2008, we recognized a one-time 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.

Year Ended December 31, 2007 Compared to Year Ended December 31, 2006

In May 2007, our Board of Directors, or Board, changed our fiscal year end from September 30 to December 31. Therefore, in order to compare the financial information for the year ended December 31, 2007 to a like period, we prepared financial information for the twelve months ended December 31, 2006, which includes the three-month transitional period ended December 31, 2006, and the nine months ended September 30, 2006. Accordingly, in the discussion that follows, we present a comparative analysis of our consolidated financial statements for the year ended December 31, 2007

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with the pro forma financial statements for the year ended December 31, 2006, as set forth in the table below, as we believe that this comparison provides a more meaningful analysis:

	Years Ended December 31,		$ Change	% Change
	2007	2006 (unaudited)		
Revenues:				
License fees	$ 1,096	$ 905	$ 191	21%
Royalties	248	314	(66)	-21%
Product sales	1,208	1,409	(201)	-14%
Total revenues	2,552	2,628	(76)	-3%
Costs and expenses:				
Cost of product sales	320	438	(118)	-27%
Research and development expenses	24,236	24,617	(381)	-2%
Selling, general and administrative expenses	20,396	8,347	12,049	>100%
Total costs and expenses	44,952	33,402	11,550	35%
Other income:				
Interest and dividend income, net	12,506	2,219	10,287	>100%
Litigation settlement	(4,000)		(4,000)	0%
Other income (expense)		(35)	35	-100%
Total other income	8,506	2,184	6,322	>100%
Loss before provision for (benefit from) income taxes	$ (33,894)	$ (28,590)	$ (5,304)	19%
Net loss per share:				
Basic and diluted	$ (2.15)	$ (2.47)		
Weighted average shares outstanding used to compute net loss per share:				
Basic and diluted	15,777	11,594		

Revenues

Total revenues were $2.6 million for both years ended December 31, 2007 and 2006. Total revenues remained stable for the year ended December 31, 2007 principally due to an increase in the recognition of deferred license fee revenues of $0.2 million as a result of the termination of our license and marketing agreement with Cytogen, offset by decreased product sales and royalty revenues.

The following table sets forth customers who represented 10% or more of our revenues for the years ended December 31, 2007 and 2006. No other company accounted for more than 10% of our total revenues in either year.

	December 31, 2007	December 31, 2006
Bayer	43%	42%
Guerbet	26%	35%
Covidien	15%	13%
Cytogen	14%	<10%

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Our revenues for the years ended December 31, 2007 and 2006 consisted of the following (in thousands):

	Years Ended December 31,		$	%
	2007	2006	Change	Change
Revenues:				
License fees	$1,096	$ 905	$ 191	21%
Royalties	248	314	(66)	-21%
Product sales	1,208	1,409	(201)	-14%
Total	$2,552	$2,628	$ (76)	-3%

License Fee Revenues

All of our license fee revenues for the years ended December 31, 2007 and 2006 consisted of deferred license fee revenues related to a license and marketing agreement signed with Cytogen in 2000 and deferred license fee revenues associated with a license and marketing agreement with Bayer signed in 1995.

Total license fee revenues for the years ended December 31, 2007 and 2006 were recognized as follows (in thousands):

	Years Ended December 31,		$	%
	2007	2006	Change	Change
License fee revenues recognized in connection with the Cytogen agreement	$ 358	$167	$ 191	>100%
License fee revenues recognized in connection with the Bayer Agreements	738	738		0%
Total	$1,096	$905	$ 191	21%

Product Sale Revenues

Product sale revenues for the years ended December 31, 2007 and 2006 consisted of the following (in thousands):

	Years Ended December 31,		$	%
	2007	2006	Change	Change
Feridex I.V.	$ 368	$ 592	$ (224)	-38%
GastroMARK	705	541	164	30%
Combidex	135	276	(141)	-51%
Total	$1,208	$1,409	$ (201)	-14%

The decrease in product sale revenues during the year ended December 31, 2007 as compared to the year ended December 31, 2006 primarily resulted from a decrease in sales of *Feridex I.V.*, a decrease in sales of bulk *Combidex* to one of our foreign marketing partners for research and development purposes, partially offset by an increase in sales of *GastroMARK* to our marketing partners. Product sales may fluctuate from period to period. Fluctuations in our 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.

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Costs and Expenses

Cost of Product Sales

We incurred costs associated with product sales during each of the years ended December 31, 2007 and 2006 of $0.3 million and $0.4 million, respectively. This constituted approximately 26% and 31% of product sales during the years ended December 31, 2007 and 2006, respectively. The slight decrease in cost of product sales as a percentage of revenues is due primarily to decreased sales of bulk *Combidex* at cost to one of our foreign marketing partners for research and development purposes during the year ended December 31, 2007 as compared to the year ended December 31, 2006. 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.

Research and Development Expenses

Research and development expenses for the years ended December 31, 2007 and 2006 consisted of the following (in thousands):

	Years Ended December 31,			
	2007	2006	$ Change	% Change
External Research and Development Expenses				
Feraheme as an IV Iron Replacement Therapeutic Agent	$10,043	$16,719	$(6,676)	-40%
Combidex	522	184	338	>100%
Other External Costs	1,851	642	1,209	>100%
Total	$12,416	$17,545	$(5,129)	-29%
Internal Research and Development Expenses	11,820	7,072	4,748	67%
Total	$24,236	$24,617	$ (381)	-2%

Total research and development expenditures incurred for the year ended December 31, 2007 amounted to $24.2 million, a slight decrease of $0.4 million from the year ended December 31, 2006. The decrease was primarily attributable to a $5.1 million decrease in external costs partially offset by a $4.7 million increase in internal costs.

The $5.1 million decrease in external costs for the year ended December 31, 2007 as compared to the year ended December 31, 2006 was due primarily to a decrease in expenditures associated with the development program for *Feraheme* as an IV iron replacement therapeutic as we completed our Phase III clinical trials, partially offset by an increase in regulatory and other costs associated with our preparation and submission of our *Feraheme* NDA, including FDA filing fees of $1.2 million, and an increase in other external costs of approximately $1.2 million associated principally with our preparation for commercial scale manufacturing of *Feraheme*.

The $4.7 million increase in internal costs for the year ended December 31, 2007 as compared to the year ended December 31, 2006 was due primarily to higher compensation and benefit costs as a result of hiring additional research and development personnel as we began to expand our development infrastructure and prepare for commercialization of *Feraheme*. At December 31, 2007, we had 50 employees in research and development as compared to 36 employees at December 31, 2006, an increase of 38%. For the year ended December 31, 2007, the amount of equity-based compensation expense included in research and development was $1.9 million, an increase of $0.9 million as compared to the year ended December 31, 2006. The increase in equity-based compensation expense was primarily attributable to increased option grants associated with new hires.

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Through the year ended September 30, 2000, we incurred aggregate internal and external research and development expenses of approximately $6.6 million related to pre-clinical and toxicology studies of *Feraheme*. Since October 1, 2000 and through the year ended December 31, 2007, we incurred aggregate external research and development expenses of approximately $40.2 million related to pre-clinical activities and clinical trials in connection with our development of *Feraheme* as an IV iron replacement therapeutic for the treatment of IDA in CKD patients.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the years ended December 31, 2007 and 2006 consisted of the following (in thousands):

	Years Ended December 31,			
	2007	2006	$ Change	% Change
Compensation, payroll taxes and benefits	$11,160	$4,801	$ 6,359	>100%
Professional and consultant fees and other expenses	9,236	3,546	5,690	>100%
Total	$20,396	$8,347	$12,049	>100%

The increase in selling, general and administrative expenses for the year ended December 31, 2007 as compared to the year ended December 31, 2006 was due primarily to increased costs associated with the establishment of our commercial operations function, including consulting costs related to the planned commercial launch of *Feraheme*, higher compensation and benefit costs related to an increased headcount in our marketing and commercial operations functions, equity-based compensation expense associated with performance-based option awards granted during 2007, and the expansion of our general administrative infrastructure. At December 31, 2007, we had 31 employees in our selling, general and administrative departments as compared to 11 employees at December 31, 2006, an increase of 182%. For the year ended December 31, 2007, the amount of equity-based compensation expense included in selling, general and administrative expenses was $6.2 million, an increase of approximately $4.0 million as compared to the year ended December 31, 2006. The increase in equity-based compensation expense was primarily attributable to $2.4 million in incremental expense associated with performance-based option awards granted during 2007, increased option grants associated with new hires and expense incurred as the result of the acceleration of certain stock options held by our former Executive Chairman of the Board when he resigned from our Board.

Other Income (Expense)

Other income (expense) for the years ended December 31, 2007 and 2006 consisted of the following (in thousands):

	Years Ended December 31,			
	2007	2006	$ Change	% Change
Interest and dividend income, net	$12,506	$2,219	$ 10,287	>100%
Litigation settlement	(4,000)		(4,000)	N/A
Other income (expense)		(35)	35	-100%
Total	$ 8,506	$2,184	$ 6,322	>100%

The increase in other income (expense) for the year ended December 31, 2007, as compared to the year ended December 31, 2006, was primarily attributable to increased interest income associated with a higher average amount of invested funds, partially offset by a $4.0 million settlement with Cytogen in the year ended December 31, 2007. The increase in funds available for investment in 2007

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was the result of our December 2006 and May 2007 financings, which resulted in combined aggregate net proceeds to us of approximately $277.4 million.

Net Loss

For the reasons stated above, we incurred a net loss of $33.9 million, or $2.15 per basic and diluted share, for the year ended December 31, 2007 as compared to a net loss of $28.6 million, or $2.47 per basic and diluted share, for the year ended December 31, 2006.

Liquidity and Capital Resources

General

We have financed our operations primarily from the sale of our equity securities, cash generated from our investing activities, and payments from our marketing and distribution partners. Our long-term capital requirements will depend on many factors, including, but not limited to, the following:

Our ability to successfully obtain regulatory approval in the U.S. for *Feraheme* as an IV iron replacement therapeutic agent in a timely manner;

The timing and magnitude of revenues from product sales of *Feraheme*, if approved;

Costs associated with our preparations for the planned U.S. commercial launch of *Feraheme*, including costs associated with building and maintaining our commercial infrastructure and executing our promotional and marketing strategy for *Feraheme*, if approved;

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

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

Costs associated with the pursuit of potential business development activities;

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

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

The impact of the current deterioration in 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.

As of December 31, 2008, our investments consisted of corporate debt securities, U.S. treasury and government agency securities, commercial paper, and ARS. We place our cash 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.

At December 31, 2008, we held a total of $54.3 million in fair market value of ARS, reflecting an impairment of approximately $12.2 million compared to our cost basis of these securities of $66.5 million. Of the $12.2 million impairment, approximately $10.5 million represents a temporary

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impairment and is reported as an unrealized loss at December 31, 2008. The remaining $1.7 million impairment represents an other-than-temporary impairment required as a result of the mark to market of certain ARS redesignated as trading securities under SFAS 115 and is recognized in our consolidated statement of operations at December 31, 2008. Greater than 90% of these ARS were rated AAA as of December 31, 2008 by at least one of the major securities rating agencies, most of which were 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 analyses consider, 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.

In November 2008, we elected to participate in a rights offering by UBS AG, or UBS, one of our brokers, which provides 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 attached to such ARS. We elected the SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115," or SFAS 159, fair value option in November 2008 with respect to the settlement rights and, accordingly, as of December 31, 2008, we have recorded an asset and net benefit equal to the estimated fair value of the settlement rights of approximately $1.6 million in our consolidated statement of operations. With the opportunity provided by the settlement rights, we will most likely sell the UBS ARS to UBS prior to final maturity and, accordingly, we have redesignated the UBS ARS that had a par value of $9.3 million and an estimated fair value of $7.6 million as trading securities. Because acceptance of the settlement rights means that we can no longer assert that we have the intent or ability to hold our UBS ARS until anticipated recovery, we have recognized an other-than-temporary impairment charge of approximately $1.7 million related to the UBS ARS which is included in other income (expense) in our consolidated statement of operations. We will be required to assess the fair value of both the settlement rights and UBS ARS assets and record changes each period until the settlement rights are exercised and the UBS ARS are redeemed. 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.

We believe that the $10.5 million temporary impairment related to our other ARS is primarily attributable to the limited liquidity of these investments, coupled with the recent 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 these instruments that we deem to be temporary, including any recoveries of previous write-downs, would be recorded to

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accumulated other comprehensive (loss) income. If we determine that any future unrealized loss is other-than-temporary, we will record a charge to earnings as appropriate. 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 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.

Based on our ability to access our cash, cash equivalents, and short-term investments, coupled with our other sources of cash, 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, however, we are uncertain when the current liquidity issues relating to ARS will improve, if at all.

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, 2008 and December 31, 2007 consisted of the following (in thousands):

	December 31,	
	2008	**2007**
Cash and cash equivalents	$ 64,182	$ 28,210
Short-term investments	94,914	258,597
Long-term investments	54,335	
Total cash, cash equivalents and investments	$213,431	$286,807

The decrease in cash and cash equivalents and investments as of December 31, 2008 as compared to December 31, 2007 is primarily the result of cash used in operations, cash used for capital expenditures, and the net impact of unrealized and realized losses on our investments, partially offset by interest income.

As of December 31, 2008, we believe that our cash, cash equivalents, and short-term investments, combined with cash we currently expect to receive from 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 development and commercialization programs for *Feraheme*.

Recent 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. We have evaluated the effect of the recent distress in the financial markets on the value of our investments and as a result, during the year ended December 31, 2008, we recorded an impairment charge of $3.0 million related to certain securities held by us. Of the $3.0 million impairment charge, $1.3 million was required after we conducted an analysis of other-than-temporary impairment factors for our securities, including the severity of declines and current financial market conditions. The remaining $1.7 was required as a result of the mark to market and resulting realization of losses on certain ARS redesignated as trading securities under SFAS 115. There can be no assurance that changing circumstances will not continue to affect our future financial position, results of operations or liquidity.

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Year Ended December 31, 2008

Cash flows from operating activities

During the year ended December 31, 2008, our use of $52.3 million of cash in operations was due principally to our net loss of approximately $71.6 million. This net loss was 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 includes compensation-related expenses associated with the hiring of additional employees for research and development and commercial operating activities, payments for activities in preparation for the planned commercialization of *Feraheme* as an IV iron replacement therapeutic agent, and costs associated with clinical trials in indications other than CKD, partially offset by a $2.4 million reversal of the 2007 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 by December 31, 2008 and as a result, the performance conditions underlying these grants of 110,000 performance-based stock options were not met.

We anticipate cash used in operating activities will increase in 2009 over current levels as we continue to advance our ongoing commercialization efforts for *Feraheme*, incur additional costs associated with our clinical trials and development of new indications for *Feraheme* in the U.S., our continued expansion of our commercial, clinical, medical, regulatory, development, finance, and manufacturing organizations in support of our planned *Feraheme* launch, and our efforts to build commercial inventory and qualify second source suppliers and manufacturers for *Feraheme*. The actual amount of these expenditures will depend on numerous factors, including the timing of expenses and the timing and progress of the regulatory approval of *Feraheme* and our development, sales and marketing efforts.

Cash flows from investing activities

Cash provided by investing activities was $87.2 million in 2008 and was primarily attributable to net proceeds from sales and maturities of our investments, partially offset by $8.2 million of cash used for capital expenditures primarily related to the occupancy, furnishing and build-out of our new corporate headquarters, which we occupied beginning in September 2008.

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.

Year Ended December 31, 2007

Cash flows from operating activities

During the year ended December 31, 2007, our use of cash in operations of $28.7 million was due principally to our net loss of approximately $33.9 million and working capital and other charges of $3.0 million, partially offset by approximately $8.2 million in non-cash expense associated with employee stock options and restricted stock units. Our net loss includes a $4.0 million settlement payment to Cytogen, an increase in compensation-related expenses associated with the hiring of additional employees for research and development and commercial operating activities, costs associated with the preparation of our NDA submission, including our payment of an NDA filing fee of $1.2 million, and payments for activities in preparation for the planned commercialization of *Feraheme* as an IV iron replacement therapeutic.

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Cash flows from investing activities

Cash used in investing activities was $216.8 million in 2007 and was primarily attributable to the purchase of investments with the proceeds received from our December 2006 and May 2007 financings, which resulted in combined net proceeds to us of approximately $277.4 million.

Cash flows from financing activities

Cash provided by financing activities was $159.3 million in 2007 and was primarily attributable to our May 2007 sale of 2.5 million shares of our common stock in an underwritten public offering. Net proceeds to us from the financing were approximately $154.5 million after deducting external transaction costs directly associated with the offering. The shares were issued pursuant to a shelf registration statement on Form S-3, which became effective upon filing. We also received approximately $4.8 million from the cash exercise of stock options during 2007.

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, 2008, 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	$ 870	$ 699	$ 171	$	$
Facility lease obligations	15,478	1,715	3,867	4,062	5,834
Purchase commitments	569	569			
Total	$16,917	$ 2,983	$ 4,038	$ 4,062	$ 5,834

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 a 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.

On May 27, 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, 2009	$ 1,687
Year Ended December 31, 2010	1,891
Year Ended December 31, 2011	1,947
Year Ended December 31, 2012	2,003
Year Ended December 31, 2013	2,059
Thereafter	5,834
Total	$ 15,421

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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. 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.

Purchase Commitments

During 2008 we entered into various agreements with third-parties for which we had remaining purchase commitments of approximately $0.6 million as of December 31, 2008. These agreements principally related to pre-clinical research activities, our information technology infrastructure, and other operational activities.

Royalty Commitments

We are the licensee of certain technologies related to certain of our imaging products under cross license agreements with Amersham Health, or Amersham, which is part of GE Healthcare, formerly Nycomed Imaging A.S. and Bayer Schering Pharma AG, formerly Schering AG. The license agreement with Amersham requires us to make payments upon the attainment of particular milestones relating to *Feridex I.V.* and *GastroMARK*. We are also required under the agreement with Amersham to pay royalties on a percentage of product sales of *Feridex I.V.* and *GastroMARK*, if any. There were no milestone payments in the years 2008, 2007 or 2006. Future milestone payments under the Amersham agreement are not expected to exceed $0.4 million. Royalty obligations under the Amersham agreement were not significant for each of the prior three years.

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.

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, please refer to Note K 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, 2008, 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 and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reported period. The most significant estimates and assumptions are used in, but not limited to, assessing investments for potential impairment and determining values of investments, accrued expenses, income taxes and equity-based compensation expense. Actual results could differ from those estimates. In making these estimates and assumptions, management employs critical accounting policies.

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Our critical accounting policies include valuation of investments and/or marketable securities and equity-based compensation.

Valuation of investments. The fair value of our investments and/or marketable securities 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, several of our municipal ARS experienced 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 analyses consider, 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 provides 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. We have estimated the fair value of these settlement rights utilizing a discounted cash flow analysis as of December 31, 2008. Certain key assumptions used in this valuation were 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 the effect of reducing the fair value of our entire ARS portfolio by approximately $1.2 million as of December 31, 2008. Similarly, holding all other factors constant, if we were to increase the average expected term utilized in our fair value calculation by one year, this change would have the effect of reducing the fair value of our ARS by approximately $1.9 million as of December 31, 2008. We also consider credit ratings with respect to our investments provided by investment ratings agencies. As of December 31, 2008, 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. For example, in late 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 independent credit rating agencies to A3 and Baa1, respectively, from their previous rating of Aaa. In contrast, the ARS having a par value of $5.0 million was re-affirmed as AAA by a different major rating agency in January 2009. As the ratings of these ARS have changed we may be required to adjust our future valuation of these ARS which may adversely affect the value of these investments.

Equity-Based Compensation. We account for our equity-based compensation arrangements with our employees and non-employee directors under SFAS No. 123R, "Share-Based Payment," or SFAS 123R, and its related implementation guidance as promulgated by both the Financial Accounting Standards Board, or the FASB, and the SEC Staff Accounting Bulletin 107. Under these pronouncements, equity-based compensation cost is 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

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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. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures are estimated based on historical experience. In addition, for awards that contain performance conditions, compensation cost will only be recognized if the performance condition is considered probable of being achieved. Management must make judgments and estimates about the probability that the performance condition will be achieved based on a number of factors, both internal and external. If factors change and we employ different assumptions in the application of SFAS 123R in future periods, the compensation expense that we record under SFAS 123R 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 straight line based on the proportionate amount of the requisite service period that has been rendered to date for each respective performance 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, which are subject to SFAS 123R requirements. 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 options and other 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 and as a result, our financial results could be materially and adversely impacted.

Impact of Recently Issued and Proposed Accounting Pronouncements

In June 2008, the FASB issued FASB Staff Position, or FSP, EITF No. 03-6-1, "Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities." The FSP addresses whether instruments granted in share-based payment transactions are participating securities prior to vesting and therefore need to be included in the earnings allocation in calculating earnings per share under the two-class method described in SFAS No. 128, "Earnings per Share." The FSP requires companies to treat unvested share-based payment awards that have non-forfeitable rights to dividend or dividend equivalents as a separate class of securities in calculating earnings per share. The FSP is effective for fiscal years beginning after December 15, 2008 and earlier application is not permitted. We do not expect it to have a significant impact on our consolidated financial statements.

In March 2008, the FASB issued SFAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133," or SFAS 161. SFAS 161 is intended to improve financial standards for derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity's financial position, financial performance, and cash flows. Entities are required to provide enhanced disclosures about: (a) how and why an entity uses derivative instruments; (b) how derivative instruments and related

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hedged items are accounted for under SFAS No. 133 and its related interpretations; and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. SFAS 161 is effective for financial statements issued for fiscal years beginning after November 15, 2008, with early adoption encouraged. Because SFAS 161 only requires additional disclosure, we do not expect it to have a significant impact on our consolidated financial statements.

Effective January 1, 2008, we adopted SFAS 159. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value, thereby providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. The amendment to SFAS 115 applies to all entities with available-for-sale and trading securities. The adoption of SFAS 159 did not have a material impact on our consolidated financial statements since we did not initially elect to apply the fair value option for any of our financial assets or liabilities as of the adoption date.

Effective January 1, 2008, we adopted Emerging Issues Task Force, or EITF, 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities," or EITF 07-3. EITF 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. The adoption of EITF 07-03 did not have a material impact on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), "Business Combinations," or SFAS 141R. SFAS 141R establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree and the goodwill acquired. SFAS 141R also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. SFAS 141R became effective on a prospective basis for our financial statements beginning on January 1, 2009. Accordingly, any future business combination we enter into would be subject to SFAS 141R.

In November 2007, the EITF reached a consensus on Issue 07-01, "Accounting for Collaborative Arrangements," or EITF 07-01, which addresses how the parties to a collaborative agreement should account for costs incurred and revenues generated on sales to third parties, how sharing payments pursuant to a collaboration agreement should be presented in the income statement and certain related disclosure questions. EITF 07-01 is effective for years beginning after December 15, 2008. Accordingly, we are in the process of evaluating the impact of EITF 07-01.

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements," or SFAS 157. This statement defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 applies under other accounting pronouncements that require or permit fair value measurements, the FASB having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, SFAS 157 does not require any new fair value measurements but rather eliminates inconsistencies in guidance found in various prior accounting policies. SFAS 157 is effective for years beginning after November 15, 2007 and interim periods within those fiscal years. In February 2008, the FASB issued FASB FSP 157-2, which delays the effective date of SFAS 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), until fiscal years beginning after November 15, 2008, and interim periods within those fiscal years. These nonfinancial items include assets and liabilities such as reporting units measured at fair value in a goodwill impairment test and nonfinancial assets acquired and liabilities assumed in a business combination. In October 2008, the FASB issued FSP No. 157-3, "Determining the Fair Value of a Financial Asset When the

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Market for That Asset is Not Active," or FSP 157-3. FSP 157-3 clarifies the application of SFAS 157 in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. FSP 157-3 was effective upon issuance, including prior periods for which financial statements have not been issued. Effective January 1, 2008, we partially adopted SFAS 157 for financial assets and liabilities recognized at fair value on a recurring basis. The partial adoption of SFAS 157 for financial assets and liabilities did not have a material impact on our consolidated financial statements. The provisions of SFAS 157 related to other nonfinancial assets and liabilities were effective for us on January 1, 2009 and will be applied prospectively. We do not expect that these additional SFAS 157 provisions will have a material impact on our consolidated financial statements.

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

As of December 31, 2008, our short- and long-term investments totaled $149.2 million and were invested in corporate debt securities, U.S. treasury and government agency securities, commercial paper, and ARS. These investments are subject to interest rate risk and will fall in value if market interest rates increase. However, even if market interest rates for comparable investments were to increase immediately and uniformly by 50 basis points, or one-half of a percentage point, from levels at December 31, 2008, this would have resulted in a hypothetical decline in fair value of our investments, excluding ARS, which are described below, of approximately $0.4 million.

At December 31, 2008, we held a total of $54.3 million in fair market value of ARS, reflecting an impairment of approximately $12.2 million compared to our cost basis of these securities of $66.5 million. Of the $12.2 million impairment, approximately $10.5 million represents a temporary impairment and is reported as an unrealized loss at December 31, 2008. The remaining $1.7 million impairment represents an other-than-temporary impairment required as a result of the mark to market of certain ARS redesignated as trading securities under SFAS 115 and is recognized in our consolidated statement of operations at December 31, 2008. Greater than 90% of these ARS were rated AAA as of December 31, 2008 by at least one of the major securities rating agencies, most of which were collateralized by student loans substantially guaranteed by the U.S. government under the Federal Family Education Loan Program. We had traditionally recorded these investments in ARS 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 analyses consider, 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 recorded a $10.5 million unrealized loss related to our ARS, other than those subject to settlement rights, to accumulated other comprehensive (loss) income as of December 31, 2008. 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 provides 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.

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 the effect of reducing the fair value of our ARS by approximately $1.2 million as of December 31, 2008. Similarly, holding all other factors constant, if we were to increase the average expected term utilized in our fair value calculation by one year, this change would have the effect of reducing the fair value of our ARS by approximately $1.9 million as of December 31, 2008.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA:

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

Management's Annual Report on Internal Control over Financial Reporting

Report of Independent Registered Public Accounting Firm

Financial Statements:

Consolidated Balance Sheets as of December 31, 2008 and 2007

Consolidated Statements of Operations for the years ended December 31, 2008 and 2007, the three months ended December 31, 2006 and the year ended September 30, 2006

Consolidated Statements of Comprehensive Loss for the years ended December 31, 2008 and 2007, the three months ended December 31, 2006 and the year ended September 30, 2006

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2008 and 2007, the three months ended December 31, 2006 and the year ended September 30, 2006

Consolidated Statements of Cash Flows for the years ended December 31, 2008 and 2007, the three months ended December 31, 2006 and the year ended September 30, 2006

Notes to Consolidated Financial Statements

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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, 2008.

Our internal control over financial reporting as of December 31, 2008 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, 2008.

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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 subsidiary at December 31, 2008 and 2007, and the results of their operations and their cash flows for the years ended December 31, 2008 and 2007, the three months ended December 31, 2006, and for the year ended September 30, 2006, 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, 2008, 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 audits (which were integrated audits for the years ended December 31, 2008 and 2007 and for the year ended September 30, 2006.) We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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

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

Boston, Massachusetts
February 27, 2009

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AMAG Pharmaceuticals, Inc.

Consolidated Balance Sheets

(in thousands, except share and per share data)

	As of December 31,	
	2008	**2007**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 64,182	$ 28,210
Short-term investments	94,914	258,597
Accounts receivable	408	223
Inventories	96	384
Prepaid and other current assets	4,710	2,800
Total current assets	164,310	290,214
Property, plant and equipment:		
Land	360	360
Buildings and improvements	9,986	5,106
Laboratory equipment	5,994	5,959
Furniture and fixtures	3,474	1,569
Construction in process	298	
Total property, plant and equipment	20,112	12,994
Less accumulated depreciation	(8,889)	(8,452)
Net property, plant and equipment	11,223	4,542
Settlement rights	1,566	
Long-term investments	54,335	
Restricted cash	521	95
Total assets	$ 231,955	$ 294,851
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,305	$ 1,733
Accrued expenses	11,571	5,547
Deferred revenue	516	738
Total current liabilities	14,392	8,018
Long-term liabilities:		
Deferred revenue and rent expense	4,149	879
Total liabilities	18,541	8,897
Commitments and contingencies (Notes K and L)		
Stockholders' equity:		
Preferred stock, par value $.01 per share, 2,000,000 shares authorized; none issued		
Common stock, par value $.01 per share, 58,750,000 shares authorized at December 31, 2008 and 25,000,000 shares authorized at December 31, 2007; 17,018,159 and 16,945,662 shares issued and outstanding at December 31, 2008 and 2007, respectively	170	169
Additional paid-in capital	411,538	402,346
Accumulated other comprehensive (loss) income	(9,959)	127

Accumulated deficit	(188,335)	(116,688)
Total stockholders' equity	213,414	285,954
Total liabilities and stockholders' equity	$ 231,955	$ 294,851

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)

	For the Years Ended December 31,		For the Three Months Ended December 31,	For the Year Ended September 30,
	2008	2007	2006	2006
Revenues:				
License fees	$ 959	$ 1,096	$ 222	$ 907
Royalties	228	248	44	317
Product sales	751	1,208	353	1,449
Total revenues	1,938	2,552	619	2,673
Costs and expenses:				
Cost of product sales	292	320	287	273
Research and development expenses	31,716	24,236	6,393	21,294
Selling, general and administrative expenses	49,536	20,396	2,197	8,011
Total costs and expenses	81,544	44,952	8,877	29,578
Other income (expense):				
Interest and dividend income, net	9,139	12,506	818	1,575
Losses on investments, net	(3,024)			
Fair value adjustment of settlement rights	1,566			
Litigation settlement (Note K)		(4,000)		
Other income (expense), net				(35)
Total other income	7,681	8,506	818	1,540
Net loss before income taxes	(71,925)	(33,894)	(7,440)	(25,365)
Income tax benefit	278			
Net loss	$(71,647)	$(33,894)	$ (7,440)	$ (25,365)
Net loss per share:				
Basic and diluted	$ (4.22)	$ (2.15)	$ (0.60)	$ (2.31)
Weighted average shares outstanding used to compute net loss per share:				
Basic and diluted	16,993	15,777	12,383	10,964

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)

	For the Years Ended December 31,		For the Three Months Ended December 31,	For the Year Ended September 30,
	2008	2007	2006	2006
Net loss	$(71,647)	$(33,894)	$ (7,440)	$ (25,365)
Other comprehensive income (loss):				
Unrealized gains (losses) on securities:				
Holding (losses) gains arising during period	(13,110)	127		57
Reclassification adjustment for losses and gains, net included in net loss	3,024			
Net unrealized (losses) gains	(10,086)	127		57
Comprehensive loss	$(81,733)	$(33,767)	$ (7,440)	$ (25,308)

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 September 30, 2005	9,878	$ 99	$ 72,326	$ (49,989)	$ (57)	$ 22,379
Net shares issued in connection with the exercise of stock options	457	4	2,593			2,597
Shares issued in connection with a financing, net of financing costs of $2.2 million	1,233	12	31,647			31,659
Shares issued in connection with employee stock purchase plan	12		94			94
Net shares issued in connection with the exercise of warrants	360	4	646			650
Non-cash equity-based compensation expense			4,003			4,003
Unrealized gains on securities, net					57	57
Net loss				(25,365)		(25,365)
Balance at September 30, 2006	11,940	119	111,309	(75,354)		36,074
Net shares issued in connection with the exercise of stock options	23	1	174			175
Shares issued in connection with a financing, net of financing costs of $0.3 million	2,103	21	122,899			122,920
Non-cash equity-based compensation expense			548			548
Net loss				(7,440)		(7,440)
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 expense			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 expense			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

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)

	For the Years Ended December 31,		For the Three Months Ended December 31,	For the Year Ended September 30,
	2008	2007	2006	2006
Net Loss	$ (71,647)	$ (33,894)	$ (7,440)	$ (25,365)
Cash flows from operating activities:				
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	1,497	798	152	398
Non-cash equity-based compensation expense	8,037	8,182	548	4,003
Loss on disposal of fixed assets				35
Amortization of premium/discount on purchased securities	482	(1,023)		66
Fair value adjustment on settlement rights	(1,566)			
Losses on investments, net	3,024			
Changes in operating assets and liabilities:				
Accounts receivable	(185)	126	(264)	(85)
Inventories	288	(40)	26	(2)
Prepaid and other current assets	(1,910)	(1,701)	(503)	(151)
Accounts payable and accrued expenses	6,596	(121)	(1,092)	6,280
Deferred revenue and rent expense	3,048	(1,047)	(138)	(896)
Total adjustments	19,311	5,174	(1,271)	9,648
Net cash used in operating activities	(52,336)	(28,720)	(8,711)	(15,717)
Cash flows from investing activities:				
Proceeds from sales or maturities of available-for-sale investments	233,194	455,608		
Proceeds from maturities of held-to-maturity investments		132,795	9,760	34,170
Purchase of available-for-sale investments	(137,438)	(693,463)	(20,001)	
Purchase of held-to-maturity investments		(110,787)	(21,599)	(31,544)
Capital expenditures	(8,178)	(884)	(379)	(912)
Restricted cash	(426)	(61)	(18)	(16)
Net cash provided by (used in) investing activities	87,152	(216,792)	(32,237)	1,698
Cash flows from financing activities:				
Proceeds from the exercise of stock options	763	4,523	175	2,597
Proceeds from the issuance of common stock under ESPP	393	260		94
Proceeds from the exercise of warrants				650
Proceeds from the issuance of common stock, net of underwriting discount and other expenses		154,479	122,920	31,659
Net cash provided by financing activities	1,156	159,262	123,095	35,000

Net increase (decrease) in cash and cash equivalents	35,972	(86,250)	82,147	20,981
Cash and cash equivalents at beginning of the year	28,210	114,460	32,313	11,332
Cash and cash equivalents at end of the year	$ 64,182	$ 28,210	$ 114,460	$ 32,313
Supplemental data:				
Non-cash investing and financing activities:				
Investments reclassified to trading, at fair value	$ 7,650	$	$	$
Non-cash stock option exercises	$	$ 683	$ 184	$ 841
Non-cash warrant exercises	$	$	$	$ 8,088

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 anemia and novel imaging agents to aid in the diagnosis of cancer and cardiovascular disease. We have one product candidate, Feraheme (ferumoxytol injection), and two approved products, Feridex I.V.® and GastroMARK®. *Feraheme* is being developed for use as an intravenous, or IV, iron replacement therapeutic agent for the treatment of iron deficiency anemia, or IDA, and as a diagnostic agent for vascular-enhanced magnetic resonance imaging, or MRI, to assess peripheral arterial disease, or PAD. In December 2007, we submitted our new drug application, or NDA, to the U.S. Food and Drug Administration, or the FDA, for marketing approval of *Feraheme* for the treatment of IDA in chronic kidney disease, or CKD, patients. In October 2008, we received a Complete Response letter from the FDA with respect to our NDA for *Feraheme* requesting certain additional clinical information, information regarding certain observations noted during a recent FDA inspection at one of our Phase III clinical sites, and resolution of certain observations noted during a recent FDA inspection of our Cambridge, Massachusetts manufacturing facility. We submitted a response in October 2008, and in December 2008 we received a second Complete Response letter from the FDA requesting data to clarify a specific chemistry, manufacturing and controls, or CMC, question, resolution of the deficiencies observed during the recent FDA inspection of our manufacturing facility, and finalization of labeling discussions for *Feraheme*. We will need to address the issues raised by the FDA with respect to our NDA in a timely and satisfactory manner in order to obtain approval to market and sell *Feraheme* in the U.S.

Feridex I.V., our liver contrast agent, is approved and has been sold in the U.S., Europe and other countries. 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*.

GastroMARK, our oral contrast agent used for delineating the bowel in MRI, is approved and marketed in the U.S, Europe and other countries.

We are subject to risks common to companies in the pharmaceutical industry including, but not limited to, uncertainty of the regulatory approval process for our product candidates, uncertainty of product development and commercialization, uncertainty of the results of clinical trials, the volatility of our stock price, the potential fluctuation of our operating results, the current credit and financial market conditions, our ability to resolve any manufacturing deficiencies, our potential inability to obtain raw materials and manufacture sufficient quantities of our products, our limited sales and marketing experience, our dependence on key personnel, our ability to manage growth, uncertainty regarding market acceptance of our products, development by us or our competitors of new technological and product innovations, uncertainties related to insurance coverage, coding and third-party reimbursement for our products, product liability, protection of proprietary technology, compliance with the regulations of the FDA and other government agencies, potential legislative and regulatory changes, and our ability to obtain additional financing, if necessary, on acceptable terms or to enter into favorable collaborations and in-licensing arrangements.

In May 2007, our Board of Directors, or Board, approved a change in our fiscal year end from September 30 to December 31. Accordingly, these consolidated financial statements reflect our operations for the years ended December 31, 2008 and 2007, the three month transition period ended December 31, 2006 and the year ended September 30, 2006.

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B. Summary of Significant Accounting Policies

Use of Estimates and Assumptions

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reported period. The most significant estimates and assumptions are used in, but not limited to, assessing investments for potential impairment and determining values of investments, accrued expenses, income taxes and equity-based compensation expense. Actual results could differ from those estimates.

Principles of Consolidation

The accompanying consolidated financial statements include our accounts and the accounts of our wholly-owned subsidiary, AMAG Securities Corporation. 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, 2008 and 2007, 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 the guidance outlined SFAS No. 115 "Accounting for Certain Investments in Debt and Equity Securities," or SFAS 115. 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, 2008 and 2007, 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 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) income," 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 brokers, which provides 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. With the opportunity provided by the settlement rights, during 2008 we redesignated these ARS as trading securities as we are likely to sell these investments to UBS.

Investments are considered to be impaired when a decline in fair value below cost basis is determined to be other-than temporary. We periodically evaluate whether a decline in fair value below

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cost basis is other-than-temporary and consider available evidence regarding our investments. In the event that the cost basis of a security significantly exceeds its fair value, we evaluate, among other factors, the duration of the period that, and extent to which, the fair value is 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, and our intent and ability to hold the investment to recovery, which may be maturity. We also consider credit ratings with respect to our investments provided by investments ratings agencies. With the exception of our ARS which are subject to the settlement rights with UBS, all of our investments are classified as available-for-sale securities and are reflected at fair value. If a decline in fair value is determined to be other-than temporary, we will record a write-down in our consolidated statement of operations and a new cost basis in the security will be established.

Fair Value of Financial Instruments

As of January 1, 2008, we partially adopted the provisions of SFAS No. 157, "Fair Value Measurements," or SFAS 157, for financial assets and liabilities recognized at fair value on a recurring basis. SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States, and expands disclosures about fair value measurements. The provisions of SFAS 157 related to other nonfinancial assets and liabilities were effective for us on January 1, 2009, and will be applied prospectively. Fair value is defined under SFAS 157 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 under SFAS 157 must maximize the use of observable inputs and minimize the use of unobservable inputs. The standard describes a fair value hierarchy to measure fair value, 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.

As of December 31, 2008, we held 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

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rights. In accordance with SFAS 157, the following table represents the fair value hierarchy for our financial assets measured at fair value on a recurring basis as of December 31, 2008 (in thousands):

	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 investments is generally determined from quoted market prices based upon either quoted prices from active markets or other significant observable market transactions at fair value.

We elected the SFAS 159 fair value option in November 2008 with respect to the UBS settlement rights and, accordingly, as of December 31, 2008, we have recorded an asset and net benefit equal to the estimated fair value of the settlement rights of approximately $1.6 million in our consolidated statement of operations. With the opportunity provided by the settlement rights during 2008, we redesignated the UBS ARS that had a par value of $9.3 million and an estimated fair value of $7.6 million as trading securities. Because acceptance of the settlement rights means that we can no longer assert that we have the intent or ability to hold our UBS ARS until anticipated recovery, we have recognized an other-than-temporary impairment charge of approximately $1.7 million related to our UBS ARS. We will be 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 will be required to periodically assess the economic ability of UBS to meet that obligation in assessing the fair value of the settlement rights.

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The following table presents both our ARS and settlement rights measured at fair value on a recurring basis using significant unobservable inputs (Level 3) as defined in SFAS 157 as of December 31, 2008 (in thousands):

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3) Auction Rate Securities and Settlement Rights
Balance at December 31, 2007	$
Transfers to Level 3	80,725
Total gains (losses) (realized or unrealized):	
Included in earnings	(109)
Included in other comprehensive (loss) income	(10,515)
Purchases (settlements), net	(14,200)
Balance at December 31, 2008	$ 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 December 31, 2008	$ (109)

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

Inventories

Inventories are stated at the lower of cost (determined on a first-in, first-out basis) or market (net realizable value). Prior to regulatory approval of our product candidates, we incur expenses for the manufacture of drug product that could potentially be available to support the commercial launch of these product candidates. Until the necessary initial regulatory approval has been received or is otherwise considered assured, we charge all such amounts to research and development expenses.

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 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.

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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. Manufacturing costs are expensed as incurred until a product has received the necessary initial regulatory approval.

Revenue Recognition

Product Sales

We follow the provisions of the SEC Staff Accounting Bulletin, or SAB, No. 104, "Revenue Recognition." We recognize revenues from product sales in the period in which the product is shipped, provided there is persuasive evidence that an arrangement exists, the price is fixed or determinable and collection of the related receivable is reasonably assured.

License fees

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. 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 FASB's Emerging Issues Task Force, or the EITF, Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables," or EITF 00-21. Under EITF 00-21, 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 arrangement are recognized as revenue over the period of performance for such undelivered items or services.

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Equity-based compensation

We account for our equity-based compensation arrangements with our employees and non-employee directors under SFAS No. 123R, "Share-Based Payment," or SFAS 123R, and its related implementation guidance as promulgated by both the FASB and SEC Staff Accounting Bulletin 107, or SAB 107. Under these pronouncements, equity-based compensation cost is 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. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures are estimated based on historical experience. In addition, for awards that contain performance conditions, compensation cost will only be recognized if the performance condition is considered probable of being achieved. Management must make judgments and estimates about the probability that the performance condition will be achieved based on a number of factors, both internal and external. If factors change and we employ different assumptions in the application of SFAS 123R in future periods, the compensation expense that we record under SFAS 123R 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 is 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 on the proportionate amount of the requisite service period that has been rendered to date for each respective performance 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, which are subject to SFAS 123R requirements. 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 options and other 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 and our financial results could be materially and adversely impacted.

Equity-based compensation to certain non-employees is accounted for in accordance with SFAS 123R, utilizing the measurement guidance of the Emerging Issues Task Force, or EITF, 96-18 "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 liabilities are recognized based on temporary differences between the financial reporting and the tax basis of assets and liabilities using statutory rates in effect for the year in which the differences are expected to reverse. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of our deferred tax assets will not be realized.

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Concentrations and Significant Customer Information

Financial instruments, which potentially subject us to concentrations of credit risk consist principally of cash equivalents, investments, accounts receivable and settlement rights. As of December 31, 2008, our cash equivalents, investments and settlement rights amounted to approximately $211.2 million. We currently invest our excess cash primarily in money market funds and investments in corporate debt securities, U.S. treasury and government agency securities, commercial paper, and ARS.

Our operations are located solely within the U.S. We are focused principally on developing and manufacturing 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, 2008 and 2007, the three month period ended December 31, 2006 and the year ended September 30, 2006. No other company accounted for more than 10% of our total revenues in any period presented below.

	For the Years Ended December 31,		For the Three Months Ended December 31, 2006	For the Year Ended September 30, 2006
	2008	2007		
Bayer	53%	43%	31%	41%
Guerbet	24%	26%	45%	37%
Covidien	17%	15%	15%	11%
Cytogen	0%	14%	< 10%	< 10%

All of the revenue attributable to Cytogen and a large portion of the revenue attributable to Bayer in all 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 and Japan, amounted to 29%, 28%, 47%, and 41%, of our total revenues for the years ended December 31, 2008 and 2007, the three months ended December 31, 2006, and the year ended September 30, 2006, 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.

Comprehensive Loss

SFAS No. 130, "*Reporting Comprehensive Income*," requires us to display comprehensive loss and its components as part of our consolidated financial statements. Comprehensive loss consists of net loss and other comprehensive (loss) income. Other comprehensive income (loss) includes changes in equity that are excluded from net (loss), which for all periods presented relates 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

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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):

	For the Years Ended December 31,		For the Three Months Ended December 31,	For the Year Ended September 30,
	2008	2007	2006	2006
Options to purchase shares of common stock	1,991	1,327	1,206	1,042
Shares of common stock issuable upon the vesting of restricted stock units	219	36	34	30
Total	2,210	1,363	1,240	1,072

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

	For the Years Ended December 31,		For the Three Months Ended December 31,	For the Year Ended September 30,
	2008	2007	2006	2006
Net loss	$ (71,647)	$ (33,894)	$ (7,440)	$ (25,365)
Weighted average common shares outstanding	16,993	15,777	12,383	10,964
Net loss per share:				
Basic and diluted	$ (4.22)	$ (2.15)	$ (0.60)	$ (2.31)

C. Investments

At December 31, 2008 our short- and long-term investments totaled $149.2 million and consisted of securities classified as trading and available-for-sale in accordance with SFAS No. 115. At December 31, 2007 our short-term investments totaled $258.6 million and consisted solely of securities classified as available-for-sale.

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The following is a summary of our available-for-sale and trading securities at December 31, 2008 and 2007 (in thousands):

	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

	December 31, 2007			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Short-term investments:				
Corporate debt securities				
Due in one year or less	$ 33,894	$ 10	$ (62)	$ 33,842
Due in one to three years	48,673	139	(74)	48,738
U.S. treasury and government agency securities				
Due in one year or less	15,841	7	(1)	15,847
Due in one to three years	25,944	108		26,052
Commercial paper				
Due in one year or less	26,745	9	(1)	26,753
Due in one to three years				
Municipal debt securities				
Due in one year or less	1,998		(8)	1,990
Due in one to three years				
Auction rate securities				
Due in one year or less				
Due after five years	105,375			105,375
Total short-term investments	$258,470	$ 273	$ (146)	$258,597

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At December 31, 2008, we held a total of $54.3 million in fair market value of ARS, reflecting an impairment of approximately $12.2 million compared to our cost basis of these securities of $66.5 million. Of the $12.2 million impairment, approximately $10.5 million represents a temporary impairment and is reported as an unrealized loss at December 31, 2008. The remaining $1.7 million impairment represents an other-than-temporary impairment, which is described below, and is recognized in our consolidated statement of operations at December 31, 2008, reducing our UBS ARS from a par value of $9.3 million to a new cost basis of $7.6 million. Of our total ARS, $46.7 million in market value are not subject to settlement rights and are classified as available-for-sale. The remaining $7.6 million are subject to settlement rights and are classified as trading securities. At December 31, 2008, all of our ARS were municipal bonds with an auction reset feature. Greater than 90% of our entire ARS portfolio was rated AAA as of December 31, 2008 by at least one of the major securities rating agencies and most of our ARS were 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. Accordingly, these securities changed from Level 2 to Level 3 within the SFAS 157 hierarchy since our initial adoption of SFAS 157 at January 1, 2008. Our valuation analyses consider, 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 recorded a realized loss of $1.7 million related to certain ARS subject to settlement rights, required as a result of the mark to market of certain ARS redesignated as trading securities under SFAS 115, and a $10.5 million unrealized loss related to our ARS, other than those subject to settlement rights, to accumulated other comprehensive (loss) income as of December 31, 2008. We believe that the temporary impairment related to these ARS is primarily attributable to the limited liquidity of these investments, coupled with the recent turmoil in the credit and capital markets. As of December 31, 2008, all of our ARS continue to pay interest according to their stated terms. Any future fluctuation in fair value related to our ARS that we deem to be temporary, including any recoveries of previous write-downs, would be recorded to accumulated other comprehensive (loss) income. If we determine that any future unrealized loss is other-than-temporary, we will record a charge to earnings as appropriate.

In November 2008, we elected to participate in a rights offering by UBS, one of our brokers, which provides 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 attached to such ARS. We elected the SFAS 159 fair value option in November 2008 with respect to the settlement rights and, accordingly, as of December 31, 2008 we have recorded an asset and net benefit equal to the estimated fair value of the settlement rights of

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approximately $1.6 million in other income (expense) in our consolidated statement of operations. We have estimated the fair value of these settlement rights utilizing a discounted cash flow analysis as of December 31, 2008. Certain key assumptions used in this valuation were 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. With the opportunity provided by the settlement rights during 2008, we redesignated the UBS ARS that had a par value of $9.3 million and an estimated fair value of $7.6 million as trading securities as we are likely to sell these investments to UBS. Because acceptance of the settlement rights means that we can no longer assert that we have the intent or ability to hold our UBS ARS until anticipated recovery, we have recognized an other-than-temporary impairment charge of approximately $1.7 million related to our UBS ARS in other income (expense) in our consolidated statement of operations. We will be 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 will be required to periodically assess the economic ability of UBS to meet that obligation 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 entire ARS portfolio as long-term investments in our consolidated balance sheet at December 31, 2008. We believe that the temporary impairment related to our ARS is primarily attributable to the limited liquidity of these investments, coupled with the recent 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 these ARS, other than those 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) income. If we determine that any future unrealized loss is other-than-temporary, we will record a charge to earnings as appropriate. 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 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. For example, in late 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 value of $5.0 million was re-affirmed as AAA by a different major rating agency in January 2009. As the ratings of these ARS have changed we may be required to adjust our future valuation of these ARS which may adversely affect the value of these investments.

Gains and losses are determined on the specific identification method and, accordingly, during 2008 we recorded other-than-temporary impairment charges of $3.0 million to our consolidated statements of operations related to certain corporate debt securities and ARS which were subject to settlement rights. Approximately $1.3 million of these impairment charges were related to corporate debt securities and were required after we conducted an analysis of other-than-temporary impairment factors, including the severity of declines and current financial market conditions as noted above. In addition, during 2008 we redesignated our ARS subject to settlement rights as trading securities and recorded an additional other-than-temporary impairment charge of $1.7 million to our consolidated statement of operations. There were no unrealized losses in our investments, which were deemed to be other-than-temporary at December 31, 2007. The following is a summary of the gross unrealized losses

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and fair value of our investments with unrealized losses that are not deemed to be other-than-temporarily impaired, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position at December 31, 2008 and 2007 (in thousands):

	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)
U.S. treasury and government agency securities						
Commercial paper						
Auction rate securities	46,685	(10,515)			46,685	(10,515)
	$80,681	$ (10,810)	$963	$ (41)	$81,644	$ (10,851)

	December 31, 2007					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Corporate debt securities	$45,427	$ (136)	$	$	$45,427	$ (136)
U.S. treasury and government agency securities	2,491	(1)			2,491	(1)
Commercial paper	9,056	(1)			9,056	(1)
Municipal debt securities	1,990	(8)			1,990	(8)
	$58,964	$ (146)	$	$	$58,964	$ (146)

With the exception of the ARS as discussed above, the unrealized losses on our investments at December 31, 2008 were primarily caused by the recent uncertainty in the capital markets and changes in interest rates. Since the decline in market value is primarily attributable to changes in these factors, and we have the ability and intent to hold these investments until a recovery of fair value, we do not consider these investments to be other-than-temporarily impaired at December 31, 2008.

D. Inventories

The major classes of inventories were as follows at December 31, 2008 and 2007 (in thousands):

	December 31, 2008	December 31, 2007
Raw materials	$ 9	$ 259
Work in process	57	96
Finished goods	30	29
Total inventories	$ 96	$ 384

The aggregate amount of overhead remaining in ending inventory as of December 31, 2008 and 2007 was not significant. Prior to regulatory approval of our product candidate, we incur expenses for the manufacture of drug product that could potentially be available to support the commercial launch of this product candidate. Until the necessary regulatory approvals have been received, we charge all such amounts to research and development expenses.

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E. Current and Long-Term Liabilities

Accrued expenses consisted of the following at December 31, 2008 and 2007 (in thousands):

	December 31, 2008	December 31, 2007
Clinical, regulatory and commercial consulting fees and expenses	$ 3,935	$ 1,388
Salaries, bonuses, and other compensation	4,989	3,009
Professional, license, and other fees and expenses	2,647	1,150
Totals	$ 11,571	$ 5,547

Deferred liabilities consisted of the following at December 31, 2008 and 2007 (in thousands):

	Deferred Revenue	Deferred Rent	Total
At December 31, 2008:			
Short-term	$ 516	$	$ 516
Long-term	1,000	3,149	4,149
Total	$ 1,516	$ 3,149	$4,665
At December 31, 2007:			
Short-term	$ 738	$	$ 738
Long-term	738	141	879
Total	$ 1,476	$ 141	$1,617

At December 31, 2008, short- and long-term deferred revenue related entirely to our collaborative agreements with Bayer and 3SBio Inc., or 3SBio, respectively. In consideration of the grant of the license to 3SBio, 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. At December 31, 2007, the entire balance of deferred revenue related to our agreements with Bayer. At December 31, 2008 and 2007, deferred rent related to the lease of our principal executive offices in Lexington, Massachusetts and our previous headquarters in Cambridge, Massachusetts, respectively.

F. Income Taxes

For the year ended December 31, 2008, we recognized a current federal income 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. There were no income tax provisions for the year ended December 31, 2007, the three months ended December 31, 2006 and the year ended September 30, 2006 given our continued net operating loss position.

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

	For the Years Ended December 31,		For the Three Months Ended December 31,	For the Year Ended September 30,
	2008	2007	2006	2006
Statutory U.S. federal tax rate	34.0%	34.0%	34.0%	34.0%
State taxes, net of federal benefit	5.9%	6.3%	6.3%	6.3%
Permanent items, net	(2.1)%	(2.1)%	(1.9)%	0.2%
Tax credits	2.1%	1.4%	30.9%	0.1%
Other	0.0%	0.0%	0.0%	0.9%
Valuation allowance	(39.5)%	(39.6)%	(69.3)%	(41.5)%
Total	0.4%	0.0%	0.0%	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):

	For the Years Ended December 31,	
	2008	2007
Assets		
Net operating loss carryforwards	$ 45,754	$ 29,573
Tax credit carryforwards	8,558	7,360
Deferred revenue	610	594
Capital loss carryforward	63	
Equity award expense	3,895	2,738
Capitalized research & development	19,123	9,928
Unrealized loss on available-for-sale securities, net	4,010	
Other	2,505	2,010
Liabilities		
Depreciation	(253)	(155)
	84,265	52,048
Valuation allowance	(84,265)	(52,048)
Net deferred taxes	$	$

Due to the uncertainty surrounding the realization of the 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 $32.2 million, $12.0 million, $4.5 million and $10.5 million for the years ended December 31, 2008 and 2007, the three months ended December 31, 2006 and the year ended September 30, 2006, respectively, primarily due to an increase in our net operating loss, or NOL, carryforwards, equity-based compensation expense, and capitalized research and development expense.

At December 31, 2008, we had federal and state NOL carryforwards of approximately $117.4 million and $93.2 million, respectively, and federal capital loss carryforwards of $0.2 million to offset future taxable income. We also had an additional $17.2 million of federal and state NOLs not

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reflected above which were attributable to deductions from the exercise of equity awards. The benefit from these deductions will be recorded as a credit to additional paid-in capital if and when realized through a reduction of taxes paid in cash. Our federal NOLs will begin to expire in 2010 and our state NOLs expire at various dates through 2013. Our capital loss carryforwards will expire in 2013. In addition, we have federal and state tax credits of approximately $6.4 million and $3.3 million, respectively, to offset future tax liabilities. Our tax credits will expire periodically through 2028 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 which, 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. We have not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since our formation due to the significant complexity and cost associated with such a study. If we have experienced a change of control as defined by Section 382 at any time since our formation, utilization of our NOL or R&D credit carryforwards would be subject to an 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.

Effective January 1, 2007, we adopted the provisions of FASB Interpretation No. 48 entitled "Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement No. 109," or FIN 48. FIN 48 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. FIN 48 also 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, 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 under FIN 48. 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, 2005, although carryforward attributes that were generated prior to tax year 2005 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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G. Equity-Based Compensation

We maintain several equity compensation plans, including our 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.

Our 2007 Plan was approved by our stockholders in November 2007 and 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 subsidiary. 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 the Compensation Committee of our Board of Directors. 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 will have a contractual term of no greater than ten years. Our Board will establish 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.

As of December 31, 2008 we have granted options and restricted stock units covering 1,137,546 shares of common stock under our 2007 Plan, of which 41,290 stock options and 5,000 restricted stock units have expired or terminated, and of which no options have been exercised and no 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, 2008 was 896,756 and 194,500, respectively. The remaining number of shares available for future grants as of December 31, 2008 was 1,074,119, 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.

In December 2008, the Board granted each of the non-employee, non-Chairman members of our Board options to purchase 5,000 shares of our common stock and granted the Chairman of our Board options to purchase 10,000 shares of our common stock under our 2007 Plan. Each of these non-employee director option grants vests in four equal annual installments beginning one year from the date of grant, has an exercise price equal to the fair market value of a share of our common stock as of the date of grant, and has a ten-year term.

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, 2008, we have granted options and restricted stock units covering 2,182,700 shares of common stock under the 2000 Plan, of which 347,325 stock options and 750 restricted stock units have expired or

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terminated, and of which stock options and restricted stock units covering 696,645 and 19,250 shares of common stock, respectively, have been exercised. The remaining number of shares underlying outstanding options and restricted stock units pursuant to the 2000 Plan as of December 31, 2008 was 1,094,730 and 24,000, 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.

Equity-based compensation expense as reflected in our consolidated statements of operations was as follows (in thousands):

	For the Years Ended December 31,		For the Three Months Ended December 31,	For the Year Ended
	2008	2007	2006	September 30,2006
Research and development	$ 3,760	$ 1,936	$ 442	$ 749
Selling, general and administrative	4,277	6,246	106	3,254
Total equity-based compensation expense	$ 8,037	$ 8,182	$ 548	$ 4,003

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 since our adoption of SFAS 123R. 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.

We estimate the fair value of equity-based compensation utilizing 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 straight line based on the proportionate amount of the requisite service period that has been rendered to date for each respective performance 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, which are subject to SFAS 123R requirements. 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 options and other 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.

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The following table summarizes the weighted average assumptions we utilized for grants of options to differing groups of optionees:

	For the Years Ended December 31,				For the Three Months Ended December 31,		For the Year Ended September 30, 2006	
	2008		2007		2006			
	Employees	Non-Employee Directors	Employees	Non-Employee Directors	Employees	Non-Employee Directors	Employees	Non-Employee Directors
Risk free interest rate (%)	2.90	1.59	4.41	3.44	4.54	4.60	4.59	4.48
Expected volatility (%)	60	59	64	62	73	73	76	77
Expected option term (years)	5.10	4.70	5.29	5.50	6.25	5.69	5.79	5.00
Dividend yield	none	none	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 subsequent issuances, 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 SAB 107 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.

In February 2008, we granted 100,000 performance-based stock options to our Chief Executive Officer, or CEO, at an exercise price of $47.08. These options will vest in equal annual installments over a three-year period but will only begin vesting upon the achievement of a performance target with respect to our commercial sale of *Feraheme* on or prior to March 31, 2009. We have deemed it improbable that the performance target associated with these options will be met by March 31, 2009 and therefore have recognized no expense related to these grants as of December 31, 2008. In addition, during 2007, we had granted 110,000 performance-based stock options to certain of our executive officers with a weighted average exercise price of $63.00, 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 by December 31, 2008 and as a result, the performance conditions underlying these grants of 110,000 performance-based stock options 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 stock option grants. For awards that contain performance conditions, compensation cost will only be recognized if certain performance goals established by our Board are considered probable of being achieved as of the date of the financial statements.

In August 2008, we granted 50,000 restricted stock units to our CEO. The closing price of our common stock on the date of grant was $41.57 per share. These restricted stock units will commence vesting upon achievement of a specific stock price target as follows: fifty percent will vest upon the first anniversary of such stock price target achievement, and the remaining fifty percent will vest on the second anniversary of such stock price target achievement; provided that if the price target is not achieved on or prior to August 5, 2012, then such grant shall automatically terminate. During 2008, we recognized approximately $0.3 million in equity-based compensation expense associated with this market condition award.

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The following table summarizes details regarding our stock option plans for the year ended December 31, 2008 (excluding restricted stock units, which are presented separately below):

	December 31, 2008			
	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (in millions)
Outstanding at beginning of year	1,327,226	$ 38.27		
Granted	903,750	42.38		
Exercised	(48,900)	15.59		
Expired and/or forfeited	(190,590)	54.44		
Outstanding at end of year	1,991,486	$ 39.14	8.4 years	$ 10.5
Outstanding at end of year vested and unvested and expected to vest	1,799,652	$ 38.39	8.3 years	$ 10.4
Exercisable at end of year	650,481	$ 26.47	7.1 years	$ 9.4

The weighted average grant date fair value of stock options granted during the years ended December 31, 2008 and 2007, the three months ended December 31, 2006 and the year ended September 30, 2006 were $22.61, $34.77, $32.13, and $12.34, respectively. The total fair value of options that vested during the years ended December 31, 2008 and 2007, the three months ended December 31, 2006 and the year ended September 30, 2006 were $7.6 million, $4.2 million, $1.4 million and $2.3 million, respectively. The aggregate intrinsic value of options exercised in the years ended December 31, 2008 and 2007, the three months ended December 31, 2006 and the year ended September 30, 2006 (excluding warrants exercised and purchases made pursuant to our 2003 Employee Stock Purchase Plan and our 2006 ESPP), measured as of the exercise date, was approximately $1.6 million, $17.2 million, $1.1 million, and $9.4 million, respectively. The intrinsic value of a stock option is the amount by which the fair market value of the underlying stock exceeds the exercise price of the common stock option.

In the year ended December 31, 2008, we issued an aggregate of 199,500 restricted stock units to employees pursuant to our 2007 Plan. With the exception of the restricted stock awards subject to market conditions and described above, in general, these grants vest ratably, on an annual basis, over a four year period. With the exception of the restricted stock awards subject to market conditions, 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 2008 was approximately $8.0 million. At December 31, 2008, the amount of unrecorded expense for all outstanding restricted stock units attributable to future periods was approximately $7.2 million, and with the exception of the restricted stock awards subject to market conditions, which we expect will vest over a 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 3.2 years. This estimate is subject to change based upon a variety of future events, which include, but are not limited to, changes in estimated forfeiture rates, achievement of a market condition earlier than expected, and the issuance of new restricted stock awards.

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The following table summarizes details regarding restricted stock units granted under our equity incentive plans for the year ended December 31, 2008:

	December 31, 2008	
	Unvested Restricted Stock Units	Weighted Average Grant Date Fair Value
Outstanding at beginning of year	35,500	$ 33.84
Granted	199,500	40.29
Vested	(10,750)	31.92
Forfeited	(5,750)	41.42
Outstanding at end of year	218,500	$ 39.62
Outstanding at end of year and expected to vest	202,331	$ 39.62

At December 31, 2008, the amount of unrecorded equity-based compensation expense attributable to future periods was approximately $33.9 million, of which $26.7 million was associated with stock options and $7.2 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 2.9 and 3.2 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, changes in whether a performance condition is considered probable, 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, 2008 and 2007, 15,905 and 3,058 shares, respectively, have been issued under our 2006 ESPP.

The assumptions used for awards granted during 2008 under our 2006 ESPP were as follows:

	For the Years Ended December 31,		For the Three Months Ended December 31, 2006	For the Year Ended September 30, 2006
	2008	2007		
Risk free interest rate (%)	0.82	4.06	0.0	5.05
Expected volatility (%)	66	33	0.0	65
Expected option term (years)	0.5	0.5	0.0	1.0
Dividend yield	none	none	none	none

The weighted average fair value for purchase rights granted under our 2006 ESPP and predecessor employee stock purchase plans during the years ended December 31, 2008 and 2007, the three months ended December 31, 2006, and the year ended September 30, 2006 was $11.83, $19.23, $0, and $11.54, respectively, and was estimated using the Black-Scholes option-pricing model.

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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 will provide 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 will be fully vested on August 6, 2009. This resulted in a non-cash charge of approximately $10,000 in the year ended December 31, 2008 with an offsetting credit to additional paid-in capital.

H. 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. As of January 1, 2007, 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 $0.6 million, $0.2 million, $36,000, and $73,000, for the years ended December 31, 2008 and 2007, the three months ended December 31, 2006 and the year ended September 30, 2006, respectively.

I. 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. We have never issued preferred stock.

Common Stock Transactions

At our Annual Meeting of Stockholders held on May 6, 2008, a proposal to amend our Certificate of Incorporation, as amended, to increase the number of shares of our common stock authorized thereunder from 25,000,000 to 58,750,000, was approved by a vote of our stockholders.

In May 2007, we sold an aggregate of 2.5 million shares of our common stock, $.01 par value per share, in an underwritten public offering at a price to the public of $65.14 per common share, resulting in gross proceeds to us of approximately $162.9 million. Net proceeds to us after deducting fees, commissions and other expenses related to the offering were approximately $154.5 million. The shares were issued pursuant to a shelf registration statement on Form S-3, which became effective upon filing.

In December 2006, we sold an aggregate of approximately 2.1 million shares of our common stock, $.01 par value per share, in an underwritten public offering at a price to the public of $62.00 per common share, resulting in gross proceeds to us of approximately $130.4 million. Net proceeds to us after deducting fees, commissions and other expenses related to the offering were approximately $122.9 million. The shares were issued pursuant to a shelf registration statement on Form S-3 and a registration statement filed pursuant to Rule 462(b) promulgated under the Securities Act of 1933, as amended.

In March 2006, we sold an aggregate of approximately 1.2 million shares of our common stock, $.01 par value per share, in an underwritten public offering resulting in gross proceeds to us of approximately $33.9 million. Net proceeds to us after deducting fees, commissions and other expenses related to the offering were approximately $31.7 million. The shares were issued pursuant to our then

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existing shelf registration statement on Form S-3 and a registration statement filed pursuant to Rule 462(b) promulgated under the Securities Act.

J. 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.

K. 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 2011. Expense associated with these operating leases for the years ended December 31, 2008 and 2007, the three months ended December 31, 2006, and the year ended September 30, 2006 amounted to approximately $0.5 million, $0.1 million, $14,000, and $79,000, respectively. Future minimum lease payments associated with all noncancellable automobile, equipment, service and lease agreements, excluding facility related leases, for the years 2009, 2010 and 2011 are estimated to be $0.7 million, $0.1 million, and $0.1 million, respectively. We lease approximately 110 automobiles for our field-based employees. This lease requires a 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.

On May 27, 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 FASB Technical Bulletin No. 85-3 "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 have received approximately $2.2 million of tenant improvement reimbursements from the landlord. These reimbursements are being recorded as a deferred rent liability in our consolidated balance sheets and are amortized on a straight line basis as a reduction to rent expense over the term of the lease. We have recorded all tenant improvements as leasehold improvements and are amortizing these improvements over the shorter of the estimated useful life of the improvement or the remaining life of the initial lease term. Amortization of leasehold improvements is included in depreciation expense.

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

Period	Minimum Lease Payments
Year Ended December 31, 2009	$ 1,687
Year Ended December 31, 2010	1,891
Year Ended December 31, 2011	1,947
Year Ended December 31, 2012	2,003
Year Ended December 31, 2013	2,059
Thereafter	5,834
Total	$ 15,421

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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.

Facility-related rent expense recorded for the years ended December 31, 2008 and 2007, the three months ended December 31, 2006, and the year ended September 30, 2006 was $1.7 million, $0.4 million, $0.1 million, and $0.1 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 2008 we entered into various agreements with third-parties for which we had remaining purchase commitments of approximately $0.6 million as of December 31, 2008. These agreements principally related to pre-clinical research activities, our information technology infrastructure, and other operational activities.

Indemnification Obligations

As permitted under Delaware law, pursuant to our certificate of incorporation, by-laws and agreements with all of our current directors 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.

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

On January 25, 2006, Cytogen Corporation, or Cytogen, filed a lawsuit against us in Massachusetts Superior Court in connection with a License and Marketing Agreement entered into in August 2000 between us and Cytogen. We filed an answer to the complaint asserting numerous counterclaims. On February 15, 2007, we settled the lawsuit with Cytogen. As a result, on February 15, 2007, each party dropped all claims against the other, and all agreements between the parties were terminated. With the termination of our agreements with Cytogen, we re-acquired the U.S. marketing rights to *Combidex* as

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well as the U.S. marketing rights to *Feraheme* for oncology imaging applications. Under the terms of the settlement, we paid Cytogen $4.0 million in cash and released to Cytogen 50,000 shares of Cytogen common stock held in escrow under the terms of the original License and Marketing Agreement. We recorded the $4.0 million payment as a non-operating expense during the first quarter of 2007.

We may periodically become subject to legal proceedings and claims arising in connection with on-going 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, 2008.

L. 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

On May 25, 2008, we entered into a Collaboration and Exclusive License Agreement, or the 3SBio License Agreeement, 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.

Bayer (formerly Berlex Laboratories, Inc.)

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 1996, the parties agreed to remove Canada from the territories subject to the Bayer Agreements. Under the terms of the supply agreement, we received payments for manufacturing the product and royalties on sales. Under the terms of the license and marketing agreement with Bayer, Bayer paid for 60% of ongoing development expenses related to *Feridex I.V.* We have not incurred any significant development expenses in recent years related to *Feridex I.V.* These agreements were terminated upon mutual agreement in November 2008. Pursuant to the termination agreement, Bayer may 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, we are recognizing $0.5 million of deferred revenues, which remained at December 31, 2008, through April 1, 2009.

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Guerbet

In 1989, we entered into a supply and distribution agreement with Guerbet S.A., or Guerbet, granting Guerbet an exclusive right to manufacture and sell *GastroMARK* in western Europe and Brazil (under the tradename Lumirem®) 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 (formerly Tyco Healthcare and Mallinckrodt, Inc.)

In 1990, we entered into a manufacturing and distribution agreement with Covidien granting Covidien 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.

Other

We are the licensee of certain technologies related to certain of our imaging products under cross-license agreements with Amersham Health, which is part of GE Healthcare (Formerly Nycomed Imaging A.S.), or Amersham, and Bayer Schering Pharma AG (formerly Schering AG). The license agreement with Amersham requires us to make payments upon the attainment of particular milestones relating to *Feridex I.V.* and *GastroMARK*. We are also required under the agreement with Amersham to pay royalties on a percentage of product sales of *Feridex I.V.* and *GastroMARK*, if any. There were no milestone payments made in 2008, 2007, or 2006. Future milestone payments under the Amersham agreement will not exceed $0.4 million.

M. Consolidated Quarterly Financial Data Unaudited

The following tables provide consolidated quarterly financial data for the years ended December 31, 2008 and 2007 (in thousands, except per share data):

	March 31, 2008	June 30, 2008	September 30, 2008	December 31, 2008
License fees	$ 184	$ 185	$ 184	$ 406
Royalties	36	89	52	51
Product sales	392	212	24	123
Total revenues	612	486	260	580
Cost of product sales	44	31	3	214
Operating expenses	13,208	19,672	24,812	23,560(a)
Interest and dividend income, net	3,266	2,199	2,021	1,653
Other income (expense), net	73	11	(1,321)	(221)
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)

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	March 31, 2007	June 30, 2007	September 30, 2007	December 31, 2007
License fees	$ 542	$ 184	$ 184	$ 186
Royalties	77	64	59	48
Product sales	294	497	260	157
Total revenues	913	745	503	391
Cost of product sales	157	101	39	23
Operating expenses	8,932	10,198	11,617	13,885
Interest and dividend income, net	1,973	2,619	4,121	3,793
Litigation Settlement	(4,000)			
Net loss	$ (10,203)	$ (6,935)	$ (7,032)	$ (9,724)
Net loss per share basic and diluted	$ (0.72)	$ (0.46)	$ (0.42)	$ (0.57)

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

(a) 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.

N. Recently Issued and Proposed Accounting Pronouncements

In June 2008, the FASB issued FASB Staff Position, or FSP, EITF No. 03-6-1, "Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities." The FSP addresses whether instruments granted in share-based payment transactions are participating securities prior to vesting and therefore need to be included in the earnings allocation in calculating earnings per share under the two-class method described in SFAS No. 128, "Earnings per Share." The FSP requires companies to treat unvested share-based payment awards that have non-forfeitable rights to dividend or dividend equivalents as a separate class of securities in calculating earnings per share. The FSP is effective for fiscal years beginning after December 15, 2008 and earlier application is not permitted. We do not expect it to have a significant impact on our consolidated financial statements.

In March 2008, the FASB issued SFAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities, an amendment of FASB Statement No. 133," or SFAS 161. SFAS 161 is intended to improve financial standards for derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity's financial position, financial performance, and cash flows. Entities are required to provide enhanced disclosures about: (a) how and why an entity uses derivative instruments; (b) how derivative instruments and related hedged items are accounted for under SFAS No. 133 and its related interpretations; and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. SFAS 161 is effective for financial statements issued for fiscal years beginning after November 15, 2008, with early adoption encouraged. Because SFAS 161 only requires additional disclosure, we do not expect it to have a significant impact on our consolidated financial statements.

Effective January 1, 2008, we adopted SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115," or SFAS 159. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value, thereby providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. The amendment to SFAS 115 applies to all entities with available-for-sale and trading securities. The adoption of SFAS 159 did not have a material impact on our consolidated financial statements since we did not initially elect to apply the fair value option for any of our

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financial assets or liabilities as of the adoption date. See Note B for discussion of fair value election in November 2008 with respect to our settlement rights.

Effective January 1, 2008, we adopted EITF 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities," or EITF 07-3. EITF 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed. The adoption of EITF 07-03 did not have a material impact on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), "Business Combinations," or SFAS 141R. SFAS 141R establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquiree and the goodwill acquired. SFAS 141R also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. SFAS 141R became effective on a prospective basis for our financial statements beginning on January 1, 2009. Accordingly, any future business combination we enter into would be subject to SFAS 141R.

In November 2007, the EITF reached a consensus on Issue 07-01, "Accounting for Collaborative Arrangements," or EITF 07-01, which addresses how the parties to a collaborative agreement should account for costs incurred and revenues generated on sales to third parties, how sharing payments pursuant to a collaboration agreement should be presented in the income statement and certain related disclosure questions. EITF 07-01 is effective for years beginning after December 15, 2008. Accordingly, we are in the process of evaluating the impact of EITF 07-01.

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements," or SFAS 157. This statement defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 applies under other accounting pronouncements that require or permit fair value measurements, the FASB having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, SFAS 157 does not require any new fair value measurements but rather eliminates inconsistencies in guidance found in various prior accounting policies. SFAS 157 is effective for years beginning after November 15, 2007, and interim periods within those fiscal years. In February 2008, the FASB issued FASB Staff Position, or FSP, 157-2, which delays the effective date of SFAS 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), until fiscal years beginning after November 15, 2008, and interim periods within those fiscal years. These nonfinancial items include assets and liabilities such as reporting units measured at fair value in a goodwill impairment test and nonfinancial assets acquired and liabilities assumed in a business combination. In October 2008, the FASB issued FSP No. 157-3, "Determining the Fair Value of a Financial Asset When the Market for That Asset is Not Active," or FSP 157-3. FSP 157-3 clarifies the application of SFAS 157 in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. FSP 157-3 was effective upon issuance, including prior periods for which financial statements have not been issued. Effective January 1, 2008, we partially adopted SFAS 157 for financial assets and liabilities recognized at fair value on a recurring basis. The partial adoption of SFAS 157 for financial assets and liabilities did not have a material impact on our consolidated financial statements. The provisions of SFAS 157 related to other nonfinancial assets and liabilities were effective for us on January 1, 2009, and will be applied prospectively. We do not expect that these additional SFAS 157 provisions will have a material impact on our consolidated financial statements.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES:

Managements' Evaluation of our Disclosure Controls and Procedures

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our "disclosure controls and procedures" (as defined in the Exchange Act Rule 13a-15(e), or Rule 15d-15(e)), with the participation of our management, have each concluded that, as of the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures were effective and were designed to ensure that information we are required to disclose in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, is accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure, and is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. It should be noted that any system of controls is designed to provide reasonable, but not absolute, assurances that the system will achieve its stated goals under all reasonably foreseeable circumstances. Our principal executive officer and principal financial officer have each concluded that our disclosure controls and procedures as of the end of the period covered by this report are effective at a level that provides such reasonable assurances.

Management's Annual Report on Internal Control Over Financial Reporting

The report of our management on both management's responsibility for financial statements and management's annual report on internal control over financial reporting is contained in Part II, Item 8 "Financial Statements and Supplementary Data" of this Annual Report on Form 10-K for the year ended December 31, 2008.

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, 2008 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 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, 2008.

ITEM 11. EXECUTIVE COMPENSATION:

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the SEC not later than 120 days after the close of our year ended December 31, 2008.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS:

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the SEC not later than 120 days after the close of our year ended December 31, 2008.

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

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the SEC not later than 120 days after the close of our year ended December 31, 2008.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES:

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the SEC not later than 120 days after the close of our year ended December 31, 2008.

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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, 2008 and 2007

Consolidated Statements of Operations for the years ended December 31, 2008 and 2007, the three months ended December 31, 2006 and the year ended September 30, 2006

Consolidated Statements of Comprehensive Loss for the years ended December 31, 2008 and 2007, the three months ended December 31, 2006 and the year ended September 30, 2006

Consolidated Statements of Stockholders' Equity for the years ended December 31, 2008 and 2007, the three months ended December 31, 2006 and the year ended September 30, 2006

Consolidated Statements of Cash Flows for the years ended December 31, 2008 and 2007, the three months ended December 31, 2006 and the year ended September 30, 2006

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).
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Representative Form of Indemnification Agreement dated as of August 9, 2004 (incorporated herein by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-3, File No. 333-119682).

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10.5*	Stock Option Agreement, dated as of November 22, 2005, between Advanced Magnetics, Inc. and Brian J.G. Pereira (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed November 22, 2005, File No. 0-14732).
10.6*	Stock Option Agreement, dated as of November 22, 2005, between Advanced Magnetics, Inc. and Brian J.G. Pereira (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed November 22, 2005, File No. 0-14732).
10.7*	Stock Option Agreement, dated as of February 7, 2006, between Advanced Magnetics, Inc. and Brian J.G. Pereira (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed February 13, 2006, File No. 0-14732).
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10.9*	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).
10.10*	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).
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10.15*	Amended and Restated Employment Agreement dated as of July 31, 2007 between the Company and David Arkowitz (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed August 3, 2007, 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).
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.
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+ 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 27, 2009

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 27, 2009
/s/ DAVID A. ARKOWITZ David A. Arkowitz	Executive Vice President, Chief Financial Officer and Chief Business Officer (Principal Financial and Accounting Officer)	February 27, 2009
/s/ MICHAEL D. LOBERG, PHD Dr. Michael D. Loberg	Director	February 27, 2009
/s/ MARK SKALETSKY Mark Skaletsky	Director	February 27, 2009
/s/ MICHAEL NARACHI Michael Narachi	Director	February 27, 2009
/s/ RON ZWANZIGER Ron Zwanziger	Director	February 27, 2009
/s/ DAVEY S. SCOON Davey S. Scoon	Director	February 27, 2009
/s/ JOSEPH V. BONVENTRE, MD, PHD Joseph V. Bonventre, MD, PhD	Director	February 27, 2009
/s/ ROBERT J. PEREZ	Director	February 27, 2009

Robert J. Perez

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