AMAG PHARMACEUTICALS INC.
Form 10-K
February 27, 2008

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended December 31, 2007

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.)
125 CambridgePark Drive Cambridge, Massachusetts	**02140**
(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 ý No o**

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K o

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

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

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

The aggregate market value of the registrant's voting stock held by non-affiliates as of June 30, 2007 was approximately $979,000,000 based on the closing price of $58.16 of the Common Stock of the registrant as reported on the NASDAQ Global Market on such date. As of February 15, 2008, there were 16,981,862 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 6, 2008, 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 benefits of ferumoxytol and Combidex®, the progress of our intended development and commercialization of ferumoxytol and Combidex, the potential market demand for ferumoxytol and the total projected U.S. I.V. iron replacement therapy market, potential clinical trials of ferumoxytol we may initiate in indications other than chronic kidney disease, the potential approval of ferumoxytol and our other product candidates in areas outside the U.S., the potential size of any future royalty or milestone fees, our intent to secure second source manufacturing facilities, the scope of our patent protection and the enforceability of our patents, future revenues, research and development expenses, and sales, general and administrative expenses, our expectations regarding our short- and long-term capital requirements and our ability to finance our operations, 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 nanoparticle technology for the development and commercialization of therapeutic iron compounds to treat anemia as well as novel imaging agents to aid in the diagnosis of cancer and cardiovascular disease. We have two approved products, Feridex I.V.® and GastroMARK®, and two product candidates, ferumoxytol and Combidex®. Throughout this Annual Report on Form 10-K, AMAG Pharmaceuticals, Inc. and our consolidated subsidiary are collectively referred to as the Company.

Ferumoxytol, our key product candidate, is being developed for use as an intravenous, or IV, iron replacement therapeutic for the treatment of iron deficiency anemia in chronic kidney disease, or CKD, patients. In December 2007, we submitted a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or the FDA, seeking marketing approval for ferumoxytol as an IV iron replacement therapeutic in CKD patients, including both dialysis dependent and non-dialysis dependent patients. Our NDA has been accepted for standard review by the FDA and we expect FDA action by late October 2008. Our NDA is supported by data from three open-label, multi-center, randomized Phase III efficacy and safety clinical studies and a fourth Phase III safety study. The three efficacy and safety studies demonstrated a statistically significant achievement of all primary and secondary endpoints. In total, over 1,700 patients and healthy volunteers were treated with ferumoxytol in eleven clinical studies. We have released data on all four of our planned Phase III clinical trials of ferumoxytol as an IV iron replacement therapeutic in patients with CKD.

On January 30, 2008, we announced additional information regarding mortality rates and adverse events from our clinical development program for ferumoxytol as an IV treatment of iron deficiency

anemia in patients with CKD. According to the U.S. Renal Data System, or USRDS, 2007 Annual Data Report, morbidity and mortality rates among non-dialysis dependent and dialysis dependent CKD patients are high due to their underlying disease. Overall, in our ferumoxytol clinical development program that included 2,074 patients, 31 deaths were observed. None of these deaths were considered to be related to study treatment. The death rate in all four Phase III trials following ferumoxytol treatment was lower than following oral iron treatment. There were a total of 19 deaths out of 1,726 ferumoxytol-treated patients, or 1.1%, as compared to eight deaths out of a total of 290 oral iron-treated patients, or 2.8% across the four studies. In addition, there were four deaths in patients who did not receive any study medication. For deaths that occurred within 30 days of the last study treatment, the death rate was also lower following ferumoxytol treatment as compared to oral iron treatment. Twelve patients treated with ferumoxytol out of 1,726 ferumoxytol-treated patients, or 0.7%, and four patients treated with oral iron out of 290 oral iron-treated patients, or 1.4%, died within 30 days of the last study treatment.

In our three open-label, multi-center, randomized Phase III efficacy and safety clinical studies, the overall incidences of adverse events, or AEs, and serious adverse events, or SAEs, occurring after study treatment were both lower following ferumoxytol treatment of two 510 milligram doses than following oral iron treatment. The AE rate was 44.0% among ferumoxytol-treated patients as compared to 53.9% among oral iron-treated patients, and the SAE rate was 9.8% among ferumoxytol-treated patients as compared to 12.1% among oral iron-treated patients. The death rate across our three Phase III efficacy studies, excluding our safety study, was 1.3% following ferumoxytol treatment and 2.8% following oral iron treatment.

There were no significant mean changes in serum phosphorus levels and no reported AEs of hypophosphatemia, a condition wherein serum levels of phosphorus are below normal range, in our clinical development program. The mean serum phosphorus level was 4.53 milligrams per deciliter prior to administration of the first dose of ferumoxytol and 4.48 milligrams per deciliter on the 35th day after the first dose of ferumoxytol in 1,562 CKD patients treated with ferumoxytol, a mean change of -0.06 milligrams per deciliter. Patients treated with oral iron had comparable serum phosphorus levels prior to administration of the first dose of oral iron and on the 35th day after the first dose of oral iron of 4.66 milligrams per deciliter and 4.68 milligrams per deciliter, respectively, with a mean change of +0.04 milligrams per deciliter. In the three Phase III ferumoxytol safety and efficacy studies, the incidence of serious "cardiac" events, as defined by the Medical Dictionary for Regulatory Activities, was lower in the 605 patients in the ferumoxytol treatment group compared with the 280 patients in the oral iron treatment group. The incidence of serious cardiac events was 2.0% in the ferumoxytol treatment group as compared to 3.6% in the oral iron treatment group.

In mid-2008 we intend to initiate additional Phase II and/or Phase III studies in patient populations other than CKD patients. Iron deficiency anemia is widely prevalent in many different patient populations, including elderly patients and women, and disease states including cancer, gastrointestinal diseases, as well as patients undergoing various surgical procedures. We believe the product characteristics of ferumoxytol could support clinical development in additional indications.

We are currently in the process of building our own internal sales and marketing function, including a direct sales force, in preparation for the potential commercial launch of ferumoxytol as an IV iron replacement therapeutic in CKD patients in the U.S. in 2009.

We are also currently evaluating our strategy for seeking approval for ferumoxytol as an IV iron replacement therapeutic in countries outside the U.S. The commercial opportunity for ferumoxytol as an IV iron replacement therapeutic varies from country to country, and in determining which markets outside the U.S. we intend to enter, we are assessing factors such as potential pricing and reimbursement, patient access to dialysis and the role of iron in medical treatment protocols in each country. We are also currently evaluating possible strategic alliances and partnerships to assist us in entering attractive foreign markets.

Combidex, our other product under development, is an investigational functional molecular imaging agent consisting of iron oxide nanoparticles for use in conjunction with magnetic resonance imaging, or MRI, to aid in the differentiation of cancerous from normal lymph nodes. In March 2005, we received an approvable letter from the FDA with respect to *Combidex,* subject to certain conditions. In December 2006, Guerbet S.A, or Guerbet, our partner, submitted a marketing authorization application, the European equivalent of an NDA, to the European Agency for the Evaluation of Medicinal Products, or the EMEA, seeking approval for *Combidex* under the tradename Sinerem® as an aid in the differentiation of lymph nodes in patients with pelvic cancers, including prostate, bladder, cervical and uterine cancer. In December 2007 Guerbet withdrew its EMEA application for Sinerem® after the Committee for Medicinal Products for Human Use indicated that the data submitted by Guerbet did not provide sufficient statistical demonstration of the efficacy of Sinerem®. Based on our review of the data from the Guerbet trial, it appears unlikely that the data from that trial will be sufficient to address the concerns raised by the FDA, which means we may have to sponsor one or more additional clinical trials to obtain approval for *Combidex*. We cannot at this time predict with certainty the timing or likelihood of our ability to satisfy the conditions specified by the FDA for approval of *Combidex*, if at all.

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

From 1991 to June 26, 2006, our common stock was traded on the American Stock Exchange under the trading symbol "AVM." As of June 27, 2006, our common stock began trading on the NASDAQ Global Market, or the NASDAQ, under the trading symbol "AMAG."

In May 2007 we changed our fiscal year end to December 31 from September 30, and therefore information is included in this report for the three months ended December 31, 2006, which we refer to as our transition period, and the calendar year ended December 31, 2007. Unless specifically indicated otherwise, any reference to "2007" relates to December 31, 2007 or the year ended December 31, 2007 and any reference to "2006" and "2005" relates to December 31, 2006 and 2005 or the year ended December 31, 2006 and 2005.

In July 2007, we changed our corporate name from Advanced Magnetics, Inc. to AMAG Pharmaceuticals, Inc. The name change was effected pursuant to Section 253 of the Delaware General Corporate Law through a merger of a newly-created, wholly-owned subsidiary with and into Advanced Magnetics, Inc. The name change did not require stockholder approval.

In August 2007, we formed a Massachusetts corporation as a wholly-owned subsidiary of our company, which is classified as a securities corporation pursuant to Chapter 63, Section 38B of the Massachusetts General Laws, for the purpose of buying, selling and holding investment securities on our own behalf. The amounts set forth in this Annual Report on Form 10-K include our accounts and the accounts of our wholly-owned subsidiary, AMAG Securities Corporation.

Our Core Technology

Our core technology is based on the characteristic properties of extremely small, coated superparamagnetic iron oxide nanoparticles. 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 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 in 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 increase the information available to the reviewing physicians. Our rights to our technology are derived from and/or protected by license agreements, patents, patent applications and trade secret protections. See "Patents and Trade Secrets."

Products and Product Candidates

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

Product or Product Candidate	Applications	Marketing Partners	U.S. Status	Foreign Status
ferumoxytol	IV iron replacement therapeutic	None	NDA for CKD accepted for standard review with expected FDA action by late October 2008	None
	Imaging agent	None	Exploratory Phase II clinical trials completed	None
Combidex	Differentiation of cancerous from normal lymph nodes	Guerbet (various countries in the European Union, South America, the Middle East, southeast Asia, Africa, Mexico, and eastern Europe); and TaeJoon (South Korea)	Received approvable letter from FDA in March 2005	Marketing authorization application submitted by Guerbet to the EMEA withdrawn in December 2007
Feridex I.V.	Diagnosis of liver lesions	Bayer Healthcare Pharmaceuticals (U.S.); and TaeJoon (South Korea)	Approved and marketed	Approved and marketed in most European Union countries
GastroMARK	Delineating the bowel in abdominal imaging	Covidien, Ltd. (U.S.); and Guerbet (various countries in the European Union, South America, the Middle East, southeast Asia, Africa and eastern Europe)	Approved and marketed	Approved and marketed in several European Union countries

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

Ferumoxytol as an IV Iron Replacement Therapeutic

Overview

IV iron replacement therapy plays a major role, along with erythropoietin, a hormone produced in the kidneys that stimulates red blood cell production, in treating certain types of chronic anemia in patients suffering from CKD as well as in many patients receiving chemotherapy. The National Kidney Foundation's Kidney Disease Outcomes Quality Initiative, or KDOQI, stages patients with CKD based on their level of kidney function, whether or not they are on dialysis, and whether or not they have received a kidney transplant. In an average adult, the normal kidney filters approximately 125 milliliters of blood per minute, and this is called the glomerular filtration rate, or GFR. The KDOQI guidelines classify patients with abnormalities of kidney structure and a GFR between 90 and 120 milliliters per minute as stage 1 CKD, and between 60 and 90 milliliters per minute as stage 2 CKD. Patients with a GFR between 30 and 60 milliliters per minute for more than 3 months, irrespective of the presence of structural abnormalities of the kidney are classified as stage 3 CKD. Likewise, patients with a GFR between 15 and 30 milliliters per minute are stage 4 CKD and those with less than 15 milliliters per minute are stage 5 CKD. Patients who are on dialysis invariably have a GFR less than 15 milliliters per minute and are classified as stage 5D. Kidney transplant recipients with a functioning kidney are classified as stages 1T through 5T CKD, based on their level of GFR.

According to the USRDS there were over 340,000 CKD patients on dialysis in the U.S. on December 31, 2005. Over 90% of these CKD 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 moderate, or stage 3, or severe, or stage 4, CKD who were not yet on dialysis. If these prevalence estimates are applied to the US Census population estimates for 2007, then the stage 3 and 4 CKD prevalence is over 18 million. Among these patients, more than 3 million have anemia based on extrapolation of data analyzed from a large health management organization. Moreover, data presented at the National Kidney Foundation Meeting in 2006 showed that 38% of anemic patients with stage 3 or 4 CKD, or over 1.3 million, had evidence of absolute iron deficiency and would therefore benefit from receiving IV iron.

CKD and Anemia

Anemia develops early during the course of CKD. Iron deficiency is a common cause of anemia in CKD patients and can be caused by multiple blood draws, hospitalizations and interventional procedures, gastrointestinal bleeding or poor nutritional intake. Iron deficiency is worse in hemodialysis patients due to the additional blood loss in the dialysis procedure. In addition, diseased kidneys do 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 erythropoietin 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 iron deficiency anemia and require iron replacement therapy.

Ferumoxytol and the Treatment of Chronic Anemia in CKD

The National Kidney Foundation's KDOQI guidelines recommend starting stage 1 through 5 CKD patients who need iron on oral iron supplements as a first-line treatment for iron deficiency anemia. 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 that cause people to stop taking the oral iron supplements. IV iron replacement therapeutics allow greater amounts of iron to be

provided to patients whose iron stores have been severely depleted while avoiding the side effects associated with oral iron supplements. However, there are certain adverse reactions and side effects associated with IV iron replacement therapeutics that may make such products less safe than oral iron.

We have completed four pivotal Phase III clinical studies for ferumoxytol as an IV iron replacement therapeutic in patients with CKD. These trials have included patients with all stages of CKD, including patients with stage 1 through 5 CKD who are not on dialysis, patients with stage 5D CKD who are on hemodialysis or peritoneal dialysis and kidney transplant recipients with stages 1 through 5 CKD, or 1T through 5T CKD. Two of our four pivotal Phase III studies were identical efficacy and safety studies in non-dialysis patients with stages 1 through 5 CKD who were randomized in a 3 to 1 ratio to receive either two IV doses of 510 milligrams of ferumoxytol 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. Among the 304 patients in the first study, for the primary efficacy endpoint on the 35th day after the first dose of the study drug, patients receiving ferumoxytol achieved a significantly greater mean increase in hemoglobin as compared to patients in the oral iron group. The mean increase in hemoglobin in the ferumoxytol group was 0.82 grams per deciliter as compared to 0.16 grams per deciliter in the oral iron group. For one secondary endpoint, 39.0% of ferumoxytol-treated patients achieved an increase in hemoglobin of greater than 1 gram per deciliter on the 35th day after the first dose of the study drug as compared to 18.4% of oral iron-treated patients, a difference that was statistically significant. For another secondary endpoint, ferumoxytol-treated patients achieved a mean increase in serum ferritin levels of 518 nanograms per milliliter on the 21st day after the first dose of the study drug as compared to 6.5 nanograms per milliliter in oral iron-treated patients, a difference that was also statistically significant. Additionally, all primary and secondary efficacy endpoints were statistically significant in both patients on ESAs and those not on ESAs. In this study, AEs occurred in 35.5% of ferumoxytol-treated patients as compared to 52.0% of oral iron-treated patients. Similarly, drug-related AEs occurred in 10.6% of ferumoxytol-treated patients as compared to 24.0% of oral iron-treated patients. There were no drug-related SAEs in either group. These results were first presented at the American Society of Nephrology's Renal Week 2006 Annual Meeting in November 2006.

The second identical efficacy and safety trial in 303 non-dialysis patients with stages 1 through 5 CKD also demonstrated a statistically significant achievement of all primary and secondary efficacy endpoints. For the primary efficacy endpoint, patients receiving ferumoxytol were found to have had a significantly greater mean increase in hemoglobin on the 35th day after the first dose of the study drug as compared to patients in the oral iron group. The mean increase in hemoglobin in the ferumoxytol group was 1.22 grams per deciliter as compared to 0.52 grams per deciliter in the oral iron group. For one secondary endpoint, 51.8% of ferumoxytol-treated patients achieved an increase in hemoglobin of greater than 1 gram per deciliter on the 35th day after the first dose of the study drug as compared to 19.5% of oral iron-treated patients, a difference that was statistically significant. For another secondary endpoint, ferumoxytol-treated patients achieved a mean increase in serum ferritin levels of 412.6 nanograms per milliliter on the 21st day after the first dose of the study drug as compared to 4.3 nanograms per milliliter in oral iron-treated patients, a difference that was also statistically significant. All primary and secondary efficacy endpoints were statistically significant in both patients on ESAs and those not on ESAs. AEs occurred in 55.9% of ferumoxytol-treated patients as compared to 58.1% of oral iron-treated patients. Drug-related AEs occurred in 21.4% of ferumoxytol-treated patients as compared to 16.2% of oral iron-treated patients. SAEs occurred in 7.7% of ferumoxytol-treated patients as compared to 13.5% of oral iron-treated patients. There were no drug-related SAEs in ferumoxytol treated patients. There was one drug-related SAE in an oral iron treated patient, a case of severe gastritis which led to discontinuation of the study drug. These results were first presented at the National Kidney Foundation Clinical Meetings in April 2007.

The third pivotal Phase III trial, an efficacy and safety trial in CKD patients on hemodialysis also demonstrated a statistically significant achievement of all primary and secondary efficacy endpoints. This study randomized 230 hemodialysis patients who were receiving stable doses of erythropoietin

therapy in a 1 to 1 ratio to receive either two 510 milligram doses of ferumoxytol within one week or 200 milligrams of oral iron daily for three weeks. For the primary endpoint, patients receiving ferumoxytol achieved a significantly greater mean increase in hemoglobin on the 35th day after the first dose of the study drug as compared to patients receiving oral iron. The mean increase in hemoglobin in the ferumoxytol group was 1.02 grams per deciliter as compared to 0.46 grams per deciliter in the oral iron group. For one secondary endpoint, 49.1% of ferumoxytol-treated patients achieved an increase in hemoglobin of greater than 1 gram per deciliter on the 35th day after the first dose of the study drug as compared to 25.0% of oral iron-treated patients, a difference that was statistically significant. For another secondary endpoint, ferumoxytol-treated patients achieved a mean increase in serum ferritin levels of 356.7 nanograms per milliliter on the 21st day after the first dose of the study drug as compared to 37.6 nanograms per milliliter in oral iron-treated patients, a difference that was also statistically significant. AEs occurred in 49.1% of patients after ferumoxytol administration and in 57.0% of patients after oral iron administration. Drug-related AEs occurred in 8.2% of patients after ferumoxytol administration and in 15.8% of patients after oral iron administration. One drug-related SAE occurred in a patient after ferumoxytol administration. The patient experienced transient hypotension and recovered without sequelae. There were no drug-related SAEs in the oral iron-treated patients in this study. These results were first presented at the American Society of Nephrology's Renal Week 2007 Annual Meeting in November 2007.

The fourth pivotal Phase III study was a double-blind, placebo-controlled, crossover safety study in 750 patients across all stages of CKD, comparing a single dose of 510 milligrams of ferumoxytol to normal saline as placebo. AEs occurred in 21.3% of patients after ferumoxytol administration and in 16.7% of patients after placebo administration. On a blinded basis, these were deemed to be related to treatment by the investigator in 5.2% of patients after ferumoxytol and in 4.5% of patients after placebo. SAEs occurred in 2.9% of patients after ferumoxytol administration and in 1.8% of patients after placebo. On a blinded basis, these SAEs were deemed to be related to treatment by the investigator in one patient after ferumoxytol and in one patient after placebo. The single SAE attributed to the drug after ferumoxytol 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 ferumoxytol administration, was treated with subcutaneous epinephrine and recovered without sequelae. The single SAE attributed to the drug after placebo administration occurred in an 81 year-old female, with non-dialysis dependent CKD, hypertension, atrial fibrillation, oxygen-dependent chronic obstructive pulmonary disease, hypothryroidism and gout. The patient developed a petechial rash one day after placebo administration, was withdrawn from the study and did not receive ferumoxytol. The results for this fourth study were first presented at the National Kidney Foundation Clinical Meetings in April 2007.

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

In March 2007, the independent Data Monitoring Committee, or DMC, that provided oversight of our ferumoxytol Phase III IV iron replacement therapy program met for the final time and informed us that it had carefully reviewed the cumulative safety data from the ferumoxytol Phase III studies and identified no safety concerns. At that meeting, the DMC reviewed cumulative safety data from 1,610 patients enrolled in the Phase III program. The DMC had also met to review cumulative safety data in October 2005, February 2006, June 2006 and October 2006. At each of these meetings, the DMC identified no safety concerns and recommended the continuation of the Phase III studies with no modifications. At all meetings, the DMC had available to it data on all AEs, SAEs and patient disposition.

The Role of ferumoxytol as a Vascular Enhancement Agent in MRI

As a blood pool agent with a long blood half-life as compared to currently approved MRI contrast agents, ferumoxytol may be useful as a vascular enhancing agent in a wide range of applications in MRI. We have completed exploratory Phase II clinical studies for use of ferumoxytol in vascular-enhanced magnetic resonance angiography, or MRA, a type of MRI. Current approved contrast agents used for MRI are gadolinium-based and are associated with severe AEs in patients with CKD. On September 28, 2007 the FDA issued a "Black Box" warning due to Nephrogenic Systemic Fibrosis, or NSF, for all gadolinium-based contrast agents in certain patients. NSF is a condition that so far has only occurred in patients with kidney disease. Currently there is no effective treatment for NSF. We are currently considering whether and how to proceed with our development program for ferumoxytol as an imaging agent.

We currently have exclusive rights to market and sell ferumoxytol worldwide.

The Role of *Combidex* in Macrophage-Enhanced MRI

MRI is a non-invasive method used to visualize internal structures, abnormalities or anatomical changes in order to diagnose disease and injury. Imaging agents play a significant role in improving the quality of diagnostic images by increasing the contrast between different internal structures or types of tissues in various disease states. Lymph node imaging plays an important role in staging cancer patients and determining appropriate patient management. *Combidex* is an investigational functional molecular imaging agent that localizes to and causes enhancement of the macrophages in normal lymph nodes. Clinical trials have demonstrated that MRI exams of nodes using *Combidex* as part of staging cancer may provide increased accuracy in the evaluation of lymph nodes as cancerous or normal. There are no MRI agents designed specifically for imaging lymph nodes currently on the market.

Many different types of cancers can spread to the lymph nodes, particularly prostate and breast cancer. According to the American Cancer Society 2007 Cancer Facts and Figures, approximately 1.4 million new cases of cancer that could spread to the lymph nodes were projected to have been diagnosed during 2006. The modalities currently used for imaging lymph nodes include computed tomography, or CT, MRI without contrast, ultrasound and positron emission tomography, or PET, alone or in combination with CT. Except for PET/CT, these imaging modalities cannot distinguish between nodes enlarged due to inflammation and enlarged cancerous nodes, nor can they identify cancerous nodes that are not enlarged. Therefore, the current practice is to assume that enlarged nodes (typically greater than ten millimeters in size) are cancerous and to perform a biopsy to establish their true status. PET relies on the increased metabolism often found in cancerous tissue, but generally cannot detect lesions less than 8 to 10 millimeters and often falsely suggests cancer in other conditions with increased metabolic activity, for example, infection. Also, PET/CT and CT expose the patient to high doses of radiation. We have demonstrated in clinical studies that *Combidex* only accumulates in normal lymph nodes and therefore may facilitate differentiation between cancerous nodes and normal nodes. Normal nodes range in size from 3 to 10 millimeters, and clinical studies have shown that MRI can identify the accumulation of *Combidex* in these small structures. CT has similar ability to identify the size of nodes, but cannot image their internal composition. PET imaging has the ability to identify cancer-related changes in metabolism, but lacks the resolution to do so in smaller nodes. We believe that *Combidex*, if approved, could enable physicians using MRI to improve diagnostic confidence in differentiating between normal and cancerous lymph nodes, irrespective of node size.

We have granted exclusive rights to market and sell *Combidex* to Guerbet in various countries in the EU, South America, the Middle East, southeast Asia, Africa, Mexico and eastern Europe under the tradename Sinerem® and to TaeJoon Pharm Co., Ltd., or TaeJoon, in South Korea. See "Licensing, Marketing and Supply Arrangements." We have exclusive rights to market *Combidex* in the U.S. and other regions not covered by our agreement with Guerbet and TaeJoon.

Feridex I.V.

Several types of cancer can spread to the liver. The ability to identify metastatic tumors in the liver plays a key role in staging patients and determining appropriate patient management. Diagnosis of metastases in the liver at an early stage can be difficult because small tumors are frequently not accompanied by detectable physical symptoms. We believe that contrast-enhanced MRI exams using *Feridex I.V.* enable the imaging of liver lesions that may not be visible with other modalities used for liver imaging.

Feridex I.V. was approved by the FDA in August 1996. Bayer Healthcare Pharmaceuticals (formerly known as Berlex Laboratories, Inc.), or Bayer, our exclusive U.S. marketing partner for *Feridex I.V.,* has been marketing *Feridex I.V.* in the U.S. since October 1996. *Feridex I.V.* was approved in August 1994 by the EU's Committee for Proprietary Medicinal Products and most of the member states of the EU have since issued local approvals to market *Feridex I.V.*. Guerbet has been marketing *Feridex I.V.* on an exclusive basis in Europe since late 1994, and subsequently acquired the rights to market *Feridex I.V.* in several other countries under the tradename Endorem . Our agreement related to *Feridex I.V.* with Guerbet terminated by its terms in 2007. 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.

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 April 1997. We initially licensed the marketing rights to *GastroMARK* on an exclusive basis to 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 strategy has included the formation of alliances with other pharmaceutical companies to facilitate the sale and distribution of our products. At present we have the following principal collaborations:

Bayer Healthcare Pharmaceuticals (formerly Berlex Laboratories, Inc.)

In February 1995, we entered into a license and marketing agreement and a supply agreement 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 agreement. Under the terms of the supply agreement, we receive payments for manufacturing the product and royalties on sales. Under the terms of our licensing and marketing agreement with Bayer, Bayer pays 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.* and do not intend to incur such expenses in the future. These agreements expire in 2010 but can be terminated earlier upon the occurrence of certain specified events.

Guerbet

In 1987, we entered into a supply and distribution agreement with Guerbet whereby Guerbet was appointed the exclusive distributor of *Feridex I.V.* in western Europe and Brazil (under the tradename Endorem®). This agreement was amended in 2002 to expand Guerbet's exclusive rights to distribute *Feridex I.V.* in various other areas, including South America, the Middle East, southeast Asia, and eastern Europe. The agreement was further amended in 2006 to expand Guerbet's exclusive rights to distribute *Feridex I.V.* in certain additional southeast Asian countries and South Africa. Guerbet is responsible for conducting clinical trials and securing the necessary regulatory approvals in the countries in its territory. Guerbet did not pursue marketing approval in all the countries in which it had rights. Under the terms of this agreement, Guerbet was obligated to pay royalties to us based on products shipped for resale. We were entitled to receive an additional percentage of Guerbet's sales in return for selling to Guerbet its requirements for the active ingredient used in *Feridex I.V.* The 1987 agreement with Guerbet terminated by its terms in 2007.

In 1989, we entered into a second 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. Guerbet has exercised its rights to manufacture and sell *Combidex* (under the tradename Sinerem®) in western Europe and Brazil. This agreement was amended in 2002 to expand Guerbet's exclusive rights to manufacture and sell *GastroMARK* and *Combidex* in various other areas, including South America, the Middle East, southeast Asia, and eastern Europe. The agreement was further amended in 2006 to expand Guerbet's exclusive rights to distribute *Combidex* in certain additional countries. However, Guerbet has not pursued marketing approval in all the countries in which it has rights. In February 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 ferumoxytol 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 *Combidex* and *GastroMARK*. The agreement is perpetual but terminable upon certain specified events.

Covidien (formerly Tyco Healthcare and Mallinckrodt Medical, 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.

Bristol-Myers Squibb Co.

In 1994, under an agreement with Bristol-Myers Squibb Co., or Bristol-Myers, we reacquired the development and marketing rights to *Combidex*, which had previously been licensed to Bristol-Myers. Pursuant to this agreement, we are obligated to pay up to a maximum of approximately $2.8 million in royalties to Bristol-Myers in connection with commercial product sales of *Combidex*. We have not paid any royalties with respect to this agreement to date.

Other

We are the licensee of certain technologies related to our 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 2007, 2006 or 2005. Future milestone payments under the Amersham agreement will not exceed $0.4 million.

We are a party to an agreement with FoxKiser Development Partners LLC, or FoxKiser, one of our regulatory consultants for *Combidex*, which provides for certain royalty payments to FoxKiser based on future commercial product sales of *Combidex*, if any. We do not expect any such royalty payments to be material.

Manufacturing and Supply Arrangements

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 bulk *Feridex I.V.* and *GastroMARK,* as well as *Feridex I.V.* finished product, *Combidex* bulk product for use in physician-sponsored clinical trials and ferumoxytol for use in human clinical trials. Our current plan is to use this facility to manufacture ferumoxytol for commercial sale if and when it is approved by the FDA. We are also currently working to identify, establish and qualify a second source manufacturing facility for the production of ferumoxytol. Use of a second-source manufacturing facility may increase the risk of certain problems, including cost overruns, process reproducibility, stability issues, or an inability to deliver required quantities of product that conform to specifications in a timely manner or the ability to continue to manufacture ferumoxytol in accordance with cGMP.

Although we have begun the work required to establish and qualify a second source manufacturing facility for ferumoxytol, we currently have one manufacturing facility at which we produce limited quantities of ferumoxytol. We have tested scale-up for production of ferumoxytol, but when we manufacture ferumoxytol 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 increase our manufacturing capacity in a timely and cost-effective manner to meet demand for ferumoxytol if and when it is approved by the FDA, and we may experience delays in manufacturing ferumoxytol. We will also need to recruit additional qualified manufacturing and quality control personnel as we prepare for production of ferumoxytol 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 ferumoxytol 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 ferumoxytol.

Raw Materials

We currently purchase the raw materials used to manufacture our products from third-party suppliers. Only in certain limited cases do we 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 our products, including ferumoxytol, are procured from a single source with no qualified alternative supplier. If any of these third-party suppliers should cease to produce the raw materials used in our products 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 the raw materials, labor disputes or shortages, manufacturing difficulties, or import or export problems, we would be unable to manufacture our products, including ferumoxytol, or be unable to manufacture our products 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 our products, including ferumoxytol, from an alternative source on commercially reasonable terms, or in a timely manner, if at all. Any inability to obtain raw materials and our reliance on sole source suppliers could adversely impact our ability to manufacture sufficient quantities of ferumoxytol.

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 pursue 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 approximately 18 U.S. patents and approximately 25 foreign patents, which expire between the years 2008 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.

Competition

Overview

The pharmaceutical and biopharmaceutical industries are subject to intense competition and rapid technological change. Most of our competitors have substantially greater financial resources and expertise in product development, manufacturing, conducting clinical trials, obtaining regulatory approval and marketing and selling approved products than we do and are developing iron replacement therapeutic products and MRI contrast agents. Products developed by our competitors may be safer and/or more effective than any products we develop or may render our technology obsolete. In addition, further technological and product developments may make other iron replacement therapy products more competitive than ferumoxytol or other imaging modalities more compelling than MRI, which would adversely impact potential sales of our iron replacement and imaging products, respectively, if such products are approved by the FDA. Certain of our collaborators are not restricted from developing and marketing certain competing imaging products and, as a result of certain cross-license agreements between us and these companies, they will be able to utilize elements of our technology in the development of certain competing contrast agents. 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, coverage and reimbursement for our products, our ability to implement effective marketing campaigns, 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 Competitive Landscape for Iron Replacement Therapy Products

Although we believe ferumoxytol may offer advantages over oral iron supplements and existing products in the iron replacement therapy market, competing iron replacement therapy products may receive greater acceptance. The iron replacement therapy market is highly sensitive to several factors including, but not limited to, the ability to obtain appropriate coverage and reimbursement, price competitiveness, and product characteristics such as dosing regimens and the means by which iron is administered. In particular, the iron replacement therapy market is extremely sensitive to the perceived relative safety profiles of the various iron replacement therapeutics currently on the market, and it will be critical for us to be able to demonstrate that ferumoxytol's safety profile is as good as or better than that of other iron replacement therapy products in order to be competitive in the marketplace.

There are currently two types of treatment options for treating iron deficiency anemia in CKD patients: oral iron supplements and IV iron. The National Kidney Foundation's KDOQI guidelines recommend starting CKD stages 1 through 5 patients who need iron on oral iron supplements as a first-line treatment for iron deficiency anemia. However, oral iron supplements have limited absorption in the gastrointestinal track, which adversely impacts 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 ferric gluconate, iron sucrose or iron dextran. The most frequently used IV iron products are currently comprised of sodium ferric gluconate or iron sucrose, 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. Ferumoxytol, if approved, would require two injections of approximately seventeen seconds each 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 current U.S. IV iron replacement therapy market at approximately $660 million in gross sales per year. Based on the projected growth of the dialysis dependent patient population by the United States Renal Data System, and the potential increased use of IV iron in the non-dialysis dependent CKD population, we believe that this market could grow to approximately $1 billion in gross sales by 2010.

There are currently four IV iron products commercially available in the U.S. for the treatment of iron deficiency anemia. Venofer®, an iron sucrose complex, and Dexferrum®, an iron dextran product, are marketed by American Regent Laboratories, Inc., or American Regent, a division of Luitpold Pharmaceuticals, Inc. Venofer® is approved for use in hemodialysis, peritoneal dialysis and non-dialysis dependent CKD patients. Dexferrum® is used in patients with documented iron deficiency in whom oral administration is unsatisfactory or impossible. Ferrlecit®, a sodium ferric gluconate marketed by Watson Pharmaceuticals, Inc., or Watson, is approved for use in hemodialysis patients. INFeD®, an iron dextran product also marketed by Watson, is used in patients with documented iron deficiency in whom oral administration is unsatisfactory or impossible.

IMS Health estimates that sales of Venofer® represent approximately 61%, sales of Ferrlecit® represent approximately 30%, sales of INFeD® represent approximately 7%, and sales of Dexferrum® represent approximately 2% of the 2007 U.S. IV iron therapy replacement market.

In addition, there are several iron replacement therapy products in various stages of clinical development in the U.S. and abroad, including VIT-45, also known as Ferinject® or Injectafer®, and soluble ferric pyrophosphate, or SFP.

American Regent has licensed the rights from Vifor (International) Ltd. to develop and commercialize VIT-45. VIT-45 is in clinical development for a variety of anemia-related indications, including CKD patients, whether or not on dialysis. 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® has been marketed in Germany since November 2007 and is scheduled to be marketed in Switzerland beginning in February 2008. In June 2006, VIT-45 was submitted for FDA review in the U.S. under the trade name Injectafer® for the treatment of iron deficiency anemia in heavy uterine bleeding, postpartum, inflammatory bowel disease and hemodialysis patients. In response to the June 2006 NDA submission, the FDA issued a non-approvable letter in July 2007. In September 2007, the sponsor submitted a response to the non-approvable letter including a statistical assessment of the mortality data, study reports for two additional studies performed among patients with CKD and responses to FDA questions. In November 2007, the sponsor changed the proposed indications to only patients with iron deficiency anemia in the post-partum condition or patients with heavy uterine bleeding. On February 1, 2008, an FDA advisory committee, the Drug Safety and Risk Management Committee, held a meeting to discuss the importance of the mortality data, SAE rates, including cardiac and infection events, and decrease in minerals such as blood phosphate level in the Injectafer® clinical development program and to advise the FDA on the marketing approval of Injectafer® for its proposed indications, including discussion on the need for additional clinical studies, a risk management plan and modification of the proposed indication or dosage regimen. The advisory committee voted that Injectafer® should only be approved for the treatment of iron deficiency anemia in post-partum women or women with heavy uterine bleeding who had an unsatisfactory response to, or were intolerant of, oral iron. The FDA is not required to follow the recommendations of the advisory committee. We believe the FDA will act upon the Injectafer® NDA sometime in March 2008, but we do not know if Injectafer® will receive U.S. approval at that time.

Rockwell Medical Technologies, Inc. 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. SFP is currently in Phase II clinical trials. In addition, in January 2008 Rockwell announced that patient enrollment had begun in a small study sponsored 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 in the treatment of iron deficiency anemia, could compete with IV iron products, including ferumoxytol.

Abbott Laboratories, Inc. has reportedly discontinued its development of IV iron oligosaccharide (FeOS) with Pharmacosmos A/S.

In addition to competition from the above branded products or product candidates, the market opportunity for ferumoxytol would be negatively affected if generic iron replacement therapy products were to be approved and achieve commercial success. 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.

MRI Contrast Agents

Factors critical to the success of our contrast agents, including ferumoxytol and *Combidex*, if approved, include market acceptance of MRI as a preferred technique for imaging. Although we believe that our contrast agents could offer advantages over competing MRI, CT or x-ray contrast agents, competing contrast agents might receive greater acceptance. Additionally, to the extent that other diagnostic techniques may be perceived as providing greater value than MRI, any corresponding decrease in the use of MRI could have an adverse effect on the demand for our contrast agent products. We may not be able to successfully develop safe and efficacious imaging products, obtain timely regulatory approvals, manufacture imaging products at commercially acceptable costs, obtain satisfactory reimbursement coverage, coding and payment for such products, successfully market such products alone or with our partners, gain satisfactory market acceptance, or otherwise successfully compete in the imaging market.

We are unaware of any approved products or drug candidates in human clinical development for use in MRI enhancement of lymph nodes other than *Combidex*. However, such products may exist and could negatively affect the marketing of our product.

Government Regulation

Overview

The development, manufacture and commercialization of our products and product candidates are subject to regulation by numerous governmental authorities in the U.S. and, in some instances, by foreign governments. Pursuant to the Federal Food, Drug, and Cosmetic Act, or the FDC Act, and the regulations promulgated thereunder, the FDA regulates the research and development, manufacturing, safety, labeling, storage, record-keeping, distribution, advertising and promotion of pharmaceutical products. The steps required by the FDA before new human pharmaceutical products, including iron replacement therapy products and contrast imaging agents, may be marketed, shipped by interstate commerce, or sold commercially in the U.S. include: (a) pre-clinical laboratory tests, pre-clinical 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 Good Clinical Practices, or GCP, to establish the safety and efficacy of the drug for its intended use; (d) submission to the FDA of an NDA; (e) approval and validation of manufacturing facilities used in production of the pharmaceutical product; and (f) review and approval of the NDA by the FDA.

The process of completing pre-clinical and clinical testing and obtaining the approval of the FDA and similar health authorities in foreign countries to market a new drug product requires a significant number of years and the expenditure of substantial resources, and is often subject to unanticipated delays. Despite our development efforts and the results of our clinical trials, we may not be able to obtain such approvals for our product candidates on a timely basis, if at all.

FDA Oversight of Pre-clinical and Clinical Studies

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.

Submission and FDA Review of an NDA

Following the conclusion 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. In conjunction with the submission of the NDA, the sponsor must pay certain fees to the FDA, which are required under PDUFA and are intended to decrease the amount of time the FDA takes to review NDAs by increasing the FDA's budget. The current fee for new NDAs that require clinical data is approximately $1.2 million. 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.

Although federal law requires that NDAs be reviewed within 180 days of their receipt, the FDA frequently requests the submission of supplementary materials, which may require significant additional time for a sponsor to prepare and/or for the FDA to review. It therefore frequently takes substantially more than 180 days to receive a decision letter from the FDA. Under the Food and Drug Administration Modernization Act, or FDAMA, 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 as 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. Any delay in obtaining regulatory approval could delay commercialization of our products and could consume substantial amounts of our resources, both financial and managerial.

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 action letter as to why it did not refer it to an advisory committee.

After completing its review of an NDA, the FDA will issue one of three types of letters: approval, approvable, or not approvable. If the sponsor receives an approval letter, it 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 an NDA substantially meets the requirements of the FDC Act, but can be approved only if specific additional information is provided or specific changes are made, the FDA can issue an approvable letter requesting such additional information or changes. Securing such additional information and/or agreeing to such proposed changes may be impractical or costly and may result in significant delays prior to final approval. If the FDA believes that an NDA cannot be approved due to one or more significant deficiencies, such as a lack of substantial evidence of efficacy or a failure to show that the drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling, then the FDA can issue a not approvable letter. If the FDA issues a not approvable letter, the sponsor may amend its application, withdraw its application, or ask the FDA to provide the applicant with a hearing on the question of whether there were grounds for denying approval.

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 market the approved product. Furthermore, even after initial FDA approval has been obtained, the FDA may require further studies 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. In addition, all companies with approved products are required to submit to the FDA reports on adverse drug experiences. These requirements include specific and timely notification of certain serious, unexpected and/or frequent AEs, as well as regular periodic reports summarizing adverse drug experiences. Product approvals may be withdrawn, and the product recalled, if compliance with regulatory standards is not maintained or if problems occur following commercialization.

Manufacturing procedures and quality control for approved drugs must conform to cGMP, which practices are described in the FDC Act and FDA guidance. cGMP requirements must be followed at all times, and domestic manufacturing establishments are subject to periodic inspections by the FDA in order to assess, among other things, cGMP compliance. 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 impose significant extra costs of compliance or limit our product sales, thereby reducing our revenues and profitability.

The FDA also places limits on the permitted marketing of approved products. Approved drug products must be promoted in a manner consistent with their terms and conditions of approval, including the scope of their approved use. 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.

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

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. Depending on our future activities, we may also need to obtain licenses or permits in other areas where we decide to manufacture, market or sell our products.

Foreign Regulation

To the extent we choose to develop, manufacture, market or sell ferumoxytol 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.

Reimbursement

In both the U.S. and foreign markets, our ability to successfully commercialize our products depends in significant part on the availability of 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 drugs which 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 our products and product candidates. 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, physician clinic, and hospital outpatient 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, or WAC. CMS typically requires two full quarters of sales data before transitioning a new product to an ASP-based reimbursement methodology.

These reimbursement policies may change prior to or after we seek to enter the CKD market in the U.S., and we cannot predict the impact any changes in reimbursement policies may have on our ability to compete effectively. In 2003, the Medicare Prescription Drug Improvement and Modernization Act, or PDIMA, required CMS to design a system that would no longer pay separately for physician-administered drugs in the end stage renal disease, or ESRD, market, but would instead bundle payments for these drugs together with other ESRD items and services under a single capitated payment. PDIMA also mandated that CMS implement a pilot, or demonstration, project to study the results of a bundled payment system. The demonstration project has not yet been implemented, but these "bundling" initiatives continue to be considered by Congress and CMS, and additional legislation is possible. Given the uncertainties surrounding bundling, we cannot predict the impact such a system would have on sales of our products in the CKD 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 scheme in the ESRD market could have a material negative impact on sales of ferumoxytol, the price we charge for ferumoxytol, and our overall revenues.

Medicare payments can also influence pricing in the non-Medicare markets, as third-party payors may base their reimbursement on the Medicare rate. 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.

If adequate reimbursement levels are not maintained by government and other third-party payors for our products and related treatments, our ability to sell our products may be limited and/or our ability to establish acceptable pricing schemes for our products 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 year ended December 31, 2007, the three months ended December 31, 2006 and the years ended September 30, 2006 and 2005. No other company accounted for more than 10% of our total revenues in any period presented below.

			For the Years Ended September 30,	
	For the Year Ended December 31, 2007	For the Three Months Ended December 31, 2006	2006	2005
Bayer	43%	31%	41%	47%
Guerbet	26%	45%	37%	20%
Covidien	15%	15%	11%	<10%
Cytogen	14%	<10%	<10%	22%

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 $0.3 million product sales backlog as of December 31, 2007 as compared to a $0.2 million product sales backlog of as of December 31, 2006.

Employees

As of February 15, 2008, we had 88 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, 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. For example, in order to achieve commercial success for ferumoxytol as an IV iron replacement therapeutic, we currently plan to and are building our own internal marketing and sales organization, including a direct sales force. We may not be able to successfully recruit and retain the qualified marketing and sales personnel that would be necessary to market and sell ferumoxytol.

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

Foreign Operations

We have no foreign operations. Revenues for the year ended December 31, 2007, the three months ended December 31, 2006, and the years ended September 30, 2006 and 2005 from customers outside of the U.S., principally in Europe and Japan, amounted to 28%, 47%, 41%, and 22%, respectively, of our total revenues.

Product Liability Insurance

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 whether in clinical trials or after approved commercial usage. However, coverage is becoming increasingly expensive and our insurance may not provide sufficient coverage to fully protect us against liability. If we are unable to maintain sufficient levels of insurance due to increased costs or if our insurance does not provide sufficient coverage against liability claims, a finding of liability could deplete our resources and reduce the assets available for our daily operations.

Research and Development

We have dedicated a significant portion of our resources in our efforts to develop our product candidates, ferumoxytol and *Combidex*. We incurred research and development expenses of $24.2 million, $6.4 million, $21.3 million and $12.0 million, during the year ended December 31, 2007, the three months ended December 31, 2006, and the years ended September 30, 2006 and 2005, respectively. We anticipate that a significant portion of our operating expenses will continue to be related to research and development in 2008.

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 the NASDAQ requirements. 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 the regulations of the NASDAQ, 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 report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and 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., 125 CambridgePark Drive, Cambridge, MA 02140.

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

ITEM 1A. RISK FACTORS:

The following 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 highly dependent on the success of our key product candidate, ferumoxytol.

We are currently investing most of our efforts and financial resources in the development and commercialization of ferumoxytol. Any failure by us to obtain marketing approval for and successfully commercialize ferumoxytol as an IV iron replacement therapeutic would have a material adverse impact on our ability to generate revenues and our ability to achieve profitability. If we are unable to generate revenues from ferumoxytol, our ability to create long-term shareholder value and our business prospects will be very limited unless we are able to successfully develop and commercialize other products.

We have two products, *Feridex I.V.* and *GastroMARK*, currently approved for marketing and sale in the U.S. and in certain foreign jurisdictions. However, sales of *Feridex I.V.* and *GastroMARK* by our marketing partners have been at relatively low levels, and we expect sales of *Feridex I.V.* and *GastroMARK* will not substantially increase from their current levels overall. We have also received an approvable letter from the FDA with respect to *Combidex*, but approval of *Combidex* remains highly uncertain and subject to the satisfaction of certain conditions imposed by the FDA.

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 our current products or product candidates. Although we intend to initiate additional clinical trials in an effort to expand the potential indications for ferumoxytol, we are not currently conducting or sponsoring research to expand our product development pipeline beyond ferumoxytol. Any failure by us to develop and commercialize additional products and product candidates or additional indications for ferumoxytol will place greater pressure on the performance of our existing products and product candidates and will materially adversely affect our ability to increase revenues, our ability to achieve profitability, and the future prospects of our business.

We may never receive regulatory approval for the marketing and commercial sale of ferumoxytol or may experience significant delays in our efforts to obtain approval for ferumoxytol.

The FDA and comparable regulatory agencies in foreign countries impose substantial requirements on the development, production and commercial introduction of all drug products. Before obtaining regulatory approval for the commercial marketing and sale of ferumoxytol, we must demonstrate through extensive pre-clinical testing and human clinical trials that ferumoxytol is safe and efficacious. We have completed and publicly announced the results of all of our planned Phase III studies of ferumoxytol as an IV iron replacement therapeutic in patients with CKD and submitted an NDA to the FDA requesting approval to market and sell ferumoxytol in the U.S. However, even though the FDA has accepted our ferumoxytol NDA for filing, it may not be approved or may not be approved in a timely manner.

The FDA has substantial discretion in the approval process and may decide that our data is insufficient for approval. Clinical 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 may review our data and determine that ferumoxytol is not efficacious and/or does not have an acceptable safety profile, which could result in the FDA issuing a letter stating that ferumoxytol is not approvable or is approvable only if certain additional conditions are met.

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, or were otherwise not properly managed. For example, the FDA guidelines generally suggest that sponsors conduct two adequate and well-controlled studies to demonstrate the safety and efficacy of a product candidate such as ferumoxytol in support of FDA approval. FDA interpretation of the statutory requirements also states that a single study may be sufficient to support approval if the FDA determines that based on relevant science and other confirmatory evidence from pertinent, adequate and well-controlled studies, there is strong evidence to establish the safety and efficacy of the drug candidate to support using a single adequate and well-controlled study to demonstrate safety and efficacy and support approval. We have chosen to conduct only a single Phase III study for ferumoxytol as an IV iron replacement therapeutic in the hemodialysis dependent CKD patient population along with two additional Phase III studies of ferumoxytol in nondialysis dependent CKD patients and one additional safety study in patients with all stages of CKD. If the FDA determines that the results of our single study in hemodialysis dependent CKD patients, together with other confirmatory evidence we provide, is not sufficiently strong to demonstrate ferumoxytol's safety and efficacy in hemodialysis dependent CKD patients, then ferumoxytol may not be approved by the FDA for our proposed indication, may be approved for a more limited indication, or the FDA may require us to conduct additional studies before approving ferumoxytol for use in hemodialysis dependent CKD patients. In addition, in discussions with us, the FDA recommended that we test ferumoxytol at doses lower than 510 milligams. We chose to conduct our studies of ferumoxytol using primarily a 510 milligram dose. If the FDA determines that the data we submitted with our NDA does not support the safety of a 510 milligram dose, it could decide not to approve ferumoxytol at this dosing regimen or require additional studies prior to approval.

Any such deficiency in the design or oversight of our Phase III clinical studies that results in the FDA requiring us to conduct additional ferumoxytol studies would cause us to incur significant additional costs, experience significant delays in our efforts to obtain regulatory approval for ferumoxytol, or even prevent us from obtaining regulatory approval for ferumoxytol. The requirement to conduct additional trials or any other delay in obtaining regulatory approval would delay the commercialization of ferumoxytol and associated revenues, and would consume extensive amounts of our resources, both financial and managerial. 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.

Ferumoxytol's approved indication may be more restrictive than proposed in our application to the FDA, which would adversely impact our ability to generate revenues from sales of ferumoxytol.

Any regulatory approvals granted by the FDA may entail limitations on the approved indications of ferumoxytol. As part of our NDA, we have requested approval to market ferumoxytol as an IV iron replacement therapy for iron deficiency anemia in all CKD patients, whether or not on dialysis. The FDA could determine that the data from our clinical trials is adequate to show safety and efficacy in only a portion of the CKD population, in which case the FDA might approve ferumoxytol only for marketing in a subset of the CKD population. Even if approved, the FDA may impose labeling requirements that adversely impact our ability to successfully market ferumoxytol. For example, if the FDA determines that our data demonstrates significant safety concerns, ferumoxytol's label could include a "black box" warning indicating significant concerns of AEs. Any such labeling requirements or limitations could significantly impair our ability to generate future revenues from product sales of ferumoxytol as an IV iron replacement therapeutic and adversely impact our ability to achieve profitability, and the future prospects for our business.

Ferumoxytol, even 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 ferumoxytol.

Even if approved, ferumoxytol will remain subject to FDA regulatory requirements and review pertaining to its manufacture, labeling, packaging, AE 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, restrictions on our continued manufacturing, marketing or sale of ferumoxytol, recalls or a refusal by the FDA to consider or approve applications for additional indications.

Significant safety or drug interaction problems could arise for ferumoxytol even after FDA approval, resulting in recalls, restrictions in ferumoxytol's label, or withdrawal of ferumoxytol 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 ferumoxytol 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 our labels or narrow our approved indications, each of which could reduce the market acceptance of ferumoxytol. In addition, if significant safety or drug interaction issues arise, FDA approval for ferumoxytol could be withdrawn and the FDA could require the recall of all existing ferumoxytol 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 ferumoxytol, and would have a severe adverse impact on our revenues, 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 ferumoxytol. 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 risk evaluation and mitigation strategies, or 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 ferumoxytol 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 ferumoxytol, or require us to expend significant additional funds on clinical studies.

Our ability to generate and grow revenues from the commercialization and sale of ferumoxytol will be limited if we do not obtain approval to market ferumoxytol for additional indications in the U.S. or if we do not obtain approval to market ferumoxytol in additional countries.

The NDA we submitted to the FDA in December 2007 requests approval to market and sell ferumoxytol in the U.S. as an IV iron replacement therapeutic for the treatment of iron deficiency anemia in CKD patients, whether or not on dialysis. We plan to conduct additional clinical trials and then seek regulatory approval to market ferumoxytol in additional indications. Before we can obtain approval to market ferumoxytol for these additional indications, we will need to successfully conduct clinical trials showing that ferumoxytol is safe and effective in these new patient populations and then apply for and obtain appropriate regulatory approvals. At this time, we have not begun any clinical studies of ferumoxytol as an IV iron replacement therapeutic in any patient populations other than CKD. 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 in additional patient populations in a timely manner or that, if completed, the results of such clinical trials will demonstrate ferumoxytol to be safe and effective in such patient populations.

To the extent we wish to manufacture, market or sell ferumoxytol 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 ferumoxytol indications in the U.S. or any failure to obtain approval outside the U.S. may limit the commercial success of ferumoxytol and our ability to grow our revenues.

Our ability to generate future revenues from ferumoxytol will depend heavily on our ability to obtain satisfactory coverage, reimbursement and pricing for ferumoxytol.

Our ability to successfully commercialize ferumoxytol will depend on the availability of adequate coverage and reimbursement for ferumoxytol 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 ferumoxytol. We expect that ferumoxytol 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 ferumoxytol if they do not receive adequate reimbursement.

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 ferumoxytol 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, limiting reimbursement where less-costly alternatives are available, 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 ferumoxytol, Medicare generally reimburses for physician-administered drugs in the dialysis center, physician clinic, and hospital outpatient settings at a rate of 106% of the drug's ASP. If CMS, or its local contractor, believes that ferumoxytol'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 ferumoxytol is approved by the FDA, and any changes in reimbursement policies may have a negative impact on the level of reimbursement available for ferumoxytol. In 2003, the PDIMA required CMS to design a system that would "bundle" payments for physician-administered drugs together with other ESRD items and services under a single capitated payment. PDIMA also mandated that CMS implement a pilot, or demonstration, project to study the results of a bundled payment system. The demonstration project has not yet been implemented, but bundling initiatives continue to be discussed by Congress and CMS, and additional legislation is possible. If bundling is initiated, it may lower utilization of physician-administered drugs in the ESRD market and may limit our ability to successfully market and sell ferumoxytol. While PDIMA applies only to Medicare, private payors and state Medicaid plans frequently adopt Medicare principles in setting their own reimbursement 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 ferumoxytol.

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 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 revenues in those countries.

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

At December 31, 2007, we had $28.2 million in cash and cash equivalents and $258.6 million classified as short-term investments. 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. 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.

Our investment portfolio included municipal auction rate securities of approximately $105.4 million as of December 31, 2007. These municipal auction rate securities have been recorded at cost, which approximated fair market value due to their variable interest rates. Auction rate securities are generally debt instruments that provide liquidity through a Dutch auction process that resets the applicable interest rate at pre-determined calendar intervals, generally 7 to 35 days. This auction mechanism generally allows existing investors to roll over their holdings and continue to own their securities or liquidate their holdings by selling their securities at par value. If auctions were to fail for securities in which we have invested, those investments will not be liquid. 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 redeems the outstanding securities, a buyer is found outside the auction process, or the securities mature which in almost all cases is more than one year and as many as 40 years in the future.

Beginning in mid-February 2008, several of our municipal auction rate securities experienced failed auctions. Since then, the continued uncertainty in the credit markets has caused additional auctions with respect to our auction rate securities to fail and prevented us from liquidating certain of our holdings of auction rate securities because the amount of these securities submitted for sale has exceeded the amount of purchase orders for these securities. There is a risk that auctions related to other securities that we own may fail and that there could be a 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 experience additional auction failures and/or determine that these declines in value of auction rate securities are other than temporary, we would recognize a loss in our consolidated statement of operations, which could be material. In addition, any future failed auctions may 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, however, we are uncertain when the current liquidity issues relating to auction rate securities 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 other investments. In addition, should our other investments cease paying or reduce the amount of interest paid to us, our interest income would suffer. These market risks associated with our investment portfolio may have an adverse effect on our results of operations, liquidity and financial condition.

Our corporate compliance program cannot ensure that we are in compliance with all applicable "fraud and abuse" 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, including ferumoxytol, 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 in the process of developing and implementing a corporate compliance program based on what we believe are current best practices in the pharmaceutical 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 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 approve ferumoxytol, restrictions on how we market and sell ferumoxytol, 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 ferumoxytol, require additional clinical trials or post-approval safety studies, or limit coverage or reimbursement for ferumoxytol. Any such new laws, regulations, decisions or interpretations may therefore have a significant adverse impact on our ability to successfully develop and commercialize ferumoxytol, and could have a material adverse impact on our ability to generate and grow our revenues and achieve profitability.

We have limited marketing and sales experience.

We have very limited experience in marketing and selling products, relying on our corporate partners to market and sell our current approved products, *Feridex I.V.* and *GastroMARK*.

In order to achieve commercial success for ferumoxytol as an IV iron replacement therapeutic, we will have to develop our own internal sales and marketing function, including a direct sales force in the U.S., enter into a collaborative arrangement with a third party or parties to market and sell ferumoxytol, or otherwise contract for these services with a third party. We are currently planning to, and we are in the process of, building our own internal sales and marketing function. Developing an internal marketing team and sales force is expensive and time-consuming. We may not be able to successfully recruit and retain the qualified marketing and sales personnel that will be necessary to effectively market and sell ferumoxytol. In addition, we will have to build our commercial infrastructure, hire our sales force, and expend substantial amounts of capital to prepare for the commercial launch of ferumoxytol before we know whether the FDA has approved the marketing and sale of ferumoxytol. If ferumoxytol is not approved by the FDA, we will 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, which would have a material adverse effect on our cash position. If, however, we choose not to market and sell ferumoxytol ourselves, we may not be able to contract with others for such services on acceptable terms, if at all.

If we are unsuccessful in developing our own sales and marketing function or if we are unsuccessful in entering into a collaborative relationship or otherwise contracting with a third party for such services, then our marketing efforts and our potential product launch of ferumoxytol as an IV iron replacement therapeutic would be delayed, and the commercialization of ferumoxytol would be severely

impaired. Furthermore, we may not be successful in marketing and selling ferumoxytol. Factors that may adversely impact our ability to effectively market and sell ferumoxytol include:

- Our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- The inability of our sales personnel to obtain access to and persuade adequate numbers of physicians to prescribe or use ferumoxytol;
- 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 creating a sales and marketing organization.

Any delay or failure in our commercial product launch of ferumoxytol as an IV iron replacement therapeutic would have a material adverse impact on our ability to generate revenues, our ability to achieve profitability, and the future prospects for our business.

The commercial success of ferumoxytol will depend upon the degree of 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, ferumoxytol may not achieve market acceptance among physicians, patients, healthcare payors or dialysis clinics. If ferumoxytol does not achieve an adequate level of market acceptance for any reason, sales of ferumoxytol, our potential profitability and our future business prospects would be severely adversely impacted. Ferumoxytol 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 ferumoxytol will depend on a number of factors, including:

- The establishment and demonstration in the medical community of the clinical efficacy and safety of ferumoxytol;
- The timing of market entry of ferumoxytol relative to competitive treatments;
- Our ability to sell ferumoxytol at competitive prices;
- The availability of sufficient third-party coverage and reimbursement;
- The relative convenience and ease of administration of ferumoxytol as compared to alternative iron therapies;
- The actual or perceived safety profile of ferumoxytol relative to alternative iron therapies;
- The availability of generic iron preparations;
- The strength of our marketing and distribution support; and
- The ferumoxytol labeling and product insert required by the FDA or regulatory agencies in other countries.

Currently IV iron therapeutic products are not widely used by physicians who treat pre-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 create a market for IV iron replacement therapeutics, specifically ferumoxytol, in the pre-dialysis CKD market. Therefore, if approved, it will be critical for us to successfully market and sell ferumoxytol to physicians who treat pre-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 ferumoxytol, if and when approved, to physicians who treat pre-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 on Medicare. Fresenius Medical Care, or Fresenius, and DaVita, Inc., or DaVita, treat more than 60% of the U.S. dialysis population. If we are unable to successfully market and sell ferumoxytol 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 ferumoxytol will be severely limited, which would have a material adverse impact on our potential profitability, and our future business prospects.

Competition in the pharmaceutical and biopharmaceutical industries is intense. If our competitors are able to develop and market products that are more effective, safer, less expensive or more convenient than ferumoxytol, our commercial opportunity for ferumoxytol will be reduced or eliminated.

The pharmaceutical and biopharmaceutical industries are subject to intense competition and rapid technological change. Most of our competitors have significantly greater financial resources and expertise in product development, manufacturing, conducting clinical trials, obtaining regulatory approvals, and marketing and selling approved products than we do. Our ferumoxytol commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer side effects, are less expensive, are easier to administer, or have more favorable pricing and reimbursement than ferumoxytol. In addition, any significant delays in the development, FDA approval or commercial launch of ferumoxytol could allow our competitors to bring products to market before we do and impair our ability to successfully commercialize ferumoxytol.

There are currently two types of treatment options for treating iron deficiency anemia in CKD patients: oral iron supplements and IV iron. We anticipate that, if approved, ferumoxytol will primarily compete with existing IV iron replacement therapies, including Venofer®, which is marketed by American Regent, Ferrlecit®, which is marketed by Watson, and certain oral iron products. Although we believe ferumoxytol will offer advantages over oral iron supplements and existing products in the IV iron replacement therapy market, competing iron replacement therapy products may receive greater market acceptance, 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 ferumoxytol even with supportive clinical data. The iron replacement market is highly sensitive to several factors including, but not limited to, the ability to obtain appropriate 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 for us to be able to demonstrate that ferumoxytol's safety profile is as good as or better than that of other IV iron replacement 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 ferumoxytol to other IV iron replacement products.

In addition to the currently marketed products, there are several iron replacement therapy products in various stages of clinical development in the U.S. and abroad, including VIT-45, also known as Ferinject® or Injectafer®, and SFP, a form of iron given as part of the hemodialysis procedure. In June 2006, The Galenica Group, a Swiss company, or Galenica, announced that Luitpold Pharmaceuticals, Inc., a subsidiary of Daiichi Sankyo, Inc. of Japan, and the U.S. licensing partner of Vifor (International), a Galenica subsidiary, submitted an NDA to the FDA for Ferinject® (under the name Injectafer®), an IV iron replacement product for the treatment of iron deficiency anemia in heavy uterine bleeding, postpartum, inflammatory bowel disease and hemodialysis patients. In response to the June 2006 NDA submission, the FDA issued a non-approvable letter in 2007. The sponsor submitted a response and changed its proposed indications to only patients with iron deficiency anemia in the post-partum condition or patients with heavy uterine bleeding. On February 1, 2008, an FDA advisory committee held a meeting to advise the FDA on the marketing approval of Injectafer® for its proposed indications. The advisory committee voted that Injectafer® should only be approved for the treatment of iron deficiency anemia in post-partum women or women with heavy uterine bleeding who

had an unsatisfactory response to, or were intolerant of, oral iron. The FDA is not required to follow the recommendations of the advisory committee. We believe the FDA will act upon the Injectafer® NDA some time in March 2008, but we do not know if Injectafer® will receive U.S. approval at that time. If any of these product candidates are approved for marketing and sale by the FDA before ferumoxytol is approved, our efforts to market and sell ferumoxytol, if approved, and our ability to generate additional revenues and achieve profitability would be adversely affected.

In addition to competition from currently approved products and products known by us to be currently under development, the market opportunity for ferumoxytol would be negatively affected if generic iron replacement therapy products were to be approved and achieve commercial success. Companies that manufacture generic products typically invest far less resources in research and development than the manufacture 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.

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 ferumoxytol.

Our inability to obtain raw materials and our reliance on sole source suppliers could adversely impact our ability to manufacture sufficient quantities of ferumoxytol, which would have a severe adverse impact on our business.

We currently purchase the raw materials used to manufacture our products, including ferumoxytol, from third-party suppliers. Only in certain limited cases do we have any long-term supply contracts with these third parties. Certain raw materials used in our products, including ferumoxytol, are procured from a single source with no qualified alternative supplier. If any of these third-party suppliers should cease to produce the raw materials used in our products 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 the raw materials, labor disputes or shortages, manufacturing difficulties, or import or export problems, we would be unable to manufacture our products, including ferumoxytol, or be unable to manufacture our products 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 ferumoxytol, 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 ferumoxytol, 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 ferumoxytol, 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 ferumoxytol and would have a material adverse impact on our ability to generate additional revenues and our ability to achieve profitability, and the future prospects of our business.

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

We currently manufacture bulk *Feridex I.V.* and *GastroMARK,* as well as *Feridex I.V.* finished product, *Combidex* bulk product for use in non-Phase III clinical trials and ferumoxytol for use in human clinical trials, in our Cambridge, MA manufacturing facility. Our current plan is to use this facility to manufacture ferumoxytol for commercial sale if and when it is approved by the FDA. Although we have begun the work to establish and qualify a second source manufacturing facility for ferumoxytol, we currently have one manufacturing facility at which we produce limited quantities of ferumoxytol. We have tested scale-up for production of ferumoxytol, but when we manufacture ferumoxytol 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 increase our manufacturing capacity in a timely and cost-effective manner to meet demand for ferumoxytol if and when it is approved by the FDA, and we may experience delays in manufacturing ferumoxytol. Furthermore, we will need to recruit additional qualified manufacturing and quality control personnel as we prepare for production of ferumoxytol 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 ferumoxytol in a timely manner, which could delay our product sales and development efforts.

In determining the required quantities of our products and the 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 need could result in unmet demand or in excess inventory, each of which would adversely impact our financial results and business prospects.

In addition, our manufacturing facility is subject to current cGMP regulations enforced by the FDA. We may not be able to continue to operate at commercial scale in compliance with cGMP regulations. Failure to operate in compliance with cGMP regulations and other applicable manufacturing requirements of various regulatory agencies could delay our development efforts and impede product sales due to the unavailability of an adequate supply of our products. Although we are working to establish and qualify a second source manufacturing facility for ferumoxytol, we may not be able to enter into agreements with manufacturers whose facilities and procedures comply with cGMP regulations and other regulatory requirements. Furthermore, use of a second-source manufacturing facility may increase the risk of certain problems, including cost overruns, process reproducibility, stability issues, or an inability to deliver required quantities of product that conform to specifications in a timely manner.

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. 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.

We may be unable to address the issues raised by the FDA in the March 2005 approvable letter with respect to Combidex, and we may not be able to obtain FDA approval for Combidex.

Although we have received an approvable letter from the FDA with respect to *Combidex*, approval of *Combidex* remains highly uncertain and subject to the satisfaction of certain conditions imposed by the FDA. We have considered whether additional data from a Phase III study sponsored by Guerbet in Europe in patients with pelvic cancers, including prostate, bladder, cervical and uterine cancer, together with other additional analyses and information we may provide to the FDA will address the concerns raised in the March 2005 approvable letter. Based on our review of the data from the Guerbet trial, it appears unlikely the data from that trial will be sufficient to address the concerns raised by the FDA, which means we may have to sponsor one or more additional clinical trials to obtain approval for

Combidex. We cannot at this time predict with certainty the timing or likelihood of our ability to satisfy the conditions specified by the FDA for approval of *Combidex*, if at all. If we are unable to successfully address the concerns of the FDA in a timely manner, the NDA for *Combidex* may not be approved, or, if approved, may be approved for a limited or much narrower indication. Any failure to successfully market and sell *Combidex* or any delay in these efforts would significantly impair or delay our ability to generate future revenues from product sales of *Combidex*, reduce the amount of cash generated from operations and adversely impact our potential 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 including:

- The timing and magnitude of costs associated with the potential commercial launch of ferumoxytol, including manufacturing costs and costs associated with hiring additional sales and marketing personnel, building our commercial infrastructure and executing promotional and marketing programs;

- The timing and magnitude of research and development expenses, in particular, those related to our development program for ferumoxytol as an IV iron replacement therapeutic;

- The timing and likelihood of FDA approval for ferumoxytol, including the magnitude of potential revenues associated with sales of ferumoxytol, if approved;

- The extent of and changes in reimbursement for our approved products from government health administration authorities, private health insurers and other third-party payors;

- The variable nature of product sales of our currently-approved products to our marketing partners and the batch size in which our products are manufactured;

- Uneven demand for our currently-approved products by end users, which affects the royalties we receive from our marketing partners; and

- The magnitude of future non-cash accounting charges we expect to record to expense in a given period as a result of our adoption of Statement of Financial Accounting Standards, or SFAS, 123R, "Share-Based Payment," or SFAS 123R.

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, we are highly reliant on certain of our executive officers, senior scientists, regulatory and clinical professionals, and manufacturing and quality control personnel, in particular our Chief Executive Officer and President, Brian J.G. Pereira, MD, and our Vice President of Scientific Operations, Jerome Lewis. If we are unable to retain these personnel, or we lose the services of our key personnel for any reason, our ferumoxytol development and commercialization efforts would be severely adversely impacted. In addition, in order to achieve commercial success for ferumoxytol as an IV iron replacement therapeutic, we will have to either develop our own internal marketing and sales function, including a direct sales force, enter into a collaborative arrangement with a third party or parties to market and sell ferumoxytol, or otherwise contract for these services with a third party. We are currently planning to, and are in the process of, building our own internal sales and marketing function, including a direct sales force. We may not be able to successfully recruit and retain the qualified marketing and sales personnel that will be necessary to effectively market and sell ferumoxytol. Furthermore, if we fail to recruit and retain additional key members of our manufacturing or quality control departments as we prepare for commercial scale

production of ferumoxytol, our ability to manufacture ferumoxytol, or to manufacture ferumoxytol in a timely and cost-effective manner, could be hindered and our product sales and development efforts delayed.

Furthermore, our expected expansion into areas and activities requiring additional expertise, such as late-stage development and marketing and sales, will require 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 complete our development projects.

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

Growth in our business has placed and may continue to place a significant strain on our employees, management, facilities and resources. In anticipation of the potential approval for ferumoxytol, we are quickly and significantly growing our regulatory, medical affairs, marketing, sales, manufacturing 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 ferumoxytol, 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 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, in-licensing opportunities, acquisitions of complementary products or businesses, and/or strategic alliances. 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 require management resources that otherwise would be available for ongoing development of our existing business and our anticipated commercial launch of ferumoxytol. 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 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.

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 ferumoxytol. In particular, we anticipate that the high levels of expenditures will continue due to the conduct of our development program for ferumoxytol as an IV iron replacement therapeutic, our development of a sales and marketing function, our preparation for commercial launch of ferumoxytol, our pursuit of additional indications for ferumoxytol, and our efforts to obtain approval for ferumoxytol outside the U.S., and that our cash-burn rate will continue to increase in the near- and long-term. Our long-term capital requirements will depend on additional factors, including, but not limited to:

- Our ability to successfully obtain regulatory approval in the U.S. for ferumoxytol as an IV iron replacement therapeutic in a timely manner;
- Costs associated with our preparations for the potential commercial launch of ferumoxytol, including costs associated with hiring additional sales and marketing personnel, building our commercial infrastructure and executing promotional and marketing programs;
- Costs associated with preparing for commercial-scale manufacturing of ferumoxytol, including costs associated with qualifying a second manufacturing facility and second source suppliers;
- Costs associated with our development of additional indications for ferumoxytol;
- Costs associated with the pursuit of potential business development activities;
- Costs associated with our pursuit of approval for ferumoxytol as an IV iron replacement therapeutic outside the U.S.;
- The magnitude of product sales and royalties;
- Our ability to establish additional development and marketing arrangements or to enter into alternative strategic relationships, if necessary;
- Costs involved in filing, prosecuting and enforcing patent claims; 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 ferumoxytol commercialization efforts and our research and development activities and to conduct future clinical trials for ferumoxytol in new indications and in countries outside the U.S. 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 likely 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.

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 ferumoxytol. 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 ferumoxytol, limit our development and commercialization of ferumoxytol, 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 approximately 18 U.S. patents and approximately 25 foreign patents, which expire between the years 2008 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 superparamagnetic iron oxide nanoparticle 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.

We are exposed to potential liability claims and we may not be able to maintain or obtain sufficient insurance coverage.

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, and 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 that 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 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.

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. This price has ranged between $43.59 and $72.95 in the fifty-two week period through February 15, 2008. 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 may have a significant impact on the market price of our common stock, including any announcements by us or our competitors regarding:

The results of discovery, preclinical studies and clinical trials;

The acquisition of technologies, product candidates or products;

The development of new technologies, product candidates or products;

Regulatory actions with respect to our product candidates or products or those of our competitors;

Developments in patents or other proprietary rights;

Public concern regarding the safety of our product candidates or products or those of our competitors;

The initiation of litigation to enforce or defend any of our assets;

Legislative initiatives by Congress or reimbursement changes by governmental or private payors; and

Significant agreements with collaborators, strategic partnerships, acquisitions, joint ventures or capital commitments.

For example, any announcement of any positive or negative developments with respect to our efforts to obtain FDA approval to market and sell ferumoxytol, 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. Our trading volume has historically been relatively low and therefore bulk sales or substantial purchases of our stock in a short period of time could cause the market price for our shares to decline or fluctuate drastically.

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 or our business. Currently, eight 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS:

None.

ITEM 2. PROPERTIES:

Our principal executive offices are located at 125 CambridgePark Drive, Cambridge Massachusetts where we lease approximately 25,000 square feet of office space pursuant to a term lease that expires in February 2009. 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. Although we believe our existing executive offices are adequate for our current needs, these facilities will likely not be adequate for our longer-term needs as we continue our efforts to commercialize ferumoxytol as an IV iron replacement therapeutic. As we continue our efforts to build our own commercial infrastructure, including sales, marketing and other functions, we will need to hire substantial additional staff and lease additional space. We believe that we will be able to lease additional space, as necessary, to house such additional personnel. 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:

None.

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

On November 27, 2007, we held a Special Meeting of Stockholders to act upon a proposal to approve our 2007 Equity Incentive Plan.

Votes "FOR" represented affirmative votes and do not include abstentions or broker non-votes. In cases where a signed proxy was submitted without designation, the shares represented by the proxy were voted "FOR" the proposal in the manner described in the Proxy Statement delivered to the holders of shares of our common stock on the record date for the meeting, October 1, 2007. There were 16,884,940 shares of our common stock issued and outstanding as of the record date.

At the special meeting, our stockholders approved our 2007 Equity Incentive Plan. The voting results from the special meeting were as follows:

For	Against	Abstain	Broker Non-Votes
8,924,584	3,510,858	8,823	0

PART II

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

Market Information

From 1991 to June 2006, our common stock was traded on the American Stock Exchange under the trading symbol "AVM." As of June 27, 2006, our common stock began trading on the NASDAQ Global Market under the trading symbol "AMAG." The table below sets forth the high and low sale prices of our common stock as reported to us by the American Stock Exchange and the NASDAQ Global Market for each of the quarters from October 1, 2005 through December 31, 2007.

	High	Low
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
Three Months Ended December 31, 2006	$ 65.32	$ 32.05
Year Ended September 30, 2006		
First quarter	$ 11.60	$ 8.30
Second quarter	$ 39.35	$ 11.01
Third quarter	$ 38.68	$ 23.01
Fourth quarter	$ 37.57	$ 29.10

Stockholders

On February 15, 2008, there were approximately 149 stockholders of record of our common stock, and we believe that the number of beneficial holders of our common stock was approximately 4,700 based on responses from brokers to a search conducted by Georgeson Shareholder on our behalf. The last reported sale price of our common stock on February 15, 2008 was $51.40 per share.

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, 2007.

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, 2007.

Comparative Stock Performance Graph

The following graph compares the yearly percentage change in the cumulative total stockholder return on our common stock with the cumulative total return on the NASDAQ Global Market and our

peer groups based on SIC Code 2834 (pharmaceutical preparations) and SIC Code 2835 (in vitro and in vivo diagnostic substances). In May 2007, we changed our fiscal year end to December 31 from September 30 and therefore we are presenting data for the five fiscal years ended September 30 as well as the three-month period ended December 31, 2007. The comparisons assume $100 was invested on September 30, 2002 in our common stock, in the NASDAQ Global Market and with our peer groups, and assumes reinvestment of dividends, if any.

COMPARISON OF CUMULATIVE TOTAL RETURN
OF ONE OR MORE COMPANIES,
PEER GROUPS, INDUSTRY
INDEXES AND/OR BROAD MARKETS

Company/Index/Market	9/30/02	9/30/03	9/30/04	9/30/05	9/30/06	9/30/07	Three months ended 12/31/07
AMAG Pharmaceuticals, Inc.	$ 100.00	$ 179.41	$ 273.73	$ 190.39	$ 668.63	$ 1,122.37	$ 1,179.86
Pharmaceutical Preparations	$ 100.00	$ 114.52	$ 120.91	$ 130.41	$ 149.46	$ 154.62	$ 151.32
Diagnostic Substances	$ 100.00	$ 153.26	$ 162.48	$ 184.85	$ 195.81	$ 234.00	$ 229.92
NASDAQ Global Market Index	$ 100.00	$ 136.80	$ 142.82	$ 150.21	$ 175.24	$ 234.74	$ 244.74

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

The information contained in the performance graph above shall not be deemed to be "soliciting material" or "filed" with the SEC, or deemed to be incorporated by reference by any general statement incorporating by reference any filing under the Exchange Act except to the extent that we specifically request that the information be treated as soliciting material or specifically incorporate this information by reference into any such filing, and will not otherwise be deemed incorporated by reference into any other filing under the Securities Act of 1933, as amended, or the Securities Act, or the Exchange Act except to the extent that we specifically incorporate it by reference.

ITEM 6. SELECTED FINANCIAL DATA:

In May 2007, we changed our fiscal year end to December 31 from September 30 and therefore the information below includes our transition period for the three months ended December 31, 2006, and our new year ended December 31, 2007.

The following table sets forth selected financial data as of and for the year ended December 31, 2007, the three months ended December 31, 2006, and the years ended September 30, 2003 through 2006. 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.

			Years ended September 30,			
	Year Ended December 31, 2007	Three Months Ended December 31, 2006	2006	2005	2004	2003
	(in thousands, except per share data)					
Statement of Operations Data						
Revenues:						
License fees	$ 1,096	$ 222	$ 907	$ 1,281	$ 2,748	$ 3,642
Royalties	248	44	317	274	240	535
Product sales	1,208	353	1,449	890	768	600
Total revenues	2,552	619	2,673	2,445	3,756	4,777
Costs and Expenses:						
Cost of product sales	320	287	273	204	117	200
Research and development expenses*	24,236	6,393	21,294	12,037	6,084	4,459
Selling, general and administrative expenses*	20,396	2,197	8,011	3,338	2,220	1,770
Total costs and expenses	44,952	8,877	29,578	15,579	8,421	6,429
Other Income (Expense):						
Interest and dividend income, net	12,506	818	1,575	419	170	113
Litigation settlement	(4,000)					
Gains on sales of securities and derivative instruments, net						2,777
Write-down of marketable securities						(644)
Other income (expense), net			(35)			148
Total other income (expense)	8,506	818	1,540	419	170	2,394
Income (loss) before provision for (benefit from) income taxes	(33,894)	(7,440)	(25,365)	(12,715)	(4,495)	742
Benefit from income taxes						(124)
Net income (loss)	$ (33,894)	$ (7,440)	$ (25,365)	$ (12,715)	$ (4,495)	$ 866
Earnings (loss) per share basic:	$ (2.15)	$ (0.60)	$ (2.31)	$ (1.47)	$ (0.57)	$ 0.13
Earnings (loss) per share diluted:	$ (2.15)	$ (0.60)	$ (2.31)	$ (1.47)	$ (0.57)	$ 0.12
Weighted average shares outstanding used to compute earnings (loss) per share:						
Basic	15,777	12,383	10,964	8,634	7,818	6,914
Diluted	15,777	12,383	10,964	8,634	7,818	7,143

	September 30,

	December 31, 2007	December 31, 2006	September 30, 2006	2005	2004	2003
			(in thousands)			
Balance Sheet Data						
Working capital (current assets less current liabilities)	$ 282,196	$ 149,474	$ 33,623	$ 21,211	$ 12,314	$ 22,579
Total assets	$ 294,851	$ 162,342	$ 47,371	$ 28,292	$ 23,811	$ 29,366
Long-term liabilities	$ 879	$ 1,688	$ 1,795	$ 2,585	$ 3,134	$ 5,266
Stockholders' equity	$ 285,954	$ 152,277	$ 36,075	$ 22,379	$ 17,546	$ 20,918

*

We adopted SFAS 123R effective October 1, 2005. Accordingly, periods prior to the date of adoption do not reflect stock-based compensation expense related to employee stock awards.

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 nanoparticle technology for the development and commercialization of therapeutic iron compounds to treat anemia as well as novel imaging agents to aid in the diagnosis of cancer and cardiovascular disease. We have two approved products, *Feridex I.V.* and *GastroMARK*, and two product candidates, ferumoxytol and *Combidex*.

Ferumoxytol, our key product candidate, is being developed for use as an IV iron replacement therapeutic for the treatment of iron deficiency anemia in CKD patients. In December 2007, we submitted an NDA to the FDA seeking marketing approval for ferumoxytol as an IV iron replacement therapeutic in CKD patients, including both dialysis dependent and non-dialysis dependent patients. The FDA has informed us that our NDA was accepted for standard review and we expect FDA action by late October 2008. Our NDA is supported by data from three open-label, multi-center, randomized Phase III efficacy and safety clinical studies and a fourth Phase III safety study. The three efficacy and safety studies demonstrated a statistically significant achievement of all primary and secondary endpoints. In total, over 1,700 patients and healthy volunteers were treated with ferumoxytol in eleven clinical studies. We have released data on all four of our planned Phase III clinical trials of ferumoxytol as an IV iron replacement therapeutic in patients with CKD.

Combidex, our other product under development, is an investigational functional molecular imaging agent consisting of iron oxide nanoparticles for use in conjunction with MRI to aid in the differentiation of cancerous from normal lymph nodes. In March 2005, we received an approvable letter from the FDA with respect to *Combidex,* subject to certain conditions. In December 2006, Guerbet, our partner, submitted a marketing authorization application, the European equivalent of an NDA, to the EMEA seeking approval for *Combidex* under the tradename Sinerem® as an aid in the differentiation of lymph nodes in patients with pelvic cancers, including prostate, bladder, cervical and uterine cancer. In December 2007 Guerbet withdrew its EMEA application for Sinerem® after the Committee for Medicinal Products for Human Use indicated that the data submitted by Guerbet did not provide sufficient statistical demonstration of the efficacy of Sinerem®. Based on our review of the data from the Guerbet trial, it appears unlikely that the data from that trial will be sufficient to address the concerns raised by the FDA, which means we may have to sponsor one or more additional clinical trials to obtain approval for *Combidex*. We cannot at this time predict with certainty the timing or likelihood of our ability to satisfy the conditions specified by the FDA for approval of *Combidex,* if at all.

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

From 1991 to June 26, 2006, our common stock was traded on the American Stock Exchange under the trading symbol "AVM." As of June 27, 2006, our common stock began trading on the NASDAQ Global Market under the trading symbol "AMAG."

In May 2007, our Board approved a change in our fiscal year end from September 30 to December 31. On June 14, 2007, we filed a transition report on Form 10-Q for the quarter ended December 31, 2006 pursuant to Rule 13a-10 of the Exchange Act for transition period reporting. Accordingly, the financial results now being reported by us in this Annual Report on Form 10-K relate to the year ended December 31, 2007, and the three-month transitional period ended December 31, 2006.

In July 2007, we changed our corporate name from Advanced Magnetics, Inc. to AMAG Pharmaceuticals, Inc. The name change was effected pursuant to Section 253 of the Delaware General

Corporate Law through a merger of a newly-created, wholly-owned subsidiary with and into Advanced Magnetics, Inc. The name change did not require stockholder approval.

In August 2007, we formed a Massachusetts corporation as a wholly-owned subsidiary of our company, which is classified as a securities corporation pursuant to Chapter 63, Section 38B of the Massachusetts General Laws, for the purpose of buying, selling and holding investment securities on our own behalf. The amounts set forth in this Annual Report on Form 10-K include our accounts and the accounts of our wholly-owned subsidiary, AMAG Securities Corporation.

Results of Operations

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

In order to compare the financial information for the year ended December 31, 2007 in Management's Discussion and Analysis of Financial Condition and Results of Operations 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. Wherever practicable, the discussion below compares the consolidated financial statements for the year ended December 31, 2007 with the pro forma financial statements for the year ended December 31, 2006, as set forth in the table below. For purposes of Management's Discussion and Analysis of Financial Condition and Results of Operations, we believe that this comparison provides a more meaningful analysis.

	Years ended December 31,			
	2007	2006	$ Change	% Change
		(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%
Loss on disposal of fixed assets		(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

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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%

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.

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*. 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 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 agreement. On January 25, 2006, Cytogen filed a lawsuit against us in Massachusetts Superior Court in connection with this license and marketing agreement. 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 discontinued its pursuit of all claims against the other, and all agreements between the parties were terminated. With the termination of our agreements with Cytogen, the U.S. marketing rights to *Combidex* as well as the U.S. marketing rights to ferumoxytol for oncology imaging applications reverted back to us. 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. In addition, 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 agreement due to its termination.

In February 1995, we entered into a license and marketing agreement and a supply agreement 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 agreement. Bayer paid us non-refundable license fees and other fees in connection with the agreements. We

account for the revenues associated with this agreement on a straight-line basis over the 15 year term of the agreement due to the existence of an established contract period. The agreement expires in 2010 but can be terminated earlier upon the occurrence of certain specified events.

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 agreement	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 size in which our products are manufactured and shipped, which creates uneven purchasing patterns by our marketing partners. We expect that revenues from our current products will not substantially change from their current levels.

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 include external expenses, such as costs of clinical trials, contract research and development expenses, commercial manufacturing process development 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. 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.

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				
Ferumoxytol as an IV Iron Replacement Therapeutic	$ 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 ferumoxytol 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 ferumoxytol 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 ferumoxytol.

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 ferumoxytol. 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 stock-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 stock-based compensation expense was primarily attributable to increased option grants associated with new hires.

We expect research and development expenses to increase as we initiate new clinical trials to develop additional indications for ferumoxytol as both a therapeutic and an imaging agent, seek approval for ferumoxytol in non-U.S. geographies, continue commercial manufacturing process development, and continue other research and development related functions and activities in support of ferumoxytol.

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 ferumoxytol. 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 ferumoxytol as an IV iron replacement therapeutic for the treatment of iron deficiency anemia in CKD patients.

We incurred aggregate internal and external research and development expenses of approximately $13.5 million through the year ended September 30, 2000 in connection with the development of *Combidex*. Since October 1, 2000 and through the year ended December 31, 2007, we incurred additional external research and development expenses of approximately $2.0 million, as well as additional internal research and development costs related to our efforts to obtain FDA approval for *Combidex*.

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 potential commercial launch of ferumoxytol, higher compensation and benefit costs related to an increased headcount in our marketing and commercial operations functions, stock-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 stock-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 stock-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.

We expect selling, general and administrative expenses to significantly increase in 2008 as we continue our efforts to augment our operational infrastructure and support ferumoxytol commercialization. We presently intend to market and sell ferumoxytol using our own commercial

organization. We expect to expend significant funds hiring our own sales force, developing our marketing infrastructure, executing related marketing and promotional programs and hiring consultants in preparation for the potential commercialization of ferumoxytol as an IV iron replacement therapeutic in patients with CKD.

Other Income (Loss)

Other income (loss) 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
Loss on disposal of fixed assets		(35)	35	-100%
Total	$ 8,506	$ 2,184	$ 6,322	>100%

The increase in other income (loss) 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 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.

Three Months Ended December 31, 2006 Compared to Three Months Ended December 31, 2005

Revenues

Total revenues were $0.6 million and $0.7 million for the three months ended December 31, 2006 and 2005, respectively, representing a decrease of approximately 7%. The decrease in revenues was primarily the result of decreased product sales. Three companies were responsible for approximately 91% of our revenues during the three months ended December 31, 2006. Bayer represented approximately 31% of our revenues, Guerbet represented approximately 45% of our revenues, and Covidien represented approximately 15% of our revenues during the three months ended December 31, 2006. Two companies were responsible for approximately 78% of our revenues during the three months ended December 31, 2005. Bayer represented approximately 28% of our revenues and Guerbet represented approximately 50% of our revenues for the three months ended December 31, 2005.

Our revenues for the three months ended December 31, 2006 and 2005 consisted of the following (in thousands):

	Three-Month Periods Ended December 31,			
	2006	2005	$ Change	% Change
Revenues:				
License fees	$ 222	$ 223	$ (1)	0%
Royalties	44	48	(4)	-8%
Product sales	353	393	(40)	-10%
Total	$ 619	$ 664	$ (45)	-7%

License Fee Revenues

All of our license fee revenues for the three months ended December 31, 2006 and 2005 consisted of deferred license fee revenues related to a license and marketing agreement signed with Cytogen in the year ended September 30, 2000 and deferred license fee revenues associated with a license and marketing agreement with Bayer signed in the year ended September 30, 1995.

During the three months ended December 31, 2006, revenues associated with our Cytogen agreement decreased slightly as compared with the three months ended December 31, 2005. At the time of signing the Cytogen agreement in 2000, we determined to account for the revenue associated with the entire $13.5 million non-refundable license fee over the development period of the products subject to the agreement as costs were incurred. The entire amount of the license fee was booked as deferred revenue upon signing the agreement. We slightly decreased our projected future research and development expenses associated with the Cytogen agreement as of December 31, 2006, based upon our then estimate of the cost of future efforts that might be required to obtain approval of *Combidex,* as compared to the estimate of such costs as of December 31, 2005. As a result, our revenue associated with the Cytogen agreement in the three months ended December 31, 2006 decreased as compared with the three months ended December 31, 2005.

Total license fee revenues for the three months ended December 31, 2006 and 2005 were recognized as follows (in thousands):

	Three-Month Periods Ended December 31,			
	2006	2005	$ Change	% Change
Deferred license fee revenues recognized in connection with the Cytogen agreement	$ 38	$ 39	$ (1)	-3%
Deferred license fee revenues recognized in connection with the Bayer agreement	184	184		0%
Total	$ 222	$ 223	$ (1)	0%

Royalty Revenue

Royalties decreased $3,392, or 7%, to $44,427 for the three months ended December 31, 2006, compared with royalties of $47,819 for the three months ended December 31, 2005. The decrease in royalties was primarily associated with slight decreases in sales of both *Feridex I.V.* and *GastroMARK* by our marketing partners and payment variations by end users for our marketed products. Royalty payments can fluctuate based on uneven demand and/or payment variations by end users for our marketed products, *Feridex I.V.* and *GastroMARK*.

Product Sale Revenues

Product sale revenues for the three months ended December 31, 2006 and 2005 consisted of the following (in thousands):

	Three-Month Periods Ended December 31,			
	2006	2005	$ Change	% Change
Feridex I.V.	$ (2)	$ 24	$ (26)	<-100%
GastroMARK	79	268	(189)	-71%
Combidex	276	101	175	>100%
Total	$ 353	$ 393	$ (40)	-10%

The decrease in product sale revenues in the three months ended December 31, 2006 as compared to the three months ended December 31, 2005 was primarily the result of a decrease in sales of both *Feridex I.V.* and *GastroMARK* to our marketing partners offset by an increase in the sale 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 size in which our products are manufactured and shipped, which creates uneven purchasing patterns by our marketing partners.

Costs and Expenses

Cost of Product Sales

We incurred costs of $0.3 million associated with product sales during the three months ended December 31, 2006 as compared to costs of $0.1 million associated with product sales during the three months ended December 31, 2005. This constituted approximately 81% and 31% of product sales during the three months ended December 31, 2006 and 2005, respectively. The increase in cost of product sales is due primarily to the sale of bulk *Combidex* at cost to one of our foreign marketing partners for research and development purposes. 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 three months ended December 31, 2006 and 2005 consisted of the following (in thousands):

	Three-Month Periods Ended December 31,			
	2006	2005	$ Change	% Change
External Research and Development Expenses				
Ferumoxytol as an IV Iron Replacement Therapeutic	$ 3,785	$ 1,760	$ 2,025	>100%
Ferumoxytol as an Imaging Agent		45	(45)	-100%
Combidex	75	95	(20)	-21%
Other External Costs	84	36	48	>100%
Total	$ 3,944	$ 1,936	$ 2,008	>100%
Internal Research and Development Expenses	2,449	1,135	1,314	>100%
Total	$ 6,393	$ 3,071	$ 3,322	>100%

Total research and development expenditures incurred in the three months ended December 31, 2006 amounted to $6.4 million, an increase of $3.3 million from the same three month period in 2005. Of the $3.3 million increase, $2.0 million was attributable to an increase in external costs and $1.3 million was attributable to an increase in internal costs.

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The $2.0 million increase in external costs was due primarily to an increase in expenditures associated with the development program for ferumoxytol as an IV iron replacement therapeutic as we moved our Phase III clinical trials toward completion as well as costs associated with a Phase I study for ferumoxytol as an IV iron replacement therapeutic. External research and development costs incurred in the three months ended December 31, 2006 do not include any non-cash charges associated with consultant stock-based compensation as compared to a non-cash charge of $0.1 million in the three months ended December 31, 2005.

The $1.3 million increase in internal costs was due primarily to higher compensation-related costs resulting from an increase in both the overall salary level and number of employees engaged in research and development activities during the three months ended December 31, 2006 as compared to the same three month period in 2005. In addition, during the three months ended December 31, 2006 our Board approved a new compensation plan for our employees. The increase in internal costs reflects bonus payments for the year ended September 30, 2006, which were approved and paid in the three months ended December 31, 2006, and a pro rata share of the 2007 bonuses for employees engaged in research and development activities. There was also an increase of approximately $0.3 million in our non-cash employee stock-based compensation charge related to SFAS 123R in the three months ended December 31, 2006 as compared to the same three month period in 2005 for employees engaged in research and development activities.

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 ferumoxytol. Since October 1, 2000 and through the three months ended December 31, 2006, we incurred aggregate external research and development expenses of approximately $30.1 million related to pre-clinical activities and clinical trials in connection with ferumoxytol.

We incurred total research and development expenses of approximately $13.5 million through the year ended September 30, 2000 in connection with the development of *Combidex*. Since October 1, 2000 and through the three months ended December 31, 2006, we incurred additional external research and development expenses of approximately $1.5 million, as well as additional internal research and development costs related to our efforts to obtain FDA approval for *Combidex*.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended December 31, 2006 and 2005 consisted of the following (in thousands):

	Three-Month Periods Ended December 31,			
	2006	2005	$ Change	% Change
Compensation, payroll taxes and benefits	$ 1,191	$ 1,375	$ (184)	-13%
Professional and consultant fees and other expenses	1,006	486	520	>100%
Total	$ 2,197	$ 1,861	$ 336	18%

The decrease in compensation, payroll taxes and benefits for the three months ended December 31, 2006 as compared to the three months ended December 31, 2005 was due to a decrease in non-cash SFAS 123R expense associated with employee stock-based compensation offset by an increase in wage, bonus and benefit expense for our employees. The decrease of approximately $0.9 million in SFAS 123R expense was due primarily to a new director compensation package approved by our Board in November 2006. The increase in compensation, payroll taxes and benefits to employees was due primarily to a new annual compensation program for our employees approved by our Board, which provided retroactive bonuses for the year ended September 30, 2006 and certain bonus opportunities for 2007. Amounts for the full bonus for the year ended September 30, 2006 and an accrual of the pro rata 2007 bonuses were included in compensation, payroll taxes and benefits for the three months ended December 31, 2006. There were no company-wide bonus plans in place during

the three months ended December 31, 2005. In addition, compensation, payroll taxes and benefits to employees increased due to an increase in the overall average salary level and the higher number of employees during the three months ended December 31, 2006 as compared to the same three-month period in 2005.

Professional and consultant fees and other expenses for the three months ended December 31, 2006 increased as compared to the same period in 2005. We incurred increased expenses for professional fees in the three months ended December 31, 2006 for consultants assisting with our efforts to comply with the internal control requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and increased external audit fees associated with these requirements. In addition, in the three months ended December 31, 2006, we incurred consultant fees associated with our search for new members of our Board, increased legal fees associated with defending the Cytogen lawsuit, increased costs associated with our November 2006 lease of additional office space, increased insurance costs, and increased recruiting costs related to various new employees.

Other Income (Loss)

Other income (loss) for the three month periods ended December 31, 2006 and 2005 consisted of interest income of $0.8 million and $0.2 million, respectively. The increase in other income in the three months ended December 31, 2006, as compared to the three months ended December 31, 2005, was primarily attributable to funds being invested in higher interest-bearing investments, combined with a higher average total dollar amount of invested funds in the three months ended December 31, 2006 as compared to the three months ended December 31, 2005 as a result of our March and December 2006 financings, which resulted in combined aggregate net proceeds to us of $154.6 million.

Net Loss

For the reasons stated above, there was a net loss of $7.4 million, or $0.60 per basic and diluted share, for the three months ended December 31, 2006 as compared to a net loss of $4.2 million, or $0.43 per basic and diluted share for the three months ended December 31, 2005.

Year Ended September 30, 2006 Compared to Year Ended September 30, 2005

Revenues

Total revenues were $2.7 million and $2.4 million for the years ended September 30, 2006 and 2005, respectively, representing an increase of approximately 9%. The increase in revenues was primarily the result of increased sales of *Feridex I.V.* and *GastroMARK*, partially offset by the recognition of a lower amount of deferred license fee revenues from a license and marketing agreement with Cytogen. Three companies were responsible for approximately 89% of our revenues during the year ended September 30, 2006. Bayer represented approximately 41% of our revenues, Guerbet represented approximately 37% of our revenues, and Covidien represented approximately 11% of our revenues in the year ended September 30, 2006. Our revenues for the years ended September 30, 2006 and 2005 consisted of the following (in thousands):

	Years Ended September 30,			
	2006	2005	$ Change	% Change
Revenues:				
License fees	$ 907	$ 1,281	$ (374)	-29%
Royalties	317	274	43	16%
Product sales	1,449	890	559	63%
Total	$ 2,673	$ 2,445	$ 228	9%

License Fee Revenues

All of our license fee revenues for the years ended September 30, 2006 and 2005 consisted of deferred license fee revenues related to a license and marketing agreement signed with Cytogen in the year ended September 30, 2000 and deferred license fee revenues associated with a license and marketing agreement with Bayer signed in the year ended September 30, 1995.

During the year ended September 30, 2006, our revenues associated with our Cytogen agreement decreased as compared with the year ended September 30, 2005. At the time of signing the Cytogen agreement in 2000, we determined to account for the revenue associated with the entire $13.5 million non-refundable license fee over the development period of the products subject to the agreement as costs were incurred. The entire amount of the license fee was booked as deferred revenue upon signing the agreement. As of September 30, 2006, we had increased our projected future research and development expenses associated with the Cytogen agreement based upon our then estimate of the cost of future efforts that might be required to obtain approval of *Combidex,* as compared to the estimate of such costs as of September 30, 2005. As a result, our revenue associated with the Cytogen agreement in the year ended September 30, 2006 decreased as compared with the year ended September 30, 2005. In the years ended September 30, 2006 and 2005, respectively, we recorded to income $0.2 million and $0.5 million of previously deferred licensing revenue associated with our license agreement with Cytogen. Revenue recognition during each of these years was based upon costs incurred to date as compared to our then current estimate of costs we expected to incur in connection with our efforts to obtain approval of *Combidex*.

Total license fee revenues for the years ended September 30, 2006 and 2005 were recognized as follows (in thousands):

	Years Ended September 30,			
	2006	2005	$ Change	% Change
Deferred license fee revenue recognized in connection with the Cytogen agreement	$ 169	$ 543	$ (374)	-69%
Deferred license fee revenue recognized in connection with the Bayer agreement	738	738		0%
Total	$ 907	$ 1,281	$ (374)	-29%

Royalty Revenue

Royalties increased $43,178, or 16%, to $317,081 for the year ended September 30, 2006, compared with royalties of $273,903 for the year ended September 30, 2005. The increase in royalties was primarily associated with an increase in sales of *GastroMARK* by two of our marketing partners and payment variations by end users for our marketed products. Royalty payments can fluctuate based on uneven demand and/or payment variations by end users for our marketed products, *Feridex I.V.* and *GastroMARK*.

Product Sale Revenues

Product sale revenues for the years ended September 30, 2006 and 2005 consisted of the following (in thousands):

	Years Ended September 30,			
	2006	2005	$ Change	% Change
Feridex I.V.	$ 619	$ 378	$ 241	64%
GastroMARK	729	428	301	70%
Combidex	101	84	17	20%
Total	$ 1,449	$ 890	$ 559	63%

The increase in product sale revenues in the year ended September 30, 2006 as compared to the year ended September 30, 2005 was primarily the result of an increase in sales of both *Feridex I.V.* and *GastroMARK* to our marketing partners. Product sales in the years ended September 30, 2006 and 2005 included the sale of bulk *Combidex* to one of our foreign marketing partners for research and development purposes. Product sales fluctuate from period to period largely as a result of unpredictable annual product demand by end users and the batch size in which our products are manufactured and shipped, which creates uneven purchasing patterns by our marketing partners. Due to the historically low volume of product sales, the impact of inflation is immaterial.

Costs and Expenses

Cost of Product Sales

We incurred costs of $0.3 million associated with product sales during the year ended September 30, 2006 as compared to costs of $0.2 million associated with product sales during the year ended September 30, 2005. This constituted approximately 19% and 23% of product sales during the years ended September 30, 2006 and 2005, respectively. 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 September 30, 2006 and 2005 consisted of the following (in thousands):

	Years Ended September 30,			
	2006	2005	$ Change	% Change
External Research and Development Expenses				
Ferumoxytol as an IV Iron Replacement Therapeutic	$ 14,694	$ 6,523	$ 8,171	>100%
Ferumoxytol as an Imaging Agent	117	160	(43)	-27%
Combidex	203	584	(381)	-65%
Other External Costs	522	299	223	75%
Total	$ 15,536	$ 7,566	$ 7,970	105%
Internal Research and Development Expenses	5,758	4,471	1,287	29%
Total	$ 21,294	$ 12,037	$ 9,257	77%

The increase in total research and development expenditures incurred in the year ended September 30, 2006 as compared to the year ended September 30, 2005 was attributable to increased external costs of $8.0 million and increased internal costs of $1.3 million. The increase in both external and internal costs was due largely to increased expenditures associated with the development program for ferumoxytol as an IV iron replacement therapeutic as we ramped up enrollment and moved our Phase III clinical trials toward completion. Internal costs for the year ended September 30, 2006 also increased due to a non-cash charge of $0.7 million for employee stock-based compensation resulting from the adoption of SFAS 123R for which there was no comparable amount in the prior year. Internal costs also increased due to higher wages associated with an increased level of staffing. External research and development costs incurred in the year ended September 30, 2006 included approximately $27,000, which represented the research and development portion of the $0.2 million non-cash charge associated with consultant stock-based compensation as compared to a non-cash charge of $0.3 million in the year ended September 30, 2005.

There was a decrease of $0.4 million for *Combidex*-related external costs in the year ended September 30, 2006 as compared to the year ended September 30, 2005, a portion of which was

attributable to our preparation for, and participation in, the March 2005 Oncologic Drugs Advisory Committee meeting.

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 ferumoxytol. Since October 1, 2000 and through the year ended September 30, 2006, we incurred aggregate external research and development expenses of approximately $26.3 million related to pre-clinical activities and clinical trials in connection with ferumoxytol.

We incurred aggregate internal and external research and development expenses of approximately $13.5 million through the year ended September 30, 2000 in connection with the development of *Combidex*. Since October 1, 2000 and through the year ended September 30, 2006, we incurred additional external research and development expenses of approximately $1.4, as well as additional internal research and development costs related to our efforts to obtain FDA approval for *Combidex*.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the years ended September 30, 2006 and 2005 consisted of the following (in thousands):

	Years Ended September 30,			
	2006	2005	$ Change	% Change
Compensation, payroll taxes and benefits	$ 5,300	$ 1,315	$ 3,985	>100%
Professional and consultant fees and other expenses	2,711	2,023	688	34%
Total	$ 8,011	$ 3,338	$ 4,673	>100%

The increase in compensation, payroll taxes and benefits for the year ended September 30, 2006 as compared to the year ended September 30, 2005 was largely due to the adoption of SFAS 123R which resulted in a non-cash charge of $3.0 million for employee stock-based compensation in the year ended September 30, 2006. There were no comparable charges in the prior year. An additional $0.2 million of non-cash expense associated with consultant stock-based compensation was also charged to selling, general and administrative expenses in the year ended September 30, 2006. A portion of the increase in selling, general and administrative expense was also due to an increase in the overall average salary level of our employees, an increase in the number of employees and increased recruiting expenses.

Professional and consulting fees and other expenses for the year ended September 30, 2006 increased as compared to the year ended September 30, 2005. We incurred increased expenses for professional fees in the year ended September 30, 2006 for consultants hired to assist with our efforts to implement the internal control requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and increased external audit fees associated with implementing these requirements in the year ended September 30, 2006. In addition, our facility costs increased in the year ended September 30, 2006 as the result of our March 2006 lease of additional office space.

Other Income (Loss)

Other income (loss) for the years ended September 30, 2006 and 2005 consisted of the following (in thousands):

	Years Ended September 30,			
	2006	2005	$ Change	% Change
Interest income	$ 1,641	$ 604	$ 1,037	>100%
Amortization of premiums on purchased investments	(66)	(185)	119	-64%
Loss on disposal of fixed assets	(35)		(35)	N/A
Total	$ 1,540	$ 419	$ 1,121	>100%

The increase in other income (loss) in the year ended September 30, 2006, as compared to the year ended September 30, 2005, was primarily attributable to funds being invested in higher interest-bearing investments, combined with a higher average total dollar amount of invested funds in the year ended September 30, 2006 as compared to the year ended September 30, 2005 as a result of our March 2006 financing, which resulted in aggregate net proceeds to us of $31.7 million.

Net Loss

For the reasons stated above, there was a net loss of $25.4 million, or $2.31 per basic and diluted share, for the year ended September 30, 2006 as compared to a net loss of $12.7 million, or $1.47 per basic and diluted share for the year ended September 30, 2005.

Liquidity and Capital Resources

General

We have financed our operations primarily from the sale of our equity securities, proceeds from our marketing and distribution partners and cash generated from our investing activities. 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 ferumoxytol as an IV iron replacement therapeutic in a timely manner;
- Costs associated with our preparations for the commercial launch of ferumoxytol, including costs associated with our hiring of additional staff and our leasing of additional office space;
- Costs associated with preparing for commercial-scale manufacturing of ferumoxytol, including costs associated with qualifying a second manufacturing facility and second source suppliers;
- Costs associated with our development of additional indications for ferumoxytol;
- Costs associated with the pursuit of potential business development activities;
- Costs associated with our pursuit of approval for ferumoxytol as an IV iron replacement therapeutic outside the U.S.;
- The magnitude of product sales and royalties;

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

Costs involved in filing, prosecuting and enforcing patent claims; and

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

As of December 31, 2007, our investments consisted of corporate debt securities, U.S. treasury and government agency securities, commercial paper, municipal debt securities, and municipal auction rate securities. 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 subject to our investment policy.

We held approximately $105.4 million in municipal auction rate securities at December 31, 2007. Our investments in auction rate securities consist solely of municipal debt securities and none of the auction rate securities in our portfolio are mortgage-backed. Beginning in mid-February 2008, several of our municipal auction rate securities experienced failed auctions. Since then, the continued uncertainty in the credit markets has caused additional auctions with respect to our auction rate securities to fail and prevented us from liquidating certain of our holdings of auction rate securities because the amount of these securities submitted for sale has exceeded the amount of purchase orders for these securities. There is a risk that auctions related to other securities that we own may fail and that there could be a 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 experience additional auction failures and/or determine that these declines in value of auction rate securities are other than temporary, we would recognize a loss in our consolidated statement of operations, which could be material. In addition, any future failed auctions may adversely impact the liquidity of our investments and accordingly we may reclassify those securities with failed auctions as long term assets in our consolidated balance sheet. 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 redeems the outstanding securities, a buyer is found outside the auction process, or the securities mature. For all of our auction rate securities, the underlying maturity date is in excess of one year and can be as far as 40 years in the future. As of February 27, 2008, approximately $75.6 million of our available-for-sale investments were municipal auction rate securities. 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, however, we are uncertain when the current liquidity issues relating to auction rate securities 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, 2007 as compared to December 31, 2006 and September 30, 2006 as compared to September 30, 2005 consisted of the following (in thousands):

	December 31,		September 30,	
	2007	2006	2006	2005
Cash and cash equivalents	$ 28,210	$ 114,460	$ 32,313	$ 11,332
Short-term investments	258,597	41,599	9,760	12,395
Total cash, cash equivalents and short-term investments	$ 286,807	$ 156,059	$ 42,073	$ 23,727

The significant increase in cash and cash equivalents as of December 31, 2007 as compared to December 31, 2006 is primarily the result of the receipt of net proceeds of approximately $154.5 million from our May 2007 public offering of common stock. The significant increase in cash and cash equivalents as of December 31, 2006 as compared to September 30, 2006 is primarily the result of the receipt of net proceeds of approximately $122.9 million from our December 2006 public offering of common stock. The increase in cash and cash equivalents as of September 30, 2006 as compared to September 30, 2005 is primarily the result of the receipt of net proceeds of approximately $31.7 million from our March 2006 public offering of common stock.

Proceeds from the issuance of our common stock, as a result of both the cash exercise of stock options and/or warrants and shares issued pursuant to our Employee Stock Purchase Plans during the year ended December 31, 2007, the three months ended December 31, 2006, and the years ended September 30, 2006 and 2005 were $4.8 million, $0.2 million, $3.3 million, and $0.6 million, respectively.

As of December 31, 2007, we believe that our cash, cash equivalents, and 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 and research and development costs related to our development and commercialization programs for ferumoxytol as an IV iron replacement therapeutic.

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 potential commercialization of ferumoxytol as an IV iron replacement therapeutic.

We anticipate cash used in operating activities will increase over current levels in 2008 as we continue to advance our ongoing commercialization program for ferumoxytol as an IV iron replacement therapeutic and incur additional costs associated with our development of new indications for ferumoxytol in the U.S., our planning and initiation of additional ferumoxytol clinical trials, our continued expansion of our commercial, clinical, medical, regulatory and manufacturing organizations in support of our anticipated ferumoxytol launch, and our efforts to qualify second source suppliers and manufacturers for ferumoxytol. 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 ferumoxytol and our development, sales and marketing efforts.

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.

Years Ended September 30, 2006 Compared to September 30, 2005

Cash flows from operating activities

Net cash used in operating activities was $15.7 million in the year ended September 30, 2006 as compared to net cash used in operating activities of $12.0 million in the year ended September 30, 2005. Cash received during the year ended September 30, 2006 included $1.6 million from customers, $0.3 million of royalty payments from our distribution and marketing partners and $1.5 million from interest income associated with our investments in various U.S. Treasury Notes, U.S. Treasury Bills and money market funds. Cash used in operating activities during the year ended September 30, 2006 included $19.1 million paid to suppliers and employees primarily in connection with our overhead and research and development activities. Cash received from sales to our marketing partners increased as a

result of increased cash collections associated with a higher level of product sales in the year ended September 30, 2006 as compared to the year ended September 30, 2005. The increase in cash paid to suppliers and employees in the year ended September 30, 2006, as compared to the year ended September 30, 2005, was principally due to cash outlays for increased wage and benefits costs associated with an increase in our workforce combined with an increased level of payments made to third-party contract research and development service providers associated with our then ongoing clinical trial activities.

Cash flows from investing activities

Cash provided by investing activities was $1.7 million in the year ended September 30, 2006 compared with cash used by investing activities of $3.3 million in the year ended September 30, 2005. Our capital expenditures during the year ended September 30, 2006 increased as compared to the year ended September 30, 2005 due to expenditures for furniture, fixtures and telecommunications equipment associated with our February 2006 lease of additional office space. Capital expenditures during the year ended September 30, 2005 included equipment associated with our manufacturing scale-up for ferumoxytol. In the year ended September 30, 2006, we purchased $31.5 million of short-term investments utilizing proceeds from our March 2006 financing. In the year ended September 30, 2005, a portion of the $9.8 million of proceeds from two maturing U.S. Treasury Notes were subsequently reinvested in short-term U.S. Treasury Bills. Proceeds from maturing short-term investments amounted to $34.2 million and $9.8 million, in the years ended September 30, 2006 and 2005, respectively.

Cash flows from financing activities

Cash provided by financing activities was $35.0 million in the year ended September 30, 2006 compared with cash provided by financing activities of $17.3 million in the year ended September 30, 2005. We also received $2.6 million from the cash exercise of stock options, and $0.7 million from the cash exercise of warrants, during the year ended September 30, 2006. On March 10, 2006, we sold approximately 1.2 million shares of our common stock in an underwritten public offering. Net proceeds to us from the financing were approximately $31.7 million after deducting external transaction costs directly associated with the common stock offering. The shares were issued pursuant to our then existing shelf registration statement on Form S-3 and a registration statement filed pursuant to Rule 462(b) promulgated under the Securities Act. Cash provided by financing activities amounted to $17.3 million in the year ended September 30, 2005, primarily the result of our June 2005 issuance of an aggregate of approximately 1.8 million shares of our common stock and warrants to purchase an aggregate of 359,999 shares of our common stock in registered direct sales of common stock and warrant units to certain investors, which resulted in net proceeds of approximately $16.7 million to us after payment of all related expenses. During the year ended September 30, 2005, we received $0.6 million from the cash exercise of stock options.

Contractual Obligations

We currently have no long-term debt obligations, capital lease obligations, long-term purchase obligations or other long-term liabilities. Future lease obligations and purchase commitments, as of December 31, 2007, 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	$ 129	$ 98	$ 31	$	$
Facility Lease Obligations	1,023	830	193		
Purchase Commitments	594	594			
Total	$ 1,746	$ 1,522	$ 224	$	$

Operating and Facility Lease Obligations

We have entered into several agreements to service and/or lease certain office and laboratory equipment under operating leases that expire through 2009.

We are a party to a lease agreement with W2007 CPD Realty, L.L.C. (successor to CambridgePark 125 Realty Corporation) for certain real property comprised of approximately 25,000 square feet of executive office space located at 125 CambridgePark Drive, Cambridge, Massachusetts. The lease has a three year term which expires on February 28, 2009 and provides for one option to extend the lease for a two year period. In 2008 and 2009, our aggregate rent payment under this lease will be approximately $0.8 million and $0.1 million, respectively. In addition to rent, we are also required to pay a proportionate share of the landlord's annual operating costs and electricity. The rent for any extension term will be determined at the time of the exercise of the option under terms set out in the lease.

In fulfillment of a security deposit requirement for the leased space described above we have issued a $60,687 irrevocable letter of credit to the landlord. 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 2007 we entered into an agreement under which we have paid approximately $1.0 million for material and manufacturing process development expenses, and for which we have a remaining purchase commitment of approximately $0.5 million as of December 31, 2007. In 2007, we also entered into an agreement for certain improvements upon our building for which we have a remaining purchase commitment of approximately $0.1 million as of December 31, 2007.

Royalty Commitments

We have certain future royalty commitments, which are dependent upon future sales and/or the attainment of certain milestones. In 1994, under an agreement with Bristol-Myers, we reacquired the development and marketing rights to *Combidex*, which had previously been licensed to Bristol-Myers. Pursuant to this agreement, we are obligated to pay up to a maximum of $2.8 million in royalties to Bristol-Myers in connection with future commercial product sales of *Combidex*. In addition, we are a party to an agreement with one of our regulatory consultants for *Combidex*, which obligates us to make certain royalty payments to the consultant based on any future commercial product sales of *Combidex* in the U.S. To date, we have not paid any royalties with respect to *Combidex*. We do not expect any such royalty payments to be material.

We are also the licensee of certain technologies related to our products under cross license agreements with Amersham Health, which is part of GE Healthcare, formerly Nycomed Imaging A.S. and Bayer Schering, 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 2007, 2006 or 2005. 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 and officers. For further discussion of how this may affect our business, please refer to Note K of 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, 2007, 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, determining values of investments and long-lived assets, accrued expenses, income taxes and stock-based compensation expense. Actual results could differ from those estimates. In making these estimates and assumptions, management employs critical accounting policies. Our critical accounting policies include valuation and impairment of investments and/or marketable securities, long-lived assets and equity-based compensation.

Valuation and impairment of investments and/or marketable securities. 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 auction rate securities which consist entirely of municipal debt securities, recorded at cost, which approximates fair market value due to their variable interest rates, which typically reset through an auction process every 7 to 35 days. This auction mechanism generally allows existing investors to roll over their holdings and continue to own their securities or liquidate their holdings by selling their securities at par value. Because of these short intervals between interest reset dates, we monitor the auctions to ensure they are successful which provides evidence that these investments that are carried at par value approximates their fair value. To the extent an auction were to fail and the securities were not liquid, we would need to seek other alternatives to determine the fair value of these securities which may not be based on quoted market transactions. We did not need to seek alternative methods of valuation for our auction rate securities held as of December 31, 2007 as all of our auction rate securities had successful auctions in January 2008. We also consider credit ratings with respect to our investments provided by investment ratings agencies. As of December 31, 2007, all of our investments conformed to the requirements of our investment policy which requires that 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.

Investments and/or marketable securities are considered to be impaired when a decline in fair value below cost basis is determined to be other than temporary. We periodically employ a methodology in evaluating whether a decline in fair value below cost basis is other than temporary that considers available evidence regarding these investments. In the event that the cost basis of a security 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, and operational and financing cash flow factors, overall market conditions and trends, and our intent and ability to hold the investment. Once a decline in fair value is determined to be other than temporary, a write-down is recorded and a new cost basis in the security is established. Assessing the above factors involves inherent uncertainty. Accordingly, write-

downs, if recorded, could be materially different from the actual market performance of investments and/or marketable securities in our portfolio, if, among other things, relevant information related to our investments and/or marketable securities was not publicly available or other factors not considered by us would have been relevant to the determination of impairment.

Long-lived assets. Currently, our long-lived assets consist primarily 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. This analysis relies on a number of factors, including changes in strategic direction, business plans, regulatory developments, economic and budget projections, technological improvements, and operating results. The test of recoverability or usefulness is a comparison of the asset carrying value to the undiscounted future operating cash flow over the asset's remaining useful life. Any write-downs would be treated as permanent reductions in the carrying amount of the asset and an operating loss would be recognized. To date, we have had recurring operating losses and the recoverability of our long-lived assets is contingent upon executing our business plan, which includes the successful development and regulatory approvals of our product candidates and significantly increasing sales. If we are unable to execute our business plan, we may be required to write down the value of our long-lived assets in future periods.

Equity-Based Compensation. On October 1, 2005, we adopted 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, or SAB 107, associated with the accounting for the stock-based compensation arrangements of our employees and certain directors, including our Employee Stock Purchase Plan. These pronouncements require that equity-based compensation cost 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 stock-based compensation expense recognized in our Consolidated Statements of Operations is based on awards ultimately expected to vest, we must make certain judgments about whether employees 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 were 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 internally and externally. 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. This model requires the input of several factors such as expected risk-free interest rate over the expected option term, expected volatility of our stock price over the expected option term, the expected option term, and expected dividend yield over the expected option term and is subject to various assumptions. 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 the historical volatility of our own common stock price over the prior period equivalent to our expected option term. For subsequent issuances, we have augmented our method of estimating our expected stock price volatility by basing it upon a blend of the historical volatility of our own common stock price and the historical volatility of other similar companies 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. We believe this valuation methodology is appropriate for estimating the fair value of stock options we grant to employees and directors which are subject to SFAS 123R requirements. These amounts 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 stock awards. The fair value of restricted stock units granted to employees and directors is determined at the grant date and is computed using the fair value method, which is based upon the estimated fair market value per share on the date of the grant. 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.

Impact of Recently Issued and Proposed Accounting Pronouncements

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. However, for some entities, the application of this statement will change current practice. SFAS 157 is effective for years beginning after November 15, 2007, and interim periods within those years. Accordingly, we are in the process of evaluating the impact of SFAS 157.

In February 2007, the FASB issued 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 elect to measure selected financial instruments and certain other items at fair value. Unrealized gains and losses on items for which the fair value option has been elected are recognized in earnings in each reporting period. SFAS 159 is effective for years beginning after January 1, 2008, and interim periods within those years. Accordingly, we are in the process of evaluating the impact of the adoption of SFAS 159.

In June 2007, the Emerging Issues Task Force, or EITF, of the FASB reached a consensus on Issue 07-03, "Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities," or EITF 07-03, which addresses the diversity which exists with respect to the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. Under this EITF, an entity would defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. EITF 07-03 is effective for years beginning after December 15, 2007 and interim periods within those years. Accordingly, we are in the process of evaluating the impact of EITF 07-03.

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 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 is effective for financial statements issued for years beginning after December 15, 2008. Accordingly, we are in the process of evaluating the impact of SFAS 141R.

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

As of December 31, 2007, our short-term investments totaled $258.6 million and were invested in fixed income securities, corporate debt securities, U.S. treasury and government agency securities, commercial paper, municipal debt securities, and municipal auction rate securities. 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 approximately 10%, from levels at December 31, 2007, this would have resulted in a hypothetical decline in fair value of our investments of approximately $0.7 million.

We held approximately $105.4 million in municipal auction rate securities at December 31, 2007. Our investments in auction rate securities consist solely of municipal debt securities and none of the auction rate securities in our portfolio are mortgage-backed. Beginning in mid-February 2008, several of our municipal auction rate securities experienced failed auctions. Since then, the continued uncertainty in the credit markets has caused additional auctions with respect to our auction rate securities to fail and prevented us from liquidating certain of our holdings of auction rate securities because the amount of these securities submitted for sale has exceeded the amount of purchase orders for these securities. There is a risk that auctions related to other securities that we own may fail and that there could be a 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 experience additional auction failures and/or determine that these declines in value of auction rate securities are other than temporary, we would recognize a loss in our consolidated statement of operations, which could be material. In addition, any future failed auctions may adversely impact the liquidity of our investments. 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 redeems the outstanding securities, a buyer is found outside the auction process, or the securities mature. For all of our auction rate securities, the underlying maturity date is in excess of one year and can be as far as 40 years in the future. 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, however, we are uncertain when the current liquidity issues relating to auction rate securities will improve, if at all.

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, 2007 and 2006

Consolidated Statements of Operations for the year ended December 31, 2007, the three months ended December 31, 2006 and the years ended September 30, 2006 and 2005

Consolidated Statements of Comprehensive Loss for the year ended December 31, 2007, the three months ended December 31, 2006 and the years ended September 30, 2006 and 2005

Consolidated Statements of Stockholders' Equity for the year ended December 31, 2007, the three months ended December 31, 2006 and the years ended September 30, 2006 and 2005

Consolidated Statements of Cash Flows for the year ended December 31, 2007, the three months ended December 31, 2006 and the years ended September 30, 2006 and 2005

Notes to Consolidated Financial Statements

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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. 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, 2007.

Our internal control over financial reporting as of December 31, 2007 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, 2007.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of AMAG Pharmaceuticals, Inc.:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, comprehensive loss, changes in stockholder's equity, and cash flows present fairly, in all material respects, the financial position of AMAG Pharmaceuticals, Inc. and its subsidiary as of December 31, 2007 and December 31, 2006, and the results of its operations and its cash flows for the year ended December 31, 2007, the three months ended December 31, 2006, and for the years ended September 30, 2006 and 2005, 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, 2007, 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 year ended December 31, 2007 and 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.

As discussed in Note B to the consolidated financial statements, the Company changed its method of accounting for share-based payments on October 1, 2005.

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, 2008

AMAG Pharmaceuticals, Inc.

Consolidated Balance Sheets

(in thousands, except share and per share data)

	As of December 31,	
	2007	**2006**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 28,210	$ 114,460
Short-term investments	258,597	41,599
Accounts receivable trade	223	349
Inventories	384	344
Prepaid expenses and interest receivable	2,800	1,099
Total current assets	290,214	157,851
Property, plant and equipment:		
Land	360	360
Buildings and improvements	5,106	4,947
Laboratory equipment	5,959	5,560
Furniture and fixtures	1,569	1,311
Total property, plant and equipment	12,994	12,178
Less accumulated depreciation	(8,452)	(7,721)
Net property, plant and equipment	4,542	4,457
Restricted cash	95	34
Total assets	$ 294,851	$ 162,342
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,733	$ 3,851
Accrued expenses	5,547	3,550
Deferred revenue	738	976
Total current liabilities	8,018	8,377
Long-term liabilities:		
Deferred revenue and rent expense	879	1,688
Total liabilities	8,897	10,065
Commitments and contingencies (Notes K and L)		
Stockholders' equity:		
Preferred stock, par value $.01 per share, authorized 2,000,000 shares; none issued		
Common stock, par value $.01 per share, 25,000,000 shares authorized; 16,945,662 and 14,065,663 shares issued and outstanding at December 31, 2007 and 2006, respectively	169	141
Additional paid-in capital	402,346	234,930
Accumulated other comprehensive income	127	
Accumulated deficit	(116,688)	(82,794)

	As of December 31,	
Total stockholders' equity	285,954	152,277
Total liabilities and stockholders' equity	$ 294,851	$ 162,342

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

AMAG Pharmaceuticals, Inc.

Consolidated Statements of Operations

(in thousands, except per share data)

	For the Year Ended December 31, 2007	For the Three Months Ended December 31, 2006	For the Years Ended September 30, 2006	2005
Revenues:				
License fees	$ 1,096	$ 222	$ 907	$ 1,281
Royalties	248	44	317	274
Product sales	1,208	353	1,449	890
Total revenues	2,552	619	2,673	2,445
Costs and expenses:				
Cost of product sales	320	287	273	204
Research and development expenses	24,236	6,393	21,294	12,037
Selling, general and administrative expenses	20,396	2,197	8,011	3,338
Total costs and expenses	44,952	8,877	29,578	15,579
Other income:				
Interest and dividend income, net	12,506	818	1,575	419
Litigation settlement (Note K)	(4,000)			
Loss on disposal of fixed assets			(35)	
Total other income	8,506	818	1,540	419
Net loss	$ (33,894)	$ (7,440)	$ (25,365)	$ (12,715)
Net loss per share:				
Basic and diluted	$ (2.15)	$ (0.60)	$ (2.31)	$ (1.47)
Weighted average shares outstanding used to compute net loss per share:				
Basic and diluted	15,777	12,383	10,964	8,634

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

AMAG Pharmaceuticals, Inc.

Consolidated Statements of Comprehensive Loss

(in thousands)

	For the Year Ended December 31, 2007	For the Three Months Ended December 31, 2006	For the Years Ended September 30,	
			2006	2005
Net loss	$ (33,894)	$ (7,440)	$ (25,365)	$ (12,715)
Other comprehensive income (loss):				
Unrealized gains (losses) on securities	127		57	(57)
Total other comprehensive income (loss)	127		57	(57)
Comprehensive loss	$ (33,767)	$ (7,440)	$ (25,308)	$ (12,772)

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

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, 2004	7,950	$ 79	$ 54,741	$ (37,274)	$	$ 17,546
Net shares issued in connection with the exercise of stock options	118	2	503			505
Shares and warrants issued in connection with a financing, net of financing costs of $0.4 million	1,800	18	16,667			16,685
Shares issued in connection with employee stock purchase plan	10		74			74
Non-cash expense associated with non-employee stock options			341			341
Other comprehensive loss					(57)	(57)
Net loss				(12,715)		(12,715)
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 expense associated with employee stock award plans			3,772			3,772
Non-cash expense associated with non-employee stock options			231			231
Other comprehensive income					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 expense associated with employee stock award plans			548			548
Net loss				(7,440)		(7,440)
Balance at December 31, 2006	14,066	141	234,930	(82,794)		152,277

					Accumulated Other Comprehensive Income (Loss)	
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 expense associated with employee stock award plans			8,182			8,182
Other comprehensive income					127	127
Net loss				(33,894)		(33,894)
Balance at December 31, 2007	16,946	$ 169	$ 402,346	$ (116,688)	$ 127	$ 285,954

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

AMAG Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows

(in thousands)

	For the Year Ended December 31, 2007	For the Three Months Ended December 31, 2006	For the Years Ended September 30, 2006	2005
Net Loss	$ (33,894)	$ (7,440)	$ (25,365)	$ (12,715)
Cash flows from operating activities:				
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	798	152	398	248
Non-cash expense associated with non-employee stock options			231	341
Non-cash expense associated with employee stock options and restricted stock units	8,182	548	3,772	
Loss on disposal of fixed assets			35	
Amortization of premium on purchased securities	(1,023)		66	185
Changes in operating assets and liabilities:				
Accounts receivable trade	126	(264)	(85)	50
Inventories	(40)	26	(2)	105
Prepaid expenses and interest receivable	(1,701)	(503)	(151)	142
Accounts payable and accrued expenses	(121)	(1,092)	6,280	930
Deferred revenue and rent expense	(1,047)	(138)	(896)	(1,281)
Total adjustments	5,174	(1,271)	9,648	720
Net cash used in operating activities	(28,720)	(8,711)	(15,717)	(11,995)
Cash flows from investing activities:				
Proceeds from maturities of available-for-sale investments	455,608			
Proceeds from maturities of held-to-maturity investments	132,795	9,760	34,170	9,839
Purchase of available-for-sale investments	(693,463)	(20,001)		
Purchase of held-to-maturity investments	(110,787)	(21,599)	(31,544)	(12,765)
Capital expenditures	(884)	(379)	(912)	(401)
Restricted cash	(61)	(18)	(16)	
Net cash (used in) provided by investing activities	(216,792)	(32,237)	1,698	(3,327)
Cash flows from financing activities:				
Proceeds from the exercise of stock options	4,523	175	2,597	504
Proceeds from the issuance of common stock under ESPP	260		94	74
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	
Proceeds from the issuance of common stock and warrants, net of underwriting discount and other expenses				16,685
Net cash provided by financing activities	159,262	123,095	35,000	17,263

Net (decrease) increase in cash and cash equivalents	(86,250)	82,147	20,981	1,941
Cash and cash equivalents at beginning of year	114,460	32,313	11,332	9,391
			For the Years Ended September 30,	
Cash and cash equivalents at end of year	$ 28,210	$ 114,460	$ 32,313	$ 11,332
Supplemental data:				
Non-cash financing activities:				
Non-cash stock option exercises	$ 683	$ 184	$ 841	$ 131
Non-cash warrant exercises	$	$	$ 8,088	$

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

Notes to Consolidated Financial Statements

A. Organization and Business

Business

AMAG Pharmaceuticals, Inc., a Delaware corporation, was founded in 1981. We are a biopharmaceutical company that utilizes our proprietary nanoparticle technology for the development and commercialization of therapeutic iron compounds to treat anemia and novel imaging agents to aid in the diagnosis of cancer and cardiovascular disease. We have two approved products, Feridex I.V.® and GastroMARK®, and we have two product candidates, ferumoxytol and Combidex®. Ferumoxytol, our key product candidate, is being developed for use as an intravenous, or IV, iron replacement therapeutic for the treatment of iron deficiency anemia in chronic kidney disease, or CKD, patients. *Combidex* is our investigational functional molecular imaging agent consisting of iron oxide nanoparticles for use in conjunction with magnetic resonance imaging, or MRI, to aid in the differentiation of cancerous from normal lymph nodes. *Feridex I.V.*, our liver contrast agent, is approved and marketed in the U.S., Europe and other countries. *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, our potential inability to obtain raw materials and manufacture sufficient quantities of our products, our lack of sales and marketing experience, our dependence on key personnel, uncertainty regarding market acceptance of products, development by us or our competitors of new technological innovations, uncertainties related to third-party reimbursement for our products, product liability, protection of proprietary technology, compliance with the regulations of the U.S. Food and Drug Administration, or the FDA, and other government agencies, and our ability to obtain additional financing, if necessary, on acceptable terms.

Change in Fiscal Year End

On May 14, 2007, our Board of Directors, or the Board, approved a change in our fiscal year end from September 30 to December 31. On June 14, 2007, we filed a transition report on Form 10-Q for the quarter ended December 31, 2006 pursuant to Rule 13a-10 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, for transition period reporting. Accordingly, these consolidated financial statements reflect our new year end of December 31 for the year ended December 31, 2007. Financial statements for the three months ended December 31, 2006 and the years ended September 30, 2006 and 2005 are also presented.

Change in Corporate Name

On July 24, 2007, we changed our corporate name from Advanced Magnetics, Inc. to AMAG Pharmaceuticals, Inc. The name change was effected pursuant to Section 253 of the Delaware General Corporate Law through a merger of a newly-created, wholly-owned subsidiary with and into Advanced Magnetics, Inc. The name change did not require stockholder approval.

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 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, determining values of investments and long-lived assets, accrued expenses, income taxes and stock-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 on August 31, 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, 2007 and 2006, 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 in Statement of Financial Accounting Standards, or 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.

Held-to-maturity securities are those securities which we have the ability and intent to hold until maturity and are recorded at amortized cost, adjusted for the amortization or accretion of premiums or discounts. Premiums and discounts are amortized or accreted over the life of the related held-to-maturity security as an adjustment to yield using the effective interest method. We had no investments classified as held-to-maturity at December 31, 2007 and two investments classified as held-to-maturity at December 31, 2006.

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

The fair value of our investments is generally determined from quoted market prices received from pricing services based upon market transactions at fair value. We also have investments in auction rate securities which consist entirely of municipal debt securities, recorded at cost, which approximates fair market value due to their variable interest rates, which typically reset through an auction process every 7 to 35 days. This auction mechanism generally allows existing investors to roll over their holdings and continue to own their securities or liquidate their holdings by selling their securities at par value. Because of these short intervals between interest reset dates, we monitor the auctions to ensure they are successful which provides evidence that these investments that are carried at par value approximates their fair value. To the extent an auction were to fail and the securities were not liquid, we would need to seek other alternatives to determine the fair value of these securities which may not be based on quoted market transactions. We did not need to seek alternative methods of valuation for our auction rate securities held as of December 31, 2007 as all of our auction rate securities had successful auctions in January 2008. 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 cost basis is other than temporary that considers 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, and operational and financing cash flow factors, overall market conditions and trends, and our intent and ability to hold the investment. Once a decline in fair value is determined to be other than temporary, we record a write-down in our Consolidated Statement of Operations and a new cost basis in the security is established. There were no unrealized losses in our investments which were deemed to be other than temporary during the year ended December 31, 2007, the three months ended December 31, 2006, and the years ended September 30, 2006 and 2005. Realized gains and losses are determined on the specific identification method and are included in interest income in the Consolidated Statements of Operations. Interest income is accrued as earned.

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 reflected in other income. 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.

Patents

We expense all patent-related costs as incurred.

Research and Development Expenses

Research and development expenses include external expenses, such as costs of clinical trials, contract research and development expenses, commercial manufacturing process development 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 or approval is otherwise considered assured. 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.

Revenue Recognition

We follow the provisions of the Securities and Exchange Commission's, or 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. 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 collaborations. Non-refundable license fees received pursuant to product development and collaboration agreements, in cases where project costs are estimable, are recognized based on costs incurred and expected remaining expenditures related to the agreement. In cases where there is an established contract period and project costs are not estimable, non-refundable license fees paid pursuant to product development and collaboration agreements are recognized on a straight-line basis over the term of the relevant agreement.

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.

Equity-Based Compensation

On October 1, 2005, we adopted Statement of Financial Accounting Standards, or 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 SEC SAB 107 in connection with the accounting for the stock-based compensation arrangements of our employees and certain directors, including our Employee Stock Purchase Plan. We adopted SFAS 123R using the modified prospective method and, accordingly, results for periods prior to October 1, 2005 do not include, and have not been revised to reflect, amounts associated with the requirements of SFAS 123R. 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 stock-based compensation expense is based on awards ultimately expected to vest, we must make certain judgments about whether employees 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 internally and externally. 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. This model requires the input of several factors such as expected risk-free interest rate over the expected option term, expected volatility of our stock price over the expected option term, the expected option term, and expected dividend yield over the expected option term and is subject to various assumptions. 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 the historical volatility of our own common stock price over the prior period equivalent to our expected option term. For subsequent issuances, we augmented our method of estimating our expected stock price volatility by basing it upon a blend of the historical volatility of our own common stock price and the historical volatility of other similar companies 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. We believe this valuation methodology is appropriate

for estimating the fair value of stock options we grant to employees and directors which are subject to SFAS 123R requirements. These amounts 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 stock awards. The fair value of restricted stock units granted to employees and directors is determined based upon the quoted market price per share on the date of grant. 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.

Stock-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

Income taxes are accounted for under the liability method. Under this method, deferred tax assets and liabilities are recorded based on temporary differences between the financial statement amounts and the tax basis of assets and liabilities measured using enacted tax rates in effect for the year in which the differences are expected to reverse. We periodically evaluate the realizability of our net deferred tax assets and record a valuation allowance if, based on the weight of available evidence, it is more likely than not that some or all of our deferred tax assets will not be realized.

Concentrations and Significant Customer Information

Financial instruments which potentially subject us to concentrations of credit risk consist principally of cash, cash equivalents, investments and accounts receivable. As of December 31, 2007, our cash, cash equivalents, and short-term investments amounted to approximately $286.8 million. We currently invest our excess cash primarily in deposits in money market funds and investments in corporate debt securities, U.S. treasury and government agency securities, commercial paper, municipal debt securities and municipal auction rate securities.

Our operations are located solely within the U.S. We are focused principally on developing and manufacturing IV iron replacement therapeutics and contrast agents for use in MRI. 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 year ended December 31, 2007, the three month period ended December 31, 2006 and the years ended September 30, 2006 and 2005. No other company accounted for more than 10% of our total revenues in any period presented below.

	For the Year Ended December 31, 2007	For the Three Months Ended December 31, 2006	For the Years Ended September 30,	
			2006	2005
Bayer	43%	31%	41%	47%
Guerbet	26%	45%	37%	20%
Covidien	15%	15%	11%	<10%
Cytogen	14%	<10%	<10%	22%

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 28%, 47%, 41%, and 22% of our total revenues for the year ended December 31, 2007, the three months ended December 31, 2006, and the years ended September 30, 2006, and 2005, 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.

Fair Value of Financial Instruments

The carrying amounts of our cash and cash equivalents, restricted cash, accounts receivable, accounts payable and accrued expenses approximated their fair value as of December 31, 2007 and 2006 due to their short-term nature. Short-term investments have been designated as available-for-sale and are carried at fair value with any net unrealized gain (loss) on investments recorded as a separate component of stockholders' equity entitled "Accumulated other comprehensive income."

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 income (loss). Other comprehensive income (loss) includes changes in equity that are excluded from net income (loss), which for all periods presented relates to unrealized holding gains and losses on available-for-sale investments.

Loss per Share

We compute basic loss per share by dividing net loss by the weighted average number of common shares outstanding during the relevant period. We did not include the following potential common shares issuable upon the exercise of outstanding options, restricted stock units, and warrants in our computation of diluted net loss per share because such options, restricted stock units and warrants were anti-dilutive due to a net loss in the relevant periods (in thousands):

	For the Year Ended December 31, 2007	For the Three Months Ended December 31, 2006	For the Years Ended September 30,	
			2006	2005
Options to purchase shares of common stock	1,327	1,206	1,042	917
Shares of common stock issuable upon the vesting of restricted stock units	36	34	30	
Warrants to purchase shares of common stock				622
Total	1,363	1,240	1,072	1,539

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

	For the Year Ended December 31, 2007	For the Three Months Ended December 31, 2006	For the Years Ended September 30, 2006	2005
Net loss	$ (33,894)	$ (7,440)	$ (25,365)	$ (12,715)
Weighted average common shares outstanding	15,777	12,383	10,964	8,634
Loss per share:				
Basic and diluted	$ (2.15)	$ (0.60)	$ (2.31)	$ (1.47)

Reclassifications

Certain amounts from the prior periods have been reclassified to conform to the current year presentation. We changed from the direct method presentation of cash flows to the indirect method presentation of cash flows in order to conform to comparable industry presentations.

C. Investments

As of December 31, 2007, our short-term investments totaled $258.6 million and consisted solely of securities classified as available-for-sale. As of December 31, 2006, our short-term investments totaled $41.6 million and consisted of corporate debt securities and U.S. treasury and government agency securities which were classified as held-to-maturity as well as municipal auction rate securities classified as available-for-sale.

At December 31, 2006, held-to-maturity securities were as follows (in thousands):

	December 31, 2006			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities				
Due in one year or less	$ 9,599	$ 1	$	$ 9,600
Due in one to three years				
U.S. treasury and government agency securities				
Due in one year or less	12,000		(4)	11,996
Due in one to three years				
	$ 21,599	$ 1	$ (4)	$ 21,596

At December 31, 2007 and 2006, approximately $105.4 million and $20.0 million, respectively, of our available-for-sale investments were auction rate securities. These auction rate securities consisted entirely of municipal debt securities recorded at cost, which approximates fair market value due to their variable interest rates, which typically reset through an auction process every 7 to 35 days. As of December 31, 2007 approximately 96% of these municipal auction rate securities were rated AAA/Aaa with the remaining 4% being rated AA/Aa3 or better, by investments rating agencies. Despite the long-term nature of their stated contractual maturities, we expect to have the ability to quickly liquidate these securities. In the event that a future auction is not able to be completed due to sell orders exceeding buy orders, we may not have the ability to quickly liquidate these investments. 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 redeems the outstanding securities, a buyer is found outside the auction process, or the securities mature. For all of our auction rate securities the underlying maturity date is in excess of one year and can be as far as 40 years in the future.

The following is a summary of our available-for-sale securities at each of December 31, 2007 and 2006 (in thousands):

	December 31, 2007			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
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
	$ 258,470	$ 273	$ (146)	$ 258,597

	December 31, 2006			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Auction rate securities				
Due in one year or less	$	$	$	$
Due after five years	20,000			20,000
	$ 20,000	$	$	$ 20,000

The following is a summary of the gross unrealized losses 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 each of December 31, 2007 and 2006 (in thousands):

	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)

	December 31, 2006					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
U.S. treasury and government agency securities	$ 11,996	$ (4)	$	$	$ 11,996	$ (4)

The unrealized losses on our investments at December 31, 2007 and 2006 were primarily caused by interest rate increases. Since the decline in market value is primarily attributable to changes in interest rates, 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, 2007 and 2006.

D. Inventories

The major classes of inventories were as follows at December 31, 2007 and 2006 (in thousands):

	December 31, 2007	December 31, 2006
Raw materials	$ 259	$ 289
Work in process	96	41
Finished goods	29	14
Total inventories	$ 384	$ 344

The aggregate amount of overhead remaining in ending inventory as of December 31, 2007 and 2006 was not significant.

E. Current and Long-Term Liabilities

Accrued expenses consisted of the following at December 31, 2007 and 2006 (in thousands):

	December 31, 2007	December 31, 2006
Clinical, regulatory and commercial consulting fees and expenses	$ 1,388	$ 2,224
Salaries, bonuses, and other compensation	3,009	791
Professional, license, and other fees and expenses	1,150	535
Totals	$ 5,547	$ 3,550

Deferred liabilities consisted of the following at December 31, 2007 and 2006 (in thousands):

	Deferred Revenue		Deferred Rent	Total
	Cytogen	Bayer		
At December 31, 2007:				
Short-term	$	$ 738	$	$ 738
Long-term		738	141	879
Total	$	$ 1,476	$ 141	$ 1,617

	Deferred Revenue			
At December 31, 2006:				
Short-term	$ 238	$ 738	$	$ 976
Long-term	120	1,474	94	1,688
Total	$ 358	$ 2,212	$ 94	$ 2,664

The decrease of Cytogen deferred revenue was related to the termination of our license agreement with Cytogen. Accordingly, because we had no remaining performance obligations under the contract,

we recognized the entire amount of remaining deferred revenue. The termination of our license agreement was in connection with the settlement of a lawsuit with Cytogen in February 2007. See Note K Commitments and Contingencies.

F. Income Taxes

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using statutory 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.

There were no income tax provisions or benefits for the year ended December 31, 2007, the three months ended December 31, 2006 or the years ended September 30, 2006 and 2005. A reconciliation of the statutory U.S. federal income tax rate to our effective income tax rate is as follows:

	For the Year Ended December 31, 2007	For the Three Months Ended December 31, 2006	For the Years Ended September 30,	
			2006	2005
Statutory U.S. federal tax rate	34.0%	34.0%	34.0%	34.0%
State taxes, net of federal benefit	6.3%	6.3%	6.3%	6.3%
Permanent items, net	(2.1)%	(1.9)%	0.2%	0.4%
Other	0.0%	0.0%	1.0%	0.0%
Valuation allowance	(38.2)%	(38.4)%	(41.5)%	(40.7)%
Total	0.0%	0.0%	0.0%	0.0%

The components of our deferred tax assets and liabilities were as follows (in thousands):

	For the Year Ended December 31, 2007	For the Three Months Ended December 31, 2006	For the Years Ended September 30,	
			2006	2005
Assets				
Net operating loss carry-forwards	$ 29,573	$ 26,657	$ 26,478	$ 17,804
Tax credit carry-forwards	7,360	6,898	4,423	4,110
Deferred revenue	594	1,035	1,124	1,490
Capital loss carry-forward		1,034	1,034	1,034
Stock option expense	2,738	1,214	1,237	137
Capitalized research & development	9,928	2,260		
Other	2,010	1,195	1,399	590
Liabilities				
Property, plant and equipment depreciation	(155)	(245)	(173)	(161)
Other			10	7
	52,048	40,048	35,532	25,011
Valuation allowance	(52,048)	(40,048)	(35,532)	(25,011)
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 $12.0 million, $4.5 million, $10.5 million

	For the Years Ended September 30,		

and $5.2 million for the year ended December 31, 2007, the three months ended December 31, 2006, and the years ended September 30, 2006 and 2005 respectively, primarily due to an increase in our net operating loss, or NOL, carryforwards, stock option expense and capitalized research and development expense.

At December 31, 2007, we had federal and state NOL carryforwards for income tax purposes of approximately $77.2 million and $53.0 million, respectively, to offset future taxable income. We also had an additional $16.2 million of federal and state NOLs not reflected above that were attributable to stock option exercises which will be recorded as an increase in additional paid in capital once they are "realized" in accordance with SFAS 123R. We also had federal and state tax credits to offset future tax liabilities of approximately $5.7 million and $2.5 million, respectively. Our NOLs will begin to expire in 2010 for federal purposes and began expiring in 2006 for state purposes. Our tax credits began to expire in 2007. These tax attributes will continue to expire through 2027 if not utilized.

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. As a result of the implementation of FIN 48, we recognized no material adjustment for unrecognized income tax benefits. At the adoption date of January 1, 2007 and also at December 31, 2007, we had no unrecognized tax benefits.

We recognize interest and penalties related to uncertain tax positions in income tax expense. As of January 1, 2007, the date of adoption of FIN 48, and December 31, 2007, we had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in our Consolidated Statements of Operations.

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, 2004, although carryforward attributes that were generated prior to tax year 2004 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.

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. Further, until a study is completed and any limitation known, no amounts are being presented as an uncertain tax position under FIN 48.

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.

Our 2007 Plan was approved by our stockholders on November 27, 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 or the Compensation Committee of our Board. Our Board may award stock options in the form of nonqualified stock options or incentive stock options, or ISOs. ISOs may be granted at an exercise price no less than fair market value 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, 2007, we have granted options covering 34,296 shares of common stock under the 2007 Plan, of which no stock options have expired or terminated, and none of which have been exercised. The remaining number of shares available for future grants as of December 31, 2007 was 3,309,459 determined by the sum of (i) 15,325, the number of shares that remained available for issuance under our 2000 Plan as of November 27, 2007; (ii) 1,328,430, the number of shares that remain issuable pursuant to awards outstanding under the 2000 Plan and which, prior to the adoption of the 2007 Plan, if unexercised would have reverted to the share reserve of the 2000 Plan; and (iii) an additional 2,000,000 shares, less 34,296 options granted and outstanding under the 2007 Plan.

Under our compensation plan for non-employee members of our Board, as revised, it is intended that once per year, each non-employee director, other than the Chairman, will be granted an option to purchase $100,000 in value of shares of our common stock and that the Chairman will be granted an option to purchase $200,000 in value of shares of our common stock, in each case determined using the Black-Scholes option pricing model. In accordance with this plan, on November 27, 2007, each of the non-employee, non-Chairman members of our Board were granted options to purchase 3,216 shares of our common stock and the Chairman of our Board was granted options to purchase 6,432 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 provides for the grant of options and other stock 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, are determined by our Board or the Compensation Committee of our Board. As of December 31, 2007, we have granted options and restricted stock units covering 2,182,700 shares of common stock under the 2000 Plan, of which 198,025 stock options and no restricted stock units have expired or terminated, and of which stock options and restricted stock units covering 647,745 and 8,500 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, 2007 was 1,292,930 and 35,500, 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. On November 27, 2007, the 2000 Plan was succeeded by our 2007 Plan and, accordingly, no further grants may be made under this plan.

On October 1, 2005, we adopted SFAS 123R and its related implementation guidance and pronouncements as promulgated by both the FASB and the SEC in SAB 107, associated with the accounting for the stock-based compensation arrangements of our employees and certain of our directors, including our Employee Stock Purchase Plan. These pronouncements require that equity-based compensation cost be measured at the grant date (based upon an estimate of the fair value of the compensation granted), or in certain circumstances, the service inception date, and recorded to expense or capitalized over the requisite service period, which generally is the vesting period. We adopted SFAS 123R using the modified prospective method and, accordingly, results for periods prior to October 1, 2005 do not include, and have not been revised to reflect, amounts associated with the requirements of SFAS 123R.

Stock-based compensation expense as reflected in our Consolidated Statements of Operations was as follows (in thousands):

	For the Year Ended December 31, 2007	For the Three Months Ended December 31, 2006	For the Years Ended September 30,	
			2006	2005
Research and development	$ 1,936	$ 442	$ 749	$ 341
Selling, general and administrative	6,246	106	3,254	
Total stock-based compensation expense	$ 8,182	$ 548	$ 4,003	$ 341

The stock-based compensation expense for the year ended December 31, 2007 included approximately $0.5 million of expense associated with our Board's decision to accelerate the vesting of options to acquire 25,000 shares of our common stock at an exercise price of $41.16 per share in connection with the retirement of our former Executive Chairman of the Board. There were no equity-based compensation costs capitalized in 2007 or prior periods as such amounts were not material. 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 recorded a full valuation allowance against our otherwise recognizable net deferred tax assets as of December 31, 2007 and 2006. Accordingly, no income tax benefits have been recognized by us since our adoption of SFAS 123R, and 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. This model requires the input of several factors such as the expected option term, expected volatility of our stock price over the expected option term, expected risk-free interest rate over the expected option term, expected dividend yield over the expected option term, and an expected forfeiture rate, which are subject to various assumptions. We also apply an estimate of future

forfeitures at the time of grant. The following table summarizes the weighted average assumptions we utilized for grants of options to differing groups of optionees:

	For the Year Ended December 31, 2007		For the Three Months Ended December 31, 2006		For the Year Ended September 30, 2006	
	Employees	Non-Employee Directors	Employees	Non-Employee Directors	Employees	Non-Employee Directors
Risk free interest rate(%)	4.41	3.44	4.54	4.60	4.59	4.48
Expected volatility(%)	64	62	73	73	76	77
Expected option term (years)	5.29	5.50	6.25	5.69	5.79	5.00
Dividend yield	none	none	none	none	none	none

Risk free interest rates utilized are based upon published U.S. Treasury yields at the date of the grant for the expected option term. 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.

Substantially all options granted have a contractual ten year term and generally vest over a four year period of continuous service. During 2007, we granted 110,000 performance-based option awards with a weighted average exercise price of $63.00. These awards will become exercisable in full immediately upon the achievement of certain performance goals established by our Board. For awards that contain performance conditions, compensation cost will only be recognized if the performance condition is considered probable of being achieved. During 2007, we recognized approximately $2.4 million in stock-based compensation expense associated with performance grants.

The following table summarizes details regarding our stock option plans for the year ended December 31, 2007 (excluding restricted stock units which are presented separately below):

	December 31, 2007			
	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value ($ in millions)
Outstanding at beginning of year	1,206,486	$ 21.06		
Granted	547,346	58.79		
Exercised	(374,481)	13.91		
Expired and/or Forfeited	(52,125)	30.56		
Outstanding at end of year	1,327,226	$ 38.27	8.6 years	$ 29.0
Outstanding at end of year vested or unvested and expected to vest	1,230,061	$ 38.56	8.6 years	$ 26.5
Exercisable at end of year	385,479	$ 18.04	7.7 years	$ 16.1

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

At December 31, 2007, the amount of unrecorded stock-based compensation expense for stock options attributable to future periods was approximately $21.3 million. Such amount will be amortized, in varying amounts, primarily to research and development or selling, general and administrative expense, on a straight line basis over a weighted average amortization period of approximately 3.0 years. This future estimate is 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 stock awards.

In the year ended December 31, 2007, we also issued an aggregate of 10,000 restricted stock units to employees pursuant to our 2000 Plan. These grants vest ratably, on an annual basis, over a four year period. The estimated fair value of restricted stock 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 these restricted stock unit awards was approximately $0.6 million. At December 31, 2007, the amount of unrecorded expense for all outstanding restricted stock units attributable to future periods was approximately $1.0 million, which is expected to be amortized primarily to expense on a straight line basis over a weighted average amortization period of approximately 2.7 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, and the issuance of new restricted stock awards.

The following table summarizes details regarding restricted stock units granted under our stock option plans for the year ended December 31, 2007:

	December 31, 2007	
	Unvested Restricted Stock Units	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2006	34,000	$ 24.92
Granted	10,000	56.58
Exercised	(8,500)	24.92
Forfeited		
Outstanding at December 31, 2007 and expected to vest	35,500	$ 33.84
Restricted Stock Units exercisable at end of year		$

Prior to October 1, 2005, we applied Accounting Principles Board Opinion No. 25 "Accounting for Stock Issued to Employees," or APB 25, and related interpretations in accounting for qualifying options granted to our employees and directors under our equity compensation plans and applied SFAS No. 123 "Accounting for Stock Issued to Employees," or SFAS 123 (as amended by SFAS 148 "Accounting for Stock-Based Compensation-Transition and Disclosure-an amendment of FASB Statement No. 123," or SFAS 148), for disclosure purposes only. The SFAS 123 and SFAS 148 disclosures for periods prior to October 1, 2005 include pro forma net loss and loss per share as if the fair value-based method of accounting had been used.

If stock-based compensation for employees had been determined based on SFAS 123, as amended by SFAS 148, our pro forma net loss and pro forma loss per share for the year ended September 30, 2005 would have been as follows (in thousands, except per share data):

	For the Year Ended September 30, 2005
Reported net loss	$ (12,715)
Pro forma stock compensation expense	(1,262)
Pro forma net loss	$ (13,977)
Reported loss per share:	
Basic and diluted	$ (1.47)
Pro forma loss per share:	
Basic and diluted	$ (1.62)

The fair value of substantially all options granted during the year ended September 30, 2005 was estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	Employees	Non-employee Directors
Risk free interest rate (%)	3.9	3.5
Expected volatility (%)	76.7	69.9
Expected option term (years)	6.25	6
Dividend yield	none	none

Employee Stock Purchase Plan

Our 2006 Employee Stock Purchase Plan, or the 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, 2007, 3,058 shares have been issued under our 2006 ESPP.

The assumptions used for awards granted during 2007 under our 2006 ESPP were as follows:

	For the Year Ended December 31, 2007
Risk free interest rate (%)	4.1
Expected volatility (%)	33.3
Expected option term (years)	0.5
Dividend yield	none

The weighted average fair value for purchase rights granted under our 2006 ESPP and predecessor employee stock purchase plans during the year ended December 31, 2007, the three months ended December 31, 2006, and the years ended September 30, 2006 and 2005 was $19.23, $0, $11.54, and $5.24, respectively, and was estimated using the Black-Scholes option-pricing model.

Stock Options Granted to Consultants

In the year ended September 30, 2005, we granted options to one of our directors pursuant to a consulting agreement. In July 2005 we entered into a one-year consulting agreement with Dr. Brian J.G. Pereira, who was then one of our directors but not an officer or employee. Under the terms of the consulting agreement, Dr. Pereira provided advice and consultation to us in the areas of business development, product marketing, medical affairs, Data Safety Monitoring Board and Scientific Advisory Board recruitment, and such other areas as we may have requested from time to time. The term of the consulting agreement was not extended. As compensation for his consulting services, Dr. Pereira received a grant of options to purchase 60,000 shares of our common stock at an exercise price of $10.80 per share. The options were exercisable with respect to 5,000 shares immediately and 5,000 additional shares vested at the beginning of each calendar month following the date of grant, beginning with August 1, 2005, such that all shares were fully vested and exercisable during 2006. This resulted in a non-cash charge of approximately $0.3 million being recorded in the year ended September 30, 2005 with an offsetting credit to additional paid-in capital, in an amount approximating the fair value of the foregoing options.

In August 2005, we entered into three-year consulting agreements with seven nonaffiliated members of our Scientific Advisory Board, or SAB. Under the terms of these consulting agreements, the SAB members provided advice and consultation to us as we progressed through our ongoing development program for ferumoxytol as an IV iron replacement therapeutic. The term of the consulting agreements could be extended for additional periods with the written consent of each party. As compensation for these consulting services, we granted these SAB members, in the aggregate, options to purchase 11,000 shares of our common stock under our 2000 Stock Plan, at an exercise price of $11.82 per share, in addition to cash compensation also associated with some of the agreements. The options were exercisable with respect to 2,750 shares immediately, and at the beginning of each quarter following the date of grant, beginning with November 1, 2005, 2,750 additional shares vested, such that all such options became fully vested and exercisable as of September 30, 2006. This resulted in a non-cash accounting charge being recorded as an expense each quarter over a one year period, of which $44,550 was charged to expense in the fourth quarter of the year ended September 30, 2005 and $93,714 was charged to expense in the year ended September 30, 2006 with an offsetting credit to additional paid-in capital, in an amount approximating the fair value of the foregoing options.

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. Through December 31, 2006, the 401(k) Plan permitted, but did not require, us to make contributions to the 401(k) Plan on behalf of our employees. Our practice, however, was to match every dollar of an employee's contributions up to the first 6% of an employee's compensation with a total maximum matching contribution of $2,000 per year. Our matching contributions vested over a five year period. In December 2006, we amended our 401(k) Plan, effective January 1, 2007, to provide, 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 $210,000, $36,000, $73,000 and $54,000, for the year ended December 31, 2007, the three months ended December 31, 2006 and the years ended September 30, 2006 and 2005, 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 Financings

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, or the Securities Act.

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

In June 2005, we sold an aggregate of approximately 1.8 million shares of our common stock and warrants to purchase an aggregate of 0.4 million shares of our common stock in registered direct sales of common stock and warrant units to affiliates of Great Point Partners, LLC and Vivo Ventures, LLC and Brian J. G. Pereira, MD, who was a director but not an officer of our Company at the time. Each unit was comprised of five shares of common stock and a warrant to purchase one share of common stock. The issue price for each unit was $47.50, and the exercise price for each warrant was $13.00 per share. The warrants had a term of three years. All of these warrants were exercised during the year ended September 30, 2006, with 136,582 shares tendered via a non-cash exchange in payment of the exercise price per the terms of the warrants, resulting in the net issuance of 220,260 shares of our common stock, and 3,157 shares issued to Dr. Pereira in exchange for cash payment of the exercise price. Net proceeds to us after deducting fees, commissions and other expenses related to the offering were approximately $16.7 million.

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 nanoparticle 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 several agreements to service and/or lease certain office and laboratory equipment under operating leases that expire through 2009. Equipment expense for the year ended December 31, 2007, the three months ended December 31, 2006, and the years ended September 30, 2006 and 2005 amounted to approximately $133,000, $14,000, $79,000, and $35,000, respectively. Future minimum lease payments associated with all noncancellable equipment, service and lease agreements (which exclude facility related leases) for the years 2008 and 2009 are estimated to be $98,000 and $31,000, respectively.

We are a party to a lease agreement with W2007 CPD Realty, L.L.C (successor to CambridgePark 125 Realty Corporation) for certain real property comprised of approximately 25,000 square feet of executive office space located at 125 CambridgePark Drive, Cambridge, Massachusetts. The lease has a three year term which expires on February 28, 2009 and provides for one option to extend the lease for a two year period. In 2008 and 2009, our aggregate rent payment under this lease will be approximately $0.8 million and $0.1 million, respectively. In addition to rent, we are also required to pay a proportionate share of the landlord's annual operating costs and electricity. The rent for any extension term will be determined at the time of the exercise of the option under terms set out in the lease.

Facility-related rent expense recorded for the year ended December 31, 2007, the three months ended December 31, 2006, and the year ended September 30, 2006 was $0.4 million, $0.1 million, and $0.1 million, respectively. There was no facility-related rent expense incurred in the year ended September 30, 2005. As of December 31, 2007, future minimum facility-related lease payments for years 2008 and 2009 are $0.8 million and $0.2 million, respectively.

In accordance with FASB Technical Bulletin No. 85-3 "Accounting for Operating Leases with Scheduled Rent Increases," rent expense is being recognized in our financial statements on a straight-line basis over the lease term, excluding extension periods. In addition, in fulfillment of a security deposit requirement for the leased space describe above, we have issued a $60,687 irrevocable letter of credit to the landlord. 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 2007, we entered into an agreement under which we have paid approximately $1.0 million for material and manufacturing process development expenses, and for which we have a remaining purchase commitment of approximately $0.5 million as of December 31, 2007. In 2007, we also entered into an agreement for certain improvements upon our building for which we have a remaining purchase commitment of approximately $0.1 million as of December 31, 2007.

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. In our recent history, 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

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*. On January 25, 2006, Cytogen filed a lawsuit against us in Massachusetts Superior Court in connection with the license and marketing agreement. 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 discontinued its pursuit of all claims against the other, and all agreements between the parties were terminated. With the termination of our agreements with Cytogen, the U.S. marketing rights to *Combidex* as well as the U.S. marketing rights to ferumoxytol for oncology imaging applications reverted back to us. 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 2007 and because the shares of Cytogen common stock were held in escrow, for which we had not previously recorded any amount in our financial statements, there was no financial statement impact with respect to the release of these shares.

We may periodically become subject to legal proceedings and claims arising in connection with on-going business activities, including being subject to claims or disputes related to patents that have been issued or 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, 2007.

L. Collaborative Agreements and Contracts

Our strategy has included the formation of alliances with other pharmaceutical companies to facilitate the sale and distribution of our products. At present we have the following principal collaborations:

Bayer Healthcare Pharmaceuticals (formerly Berlex Laboratories, Inc.)

In February 1995, we entered into a license and marketing agreement and a supply agreement 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 agreement. Under the terms of the supply agreement, we receive payments for manufacturing the product and royalties on sales. Under the terms of the license and marketing agreement with Bayer, Bayer pays 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.* and do not intend to incur such expenses in the future. These agreements expire in 2010 but can be terminated earlier upon the occurrence of certain specified events.

Guerbet

In 1987, we entered into a supply and distribution agreement with Guerbet whereby Guerbet was appointed the exclusive distributor of *Feridex I.V.* in western Europe and Brazil (under the tradename Endorem®). This agreement was amended in 2002 to expand Guerbet's exclusive rights to distribute *Feridex I.V.* in various other areas, including South America, the Middle East, southeast Asia, and eastern Europe. The agreement was further amended in 2006 to expand Guerbet's exclusive rights to distribute *Feridex I.V.* in certain additional southeast Asian countries and South Africa. Guerbet is responsible for conducting clinical trials and securing the necessary regulatory approvals in the countries in its territory. Guerbet did not pursue marketing approval in all the countries in which it had rights. Under the terms of this agreement, Guerbet was obligated to pay royalties to us based on products shipped for resale. We were entitled to receive an additional percentage of Guerbet's sales in return for selling to Guerbet its requirements for the active ingredient used in *Feridex I.V.* The 1987 agreement with Guerbet terminated by its terms in 2007.

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. Guerbet has exercised its rights to manufacture and sell *Combidex* (under the tradename Sinerem®) in western Europe and Brazil. This agreement was amended in 2002 to expand Guerbet's exclusive rights to manufacture and sell *GastroMARK* and *Combidex* in various other areas, including South America, the Middle East, southeast Asia, and eastern Europe. The agreement was further amended in 2006 to expand Guerbet's exclusive rights to distribute *Combidex* in certain additional countries. However, Guerbet has not pursued marketing approval in all the countries in which it has rights. In February 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 ferumoxytol 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 *Combidex* and *GastroMARK*. The agreement is perpetual but terminable upon certain specified events.

Covidien (formerly Tyco Healthcare and Mallinckrodt Medical, 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.

Bristol-Myers Squibb Co.

In 1994, under an agreement with Bristol-Myers Squibb Co., or Bristol-Myers, we reacquired the development and marketing rights to *Combidex*, which had previously been licensed to Bristol-Myers. Pursuant to this agreement, we are obligated to pay up to a maximum of approximately $2.8 million in royalties to Bristol-Myers in connection with commercial product sales of *Combidex*. We have not paid any royalties with respect to this agreement to date.

Other

We are the licensee of certain technologies related to our 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 2007, 2006 or 2005. Future milestone payments under the Amersham agreement will not exceed $0.4 million.

We are a party to an agreement with FoxKiser Development Partners LLC, or FoxKiser, one of our regulatory consultants for *Combidex*, which provides for certain royalty payments to FoxKiser based on future commercial product sales of *Combidex*, if any.

M. Consolidated Quarterly Financial Data Unaudited

The following tables provide consolidated quarterly financial data for the years ended December 31, 2007 and September 30, 2006 (in thousands, except per share data):

	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)
Loss per share basic and diluted	$ (0.72)	$ (0.46)	$ (0.42)	$ (0.57)

	March 31, 2006	June 30, 2006	September 30, 2006	December 31, 2006
License fees	$ 229	$ 237	$ 217	$ 222
Royalties	79	133	58	44
Product sales	406	574	76	353
Total revenues	714	944	351	619
Cost of product sales	51	90	10	287
Operating expenses	6,052	8,107	10,214	8,590
Interest and dividend income, net	255	584	561	818
Loss on disposal of assets			(35)	
Net loss	$ (5,134)	$ (6,669)	$ (9,347)	$ (7,440)
Loss per share basic and diluted	$ (0.50)	$ (0.57)	$ (0.78)	$ (0.60)

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

N. Transition Period Comparative Data

The following table presents certain unaudited financial information for the three months ended December 31, 2006 and December 31, 2005 (in thousands, except per share data):

	December 31, 2006	December 31, 2005
Revenues	$ 619	$ 664
Cost of product sales	287	122
Operating expenses	8,590	4,932
Interest income	818	175
Loss on disposal of assets		
Net loss	$ (7,440)	$ (4,215)
Loss per share basic and diluted	$ (0.60)	$ (0.43)
Weighted average shares outstanding used to compute net loss per share:		
Basic and diluted	12,383	9,886

O. Recently Issued and Proposed Accounting Pronouncements

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. However, for some entities, the application of this statement will change current practice. SFAS 157 is effective for years beginning after November 15, 2007, and interim periods within those years. Accordingly, we are in the process of evaluating the impact of SFAS 157.

In February 2007, the FASB issued 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 elect to measure selected financial instruments and certain other items at fair value. Unrealized gains and losses on items for which the fair value option has been elected are recognized in earnings in each reporting period. SFAS 159 is effective for years beginning after January 1, 2008, and interim periods within those years. Accordingly, we are in the process of evaluating the impact of the adoption of SFAS 159.

In June 2007, the EITF reached a consensus on Issue 07-03, "Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities," or EITF 07-03, which addresses the diversity which exists with respect to the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. Under this EITF, an entity would defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. EITF 07-03 is effective for years beginning after December 15, 2007 and interim periods within those years. Accordingly, we are in the process of evaluating the impact of EITF 07-03.

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 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 is effective for financial statements issued for years beginning after December 15, 2008. Accordingly, we are in the process of evaluating the impact of SFAS 141R.

P. Subsequent Events

Beginning in mid-February 2008, several of our municipal auction rate securities experienced failed auctions. Since then, the continued uncertainty in the credit markets has caused additional auctions with respect to our auction rate securities to fail and prevented us from liquidating certain of our holdings of auction rate securities because the amount of these securities submitted for sale has exceeded the amount of purchase orders for these securities. At December 31, 2007, approximately $105.4 million of our available-for-sale investments were municipal auction rate securities. In the event we need to access our investments in these securities, we will not be able to do so until a future auction on these investments is successful, the issuer redeems the outstanding securities, a buyer is found outside the auction process, or the securities mature. If the issuers are unable to successfully close future auctions and their credit ratings deteriorate, we may be required to adjust the carrying value of these investments through an impairment charge, which could be material. In addition, due to our inability to quickly liquidate these investments, we may reclassify those securities with failed auctions as long-term assets in our consolidated balance sheet.

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, has 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 Exchange Act 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 concluded that our disclosure controls and procedures 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 to the SEC for the year ended December 31, 2007.

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, 2007 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION:

None.

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, 2007.

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, 2007.

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, 2007.

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 within 120 days after the close of our year ended December 31, 2007.

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, 2007.

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, 2007 and 2006

Consolidated Statements of Operations for the year ended December 31, 2007, the three months ended December 31, 2006 and the years ended September 30, 2006 and 2005

Consolidated Statements of Comprehensive Loss for the year ended December 31, 2007, the three months ended December 31, 2006 and the years ended September 30, 2006 and 2005

Consolidated Statements of Stockholders' Equity for the year ended December 31, 2007, the three months ended December 31, 2006 and the years ended September 30, 2006 and 2005

Consolidated Statements of Cash Flows for the year ended December 31, 2007, the three months ended December 31, 2006 and the years ended September 30, 2006 and 2005

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.

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3.1, 4.1	Certificate of Incorporation of the Company, as amended (incorporated herein by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, 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 30, 2007, File No. 0-14732).
3.3	Certification of Ownership and Merger (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed July 24, 2007, File No. 0-14732).
4.3	Specimen certificate representing the Company's Common Stock (incorporated herein by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, File No. 0-14732).
10.1*	Advanced Magnetics, Inc. Amended and Restated 2000 Stock Plan (incorporated herein by reference to Appendix A to the Company's definitive proxy statement for the year ended September 30, 2005, File No. 0-14732).
10.2	Contrast Agent Agreement between the Company and Guerbet S.A. dated as of September 29, 1989 (incorporated herein by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K for the year ended September 30, 1989, File No. 0-14732) (confidential treatment

Exhibit Number	Description
	previously granted).

10.3	License, Supply and Marketing Agreement between the Company and Mallinckrodt Medical, Inc. dated as of June 28, 1990 (incorporated herein by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K for the year ended September 30, 1990, File No. 0-14732) (confidential treatment previously granted).
10.4	Technology License Agreement between the Company and Squibb Diagnostics, dated as of February 5, 1991 (incorporated herein by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-K for the year ended September 30, 1991, File No. 0-14732) (confidential treatment previously granted).
10.5	Termination Agreement dated as of August 30, 1994 between the Company and Bristol-Myers Squibb Co. (incorporated herein by reference to Exhibit 10.26 to the Company's Annual Report on Form 10-K, for the year ended September 30, 1994, File No. 0-14732).
10.6	License and Marketing Agreement between the Company and Berlex Laboratories, Inc. dated as of February 1, 1995 (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, as amended, for the quarter ended December 31, 1994, File No. 0-14732) (confidential treatment previously granted).
10.7	Supply Agreement between the Company and Berlex Laboratories, Inc. dated as of February 1, 1995 (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, as amended, for the quarter ended December 31, 1994, File No. 0-14732) (confidential treatment previously granted).
10.8*	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).
10.9*	Specimen of Stock Option Grant in connection with 2000 Stock Plan (employees) (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2005, File No. 0-14732).
10.10*	Specimen of Stock Option Grant in connection with 2000 Stock Plan (non-employees) (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2005, File No. 0-14732).
10.11*	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).
10.12*	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).
10.13*	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).
10.14*	Restricted Stock Unit Agreement, dated as of February 7, 2006, by and 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 February 13, 2006, File No. 0-14732).
10.15*	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).
10.16*	Summary of the Advanced Magnetics, Inc. Change of Control Policy applicable to executive officers (incorporated herein by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed February 13, 2006, File No. 0-14732).

10.17	Lease Agreement, dated as of February 28, 2006, by and between Advanced Magnetics, Inc. and CambridgePark 125 Realty Corporation, (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed March 3, 2006, File No. 0-14732).
10.18	First Amendment to Lease, dated as of November 29, 2006, by and between Advanced Magnetics, Inc. and CambridgePark 125 Realty Corporation. (incorporated herein by reference to Exhibit 10.40 to the Company's Annual Report on Form 10-K filed December 1, 2006, File No. 0-14732).
10.19	Settlement Agreement between the Company and Cytogen Corporation dated as of February 15, 2007 (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed February 20, 2007, File No. 0-14732).
10.20*	Advanced Magnetics, Inc. 2006 Employee Stock Purchase Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2007, File No. 0-14732).
10.21	Agreement between the Company and FoxKiser Development Partners LLC dated as of April 19, 2002 (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2007, File No. 0-14732).
10.22	Amendment to Agreement between the Company and FoxKiser Development Partners LLC dated as of January 25, 2005 (incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2007, File No. 0-14732).
10.23*	Summary of the Company's Director Compensation Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, File No. 0-14732).
10.24*	Employment Agreement dated as of August 6, 2007 between the Company and Lee F. Allen (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, File No. 0-14732).
10.25*	Amended and Restated Employment Agreement dated as of July 31, 2007 between the Company and Brian J.G. Pereira, MD. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 3, 2007, File No. 0-14732).
10.26*	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).
10.27*	Amended and Restated Employment Agreement dated as of July 31, 2007 between the Company and Joseph L. Farmer (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed August 3, 2007, File No. 0-14732).
10.28*	Amended and Restated Employment Agreement dated as of July 31, 2007 between the Company and Louis Brenner (incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed August 3, 2007, File No. 0-14732).
10.29*	Amended and Restated Employment Agreement dated as of July 31, 2007 between the Company and Timothy G. Healey (incorporated herein by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed August 3, 2007, File No. 0-14732).
10.30*	Amended and Restated Employment Agreement dated as of July 31, 2007 between the Company and Jerome Lewis (incorporated herein by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed August 3, 2007, File No. 0-14732).

10.31	Second Amendment to Lease, dated as of August 27, 2007, by and between the Company and W2007 CPD Realty, LLC (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed August 28, 2007, File No. 0-14732).
10.32*	AMAG Pharmaceuticals, Inc. 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed November 30, 2007, File No. 0-14732).
10.33*	Form of Option Agreement (ISO) in connection with the Company's 2007 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed November 30, 2007, File No. 0-14732).
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21.1++	Subsidiaries of the Company
23.1++	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
31.1++	Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2++	Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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

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, 2008

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ BRIAN J. G. PEREIRA Brian J. G. Pereira, MD	Chief Executive Officer, President and Director (Principal Executive Officer)	February 27, 2008
/s/ DAVID A. ARKOWITZ David A. Arkowitz	Chief Financial Officer and Chief Business Officer (Principal Financial and Accounting Officer)	February 27, 2008
/s/ MICHAEL D. LOBERG Dr. Michael D. Loberg	Director	February 27, 2008
/s/ MARK SKALETSKY Mark Skaletsky	Director	February 27, 2008
/s/ MICHAEL NARACHI Michael Narachi	Director	February 27, 2008
/s/ RON ZWANZIGER Ron Zwanziger	Director	February 27, 2008
/s/ DAVEY S. SCOON Davey S. Scoon	Director	February 27, 2008

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23.1++	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
31.1++	Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2++	Certification Pursuant to Rule 13a-14(a)/15d-14(a) of the Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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