UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended September 30, 2005

OR

☐ **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

Advanced Magnetics, 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.)
61 Mooney Street, Cambridge, Massachusetts	**02138**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code **(617) 497-2070**

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

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

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** ☒ **No** ☐

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. ☐

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). **Yes** ☐ **No** ☒

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

The aggregate market value of the registrant's voting stock held by non-affiliates as of March 31, 2005 was approximately $47,400,000 based on the closing price of the Common Stock of the registrant as reported on the American Stock Exchange on such date. As of December 12, 2005, there were 9,910,229 shares of the registrant's Common Stock, par value $.01 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a Definitive Proxy Statement for its 2005 Annual Meeting of Stockholders, scheduled to be held on February 7, 2006, pursuant to Regulation 14A within 120 days of the end of the fiscal year ended September 30, 2005. Portions of such Proxy Statement are incorporated by reference in Part III hereof.

ADVANCED MAGNETICS, INC.
FORM 10-K
FOR THE FISCAL YEAR ENDED SEPTEMBER 30, 2005
TABLE OF CONTENTS

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 federal securities laws. In this Annual Report on Form 10-K, words such as "may," "will," "expects," "intends," and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. 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 factors discussed in Part II, Item 7 under "Certain Factors That May Affect Future Results" 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 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

Advanced Magnetics, Inc. was incorporated in Delaware in November 1981 and is a developer of superparamagnetic iron oxide nanoparticles used in pharmaceutical products. We are dedicated to the development and commercialization of our proprietary nanoparticle technology for use in 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, the key product in our development pipeline, is in Phase III multi-center clinical trials for use as an iron replacement therapeutic in chronic kidney disease patients, whether or not on dialysis. In August 2005, we announced our plan to revise the Phase III development program for ferumoxytol in intravenous (IV) iron replacement therapy based on discussions with the U.S. Food and Drug Administration, or FDA. The modifications to the Phase III program will, among other things, result in additional patients being enrolled in the ferumoxytol chronic kidney disease, or CKD, efficacy studies and the re-design of the hemodialysis efficacy study currently under way. We also announced that we plan to add additional patients to our large-scale safety study to provide a more robust safety database for the New Drug Application, or NDA, for ferumoxytol. In August 2005 we also announced the formation of a Scientific Advisory Board to advise us on clinical development, market preparation, pre-launch and other strategic activities in our efforts to complete our development program for ferumoxytol and a Data Monitoring Committee to provide independent oversight of the Phase III iron replacement therapy program. We expect to submit an NDA for ferumoxytol in IV iron replacement therapy to the FDA in mid calendar year 2007.

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. We have submitted a formal meeting request to the FDA to discuss next steps in the regulatory process for *Combidex*. Due to our limited resources and the priority we are placing on completion of the Phase III development program for ferumoxytol in iron replacement therapy, we do not currently intend to sponsor additional clinical studies for *Combidex*. However, we are reviewing and evaluating existing studies, including studies sponsored by our European partner, Guerbet, to determine whether such studies will address the concerns raised by the FDA in the March 2005 approvable letter. Until we complete our

evaluation of these studies and meet with the FDA to discuss next steps, we cannot predict with certainty the timing or cost of the efforts that would be necessary to satisfy the conditions specified by the FDA for approval of *Combidex* or our ability to complete those efforts in a timely or cost-effective manner, if at all.

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

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 bio-available iron that is easily absorbed 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 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 results 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

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 product candidates and the primary markets for our approved products.

Product	Applications	Marketing Partners	U.S. Status	Foreign Status
ferumoxytol	Iron replacement therapy	None	Phase III clinical trials ongoing	None
	MRI contrast agent	Cytogen Corporation (United States) for oncology imaging applications only	Exploratory Phase II clinical trials completed	None
Combidex	Differentiation of cancerous from normal lymph nodes	Cytogen Corporation (United States), Guerbet (various countries in the European Union, South America, the Middle East, Southeast Asia and the former Soviet Union)	Received approvable letter from FDA in March 2005	Phase III clinical trials ongoing by our European partner
Feridex I.V.	Diagnosis of liver lesions	Berlex Laboratories, Inc. (United States), Eiken Chemical Co., Ltd. (Japan)*, Guerbet (various countries in the European Union and South America, the Middle East, Southeast Asia and the former Soviet Union)	Approved and marketed	Approved and marketed in Japan* and most European Union countries
GastroMARK	Delineating the bowel in abdominal imaging	Mallinckrodt, Inc. (United States), Guerbet (various countries in the European Union and South America, the Middle East, Southeast Asia and the former Soviet Union)	Approved and marketed	Approved and marketed in several European Union countries

* Eiken Chemical Co., Ltd., or Eiken, has recently informed us of its desire to terminate its existing supply and marketing agreement with us with respect to *Feridex I.V.* due to increased competition and limited sales of the product in Japan. With our permission, Eiken has begun the process of withdrawing *Feridex I.V.* as an approved product in Japan with the appropriate regulatory authorities. We expect the withdrawal and the termination of our supply and marketing agreement with Eiken to take effect in early calendar year 2007.

For a discussion of the substantive regulatory requirements applicable to the development process, see "Government Regulation and Reimbursement."

Ferumoxytol as an 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 or kidney failure, as well as in many patients receiving chemotherapy. According to the United States Renal Data System or USRDS, there are over 350,000 CKD patients on dialysis in the United States, the majority of whom suffer from anemia and receive erythropoietin and IV iron replacement therapy to manage their condition. Additionally, according to the National Kidney Foundation, there are approximately 8 million people in the United States suffering from moderate (stage 3) or severe (stage 4) CKD who are not yet on dialysis. Some of these patients suffer from anemia and would benefit from receiving erythropoietin and IV iron replacement therapy.

Kidney Disease and Anemia

Diseased kidneys do not produce enough erythropoietin to stimulate sufficient production of red blood cells to meet the body's needs. Consequently, people with CKD often develop anemia. To increase red blood cell production, anemic CKD patients are given recombinant erythropoietin therapy, which in turn increases their need for iron. Long-term use of erythropoietin therapy causes the body to progressively deplete its iron stores to meet this increased need for iron. As a result, the majority of these CKD patients eventually develop iron deficiency anemia and require iron replacement therapy. In addition, when iron stores become too low, erythropoietin therapy becomes less effective in treating anemia. Iron deficiency is often worse in hemodialysis patients in particular due to blood loss in the dialysis procedure or from intermittent gastrointestinal bleeding.

Ferumoxytol and the Treatment of Chronic Anemia

The National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines recommend starting patients who need iron on oral iron supplements as a first-line treatment for iron deficiency anemia in CKD patients. For most patients receiving erythropoietin, 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 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.

If approved by the FDA, we believe ferumoxytol would be an effective iron replacement therapy for CKD patients, whether or not on dialysis. Clinical studies to date show that ferumoxytol has greater flexibility in both the time of administration and the amount of iron that can be given to a patient as compared to IV iron replacement therapeutics currently on the market in the United States. Phase III multi-center clinical studies for ferumoxytol for use in iron replacement therapy in anemic CKD patients, whether or not on dialysis, are ongoing in the United States. We currently project the submission of the NDA for ferumoxytol in iron replacement therapy to the FDA in mid calendar year 2007 based on the current progress of our Phase III clinical program.

We do not currently have a marketing partner for ferumoxytol as an iron replacement therapy.

The Role of *Combidex* in Contrast-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. *Combidex* is an investigational functional molecular imaging agent that localizes to and causes contrast enhancement of normal lymph nodes. Clinical trials have demonstrated that MRI exams of lymph nodes using *Combidex* as part of staging cancer provide increased accuracy in the evaluation of lymph nodes as cancerous or normal, which we believe will allow for a safe, cost-effective way to improve patient diagnosis and staging. There are no MRI agents designed specifically for imaging lymph nodes currently on the market.

Lymph nodes are frequently the site for metastases of different types of cancer, particularly breast cancer and prostate cancer. According to the American Cancer Society 2005 Cancer Facts and Figures, over 900,000 new cases of cancer that could spread to the lymph nodes will have been diagnosed during 2005. Lymph node imaging plays a role in staging patients and determining appropriate patient management. There are currently no available non-invasive methods for distinguishing between lymph nodes enlarged by the infiltration of cancerous cells as opposed to inflammation. 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 8-10 mm and often falsely suggests cancer in other conditions with increased metabolic activity, for example, infection. We have demonstrated in clinical studies that *Combidex* only accumulates in normal lymph node tissue and can therefore facilitate differentiation between cancerous nodes and normal nodes. We believe that *Combidex* will enable doctors 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* in the United States to Cytogen Corporation, or Cytogen, and in various countries in the European Union, or EU, South America, the Middle East, Southeast Asia and the former Soviet Union to Guerbet under the tradename Sinerem™. See "Licensing, Marketing and Supply Arrangements."

The Role of Ferumoxytol in Contrast-enhanced 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 contrast agent in a wide range of applications in MRI. We recently completed exploratory Phase II clinical studies for use of ferumoxytol in contrast-enhanced magnetic resonance angiography, or MRA, a type of MRI. We plan to evaluate the data from these Phase II studies to determine the appropriate regulatory strategy, if any, for a Phase III development program for ferumoxytol in MRI. However, given our limited resources and the priority we are placing on completion of the Phase III development program for ferumoxytol in iron replacement therapy, we may not be able to advance the ferumoxytol MRI program in the near future.

We have granted exclusive rights to market ferumoxytol, for oncology imaging applications only, in the United States to Cytogen, although no such clinical applications are currently planned or contemplated. We do not currently have a marketing partner for ferumoxytol in MRA or non-oncology MRI applications. See "Licensing, Marketing and Supply Arrangements."

Feridex I.V.

The liver is often the site for metastasis of different types of cancer, particularly colon cancer. 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. Berlex Laboratories, Inc., or Berlex, our exclusive U.S. marketing partner for *Feridex I.V.,* has been marketing *Feridex I.V.* in the United States since October 1996. *Feridex I.V.* was approved in August 1994 by the European Union's Committee for Proprietary Medicinal Products and most of the member states of the EU have since issued local approvals to market the product. Guerbet has been marketing the product on an exclusive basis in Europe since late 1994, and subsequently acquired the rights to market the product in several other countries under the tradename Endorem™. Eiken received regulatory approval to market *Feridex I.V.* in Japan in July 1997 and has been marketing the product on an exclusive basis in Japan since September 1997 through its affiliate Tanabe Seiyaku, Ltd. Eiken recently informed us of its desire to terminate its existing supply and marketing agreement with us with respect to *Feridex I.V.* due to increased competition and limited sales of the product in Japan. With our permission, Eiken has begun the process of withdrawing *Feridex I.V.* as an approved product in Japan. 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 marking 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.

Our marketing partner, Mallinckrodt, Inc., or Mallinckrodt, has been marketing *GastroMARK* in the United States since April 1997. We have licensed the marketing rights to *GastroMARK* on an exclusive basis to Guerbet in western Europe and Brazil. Guerbet has been marketing the product in several EU countries since 1993 under the tradename Lumirem™, and subsequently acquired the rights to market the product in several other countries. See "Licensing, Marketing and Supply Arrangements."

Licensing, Marketing and Supply Arrangements

Our marketing strategy includes forming alliances with pharmaceutical companies to facilitate the sale and distribution of our products. At present we have the following principal collaborations:

BERLEX LABORATORIES, INC. In February 1995, we entered into a license and marketing agreement and a supply agreement with Berlex, granting Berlex a product license and exclusive marketing rights to *Feridex I.V.* in the United States and Canada. In 1996, the parties agreed to remove Canada from the territories subject to the agreement. Under the terms of the agreement, we receive payments for manufacturing the product and royalties on sales. Under the terms of our agreements with Berlex, Berlex pays for 60% of ongoing development expenses related to *Feridex I.V.* These agreements expire in 2010 but can be terminated earlier upon the occurrence of certain specified events. Under the terms of the license and marketing agreement, we have the right to terminate the exclusive marketing rights based on the failure of Berlex to achieve minimum sales targets, but we have not exercised that right at this time.

CYTOGEN CORP. In August 2000, we entered into a license and marketing agreement and a supply agreement with Cytogen. Cytogen has exclusive United States marketing rights to *Combidex*, our 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 addition, Cytogen has the exclusive right to market and sell ferumoxytol, for oncology imaging applications only, in the United States. However, we have decided not to pursue the development of ferumoxytol for oncology imaging applications. Under the terms of our agreement, we also agreed to grant to Cytogen the exclusive right to market and sell *Feridex I.V.* in the United States if our existing marketing arrangement with Berlex for *Feridex I.V.* terminates for any reason. Upon signing the agreements with Cytogen, we received 1,500,000 shares of Cytogen common stock as a non-refundable license fee. An additional 500,000 shares of Cytogen common stock were placed in escrow to be released to us upon satisfaction of certain milestones under the agreements. As a result of a 10 for 1 reverse stock split of Cytogen's common stock, which became effective in October 2002, these escrowed shares have been converted into 50,000 shares of Cytogen common stock. The release of 25,000 of these shares is dependent upon progress in the development of ferumoxytol for oncology imaging applications, and we do not anticipate achieving this milestone. The release of the other 25,000 shares is dependent upon issuance by the FDA of an approval letter relating to *Combidex*. Cytogen has agreed to pay us for manufacturing and supplying the products and royalties on sales, if any, relating to the products licensed to them. These agreements have an initial ten-year term with automatic five-year extensions, but can be terminated earlier upon the occurrence of certain specified events.

EIKEN CHEMICAL CO., LTD. In 1988, we entered into a supply and marketing agreement with Eiken granting Eiken the exclusive right to manufacture and distribute *Feridex I.V.* in Japan. Eiken was responsible for conducting clinical trials and securing the necessary regulatory approval in Japan, which was obtained in 1997. Under the terms of the agreement, as amended, Eiken paid us an up-front license fee and agreed to pay royalties based upon products shipped for resale. Eiken has recently informed us of

its desire to terminate this agreement due to increased competition and limited sales of *Feridex I.V.* in Japan. With our permission, Eiken has begun the process of withdrawing *Feridex I.V.* as an approved product with the appropriate regulatory authorities in Japan. We expect the withdrawal and the termination of our agreement with Eiken to take effect in early calendar year 2007.

GUERBET. In 1987, we entered into a supply and distribution agreement with Guerbet. Under this agreement, 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, eastern Europe, and the former Soviet Union. Guerbet is responsible for conducting clinical trials and securing the necessary regulatory approvals in the countries in its territory. Guerbet has not pursued marketing approval in all the countries in which it has rights. Under the terms of this agreement, Guerbet is obligated to pay royalties based on products shipped for resale. We are 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 agreement terminates on the later of (i) the expiration of the last to expire technology patent related to *Feridex I.V.* or (ii) ten years after the date all necessary approvals were obtained in France.

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 Advanced Magnetics MRI contrast agents. 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, eastern Europe and the former Soviet Union. 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, and accordingly, all such rights reverted back to us. Under the terms of this second distribution agreement, Guerbet has agreed to pay us royalties and a percentage of net sales as the purchase price for the active ingredient 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.

MALLINCKRODT, INC. (a division of Tyco-Healthcare). In 1990, we entered into a manufacturing and distribution agreement with Mallinckrodt granting Mallinckrodt a product license and co-marketing rights to *GastroMARK* in the United States, Canada and Mexico and Mallinckrodt currently has rights to *GastroMARK* in the United States only. Under the terms of the agreement, we receive royalties based on Mallinckrodt's *GastroMARK* sales as well as a percentage of sales for supplying the active ingredient. The agreement is perpetual but terminable upon certain specified events.

SQUIBB DIAGNOSTICS (a division of Bristol-Myers Squibb Co.). In 1994, under an agreement with Squibb Diagnostics, we reacquired the development and marketing rights to *Combidex*, which had previously been licensed to Squibb Diagnostics. Pursuant to this agreement, we are obligated to pay up to a maximum of $2,750,000 in royalties to Squibb Diagnostics in connection with product sales of *Combidex*.

OTHER. We are the licensee of certain technologies related to our products under cross-license agreements with Nycomed Imaging A.S. of Oslo, Norway (now known as Amersham Health, which is part of GE Healthcare), or Nycomed, and Schering AG of Berlin, Germany. The license agreement with Nycomed 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 Nycomed to pay royalties on a percentage of product sales of *Feridex I.V.* and *GastroMARK*, if any. There were no milestone payments made in fiscal years 2005, 2004 or 2003. Future milestone payments under the Nycomed agreement will not exceed $400,000.

Manufacturing and Supply Arrangements

Our Cambridge, Massachusetts facility is registered with the FDA and is subject to current Good Manufacturing Practices, or cGMP, as prescribed by the FDA. At this facility, we currently manufacture *Feridex I.V.* bulk product for sale to Guerbet, *Feridex I.V.* finished product for sale to Berlex, *GastroMARK* bulk product for sale to Guerbet and Mallinckrodt, *Combidex* bulk product for use in clinical trials and ferumoxytol finished product for use in human clinical trials. We also intend to manufacture *Combidex* bulk product for commercial use, subject to FDA approval, at this facility. We intend to use a contract manufacturer for the final manufacturing of *Combidex*.

Raw Materials

We currently purchase the raw materials used to manufacture our products from third-party suppliers. Although certain of our raw materials are readily available, others may be obtained only from qualified suppliers. Certain raw materials used in our products are procured from a single source with no qualified alternative supplier. 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. During fiscal 2005 one of our suppliers notified us of its decision to discontinue manufacturing a key raw material in our manufacturing process for our products. At that time, we purchased all remaining inventory from the supplier and have since identified an alternative supplier and are continuing our efforts to find a second qualified supplier of this raw material. We do not anticipate an interruption to our manufacturing processes based on the lack of qualified alternative suppliers for any of our raw materials.

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 United States and in appropriate foreign countries. We currently hold over 20 U.S. patents and over 30 foreign patents, which expire between the years 2006 and 2020, some of which are 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.

In addition, we have patent applications pending, 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 Nycomed and Schering AG. Our proprietary position depends in part on these licenses, and termination of the licenses for any reason could have a material adverse effect on us by limiting or prohibiting the commercial sale of our contrast agents.

Competition

The pharmaceutical and biopharmaceutical industries are subject to intense competition and rapid technological change. Certain companies, including some of our collaborators, which have greater human and financial resources dedicated to product development and clinical testing than we do, are developing IV iron replacement therapy products and MRI contrast agents. Our collaborators are not restricted from developing and marketing certain competing products and, as a result of certain cross-license agreements among Advanced Magnetics and certain of our competitors (including one of our collaborators), our competitors 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 compete successfully will depend on a number of factors including the implementation of effective marketing campaigns by us and/or our marketing and distribution partners, development of efficacious products, timely receipt of regulatory approvals and our ability to manufacture our products at commercially acceptable costs. Additionally, although we believe ferumoxytol will offer advantages over existing products in the IV iron replacement therapy market, competing IV iron replacement therapy products may receive greater acceptance. The IV 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 perceived safety profiles and dosing regimens. In addition, market acceptance of MRI as an appropriate technique for imaging the lymphatic system and the use of our products as part of such imaging, is critical to the success of *Combidex*, if approved. Although we believe that our contrast agents 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 efficacious products, obtain timely regulatory approvals, manufacture products at commercially acceptable costs, market our products alone or with our partners, gain satisfactory market acceptance, or otherwise successfully compete in the future.

IV Iron Replacement Therapy Products

The IV iron therapy market is estimated at approximately $350 million in gross sales per year in the United States. Based on the projected growth of the hemodialysis and CKD patient population by the United States Renal Data System, this market could grow to approximately $1 billion by 2010. There are several IV iron replacement therapy products on the market and in various stages of clinical development in the United States and abroad. Currently, American Regent Laboratories, Inc., or American Regent, a division of Luitpold Pharmaceuticals, or Luitpold, markets Venofer®, an iron sucrose formulation, and Dexferrum®, an iron dextran product. In June 2005 *Venofer* received approval from the FDA expanding its label to include the treatment of iron deficiency anemia in non-dialysis dependent CKD patients and in October 2005 received approval from the FDA for the treatment of iron deficiency in peritoneal dialysis patients. Additionally, during 2005, Luitpold entered into an agreement with Vifor International Ltd., the developer of *Venofer*, for the commercialization of its next-generation IV iron product, VIT-45. VIT-45 is in clinical development worldwide for a variety of anemia-related indications, including CKD patients, whether or not on dialysis. Market launch for VIT-45 is expected in calendar year 2008 or 2009. Watson Pharmaceuticals, Inc., or Watson, markets Ferrlecit®, a sodium ferric gluconate in sucrose injection, and INFeD®, an iron dextran product. We believe that Watson is currently pursuing additional clinical studies to expand the indication of *Ferrlecit* to include CKD patients not yet on dialysis, peritoneal dialysis patients and anemic chemotherapy patients.

In addition, Abbott Laboratories, Inc. has entered into a license and development agreement in the United States with Pharmacosmos A/S of Denmark for the development of Feoligosaccharide (FeOS), an IV iron replacement product for use in hemodialysis patients receiving erythropoietin. We are unaware of the status of this product in the United States. Rockwell Medical Technologies, Inc. is developing a

dialysate concentrate product containing Ferric pyrophosphate (FePPi), a water-soluble form of iron, to be used as a treatment for anemia in dialysis patients. This product is currently in Phase II clinical development.

MRI Contrast Agents

There are several MRI contrast agents for imaging lesions of the liver on the market and in various phases of clinical testing in the United States and abroad. Schering AG has two products: Resovist®, a carboxydextran superparamagnetic iron oxide formulation, and Primovist™, gadolinium EOB-DTPA, a chelated gadolinium compound used to detect and characterize liver lesions by MRI. *Resovist* has received approval in the European Union, some non-EU countries and Japan. *Resovist* is in Phase III clinical studies in the United States. *Primovist* was given Europe-wide approval in September 2004. The status of *Primovist* in Japan is unknown. Schering is in clinical development in Europe with Supravist® (SHU 555 C) for use as an MRI contrast agent. GE Healthcare has its MnDPDP product, Teslascan®, for MRI of liver lesions which is approved and marketed in the United States and Europe. Bracco S.p.A., or Bracco, has MultiHance® (Gadolinium BOPTA), a chelated gadolinium compound which is approved and marketed in the United States and Europe. We are unaware of any approved products or drug candidates in human clinical development for use in contrast-enhanced MRI of lymph nodes other than *Combidex*. However, such products may exist and could negatively affect the marketing of our products.

There are currently no contrast agents approved by the FDA for MRA in the United States. Products in development include Epix Pharmaceuticals, Inc.'s, or Epix, Vasovist®, a gadolinium-based contrast agent, which received an approvable letter in November 2005 from the FDA. *Vasovist* received approval in Europe during 2005 and is licensed to Schering AG. Epix is also developing EP-2104R to enable the detection of blood clots. EP-2104R is in Phase II studies. Guerbet is developing Vistarem® (P-792), a gadolinium-based contrast agent that is in clinical development in Europe and the United States for myocardial perfusion. Schering AG has two MRA agents in development: Gadovist®, gadolinium D3-butrol, for MRA which has been approved for CNS and vessel visualization in Europe and Canada and Gadomer®, a gadolinium-based contrast agent which is in development for coronary vessel imaging and cardiac perfusion imaging. We are not aware of the stage of development of *Gadomer*. Bracco's gadolinium-based agent B-22956/1 began human clinical development in Europe. We are not aware of the stage of development for Ferropharm GmbH's VSOP-C184, a citrate-coated iron oxide, for use in MRA applications.

Resources of Our Competitors

Many of our competitors have substantially greater capital, research and development, manufacturing and marketing resources and experience than we do and represent significant competition for us. Products developed by such companies may be 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, and adversely impact sales of our iron replacement and imaging products, respectively, if such products are approved by the FDA.

Government Regulation and Reimbursement

The production and marketing of our products and our ongoing research and development activities are subject to regulation for safety, efficacy and quality by numerous governmental authorities in the United States and other countries. Pharmaceutical products used for intravenous or oral administration in humans are principally governed by FDA regulations in the United States and by comparable government regulations in foreign countries. Various federal, state and local statutes and regulations also govern or influence the research and development, manufacturing, safety, labeling, storage, record-keeping, distribution and marketing of such products. 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, the expenditure of substantial resources and is often subject to unanticipated delays. Despite our development efforts and the results of clinical trials, we may not be able to obtain such approvals for our product candidates on a timely basis, if at all.

Clinical testing of pharmaceutical products is itself subject to approvals by various governmental regulatory authorities. Our clinical trials are conducted in accordance with specific protocols, which are filed with the FDA and other regulatory authorities. If such protocols are not approved or if the FDA determines that there are flaws in the design of the protocols or the clinical trials during the course of the studies, we may not be permitted to continue our clinical trials or we may be required to revise our protocols during the course of the clinical trials. Any deficiency in the design or oversight of our clinical studies by us could further delay or prevent us from obtaining regulatory approval and could significantly increase the costs of such clinical trials, which could delay or prevent us from obtaining approval for our product candidates on a timely basis, if at all.

Our failure to obtain requisite governmental approvals, our failure to obtain approvals of the scope requested, or any withdrawal or suspension by the FDA or foreign authorities of any approvals will delay or preclude us and our licensees and collaborators from marketing our products, limit the commercial use of the products and impair our ability to generate revenue, whether from product sales, royalties or milestone payments.

The steps required by the FDA before new human pharmaceutical products, including iron replacement therapy products and contrast agents, may be marketed in the United States include: (a) pre-clinical laboratory tests, pre-clinical studies and formulation studies; (b) the submission to the FDA of a request for authorization to conduct clinical trials subject to an IND to which the FDA must not object within 30 days of its initial filing prior to the commencement of human clinical trials; (c) adequate and well-controlled human clinical trials 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 before the drug product may be shipped or sold commercially. Foreign regulatory authorities require similar investigations and processes to be conducted and may impose additional hurdles that would require separate tests and trials.

Pre-clinical tests include the laboratory evaluation of product chemistry. Pre-clinical studies include animal studies to assess the potential safety and efficacy of the product. Pre-clinical test and study results are submitted to the FDA as a part of an IND and are reviewed by the FDA prior to the commencement of human clinical trials. The submission of an IND might not result in FDA authorization to commence clinical trials. If there are no objections from the FDA within 30 days of filing the IND, clinical trials are typically conducted in three sequential phases, although the phases may overlap. Phase I involves the initial administration of the drug to a small group of humans, either healthy volunteers or patients, to test for safety, dosage tolerance, absorption, distribution, metabolism, excretion and clinical pharmacology and, if possible, early indications of effectiveness. Phase II involves studies in a small sample of the actual intended patient population to assess the preliminary efficacy of the investigational drug for a specific clinical indication, to ascertain dose tolerance and the optimal dose range and to collect additional clinical information relating to safety and potential adverse effects. Once an investigational drug is found to have some efficacy and an acceptable clinical safety profile in the targeted patient population, Phase III studies can be initiated to further establish safety and efficacy of the investigational drug in a broader sample of the target patient population. The results of the clinical trials together with the results of the pre-clinical tests and studies and complete manufacturing information are submitted in an NDA to the FDA for approval. In member countries of the EU, the equivalent of an NDA is referred to as a Dossier, and is filed with the European Medicines Agency. The governing regulatory agency 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.

Both before and after approval is obtained, a product, its manufacturer, and the holder of the NDA for the product are subject to comprehensive regulatory oversight. Violations of regulatory requirements at any stage, including the pre-clinical and clinical testing process, the approval process, or thereafter, including after approval, may result in various adverse consequences, including the FDA's delay in approving or refusal to approve a product, withdrawal of an approved product from the market, and/or the imposition of criminal penalties against the manufacturer and/or NDA holder. If an NDA is submitted to the FDA, the application may not be approved in a timely manner, if at all. Any delay in obtaining regulatory approvals could delay our product commercialization and associated revenue and consume extensive amounts of our resources, both financial and managerial. In addition, later discovery of previously unknown problems may result in restrictions on a product, manufacturer, or NDA holder, including withdrawal of the product from the market. Also, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

There are several conditions that must be met in order for final approval of an NDA to be granted by the FDA. Among the conditions for NDA approval is the requirement that a prospective manufacturer's manufacturing procedures conform to cGMP, requirements which must be followed at all times. 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 United States, foreign manufacturing establishments must 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, limiting product sales, thereby reducing our revenue and profitability. In addition, the labeling of the product must also be approved by the FDA prior to final approval of the product.

Once the FDA determines that a product is approvable, it will issue an action letter, known as an "approvable letter," indicating if any additional information must be provided or if any additional conditions must be met prior to final approval. Securing such additional information and/or complying with such conditions may be costly and result in significant delays prior to final approval. Even if initial marketing approval is granted, such approval may entail limitations on the indicated uses for which a product may be used and impose labeling requirements which may adversely impact our ability to market our products. Furthermore, even after initial FDA approval has been obtained, further studies, including post-market studies, may be required to provide additional information. Results of such post-market programs may limit or expand the further marketing of the product. Additionally, product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing.

We are also subject to foreign regulatory requirements governing development, manufacturing and sales of pharmaceutical products that 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 may be more or less rigorous from country to country, and the time required for approval may be longer or shorter than that required in the United States.

We are 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. We hold Registration Certificates from the United States Drug Enforcement Agency and the Commonwealth of Massachusetts Department of Public Health for handling controlled substances. We are registered with the United States

Environmental Protection Agency, or the EPA, as a generator of hazardous waste. All hazardous waste disposal 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 in effect a safety program to assure compliance with all of these regulations.

In both the United States and foreign markets, our ability to commercialize our products successfully depends in part on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, private health insurers and other third-party payors. Significant uncertainty exists as to the reimbursement status of newly-approved health care products, products used for indications not approved by the FDA and products which have competitors for their approved indications. 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 or our ability to establish acceptable pricing schemes for our products may be impaired, thereby reducing our revenue.

Major Customers

Three companies, Berlex, Cytogen, and Guerbet, accounted for 47%, 22% and 20%, respectively, of our revenues in fiscal 2005. Three companies, Cytogen, Guerbet, and Berlex, accounted for 55%, 20% and 20%, respectively, of our revenues in fiscal 2004. Two companies, Cytogen and Berlex, accounted for 61% and 23%, respectively, of our revenues in fiscal 2003. No other company accounted for more than 10% of our total revenues in fiscal 2005, 2004 or 2003. All of the revenue attributable to Cytogen and a significant portion of the revenue attributable to Berlex in each of fiscal 2005, 2004 and 2003 was deferred revenue that was recognized in those fiscal years, respectively.

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. However, we had a product sales backlog of approximately $201,000 as of September 30, 2005.

Employees

As of December 12, 2005, we had approximately 36 employees, 2 of whom were part-time and 25 of whom were engaged in research and development. Our success depends in part on our ability to recruit and retain talented and trained scientific personnel and senior management. We have been successful to date in obtaining and retaining such personnel, but may not be successful in the future.

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

Foreign Operations

We have no foreign operations. Revenues in fiscal 2005, 2004 and 2003 from customers and licensees outside of the United States, principally in Europe and Japan, amounted to 22%, 21% and 13%, respectively, of our total revenues.

Product Liability Insurance

The administration of our products to humans, whether in clinical trials or after marketing approvals are obtained and the product is in use commercially, 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 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 to research and development as a method of producing new products, improving existing products and growing our revenues. We estimate that approximately 60% to 65% of our employees' time has been devoted to research and development for each of the last three fiscal years. We incurred research and development expenses of $12,037,549, $6,083,839, and $4,458,980 in fiscal 2005, 2004 and 2003, respectively. We anticipate that a significant portion our operating expenses will continue to be related to development in fiscal 2006.

Code of Ethics

In 2003, we adopted a code of ethics that applies to our officers, directors and employees. We have posted the text of our code of ethics on our website at http://www.advancedmagnetics.com in the "Investors" section. In addition, 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 in the future.

Subsequent Event

On November 15, 2005, the Board of Directors elected Dr. Brian J.G. Pereira to serve as President of Advanced Magnetics, and on November 22, 2005 we entered into a three-year employment agreement with Dr. Pereira. Under the terms of the employment agreement, we agreed to pay Dr. Pereira an annual salary of $400,000. In addition, Dr. Pereira is eligible to earn an annual bonus of up to $100,000 per year upon the achievement of certain performance goals determined by our Chief Executive Officer. The employment agreement also provides Dr. Pereira with a monthly automobile allowance of $1,200. Under the terms of the employment agreement, Dr. Pereira will receive one month of severance pay for each month of his employment with Advanced Magnetics up to a maximum of twelve months in the event we terminate his employment without "cause," as defined in the agreement, or he resigns for "good reason," as defined in the agreement. The severance period will begin to decrease on the second anniversary of his employment so that for every full month of employment during the final year of the agreement, the severance period will be reduced by one month. Therefore, as of the third anniversary of employment, all severance payment obligations to Dr. Pereira shall have terminated. We also agreed to provide Dr. Pereira with a ten-year term life insurance policy in the face amount of $2 million for the benefit of persons designated by Dr. Pereira. We expect the annual premium for such policy to be approximately $1,700 to $2,500.

In connection with his election as President, the Board also granted Dr. Pereira options to purchase 250,000 shares of common stock under the terms of the 2000 Stock Plan at an exercise price of $9.10, the fair market value of a share of our common stock on the date of grant. The options were exercisable with respect to 100,000 shares on the date of grant, and the options become exercisable with respect to an additional 50,000 shares on each of the first, second and third anniversaries of the grant date. In the event we terminate Dr. Pereira's employment without "cause" or Dr. Pereira terminates his employment for "good reason", the options will automatically become exercisable in full with respect to all 250,000 shares. The options will also become immediately exercisable in full upon the consummation of a "change of control," as defined in Dr. Pereira's option agreements. In addition, the Board agreed to grant Dr. Pereira an additional option to purchase 100,000 shares of common stock following approval of the amendment and restatement of the 2000 Stock Plan described in this proxy statement at an exercise price equal to the

fair market value of our common stock on the date of grant so long as Dr. Pereira is still employed by us at that time. Such option would be exercisable in equal annual installments over three years.

Available Information

Our internet website address is http://www.advancedmagnetics.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.

For additional information regarding our segments, 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.

ITEM 2. PROPERTIES:

Our operations are located in a building we own of approximately 25,000 square feet in Cambridge, Massachusetts. Although we believe this facility is adequate for our current needs, it will not be adequate for our longer-term needs if we continue our efforts to commercialize ferumoxytol as an IV iron replacement therapeutic ourselves without the assistance of a strategic partner, in which case we will need to hire additional staff and lease additional space. We believe that we will be able to lease additional space, if necessary, to house such additional personnel. Although we have no present intention of doing so, if we decide to expand our manufacturing capacity, we might not be able to do so on a timely basis, if at all, because the acquisition of, and required regulatory approvals for, additional pharmaceutical manufacturing space can be time-consuming and expensive.

ITEM 3. LEGAL PROCEEDINGS:

We and certain of our officers were sued in an action entitled *David D. Stark, M.D. v. Advanced Magnetics, Inc., Jerome Goldstein, Ernest V. Groman and Lee Josephson,* Civil Action No. 92-12157-WGY, in the United States District Court for the District of Massachusetts on September 3, 1992. The plaintiff, a former consultant, claims that he was incorrectly omitted as an inventor or joint inventor on certain of our patents and on pending applications, and seeks injunctive relief and unspecified damages. The District Court has stayed this federal action pending resolution of an appeal in the Massachusetts Appeals Court of summary judgment in our favor as well as resolution of a jurisdictional issue. As noted below, the Massachusetts Appeals Court has decided the appeal, but the federal action remains stayed as of this date. While the outcome of the action cannot be determined, we believe the action is without merit and intend to defend the action vigorously. However, we may not be able to successfully defend this action and our failure to prevail for any reason could deplete our resources and reduce the assets available for our daily operations.

We and certain of our officers were sued in *David D. Stark, M.D. v. Advanced Magnetics, Inc., Jerome Goldstein, Ernest V. Groman and Lee Josephson,* Civil Action No. 93-02846-C, in the Superior Court Department of the Massachusetts Trial Court for Middlesex County on May 17, 1993. This case involves claims of breach of contract, breach of good faith and fair dealing, breach of implied contract, misappropriation of trade secrets, conversion, negligent misrepresentation, misrepresentation, unjust enrichment, unfair trade practices and tortious interference with contractual or advantageous relations. The Superior Court granted partial summary judgment in our favor and dismissed the unfair trade practices and tort counts. The plaintiff's contract claims have been dismissed with prejudice and final judgment was entered against the plaintiff. The plaintiff filed an appeal in *David D. Stark, M.D. v. Advanced Magnetics, Inc., Jerome Goldstein, Ernest V. Groman and Lee Josephson,* Appeal No. 98-P-1749,

in the Massachusetts Appeals Court, on January 25, 1999. On October 13, 2000, the Massachusetts Appeals Court reversed the grant of partial summary judgment in our favor and remanded the case to the Superior Court. While the outcome of the action cannot be determined, we believe the action is without merit and intend to defend the action vigorously. However, we may not be able to successfully defend this action and our failure to prevail for any reason could deplete our resources and reduce the assets available for our daily operations.

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

No matters were submitted to a vote of our security holders during the quarter ended September 30, 2005.

Executive Officers of the Registrant:

Jerome Goldstein, 66, is a founder of Advanced Magnetics and has been our Chief Executive Officer, Chairman of the Board of Directors and Treasurer since our organization in November 1981. Mr. Goldstein also served as our President from 1981 to 1997 and from February 2001 to November 2005. Mr. Goldstein was a co-founder of Clinical Assays, Inc., serving from 1972 to 1980 as Vice President and then as President.

Brian J.G. Pereira, 47, was elected President of Advanced Magnetics in November 2005 and has served as a member of our Board of Directors since July 2004. Dr. Pereira served as President and Chief Executive Officer of the New England Health Care Foundation, a physician's group at Tufts-New England Medical Center from October 2001 to November 2005, and held various other positions at Tufts-New England Medical Center from 1993 to 2001. He is a Professor of Medicine at Tufts University School of Medicine and at the Sackler School of Biomedical Sciences of Tufts University. Dr. Pereira served as President of the National Kidney Foundation from 2002 to 2004, and has served on the editorial board of twelve scientific journals. He also serves as a director of the National Kidney Foundation, Aksys, Inc., Kidney Care Partners, Wellbound Inc., and Satellite Health Care Inc. In addition, Dr. Pereira is a member of the advisory boards of Amgen, Inc. and Sigma-Tau Pharmaceuticals, Inc. along with several other organizations.

Michael N. Avallone, 54, joined us in July 2004 as Chief Financial Officer and has also been Vice President of Finance since August 2004. From 2000 to 2004, Mr. Avallone was employed at Boston Biomedica, Inc., first as Corporate Controller and later as Vice President, Finance and Chief Financial Officer. Prior to 2000, he served in a number of executive positions in accounting and finance at affiliates of NSTAR (formerly BEC Energy).

Joseph L. Farmer, 33, joined us as General Counsel and Vice President of Legal Affairs and Assistant Secretary in February 2005. Prior to joining us, Mr. Farmer was an associate in the business practice group of the law firm Testa, Hurwitz and Thibeault, LLP in Boston, MA from September 1997 to February 2005.

PART II

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

Our common stock is listed on the American Stock Exchange under the symbol AVM.

The table below sets forth the high and low sale prices of our common stock as reported to us by the American Stock Exchange for the fiscal quarters of 2005 and 2004.

		First	Second	Third	Fourth
2005	High	$15.77	$24.25	$11.74	$12.70
	Low	11.70	6.00	7.60	8.52
2004	High	15.24	13.35	15.49	16.43
	Low	8.70	9.70	8.00	13.01

On December 12, 2005, there were approximately 221 stockholders of record and we believe that the number of beneficial holders of common stock was approximately 2,220 based on responses from brokers to a search conducted by Georgeson Shareholder, as proxy solicitor, on our behalf. The last reported sale price of our common stock on December 12, 2005 was $10.59 per share. 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.

See Part III, Item 12 for information regarding securities authorized for issuance under our equity compensation plans.

The following table provides information about purchases by us during the quarter ended September 30, 2005 of our equity securities that are registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended. No purchases were made during the quarter by or on behalf of us by any person or entity acting, directly or indirectly, in concert with us for the purpose of acquiring our securities or by an affiliate of ours who, directly or indirectly, controls our purchases of such securities, whose purchases are controlled by us, or whose purchases are under common control with ours.

ISSUER PURCHASES OF EQUITY SECURITIES

Period	Total Number of Shares Purchased(1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs(2)	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs(2)
July 1 through July 31, 2005	—	—	—	—
August 1 through August 31, 2005	3,000	$ 10.06	—	—
September 1 through September 30, 2005	—	—	—	—
Total	3,000	$ 10.06	—	—

(1) Consists solely of shares tendered by current and former employees as payment of the exercise price of stock options granted in accordance with provisions of both our equity compensation plans and individual stock option agreements.

(2) The Company does not currently have any publicly announced repurchase programs or plans.

ITEM 6. SELECTED FINANCIAL DATA:

The selected financial data set forth below has been derived from our audited financial statements. This information should be read in conjunction with the financial statements and the related notes thereto included in Part II, Item 8 of this Annual Report on Form 10-K, "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in Part II, Item 7 of this Annual Report on Form 10-K, and other financial information included elsewhere in this Annual Report on Form 10-K.

	For the years ended September 30,				
	2005	2004	2003	2002	2001
Statement of Operations Data:					
Revenues:					
License fees	$ 1,280,867	$ 2,747,695	$3,642,052	$ 4,020,617	$ 4,640,198
Product sales	890,398	768,189	600,444	965,820	633,480
Royalties	273,903	240,000	535,000	725,000	700,000
Total revenues	2,445,168	3,755,884	4,777,496	5,711,437	5,973,678
Costs and Expenses:					
Cost of product sales	204,080	117,015	199,561	214,357	204,399
Research and development expenses	12,037,549	6,083,839	4,458,980	4,029,115	3,622,102
Selling, general and administrative expenses	3,337,589	2,219,777	1,770,402	1,712,234	1,667,066
Total costs and expenses	15,579,218	8,420,631	6,428,943	5,955,706	5,493,567
Other Income (Expense):					
Interest and dividend income	419,435	169,547	112,730	255,928	697,162
Gains and (losses) on sales of securities and derivative instruments, net	—	—	2,777,003	610,378	(579,418)
Write-down of marketable securities*	—	—	(644,310)	(2,331,956)	(4,659,800)
Other income, net	—	—	148,129	3,647	258,122
Total other income (expense)	419,435	169,547	2,393,552	(1,462,003)	(4,283,934)
Income (loss) before provision for (benefit from) income taxes	(12,714,615)	(4,495,200)	742,105	(1,706,272)	(3,803,823)
Income tax (benefit) provision	—	—	(124,752)	—	25,362
Net income (loss)	$(12,714,615)	$(4,495,200)	$ 866,857	$(1,706,272)	$(3,829,185)
Earnings (loss) per share—basic:	$ (1.47)	$ (0.57)	$ 0.13	$ (0.26)	$ (0.57)
Earnings (loss) per share—diluted:	$ (1.47)	$ (0.57)	$ 0.12	$ (0.26)	$ (0.57)
Weighted average shares outstanding used to compute earnings (loss) per share:					
Basic	8,633,827	7,817,918	6,914,323	6,636,798	6,701,113
Diluted	8,633,827	7,817,918	7,143,455	6,636,798	6,701,113

* In fiscal 2001, the write-down in marketable securities of $4,659,800 occurred in the fourth fiscal quarter.

	September 30,				
	2005	2004	2003	2002	2001
Balance sheet data:					
Working capital	$21,211,412	$12,313,754	$22,579,478	$14,233,904	$18,734,388
Total assets	$28,291,982	$23,810,611	$29,365,613	$22,484,002	$27,448,667
Long-term liabilities—deferred revenue	$ 2,584,894	$ 3,134,435	$ 5,265,669	$ 7,774,131	$11,444,384
Stockholders' equity	$22,379,159	$17,546,455	$20,918,075	$10,650,267	$11,512,294
Cash dividends declared per common share, for the year ended:	$ —	$ —	$ —	$ —	$ —

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS:

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 federal securities laws. In this Annual Report on Form 10-K, words such as "may," "will," "expects," "intends," and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. 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 factors discussed in this Part II, Item 7 under "Certain Factors That May Affect Future Results" 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 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.

Overview

Advanced Magnetics, Inc. was incorporated in Delaware in November 1981 and is a developer of superparamagnetic iron oxide nanoparticles used in pharmaceutical products. We are dedicated to the development and commercialization of our proprietary nanoparticle technology for use in 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, the key product in our development pipeline, is in Phase III multi-center clinical trials for use as an iron replacement therapeutic in chronic kidney disease patients, whether or not on dialysis. In August 2005, we announced our plan to revise the Phase III development program for ferumoxytol in intravenous (IV) iron replacement therapy based on discussions with the U.S. Food and Drug Administration, or FDA. The modifications to the Phase III program will, among other things, result in additional patients being enrolled in the ferumoxytol chronic kidney disease, or CKD, efficacy studies and the re-design of the hemodialysis efficacy study currently under way. In addition, we announced that we plan to add additional patients to our large-scale safety study to provide a more robust safety database for the New Drug Application, or NDA. In August 2005 we also announced the formation of a Scientific Advisory Board to advise us on clinical development, market preparation, pre-launch and other strategic activities in our efforts to complete our development program for ferumoxytol and a Data Monitoring Committee to provide independent oversight of the Phase III iron replacement therapy program. We expect to submit an NDA for ferumoxytol in IV iron replacement therapy to the FDA in mid calendar year 2007.

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. We have submitted a formal meeting request to the FDA to discuss next steps in the regulatory process for *Combidex*. Due to our limited resources and the priority we are placing on completion of the Phase III development program for ferumoxytol in iron replacement therapy, we do not currently intend to sponsor additional clinical studies for *Combidex*. However, we are reviewing and evaluating existing studies, including studies sponsored by our European partner, Guerbet, to determine whether such studies will address the concerns raised by the FDA in the March 2005 approvable letter. Until we complete our evaluation of these studies and meet with the FDA to discuss next steps, we cannot predict with certainty

the timing or cost of the efforts that would be necessary to satisfy the conditions specified by the FDA for approval of *Combidex* or our ability to complete those efforts in a timely or cost-effective manner, if at all.

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

Results of Operations

Fiscal 2005 Compared to Fiscal 2004

Revenues

Total revenues for the fiscal year ended September 30, 2005 were $2,445,168 compared to $3,755,884 for the fiscal year ended September 30, 2004. The decrease in revenues was primarily the result of a decrease in the recognition of deferred license fee revenue from a licensing and marketing agreement covering *Combidex*, partially offset by an increase in product sales and royalties from our distribution and marketing partners. The majority of our revenue for the fiscal years ended September 30, 2005 and 2004 constituted recognition of deferred revenue. Our revenues for the fiscal years ended September 30, 2005 and 2004 consisted of the following:

	Years Ended September 30, 2005	2004	$ Change	% Change
Revenues:				
License fees	$1,280,867	$2,747,695	$(1,466,828)	(53)%
Royalties	273,903	240,000	33,903	14 %
Product sales	890,398	768,189	122,209	16 %
Total revenues	$2,445,168	$3,755,884	$(1,310,716)	(35)%

License Fee Revenue

All of our license fee revenue for the fiscal years ended September 30, 2005 and 2004 consisted of deferred license fee revenue related to a license and marketing agreement signed with Cytogen Corporation, or Cytogen, in fiscal 2000 and deferred license fee revenue associated with a license and marketing agreement with Berlex Laboratories, Inc., or Berlex, signed in fiscal 1995.

In August 2000, we entered into a license and marketing agreement with Cytogen in which, among other things, we granted Cytogen exclusive United States marketing rights to *Combidex*. At the time of signing that agreement, we received shares of common stock of Cytogen with a market value of $13,546,875 as a non-refundable licensing fee. We determined to account for the revenue associated with this 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. Recognition of the remainder of the deferred revenue associated with this agreement, which was $564,642 as of September 30, 2005, is expected to occur when currently projected expenses are incurred in connection with our efforts to obtain approval of *Combidex*. We increased our projected future research and development expenses associated with the Cytogen agreement, as of September 30, 2005, based upon our most recent 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, 2004. As a result, our revenue associated with the Cytogen agreement in the fiscal year ended September 30, 2005 decreased as compared with the year ended September 30, 2004. In the fiscal years ended September 30, 2005 and 2004, respectively, we recorded to income $543,112 and $2,009,940 of previously deferred licensing revenue associated with our license and marketing agreement with Cytogen. Revenue recognition during the fiscal year was based upon costs incurred to date compared to our current estimate of costs we may incur, if any, in connection with our efforts to obtain approval of *Combidex*. We expect future license fee revenue under this agreement to

continue to fluctuate due to changes in our activities and our related estimate of costs we may incur under our license and marketing agreement with Cytogen.

In February 1995, we entered into a license and marketing agreement and a supply agreement with Berlex, granting Berlex a product license and exclusive marketing rights to *Feridex I.V.* in the United States and Canada. In 1996, the parties agreed to remove Canada from the territories subject to the agreement. Berlex paid us non-refundable license fees and other fees in connection with the agreements. We have determined to account for the revenue associated with this agreement on a straight-line basis over the term of the agreement due to the existence of an established contract period. Recognition of the remainder of the deferred revenue as license fee revenue, which approximated $3,134,435 as of September 30, 2005, is expected to occur proportionately over the remaining term of the agreement. In both fiscal years ended September 30, 2005 and 2004, we recorded to income $737,755 of previously deferred licensing revenue associated with our license and marketing agreement with Berlex. The agreement expires in 2010 but can be terminated earlier upon the occurrence of certain specified events.

Total license fee revenue for the fiscal years ended September 30, 2005 and 2004 was recognized as follows:

	Years Ended September 30, 2005	2004	$ Change	% Change
Deferred license fee revenue recognized in connection with the Cytogen agreement	$ 543,112	$2,009,940	$(1,466,828)	(73)%
Deferred license fee revenue recognized in connection with the Berlex agreement	737,755	737,755	—	0 %
Total	$1,280,867	$2,747,695	$(1,466,828)	(53)%

Royalty Revenue

Royalties increased $33,903, or 14%, to $273,903 for the fiscal year ended September 30, 2005, compared with royalties of $240,000 for the fiscal year ended September 30, 2004. Royalty payments can fluctuate based on uneven demand by end users for our marketed products, *Feridex I.V.* and *GastroMARK*, however we expect royalties to generally remain at current levels due to the competitive landscape for our marketed products.

Product Sale Revenue

Product sale revenue for the fiscal years ended September 30, 2005 and 2004 consisted of the following:

	Years Ended September 30, 2005	2004	$ Change	% Change
Feridex I.V.	$ 378,007	$ 431,823	$ (53,816)	(12)%
GastroMARK	427,864	336,366	91,498	27 %
Combidex	84,527	—	84,527	(100)%
Total	$ 890,398	$ 768,189	$ 122,209	16 %

The increase in product sale revenue in the fiscal year ended September 30, 2005 as compared to the fiscal year ended September 30, 2004 was primarily the result of the sale of bulk *Combidex* to one of our foreign marketing partners for research and development purposes. The increase is also partially due to the fluctuation of our product sales to our marketing partners based on annual product demand by end users and the batch size in which our products are manufactured and shipped, which create uneven purchasing patterns by our marketing partners. We expect revenue from product sales to continue to fluctuate from year to year as a result of these factors.

Costs and Expenses

Cost of Product Sales

We incurred costs of $204,080 associated with product sales during the fiscal year ended September 30, 2005 compared to costs of $117,015 associated with product sales during the fiscal year ended September 30, 2004, an increase of $87,065 or 74%. These costs constituted approximately 23% and 15% of product sales during the fiscal years ended September 30, 2005 and 2004, respectively. 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, consulting fees and professional fees and expenses, and internal expenses, such as compensation of employees engaged in research and development activities, the manufacture of limited quantities of product needed to support research and development efforts, related costs of facilities, and other general costs related to research and development.

At the end of fiscal 2000, we adopted the guidance under SEC Staff Accounting Bulletin No. 101, also known as SAB 101, "Revenue Recognition in Financial Statements" (later revised as Staff Accounting Bulletin No. 104). As a result of this change of accounting method, we have tracked our internal research and development expenses since this time in relation to our license and marketing agreement with Cytogen and not by specific research and development project and therefore we can only provide external research and development costs and not total costs by project since the end of fiscal 2000.

Research and development expenses for the fiscal years ended September 30, 2005 and 2004 consisted of the following:

	Years Ended September 30,			
	2005	2004	$ Change	% Change
External Research and Development Expenses				
Ferumoxytol in Iron Replacement Therapy	$ 6,522,648	$1,919,017	$4,603,631	240%
Ferumoxytol in MRA	159,752	114,063	45,689	40%
Combidex	584,657	222,548	362,109	163%
Other external costs	299,564	134,861	164,703	122%
Total	$ 7,566,621	$2,390,489	$5,176,132	217%
Internal Research and Development Costs	4,470,928	3,693,350	777,578	21%
Total Research and Development Costs	$12,037,549	$6,083,839	$5,953,710	98%

External costs associated with research and development expenditures were $7,566,621 in the fiscal year ended September 30, 2005 as compared to external costs of $2,390,489 in the fiscal year ended September 30, 2004, an increase of $5,176,132. In addition, internal costs associated with research and development activities were $4,470,928 in the fiscal year ended September 30, 2005 compared to $3,693,350 in the fiscal year ended September 30, 2004, an increase of $777,578. The increase in both external and internal costs is due largely to increased expenditures associated with the clinical development program for ferumoxytol in iron replacement therapy as well as increased *Combidex*-related expenses, a portion of which was attributable to our preparation for and participation in the March 2005 Oncologic Drugs Advisory Committee, or ODAC, meeting. We currently expect *Combidex*-related expenses to decrease in fiscal 2006. However, we expect overall research and development expenses to increase over the next twelve months and to remain at high levels for at least the next 18 to 24 months as a result of increased patient enrollment costs, fees associated with our third party contract research and development service providers in connection with our Phase III clinical trials for ferumoxytol in iron replacement therapy and the costs associated with any additional studies we may need to conduct as part of our NDA

submission for ferumoxytol. However, research and development expenses can vary based upon the pace of patient enrollment in our Phase III clinical studies.

Through the end of fiscal 2000, we incurred aggregate internal and external research and development expenses of approximately $6,550,000 related to pre-clinical and toxicology studies of ferumoxytol. Since the end of fiscal 2000 and through the fiscal year ended September 30, 2005, we incurred aggregate external research and development expenses of approximately $11,510,000 related to pre-clinical activities and clinical trials in connection with ferumoxytol.

In August 2005, we announced our plan to revise the Phase III development program for ferumoxytol in IV iron replacement therapy based on discussions with the FDA. The modifications to the Phase III program will, among other things, result in additional patients being enrolled in the ferumoxytol CKD efficacy studies and the re-design of the current hemodialysis efficacy study. In addition, we announced that we plan to add additional patients to our large-scale safety study to provide a more robust safety database for the NDA. We currently estimate the total future cost of external efforts necessary to complete development of ferumoxytol as an iron replacement therapeutic, including costs related to ongoing and future clinical trial activities, to range from approximately $16 to $18 million over approximately the next 24 months. These external costs and the expected timing could increase, however, if we experience further delays in our clinical development program due to slow enrollment, unexpected results from our clinical sites that affect our ability to complete the studies in a timely manner, inadequate performance or errors by third party contract research and development service providers or deficiencies in the design or oversight by us of these studies, or if we need to conduct additional clinical trials or we otherwise experience a delay in the submission of our NDA to the FDA for ferumoxytol in iron replacement therapy. Any such delay would also delay the commercialization of ferumoxytol as an iron replacement therapeutic. Since we have not yet determined which clinical indications we may seek for the development of ferumoxytol in MRI, if any, we cannot make a specific dollar estimate of the projected external efforts necessary to complete development for ferumoxytol in MRI.

We incurred aggregate internal and external research and development expenses of approximately $13,500,000 through the end of fiscal 2000 in connection with the development of *Combidex*. Since fiscal 2000, we have incurred additional external research and development expenses of approximately $1,185,400, as well as additional internal research and development costs related to our efforts to obtain FDA approval for *Combidex*. Due to our limited resources and the priority we are placing on completion of the Phase III development program for ferumoxytol in iron replacement therapy, we do not currently intend to sponsor additional clinical studies for *Combidex* in the near future. However, we are reviewing and evaluating existing studies, including studies sponsored by our European partner, Guerbet, to determine whether such studies will address the concerns raised by the FDA in the March 2005 approvable letter. Until we complete our evaluation of these studies and meet with the FDA to discuss next steps, we cannot predict with certainty the timing or cost of the efforts that would be necessary to satisfy the conditions specified by the FDA for approval of *Combidex* or our ability to complete those efforts in a timely or cost-effective manner, if at all.

Since completion of our research and development projects requires regulatory approvals that are out of our control and subject to the delays and other uncertainties described in Part I, Item 1 under the heading “Government Regulation and Reimbursement,” we cannot estimate the anticipated completion date of each of our major research and development projects or the period in which material net cash inflows from such projects could be expected to commence, if at all. Furthermore, due to the risks and uncertainties identified below in the section entitled “Certain Factors That May Affect Future Results,” including, but not limited to, those risks and uncertainties associated with clinical trials, the receipt of regulatory approval and our ability to raise additional capital, if necessary, we may not be able to complete our research and development projects or complete them in a timely fashion.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the fiscal years ended September 30, 2005 and 2004 consisted of the following:

	Years Ended September 30, 2005	2004	$ Change	% Change
Compensation, payroll taxes and benefits	$1,315,186	$1,073,585	$ 241,601	23%
Professional and consultant fees	1,201,149	455,716	745,433	164%
Facilities, insurance and other	821,254	690,476	130,778	19%
Total	$3,337,589	$2,219,777	$1,117,812	50%

The increase in selling, general and administrative costs in the fiscal year ended September 30, 2005, as compared to the fiscal year ended September 30, 2004, was primarily related to increased wage and benefits expenses due to an increase in the overall average salary level of our employees, increased utility costs, and increased professional fees related to consultants hired to assist with our efforts to implement the internal control requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and to our professional fees associated with our evaluation, in the fiscal year ended September 30, 2005, of various strategic opportunities. In addition, professional and consultant fees include a non-cash charge of approximately $300,000 associated with stock options granted in fiscal 2005 to these consultants.

Other Income

Other income for the fiscal years ended September 30, 2005 and 2004 consisted of the following:

	Years Ended September 30, 2005	2004	$ Change	% Change
Interest income	$ 604,193	$ 382,738	$221,455	58 %
Amortization of premiums on purchased investments	(184,758)	(213,191)	28,433	(13)%
Total	$ 419,435	$ 169,547	$249,888	147 %

The increase in other income in the fiscal year ended September 30, 2005, as compared to the fiscal year ended September 30, 2004, was attributable to the higher level of interest income earned in the fiscal year ended September 30, 2005 associated with the investment of the net proceeds from our June 2005 financing in interest-bearing investments and an overall increase in the size of our holdings in interest bearing investments in fiscal 2005 as compared to fiscal 2004 combined with an increase in short term interest rates. This increase in interest income was combined with decreased amortization expense of a purchase premium, during the fiscal year ended September 30, 2005, associated with the January 31, 2005 maturity of a $4,935,000 U.S. Treasury Note which was previously purchased at an amount in excess of face value.

Income Taxes

We had no annualized income tax provision for the fiscal years ended September 30, 2005 or 2004, as we incurred a loss in each of those fiscal years. Due to the uncertainty of the realizability of our deferred tax assets, including loss carryforwards, a full valuation allowance has been recorded as of September 30, 2005 and 2004 against these assets.

Net Loss

For the reasons stated above, there was a net loss of ($12,714,615), or ($1.47) per basic and diluted share, for the fiscal year ended September 30, 2005 compared to a net loss of ($4,495,200), or ($0.57) per basic and diluted share, for the fiscal year ended September 30, 2004.

Fiscal 2004 Compared to Fiscal 2003

Revenues

Total revenues for the fiscal year ended September 30, 2004 were $3,755,884 compared to $4,777,496 for the fiscal year ended September 30, 2003. The decrease in revenues was primarily the result of a decrease in the recognition of deferred license fee revenue from a license and marketing agreement covering *Combidex* as discussed further hereunder. Our revenues for the fiscal years ended September 30, 2004 and 2003 consisted of the following:

	Years Ended September 30, 2004	2003	$ Change	% Change
Revenues:				
License fees	$2,747,695	$3,642,052	$ (894,357)	(25)%
Royalties	240,000	535,000	(295,000)	(55)%
Product sales	768,189	600,444	167,745	28 %
Total revenues	$3,755,884	$4,777,496	$(1,021,612)	(21)%

License Fee Revenue

All of the license fee revenues for the fiscal year ended September 30, 2004 consisted of deferred license fee revenue related to a license and marketing agreement signed with Cytogen in fiscal 2000 and deferred license fee revenue associated with the license and marketing agreement with Berlex signed in fiscal 1995.

In August 2000, we entered into a license and marketing agreement with Cytogen, which covers ferumoxytol for oncology imaging and *Combidex*. At the time of signing that agreement, we received shares of common stock of Cytogen with a market value of $13,546,875 as a non-refundable licensing fee. We have determined to account for the revenue associated with this fee over the development period as costs are incurred. The entire amount of the license fee was booked as deferred revenue upon signing the agreement; $2,009,940 of that deferred revenue was recognized as revenue in fiscal 2004 and $2,904,297 was recognized in fiscal 2003.

In February 1995, we entered into a license and marketing agreement and a supply agreement with Berlex, granting Berlex a product license and exclusive marketing rights *to Feridex I.V.* in the United States and Canada. In 1996, the parties agreed to remove Canada from the territories subject to the agreement. Berlex paid us non-refundable license fees and other fees in connection with the agreements. We have determined to account for the revenue associated with this agreement on a straight-line basis over the term of the agreement due to the existence of an established contract period. $737,755 of deferred revenue was recognized as license fee revenue in both fiscal 2004 and 2003 in connection with the Berlex agreements.

Total license fee revenue decreased to $2,747,695 in the fiscal year ended September 30, 2004 from $3,642,052 in the fiscal year ended September 30, 2003 and was recognized as revenue as follows:

	Years Ended September 30, 2004	2003	$ Change	% Change
Deferred license fee revenue recognized in connection with the Cytogen agreement	$2,009,940	$2,904,297	$(894,357)	(31)%
Deferred license fee revenue recognized in connection with the Berlex agreement	737,755	$ 737,755	—	0 %
Total	$2,747,695	$3,642,052	$(894,357)	(25)%

During the fiscal year ended September 30, 2004, we incurred lower expenses associated with our Cytogen agreement and revised upward our remaining estimate of research and development expenses based on our ongoing efforts to obtain approval of *Combidex*, as compared with the prior fiscal year and, as

a result, our revenue associated with this agreement decreased. The decrease in expenses related to the Cytogen agreement incurred in the fiscal year ended September 30, 2004 as compared to the prior fiscal year was primarily the result of a lower level of internal research and development expenses combined with the timing of expenditures incurred related to our efforts to obtain approval of *Combidex*. Such decrease in expenses led to the recognition of lower amounts of revenue during the fiscal year ended September 30, 2004 as compared to the fiscal year ended September 30, 2003.

Royalty Revenue

Royalties decreased by approximately $295,000, or 55%, to approximately $240,000 for the fiscal year ended September 30, 2004, compared with royalties of approximately $535,000 for the fiscal year ended September 30, 2003. The reduction in royalties reflects a significant decrease in sales of *Feridex I.V.* by our marketing partners during fiscal year 2004 primarily due to the highly competitive overseas market for this product.

Product Sale Revenue

Product sale revenue for the fiscal years ended September 30, 2004 and 2003 consisted of the following:

	Years Ended September 30,			
	2004	2003	$ Change	% Change
Feridex I.V.	$431,823	$337,440	$ 94,383	28%
GastroMARK	336,366	263,004	73,362	28%
Total	$768,189	$600,444	$167,745	28%

The increase in product sale revenue in the fiscal year ended September 30, 2004 as compared to the fiscal year ended September 30, 2003 was primarily a result of the fluctuation of our product sales to our marketing partners based on uneven demand by end users for our marketed products, *Feridex I.V.* and *GastroMARK*, and the batch size in which our products are manufactured and shipped, which creates uneven purchasing patterns by our marketing partners. We did not have any product sales in the fourth quarter of 2004.

Costs and Expenses

Cost of Product Sales

We incurred costs of $117,015 associated with product sales during the fiscal year ended September 30, 2004 compared with costs of $199,561 for the fiscal year ended September 30, 2003, a decrease of $82,546, or 41%. This constituted approximately 15% and 33%, of product sales during those periods, respectively. The reduction of cost of goods sold as a percentage of revenue is due to a shift in the mix within our *Feridex I.V.* product family combined with production efficiencies achieved. Our gross margins are dependent on the mix of customers, prices we charge for our products, and the product mix. The higher gross margin in the fiscal year ended September 30, 2004 is a result of favorable unit volume increases, product mix 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, consulting fees and expenses and professional fees, and internal expenses, such as compensation of employees engaged in research and development activities, the manufacture of limited quantities of product needed to support research and development efforts and related costs of facilities and other general costs related to research and development.

At the end of fiscal 2000, we adopted the guidance under SAB 101 (later revised as Staff Accounting Bulletin No. 104). As a result of this change of accounting method we have tracked our internal research and development expenses since this time in relation to our license and marketing agreement with Cytogen and not by specific research and development project.

Research and development expenses for the fiscal years ended September 30, 2004 and 2003 consisted of the following:

	Years Ended September 30,			
	2004	2003	$ Change	% Change
External Research and Development Expenses				
Ferumoxytol in Iron Replacement Therapy	$1,919,017	$1,190,109	$ 728,908	61 %
Ferumoxytol in MRA	114,063	94,867	19,196	20 %
Combidex	222,548	186,940	35,608	19 %
Other external costs	134,861	209,169	(74,308)	(36)%
Total	$2,390,489	$1,681,085	$ 709,404	42 %
Internal Research and Development Costs	3,693,350	2,777,895	915,455	33 %
Total Research and Development Costs	$6,083,839	$4,458,980	$1,624,859	36 %

The increase in total expenditures from the fiscal year ended September 30, 2003 to the fiscal year ended September 30, 2004 was attributable to increased external costs of approximately $709,000 and increased internal costs of approximately $915,000. The increase in external costs is due primarily to increased expenditures associated with the Phase III development program for ferumoxytol in iron replacement therapy of approximately $1,774,000 as well as additional toxicology studies required for both ferumoxytol in iron replacement therapy and *Combidex* of approximately $244,000. This increase was partially offset by a decrease of approximately $1,191,000 in Phase II expenses due to the completion of Phase II clinical trials for ferumoxytol in iron replacement therapy. The increase in internal research and development costs is primarily attributable to an increase in costs associated with the addition of clinical development employees coupled with increased expenditures associated with scale-up efforts.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the fiscal years ended September 30, 2004 and 2003 consisted of the following:

	Years Ended September 30,			
	2004	2003	$ Change	% Change
Compensation, payroll taxes and benefits	$1,073,585	$ 984,435	$ 89,150	9%
Professional and consultant fees	455,716	345,538	110,178	32%
Facilities, insurance and other	690,476	440,429	250,047	57%
Total	$2,219,777	$1,770,402	$ 449,375	25%

The increase in expenditures for selling, general and administrative costs in the fiscal year ended September 30, 2004 was primarily due to increased professional fees, insurance costs and higher utility and maintenance costs as compared with the prior fiscal year.

Other Income and Expenses

Other income and expenses were comprised of interest, dividends and net gains on sales of securities as follows:

	Years Ended September 30, 2004	2003	$ Change	% Change
Interest income	$ 382,738	$ 38,880	$ 343,858	884 %
Amortization of bond premiums	(213,191)	$ —	(213,191)	—
Dividend income	—	73,850	(73,850)	(100)%
Gains on sale of marketable securities	—	3,342,648	(3,342,648)	(100)%
Losses on sale of marketable securities	—	(565,645)	565,645	(100)%
Write-down of marketable securities	—	(644,310)	644,310	(100)%
Other income	—	148,129	(148,129)	(100)%
Total	$ 169,547	$2,393,552	$(2,224,005)	(93)%

The increase in interest income in the fiscal year ended September 30, 2004 was primarily attributable to a substantial increase during the fiscal year in our interest-bearing investments, mainly U.S. Treasury Notes, as compared to the fiscal year ended September 30, 2003. There was no dividend income in the fiscal year ended September 30, 2004 as compared to $73,850 in the fiscal year ended September 30, 2003 because we did not own any dividend-paying securities during the fiscal year ended September 30, 2004. There were no gains on the sale of securities in the fiscal year ended September 30, 2004 compared to gains on the sale of securities of $3,342,648 in the fiscal year ended September 30, 2003 because we did not sell any securities during the fiscal year ended September 30, 2004. Offsetting the gain of $3,342,648 in the fiscal year ended September 30, 2003, we recognized $565,645 in losses in the fiscal year September 30, 2003. A portion of the gains realized on sales of securities in the fiscal year ended September 30, 2003 were on securities that were previously written down to a new cost basis. During the fiscal year ended September 30, 2003, we determined that the decline in the carrying value of two securities below their original basis was an other-than-temporary decline. Accordingly, we recorded a write-down of marketable securities of $644,310 for the fiscal year ended September 30, 2003 and established a new cost basis for these securities on our balance sheet. In making this determination, we considered, among other factors, the duration of the period that, and extent to which, the fair value of these securities was less than their original cost basis, the financial health and business outlook of the companies that issued the securities, including industry and sector performance, and overall market conditions and trends. We employed a methodology in evaluating whether a decline in the fair value of the marketable securities in our portfolio below cost basis was other-than-temporary that considered available evidence regarding such marketable securities. We believe there was no other-than-temporary decline in value for the fiscal year ended September 30, 2004. Other income of $148,129 was recorded in fiscal 2003, representing the difference between the cash surrender value of a life insurance policy on the lives of our Chief Executive Officer and his spouse and the guaranteed amount recorded in prior periods. The policy was terminated and we received the cash value of $761,747 on October 29, 2003.

Income Taxes

We had no annualized income tax provision for the fiscal year ended September 30, 2004 as we incurred a loss in that fiscal period. Due to the uncertainty of the realizability of our deferred tax assets, including loss carryforwards, a full valuation allowance has been recorded as of September 30, 2004 against these assets. We received an income tax refund of $124,752 during the fiscal year ended September 30, 2003. This amount was a result of a change in the tax laws relating to the alternative minimum taxes paid in previous years. We had no income tax provision for the fiscal year ended September 30, 2003 due to sufficient net loss carry-forwards.

Cumulative Effect of Accounting Change

In fiscal 2000, we adopted the guidance under SAB 101 (later revised as Staff Accounting Bulletin No. 104). The effect of applying this change in accounting principle was a charge in 1999 of $7,457,717, or $1.11 per share. This cumulative change in accounting principle reflects the reversal of license fees and milestone payments that had been recognized in prior years. Previously, we had recognized license fee revenue when the fees were non-refundable, a technology transfer occurred, no explicit commitment or obligation for scientific achievement existed, and the other portions of the agreement, principally supply and royalty, were priced at fair value. Under the new accounting method, applied retroactive to October 1, 1999, these payments, associated with the Berlex agreement, were recorded as deferred revenue to be recognized evenly over the remaining term of the related agreement. For each of the years ended September 30, 2004 and September 30, 2003, we recognized $737,755 in revenue that was included in the cumulative effect adjustment as of October 1, 1999.

Net Income (Loss)

For the reasons stated above, there was a net loss of ($4,495,200), or ($0.57) per basic and diluted share, for the fiscal year ended September 30, 2004 compared to net income of $866,857, or $0.13 per basic share and $0.12 per diluted share, for the fiscal year ended September 30, 2003.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through proceeds received from our marketing and distribution partners, cash generated from our investing activities and the sale of our equity securities. Both our near- and long-term capital requirements will depend on many factors, including, but not limited to, the following:

- the progress of, and our ability to successfully complete, clinical trials for ferumoxytol as an iron replacement therapeutic in a timely and cost-effective manner;
- our ability to complete our development program for ferumoxytol as an iron replacement therapeutic within our projected budget;
- our ability to establish additional development and marketing arrangements or to enter into alternative strategic relationships;
- our ability to raise additional capital on terms and within a timeframe acceptable to us;
- our potential need to hire additional staff and lease additional space as part of our commercialization efforts for ferumoxytol;
- our ability to successfully obtain regulatory approvals for our products, including our ability to satisfy the conditions specified by the FDA for approval of *Combidex*;
- the magnitude of product sales and royalties; and
- the costs involved in filing, prosecuting and enforcing patent claims.

Since the beginning of fiscal 2004, we have invested in short-term and long-term U.S. Treasury Notes and U.S. Treasury Bills. As of September 30, 2005, the maturities of these investments ranged from less than one month to less than five months. In addition, we maintain most of our surplus cash primarily in money market funds classified as cash equivalents. A significant decline in value of these money market funds would result in a substantial reduction in our total assets and cash available for daily operations. We have limited insurance protection for these money market accounts available through the Securities Investor Protection Corporation, or SIPC.

Cash and cash equivalents (which consist of cash on hand, money market funds and U. S. Treasury Bills having an original maturity of less than three months), short-term investments and long-term investments consisted of the following:

	Years Ended September 30,			
	2005	2004	$ Change	% Change
Cash and cash equivalents	$11,332,088	$ 9,391,363	$ 1,940,725	21 %
Short-term investments	12,395,210	4,942,915	7,452,295	151 %
Subtotal	23,727,298	14,334,278	9,393,020	66 %
Long-term investment	—	4,768,159	(4,768,159)	(100)%
Total cash, cash equivalents and investments	$23,727,298	$19,102,437	$ 4,624,861	24 %

The increase in cash and cash equivalents as of September 30, 2005 as compared to September 30, 2004 is primarily the result of our investment of $16.7 million in net proceeds from our June 2005 financing, as discussed further hereunder. Proceeds from the issuance of our common stock, as a result of both the cash exercise of stock options and shares issued pursuant to our Employee Stock Purchase Plan during the fiscal years ended September 30, 2005 and 2004 were $578,400 and $1,080,148, respectively. As of September 30, 2005, we believe that our cash, cash equivalents, short and long-term investments, combined with cash we currently expect to receive from other sources, will be sufficient to satisfy our future cash flow needs for approximately the next eighteen months. In order to fund our longer-term cash flow needs we will consider various financing alternatives, including possible future strategic partnerships or additional equity or debt financing. These financing arrangements may not be available to us on terms or within a timeframe acceptable to us, if at all.

We filed a shelf registration statement on Form S-3 with the SEC, which was declared effective on December 21, 2004. Under this registration statement, we may offer and sell, from time to time, up to $50 million of common stock, preferred stock and warrants. We offered and sold an aggregate of approximately $17.1 million of common stock and warrants in June 2005. As a result, we may offer and sell up to an additional $32.9 million of common stock, preferred stock and warrants under the shelf registration statement going forward, so long as we remain eligible to use Form S-3 in accordance with SEC rules. The proceeds from the June 2005 financing have been invested in U.S. Treasury Bills and money market funds and will be used to fund our clinical development programs, including our continued development of ferumoxytol as an iron replacement therapeutic, and for general working capital purposes. Unless otherwise described in a prospectus supplement, we expect to use the net proceeds from any sale of the offered securities for general corporate purposes, which may include, but are not limited to, working capital, ongoing research and development activities, and capital expenditures. Pending any specific utilization, the proceeds from any sale of offered securities may be invested in a manner designed to ensure levels of liquidity which correspond to our current and foreseeable cash needs. Such investments may include, but not be limited to, short-term investments, including government notes, or other interest-bearing investments. There is no assurance that we will be able to sell additional securities pursuant to the registration statement on acceptable terms and within a timeframe acceptable to us, if at all. This Annual Report on Form 10-K for the fiscal year ended September 30, 2005 shall not constitute an offer to sell or the solicitation of an offer to buy nor shall there be any sale of the securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state. The offering of the securities will be made only by means of a prospectus.

Net cash used in operating activities was $11,995,284 in the fiscal year ended September 30, 2005 compared to net cash used in operating activities of $6,225,910 in the fiscal year ended September 30, 2004. Cash received during the fiscal year ended September 30, 2005 included $1,081,109 from customers, $323,478 of royalties from our distribution and marketing partners, and $539,505 from interest income associated with our investments in various U.S. Treasury Bills, U. S. Treasury Notes, and money market funds. Cash used in operating activities during the fiscal year ended September 30, 2005 included $13,939,376 paid to suppliers and employees primarily in connection with our operating and research and

development activities. Cash received from interest income increased in the fiscal year ended September 30, 2005 as a result of the increase in our interest-bearing investments associated with the investment of the proceeds from our June 2005 financing and the increase in short term interest rates. Cash received from royalties in fiscal year 2005 was associated with increased sales of *Feridex I.V.* and *GastroMARK* by our distributors and marketing partners. These increases were offset by an increase in fiscal year 2005 in cash paid to suppliers principally due to cash outlays for our clinical development activities, professional fees related to consultants hired to assist with our efforts to implement the internal control requirements of Section 404 of the Sarbanes-Oxley Act of 2002, insurance payments, manufacturing supplies, and professional fees associated with our evaluation of various strategic opportunities. The increase in accounts payable and accrued expenses as of September 30, 2005 as compared to September 30, 2004 is mainly associated with accruals for costs associated with third party contract research and development service providers and patient enrollment costs and fees, which is reflective of an increased level of activity as of September 30, 2005 associated with our ongoing Phase III clinical trials for ferumoxytol in iron replacement therapy. We also expended approximately $300,000 in fiscal year 2005 and $420,000 in fiscal year 2004 in connection with the purchase of the remaining inventory from a supplier of a key raw material in the manufacturing process for our products, who informed us of its intent to cease manufacturing this raw material. Because we have identified another supplier of this raw material and are continuing to identify a second source supplier, we do not expect inventory purchases to continue at this increased level. We anticipate cash used in operating activities will increase over current levels based on continued increases in research and development expenses related to the conduct of Phase III clinical trials for ferumoxytol in iron replacement therapy, expenses associated with additional clinical trials we may have to conduct in connection with our NDA submission for ferumoxytol, and expected increases in selling, general and administrative expenses, including costs related to compliance with corporate governance requirements. Cash used in operating activities could also increase if we hire additional staff and lease additional office space should we choose to continue our efforts to commercialize ferumoxytol without the assistance of a marketing partner.

Net cash used in operating activities was $6,225,910 in the fiscal year ended September 30, 2004 compared to net cash used in operating activities of $4,932,070 in the fiscal year ended September 30, 2003. Cash received during the fiscal year ended September 30, 2004 included $1,099,481 from customers, $230,304 from royalties and $337,556 from interest income. Cash used in operating activities during the fiscal year ended September 30, 2004 included $7,893,251 paid to suppliers and employees. Cash used in operating activities increased in fiscal 2004 principally due to a decrease in royalties and product sales and an increase in research and development expenditures.

We expect to continue to incur substantial research and development cash expenditures, including costs related to ongoing and future clinical studies, in order to commercialize our product candidates based on our core superparamagnetic iron oxide nanoparticle technology, including ferumoxytol as an iron replacement therapeutic. We expect research and development expenses to increase over the next 12 months and to remain at high levels for at least the next 18 to 24 months as a result of increased patient enrollment costs, fees associated with our third party contract research and development service providers in connection with our Phase III clinical trials for ferumoxytol in iron replacement therapy and the costs associated with any additional studies we may need to conduct as part of our NDA submission for ferumoxytol.

In addition to our internal research and development costs, we currently estimate that the future cash expenditures of the external efforts necessary to complete development of ferumoxytol as an iron replacement therapeutic will be in the range of approximately $16 to $18 million over approximately the next 24 months. These external costs could increase, however, if we experience significant delays in our clinical program due to slow enrollment, unexpected results from our clinical sites that affect our ability to complete the studies in a timely manner, inadequate performance or errors by third party contract research and development service providers, or deficiencies in the design or oversight by us of these studies, or if we need to conduct additional clinical trials or we otherwise experience a delay in the submission of our NDA

for ferumoxytol in iron replacement therapy. Any such delay would also delay the commercialization of ferumoxytol as an iron replacement therapeutic. As a result of modifications to the Phase III development program based on discussions with the FDA, we currently plan to submit the NDA for ferumoxytol to the FDA in mid calendar year 2007. This submission could be further delayed, however, if we experience delays in any one of our Phase III clinical trials in iron replacement therapy. Also, until we complete our evaluation of existing clinical studies and meet with the FDA to discuss next steps, we cannot predict with certainty the timing or cost of the efforts that would be necessary to satisfy the conditions specified by the FDA for approval of *Combidex* or our ability to complete those efforts in a timely or cost-effective manner, if at all.

Although we have entered into strategic relationships in the past which provided for non-refundable license fees and milestone payments while we were developing our products, we may choose not to do so or may not be able to secure similar arrangements or alternative strategic relationships in the future on terms that are acceptable to us with respect to ferumoxytol. In addition, although in the past we have generated cash through the sale of our equity securities, we may not be able to secure such financing in the future on acceptable terms or within an acceptable timeframe, if at all. If we are unable to fund our future research and development expenses out of product sales, working capital, sales of debt or equity securities, or other strategic arrangements in the manner we anticipate, we could be forced to obtain alternative sources of financing, seek other alternatives or curtail our development activity, any of which could adversely impact the future prospects of our business.

Cash used in investing activities was $3,327,449 in the fiscal year ended September 30, 2005 compared with cash used in investing activities of $9,364,002 and cash provided of $10,570,086 in the fiscal years ended September 30, 2004 and 2003, respectively. Cash used in investing activities in the fiscal year ended September 30, 2005 included $12,765,397 for the purchase of short-term investments and $401,289 in capital expenditures, partially offset by $9,839,237 of proceeds from the maturities of a U.S. Treasury Note and a U. S. Treasury Bill. Cash used in investing activities in the fiscal year ended September 30, 2004 included $ 48,766,408 for the net purchase of U.S. Treasury Notes and $201,484 in capital expenditures, partially offset by $38,842,143 of proceeds from the maturities of U.S. Treasury Notes and $761,747 received relative to a short-term asset which represented the cash value of a split-dollar life insurance policy on our Chief Executive Officer that was terminated at the end of fiscal 2003. Cash provided by investing activities in the fiscal year ended September 30, 2003 included proceeds from the sale of marketable securities of $12,094,579, offset by cash used for the purchase of marketable securities of $1,291,425 and $167,089 in capital expenditures.

Capital expenditures of $401,289, $201,484 and $167,089 in the fiscal years ended September 30, 2005, 2004 and 2003, respectively, related primarily to the completion in fiscal 2005 of our efforts to upgrade production associated with our manufacturing scale-up of ferumoxytol and computer equipment. We expect our capital expenditures for fiscal 2006 to return the levels incurred in fiscal years 2003 and 2004. However, our expected capital expenditures could increase if we hire additional staff and lease additional space should we choose to commercialize ferumoxytol without the assistance of a marketing partner.

Cash provided by financing activities amounted to $17,263,458 in the fiscal year ended September 30, 2005, primarily the result of our June 2005 issuance of an aggregate of 1,799,995 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. In addition, proceeds from the issuance of our common stock, as a result of both the cash exercise of stock options and shares issued pursuant to our Employee Stock Purchase Plan during fiscal years ended September 30, 2005 and 2004 was $578,400 and $1,080,148, respectively. Cash provided by financing activities was $9,705,291 during the fiscal year ended September 30, 2003. This amount included $220,292 for the exercise of stock options and for the purchase of common stock under our Employee Stock Purchase Plan, and $9,484,999 in net proceeds from the private placement of our common stock in July 2003 to certain institutional investors.

Contractual Obligations

We currently have no long-term debt obligations, capital lease obligations, purchase obligations or other long-term liabilities. Future lease obligations, as of September 30, 2005, are summarized in the chart below.

	Payment due by period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating Lease Obligations	$38,000	$35,000	$3,000	$ —	$ —
Total	$38,000	$35,000	$3,000	$ —	$ —

Operating Lease Obligations

We have entered into several agreements to service and/or lease certain office equipment, laboratory equipment, and one vehicle; such agreements expire in 2006 and 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 Squibb Diagnostics, a division of Bristol-Myers Squibb Co., we reacquired the development and marketing rights to *Combidex*, which had previously been licensed to Squibb Diagnostics. Pursuant to this agreement, we are obligated to pay up to a maximum of $2,750,000 in royalties to Squibb Diagnostics in connection with future product sales of *Combidex*. We are also the licensee of certain technologies related to our products under cross license agreements with Nycomed Imaging A.S. of Oslo, Norway (now known as Amersham Health, which is part of GE Healthcare), or Nycomed, and Schering AG. The license agreement with Nycomed 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 Nycomed to pay royalties on a percentage of product sales of *Feridex I.V.* and *GastroMARK*, if any. There were no milestone payments in fiscal years 2005, 2004 or 2003. Future milestone payments under the Nycomed agreement are not expected to exceed $400,000. Royalty payments under the Nycomed agreement were less than $105,000 for each of the prior three fiscal years.

Other

In fiscal 2005, we paid liquidated damages of approximately $62,000 as a result of our failure to meet certain contractual obligations, which failure was subsequently remedied.

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 L of Notes to Financial Statements included in Part II, Item 8 “Financial Statements and Supplementary Data” of this Annual Report on Form 10-K.

The foregoing discussion includes forward-looking statements that are subject to risks and uncertainties and actual results may differ materially from those currently anticipated depending on a variety of factors including those discussed below. See “Certain Factors That May Affect Future Results.”

Off-Balance Sheet Arrangements

We have no 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 revenue and expenses during the reported period. In making these estimates and assumptions, management employs critical accounting policies. For us, these critical accounting policies are principally the policies of revenue recognition associated with license fees, policies regarding impairment of investments and/or marketable securities and policies regarding long-lived assets.

Revenue recognition associated with license fees. Non-refundable license fees received pursuant to product development and collaboration agreements, in cases where project costs are estimable, are recognized as we incur our development expenses. In such cases, the actual total development expenses can differ significantly from the estimated total development expenses. These differences could be attributable to delays in or cessation of the development of certain of our products, future results from clinical trials, discussions and correspondence with the FDA on the approval process for our products, relationships with our marketing partners or clinical trial partners or other factors. Any of these factors, individually or in the aggregate, could cause future estimates to be materially revised, or estimates to be materially different from actual results, thereby materially affecting the associated revenue recognition of the non-refundable license fee. In cases where 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.

Impairment of investments and/or marketable securities. Investments and marketable securities are considered to be impaired when a decline in fair value below cost basis is determined to be other than temporary. Although we held only U.S. Treasury Notes and Bills at September 30, 2005, we have employed 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; 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 marketable securities in our portfolio, if, among other things, relevant information related to our marketable securities was not publicly available or other factors not considered by us would have been relevant to the determination of impairment. The Company classifies its holdings of U. S. Treasury Bills having an original maturity of three months or less as cash and cash equivalents, in accordance with the provisions of Statement of Financial Accounting Standards No. 95 “Statement of Cash Flows”.

Long-lived assets. 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. 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 that includes successful development and regulatory approvals of our future products 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.

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 December 2004, the Financial Accounting Standards Board, also known as the FASB, issued a revision to SFAS 123 "Share-Based Payment," also known as SFAS 123R, that amends existing accounting pronouncements for share-based payment transactions in which an enterprise receives employee and certain nonemployee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise's equity instruments or that may be settled by the issuance of such equity instruments. SFAS 123R, together with guidance included in Staff Accounting Bulletin No. 107 issued by the SEC on March 29, 2005, also known as SAB 107, eliminates the ability to account for share-based compensation transactions using APB 25 and generally requires such transactions be accounted for using a fair-value-based method. SFAS 123R applies to awards that are granted, modified, or settled in periods beginning after its applicable effective date. In April 2005, the SEC issued a release amending the effective date of SFAS 123R for each registrant to the start of the registrant's first fiscal year beginning after June 15, 2005. SFAS 123R allows for three alternative transition methods. We intend to adopt the modified prospective application method. We currently intend to adopt SFAS 123R and SAB 107 in the first quarter of fiscal 2006. Our adoption of SFAS 123R will cause us to record a noncash accounting charge as an expense each quarter in an amount approximating the fair value of such share-based compensation meeting the criteria outlined in the provisions of SFAS 123R. As of September 30, 2005, we had 343,250 stock options outstanding which had not yet become vested. Based upon the number of options outstanding as of December 12, 2005, we expect to record a noncash accounting charge over the course of fiscal year 2006 of approximately $2,200,000. Beginning with the first quarter in fiscal 2006, the noncash accounting charge will vary based on the number of options that vest in a given quarter. The noncash accounting charge for the first quarter of fiscal year 2006 is estimated to be approximately $1,250,000. This amount and the amount applicable to future quarters are subject to further quarterly adjustments based upon a variety of factors, which include but are not limited to, the issuance of new options.

In November 2004, the FASB issued SFAS No. 151 "Inventory Costs—an amendment of ARB No. 43, Chapter 4," or SFAS 151. This pronouncement, which becomes effective for interim or annual periods beginning after June 15, 2005, clarifies existing accounting guidance relating to accounting for certain abnormal costs of production. The adoption of SFAS 151 did not have a material impact on our results of operations or financial condition.

In May 2005, the FASB Emerging Issues Task Force, or EITF, issued EITF No. 00-19-1 "Application of EITF Issue No. 00-19 to Freestanding Financial Instruments Originally Issued as Employee Compensation". This pronouncement clarifies existing accounting guidance relative to freestanding financial instruments originally issued as employee compensation. EITF No. 00-19-1 becomes effective concurrent with the effective date of SFAS 123R. We believe the adoption of this pronouncement will not have a material impact on our results of operations or financial condition.

In May 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Corrections, a replacement of APB Opinion No. 20, Accounting Changes and FASB Statement No. 3, Reporting Accounting Changes in Interim Financial Statements". This pronouncement amends prior guidance on accounting for, and the reporting of, accounting changes and error corrections, and also establishes, unless impracticable, retrospective application as the required method for reporting a change in accounting principle absent explicit transition requirements specific to the newly adopted accounting principle. The pronouncement also provides guidance for determining whether retrospective application of a change in accounting principle is impracticable and for reporting a change when retrospective application is impracticable. The provisions of this pronouncement are effective for accounting changes and corrections of errors made in fiscal periods beginning after December 15, 2005. The adoption of the provisions of this

pronouncement is not expected to have a material impact on the Company's financial position or results of operations.

In July 2005, the FASB issued a proposed interpretation entitled "Accounting for Uncertain Tax Positions". This proposal is intended to clarify existing accounting for uncertain tax positions by requiring recognition in the financial statements of the best estimate of a tax position only if that position is probable of being sustained upon audit by a taxing authority, based solely on the technical merits of the position.

In August 2005, the FASB issued FASB Staff Position No. 123(R)-1, "Classification and Measurement of Freestanding Financial Instruments Originally Issued in Exchange for Employee Services under FASB Statement No. 123(R)". This pronouncement defers certain requirements of SFAS 123R relative to accounting for freestanding financial instruments issued to employees when the rights conveyed to the holder are no longer dependent on the holder being an employee of the company. The adoption of the provisions of this pronouncement is not expected to have a material impact on our financial position or results of operations.

In October 2005, the FASB issued FASB Staff Position No. FAS 123(R)-2 "Practical Accommodation to the Application of Grant Date as Defined in FASB Statement No. 123(R)". This pronouncement offers guidance relative to the implementation of SFAR 123R as to when a mutual understanding of the key terms and conditions of a stock-based compensation award have been reached in order to determine the grant date of such an award. The adoption of the provisions of this pronouncement is not expected to have a material impact on our financial position or results of operations.

In November 2005, the FASB issued FASB Staff Position No. FAS 115-1 and FAS 124-1 "The Meaning of Other Than-Temporary Impairment and Its Application to Certain Investments". This proposal addresses the determination as to when an investment is considered impaired, whether that impairment is other than temporary, and the measurement of an impairment loss. The adoption of the provisions of this pronouncement is not expected to have a material impact on our financial position or results of operations.

In November 2005, the FASB issued FASB Staff Position No. 123(R)-3 "Transition Election related to Accounting for the Tax Effects of Share-Based Payment Awards". This pronouncement provides an elective alternative transition method relative to the SFAS 123R requirement regarding the computation of certain tax benefits. The adoption of the provisions of this pronouncement is not expected to have a material impact on our financial position or results of operations.

In September 2005, the FASB issued a revised exposure draft on "Earnings per Share—an amendment of FASB Statement No. 128". This proposed statement would clarify existing guidance for mandatorily convertible instruments, the treasury stock method, contracts that may be settled in cash or shares, and contingently issued shares.

In September 2005, the FASB issued a proposed FASB Staff Position entitled FIN 46(R)-c "Determining the Variability to be Considered In Applying FASB Interpretation No. 46(R)". This proposal addresses how a reporting enterprise should determine variability to be considered when applying FASB Interpretation No. 46 (revised December 2003).

Certain Factors That May Affect Future Results

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 cannot predict the results and progress of our clinical trials for ferumoxytol in iron replacement therapy, and our ability to successfully complete the development of ferumoxytol in iron replacement therapy is uncertain.

The development of new pharmaceutical products is highly uncertain and subject to a variety of inherent risks of failure. For example, ferumoxytol may be found to be unsafe, to have harmful side effects on humans, to be ineffective or may otherwise fail to meet regulatory standards or receive necessary regulatory approvals. Before obtaining regulatory approvals for the commercial sale of ferumoxytol, we must demonstrate through extensive pre-clinical testing and human clinical trials that ferumoxytol is safe and efficacious. Ferumoxytol in iron replacement therapy is currently in Phase III multi-center clinical studies. If ferumoxytol in iron replacement therapy fails in Phase III clinical trials or our Phase III clinical trials do not demonstrate sufficient safety and efficacy of ferumoxytol in iron replacement therapy, we will be unable to obtain regulatory approval for, and market, ferumoxytol as an iron replacement therapeutic, thereby reducing our potential future revenues and adversely impacting the future prospects for our business. Our results from pre-clinical testing and early clinical trials of ferumoxytol in iron replacement therapy may not be predictive of results obtained in subsequent human clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. We cannot be sure that the data obtained from our Phase III clinical trials for ferumoxytol in iron replacement therapy will support the indication we are seeking or demonstrate sufficient safety and efficacy to obtain regulatory approvals.

Our ability to complete our clinical trials for ferumoxytol in iron replacement therapy in a timely and cost-effective manner is also subject to a number of uncertainties, many of which are out of our control. For example, the completion rate of our clinical trials depends, in large part, on patient enrollment. We rely on third-party clinical trial sites to find suitable patients for our clinical trial programs for ferumoxytol in iron replacement therapy. If these third parties do not find suitable patients in the timeframe for which we have planned, we will not be able to complete our clinical trials according to our expected schedule. Any such delays could result in an increase in development costs for ferumoxytol in iron replacement therapy, a delay in making regulatory submissions, and a delay in the commercialization of our iron replacement therapy product, thereby significantly impairing or delaying our ability to generate future revenues from sales of ferumoxytol in iron replacement therapy and adversely impacting the future prospects for our business.

In addition, clinical trials are often conducted with patients in the most advanced stages of disease. During the course of treatment, these patients can die or suffer adverse medical effects for reasons that may not be related to the investigational product being tested, but which can nevertheless adversely affect clinical trial results for ferumoxytol in iron replacement therapy or approvals by the U.S. Food and Drug Administration, also known as the FDA. Any unexpected results from our clinical sites for ferumoxytol in iron replacement therapy could hinder our ability to complete our Phase III studies in a timely manner, if at all.

If we are unable to fund any of our clinical studies or complete the regulatory review and approval process for ferumoxytol in iron replacement therapy with our existing cash and cash generated from operations, we will need to seek other sources of financing or alternative strategic arrangements which may not be available on acceptable terms or on an acceptable timeframe, if at all. If we are unable to obtain such alternate financing on terms acceptable to us or within a timeframe acceptable to us, or to enter into other strategic arrangements, we may be forced to curtail our development activities with respect to ferumoxytol in iron replacement therapy.

As a result of these and other risks and uncertainties, our development program for ferumoxytol in iron replacement therapy may not be completed successfully. Any delays or failures in the development of ferumoxytol in iron replacement therapy will delay or prevent generation of revenue from such product candidate, will negatively impact our ability to generate positive cash flow and become profitable, and adversely impact the future prospects for our business.

The successful completion of our clinical trials for ferumoxytol in iron replacement therapy depends, in part, on the performance of third-party contract research and development service providers.

We rely on third-party contract research organizations for a variety of activities in our iron replacement therapy development program, including monitoring of our clinical sites, collection and analysis of data, drafting study reports and assisting in regulatory submissions. We also rely on third-party service providers in our iron therapy replacement development program for clinical laboratory testing and randomization of clinical trial subjects. In addition to our internal research and development costs, we currently estimate that the future cost of the external efforts necessary to complete development of ferumoxytol as an iron replacement therapeutic will be in the range of approximately $16 to $18 million over approximately the next 24 months. These external costs could increase, however, if we experience significant delays in our clinical development program due to slow enrollment, unexpected results from our clinical sites that affect our ability to complete the studies in a timely manner, inadequate performance or errors by third-party contract research and development service providers, or any deficiencies in the design or oversight of these studies by us, or if we need to conduct additional clinical trials or we otherwise experience a delay in the submission of our NDA for ferumoxytol in iron replacement therapy. Any such delay would also delay the commercialization of ferumoxytol as an iron replacement therapeutic. In addition, if any of these third-party contract research and development service providers should fail to perform or should perform inadequately or in violation of current Good Clinical Practices, our regulatory submissions could be delayed or the data in support of such submissions tainted, which could negatively impact the timing or possibility of obtaining regulatory approval for ferumoxytol in iron replacement therapy. Such delays could also result in increased costs associated with our iron replacement therapy development program. Any delay in, or failure to obtain regulatory approval of, ferumoxytol in iron replacement therapy in a timely manner would significantly impair or delay our ability to generate future revenues from product sales and adversely impact the future prospects for our business.

We may not be able to obtain the necessary regulatory approvals in order to market and sell our products, and the approval process is costly and lengthy.

Prior to marketing, every product candidate must undergo an extensive regulatory approval process in the United States and in every other country in which we intend to test and market our product candidates and products. This regulatory process includes testing and clinical trials of product candidates to demonstrate safety and efficacy and can take many years and require the expenditure of substantial resources. Data obtained from pre-clinical trials and clinical trials may not support our expected results in one or more indications or may be subject to varying interpretations. Unexpected or unfavorable data obtained from pre-clinical testing and clinical trials can delay, limit or prevent regulatory approval by the FDA or similar regulatory bodies in foreign countries. In addition, changes in FDA or foreign regulatory approval policies or requirements may occur or new regulations may be promulgated which may result in a delay or failure to receive FDA or foreign regulatory approval. Delays and related costs in obtaining regulatory approvals could delay our product commercialization and revenue and consume our resources, both financial and managerial.

In 2004, we initiated Phase III multi-center clinical studies for one of our product candidates, ferumoxytol, for use in iron replacement therapy. Before applying for FDA approval to market ferumoxytol for use in iron replacement therapy, large-scale Phase III human clinical trials that demonstrate the safety and efficacy of ferumoxytol in iron replacement therapy to the satisfaction of the FDA and other regulatory authorities must be completed. These clinical trials, and the support from

third-party contract research and development service providers necessary for us to conduct them, will entail the expenditure of significant corporate resources, both financial and managerial. We may not be able to successfully complete these clinical trials for ferumoxytol iron replacement therapy, or, if completed, we may not obtain the desired results or, even if we do, we may not be able to obtain regulatory approval or obtain regulatory approval of the desired scope.

Clinical testing of pharmaceutical products is itself subject to approvals by various governmental regulatory authorities. We conduct our Phase III clinical trials for ferumoxytol in iron replacement therapy in accordance with specific protocols, which are filed with the FDA or other relevant authorities. We may not be permitted by regulatory authorities to continue these clinical trials, or we may be required to revise our protocols during the course of these clinical trials, if such protocols are not approved or if the FDA determines that there are flaws in the design of the protocols or the trials during the course of the studies. For example, in August 2005 we announced our plan to revise the Phase III development program for ferumoxytol in IV iron replacement therapy based on discussions that took place during a meeting with the FDA. The modifications to the Phase III program will, among other things, result in additional patients being enrolled in the ferumoxytol chronic kidney disease, or CKD, efficacy studies and the re-design of the current hemodialysis efficacy study. In addition, we announced that we plan to add additional patients to our large-scale safety study to provide a more robust safety database for the New Drug Application, or NDA. Any deficiency in the design or oversight of our Phase III clinical studies by us could further delay or prevent us from obtaining regulatory approval and could significantly increase the costs of such clinical trials and negatively affect our future prospects and stock price. We may also be required to demonstrate that ferumoxytol in iron replacement therapy represents an improved form of treatment over existing therapies in order to receive regulatory approval and we may be unable to do so without conducting further clinical studies, if at all. If, upon completion of our current Phase III clinical trial program, we need to perform additional studies, we could incur significant additional costs and experience significant delays in our efforts to obtain regulatory approval for ferumoxytol in iron replacement therapy. Any such requirement could also result in delays in, or the prevention of, our ability to make regulatory submissions and delays in, or the prevention of, the commercialization of our products. Any such delays would significantly impair or delay our ability to generate future revenues from product sales of ferumoxytol in iron replacement therapy and adversely impact the future prospects for our business.

We recently completed exploratory Phase II clinical trials of ferumoxytol for use as a contrast agent in magnetic resonance imaging, also known as MRI. We plan to evaluate the data from these Phase II studies to determine the appropriate regulatory strategy, if any, for a Phase III development program for ferumoxytol in MRI. However, given the priority we are placing on completion of the Phase III development program for ferumoxytol in iron replacement therapy, we do not currently possess the financial or human resources necessary to conduct Phase III clinical trials for ferumoxytol as a contrast agent in MRI, and we may not be able to advance the ferumoxytol MRI program in the near future.

Final regulatory approvals may not be obtained for ferumoxytol, either as an iron replacement therapeutic or as a contrast agent for use in MRI. Failure to obtain requisite governmental approvals or failure to obtain approvals of the scope requested could delay and may preclude us or our potential licensees or other collaborators, if any, from marketing our ferumoxytol products or limit the commercial use of our ferumoxytol products. Alternatively, regulatory approvals may entail limitations on the indicated uses of our ferumoxytol products and impose labeling requirements which may also adversely impact our ability to market such products.

On March 3, 2005, the FDA's Oncologic Drugs Advisory Committee voted to not recommend approval of the proposed broad indication for *Combidex*. Subsequently, in March 2005, we received an approvable letter from the FDA with respect to *Combidex*, subject to certain conditions. We have submitted a formal meeting request to the FDA to discuss next steps in the regulatory process for *Combidex*. Due to our limited resources and the priority we are placing on completion of the Phase III development program for ferumoxytol in iron replacement therapy, we do not currently intend to sponsor additional clinical studies for *Combidex* in the near future. However, we are reviewing and evaluating

existing studies, including studies sponsored by our European partner, Guerbet, to determine whether such studies will address the concerns raised by the FDA in the March 2005 approvable letter. Until we complete our evaluation of these studies and meet with the FDA to discuss next steps, we cannot predict with certainty the timing or costs of the efforts that would be necessary to satisfy the conditions specified for approval of *Combidex* in the approvable letter, or our ability to complete those efforts in a timely or cost-effective manner, if at all. Although we have received an approvable letter from the FDA, final approval of *Combidex* remains subject to the satisfaction of certain conditions imposed by the FDA and final labeling must be resolved. We may be unable to address the conditions imposed in the March 2005 approvable letter to the satisfaction of the FDA, or we may be unable to satisfy these conditions in a timely manner and/or without the expenditure of significant additional resources, both financial and managerial. 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 truncated indication. If we are unable to obtain approval or are unable to obtain approval for our requested indication or if the FDA recommends labeling that imposes limitations on the use of *Combidex*, our partners' ability to market the product to the medical community may be prevented or hindered. 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 available to fund research and development or other activities and adversely impact the future prospects for our business.

Our operating results will likely fluctuate so you should not rely on a good or bad quarter to predict how we will perform over time.

Our future operating results will likely vary from quarter to quarter or from year to year depending on a number of factors including:

- the timing and magnitude of external research and development expenses, in particular, those related to our Phase III clinical trials for ferumoxytol in iron replacement therapy;
- the variable nature of our product sales to our marketing partners and the batch size in which our products are manufactured;
- uneven demand for our products by end users which affects the royalties we receive from our marketing partners;
- the magnitude of the non-cash accounting charge we will record as an expense in a given period following our adoption of Statement of Financial Accounting Standards Number 123R or SFAS 123R;
- the timing of our recognition of deferred revenue, which is affected by fluctuations in our activities under our license and marketing agreement with Cytogen Corporation, or Cytogen;
- the timing and likelihood of FDA approval of *Combidex*, including the magnitude of potential costs we may incur, if any, to satisfy the conditions specified by the FDA for approval of *Combidex*; and
- the extent of reimbursement for the cost of our approved products from government health administration authorities, private health insurers and other third-party payors.

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 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 $6.00 and $24.25 in the fifty-two week period through December 12, 2005. The stock market has from time to time experienced extreme price and volume fluctuations, particularly in the biotechnology and life sciences sector, which have often been unrelated to the operating performance of particular companies. Various factors and events, including announcements by us or our competitors concerning results of regulatory actions, technological innovations, new products, clinical trial results, agreements with collaborators, governmental regulations, developments in patent or other proprietary rights, or public concern regarding the safety of products developed by us or others, may have a significant impact on the market price of our common stock. Thus, as a result of events both within and beyond our control, our stock price could fluctuate significantly or lose value rapidly. As of December 12, 2005, our shares had an average 90 calendar day trading volume of approximately 11,000 shares. 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.

We have a limited number of customers and are dependent on our collaborative relationships.

Our strategy for the development, commercialization and marketing of our product candidates has been to enter into strategic relationships with various corporate partners, licensees and other collaborators. We rely on a limited number of marketing and distribution partners to market and sell our approved products, Feridex I.V.® and GastroMARK® , both in the United States and in foreign countries, and we depend on these strategic partners for a significant portion of our revenue. Three companies were responsible for approximately 89% of our revenue during the fiscal year ended September 30, 2005. Berlex Laboratories, Inc. represented approximately 47% of our revenue, Guerbet represented approximately 20% of our revenue, and Cytogen represented approximately 22% of our revenue in the fiscal year ended September 30, 2005. The majority of our revenue for the fiscal year ended September 30, 2005 constituted recognition of deferred revenue. A decrease in revenue from any of our significant marketing or distribution partners could seriously impair our overall revenues. In some cases, we have granted exclusive rights to these partners. If these partners are not successful in marketing our products, or if these partners fail to meet minimum sales requirements or projections, our ability to generate revenue would be substantially harmed. For example, to date, we have not generated significant revenues on royalties from the sale of our approved products by our marketing partners. In addition, we might incur further costs in an attempt to enforce our contractual rights, renegotiate agreements, find new partners or market our own products. In some cases, we are dependent upon some of our collaborators to manufacture and market our products. We may not be able to derive any revenues from these arrangements. If any of our collaborators breaches its agreement with us or otherwise fails to perform, such event could impair our revenue and impose additional costs on us. In addition, many of our corporate partners have considerable discretion in electing whether to pursue the development of any additional products and may pursue technologies or products either on their own or in collaboration with competitors. Given these and other risks, our current and future collaborative efforts may not be successful. Failure of these efforts would materially adversely impact our ability to generate revenue from product sales, thereby decreasing the amount of cash from operations available to support our development efforts for ferumoxytol as an iron replacement therapeutic.

Due to the high cost of our research and development activities, in particular the cost of clinical trials for ferumoxytol in iron replacement therapy, our inability to secure strategic partners or alternative strategic arrangements could limit our ability to continue developing ferumoxytol or force us to raise additional capital through alternative means which may not be available to us on acceptable terms or within an acceptable timeframe, if at all. Any delay in, or termination of, any of our research and development projects due to insufficient funds resulting from lack of revenue from strategic partners or alternative capital raising or strategic arrangements would reduce our potential revenues and negatively

impact our stock price. In addition, if, in the future, we are unable to enter into collaborative agreements related to ferumoxytol in either iron replacement therapy or MRI, or choose not to enter into collaborative agreements, we would need to develop an internal sales and marketing department, including a direct sales force, or contract for these services from a third party, in order to market and sell ferumoxytol since we do not have the necessary sales and marketing expertise at this time. If we are unable to successfully recruit and retain the necessary sales and marketing personnel, to obtain the financing to support these efforts, or to contract with third parties for these services on acceptable terms, if at all, our product marketing efforts and potential product launches would be delayed and the commercialization of ferumoxytol would be severely impaired. Any delay in the product launch of ferumoxytol in iron replacement therapy or MRI would delay any potential revenue from these product candidates.

We are dependent on a limited number of products and product candidates.

We have two products, *Feridex I.V.* and *GastroMARK*, currently approved for marketing and sale in the United States and in certain foreign jurisdictions. Our only other products currently under development, *Combidex* and ferumoxytol as an iron replacement therapeutic and as a contrast agent in MRI, are not yet approved for marketing or sale in the United States or in any other country. Sales of *Feridex I.V.* and *GastroMARK* by our marketing partners have been at relatively low levels in recent years, and we expect sales of *Feridex I.V.* and *GastroMARK* will remain at current low levels overall. We may not be able to obtain regulatory approval for *Combidex* or ferumoxytol as an iron replacement therapeutic or as a contrast agent in MRI in the United States or in any other country. Even if approved, *Combidex* and ferumoxytol, in both iron replacement therapy and MRI, may fail to achieve market acceptance. In this event, we do not currently have an alternative source of revenue or profits, other than *Feridex I.V.* and *GastroMARK*. Any failure by us to obtain approval of *Combidex* or ferumoxytol in iron replacement therapy or as a contrast agent in MRI will have a material adverse impact on our ability to generate additional revenues, our ability to achieve profitability, and on the future prospects for our business.

In addition, although we have dedicated significant resources to our research and development efforts, we may not develop new applications for our existing technology or expand the indications for our current products or product candidates for development into future product candidates. We are not currently conducting or sponsoring research to expand our development pipeline. Any failure by us to develop and commercialize additional products and product candidates 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 not be successful in competing with other companies or our technology may become obsolete.

The pharmaceutical and biopharmaceutical industries are subject to intense competition and rapid technological change. We believe that our ability to compete successfully will depend on a number of factors including our ability to develop efficacious products, our timely receipt of regulatory approvals, our ability to manufacture products at commercially acceptable costs, and the implementation of effective marketing campaigns by us or our marketing and distribution partners. We may not be able to successfully develop efficacious products, obtain timely regulatory approvals, manufacture products at commercially acceptable costs, market our products alone or with our partners, gain satisfactory market acceptance or otherwise successfully compete in the future.

We have many competitors currently developing and or marketing IV iron replacement therapy products and MRI contrast agents, many of whom have substantially greater capital and other resources than we do and represent significant competition for us. These companies may succeed in developing technologies and products that are more effective or less costly than any that we may develop, and may be more successful than we are in developing, manufacturing and marketing products. In addition, our collaborators are not restricted from developing and marketing certain competing products and, as a result of certain cross-license agreements with our competitors (including one of our collaborators), our competitors 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. Additionally, further technological and product developments may make other iron replacement therapy products more competitive than ferumoxytol or other imaging modalities more compelling than MRI, and adversely impact sales of our iron replacement therapy and imaging products, respectively.

We will likely need additional capital to achieve our business objectives.

We have expended and will continue to expend substantial funds to complete the research, development, clinical trials, regulatory approvals and other activities necessary to achieve final commercialization of our product candidates, *Combidex* and ferumoxytol as an iron replacement therapeutic and as a contrast agent in MRI. In particular, we anticipate that the high levels of expenditures related to our research and development activities will continue due to the conduct of Phase III clinical studies for ferumoxytol in iron replacement therapy and that our cash-burn rate will continue to increase in the near term. Our near- and long-term capital requirements will also depend on additional factors, including, but not limited to,

- the progress of, and our ability to successfully complete, clinical trials for ferumoxytol as an iron replacement therapeutic in a timely and cost-effective manner;
- our ability to complete our development program for ferumoxytol as an iron replacement therapeutic within our projected budget;
- our ability to establish additional development and marketing arrangements or to enter into alternative strategic relationships;
- our ability to raise additional capital on terms and within a timeframe acceptable to us;
- our potential need to hire additional staff and lease additional space as part of our commercialization efforts for ferumoxytol;
- our ability to successfully obtain regulatory approvals for our products, including our ability to satisfy the conditions specified by the FDA for approval of *Combidex*;
- the magnitude of product sales and royalties; and
- the costs involved in filing, prosecuting and enforcing patent claims.

We estimate that our existing cash resources, combined with cash we currently expect to receive from other sources, will be sufficient to finance our operations for approximately the next 18 months. Thereafter, we will likely require additional funds or need to establish alternative strategic arrangements to continue our research and development activities, including our iron replacement therapy development program, to conduct future clinical trials for ferumoxytol in new indications and to market and sell our products. 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 obtain raw materials and our reliance on sole source suppliers could adversely impact our business.

We currently purchase the raw materials used to manufacture our products from third-party suppliers. We do not, however, have any long-term supply contracts with these third parties. Certain raw materials used in our products 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, we would be

unable to manufacture our products until we were able to qualify an alternative source. For example, during fiscal 2005 one of our suppliers notified us of its decision to discontinue manufacturing a key raw material in our manufacturing process for our products. At that time, we purchased all remaining inventory from the supplier and have since identified an alternative supplier and are continuing our efforts to find a second supplier of this raw material. 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 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 our products, both for commercial sale and for use by us in our ongoing 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 our products, 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 hinder our ability to generate revenues from sales of our products or reduce the revenues realized from such sales and could impede our development efforts with respect to our product candidates.

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 our executive officers, senior scientists, clinical staff, and manufacturing and quality control personnel, including our Chief Executive Officer, Jerome Goldstein. If we are unable to attract and retain qualified scientific and technical personnel for the development activities conducted or sponsored by us, including our Phase III clinical trials for ferumoxytol in iron replacement therapy, or we fail to hire qualified people or lose the services of our key personnel, our product development efforts could be delayed or curtailed. If we fail to attract and retain key members of our manufacturing or quality control departments, our ability to manufacture our products, or to manufacture our products in a timely and cost-effective manner, could be hindered and our product sales and development efforts delayed. Furthermore, our possible expansion into areas and activities requiring additional expertise, such as late-stage clinical development and marketing and sales, may require the addition of new management personnel or the development of additional expertise by existing management personnel, which would increase our projected research and development costs and accelerate our need for additional financing. 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.

We lack marketing and sales experience.

We have limited experience in marketing and selling our products and rely on our corporate partners to market and sell *Feridex I.V.* and *GastroMARK* and have agreed to permit Cytogen to do so, pending FDA approval, for *Combidex*. In order to achieve commercial success for ferumoxytol in iron replacement therapy or MRI, we may have to develop a marketing and sales force or enter into arrangements with others to market and sell our products. If we choose to market and sell ferumoxytol in iron replacement therapy or MRI ourselves, we may encounter difficulties in attracting and retaining qualified marketing and sales personnel. In addition, in order to establish our own marketing and sales force, we would have to raise substantial amounts of additional capital to support the costs associated with such an effort. We may not be able to secure such additional financing on terms or within a timeframe acceptable to us, if at all. If we fail to raise the necessary capital, or choose not to market and sell ferumoxytol in iron replacement

therapy or MRI ourselves, we may not be able to enter into marketing and sales agreements with others on acceptable terms, if at all. Furthermore, whether we market and sell ferumoxytol in iron replacement therapy or MRI ourselves or through marketing and sales arrangements, we, or our corporate partners, may not be successful in marketing and selling these or any of our other products.

We cannot be certain that our products will be accepted in the marketplace.

For a variety of reasons, many of which are beyond our control, our products may not achieve market acceptance or become commercially successful. If our products do not receive market acceptance for any reason, it may limit sales of our products and reduce our revenues from royalties and direct sales, if any. The degree of market acceptance of any of our products will depend on a number of factors, including:

- the establishment and demonstration in the medical community of the clinical efficacy and safety of our products;
- our products' potential advantage over existing treatments or diagnostic methods; and
- reimbursement policies of government and third-party payors, including insurance companies.

For example, even if we obtain regulatory approval to sell our products, physicians and health care payors could conclude that our products are not safe or effective and decide not to use them to treat patients. Our competitors may also develop new technologies or products which are more effective or less costly, or that are perceived as more effective or cost-effective than our products. Physicians, patients, third-party payors or the medical community in general may fail to accept or choose not to use any of the products that we develop.

To date, we have not generated significant revenues on royalties from the sale of our approved products by our marketing partners, and these products have not achieved broad market acceptance. *Feridex I.V.* and *GastroMARK*, approved in 1996 and 1997, respectively, represented an alternative technology platform for physicians to adopt in MRI. *Feridex I.V.* sales have decreased from their peak based on changes in MRI technology and competition in the market, and we expect product sales of *Feridex I.V.* to remain at current low levels overall. *Combidex*, if approved, will represent a shift in the diagnostic process that physicians could use to stage and monitor cancer patients that may not be adopted by physicians. In addition, ferumoxytol, if approved in iron replacement therapy, will represent an alternative to existing products or procedures that might not be adopted by the medical community. If our approved products or future products are not adopted by physicians, revenues will be delayed or fail to materialize, and our ability to achieve profitability will be significantly adversely effected.

Our success is dependent on third-party reimbursement.

In both the United States and foreign markets, our ability to commercialize our products will depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, private health insurers and other third-party payors. We expect that our products will be purchased by hospitals, clinics, doctors and other users that bill various third-party payors, such as Medicare, Medicaid and other government insurance programs, and private payors including indemnity insurers and managed care organizations such as health maintenance organizations. Most of these third-party payors provide coverage for iron replacement therapeutics and for MRI for some indications but may not include a separate payment for the use of an MRI contrast agent. Third-party private payors often mirror Medicare coverage policy and payment limitations in setting their own reimbursement payment and coverage policies. Reimbursement rates vary depending on the procedure performed, the third-party payor, the type of insurance plan and other factors.

In the United States, there have been, and we expect there will continue to be, a number of federal and state proposals to reform the health care system. Significant uncertainty exists as to the reimbursement status of newly-approved healthcare products and products which have competitors for their approved indications. If Medicare or third-party payors do not approve our therapeutic products, MRI products

and/or related MRI procedures for reimbursement, or do not approve them for adequate levels of reimbursement, the adoption of our products may be limited. Sales may suffer as some physicians or their patients will opt for a competing product that is approved for sufficient reimbursement, or some patients may forgo the treatment or MRI procedure instead of paying out-of-pocket for costs associated with the treatment or procedure and contrast agent, and our ability to generate revenue may be impaired. Even if third-party payors make reimbursement available, these payors' reimbursement policies may be insufficient, which may negatively impact us and our corporate partners' ability to sell our products on a profitable basis.

Health care reform is an area of continuing national and international attention and a priority of many government officials. Future changes could impose limitations on the prices that can be charged in the United States and elsewhere for our products or the amount of reimbursement available for our products from government agencies or third-party private payors. The increasing use of managed care organizations, health maintenance organizations and the growing trend in capitated coverage as well as continued legislative proposals to reform healthcare and government insurance programs could significantly influence the purchase of healthcare services and products, resulting in lower prices and reduced demand for our products which could harm our ability to profit from product sales. In addition, recent and possible future legislation and regulations affecting the pricing of pharmaceuticals may change reimbursement in ways adverse to us that may affect the marketing of our current or future products. While we cannot predict the likelihood of adoption of any of these legislative or regulatory proposals, if the government or a private third-party payor adopts these proposals, our ability to price our products at desired levels would be adversely affected.

We need to maintain, and possibly increase, our manufacturing capabilities in order to commercialize our products.

We manufacture bulk *Feridex I.V.* and *GastroMARK,* as well as *Feridex I.V.* finished product, for sale by our marketing partners, *Combidex* bulk product for use in clinical trials and ferumoxytol for use in human clinical trials, in our Cambridge, MA manufacturing facility. Pending FDA approval, we intend to manufacture *Combidex* formulated drug product in bulk at our manufacturing facility as well. This facility is subject to current Good Manufacturing Practices regulations prescribed by the FDA, also known as cGMP. 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 our products and product candidates. In addition, we are dependent on contract manufacturers for the final production of *Combidex* and do not currently have any long-term contracts in place with any third-party manufacturers to conduct this work. In the event that we are unable to arrange final manufacturing for *Combidex*, we will not be able to develop and commercialize this product as planned. Additionally, we may not be able to enter into agreements for the manufacture of future products with manufacturers whose facilities and procedures comply with cGMP regulations and other regulatory requirements. Furthermore, such manufacturers may not be able to deliver required quantities of product that conform to specifications in a timely manner.

We currently have only one manufacturing facility at which we produce limited quantities of ferumoxytol. Although we have tested scale-up for production of ferumoxytol, 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, and we may experience delays in manufacturing ferumoxytol. Furthermore, if we fail to attract and retain key members of our manufacturing or quality control departments, we may be unable to manufacture our products and product candidates 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. As a result, we may lose sales and fail to generate increased revenue.

We may not be able to obtain the necessary regulatory approvals in order to market and sell our products in foreign countries.

Until we or our marketing partners obtain the required regulatory approvals for ferumoxytol as an iron replacement therapeutic or for *Combidex* in any specific foreign country, neither we nor our marketing partners will be able to sell these product candidates in that country. International regulatory authorities have imposed numerous and varying regulatory requirements, and the approval procedures could involve testing in addition to that required by the FDA. Furthermore, approval by one regulatory authority does not ensure approval by any other regulatory authority. In addition, in some cases, we are dependent upon some of our collaborators to conduct clinical testing and to obtain regulatory approvals. We, or our collaborators, may not be able to obtain final regulatory approvals for ferumoxytol in iron replacement therapy or for *Combidex*, or any other products developed by us, in foreign countries. Any failure to obtain the necessary governmental approvals or failure to obtain approvals of the scope requested could delay, and may preclude us or our licensees or other collaborators from marketing, our product candidates or limit the commercial use of our product candidates in these foreign jurisdictions. Alternatively, foreign regulatory approvals may entail limitations on the indicated uses of our product candidates and impose labeling requirements which may also adversely impact our ability to market our product candidates.

We may be unable to comply with continuing regulatory requirements even after our products have been approved for marketing.

Even if we obtain regulatory approval for our product candidates, a marketed product and its manufacturer are subject to continuing regulatory review. Noncompliance with the regulatory requirements of the approval process at any stage may result in adverse consequences, including the FDA's withdrawal of an approved product from the market or, under certain circumstances, the imposition of criminal penalties. We may be restricted or prohibited from marketing or manufacturing a product, even after obtaining product approval, if previously unknown problems with the product or its manufacture are subsequently discovered. Any such adverse consequence could limit or preclude our ability to sell our products commercially which would hinder our ability to generate revenue through royalties or direct sales of our products.

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 either our patents or patents of our licensors may harm our ability to commercialize our products. 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 distraction of our management. An adverse ruling in any litigation or administrative proceeding could prevent us from marketing and selling our products, limit

our development of our product candidates 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 or our marketing partners from making or selling products. We also may be required to obtain licenses to use the relevant technology, and licenses may not be available on commercially reasonable terms, if at all.

We currently hold over 20 U.S. patents and over 30 foreign patents, which expire between the years 2006 and 2020, some of which are 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. 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. In addition, the termination of any of our existing licensing arrangements could impair our revenues and impose additional costs which could limit our ability to sell our products commercially.

The laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States. 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 United States 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 particularly as our Phase III clinical trial activities for ferumoxytol in iron replacement therapy continue, 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 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, 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.

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

In the fiscal year ended September 30, 2005, we invested a significant amount of our surplus cash in U.S. Treasury Bills classified as held-to-maturity which are, as a result, recorded at amortized cost. As of September 30, 2005, all but one of our investments were classified as held-to-maturity and, as a result, were recorded at amortized cost. The other investment was recorded as available-for-sale and was marked-to-market during the year ended September 30, 2005 to reflect a temporary decline in value which was recorded as a separate component of stockholders' equity entitled "Accumulated other comprehensive loss." As of September 30, 2005, the maturities of these investments ranged from less than one month to less than five months. 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 10% from levels at September 30, 2005, we estimate that the fair value of these investments would decline by an immaterial amount. Therefore, we believe our exposure to interest rate risk is not substantial.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA:

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

Report of Independent Registered Public Accounting Firm

Financial Statements:

Balance Sheets—September 30, 2005 and 2004

Statements of Operations—for the years ended September 30, 2005, 2004 and 2003

Statements of Comprehensive Income (Loss)—for the years ended September 30, 2005, 2004 and 2003

Statements of Stockholders' Equity—for the years ended September 30, 2005, 2004 and 2003

Statements of Cash Flows—for the years ended September 30, 2005, 2004 and 2003

Reconciliation of Net Income (Loss) to Net Cash Used in Operating Activities—for the years ended September 30, 2005, 2004 and 2003

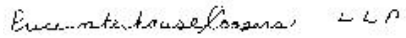
Notes to Financial Statements

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Advanced Magnetics, Inc.:

In our opinion, the financial statements listed in the accompanying index present fairly, in all material respects, the financial position of Advanced Magnetics, Inc. at September 30, 2005 and September 30, 2004, and the results of its operations and its cash flows for each of the three years in the period ended September 30, 2005 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes 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. We believe that our audits provide a reasonable basis for our opinion.



Boston, Massachusetts
December 14, 2005

Advanced Magnetics, Inc.

Balance Sheets

	September 30, 2005	September 30, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,332,088	$ 9,391,363
Short-term investments	12,395,210	4,942,915
Accounts receivable—trade	—	49,575
Inventories	367,788	473,038
Prepaid expenses and interest receivable	444,255	586,584
Total current assets	24,539,341	15,443,475
Property, plant and equipment:		
Land	360,000	360,000
Buildings and improvements	4,723,496	4,660,972
Laboratory equipment	7,290,967	7,018,563
Furniture and fixtures	910,847	877,666
Total property, plant and equipment	13,285,310	12,917,201
Less—accumulated depreciation	(9,532,669)	(9,318,224)
Net property, plant and equipment	3,752,641	3,598,977
Long-term investment	—	4,768,159
Total assets	$ 28,291,982	$ 23,810,611
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 886,190	$ 466,936
Accrued expenses	1,327,556	817,276
Deferred revenue	1,114,183	1,845,509
Total current liabilities	3,327,929	3,129,721
Long-term liabilities:		
Deferred revenue	2,584,894	3,134,435
Total liabilities	5,912,823	6,264,156
Commitments and contingencies (Note L)	—	—
Stockholders' equity:		
Preferred stock, par value $.01 per share, authorized 2,000,000 shares; none issued	—	—
Common stock, par value $.01 per share, 15,000,000 shares authorized; 9,878,354 shares issued and outstanding at September 30, 2005 and 7,949,931 shares issued and outstanding at September 30, 2004	98,784	79,499
Additional paid-in capital	72,326,602	54,741,302
Accumulated deficit	(49,988,961)	(37,274,346)
Accumulated other comprehensive loss	(57,266)	—
Total stockholders' equity	22,379,159	17,546,455
Total liabilities and stockholders' equity	$ 28,291,982	$ 23,810,611

The accompanying notes are an integral part of the financial statements.

Advanced Magnetics, Inc.

Statements of Operations

	For the years ended September 30,		
	2005	2004	2003
Revenues:			
License fees	$ 1,280,867	$ 2,747,695	$3,642,052
Royalties	273,903	240,000	535,000
Product sales	890,398	768,189	600,444
Total revenues	2,445,168	3,755,884	4,777,496
Costs and expenses:			
Cost of product sales	204,080	117,015	199,561
Research and development expenses	12,037,549	6,083,839	4,458,980
Selling, general and administrative expenses	3,337,589	2,219,777	1,770,402
Total costs and expenses	15,579,218	8,420,631	6,428,943
Other income (expense):			
Interest and dividend income	419,435	169,547	112,730
Gains and losses on sales of securities	—	—	2,777,003
Write-down of marketable securities	—	—	(644,310)
Other income, net	—	—	148,129
Total other income (expense)	419,435	169,547	2,393,552
Income (loss) before provision for (benefit from) income taxes	(12,714,615)	(4,495,200)	742,105
Benefit from income taxes	—	—	(124,752)
Net income (loss)	$(12,714,615)	$(4,495,200)	$ 866,857
Earnings (loss) per share:			
Basic	$ (1.47)	$ (0.57)	$ 0.13
Diluted	$ (1.47)	$ (0.57)	$ 0.12
Weighted average shares outstanding used to compute earnings (loss) per share:			
Basic	8,633,827	7,817,918	6,914,323
Diluted	8,633,827	7,817,918	7,143,455

The accompanying notes are an integral part of the financial statements.

Advanced Magnetics, Inc.

Statements of Comprehensive Income (Loss)

	For the years ended September 30,		
	2005	2004	2003
Net income (loss)	$(12,714,615)	$(4,495,200)	$ 866,857
Other comprehensive income (loss):			
Unrealized gains (losses) on securities	(57,266)	—	1,791,830
Reclassification adjustment for (gains) losses included in net income	—	—	(2,132,694)
Total other comprehensive loss	(57,266)	—	(340,864)
Comprehensive income (loss)	$(12,771,881)	$(4,495,200)	$ 525,993

The accompanying notes are an integral part of the financial statements.

Advanced Magnetics, Inc.

Statements of Stockholders' Equity

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance at September 30, 2002	6,644,642	$66,446	$43,888,960	$(33,646,003)	$ 340,864	$10,650,267
Shares issued in connection with the exercise of stock options	56,000	560	184,972	—	—	185,532
Shares and warrants issued in connection with the financing	1,047,120	10,471	9,474,528	—	—	9,484,999
Shares issued in connection with employee stock purchase plan	10,345	104	34,656	—	—	34,760
Non-cash expense associated with stock options	—	—	36,524	—	—	36,524
Other comprehensive loss	—	—	—	—	(340,864)	(340,864)
Net income	—	—	—	866,857	—	866,857
Balance at September 30, 2003	7,758,107	$77,581	$53,619,640	$(32,779,146)	$ —	$20,918,075
Net shares issued in connection with the exercise of stock options	174,600	1,746	1,010,195			1,011,941
Shares issued in connection with employee stock purchase plan	17,224	172	68,035			68,207
Non-cash expense associated with stock options			43,432			43,432
Net loss				(4,495,200)		(4,495,200)
Balance at September 30, 2004	7,949,931	$79,499	$54,741,302	$(37,274,346)	$ —	$17,546,455
Net shares issued in connection with the exercise of stock options	118,738	1,188	503,471			504,659
Shares and warrants issued in connection with the financing	1,799,995	18,000	16,667,058			16,685,058
Shares issued in connection with employee stock purchase plan	9,690	97	73,644			73,741
Non-cash expense associated with stock options			341,127			341,127
Other comprehensive loss					(57,266)	(57,266)
Net loss				(12,714,615)		(12,714,615)
Balance at September 30, 2005	9,878,354	$98,784	$72,326,602	$(49,988,961)	$ (57,266)	$22,379,159

The accompanying notes are an integral part of the financial statements.

Advanced Magnetics, Inc.

Statements of Cash Flows

	For the years ended September 30,		
	2005	2004	2003
Cash flows from operating activities:			
Cash received from customers	$ 1,081,109	$ 1,099,481	$ 514,675
Cash paid to suppliers and employees	(13,939,376)	(7,893,251)	(6,474,099)
Dividends and interest received	539,505	337,556	112,730
Royalties received	323,478	230,304	641,743
Income taxes refund	—	—	124,752
Other income	—	—	148,129
Net cash used in operating activities	(11,995,284)	(6,225,910)	(4,932,070)
Cash flows from investing activities:			
Proceeds from sales of marketable securities	—	—	12,094,579
Life insurance policy surrender value received	—	761,747	—
Proceeds from maturities of short-term investments	9,839,237	38,842,143	—
Purchase of marketable securities	—	—	(1,291,425)
Purchase of short-term investments	(12,765,397)	(48,766,408)	—
Capital expenditures	(401,289)	(201,484)	(167,089)
Increase in other assets	—	—	(65,979)
Net cash provided by (used in) investing activities	(3,327,449)	(9,364,002)	10,570,086
Cash flows from financing activities:			
Proceeds from the cash exercise of stock options	504,659	1,011,941	185,532
Proceeds from the issuance of common stock under the Employee Stock Purchase Plan	73,741	68,207	34,760
Net proceeds from the issuance of common stock and warrants to purchase common stock	16,685,058	—	9,484,999
Net cash provided by financing activities	17,263,458	1,080,148	9,705,291
Net increase (decrease) in cash and cash equivalents	1,940,725	(14,509,764)	15,343,307
Cash and cash equivalents at beginning of year	9,391,363	23,901,126	8,557,819
Cash and cash equivalents at end of year	$ 11,332,088	$ 9,391,363	$23,901,126
Supplemental data:			
Non-cash operating activities:			
Stock dividend received	$ —	$ —	$ 29,720
Non-cash financing activities:			
Non-cash stock option exercises (via mature shares)	$ 131,156	$ 250,697	$ —

The accompanying notes are an integral part of the financial statements.

Advanced Magnetics, Inc.

Reconciliation of Net Income (Loss)

to Net Cash Used in Operating Activities

	For the years ended September 30,		
	2005	2004	2003
Net income (loss)	$(12,714,615)	$(4,495,200)	$ 866,857
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Depreciation	247,625	206,772	205,678
Non-cash expense associated with stock options	341,127	43,432	36,524
Net realized gains on sales of marketable securities	—	—	(2,777,003)
Write-down of marketable securities	—	—	644,310
Amortization of premium on purchased securities	184,758	213,191	—
Changes in operating assets and liabilities:			
Accounts receivable—trade	49,575	316,686	(160,776)
Inventories	105,250	(205,277)	(135,089)
Prepaid expenses and interest receivable	142,329	(122,132)	(78,245)
Accounts payable and accrued expenses	929,534	564,313	255,855
Deferred revenue	(1,280,867)	(2,747,695)	(3,642,052)
Other assets—short term	—	—	(761,747)
Other assets—long term	—	—	613,618
Total adjustments	719,331	(1,730,710)	(5,798,927)
Net cash used in operating activities	$(11,995,284)	$(6,225,910)	$(4,932,070)

The accompanying notes are an integral part of the financial statements.

A. Summary of Accounting Policies:

Business

Founded in November 1981, Advanced Magnetics, Inc., a Delaware corporation, is a developer of superparamagnetic iron oxide nanoparticles used in pharmaceutical products. We are dedicated to the development and commercialization of our proprietary nanoparticle technology for use in 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 we have two product candidates, ferumoxytol and Combidex®. Ferumoxytol, the key product in our development pipeline, is currently in Phase III multi-center clinical trials for use as an iron replacement therapeutic in chronic kidney disease patients, whether or not on dialysis. *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 Europe, Japan, the United States and other countries. *GastroMARK*, our oral contrast agent used for delineating the bowel in MRI, is approved and marketed in Europe, the United States and other countries.

We are subject to risks common to companies in the industry including, but not limited to, uncertainty of the results of clinical trials, uncertainty regarding the regulatory approval process for our product candidates, uncertainty of product development and commercialization, our reliance on a limited number of customers, our dependence on our collaborative relationships, our need for additional capital, 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, product liability, protection of proprietary technology, and compliance with the regulations of the U.S. Food and Drug Administration, also known as the FDA, and other government agencies.

Use of Estimates

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 amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reported period. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash on hand, money market funds and U.S. Treasury Bills having an original maturity of less than three months. Substantially all of the cash and cash equivalents at September 30, 2005 and 2004 were held in a either a commercial bank, money market accounts and U.S. Treasury Bills, the latter of which are classified as cash equivalents in accordance with the provisions of Statement of Financial Accounting Standards, also known as SFAS, No. 95 “Statement of Cash Flows”. We have limited insurance protection for amounts held in our commercial bank accounts through the Federal Deposit Insurance Corporation. We have limited insurance protection for amounts held in our money market account available through the Securities Investor Protection Corporation, also known as SIPC.

Investments

As of September 30, 2005, our short-term investments consisted of a U.S. Treasury Bill with a maturity date of January 26, 2006 and a U.S. Treasury Note with a maturity date of February 15, 2006. The U.S. Treasury Bill was classified as held-to-maturity and, as a result, was recorded at cost. The U.S. Treasury Note was classified as available-for-sale and was marked-to-market during the year ended

September 30, 2005, to reflect a temporary decline in value, which was recorded as a separate component of stockholders' equity entitled "Accumulated other comprehensive loss." The fair value of our investments is determined from quoted market prices. Net unrealized gains and losses on marketable securities (excluding other-than-temporary losses) are recorded as a separate component of stockholders' equity entitled "Accumulated other comprehensive income (loss)." Interest income is accrued as earned.

Investments are considered to be impaired when a decline in fair value below cost basis is determined to be other than temporary. We employ a methodology in evaluating whether a decline in fair value below cost basis is other than temporary that considers available evidence regarding our marketable securities. 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 investee, including industry and sector performance, changes in technology, 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.

Inventories

Inventories are stated at the lower of cost (determined on a first-in, first-out basis) or market (net realizable value). We expense all costs associated with production of products until such time as regulatory approvals are obtained.

Property, Plant and Equipment

Property, plant and equipment are stated at cost. The cost of additions and improvements is charged to the property accounts while maintenance and repairs are 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.

Depreciation

Depreciation is recorded by the straight-line method based on rates sufficient to provide for retirement over estimated useful lives as follows: buildings - 40 years; laboratory equipment and furniture and fixtures - 5 years; and building improvements - over the shorter of the remaining useful life of the building or the life of the improvement.

Research and Development Expenses

Research and development expenses include external expenses, such as costs of clinical trials, contract research and development expenses, consulting fees and professional fees and expenses, and internal expenses, such as compensation of employees engaged in research and development activities, the manufacture of limited quantities of product needed to support research and development efforts, related costs of facilities, and other general costs related to research and development. Research and development costs are expensed as incurred until a product is commercially available for sale.

Revenue Recognition

Product revenue is recognized upon shipment to the customer and satisfaction of all obligations. 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.

Stock-Based Compensation

We have several stock-based compensation plans. We apply Accounting Principles Board Opinion No. 25 "Accounting for Stock Issued to Employees," also known as APB 25, and related interpretations in accounting for qualifying options granted to our employees under our plans and apply Statement of Financial Accounting Standards, or SFAS, No. 123 "Accounting for Stock Issued to Employees," also known as SFAS 123 (as amended by SFAS 148 "Accounting for Stock-Based Compensation-Transition and Disclosure-an amendment of FASB Statement No. 123," also known as SFAS 148), for disclosure purposes only. The SFAS 123 and SFAS 148 disclosures include pro forma net loss and loss per share as if the fair value-based method of accounting had been used. Stock-based compensation to non-employees is accounted for in accordance with SFAS 123, SFAS 148 and related interpretations.

If stock-based compensation for employees had been determined based on SFAS 123, as amended by SFAS 148 "Accounting for Stock-Based Compensation-Transition and Disclosure-an amendment of FASB Statement No. 123", also known as SFAS 148, our pro forma net income (loss) and pro forma earnings (loss) per share for the fiscal year ending September 30, 2005, 2004 and 2003 would have been as follows:

	For the years ended September 30,		
	2005	2004	2003
Reported net income (loss)	$(12,714,615)	$(4,495,200)	$ 866,857
Pro forma stock compensation expense	(1,262,701)	(629,424)	(330,817)
Pro forma net income (loss)	$(13,977,316)	$(5,124,624)	$ 536,040
Reported earnings (loss) per share:			
Basic	$ (1.47)	$ (0.57)	$ 0.13
Diluted	$ (1.47)	$ (0.57)	$ 0.12
Pro forma earnings (loss) per share:			
Basic	$ (1.62)	$ (0.66)	$ 0.08
Diluted	$ (1.62)	$ (0.66)	$ 0.08

The fair value of substantially all options granted during fiscal years 2005, 2004 and 2003 was estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions: (1) expected life of 6.25 years in 2005, and 6.0 years in 2004 and 2003, respectively; (2) expected volatility of 76.7% in 2005, 69.9% in 2004, and 64.1% in 2003; and (3) weighted average risk-free interest rates of 3.90% in 2005, 3.64% in 2004 and 3.42% in 2003; and (4) no dividend yield.

In the fiscal year ended September 30, 2005, the assumptions used for awards under our 2003 Employee Stock Purchase Plan were as follows: (1) expected life of 1.0 years; (2) expected volatility of 106.0%; (3) weighted average risk-free interest rate of 3.25% and (4) no dividend yield. In the fiscal year ended September 30, 2004, the assumptions used for awards under our 2003 Employee Stock Purchase Plan were as follows: (1) expected life of 1.0 years; (2) an expected volatility of 77.3%; (3) a weighted average risk-free interest rate of 1.41% and (4) no dividend yield. In the fiscal year ended September 30,

2003, the assumptions used for awards under our 2003 Employee Stock Purchase Plan were as follows: (1) expected life of 1.0 years; (2) an expected volatility of 40.8%; (3) a weighted average risk-free interest rate of 2.04% and (4) no dividend yield.

The weighted average grant date fair value of stock awards granted during the fiscal years ended September 30, 2005, 2004 and 2003 was $9.47, $7.78, and $3.74 per share, respectively. For purposes of the pro forma information, the estimated fair values of the employee stock options are amortized to expense using the straight-line method over the vesting period.

The pro forma effects of applying SFAS 123 in this pro forma disclosure are not indicative of future amounts. SFAS 123 does not apply to awards granted prior to 1995. We anticipate granting additional awards in future years. See also Notes G, M and O of Notes to Financial Statements hereunder.

Other Income

We had other income of $148,129 in the year ended September 30, 2003 as a result of the increased cash surrender value of a cash value life insurance policy. The life insurance policy was terminated and the surrender value was paid on October 29, 2003.

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 September 30, 2005, our cash, cash equivalents, short and long term investments amounted to $23,727,298 of which $16,361,766 was invested in U.S. Treasury Notes and U.S. Treasury Bills. We currently invest our excess cash primarily in deposits in one commercial bank and money market funds.

Our operations are located solely within the United States. We are focused principally on developing and manufacturing iron replacement therapeutics and contrast agents for use in MRI. We perform ongoing credit evaluations of our customers and generally do not require collateral. Three companies, Berlex Laboratories, Inc., or Berlex, Cytogen Corporation, or Cytogen, and Guerbet, accounted for 47%, 22% and 20%, respectively, of our revenues in fiscal 2005. Three companies, Cytogen, Guerbet and Berlex, accounted for 55%, 20% and 20%, respectively, of our revenues in fiscal 2004. Two companies, Cytogen and Berlex, accounted for 61% and 23%, respectively, of our revenues in fiscal 2003. No other company accounted for more than 10% of our total revenues in fiscal 2005, 2004 or 2003. All of the revenue attributable to Cytogen and a significant portion of the revenue attributable to Berlex in fiscal 2005, fiscal 2004 and fiscal 2003 was previously deferred revenue related to up-front license fees.

In fiscal 2005, 2004 and 2003, revenues from customers and licensees outside of the United States, principally in Europe and Japan, amounted to 22%, 21% and 13%, respectively, of our total revenues.

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.

Loss per Share

We compute basic loss per share by dividing net loss by the weighted average number of common shares outstanding during the respective period. Options to purchase a total of 917,272 and 854,366 shares of common stock that were outstanding at September 30, 2005 and September 30, 2004, respectively, were excluded from the computation of diluted net loss per share for these fiscal years because such options were anti-dilutive as we had a net loss in each of these fiscal years. Warrants to purchase 261,780 shares of common stock issued in July 2003 at an exercise price of $15.50 per share and warrants to purchase 359,999 shares of common stock issued in June 2005 at an exercise price of $13.00 were excluded from the computation of diluted loss per share for each of the fiscal years ended September 30, 2005 and 2004 because such warrants were anti-dilutive as we incurred a net loss in each of these fiscal years.

The components of basic and diluted loss per share were as follows:

	For the Years ended September 30,		
	2005	2004	2003
Net income (loss) (A)	$(12,714,615)	$(4,495,200)	$ 866,857
Weighted average common shares outstanding (B)	8,633,827	7,817,918	6,914,323
Common stock equivalents	—	—	229,132
Sum of weighted average common shares outstanding and common stock equivalents (C)	8,633,827	7,817,918	7,143,455
Earnings (loss) per share:			
Basic (A/B)	$ (1.47)	$ (0.57)	$ 0.13
Diluted (A/C)	$ (1.47)	$ (0.57)	$ 0.12

B. Effect of Accounting Change:

In fiscal 2000, we adopted the guidance under Securities and Exchange Commission Staff Accounting Bulletin No. 101, also known as SAB 101, "Revenue Recognition in Financial Statements" (later revised as Staff Accounting Bulletin No. 104). For each of the years ended September 30, 2005, 2004 and 2003, we recognized $737,755 in revenue that was included in the cumulative effect adjustment as of October 1, 1999.

C. Investments:

As of September 30, 2005, our short-term investments consisted of a U.S. Treasury Bill with a maturity date of January 26, 2006 and a U.S. Treasury Note with a maturity date of February 15, 2006. As of September 30, 2004, our short-term investments consisted of a U.S. Treasury Note with a maturity date of January 31, 2005 and our long-term investments consisted of a U.S. Treasury Note with a maturity date of February 15, 2006. At September 30, 2005, the U.S. Treasury Note which matures on February 15, 2006 had a market value of $4,534,050. It was recorded as available-for-sale and was marked-to-market during the fiscal year ended September 30, 2005, to reflect a temporary decline in value, which was recorded as a separate component of stockholders' equity entitled "Accumulated other comprehensive loss." Our remaining short-term and long-term investments for each of the fiscal years ended September 30, 2005 and September 30, 2004 have been classified as held-to-maturity and, as a result, are recorded at amortized cost.

During the year ended September 30, 2003, gross realized gains and gross realized losses on the sale of marketable securities were $3,342,648 and $565,645, respectively, resulting in a net realized gain of $2,777,003.

In fiscal 2003, we determined that the decline in the carrying value of two securities below their original basis was an other-than-temporary decline and recorded a $644,310 write-down of such shares to a new cost basis.

Interest, dividends and net gains on sales of securities and write-down of marketable securities consist of the following:

	For the years ended September 30,		
	2005	2004	2003
Interest income	$ 604,193	$ 382,738	$ 38,880
Amortization of premiums on purchased investments	(184,758)	(213,191)	—
Dividend income	—	—	73,850
Total	$ 419,435	$ 169,547	$ 112,730
Net gains on sales of securities	$ —	$ —	$2,777,003
Write-down of marketable securities	$ —	$ —	$ (644,310)

D. Inventories:

The major classes of inventories were as follows at September 30:

	2005	2004
Raw materials	$297,188	$404,001
Work in process	33,391	21,837
Finished goods	37,209	47,200
Total inventories	$367,788	$473,038

The aggregate amount of overhead remaining in ending inventory as of September 30, 2005 and September 30, 2004 was $26,383 and $31,591, respectively.

E. Current and Long-Term Liabilities:

Accrued expenses consist of the following at September 30:

	2005	2004
Clinical trials	$ 802,616	$390,544
Professional fees	192,800	207,000
Salaries and other compensation	209,340	176,482
License and royalty fees	83,000	16,500
Other	39,800	26,750
Totals	$1,327,556	$817,276

Deferred revenue consisted of the following at September 30, 2005 and 2004:

	Cytogen	Berlex	Total
At September 30, 2005:			
Short term	$ 376,428	$ 737,755	$1,114,183
Long term	188,214	2,396,680	2,584,894
Total	$ 564,642	$3,134,435	$3,699,077
At September 30, 2004			
Short term	$1,107,754	$ 737,755	$1,845,509
Long term	—	3,134,435	3,134,435
Total	$1,107,754	$3,872,190	$4,979,944

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 fiscal 2005 or 2004. In fiscal 2003, we recorded an income tax benefit in the amount of $124,752 as the result of an income tax refund. This amount related to a refund of federal alternative minimum taxes paid during fiscal 2000. We were eligible for this refund due to a change in tax law.

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

	For the years ended September 30,		
	2005	2004	2003
Statutory U.S. federal tax rate	34.00 %	34.00 %	34.00 %
State taxes, net of federal benefit	6.30 %	6.30 %	6.30 %
Permanent items	0.44 %	3.39 %	(2.90)%
Tax refund	—	—	(16.80)%
Valuation allowance	(40.74)%	(43.69)%	(37.40)%
Total	0.00 %	0.00 %	(16.80)%

The components of the deferred tax assets and liabilities were as follows at September 30:

	2005	2004	2003
Assets			
Net operating loss carry-forwards	$ 17,804,261	$ 12,623,394	$ 9,890,625
Research and experimentation tax credit carry-forward	4,109,568	3,832,541	3,622,578
Deductible intangibles	39,108	49,310	59,511
Deferred revenue	1,489,619	2,005,424	3,111,921
Capital loss carry-forward	1,034,055	1,034,055	1,034,055
Other	688,008	414,644	248,134
Liabilities			
Property, plant and equipment depreciation	(161,325)	(135,354)	(117,584)
Other	7,249	(53,733)	(42,727)
Subtotal	25,010,543	19,770,281	17,806,513
Valuation allowance	(25,010,543)	(19,770,281)	(17,806,513)
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 as of September 30, 2005, 2004 and 2003. In fiscal 2003, we recorded an income tax benefit in the amount of $124,752 as a result of an income tax refund. This amount related to a refund of the alternative minimum taxes paid during fiscal year 2000. We were eligible for this refund due to a change in tax law.

At September 30, 2005, we had unused net operating loss, or NOL, carryforwards for federal income tax purposes of approximately $47,000,000 which begin to expire in fiscal 2010. We also have unused state NOL carryforwards of approximately $35,000,000 which begin to expire in fiscal 2006. We also have federal research and experimentation credits of approximately $3,500,000 which begin to expire in fiscal 2006. The Company also has approximately $3,041,000 of capital loss carryforwards which begin to expire in 2007.

Included in the NOL and tax credit carryforwards discussed above is approximately $654,000 reflecting the benefit of deductions from the exercise of stock options. This benefit will be credited to additional paid-in capital when realized.

G. Stock Plans:

Our 2000 Stock Plan, approved by our shareholders, provides for the grant of options to our directors, officers, employees and consultants to purchase up to an aggregate of 1,000,000 shares of common stock at a price determined by the Board of Directors. The terms and conditions of each option grant, including, but not limited to, the number of shares, the exercise price, term of the option and vesting requirements, are determined by the Board of Directors. Options to purchase 713,000 shares have been granted under the 2000 Stock Plan as of September 30, 2005, 52,625 of which have expired and 80,825 of which have been exercised. The number of shares available for future grants as of September 30, 2005 was 339,625.

Our 1993 Stock Plan, approved by our shareholders, provided for the grant of options to our directors, officers, employees and consultants to purchase up to an aggregate of 700,000 shares of common stock at a price equal to at least the fair market value, or the minimum legal consideration, of the stock at the date of the grant for incentive stock options and non-statutory stock options, respectively. No further grants may be made under our 1993 Stock Plan. The maximum term of the options under the 1993 Stock Plan is ten years, with limited exceptions. The remaining number of shares subject to outstanding options pursuant to this plan as of September 30, 2005 was 312,722.

On November 5, 1991, our Board of Directors adopted the 1992 Non-Employee Director Stock Option Plan which our shareholders subsequently approved. No further grants may be made under the 1992 Plan. The 1992 Plan provided for the grant to each non-employee director holding such position on November 5, 1991 and 1996, of an option to purchase 5,000 shares of common stock at a price equal to the fair market value of the stock at the date of the grant, vesting in equal installments over a five year period. The 1992 Plan also provided for the grant to new members of the Board of Directors, on the date of each such director's election, and on each fifth anniversary thereof, of an option to purchase 5,000 shares of common stock. The remaining number of shares subject to outstanding options pursuant to this plan as of September 30, 2005 was 5,000.

On November 10, 1992, our Board of Directors adopted the 1993 Non-Employee Director Stock Option Plan which our shareholders subsequently approved. No further grants may be made under the 1993 Plan. The 1993 Plan provided for the grant to each non-employee director holding such position on November 10, 1992, and 1998, of an option to purchase 5,000 shares of common stock at a price equal to the fair market value of the stock at the date of the grant, vesting in equal installments over a five year period. The 1993 Plan also provided for the grant to new members of the Board of Directors, on the date of each such director's election, and on each sixth anniversary thereof, of an option to purchase 5,000 shares of common stock. The remaining number of shares subject to outstanding options pursuant to this plan as of September 30, 2005 was 20,000.

Stock option activity is as follows for the years ended September 30:

	2005		2004		2003	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of year*	854,366	$ 7.24	879,347	$ 6.06	763,097	$ 5.89
Granted	243,500	13.29	193,500	12.00	189,000	5.84
Exercised	(127,719)	4.98	(197,981)	6.38	(56,000)	3.31
Expired and/or Forfeited	(52,875)	7.99	(20,500)	9.90	(16,750)	3.39
Outstanding at year end*	917,272	$ 9.11	854,366	$ 7.24	879,347	$ 6.06
Options exercisable at year-end*	574,022	$ 7.80	470,991	$ 6.78	522,753	$ 6.99
Weighted average fair value of options granted during the year	$ 9.47		$ 7.78		$ 3.74	

* These figures do not include warrants outstanding and/or exercisable. See Note I of Notes to Financial Statements hereunder.

The following table summarizes information about stock options outstanding and exercisable at September 30, 2005:

	Options Outstanding			Options Exercisable	
Range of exercise prices	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$1.00–$3.38	167,125	5.5	$ 3.01	150,625	$ 3.09
$3.39–$5.06	96,481	5.5	3.99	81,606	4.01
$5.07–$7.59	85,250	6.0	5.25	41,750	5.22
$7.60–$11.39	272,597	6.8	10.19	156,597	10.24
$11.40–$17.09	269,819	7.5	13.78	137,444	12.69
$17.10–$20.32	26,000	9.4	20.32	6,000	20.32
Total	917,272	6.6	$ 9.11	574,022	$ 7.80

Our standard stock option agreement allows for payment for the exercise of vested stock options either through cash remittance to us in exchange for newly issued shares, or through a non-cash exchange of previously issued shares held by the recipient in exchange for our 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 by us. The dollar value of these non-cash stock option exercises in the fiscal years ended September 30, 2005 and 2004 amounted to $131,156 and $250,697, respectively, associated with the net issuance of 24,638 and 30,369 shares, respectively; we believe all of these non-cash stock option exercise transactions involved shares held by the recipients for a period of time exceeding six months, and thus, such non-cash transactions are not subject to remeasurement under the applicable accounting rules. In the fiscal year ended September 30, 2005, substantially all options granted were at a price equal to the closing price of our common stock on the American Stock Exchange on the grant date.

Employee Stock Purchase Plan

Our 2003 Employee Stock Purchase Plan provides for the issuance of up to 100,000 shares of our common stock to eligible employees. Under the terms of the 2003 Employee Stock Purchase Plan, eligible employees may purchase shares in five annual offerings through payroll deductions of up to a maximum of 10% of the employee's earnings, at a price equal to the lower of 85% of the fair market value of the stock

on the applicable annual offering commencement date of June 1 or termination date of May 31. As of September 30, 2005, 37,259 shares have been issued under the 2003 Employee Stock Purchase Plan.

The weighted average fair value for each purchase right granted during fiscal 2005, 2004 and 2003 under our 2003 Employee Stock Purchase Plan and the predecessor plan in effect since 1997 was $5.24, $1.72 and $0.97, respectively, and was estimated using the Black-Scholes option-pricing model.

Stock Options Granted to Consultants

In fiscal 2005, we granted options to one of our directors pursuant to a consulting agreement; see Note M "Related Party Transactions" of Notes to Financial Statements hereunder.

In August 2005 we entered into three-year consulting agreements with seven nonaffiliated members of our newly created Scientific Advisory Board. Under the terms of these consulting agreements, the members will provide advice and consultation to us as we progress through our ongoing development program for ferumoxytol in IV iron replacement therapy. The term of the consulting agreements may be extended for additional periods with the written consent of each party. As compensation for these consulting services, we granted these members, in the aggregate, options to purchase 11,000 shares of our common stock under the 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 will vest, such that by May 1, 2006 all shares will be fully vested and exercisable. This results 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 fiscal year 2005 (with a corresponding credit to additional paid-in capital), in an amount approximating the fair value of the foregoing options.

In fiscal 2003, we granted an option to purchase 10,000 shares of our common stock to a scientific consultant under the 2000 Stock Plan. This option vested over a two-year period commencing in March 2003. We have recorded an expense of $3,116, $43,432 and $30,881 for the fiscal years ended September 30, 2005, 2004 and 2003, respectively, associated with this option and have recorded an offsetting credit to additional paid-in capital. This option was remeasured at every balance sheet date until completion of services. Vesting concluded in the second quarter of fiscal 2005. In fiscal 2005, we granted a new option to purchase 8,000 shares of our common stock to this scientific consultant under the 2000 Stock Plan. This option vests over a two-year period commencing in July 2005. We have recorded a non-cash accounting charge of $40,103 in the fourth quarter of the fiscal year ended September 30, 2005, associated with these options and have recorded an offsetting credit to additional paid-in capital. These options will be remeasured at every balance sheet date until completion of services. Vesting will conclude in the third quarter of fiscal 2007.

In fiscal 2002, we granted an option to purchase 10,000 shares of our common stock to a scientific consultant under the 2000 Stock Plan. This option vested over a two-year period commencing in October 2001. We have recorded an expense of $5,643 for the fiscal year ended September 30, 2003 associated with this option and have recorded an offsetting credit to additional paid-in capital. Vesting would have concluded in the fourth quarter of fiscal 2003, but the consulting agreement was terminated in August of 2003 and the option expired in September 2003.

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. We match every dollar each employee contributes to the 401(k) Plan up to six percent of each employee's salary to a maximum of $2,000 annually per employee. 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 $53,999, $40,433, and $41,946, for the fiscal years 2005, 2004 and 2003, respectively.

I. Common Stock Transactions:

In June 2005, we sold an aggregate of 1,799,995 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 affiliates of Great Point Partners, LLC and Vivo Ventures, LLC and one of our directors. 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 have a term of three years. We realized net proceeds of $16,685,058 after deduction of $414,899 of incremental external costs associated with the financing, such costs being charged against paid-in capital.

On July 2, 2003, we sold an aggregate of 1,047,120 shares of our common stock and warrants to purchase 261,780 shares of our common stock at an exercise price of $15.50 and with a term of three years in a private placement to the following institutional investors: Bonanza Master Fund Ltd., Liongate Capital, Inc., Gryphon Master Fund, L.P., Smithfield Fiduciary LLC, Mainfield Enterprises Inc., Vertical Ventures Investments, LLC, BayStar Capital II, LP and SDS Merchant Fund, L.P. We realized net proceeds of $9,484,999 after deduction of transaction costs. Coastline Capital Partners, an Institutional Division of Western International Securities, acted as the placement agent for the transaction and it was paid approximately $500,000 for its services. The securities were issued to accredited investors in a private placement transaction exempt from registration pursuant to Section 4(2) of the Securities Act of 1933 and Rule 506 of Regulation D as an issuer transaction not involving a public offering.

In November 1997, the Board of Directors extended the authorization granted in May 1996 to purchase up to 250,000 shares of our common stock on the open market. In November 2000, the Board of Directors authorized the purchase of up to 1,000,000 shares, including the number previously authorized, of our common stock on the open market at prevailing market prices. Cumulatively, through September 30, 2003, we had purchased 266,900 shares for $2,027,166. All shares have been retired. In November 2003, the Board of Directors revoked the authorization to purchase these common shares.

J. Preferred Stock:

Our certificate of incorporation authorizes our Board of Directors 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 the Board of Directors. There were no preferred shares issued or outstanding as of September 30, 2005, 2004 or 2003.

K. Segment Information:

We have determined that we conduct our operations in one business segment. In fiscal 2005, 2004 and 2003, revenues from customers and licensees outside of the United States, principally in Europe and Japan, amounted to 22%, 21% and 13%, respectively, of our total revenues. Long-lived assets consist entirely of property and equipment and are located in the United States for all periods presented.

L. Commitments and Contingencies:

Legal Proceedings

We and certain of our officers were sued in an action entitled *David D. Stark, M.D. v. Advanced Magnetics, Inc., Jerome Goldstein, Ernest V. Groman and Lee Josephson,* Civil Action No. 92-12157-WGY, in the United States District Court for the District of Massachusetts on September 3, 1992. The plaintiff, a former consultant, claims that he was incorrectly omitted as an inventor or joint inventor on certain of our patents and on pending applications, and seeks injunctive relief and unspecified damages. The District

Court has stayed this federal action pending resolution of an appeal in the Massachusetts Appeals Court of summary judgment in our favor as well as resolution of a jurisdictional issue. As noted below, the Massachusetts Appeals Court has decided the appeal, but the federal action remains stayed as of this date. While the outcome of the action cannot be determined, we believe the action is without merit and intend to defend the action vigorously. However, we may not be able to successfully defend this action and our failure to prevail for any reason could deplete our resources and reduce the assets available for our daily operations.

We and certain of our officers were sued in *David D. Stark, M.D. v. Advanced Magnetics, Inc., Jerome Goldstein, Ernest V. Groman and Lee Josephson,* Civil Action No. 93-02846-C, in the Superior Court Department of the Massachusetts Trial Court for Middlesex County on May 17, 1993. This case involves claims of breach of contract, breach of good faith and fair dealing, breach of implied contract, misappropriation of trade secrets, conversion, negligent misrepresentation, misrepresentation, unjust enrichment, unfair trade practices and tortious interference with contractual or advantageous relations. The Superior Court granted partial summary judgment in our favor and dismissed the unfair trade practices and tort counts. The plaintiff's contract claims have been dismissed with prejudice and final judgment was entered against the plaintiff. The plaintiff filed an appeal in *David D. Stark, M.D. v. Advanced Magnetics, Inc., Jerome Goldstein, Ernest V. Groman and Lee Josephson,* Appeal No. 98-P-1749, in the Massachusetts Appeals Court, on January 25, 1999. On October 13, 2000, the Massachusetts Appeals Court reversed the grant of partial summary judgment in our favor and remanded the case to the Superior Court. While the outcome of the action cannot be determined, we believe the action is without merit and intend to defend the action vigorously. However, we may not be able to successfully defend this action and our failure to prevail for any reason could deplete our resources and reduce the assets available for our daily operations.

Commitments

Operating Lease Obligations

We lease and/or service equipment under several agreements that expire in 2006 and 2007. Office and laboratory equipment rental expenses for the years ended September 30, 2005, 2004 and 2003 amounted to $34,532, $25,423 and $14,619, respectively. Future minimum lease and service payments associated with all noncancellable equipment service and lease agreements for fiscal year 2006 and fiscal year 2007 are estimated to be $35,000 and $3,000 respectively.

We previously leased laboratory, office and warehouse space under an agreement that expired in fiscal 2003. Rental expenses for the year ended September 30, 2003 amounted to $4,836.

Guarantor Arrangements

In November 2002, the Financial Accounting Standards Board, also known as the FASB, issued FASB Interpretation No. 45, also known as FIN 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others an interpretation of FASB Statements No. 5, 57, and 107 and rescission of FASB Interpretation No. 34." FIN 45 elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. It also requires that a guarantor recognize, at the inception of certain types of guarantees, a liability for the fair value of those guarantees. The initial recognition and measurement provisions of FIN 45 are applicable on a prospective basis for guarantees issued or modified after December 31, 2002.

The following is a summary of our agreements in effect as of September 30, 2005 that we have determined are within the scope of FIN 45.

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

As is customary in our industry, the marketing and distribution agreements that we enter into in the ordinary course of our business in connection with the sale and distribution of our products contain indemnification provisions. Pursuant to these agreements, we indemnify, hold harmless, and agree to reimburse the indemnified party for all or a portion of the losses suffered or incurred by the indemnified party, generally our business partners, in connection with any U.S. patent or any copyright or other intellectual property infringement claim by any third party with respect to our products. The terms of these indemnification obligations vary. 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 obligations is immaterial.

We enter into agreements with certain institutions and physicians in the ordinary course of our business in connection with the clinical development of our product candidates. These agreements generally include standard indemnification provisions pursuant to which we indemnify, hold harmless, and agree to reimburse the indemnified party against certain claims by third parties arising out of the clinical development activities performed by the indemnified party. The maximum potential amount of future payments we could be required to make under these indemnification obligations is not capped; however, we have general and umbrella insurance policies that should enable us to recover a portion of any amounts paid. In our recent history, we have not incurred any costs to defend lawsuits or settle claims related to these indemnification obligations. As a result, we believe the estimated fair value of these obligations is immaterial.

Agreements

Our marketing strategy includes forming alliances with pharmaceutical companies to facilitate the sale and distribution of our products. At present we have the following principal collaborations:

BERLEX LABORATORIES, INC. In February 1995, we entered into a license and marketing agreement and a supply agreement with Berlex, granting Berlex a product license and exclusive marketing rights to *Feridex I.V.* in the United States and Canada. In 1996, the parties agreed to remove Canada from the territories subject to the agreement. Under the terms of the agreement, we receive payments for manufacturing the product and royalties on sales. Under the terms of our agreements with Berlex, Berlex pays for 60% of ongoing development expenses related to *Feridex I.V.* These agreements expire in 2010 but can be terminated earlier upon the occurrence of certain specified events. Under the terms of the license and marketing agreement, we have the right to terminate the exclusive marketing rights based on the failure of Berlex to achieve minimum sales targets, but we have not exercised that right at this time.

CYTOGEN CORP. In August 2000, we entered into a license and marketing agreement and a supply agreement with Cytogen. Cytogen has exclusive United States marketing rights to *Combidex*, our 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 addition, Cytogen has the exclusive right to market and sell ferumoxytol, for oncology imaging applications only, in the United States, however, we have decided not to pursue the development of ferumoxytol for oncology imaging applications. Under the terms of our agreement, we also agreed to grant to Cytogen the exclusive right to market and sell *Feridex I.V.* in the United States if our existing marketing arrangement with Berlex for *Feridex I.V.* terminates for any reason. Upon signing the agreements with Cytogen, we received 1,500,000 shares of Cytogen common stock as a non-refundable license fee. An additional 500,000 shares of Cytogen common stock were placed in escrow to be released to us upon satisfaction of certain

milestones under the agreements. As a result of a 10 for 1 reverse stock split of Cytogen's common stock, which became effective in October 2002, these escrowed shares have been converted into 50,000 shares of Cytogen common stock. The release of 25,000 of these shares is dependent upon progress in the development of ferumoxytol for oncology imaging applications, and we do not anticipate achieving this milestone. The release of the other 25,000 shares is dependent upon issuance by the FDA of an approval letter relating to *Combidex*. Cytogen has agreed to pay us for manufacturing and supplying the products and royalties on sales, if any, relating to the products licensed to them. These agreements have an initial ten-year term with automatic five-year extensions, but can be terminated earlier upon the occurrence of certain specified events.

EIKEN CHEMICAL CO., LTD. In 1988, we entered into a supply and marketing agreement with Eiken Chemical Co., Ltd, or Eiken, granting Eiken the exclusive right to manufacture and distribute *Feridex I.V.* in Japan. Eiken was responsible for conducting clinical trials and securing the necessary regulatory approval in Japan, which was obtained in 1997. Under the terms of the agreement, as amended, Eiken paid us an up-front license fee and agreed to pay royalties based upon products shipped for resale. Eiken has recently informed us of its desire to terminate this agreement due to increased competition and limited sales of *Feridex I.V.* in Japan. With our permission, Eiken has begun the process of withdrawing *Feridex I.V.* as an approved product with the appropriate regulatory authorities in Japan. We expect the withdrawal and the termination of our agreement with Eiken to take effect in early calendar year 2007.

GUERBET. In 1987, we entered into a supply and distribution agreement with Guerbet. Under this agreement, 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, eastern Europe, and the former Soviet Union. Guerbet is responsible for conducting clinical trials and securing the necessary regulatory approvals in the countries in its territory. Guerbet has not pursued marketing approval in all the countries in which it has rights. Under the terms of this agreement, Guerbet is obligated to pay royalties based on products shipped for resale. We are 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 agreement terminates on the later of (i) the expiration of the last to expire technology patent related to *Feridex I.V.* or (ii) ten years after the date all necessary approvals were obtained in France.

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 Advanced Magnetics MRI contrast agents. 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, eastern Europe and the former Soviet Union. 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, and accordingly, all such rights reverted back to us. Under the terms of this second distribution agreement, Guerbet has agreed to pay us royalties and a percentage of net sales as the purchase price for the active ingredient 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.

MALLINCKRODT, INC. (a division of Tyco-Healthcare). In 1990, we entered into a manufacturing and distribution agreement with Mallinckrodt granting Mallinckrodt a product license and co-marketing rights to *GastroMARK* in the United States, Canada and Mexicoand Mallinckrodt currently has rights to *GastroMARK* in the United States only. Under the terms of the agreement, we receive royalties based on Mallinckrodt's *GastroMARK* sales as well as a percentage of sales for supplying the active ingredient. The agreement is perpetual but terminable upon certain specified events.

SQUIBB DIAGNOSTICS (a division of Bristol-Myers Squibb Co.). In 1994, under an agreement with Squibb Diagnostics, we reacquired the development and marketing rights to *Combidex*, which had previously been licensed to Squibb Diagnostics. Pursuant to this agreement, we are obligated to pay up to a maximum of $2,750,000 in royalties to Squibb Diagnostics in connection with product sales of *Combidex*.

OTHER. We are the licensee of certain technologies related to our products under cross-license agreements with Nycomed Imaging A.S. of Oslo, Norway (now known as Amersham Health, which is part of GE Healthcare), or Nycomed, and Schering AG of Berlin, Germany. The license agreement with Nycomed requires us to make payments upon the attainment of particular milestones relating to *Feridex I.V.* and *GastroMARK*. We are also required under the Nycomed agreement to pay royalties on a percentage of product sales of *Feridex I.V.* and *GastroMARK*, if any. There were no milestone payments in fiscal years 2005, 2004 or 2003. Future milestone payments under the Nycomed agreement will not to exceed $400,000.

M. Related Party Transactions:

Lisa Gordon, the daughter of Jerome Goldstein, our Chairman of the Board, Chief Executive Officer and Treasurer, joined us as Director of Business Development and Investor Relations in May 2001 and is presently Vice President of Business Development. We made salary payments to Ms. Gordon of $155,430, $151,666, and $138,763 for services rendered during the fiscal years ended September 30, 2005, 2004 and 2003, respectively. Rachel Konforty, who is also the daughter of Jerome Goldstein, was employed by us as General Counsel and Assistant Secretary from October 2002 through February 2005. Ms. Konforty accrued salary and bonus of $98,745 in the fiscal year ended September 30, 2005; we made salary payments to Ms. Konforty of $ $110,451 and $103,995 for services rendered during the fiscal years ended September 30, 2004 and 2003, respectively. Ms. Konforty and Ms. Gordon were also eligible during the fiscal years ended September 30, 2005, 2004 and 2003 for employee benefits plans and programs available generally to all salaried employees, including option grants.

During fiscal 1991, a split-dollar life insurance policy on the lives of Jerome Goldstein, our Chief Executive Officer, and his wife, Marlene Kaplan Goldstein, was established with a trust for the benefit of the family members of Mr. Goldstein and with his spouse as beneficiary. The intent of the policy was to provide liquidity to the estate of Mr. Goldstein and his spouse, whose primary assets at the time were holdings of our common stock, which represented approximately 24% of the shares outstanding at the time, so that the trust would not be forced to sell shares, potentially creating downward pressure on the share price. We paid the premiums related to the life insurance policy, excluding the pure term life protection portion of the premiums which was paid by the trust. In September 2003, we decided to terminate the policy, whose cash surrender value at the time was $1,004,137. $761,747 of this amount was received by us on October 29, 2003 as a reimbursement for the premiums we paid and the remainder was remitted to the trust. At September 30, 2003, the cash surrender value of the life insurance policy was $761,747 and was presented in current assets. The increase in the cash surrender value net of premiums paid was presented in other income.

In July 2005 we entered into a one-year consulting agreement with Dr. Brian J.G. Pereira, one of our directors. Under the terms of the consulting agreement, Dr. Pereira provides 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 request from time to time. The term of the consulting agreement may be extended for additional periods with the written consent of each party. 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 at the beginning of each calendar month following the date of grant, beginning with August 1, 2005, 5,000 additional shares will vest, such that by June 1, 2006 all shares will be fully vested and exercisable. This results in a non-cash accounting charge being recorded as an expense each quarter over a one year period (of which $253,358 was charged to expense in the fourth

quarter of fiscal year 2005 with an offsetting credit to additional paid-in capital), in an amount approximating the fair value of the foregoing options.

In November 2005, Dr. Pereira was elected by the Board of Directors to serve as President of Advanced Magnetics and on November 22, 2005 we entered into a three-year employment agreement with Dr. Pereira. Please see Note P for additional information.

N. Consolidated Quarterly Financial Data—Unaudited:

The following table provides quarterly financial data for the fiscal years ended September 30, 2005, and 2004.

	(Unaudited) Fiscal 2005 Quarters Ended			
	September 30	June 30	March 31	Dec. 31, 2004
License fees	$ 237,550	$ 234,439	$ 374,439	$ 434,439
Royalties	81,359	75,967	49,577	67,000
Product sales	88,543	92,555	188,475	520,825
Total revenues	407,452	402,961	612,491	1,022,264
Cost of product sales	45,884	9,067	54,194	94,935
Operating expenses	4,124,810	3,747,995	3,963,074	3,539,259
Interest income	186,706	100,969	68,942	62,818
Net loss	$(3,576,536)	$(3,253,132)	$(3,335,835)	$(2,549,112)
Loss per share—basic and diluted	$ (0.36)	$ (0.38)	$ (0.42)	$ (0.32)

	Fiscal 2004 Quarters Ended			
	September 30	June 30	March 31	Dec. 31, 2003
License fees	$ 814,217	$ 722,690	$ 608,824	$ 601,964
Royalties	70,000	70,000	70,000	30,000
Product sales	(619)	681,102	87,706	—
Total revenues	883,598	1,473,792	766,530	631,964
Cost of product sales	—	84,209	32,806	—
Operating expenses	3,151,587	2,219,711	1,349,569	1,582,749
Interest income	57,177	52,441	49,844	10,085
Net loss	$(2,210,812)	$ (777,687)	$ (566,001)	$ (940,700)
Loss per share—basic and diluted	$ (0.28)	$ (0.10)	$ (0.07)	$ (0.12)

O. Recently Issued and Proposed Accounting Pronouncements:

In December 2004, the FASB, issued a revision to SFAS 123 "Share-Based Payment," also known as SFAS 123R, that amends existing accounting pronouncements for share-based payment transactions in which an enterprise receives employee and certain nonemployee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise's equity instruments or that may be settled by the issuance of such equity instruments. SFAS 123R, together with guidance included in Staff Accounting Bulletin No. 107 issued by the United States Securities and Exchange Commission, or SEC, on March 29, 2005, also known as SAB 107, eliminates the ability to account for share-based compensation transactions using APB 25 and generally requires such transactions be accounted for using a fair-value-based method. SFAS 123R applies to awards that are granted, modified, or settled in periods beginning after its applicable effective date. In April 2005, the SEC issued a release amending the effective date of SFAS 123R for each registrant to the start of the registrant's first fiscal year beginning after June 15, 2005. SFAS 123R allows for three alternative transition methods. We intend to adopt the modified prospective application method. We currently intend to adopt SFAS 123R and SAB 107 in the first quarter of fiscal 2006. Our adoption of SFAS 123R will cause us to record a noncash accounting charge as an expense each quarter in an amount approximating the fair value of such

share-based compensation meeting the criteria outlined in the provisions of SFAS 123R. As of September 30, 2005, we had 343,250 stock options outstanding which had not yet become vested. Based upon the number of options outstanding as of December 12, 2005, we expect to record a noncash accounting charge over the course of fiscal year 2006 of approximately $2,200,000. Beginning with the first quarter in fiscal 2006, the noncash accounting charge will vary based on the number of options that vest in a given quarter. The noncash accounting charge for the first quarter of fiscal year 2006 is estimated to be approximately $1,250,000. This amount and the amount applicable to future quarters are subject to further quarterly adjustments based upon a variety of factors, which include but are not limited to, the issuance of new options.

In November 2004, the FASB issued SFAS No. 151 "Inventory Costs—an amendment of ARB No. 43, Chapter 4," or SFAS 151. This pronouncement, which becomes effective for interim or annual periods beginning after June 15, 2005, clarifies existing accounting guidance relating to accounting for certain abnormal costs of production. We believe adoption of SFAS 151 will not have a material impact on our results of operations or financial condition.

In May 2005, the FASB Emerging Issues Task Force, or EITF, issued EITF No. 00-19-1 "Application of EITF Issue No. 00-19 to Freestanding Financial Instruments Originally Issued as Employee Compensation". This pronouncement clarifies existing accounting guidance relative to freestanding financial instruments originally issued as employee compensation. EITF No. 00-19-1 becomes effective concurrent with the effective date of SFAS 123R. We believe the adoption of this pronouncement will not have a material impact on our results of operations or financial condition.

In May 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Corrections, a replacement of APB Opinion No. 20, Accounting Changes and FASB Statement No 3, Reporting Accounting Changes in Interim Financial Statements". This pronouncement amends prior guidance on accounting for, and the reporting of, accounting changes and error corrections, and also establishes, unless impracticable, retrospective application as the required method for reporting a change in accounting principle absent explicit transition requirements specific to the newly adopted accounting principle. The pronouncement also provides guidance for determining whether retrospective application of a change in accounting principle is impracticable and for reporting a change when retrospective application is impracticable. The provisions of this pronouncement are effective for accounting changes and corrections of errors made in fiscal periods beginning after December 15, 2005. The adoption of the provisions of this pronouncement is not expected to have a material impact on our financial position or results of operations.

In July 2005, the FASB issued a proposed interpretation entitled "Accounting for Uncertain Tax Positions". This proposal is intended to clarify existing accounting for uncertain tax positions by requiring recognition in the financial statements of the best estimate of a tax position only if that position is probable of being sustained upon audit by a taxing authority, based solely on the technical merits of the position.

In August 2005, the FASB issued FASB Staff Position No. 123(R)-1, "Classification and Measurement of Freestanding Financial Instruments Originally Issued in Exchange for Employee Services under FASB Statement No. 123(R)". This pronouncement defers certain requirements of SFAS 123R relative to accounting for freestanding financial instruments issued to employees when the rights conveyed to the holder are no longer dependent on the holder being an employee of the company. The adoption of the provisions of this pronouncement is not expected to have a material impact on our financial position or results of operations.

In October 2005, the FASB issued FASB Staff Position No. FAS 123(R)-2 "Practical Accommodation to the Application of Grant Date as Defined in FASB Statement No. 123(R)". This pronouncement offers guidance relative to the implementation of SFAR 123R as to when a mutual understanding of the key terms and conditions of a stock-based compensation award have been reached in order to determine the grant date of such an award. The adoption of the provisions of this pronouncement is not expected to have a material impact on our financial position or results of operations.

In November 2005, the FASB issued FASB Staff Position No. FAS 115-1 and FAS 124-1 "The Meaning of Other Than-Temporary Impairment and Its Application to Certain Investments". This proposal addresses the determination as to when an investment is considered impaired, whether that impairment is other than temporary, and the measurement of an impairment loss. The adoption of the provisions of this pronouncement is not expected to have a material impact on our financial position or results of operations.

In November 2005, the FASB issued FASB Staff Position No. 123(R)-3 "Transition Election related to Accounting for the Tax Effects of Share-Based Payment Awards". This pronouncement provides an elective alternative transition method relative to the SFAS 123R requirement regarding the computation of certain tax benefits. The adoption of the provisions of this pronouncement is not expected to have a material impact on our financial position or results of operations.

In September 2005, the FASB issued a revised exposure draft on "Earnings per Share—an amendment of FASB Statement No. 128". This proposed statement would clarify existing guidance for mandatorily convertible instruments, the treasury stock method, contracts that may be settled in cash or shares, and contingently issued shares.

In September 2005, the FASB issued a proposed FASB Staff Position entitled FIN 46(R)-c "Determining the Variability to be Considered In Applying FASB Interpretation No. 46(R)". This proposal addresses how a reporting enterprise should determine variability to be considered when applying FASB Interpretation No. 46 (revised December 2003).

P. Subsequent Event

On November 15, 2005, the Board of Directors elected Dr. Brian J.G. Pereira to serve as President of Advanced Magnetics, and on November 22, 2005 we entered into a three-year employment agreement with Dr. Pereira. Under the terms of the employment agreement, we agreed to pay Dr. Pereira an annual salary of $400,000. In addition, Dr. Pereira is eligible to earn an annual bonus of up to $100,000 per year upon the achievement of certain performance goals determined by our Chief Executive Officer. The employment agreement also provides Dr. Pereira with a monthly automobile allowance of $1,200. Under the terms of the employment agreement, Dr. Pereira will receive one month of severance pay for each month of his employment with Advanced Magnetics up to a maximum of twelve months in the event we terminate his employment without "cause," as defined in the agreement, or he resigns for "good reason," as defined in the agreement. The severance period will begin to decrease on the second anniversary of his employment so that for every full month of employment during the final year of the agreement, the severance period will be reduced by one month. Therefore, as of the third anniversary of employment, all severance payment obligations to Dr. Pereira shall have terminated. We also agreed to provide Dr. Pereira with a ten-year term life insurance policy in the face amount of $2 million for the benefit of persons designated by Dr. Pereira. We expect the annual premium for such policy to be approximately $1,700 to $2,500.

In connection with his election as President, the Board also granted Dr. Pereira options to purchase 250,000 shares of common stock under the terms of the 2000 Stock Plan at an exercise price of $9.10, the fair market value of a share of our common stock on the date of grant. The options were exercisable with respect to 100,000 shares on the date of grant, and the options become exercisable with respect to an additional 50,000 shares on each of the first, second and third anniversaries of the grant date. In the event we terminate Dr. Pereira's employment without "cause" or Dr. Pereira terminates his employment for "good reason", the options will automatically become exercisable in full with respect to all 250,000 shares. The options will also become immediately exercisable in full upon the consummation of a "change of control," as defined in Dr. Pereira's option agreements. In addition, the Board agreed to grant Dr. Pereira an additional option to purchase 100,000 shares of common stock following approval of the amendment and restatement of the 2000 Stock Plan described in this proxy statement at an exercise price equal to the fair market value of our common stock on the date of grant so long as Dr. Pereira is still employed by us at that time. Such option would be exercisable in equal annual installments over three years.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES:

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our "disclosure controls and procedures" (as defined in 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 are effective and are 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.

There were no changes in our internal control over financial reporting that occurred during our last fiscal quarter 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 AND EXECUTIVE OFFICERS OF THE REGISTRANT:

Except as stated below, 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 fiscal year ended September 30, 2005. The information required by this item with respect to our executive officers can be found in Part I hereof, except with respect to Section 16(a) beneficial ownership reporting compliance of our executive officers, which 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 fiscal year ended September 30, 2005.

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 fiscal year ended September 30, 2005.

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 fiscal year ended September 30, 2005.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS:

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 fiscal year ended September 30, 2005.

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 fiscal year ended September 30, 2005.

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.

   Balance Sheets—September 30, 2005 and 2004

   Statements of Operations—for the years ended September 30, 2005, 2004 and 2003

   Statements of Comprehensive Income (Loss)—for the years ended September 30, 2005, 2004 and 2003

   Statements of Stockholders' Equity—for the years ended September 30, 2005, 2004 and 2003

   Statements of Cash Flows—for the years ended September 30, 2005, 2004 and 2003

   Reconciliation of Net Income (Loss) to Net Cash Used in Operating Activities—for the years ended September 30, 2005, 2004 and 2003

   Notes to Financial Statements

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

3. Exhibit Index.

Exhibit Number	Description
3.1	Certificate of Incorporation of the Company, as amended (incorporated herein by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2000, File No. 0-14732).
3.2	By-Laws of the Company, as amended (incorporated herein by reference to Exhibit 3.2 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2000, File No. 0-14732).
4.1	Specimen certificate representing the Company's Common Stock (incorporated herein by reference to Exhibit 6 to the Company's Registration Statement on Form 8-A, Reg. No. 1-10865).
4.2	Description of Capital Stock contained in Exhibits 3.1 and 3.2.
4.3	Form of Common Stock Purchase Warrant (incorporated herein by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-3 (No. 333-107517)).
4.4	Form of Common Stock Purchase Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K dated June 1, 2005 (File No. 333-119682)).
10.1*	1992 Non-Employee Director Stock Option Plan (incorporated herein by reference to Exhibit 10.4 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 1991, File No. 0-14732).
10.2*	1993 Stock Plan, as amended on February 2, 1999 (incorporated herein by reference to Appendix A to the Company's definitive proxy statement for the fiscal year ended September 30, 1998, File No. 0-14732).
10.3*	1993 Non-Employee Director Stock Option Plan (incorporated herein by reference to Exhibit 10.6 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 1992, File No. 0-14732).

10.4*	2003 Employee Stock Purchase Plan (incorporated herein by reference to Appendix A to the Company's definitive proxy statement for the fiscal year ended September 30, 2002, File No. 0-14732).
10.5*	2000 Stock Plan (incorporated herein by reference to Appendix B to the Company's definitive proxy statement for the fiscal year ended September 30, 2000, File No. 0-14732).
10.6	Clinical Testing, Supply and Marketing Agreement between the Company and Guerbet S.A. dated May 22, 1987 (incorporated herein by reference to the exhibits to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 1987, File No. 0-14732) (confidential treatment previously granted).
10.7	Clinical Testing, Supply and Marketing Agreement between the Company and Eiken Chemical Co., Ltd. dated August 30, 1988 (incorporated herein by reference to the exhibits to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 1988, File No. 0-14732) (confidential treatment previously granted).
10.8	Contrast Agent Agreement between the Company and Guerbet S.A. dated September 29, 1989 (incorporated herein by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 1989, File No. 0-14732) (confidential treatment previously granted).
10.9	Amendment to Clinical Testing, Supply and Marketing Agreement between the Company and Eiken Chemical Co., Ltd. dated September 29, 1990 (incorporated herein by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 1990, File No. 0-14732) (confidential treatment previously granted).
10.10	License, Supply and Marketing Agreement between the Company and Mallinckrodt Medical, Inc. dated June 28, 1990 (incorporated herein by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 1990, File No. 0-14732) (confidential treatment previously granted).
10.11	Technology License Agreement between the Company and Squibb Diagnostics, dated February 5, 1991 (incorporated herein by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 1991, File No. 0-14732) (confidential treatment previously granted).
10.12	Agreement of Amendment to Clinical Testing, Supply and Marketing Agreement between the Company and Guerbet, S.A., dated August 13, 1990 (incorporated herein by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 1991, File No. 0-14732).
10.13	Termination Agreement dated 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 fiscal year ended September 30, 1994, File No. 0-14732).
10.14	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 fiscal quarter ended December 31, 1994, File No. 0-14732) (confidential treatment previously granted).
10.15	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 fiscal quarter ended December 31, 1994, File No. 0-14732) (confidential treatment previously granted).
10.16	License and Marketing Agreement between the Company and Cytogen Corporation dated August 25, 2000 (incorporated herein by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2000, File No. 0-14732) (confidential treatment previously granted).

10.17	Supply Agreement between the Company and Cytogen Corporation dated August 25, 2000 (incorporated herein by reference to Exhibit 10.20 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2000, File No. 0-14732) (confidential treatment previously granted).
10.18*	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 (No. 333-119682)).
10.19*	Specimen of Stock Option Grant in connection with 1992 Non-Employee Director Stock Plan (incorporated herein by reference to Exhibit 10.20 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2004, File No. 0-14732).
10.20*	Specimen of Stock Option Grant in connection with 1993 Non-Employee Director Stock Plan (incorporated herein by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2004, File No. 0-14732).
10.21*	Specimen of Stock Option Grant in connection with 1993 Stock Plan (incorporated herein by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2004, File No. 0-14732).
10.22*	Specimen of Stock Option Grant in connection with 2000 Stock Plan (employees) (incorporated herein by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2004, File No. 0-14732).
10.23*	Specimen of Stock Option Grant in connection with 2000 Stock Plan (non-employees) (incorporated herein by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2004, File No. 0-14732).
10.24*	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 fiscal quarter ended March 31, 2005, File No. 0-14732).
10.25*	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 fiscal quarter ended March 31, 2005, File No. 0-14732).
10.26	Securities Purchase Agreement dated as of June 1, 2005, by and among the Company and each of those persons and entities whose names are set forth on the Schedule of Purchasers attached thereto as Exhibit A (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 1, 2005, File No. 333-119682).
10.27	Securities Purchase Agreement dated as of June 2, 2005, by and among Advanced Magnetics, Inc., a Delaware corporation and each of those persons and entities whose names are set forth on the Schedule of Purchasers attached thereto as Exhibit A (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 2, 2005, File No. 333-119682).
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10.29*	Employment Agreement dated as of November 22, 2005, between Advanced Magnetics, Inc. and Brian J.G. Pereira (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed November 22, 2005, File No. 0-14732).
10.30*	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).
10.31*	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).
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.

ADVANCED MAGNETICS, INC.

By: /s/ JEROME GOLDSTEIN
Jerome Goldstein,
Chairman of the Board of Directors,
Chief Executive Officer and Treasurer

Date: December 14, 2005

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/ JEROME GOLDSTEIN Jerome Goldstein	Chairman of the Board of Directors, Chief Executive Officer and Treasurer (principal executive officer and principal financial officer)	December 14, 2005
/s/ MICHAEL N. AVALLONE Michael N. Avallone	Vice President—Finance and Chief Financial Officer (principal accounting officer)	December 14, 2005
/s/ SHELDON L. BLOCH Sheldon L. Bloch	Director	December 14, 2005
/s/ MICHAEL D. LOBERG Dr. Michael D. Loberg	Director	December 14, 2005
/s/ EDWARD B. ROBERTS Dr. Edward B. Roberts	Director	December 14, 2005
/s/ BRIAN J. G. PEREIRA Brian J. G. Pereira, MD	Director and President	December 14, 2005
/s/ MARK SKALETSKY Mark Skaletsky	Director	December 14, 2005
/s/ THEODORE I. STEINMAN Theodore I. Steinman, MD	Director	December 14, 2005

EXHIBIT INDEX

Exhibit Number	Description
3.1	Certificate of Incorporation of the Company, as amended (incorporated herein by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2000, File No. 0-14732).
3.2	By-Laws of the Company, as amended (incorporated herein by reference to Exhibit 3.2 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2000, File No. 0-14732).
4.1	Specimen certificate representing the Company's Common Stock (incorporated herein by reference to Exhibit 6 to the Company's Registration Statement on Form 8-A, Reg. No. 1-10865).
4.2	Description of Capital Stock contained in Exhibits 3.1 and 3.2.
4.3	Form of Common Stock Purchase Warrant (incorporated herein by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-3 (No. 333-107517)).
4.4	Form of Common Stock Purchase Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K dated June 1, 2005 (File No. 333-119682)).
10.1*	1992 Non-Employee Director Stock Option Plan (incorporated herein by reference to Exhibit 10.4 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 1991, File No. 0-14732).
10.2*	1993 Stock Plan, as amended on February 2, 1999 (incorporated herein by reference to Appendix A to the Company's definitive proxy statement for the fiscal year ended September 30, 1998, File No. 0-14732).
10.3*	1993 Non-Employee Director Stock Option Plan (incorporated herein by reference to Exhibit 10.6 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 1992, File No. 0-14732).
10.4*	2003 Employee Stock Purchase Plan (incorporated herein by reference to Appendix A to the Company's definitive proxy statement for the fiscal year ended September 30, 2002, File No. 0-14732).
10.5*	2000 Stock Plan (incorporated herein by reference to Appendix B to the Company's definitive proxy statement for the fiscal year ended September 30, 2000, File No. 0-14732).
10.6	Clinical Testing, Supply and Marketing Agreement between the Company and Guerbet S.A. dated May 22, 1987 (incorporated herein by reference to the exhibits to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 1987, File No. 0-14732) (confidential treatment previously granted).
10.7	Clinical Testing, Supply and Marketing Agreement between the Company and Eiken Chemical Co., Ltd. dated August 30, 1988 (incorporated herein by reference to the exhibits to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 1988, File No. 0-14732) (confidential treatment previously granted).
10.8	Contrast Agent Agreement between the Company and Guerbet S.A. dated September 29, 1989 (incorporated herein by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 1989, File No. 0-14732) (confidential treatment previously granted).
10.9	Amendment to Clinical Testing, Supply and Marketing Agreement between the Company and Eiken Chemical Co., Ltd. dated September 29, 1990 (incorporated herein by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 1990, File No. 0-14732) (confidential treatment previously granted).

10.10	License, Supply and Marketing Agreement between the Company and Mallinckrodt Medical, Inc. dated June 28, 1990 (incorporated herein by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 1990, File No. 0-14732) (confidential treatment previously granted).
10.11	Technology License Agreement between the Company and Squibb Diagnostics, dated February 5, 1991 (incorporated herein by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 1991, File No. 0-14732) (confidential treatment previously granted).
10.12	Agreement of Amendment to Clinical Testing, Supply and Marketing Agreement between the Company and Guerbet, S.A., dated August 13, 1990 (incorporated herein by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 1991, File No. 0-14732).
10.13	Termination Agreement dated 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 fiscal year ended September 30, 1994, File No. 0-14732).
10.14	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 fiscal quarter ended December 31, 1994, File No. 0-14732) (confidential treatment previously granted).
10.15	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 fiscal quarter ended December 31, 1994, File No. 0-14732) (confidential treatment previously granted).
10.16	License and Marketing Agreement between the Company and Cytogen Corporation dated August 25, 2000 (incorporated herein by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2000, File No. 0-14732) (confidential treatment previously granted).
10.17	Supply Agreement between the Company and Cytogen Corporation dated August 25, 2000 (incorporated herein by reference to Exhibit 10.20 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2000, File No. 0-14732) (confidential treatment previously granted).
10.18*	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 (No. 333-119682)).
10.19*	Specimen of Stock Option Grant in connection with 1992 Non-Employee Director Stock Plan (incorporated herein by reference to Exhibit 10.20 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2004, File No. 0-14732).
10.20*	Specimen of Stock Option Grant in connection with 1993 Non-Employee Director Stock Plan (incorporated herein by reference to Exhibit 10.21 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2004, File No. 0-14732).
10.21*	Specimen of Stock Option Grant in connection with 1993 Stock Plan (incorporated herein by reference to Exhibit 10.22 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2004, File No. 0-14732).
10.22*	Specimen of Stock Option Grant in connection with 2000 Stock Plan (employees) (incorporated herein by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2004, File No. 0-14732).

10.23*	Specimen of Stock Option Grant in connection with 2000 Stock Plan (non-employees) (incorporated herein by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2004, File No. 0-14732).
10.24*	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 fiscal quarter ended March 31, 2005, File No. 0-14732).
10.25*	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 fiscal quarter ended March 31, 2005, File No. 0-14732).
10.26	Securities Purchase Agreement dated as of June 1, 2005, by and among the Company and each of those persons and entities whose names are set forth on the Schedule of Purchasers attached thereto as Exhibit A (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 1, 2005, File No. 333-119682).
10.27	Securities Purchase Agreement dated as of June 2, 2005, by and among Advanced Magnetics, Inc., a Delaware corporation and each of those persons and entities whose names are set forth on the Schedule of Purchasers attached thereto as Exhibit A (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 2, 2005, File No. 333-119682).
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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.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (File No. 333-119682) and in the Registration Statements on Form S-8 (File Nos. 333-72700, 33-62522, 33-8697, 33-13953, 33-40744, 33-46963, 333-28417, 333-82292, and 333-105172) of Advanced Magnetics, Inc. of our report dated December 14, 2005 relating to the financial statements, which appears in this Form 10-K.

/s/ PRICEWATERHOUSECOOPERS LLP
Boston, Massachusetts
December 14, 2005

Exhibit 31.1

CERTIFICATIONS

I, Jerome Goldstein, certify that:

1. I have reviewed this Annual Report on Form 10-K of Advanced Magnetics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) [Paragraph omitted in accordance with SEC transition instructions contained in SEC Release 34-47986];

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably like to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonable likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: December 14, 2005

/s/ JEROME GOLDSTEIN

Jerome Goldstein
Chairman of the Board of Directors,
Chief Executive Officer and Treasurer
(principal executive and financial officer)

Exhibit 31.2

CERTIFICATIONS

I, Michael N. Avallone, certify that:

1. I have reviewed this Annual Report on Form 10-K of Advanced Magnetics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) [Paragraph omitted in accordance with SEC transition instructions contained in SEC Release 34-47986];

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: December 14, 2005

/s/ MICHAEL N. AVALLONE

Michael N. Avallone
Vice President—Finance and Chief Financial Officer
(principal accounting officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Advanced Magnetics, Inc. (the "Company") on Form 10-K for the period ending September 30, 2005 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jerome Goldstein, Chairman of the Board of Directors, Chief Executive Officer and Treasurer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ JEROME GOLDSTEIN

Jerome Goldstein
Chairman of the Board of Directors,
Chief Executive Officer and Treasurer
December 14, 2005

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Advanced Magnetics, Inc. (the "Company") on Form 10-K for the period ending September 30, 2005 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael N. Avallone, Vice President—Finance and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ MICHAEL N. AVALLONE
Michael N. Avallone
Vice President—Finance and Chief Financial Officer
December 14, 2005