Use these links to rapidly review the document
TABLE OF CONTENTS
INDEX TO FINANCIAL STATEMENTS

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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, 2004

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 Exchange Act 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, 2004 was approximately $53,583,538 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 8, 2004, there were 7,992,054 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 1, 2005, pursuant to Regulation 14A within 120 days of the end of the fiscal year ended September 30, 2004. 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, 2004
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 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, 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 cardiovascular disease and cancer.

Combidex® is our investigational molecular imaging agent consisting of iron oxide nanoparticles for use in conjunction with magnetic resonance imaging, also known as MRI, to aid in the differentiation of cancerous from non-cancerous lymph nodes. *Combidex* received an approvable letter, subject to certain conditions, from the U.S. Food and Drug Administration, also known as the FDA, in June 2000. In September 2004, we submitted a complete response to the approvable letter, which was accepted by the FDA and assigned a user fee goal date of March 30, 2005. For a discussion of FDA procedures regarding the user fee goal date, see "Government Regulation and Reimbursement."

Ferumoxytol, the next-generation product in our development pipeline, is currently in Phase III multi-center clinical trials for use as an iron replacement therapeutic in anemic chronic kidney disease patients, whether or not on dialysis. Exploratory Phase II clinical trials of ferumoxytol for use as a contrast agent in MRA are currently ongoing.

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.

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 their use in pharmaceutical products such as iron replacement therapeutics and MRI contrast agents. In the area of iron replacement therapy, because 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, products using our core technology are well-suited for use in intravenous

(IV) iron replacement therapy. When our nanoparticles are used as MRI contrast agents because our iron oxide nanoparticles become strongly magnetic when placed in a magnetic field, but lose their magnetism once the field is removed. Use of our nanoparticles results in 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 in development by the Company, 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
Combidex	Differentiation of cancerous from non-cancerous lymph nodes.	Cytogen Corporation (United States), Guerbet (various countries in Europe and South America, the Middle East, Southeast Asia, and the former Soviet Union).	Complete response to approvable letter accepted by FDA. User fee goal date of March 30, 2005.	Phase III clinical trials underway.
ferumoxytol	Iron replacement therapy.	None.	Phase III clinical trials underway.	None.
	Magnetic resonance angiography.	None.	Phase II clinical trials underway.	None.
Feridex I.V.	Diagnosis of liver lesions.	Berlex Laboratories, Inc. (United States), Eiken Chemical Co., Ltd. (Japan), Guerbet (various countries in Europe 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.	Guerbet (various countries in Europe and South America, the Middle East, Southeast Asia, and the former Soviet Union), Mallinckrodt, Inc. (United States).	Approved and marketed.	Approved and marketed in several European Union countries.

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

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 injectable imaging agent that localizes to and causes contrast enhancement of the 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 non-cancerous, which we believe will allow for improved patient diagnosis and staging and provide a safe, cost-effective way to assess medical treatments and to improve patient

outcomes. 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 2004 Cancer Facts and Figures, approximately 900,000 new cases of cancer that could spread to the lymph nodes will be diagnosed during 2004. 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 imaging modalities currently used for imaging lymph nodes are computed tomography, also known as CT, and MRI without contrast. 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. We have demonstrated in clinical studies that *Combidex* only accumulates in non-cancerous lymph node tissue and can therefore facilitate differentiation between cancerous nodes and other 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 and in various countries in Europe, South America, the Middle East, southeast Asia and the former Soviet Union to Guerbet under the tradename Sinerem™. See "Licensing, Marketing and Supply Arrangements."

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 chronic kidney disease, also known as CKD, or kidney failure as well as in many patients receiving chemotherapy. According to the National Kidney Foundation, there are approximately 300,000 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 over 8 million people in the United States suffering from moderate or severe 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 guidelines recommend starting patients who need iron on oral iron supplements as a first-line treatment for anemia. 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 taking oral iron supplements.

If approved by the FDA, we believe ferumoxytol would be an effective iron replacement therapy for patients receiving erythropoietin. Clinical studies to date show that ferumoxytol has greater flexibility in both the 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. In 2004, we initiated Phase III multi-center clinical studies for ferumoxytol for use in iron replacement therapy in anemic CKD patients, whether or not on dialysis. We expect to initiate the last of our Phase III clinical studies, a large scale safety study, in early calendar year 2005. We anticipate that we will submit a New Drug Application, also known as an NDA, to the FDA for ferumoxytol in iron replacement therapy in the first half of 2006 based on the current progress of our Phase III clinical program.

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

The Role of Ferumoxytol in Contrast-enhanced MRA

There are no approved contrast agents for use in magnetic resonance angiography, also known as MRA. However, contrast-enhanced MRA is currently practiced "off-label" with some of the gadolinium-based contrast agents available today. These gadolinium-based contrast agents are of limited clinical value for the diagnosis of cardiovascular disease due to the rapid spread of these agents out of the vascular system and into surrounding tissue. We believe that ferumoxytol, a true intravascular blood pool agent that does not spread into the adjacent tissue and remains in the blood stream for an extended period of time, will significantly improve the ability to perform contrast-enhanced MRA and will provide more clinically useful information for physicians seeking to perform non-invasive cardiovascular disease assessment.

In addition, new medical theory suggests that the majority of heart attacks and strokes may be caused by the rupture of coronary plaques rather than blood flow restriction, as once commonly thought. The plaques that are prone to rupture are commonly referred to as "vulnerable plaques." We believe that the characteristics of ferumoxytol could allow physicians not only to image the vascular system to diagnose a variety of vascular diseases, including blood flow restrictions, but could also allow physicians to distinguish vulnerable plaque from stable plaque.

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. Ferumoxytol is currently in Phase II exploratory clinical studies for use in contrast-enhanced MRA. We anticipate that Phase III clinical trials for ferumoxytol for use in contrast-enhanced magnetic resonance applications could begin during calendar year 2005.

We do not currently have a marketing partner for ferumoxytol in MRA or non-oncology MRI applications. 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. See "Licensing, Marketing and Supply Arrangements."

Feridex I.V.

The liver is a principal site for metastasis of primary cancer originating in other parts of the body, particularly colon cancer, a common type of cancer in the United States. The ability to identify metastatic tumors in the liver has a significant impact on physicians' treatment plans for cancer. Because treatment plans can vary widely based on the level of metastatic disease, proper staging is a critical component of patient management. Diagnosis of metastases 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 CT scanning or ultrasound, the most widely used techniques for liver imaging. Through the use of *Feridex I.V.*, liver scans may be performed using contrast-enhanced MRI instead of, or in addition to, CT scanning and ultrasound.

Feridex I.V. was approved by the FDA in August 1996. 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 European Union, also known as 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. See "Licensing, Marketing and Supply Arrangements."

GastroMARK

MRI of organs and tissues in the abdomen without contrast agents is difficult because these 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, 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, and subsequently acquired the rights to market the product in several other countries under the tradename Lumirem™. 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 agreements, Berlex paid a $5,000,000 non-refundable license fee in fiscal 1995 and an additional $5,000,000 non-refundable license fee in October 1996 upon the FDA's marketing approval of *Feridex I.V.* In addition, we receive payments for manufacturing the product and royalties on sales. Under the terms of the agreements, 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 molecular imaging agent consisting of iron oxide nanoparticles for use in conjunction with MRI to aid in the differentiation of cancerous from non-cancerous lymph nodes. In addition, Cytogen has the exclusive right to market and sell ferumoxytol for oncology imaging applications 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 manufacturing and distribution 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 a license fee of $1,500,000 and agreed to pay royalties based upon products shipped for resale. 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 1990, we entered into a second manufacturing and distribution agreement with Eiken granting Eiken the exclusive right to manufacture and distribute *GastroMARK* and *Combidex* in Japan. In addition, for a period of 180 days after we file an Investigational New Drug Application, also known as an IND, for any future Advanced Magnetics MRI contrast agent, Eiken has a right of first refusal to elect to manufacture and distribute such product in Japan. Upon execution of our second manufacturing and distribution agreement with Eiken, it paid us a license fee of $1,000,000. Additionally, Eiken agreed to pay us royalties on sales of all products shipped for resale by Eiken under the agreement. The agreement is perpetual but terminable upon certain specified events. Due to market conditions in Japan, Eiken subsequently decided not to market *GastroMARK* or *Combidex* and rights to these products in Japan have reverted back to us. Additionally, Eiken has decided not to exercise its option to develop ferumoxytol for marketing in Japan.

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 their 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, as amended, Guerbet paid us license fees of $250,000 upon execution of the agreement and $250,000 on the first anniversary of execution of the agreement. In addition, 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 their 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 rights to ferumoxytol, and accordingly, we retain the rights to manufacture and sell ferumoxytol worldwide for all applications other than oncology imaging. Under the terms of this second distribution agreement, Guerbet paid us a license fee in 1989 of $700,000. In addition, 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. Mallinckrodt currently has rights to *GastroMARK* in the United States only. Under the terms of the agreement, we reserved the right to sell *GastroMARK* through our own direct sales personnel. Mallinckrodt paid $1,350,000 in license fees and a $500,000 non-refundable milestone payment upon FDA marketing approval of *GastroMARK*. In addition, 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 and Schering AG of Berlin, Germany that require us to make payments in accordance with these agreements upon the attainment of particular milestones relating to *Feridex I.V.* and *GastroMARK*. We are also required under these agreements 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 2004, 2003 or 2002. Future milestone payments under these agreements are not to exceed $400,000. Royalty payments under these agreements were less than $105,000 for each of the prior three fiscal years.

Manufacturing and Supply Arrangements

Our Cambridge, Massachusetts facility is registered with the FDA and is subject to current Good Manufacturing Practices, also known as 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 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. 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 2005 and 2020, some of which are subject to extension under FDA regulations. 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 Imaging A.S. 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 MRI contrast agents and IV iron replacement therapy products. 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 product manufacturing 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, reimbursement, price competitiveness and product characteristics such as perceived safety profiles and dosing regimens. In addition, market acceptance of both MRI as an appropriate technique for imaging the lymphatic system and cardiac imaging, and the use of our products as part of such imaging, is critical to the success of our contrast agent products. 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 such as CT and x-ray 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 currently generates approximately $300 million 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 which are in various phases of clinical testing in the United States and abroad. Currently, American Regent Laboratories, Inc., or American Regent, markets Venofer®, an iron sucrose formulation, and Dexferrum®, an iron dextran product. We believe American Regent is conducting additional clinical studies with *Venofer*. Watson Pharmaceuticals, Inc., or Watson, markets Ferrlecit®, a sodium ferric gluconate in sucrose injection, and INFeD®, an iron dextran product. Watson is currently pursuing additional clinical studies to expand the indication of *Ferrlecit* to include a pediatric hemodialysis indication, 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. 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 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 some EU and non-EU countries, including Japan. Clinical trials are proceeding in the United States. *Primovist* was approved in Sweden in 2004 and is expected to be approved in most EU countries by the end of calendar year 2004. Submission for approval of *Primovist* in Japan and other Asian countries is expected by the end of calendar year 2004. Schering is in Phase III development in Europe with Supravist® (SHU 555 C) for use as an MRI contrast agent. GE Healthcare has received marketing approval in the United States and Europe for its MnDPDP product, Teslascan®, for MRI of liver lesions. Bracco S.p.A., or Bracco, has received marketing approval in Europe and the United States for MultiHance® (Gadolinium BOPTA), a chelated gadolinium compound. To our knowledge, there are no approved products or drug candidates in human clinical development for use in contrast-enhanced MRI of lymph nodes other than *Combidex*. Although we are unaware of any such products, those products may exist and could negatively affect the marketing of our products.

In the area of oral contrast agents, Pharmacyclics, Inc.'s gadolinium-based product candidate, GADOLITE®, is currently not approved by the FDA and we do not know its status. Bracco received marketing FDA approval in December 1997 in the United States for Lumenhance®, its liposomal encapsulated oral manganese compound, but it is not being marketed at this time. In October 1997, the FDA approved Ferriseltz®, an oral MRI agent produced by Oncomembrane, Inc. We do not know how, or if, Bracco and Oncomembrane are planning to market these products.

There are currently no contrast agents approved by the FDA for MRA. Products in development include Epix Pharmaceuticals, Inc.'s MS-325, a gadolinium-based contrast agent. The FDA has accepted the NDA for MS-325 and as of October 2004 has extended its NDA action date until January 2005. MS-325 is licensed to Schering AG. Epix Pharmaceuticals is also developing EP-2104R to enable the detection of blood clots. EP-2104R has begun human clinical development. Guerbet is developing

Vistarem® (P-792), a gadolinium-based contrast agent that is in Phase III 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 MRA in 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 has begun 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.

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

The steps required by the FDA before a new human pharmaceutical product, 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 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 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, reducing our profitability, and limit product sales, thereby reducing our revenue. 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.

Under the Prescription Drug User Fee Act, also known as PDUFA, the FDA pledged to Congress that they would take action on a percentage of NDAs, resubmissions and supplements within specified time periods, the expiration of such time period being commonly referred to as the user fee goal date. For a resubmission of the type we recently made for *Combidex*, the FDA guarantees that 90% of those submissions will be reviewed by the assigned user fee goal date. We have no assurance, however, that the FDA will in fact act by this date, nor what action the FDA will take if it does act. The FDA could respond by issuing an additional approvable letter with further conditions for approval or by issuing a not approvable letter.

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, also known as 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, 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. Three companies, Cytogen, Berlex and Guerbet, accounted for 58%, 20% and 11%, respectively, of our revenues in fiscal 2002. No other company accounted for more than 10% of our total revenues in fiscal 2004, 2003 or 2002. All of the revenue attributable to Cytogen and a significant portion of the revenue attributable to Berlex in fiscal 2004, 2003 and 2002, was deferred revenue that was recognized in those fiscal years respectively.

Backlog

Generally, product orders from our customers are fulfilled within several weeks of receipt of a customer order. Thus, we did not have a significant sales backlog as of September 30, 2004 and 2003.

Employees

As of December 8, 2004, we had 27 employees, 2 of whom were part-time and 18 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 2004, 2003 and 2002 from customers and licensees outside of the United States, principally in Europe and Japan, amounted to 21%, 13% and 20%, 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 amounts to 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 $6,083,839, $4,458,980 and $4,029,115 in fiscal 2004, 2003 and 2002, respectively. We anticipate that a significant portion our operating expenses will continue to be related to development in fiscal 2005.

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 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.

ITEM 2. PROPERTIES:

Our operations are located in a building we own of approximately 25,000 square feet in Cambridge, Massachusetts. We believe this facility remains adequate for our current and anticipated short-term needs and that we will be able to lease additional comparable space, if necessary. However, the acquisition of, and required regulatory approvals for, additional pharmaceutical manufacturing space can be time-consuming and expensive. 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.

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 continue to defend the action vigorously. 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 continue to defend the action vigorously. 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, 2004.

Executive Officers of the Registrant:

Jerome Goldstein, 65, 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 was President from 1981 to 1997 and was re-elected President in 2001 following the resignation of our former President in 2001. Mr. Goldstein was a co-founder of Clinical Assays, Inc., serving from 1972 to 1980 as Vice President and then as President.

Michael N. Avallone, 53, 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).

Rachel Konforty, 35, joined us as General Counsel and Assistant Secretary in September 2002. Prior to September 2002, Ms. Konforty was an associate of White & McNamara, P.C. In 1999 and 2000, Ms. Konforty served as an intern with the National Public Defenders Office of Israel and the Israeli law firm of Yigal Arnon & Co. From 1998 to 1999, Ms. Konforty was an associate of Skadden, Arps, Slate, Meagher & Flom, LLP.

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 on the American Stock Exchange for the fiscal quarters of 2003 and 2004.

		First	Second	Third	Fourth
2003	High	$ 5.14	$ 4.80	$ 12.20	$ 13.74
	Low	3.97	4.04	4.20	8.35
2004	High	15.24	13.35	15.49	16.43
	Low	8.70	9.70	8.00	13.01

On December 8, 2004, there were approximately 230 stockholders of record and we believe that the number of beneficial holders of common stock was approximately 2,150 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 8, 2004 was $14.00 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.

We did not repurchase any of our outstanding securities during the fourth quarter of fiscal year 2004.

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 I, 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 I, 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,				
	2004	2003	2002	2001	2000**
Statement of Operations Data:					
Revenues:					
License fees	$ 2,747,695	$ 3,642,052	$ 4,020,617	$ 4,640,198	$ 1,124,049
Product sales	768,189	600,444	965,820	633,480	1,253,537
Royalties	240,000	535,000	725,000	700,000	825,000
Contract research and development	—	—	—	—	106,003
Total revenues	3,755,884	4,777,496	5,711,437	5,973,678	3,308,589
Costs and Expenses:					
Cost of product sales	117,015	199,561	214,357	204,399	239,228
Research and development expenses	6,083,839	4,458,980	4,029,115	3,622,102	4,626,663
Selling, general and administrative expenses	2,219,777	1,770,402	1,712,234	1,667,066	3,013,796
Total costs and expenses	8,420,631	6,428,943	5,955,706	5,493,567	7,879,687
Other Income (Expense):					
Interest and dividend income	169,547	112,730	255,928	697,162	827,780
Gains and (losses) on sales of securities and derivative instruments, net	—	2,777,003	610,378	(579,418)	(62,450)
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)	169,547	2,393,552	(1,462,003)	(4,283,934)	765,330
Income (loss) before provision for (benefit from) income taxes and cumulative effect of accounting change	(4,495,200)	742,105	(1,706,272)	(3,803,823)	(3,805,768)
Income tax (benefit) provision	—	(124,752)	—	25,362	—
Income (loss) before cumulative effect of accounting change	(4,495,200)	866,857	(1,706,272)	(3,829,185)	(3,805,768)
Cumulative effect of accounting change**	—	—	—	—	(7,457,717)
Net income (loss)	$ (4,495,200)	$ 866,857	$ (1,706,272)	$ (3,829,185)	$ (11,263,485)
Earnings (loss) per share—basic:					
Income (loss) per share before cumulative effect of accounting change	$ (0.57)	$ 0.13	$ (0.26)	$ (0.57)	$ (0.56)
Cumulative effect of accounting change	—	—	—	—	(1.11)
Basic	$ (0.57)	$ 0.13	$ (0.26)	$ (0.57)	$ (1.67)
Earnings (loss) per share—diluted:					
Income (loss) per share before cumulative effect of accounting change	$ (0.57)	$ 0.12	$ (0.26)	$ (0.57)	$ (0.56)
Cumulative effect of accounting change	—	—	—	—	(1.11)
Diluted	$ (0.57)	$ 0.12	$ (0.26)	$ (0.57)	$ (1.67)
Weighted average shares outstanding used to compute earnings (loss) per share:					
Basic	7,817,918	6,914,323	6,636,798	6,701,113	6,758,825
Diluted	7,817,918	7,143,455	6,636,798	6,701,113	6,758,825

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

** In fiscal 2000, we adopted the guidelines set forth in SEC Staff Accounting Bulletin 101, also known as SAB 101, "Revenue Recognition in Financial Statements" (later revised as Staff Accounting Bulletin No. 104). The effect of applying this change in accounting principle was a charge 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 were recorded as deferred revenue to be recognized evenly over the remaining term of the related agreement.

	2004	2003	2002	2001	2000
Balance sheet data:					
Working capital	$ 12,313,754	$ 22,579,478	$ 14,233,904	$ 18,734,388	$ 25,706,905
Total assets	$ 23,810,611	$ 29,365,613	$ 22,484,002	$ 27,448,667	$ 35,667,591
Long-term liabilities—deferred revenue	$ 3,134,435	$ 5,265,669	$ 7,774,131	$ 11,444,384	$ 15,977,599
Stockholders' equity	$ 17,546,455	$ 20,918,075	$ 10,650,267	$ 11,512,294	$ 14,305,632
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 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, 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 cardiovascular disease and cancer.

Combidex® is our investigational molecular imaging agent consisting of iron oxide nanoparticles for use in conjunction with magnetic resonance imaging, also known as MRI, to aid in the differentiation of cancerous from non-cancerous lymph nodes. *Combidex* received an approvable letter, subject to certain conditions, from the U.S. Food and Drug Administration, also known as the FDA, in June 2000. In September 2004, we submitted a complete response to the approvable letter, which was accepted by the FDA and assigned a user fee goal date of March 30, 2005. For a discussion of FDA procedures regarding the user fee goal date, see "Government Regulation and Reimbursement" in Part I, Item 1 of this Annual Report on Form 10-K.

Ferumoxytol, the next-generation product in our development pipeline, is currently in Phase III multi-center clinical trials for use as an iron replacement therapeutic in anemic chronic kidney disease patients, whether or not on dialysis. Exploratory Phase II clinical trials of ferumoxytol for use as a contrast agent in MRA are currently ongoing.

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.

Since our inception in 1981, 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. To date, our marketing partners have had limited commercial success in the sales and marketing of *Feridex I.V.* and *GastroMARK.* Our long-term success will depend, in part, on our ability to obtain FDA approval of *Combidex* and the sales and marketing efforts of Cytogen Corporation, or Cytogen, which has exclusive United States marketing rights for *Combidex*. Additionally, our success will depend on our ability to successfully develop and obtain FDA approval for ferumoxytol as an iron replacement therapeutic and as a contrast agent for MRI. The process of bringing ferumoxytol to market will involve the expenditure of significant resources, both financial and managerial, and may require that we obtain future financing or enter into strategic partnerships to support these efforts. Our future success also depends on our ability to maintain and scale-up our

manufacturing capabilities, to hire and retain key employees, and to successfully respond to technological and other changes in the marketplace.

Our revenues include non-cash license fees paid at inception of a contract and recognized over time in connection with our collaborative and strategic agreements, royalties from the sale of our approved products to end users and product sales to our marketing partners. To date, we have not generated significant revenues on royalties from the sale of our approved products by our marketing partners. In addition, sales of *Feridex I.V.* by our marketing partners to end users have been on a downward trend and we expect product sales to remain at current low levels overall. We expect future revenue we generate will continue to fluctuate from quarter to quarter as a result of the variable nature of our product sales to our marketing partners and the variability of our license fee revenue due to fluctuations in our activities related to the project goals governed by our collaborative and strategic agreements. In future years, we will seek to generate revenue from a combination of product sales and royalties resulting from the license of our approved products. We may also seek to generate revenues from up-front license fees and milestone payments if we choose to enter into future collaborative or strategic relationships. We may not be able to generate significant revenues from our product sales and royalties or we may not be able to enter into future collaborative or strategic relationships on favorable terms, if at all. Any failure to generate future revenues in the manner anticipated may hinder our ability to become profitable.

A substantial portion of our expenses consists of research and development expenses. In our Phase III development efforts for ferumoxytol in iron replacement therapy, we rely to a greater degree on contract research and development service providers as compared to other development initiatives in the past. We expect that research and development expenses will continue to be a significant portion of our total expenses. In addition, a substantial portion of our expenses consists of selling, general and administrative expenses. We expect selling, general and administrative expenses to increase on a going-forward basis as we continue our efforts to comply with new corporate governance requirements and as a result of additional insurance obligations. Our operating results may continue to vary significantly from quarter to quarter and from year to year depending on a number of factors, including:

- the timing of our recognition of deferred revenue which is affected by the performance of our obligations under our license agreements;
- the timing of external research and development expenses, which may fluctuate from quarter to quarter;
- the timing of FDA approval of *Combidex* and ferumoxytol;
- market acceptance of *Combidex* and ferumoxytol, if approved;
- 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; 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.

Revenue or profits in any period will not necessarily be indicative of results in subsequent periods and we may not achieve profitability or grow revenue in the future.

Results of Operations

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.

	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

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 Laboratories, Inc., or 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. Recognition of the remainder of the deferred revenue is expected to occur when future expenses are incurred related to the agreement.

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. Recognition of the remainder of the deferred revenue as license fee revenue is expected to occur proportionately over the remaining term of the agreement.

In summary, 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)	(30.8)%
Deferred license fee revenue recognized in connection with the Berlex agreement	737,755	737,755	—	0.0%
Total	$ 2,747,695	$ 3,642,052	$ (894,357)	(24.6)%

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 is 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*.

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. Although royalty payments can fluctuate from quarter to quarter based on uneven demand for our products by end users, we expect that royalty payments will remain at current low levels.

Product Sale Revenue

Product sale revenue 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 of product sale revenue in the fiscal year ended September 30, 2004 was primarily a result of the fluctuation of our product sales to our marketing partners from period to period based on uneven purchasing patterns of our distributors and the batch size in which our products are manufactured and shipped. 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 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 cannot provide total research and development costs by project since the end of fiscal 2000.

Research and development expenses 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 fiscal year ended September 30, 2003 to 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. 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.

We expect research and development expenses to continue to increase as a result of the continued initiation of sites and increased patient enrollment and third party service provider fees in our Phase III clinical trials for ferumoxytol in iron replacement therapy.

In the third fiscal quarter of 2004, we commenced Phase III clinical trials of ferumoxytol for use in iron replacement therapy and are continuing exploratory Phase II clinical trials of ferumoxytol for use in magnetic resonance angiography, also known as MRA. 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, 2004, we incurred aggregate external research and development expenses of

approximately $4,825,000 related to pre-clinical activities and clinical trials in connection with ferumoxytol. The estimated cost of the external efforts necessary to complete development of ferumoxytol as an iron replacement therapeutic, including costs related to ongoing and future clinical trial activities, is currently estimated to range from approximately $15,000,000 to $17,000,000. 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, or inadequate performance or errors by third party contract research and development service providers. We currently expect to submit a New Drug Application, also known as NDA, to the FDA for ferumoxytol in iron replacement therapy during the first half of 2006 based on the current status of the Phase III clinical program. This submission could be delayed, however, if we experience delays in any one of our Phase III clinical trials in iron replacement therapy. Any delays in our clinical development program or in the preparation of our submission of an NDA in connection with ferumoxytol in iron replacement therapy could delay the commercialization of ferumoxytol in this application. Since we have not yet determined which clinical indications we may seek for the development of ferumoxytol in MRI, we cannot make a specific dollar estimate of the projected external efforts necessary to complete development for ferumoxytol in MRI.

In June 2000, we received an approvable letter, subject to certain conditions, from the FDA for *Combidex*. During the fiscal quarter ended September 30, 2004, we submitted a complete response to the approvable letter, which was accepted by the FDA and assigned a user fee goal date of March 30, 2005. 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*. We have incurred additional external research and development expenses of approximately $602,000 since fiscal 2000 related to *Combidex* primarily in connection with ongoing clinical research expenses and consulting fees. In addition, we have incurred internal research and development costs related to our efforts to satisfy the conditions specified in the approvable letter from the FDA since fiscal 2000.

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 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. 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 third-party reimbursement policies and decisions, 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 consisted of the following:

	Years Ended September 30,			
	2004	2003	$ Change	% Change
Salaries, wages, payroll taxes and benefits	$ 1,073,585	$ 984,435	$ 89,150	9%
Professional fees	455,716	345,538	110,178	32%
Insurance costs	184,150	59,866	124,284	208%
Facilities and other	506,326	380,563	125,763	33%
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. We expect selling, general and administrative expenses to continue to increase significantly on a going-forward basis in relation to our

efforts to comply with new corporate governance requirements and as a result of additional insurance obligations.

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.

Fiscal 2003 Compared to Fiscal 2002

Revenues

Total revenues for the fiscal year ended September 30, 2003 were $4,777,496 compared to $5,711,437 for the fiscal year ended September 30, 2002.

	Years Ended September 30,			
	2003	2002	$ Change	% Change
Revenues:				
License fees	$ 3,642,052	$ 4,020,617	$ (378,565)	(9)%
Royalties	535,000	725,000	(190,000)	(26)%
Product sales	600,444	965,820	(365,376)	(38)%
Total revenues	$ 4,777,496	$ 5,711,437	$ (933,941)	(16)%

License Fee Revenue

License fee revenues for the fiscal year ended September 30, 2003 were $3,642,052, consisting of $737,755 of license fee revenue associated with the license and marketing agreement signed in 1995 with Berlex and $2,904,297 of license fee revenue from Cytogen related to a license and marketing agreement signed in fiscal 2000. License fee revenues for the fiscal year ended September 30, 2002 were $4,020,617, consisting of $737,755 in revenue from Berlex and $3,282,862 in revenue from Cytogen.

	Years Ended September 30,			
	2003	2002	$ Change	% Change
Deferred license fee revenue recognized in connection with the Cytogen agreement	$ 2,904,297	$ 3,282,862	$ (378,565)	(12)%
Deferred license fee revenue recognized in connection with the Berlex agreement	737,755	737,755	—	0%
Total	$ 3,642,052	$ 4,020,617	$ (378,565)	(9)%

Royalty Revenue

Royalties for the fiscal year ended September 30, 2003 were $535,000 as compared to $725,000 in fiscal 2002. The reduction in royalties is primarily the result of lower sales to end users, primarily *Feridex I.V.* in Japan, due to increased competition in the marketplace. Our royalty revenues are entirely dependent on sales of our products by our marketing partners.

Product Sale Revenue

Product sale revenue consisted of the following:

	Years Ended September 30,			
	2003	2002	$ Change	% Change
Feridex I.V.	$ 337,440	$ 701,648	$ (364,208)	(52)%
GastroMARK	263,004	264,172	(1,168)	0%
Total	$ 600,444	$ 965,820	$ (365,376)	(38)%

This decrease is a result of the variable nature of our product sales to our marketing partners from period to period based on uneven purchasing patterns of our distributors and the batch size in which our products are manufactured and shipped.

Costs and Expenses

Cost of Product Sales

The cost of product sales for the fiscal year ended September 30, 2003 was $199,561 as compared to $214,357 for the fiscal year ended September 30, 2002. The cost of product sales for fiscal 2003 was less than in fiscal 2002 because of lower product sales overall. Cost of product sales as a percentage of product sales was 33% in fiscal 2003 compared with 22% for fiscal 2002. Our gross margins are dependent on the mix of customers and the product mix. The lower gross margin in fiscal 2003 is due to reduced sales of our higher gross margin product.

Research and Development Expenses

Research and development expenses for the fiscal year ended September 30, 2003 were $4,458,980 compared to $4,029,115 for the fiscal year ended September 30, 2002. The increase was primarily attributable to an increase in external research and development programs related to the clinical development of ferumoxytol in iron replacement therapy and MRA.

	Years Ended September 30,			
	2003	2002	$ Change	% Change
External Research and Development Expenses				
Ferumoxytol in Iron Replacement Therapy	$ 1,190,109	$ 851,979	$ 338,130	40%
Ferumoxytol in MRA	94,867	73,500	21,367	29%
Combidex	186,940	142,412	44,528	31%
Other external costs	209,169	321,574	(112,405)	(35)%
Total	$ 1,681,085	$ 1,389,465	$ 291,620	21%
Internal Research and Development Costs	2,777,895	2,639,650	138,245	5%
Total Research and Development Costs	$ 4,458,980	$ 4,029,115	$ 429,865	11%

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the fiscal year ended September 30, 2003 of $1,770,402 increased slightly when compared to fiscal 2002 expenses of $1,712,234.

	Years Ended September 30,			
	2003	2002	$ Change	% Change
Salaries, wages, payroll taxes and benefits	$ 984,435	$ 862,827	$ 121,608	14%
Professional fees	345,538	312,508	33,030	11%
Insurance costs	59,866	36,244	23,622	65%
Facilities and other	380,563	500,655	(120,092)	(24)%
Total	$ 1,770,402	$ 1,712,234	$ 58,168	3%

Other Income and Expenses

Other income and expenses were comprised of the following in the fiscal years ended September 30, 2003 and 2002:

	Years Ended September 30,			
	2003	2002	$ Change	% Change
Interest income	$ 38,880	$ 116,312	$ (77,432)	(67)%
Dividend income	73,850	139,616	(65,766)	(47)%
Gains on sale of marketable securities	3,342,648	1,837,245	1,505,403	82%
Losses on sale of marketable securities	(565,645)	(1,226,867)	661,222	(54)%
Write-down of marketable securities	(644,310)	(2,331,956)	1,687,646	(72)%
Other income	148,129	3,647	144,482	3962%
Total	$ 2,393,552	$ (1,462,003)	$ 3,855,555	(264)%

Interest and dividend income was $112,730 and net gains and losses on sales of securities were $2,777,003 for the fiscal year ended September 30, 2003 compared to $255,928 and $610,378, respectively, for the fiscal year ended September 30, 2002. Interest income for the fiscal year ended September 30, 2003 was $38,880 compared to $116,312 for the fiscal year ended September 30, 2002. Interest income decreased by $77,432 for the fiscal year ended September 30, 2003 as compared to the prior year due to lower interest rates on our money market account. Dividend income decreased by $65,766 for the fiscal year ended September 30, 2003 as compared to the prior year primarily due to a reduction in dividend-earning investments. Gains and losses on marketable securities fluctuated due to market changes as well as a shift in the composition of our security holdings. As of September 30, 2003, we no longer held any marketable securities. Fiscal 2003 results included a write-down of marketable securities in the first fiscal quarter of 2003 of $644,310 compared with a write-down of marketable securities in the fourth fiscal quarter of 2002 of $2,331,956.

Income Taxes

We received an income tax refund of $124,752 during the fiscal year ended September 30, 2003. This amount is 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. We had no income tax provision or benefit for the fiscal year ended September 30, 2002. We did not record any benefits associated with our deferred tax assets due to the uncertainties of their realizability.

Cumulative Effect of Accounting Change

For each of the years ended September 30, 2003 and September 30, 2002, we recognized $737,755 in revenue that was included in the cumulative effect adjustment as of October 1, 1999 due to our adoption of the guidance under SAB 101 (later revised as Staff Accounting Bulletin No. 104).

Net Income (Loss)

For the reasons stated above, in the fiscal year ended September 30, 2003, we recorded net earnings of $866,857 or $0.13 per basic share and $0.12 per diluted share; in the fiscal year ended September 30, 2002, we recorded a net loss of $(1,706,272), or $(0.26) per basic and diluted share.

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.

Prior to fiscal 2004, our investments consisted mainly of marketable securities classified as available-for-sale. Since the beginning of fiscal 2004, we have invested in short-term and long-term U.S. Treasury Notes classified as held-to-maturity. As of September 30, 2004, the maturities of these investments ranged from less than one month to less than seventeen months. In addition, we maintain our cash primarily in a money market mutual fund classified as a cash equivalent. A significant decline in value of this money market mutual fund would result in a substantial reduction in our total assets and cash available for daily operations. We have limited insurance protection for this money market account available through the Securities Investor Protection Corporation, also known as SIPC.

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

	Years Ended September 30,			
	2004	2003	$ Change	% Change
Cash and cash equivalents	$ 9,391,363	$ 23,901,126	$ (14,509,764)	(61)%
Short-term investment	4,942,915	—	4,942,915	—
Subtotal	14,334,278	23,901,126	(9,566,848)	(40)%
Long-term investment	4,768,159	—	4,768,159	—
Total cash, cash equivalents and investments	$ 19,102,437	$ 23,901,126	$ (4,798,689)	(20)%

The decrease in cash and cash equivalents during the period ended September 30, 2004 is primarily the result of the purchase of our short-term and long-term investments and the funding of operating activities. The decrease in total cash, cash equivalents and investments in the period ended September 30, 2004 is primarily the result of cash used to fund operating activities. We believe that our cash, cash equivalents, short and long-term investments as of September 30, 2004, combined with cash received from anticipated future sales in fiscal year 2005, will be sufficient to cover our future operating cash flow needs, including the increase in research and development costs related to Phase III clinical trials for ferumoxytol in iron replacement therapy, for at least eighteen months. In order to fund our longer-term cash flow needs, if necessary, we will consider from time to time various financing alternatives, including possible future strategic partnerships or additional equity or debt financing. These financing arrangements may not be available to us on acceptable terms, if at all.

At September 30, 2003, our cash and cash equivalents totaled $23,901,126, compared with $8,557,819 at September 30, 2002. We had no marketable securities at September 30, 2003 compared to $9,011,325 at September 30, 2002. The increase in cash and cash equivalents was the result of a financing completed in July 2003 which resulted in net proceeds of $9,484,999 to us, and the sale of all

of our marketable securities, which was partially offset by cash used of $4,932,070 in our operating activities in fiscal year 2003.

On October 12, 2004, we filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission, also known as the SEC. Under this registration statement, we may offer and sell, from time to time, up to $50,000,000 of common stock, preferred stock and warrants. 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 the 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 bonds, or other interest-bearing investments. This registration statement has not yet been declared effective by the SEC and there is no assurance that sales of securities will be made pursuant to the registration statement. The securities may not be sold nor may offers to buy be accepted prior to the time the registration statement becomes effective. This Annual Report on Form 10-K does not constitute an offer to sell or the solicitation of an offer to buy the securities. The offering of the securities will be made only by means of a prospectus. In addition, this Annual Report on Form 10-K 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.

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 associated with our investments in various U.S. Treasury Notes. Cash used in operating activities during the fiscal year ended September 30, 2004 included $7,893,251 paid to suppliers and employees primarily in connection with our operating and research and development activities. Cash received from customers increased in the fiscal year ended September 30, 2004 as a result of increased collections from prior trade accounts receivable. In addition, interest income increased in the fiscal year ended September 30, 2004 as a result of the increase in our interest-bearing investments. These increases were offset by an increase in fiscal year 2004 in cash paid to suppliers principally due to cash outlays for regulatory fees, insurance payments and manufacturing supplies, and a reduction in royalties received as a result of increased competition in the marketplace. The increase in accounts payable and accrued expenses in fiscal year 2004 is mainly associated with billings from clinical development providers and sites. We expended approximately $420,000 in fiscal year 2004 in connection with the purchase of the remaining inventory from a supplier exiting the business. We do not expect inventory purchases to continue at this increased level. We also expended approximately $220,000 in connection with the pre-payment of our insurance obligations which were recorded in the fiscal year ended September 30, 2004. 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 and expected increases in selling, general and administrative expenses, including costs related to compliance with new corporate governance requirements and additional insurance obligations. Subsequent to September 30, 2004, we paid approximately $476,000 for the renewal of a fiscal year 2005 government license; approximately $173,000 of this payment was reimbursed to us from distributors, in the first quarter of fiscal year 2005, in accordance with existing contractual arrangements.

Net cash used in operating activities was $4,932,070 in the fiscal year ended September 30, 2003 compared to net cash used in operating activities of $4,160,348 in the fiscal year ended September 30, 2002. Cash received during the fiscal year ended September 30, 2003 included $514,675 from customers, $641,743 from royalties and $112,730 from dividend and interest income. Cash used in operating activities during the fiscal year ended September 30, 2003 included $6,474,099 paid to

suppliers and employees. Cash used in operating activities increased in fiscal 2003 principally due to a decrease in royalties and product sales and an increase in research and development expenditures.

We expect to incur continued research and development expenses, including costs related to clinical studies, and other costs, in order to commercialize products based on our core superparamagnetic iron oxide nanoparticle technology, including ferumoxytol as an iron replacement therapeutic and as an MRA contrast agent. We estimate we may incur up to approximately $13,600,000 of external costs over the next eighteen months associated with clinical trial studies. 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 in the future. 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, if at all. If we are unable to fund our future research and development expenses out of product sales, working capital or sales of equity securities in the manner we anticipate, we could be forced to obtain alternative sources of financing, seek other alternatives or to curtail our development activity.

Cash used in investing activities was $9,364,002 in the fiscal year ended September 30, 2004 compared with cash provided by investing activities of $10,570,086 and $941,870 in the fiscal years ended September 30, 2003 and 2002, respectively. 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. Cash provided by investing activities in the fiscal year ended September 30, 2002 included proceeds from the sale of marketable securities of $6,728,059, offset by the purchase of marketable securities of $5,733,208.

Capital expenditures of $201,484 and $167,089 in the fiscal years ended September 30, 2004 and 2003, respectively, related primarily to the continuation of our efforts to upgrade production and computer equipment. We expect future expenditures to increase as we continue our manufacturing scale-up of ferumoxytol. Capital expenditures of $36,934 in the fiscal year ended September 30, 2002 related to the continuation of our efforts to upgrade laboratory, production and computer equipment.

Cash provided by financing activities from the issuance of our common stock as a result of the cash exercise of stock options and purchases under our employee stock purchase plan during the fiscal years ended September 30, 2004 and 2003 was $1,080,148 and $220,292, respectively. Cash provided by financing activities was $9,705,291 from the issuance of our common stock during the fiscal year ended September 30, 2003. This amount included $185,532 for the exercise of stock options by employees, $34,760 for the purchase of common stock under our 2003 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. Cash provided by financing activities was $34,436 from the issuance of our common stock during the fiscal year ended September 30, 2002. No cash was used in financing activities during the fiscal years ended September 30, 2004, 2003 and 2002.

Our future capital requirements will depend on many factors, including, but not limited to:

- our ability to establish additional development and marketing arrangements or to raise additional capital, through other financing activities in order to provide funding to support our research and development activities, including the conduct of clinical trials and efforts to obtain regulatory approvals;
- progress with clinical trials for our therapeutic and diagnostic products;
- the magnitude of our development programs;

- the time involved in obtaining regulatory approvals;
- the magnitude of product sales;
- competing technological and market developments; and
- the costs involved in filing, prosecuting and enforcing patent claims.

Contractual Obligations

We currently have no long-term debt obligations, capital lease obligations, purchase obligations or other long-term liabilities. Future lease and purchase order commitments and obligations, as of September 30, 2004, 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	$ 59,000	$ 37,000	$ 22,000	$ —	$ —
Purchase Order Commitments	101,000	101,000	—	—	—
Total	$ 160,000	$ 138,000	$ 22,000	$ —	$ —

Operating Lease Obligations

We lease certain office equipment and one vehicle under several agreements that expire in 2005 and 2006.

Purchase Order Commitments

We entered into an agreement with an FDA-approved manufacturer to reserve manufacturing capacity in exchange for payments amounting to approximately $101,000, which we are committed to paying in the first quarter of fiscal year 2005. This amount is included in the table above.

Royalty Commitments

We also 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. and Schering AG that require us to make payments in accordance with these agreements upon the attainment of particular milestones relating to *Feridex I.V.* and *GastroMARK*. We are required under those agreements 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 2004, 2003 or 2002. Future milestone payments under these agreements are not to exceed $400,000. Royalty payments under these agreements were less than $105,000 for each of the prior three fiscal years.

Other

In each of November and December 2004, we paid liquidated damages of approximately $43,000 as a result of our failure to meet certain contractual obligations, such failure which was subsequently remedied. There is no assurance that we will not be obligated to pay additional liquidated damages if we fail to meet our contractual obligations in the future.

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 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 and royalties, 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.

Revenue recognition associated with royalties. We receive royalty revenues under license and marketing agreements with several companies that sell our products. The license agreements provide for the payment of royalties to us based on sales of the licensed product. We record these revenues based on estimates of the sales that occurred during the relevant period. The relevant period estimates of sales are based on interim data provided by licensees and analysis of historical royalties paid to us (adjusted for any changes in facts and circumstances, as appropriate). We maintain regular communication with our licensees in order to gauge the reasonableness of our estimates. Differences between actual royalty revenues and estimated royalty revenues are reconciled and adjusted for in the period which they become known, typically the following quarter. Historically, adjustments have not been material based on actual amounts paid by licensees. There are no future performance obligations on our part under these license agreements. Under this policy, revenue can vary due to factors such as resolution of royalty disputes and arbitration. Royalty revenue is not recognized in any circumstances unless collectibility is reasonably assured.

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 at September 30, 2004, 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 Notes 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 March 2004, the Financial Accounting Standards Board, also known as the FASB, issued a proposed Statement, "Share-Based Payment", that addresses the accounting for share-based payment transactions in which an enterprise receives employee 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. The proposed Statement would eliminate the ability to account for share-based compensation transactions using Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees", also known as APB 25, and generally would require instead that such transactions be accounted for using a fair-value-based method. In October 2004, the FASB delayed the effective date of its proposed Statement, "Share-Based Payment". The proposed Statement's effective date would be applicable for awards that are granted, modified, or settled in cash in interim or annual periods beginning after June 15, 2005. The FASB recently decided to include in the proposed Statement two transition methods: one that provides for prospective application and one that provides for retrospective application.

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 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 testing and clinical trials are subject to varying interpretations, which can delay, limit or prevent regulatory approval by the U.S. Food and Drug Administration, also known as 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. Exploratory Phase II clinical trials of ferumoxytol for use as a contrast agent in magnetic resonance angiography, also known as MRA, are currently ongoing. Before applying for FDA approval to market ferumoxytol, large-scale Phase III human clinical trials that demonstrate the safety and efficacy of ferumoxytol to the satisfaction of the FDA and other regulatory authorities must be completed. These clinical trials, and the support from third-party contractors 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 or, if completed, we may not be able to obtain regulatory approval or obtain regulatory approval of the desired scope. Any deficiency in the design of our clinical studies, or oversight by us, could delay or prevent us from obtaining regulatory approval and could significantly increase the costs of such clinical trials. In addition, slow enrollment, unexpected results from our clinical sites or inadequate performance by third-party service providers, among other factors, could also delay regulatory approval and increase costs associated with obtaining such approval.

In June 2000, we received an approvable letter, subject to certain conditions, for Combidex®, our investigational molecular imaging agent consisting of iron oxide nanoparticles for use in conjunction with MRI to aid in the differentiation of cancerous from non-cancerous lymph nodes. In September 2004, we submitted a complete response to the approvable letter, which was accepted by the FDA, and assigned a user fee goal date of March 30, 2005. Despite the FDA's acceptance of the complete response, the FDA could respond to this submission by issuing an additional approvable letter with further conditions for approval or the FDA could issue a not approvable letter. If the FDA imposes additional conditions to approval, *Combidex* may not be approved for the indication we are seeking. If we are unable to obtain approval for this application or if the FDA requires labeling that imposes limitations on the use of *Combidex*, our partners' ability to market the product to the medical community may be hindered. In addition, we have no assurance that the FDA will act by the user fee goal date of March 30, 2005. Any failure to successfully market and sell *Combidex* or delay in these efforts, would reduce the amount of cash generated from operations available to fund research and development or other activities which could force us to seek other financing alternatives.

We may also be required to demonstrate that ferumoxytol represents an improved form of treatment over existing therapies or diagnostics in order to receive regulatory approval and we may be unable to do so without conducting further clinical studies, if at all. These types of clinical trials could be significantly large and expensive studies. If we are unable to fund any of our clinical studies with

cash generated from operations, we may need to seek other sources of financing which may not be available on acceptable terms, if at all. If we are unable to obtain such alternate financing, we may be forced to curtail our development activities.

Final regulatory approvals may not be obtained for *Combidex* or ferumoxytol or any other products developed by us. Failure to obtain requisite 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 products or limit the commercial use of our products. Alternatively, regulatory approvals may entail limitations on the indicated uses of our products and impose labeling requirements which may also adversely impact our ability to market our products.

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 partnerships 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 U.S. and in foreign countries, and we depend on these strategic partners for a significant portion of our revenue. Three companies were responsible for approximately 95% of our revenue during the fiscal year ended September 30, 2004. Berlex Laboratories, Inc. represented approximately 20% of our revenue, Guerbet represented approximately 20% of our revenue, and Cytogen Corporation, or Cytogen, represented approximately 55% of our revenue in the fiscal year ended September 30, 2004, respectively, all of which constituted recognition of deferred revenue. A decrease in revenue from any of our significant marketing and 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 harmed. In addition, we might incur additional 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 breach its agreement with us or otherwise fail to perform, such event could impair our revenue and impose on us additional costs. 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 could delay our product development or impair commercialization of our products.

Due to the high cost of our research and development activities, in particular the anticipated cost of clinical trials for ferumoxytol in iron replacement therapy, our inability to secure strategic partners 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, 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 would reduce our potential revenues. In addition, if, in the future, we are unable to enter into collaborative agreements related to ferumoxytol, 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, if necessary, 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 severely impaired.

We cannot predict the results and progress of our clinical trials for ferumoxytol and our ability to complete the development of ferumoxytol is uncertain.

The development of new pharmaceutical products is highly uncertain and subject to a variety of inherent risks of failure. For example, our products 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 any of our product candidates, we must demonstrate through extensive pre-clinical testing and human clinical trials that the product is safe and efficacious. If our products fail in human clinical trials, we will be unable to obtain regulatory approval for, and market, our products, thereby reducing our potential future revenues. For example, although we have received promising results from pre-clinical testing and early clinical trials of ferumoxytol, these results may not be predictive of results obtained in subsequent 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 clinical trials for ferumoxytol will demonstrate sufficient safety and efficacy to obtain regulatory approvals.

The completion rate of our clinical trials also depends on patient enrollment. We rely on third-party clinical trial sites to find suitable patients for our clinical trial programs for ferumoxytol. 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. Such a delay could result in an increase in development costs for ferumoxytol, a delay in making regulatory submissions and a delay in the commercialization of our products. 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 or approvals by the FDA. Any unexpected results from our clinical sites could hinder our ability to complete the studies in a timely manner, if at all, which could result in increased costs associated with the ferumoxytol development program and negatively impact our ability to obtain FDA approval.

Clinical testing of pharmaceutical products is itself subject to approvals by various governmental regulatory authorities. We conduct our clinical trials in accordance with specific protocols, which are filed with the FDA or other relevant authorities. We may not be permitted by regulatory authorities to commence or continue clinical trials. Any delays in, or termination of, our clinical trial efforts for ferumoxytol could negatively affect our future prospects and stock price. In addition, if the FDA requires us to perform additional studies for our product candidates, we could incur significant additional costs and experience significant delays in our efforts to complete our clinical trials. This could also result in delays in our ability to make regulatory submissions and delays in the commercialization of our products.

In addition, although we have dedicated significant resources to our research and development efforts, we may not be successful in finding new applications for our technology or in expanding the indications for our current products or product candidates for development into future product candidates.

As a result of these and other risks and uncertainties, our development program for ferumoxytol may not be completed successfully. Any delays or failures in the development of ferumoxytol will delay or prevent generation of revenue from such product candidate and may damage our ability to become profitable.

The successful completion of our clinical trials for ferumoxytol depends, in part, on the performance of third-party service providers.

We rely on third-party contract research organizations for a variety of activities in our ferumoxytol 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 ferumoxytol development program for clinical laboratory testing and randomization of clinical trial subjects. The estimated cost of the external efforts necessary to complete development of ferumoxytol as an iron replacement therapeutic, including costs related to services provided by third-party contract research organizations and service providers, is currently estimated to range from approximately $15,000,000 to $17,000,000. If any of these third-party contractors 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. Such delays could also result in increased costs associated with the ferumoxytol development program in iron replacement therapy. Any delay in, or failure to obtain regulatory approval of ferumoxytol would significantly impair our ability to generate future revenues from product sales.

We may 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. In particular, we anticipate that the significant increase in our research and development activities over the next eighteen months due to the conduct of Phase III clinical studies for ferumoxytol in iron replacement therapy will cause an appreciable increase in our cash-burn rate. We estimate that our existing cash resources will be sufficient to finance our operations at current and projected levels of development and general corporate activity for at least the next eighteen months. Thereafter, we may require additional funds to continue our research and development activities, in particular the continued development of ferumoxytol in iron replacement therapy, to prepare for submission for regulatory approval for ferumoxytol in iron replacement therapy, to conduct future clinical trials for ferumoxytol in MRI, to expand commercial-scale manufacturing capabilities and to market and sell our products. We may seek such financing through arrangements with collaborative partners or through public or private equity or debt financings. We may not be able to obtain financing on acceptable terms, if at all. Any additional equity financings could be dilutive to our stockholders. In addition, the terms any debt financing could greatly restrict our ability to raise additional capital and may provide rights and preferences to such investors which are not available to current stockholders. If adequate additional funds are not available to us in the long-term, we may be required to curtail significantly one or more of our research and development programs or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain of our products or product candidates on terms that we might otherwise find unacceptable.

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 *Combidex* or ferumoxytol in any specific foreign country, we and our marketing partners will be unable to sell these products 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 *Combidex* or ferumoxytol, or any other products developed by us, in foreign jurisdictions. 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 products or limit the commercial use of our products in these foreign jurisdictions. Alternatively, foreign regulatory approvals may entail limitations on the indicated uses of our products and impose labeling requirements which may also adversely impact our ability to market our products.

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 and manufacturing and quality control personnel, including our Chief Executive Officer, Jerome Goldstein. 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 manner, could be hindered and our product sales and development efforts delayed. If we are unable to attract and retain qualified scientific and technical personnel for the research and development activities conducted or sponsored by us, and we lose the services of these employees as a result, our product development efforts could be delayed or curtailed. 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. 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 research and development projects.

An inability to obtain raw materials and our reliance on a sole source supplier 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. This may require repeated testing of the alternative 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. 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. 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 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.

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. *Feridex I.V.* and *GastroMARK*, approved in 1996 and 1997, respectively, represented an alternative technology platform for physicians to adopt. *Feridex I.V.* sales have decreased from their peak based on changes in magnetic resonance imaging, also known as MRI, technology and competition in the market. *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, may 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.

We lack marketing and sales experience.

We have limited experience in marketing and selling our products and product candidates 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 any product candidate approved by the FDA for which we do not have a marketing partner, 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 any of our product candidates 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 acceptable to us, if at all. If we fail to raise the necessary capital, or choose not to market and sell our product candidates 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 our products ourselves or through marketing and sales arrangements, we, or our corporate partners, may not be successful in marketing and selling our products.

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 delay in approving or its refusal to approve a product, 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 operating results may fluctuate so you should not rely on a good or bad quarter to predict how we will perform over time.

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

- the timing of our recognition of deferred revenue, which is affected by the performance of our obligations under our license agreements,

- the timing of external research and development expenses, which may fluctuate from quarter to quarter,
- the timing and likelihood of FDA approval of *Combidex* or ferumoxytol,
- market acceptance of *Combidex* or ferumoxytol, if approved,
- the variable nature of our products 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, 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, 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.

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 the implementation of effective marketing campaigns by us or our marketing and distribution partners, development of efficacious products, timely receipt of regulatory approvals and product manufacturing at commercially acceptable costs. 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, 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 may not be able to successfully complete Phase III clinical trials for ferumoxytol for iron replacement therapy, or, if completed, may not be able to obtain regulatory approval. In addition, although we believe ferumoxytol will present benefits over existing products in the iron replacement therapy market, this market is highly sensitive to several factors including, but not limited to, reimbursement, price competitiveness and product characteristics such as perceived safety profiles and dosing regimens. Competing iron replacement therapy products may receive greater market acceptance than ferumoxytol.

Market acceptance of both MRI as an appropriate technique for imaging the lymphatic system and cardiovascular imaging, and the use of our products as part of such imaging, is critical to the success of our contrast agent products. For example, many cardiovascular imaging procedures are currently being performed using other imaging modalities, such as x-ray, computed tomography, also known as CT, and other imaging methods. In addition, many contrast-enhanced MRA procedures are currently conducted with gadolinium-based contrast agents which are not specifically approved for use in MRA. Although we believe that ferumoxytol offers advantages over competing MRI contrast agents and contrast agents

used in other imaging modalities, 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 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, and ferumoxytol for use in human clinical trials, in our manufacturing facility. Pending FDA approval, we intend to manufacture *Combidex* formulated drug product 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 obtain or retain 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 are currently testing scale-up for production of ferumoxytol, some aspects of our manufacturing processes may not be easily scalable to allow for production in larger volumes, resulting in 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 this product. 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.

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 $8.00 and $16.43 in the fifty-two week period prior to December 8, 2004. The stock market has from time to time experienced extreme price and volume fluctuations, particularly in the biotechnology 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. In addition, sales of a substantial number of shares of our common stock by stockholders could adversely affect the market price of our shares. As of December 8, 2004, our shares had an average 90 calendar day trading

volume of approximately 11,000 shares. Bulk sales or purchases of our stock in a short period of time could cause the market price for our shares to decline or fluctuate drastically.

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 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 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 any of these legislative or regulatory proposals, if the government or a private third-party payor adopts these proposals they could limit our ability to price our products at desired levels.

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 of 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.

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 in clinical trials and commercial use. However, coverage is becoming increasingly expensive and costs will continue to increase significantly, particularly as our Phase III clinical trial activities for ferumoxytol 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 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, these substances could adversely affect the value and the ability to transfer or encumber the property.

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

In the fiscal year ended September 30, 2004, we acquired a significant amount of short-term and long-term investments consisting of U.S. Treasury Notes classified as held-to-maturity which are, as a result, recorded at amortized cost. As of September 30, 2004, the maturities of these investments ranged from less than one month to less than seventeen months. Although we anticipate holding these investments until they mature, 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, 2004, we estimate that the fair value of our investments would decline by an immaterial amount.

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 Item 8 are as follows:

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, 2004 and September 30, 2003, and the results of its operations and its cash flows for each of the three years in the period ended September 30, 2004 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
November 26, 2004

Advanced Magnetics, Inc.

Balance Sheets

	September 30,	
	2004	2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 9,391,363	$ 23,901,126
Short-term investment	4,942,915	—
Accounts receivable—trade	49,575	366,261
Inventories	473,038	267,761
Prepaid expenses and interest receivable	586,584	464,452
Other assets	—	761,747
Total current assets	15,443,475	25,761,347
Property, plant and equipment:		
Land	360,000	360,000
Buildings and improvements	4,660,972	4,628,295
Laboratory equipment	7,018,563	6,933,871
Furniture and fixtures	877,666	793,552
Total property, plant and equipment	12,917,201	12,715,718
Less—accumulated depreciation	(9,318,224)	(9,111,452)
Net property, plant and equipment	3,598,977	3,604,266
Long-term investment	4,768,159	—
Total assets	$ 23,810,611	$ 29,365,613
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 466,936	$ 118,282
Accrued expenses	817,276	601,616
Deferred revenue	1,845,509	2,461,971
Total current liabilities	3,129,721	3,181,869
Long-term liabilities:		
Deferred revenue	3,134,435	5,265,669
Total liabilities	6,264,156	8,447,538
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, authorized 15,000,000 shares; issued and outstanding 7,949,931 shares at September 30, 2004 and 7,758,107 shares at September 30, 2003	79,499	77,581
Additional paid-in capital	54,741,302	53,619,640
Accumulated deficit	(37,274,346)	(32,779,146)
Total stockholders' equity	17,546,455	20,918,075
Total liabilities and stockholders' equity	$ 23,810,611	$ 29,365,613

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

Advanced Magnetics, Inc.

Statements of Operations

	For the years ended September 30,		
	2004	2003	2002
Revenues:			
License fees	$ 2,747,695	$ 3,642,052	$ 4,020,617
Royalties	240,000	535,000	725,000
Product sales	768,189	600,444	965,820
Total revenues	3,755,884	4,777,496	5,711,437
Costs and expenses:			
Cost of product sales	117,015	199,561	214,357
Research and development expenses	6,083,839	4,458,980	4,029,115
Selling, general and administrative expenses	2,219,777	1,770,402	1,712,234
Total costs and expenses	8,420,631	6,428,943	5,955,706
Other income (expense):			
Interest and dividend income	169,547	112,730	255,928
Gains and losses on sales of securities	—	2,777,003	610,378
Write-down of marketable securities	—	(644,310)	(2,331,956)
Other income, net	—	148,129	3,647
Total other income (expense)	169,547	2,393,552	(1,462,003)
Income (loss) before provision for (benefit from) income taxes	(4,495,200)	742,105	(1,706,272)
Benefit from income taxes	—	(124,752)	—
Net income (loss)	$ (4,495,200)	$ 866,857	$ (1,706,272)
Earnings (loss) per share:			
Basic	$ (0.57)	$ 0.13	$ (0.26)
Diluted	$ (0.57)	$ 0.12	$ (0.26)
Weighted average shares outstanding used to compute earnings (loss) per share:			
Basic	7,817,918	6,914,324	6,636,798
Diluted	7,817,918	7,143,455	6,636,798

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,		
	2004	2003	2002
Net income (loss)	$ (4,495,200)	$ 866,857	$ (1,706,272)
Other comprehensive income:			
Unrealized gains (losses) on securities	—	1,791,830	(935,927)
Reclassification adjustment for (gains) losses included in net income	—	(2,132,694)	1,721,578
Total other comprehensive income (loss)	—	(340,864)	785,651
Comprehensive income (loss)	$ (4,495,200)	$ 525,993	$ (920,621)

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

Advanced Magnetics, Inc.

Statements of Stockholders' Equity

	Common Stock		Additional Paid-in Capital	Retained Earnings (Deficit)	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance at September 30, 2001	6,633,895	$ 66,339	$ 43,830,473	$ (31,939,731)	$ (444,787)	$ 11,512,294
Shares issued in connection with the exercise of stock options	3,000	30	9,151	—	—	9,181
Shares issued in connection with employee stock purchase plan	7,747	77	25,178	—	—	25,255
Non-cash expense associated with stock options	—	—	24,158	—	—	24,158
Other comprehensive income	—	—	—	—	785,651	785,651
Net loss	—	—	—	(1,706,272)	—	(1,706,272)
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

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

Advanced Magnetics, Inc.

Statements of Cash Flows

	For the years ended September 30,		
	2004	2003	2002
Cash flows from operating activities:			
Cash received from customers	$ 1,099,481	$ 514,675	$ 1,103,044
Cash paid to suppliers and employees	(7,893,251)	(6,474,099)	(6,189,861)
Dividends and interest received	337,556	112,730	226,208
Royalties received	230,304	641,743	700,261
Income taxes refund	—	124,752	—
Other income	—	148,129	—
Net cash used in operating activities	(6,225,910)	(4,932,070)	(4,160,348)
Cash flows from investing activities:			
Proceeds from sales of marketable securities	—	12,094,579	6,728,059
Life insurance policy surrender value received	761,747	—	—
Proceeds from maturities of short-term investments	38,842,143	—	—
Purchase of marketable securities	—	(1,291,425)	(5,733,208)
Purchase of investments	(48,766,408)	—	—
Capital expenditures	(201,484)	(167,089)	(36,934)
Proceeds from sale of fixed assets	—	—	48,000
Increase in other assets	—	(65,979)	(64,047)
Net cash provided by (used in) investing activities	(9,364,002)	10,570,086	941,870
Cash flows from financing activities:			
Proceeds from the cash exercise of stock options	1,011,941	185,532	9,181
Proceeds from the issuance of common stock under the Employee Stock Purchase Plan	68,207	34,760	25,255
Net proceeds from the issuance of common stock and warrants to purchase common stock	—	9,484,999	—
Net cash provided by financing activities	1,080,148	9,705,291	34,436
Net increase (decrease) in cash and cash equivalents	(14,509,764)	15,343,307	(3,184,042)
Cash and cash equivalents at beginning of year	23,901,126	8,557,819	11,741,861
Cash and cash equivalents at end of year	$ 9,391,363	$ 23,901,126	$ 8,557,819
Supplemental data:			
Non-cash operating activities:			
Stock dividend received	$ —	$ 29,720	$ —
Non-cash financing activities:			
Non-cash stock option exercises	$ 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,		
	2004	2003	2002
Net income (loss)	$ (4,495,200)	$ 866,857	$ (1,706,272)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Depreciation	206,772	205,678	88,423
Gains of disposal of property, plant and equipment	—	—	(3,647)
Non-cash expense associated with stock options	43,432	36,524	24,158
Net realized gains on sales of marketable securities	—	(2,777,003)	(610,378)
Write-down of marketable securities	—	644,310	2,331,956
Stock dividend received	—	—	(29,720)
Amortization of premium on purchased securities	213,191	—	—
Changes in operating assets and liabilities:			
Accounts receivable—trade	316,686	(160,776)	112,485
Inventories	(205,277)	(135,089)	(45,251)
Prepaid expenses and interest receivable	(122,132)	(78,245)	(219,464)
Accounts payable and accrued expenses	564,313	255,855	(82,021)
Deferred revenue	(2,747,695)	(3,642,052)	(4,020,617)
Other assets—short term	—	(761,747)	—
Other assets—long term	—	613,618	—
Total adjustments	(1,730,710)	(5,798,927)	(2,454,076)
Net cash used in operating activities	$ (6,225,910)	$ (4,932,070)	$ (4,160,348)

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

Notes to 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 cardiovascular disease and cancer.

We are subject to risks common to companies in the industry including, but not limited to, uncertainty of product development and commercialization, dependence on key personnel and collaborative relationships, 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 Notes having an original maturity of less than three months. Substantially all of the cash and cash equivalents at September 30, 2004 and 2003 were held in a either a commercial bank and/or money market account. In addition, we classify our holdings of U.S. Treasury Notes 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, 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, 2004, our short-term investments consisted of a U.S. Treasury Note with a maturity date of January 31, 2005 and our long-term investment consisted of a U.S. Treasury Note with a maturity date of February 15, 2006. Our short-term and long-term investments are classified as held-to-maturity and, as a result, are recorded at amortized cost. We held no short-term or long-term investments or marketable securities as of September 30, 2003. 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 "Other comprehensive income (loss)." Interest income is accrued as earned. Dividend income is accrued on the ex-dividend date, and net realized gains and losses are computed on the basis of average cost and are recognized when realized.

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.

Revenue Recognition

Product revenue is recognized upon shipment to the customer and satisfaction of all obligations. Royalty revenue is recognized as the related product sales are recognized. 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.

At September 30, 2004 and 2003 we had no allowance for doubtful accounts.

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 SFAS No. 123

"Accounting for Stock Issued to Employees", also known as SFAS 123, for disclosure purposes only. The SFAS 123 disclosures include pro forma net income and earnings 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 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, 2004, 2003 and 2002 would have been as follows:

	For the years ended September 30,		
	2004	2003	2002
Reported net income (loss)	$ (4,495,200)	$ 866,857	$ (1,706,272)
Pro forma stock compensation expense	(629,424)	(330,817)	(297,244)
Pro forma net income (loss)	$ (5,124,624)	$ 536,040	$ (2,003,516)
Reported earnings (loss) per share:			
Basic	$ (0.57)	$ 0.13	$ (0.26)
Diluted	$ (0.57)	$ 0.12	$ (0.26)
Pro forma earnings (loss) per share:			
Basic	$ (0.66)	$ 0.08	$ (0.30)
Diluted	$ (0.66)	$ 0.08	$ (0.30)

The fair value of each option granted during 2004, 2003 and 2002 was estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions: (1) expected life of 6.0 years in 2004, 2003 and 2002; (2) expected volatility of 69.9% in 2004, and 64.1% in 2003 and 2002 and (3) weighted average risk-free interest rates of 3.64% in 2004, 3.42% in 2003, and 4.26% in 2002; 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 years ended September 30, 2004, 2003 and 2002 was $7.78, $3.74 and $2.24 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.

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. We had other income of $3,647 in the year ended September 30, 2002 as a result of gains from the sale of certain capital assets.

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 equivalents, investments and accounts receivable. As of September 30, 2004, our cash, cash equivalents, short and long term investments amounted to $19,102,437 of which $17,702,062 were invested in U.S. Treasury Notes. We currently invest our excess cash primarily in deposits in one commercial bank and money market mutual 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 magnetic resonance imaging, also known as MRI. We perform ongoing credit evaluations of our customers and generally do not require collateral. Three companies, Cytogen Corporation, or Cytogen, Guerbet and Berlex Laboratories, Inc., or 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. Three companies, Cytogen, Berlex and Guerbet, accounted for 58%, 20% and 11%, respectively, of our revenues in fiscal 2002. No other company accounted for more than 10% of our total revenues in fiscal 2004, 2003 or 2002. All of the revenue attributable to Cytogen and a significant portion of the revenue attributable to Berlex in fiscal 2004, fiscal 2003 and fiscal 2002 was previously deferred revenue related to up-front license fees.

In fiscal 2004, 2003 and 2002, revenues from customers and licensees outside of the United States, principally in Europe and Japan, amounted to 21%, 13% and 20%, 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.

Earnings (Loss) per Share

We compute basic earnings (loss) per share by dividing net income (loss) by the weighted average number of common shares outstanding during the respective period. We compute diluted earnings per share by dividing net income by the sum of weighted average common shares outstanding and common stock equivalents during the respective period. Common stock equivalents consist of the net common shares issuable upon the exercise of in-the-money stock options under the treasury stock method.

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

	For the Years ended September 30,		
	2004	2003	2002
Net income (loss) (A)	$ (4,495,200)	$ 866,857	$ (1,706,272)
Weighted average common shares outstanding (B)	7,817,918	6,914,323	6,636,798
Common stock equivalents	—	229,132	—
Sum of weighted average common shares outstanding and common stock equivalents (C)	7,817,918	7,143,455	6,636,798
Earnings (loss) per share:			
Basic (A/B)	$ (0.57)	$ 0.13	$ (0.26)
Diluted (A/C)	$ (0.57)	$ 0.12	$ (0.26)

Options to purchase a total of 854,366 and 763,097 shares of common stock that were outstanding for fiscal 2004 and 2002, respectively, were excluded from the computation of diluted earnings (loss) per share because such options were anti-dilutive as we had a net loss in these fiscal years. Warrants to purchase 261,780 shares of common stock at an exercise price of $15.50 were excluded from the computation of diluted earnings (loss) per share for the year ended September 30, 2004 because such warrants were anti-dilutive as we incurred a net loss in this fiscal year; in addition, these warrants were not included in the computation of diluted net earnings per share for the year ended September 30, 2003, because they were out-of-the-money.

Reclassifications

Certain amounts from the prior fiscal years have been reclassified to conform to the current year's presentation.

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, 2004, 2003 and 2002, 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, 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. Our short-term and long-term investments have been classified as held-to-maturity and, as a result, are recorded at amortized cost. We held no short-term or long-term investments or marketable securities as of September 30, 2003.

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. During the year ended September 30, 2002, gross realized gains and gross realized losses on the sale of marketable securities were $1,837,245 and $1,226,867, respectively, resulting in a net realized gain of $610,378.

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. In fiscal 2002 we determined that the decline in the carrying value of Cytogen common stock below its cost basis was an other-than-temporary decline and recorded a $1,692,800 write-down of the shares in fiscal 2002, to a new cost basis at September 30, 2002 of $294,400. In fiscal 2002, we also determined that the decline in the carrying value of two other securities below their original basis was an other-than-temporary decline and recorded a $639,156 write-down of such shares to a new cost basis.

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

	For the years ended September 30,		
	2004	2003	2002
Interest income	$ 169,547	$ 38,880	$ 116,312
Dividend income	—	73,850	139,616
Total	$ 169,547	$ 112,730	$ 255,928
Net gains on sales of securities	—	$ 2,777,003	$ 610,378
Write-down of marketable securities	—	$ (644,310)	$ (2,331,956)

D. Inventories:

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

	2004	2003
Raw materials	$ 404,001	$ 267,761
Work in process	21,837	—
Finished goods	47,200	—
Total inventories	$ 473,038	$ 267,761

The aggregate amount of overhead charged to and remaining in inventory as of September 30, 2004 was $31,591.

E. Current and Long-Term Liabilities:

Accrued expenses consist of the following at September 30:

	2004	2003
Clinical trials	$ 390,544	$ 226,098
Professional fees	207,000	141,501
Salaries and other compensation	176,482	208,767
License and royalty fees	16,500	15,000
Other	26,750	10,250
Totals	$ 817,276	$ 601,616

Deferred revenue consisted of the following at September 30, 2004 and 2003:

	Cytogen	Berlex	Total
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
At September 30, 2003			
Short term	$ 1,724,216	$ 737,755	$ 2,461,971
Long term	1,393,480	3,872,189	5,265,669
Total	$ 3,117,696	$ 4,609,944	$ 7,727,640

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 2004 nor 2002. 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,		
	2004	2003	2002
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	3.39%	(2.90)%	1.70%
Tax refund	—	(16.80)%	
Valuation allowance	(43.69)%	(37.40)%	(42.00)%
Total	0.00%	(16.80)%	0.00%

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

	2004	2003	2002
Assets			
Net operating loss carry-forwards	$ 12,623,394	$ 9,890,625	$ 8,398,229
Research and experimentation tax credit carry-forward	3,832,541	3,622,578	3,357,280
Deductible intangibles	49,310	59,511	69,713
Deferred revenue	2,005,424	3,111,921	4,578,575
Write-down of marketable securities	—	—	2,815,580
Capital loss carry-forward	1,034,055	1,034,055	—
Other	414,644	248,134	344,884
Liabilities			
Property, plant and equipment depreciation	(135,354)	(117,584)	(113,441)
Other	(53,733)	(42,727)	(817,711)
subtotal	19,770,281	17,806,513	18,633,109
Valuation allowance	(19,770,281)	(17,806,513)	(18,633,109)
Net deferred taxes	$ —	$ —	$ —

Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has recorded a full valuation allowance against its otherwise recognizable net deferred tax assets as of September 30, 2004, 2003 and 2002. Realization of favorable tax attributes is therefore reflected as a tax benefit in the provision for income taxes.

At September 30, 2004, we had unused net operating loss, or NOL, carryforwards for federal income tax purposes of approximately $33,496,929 which begin to expire in fiscal 2010. We also have unused state NOL carry-forwards of approximately $19,688,007 which begin to expire in fiscal 2005. We also have federal research and experimentation credits of approximately $3,254,000 which begin to expire in fiscal 2005.

Included in the NOL and tax credit carryforwards discussed above is a deferred tax asset of approximately $121,231 reflecting the benefit of deductions from the exercise of stock options. The benefit from this deferred tax asset 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 469,500 shares have been granted under the 2000 Stock Plan as of September 30, 2004, 3,500 of which have expired and 40,625 of which have been exercised. The number of shares available for future grants as of September 30, 2004 was 534,000.

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, 2004 was 408,991.

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, 2004 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, 2004 was 15,000.

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

	2004		2003		2002	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of year*	879,347	$ 6.06	763,097	$ 5.89	701,700	$ 6.56
Granted	193,500	$ 12.00	189,000	$ 5.84	115,000	$ 3.60
Exercised	(197,981)	$ 6.38	(56,000)	$ 3.31	(3,000)	$ 3.06
Expired	(20,500)	$ 9.90	(16,750)	$ 3.39	(50,603)	$ 10.62
Outstanding at year end *	854,366	$ 7.24	879,347	$ 6.06	763,097	$ 5.89
Options exercisable at year-end *	470,991	$ 6.78	522,753	$ 6.99	431,472	$ 7.62
Weighted average fair value of options granted during the year	$ 7.78		$ 3.74		$ 2.24	

* 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, 2004:

	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	218,375	6.4	$ 3.07	138,750	$ 3.08
$3.39–$5.06	137,625	6.4	3.96	96,000	3.94
$5.07–$7.59	106,750	7.3	5.23	31,750	5.14
$7.60–$12.27	288,616	5.8	10.42	193,491	10.75
$12.28–$14.70	103,000	9.6	13.60	11,000	13.04
Total	854,366	6.7	$ 7.24	470,991	$ 6.78

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 newly issued shares of the Company. 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 year ended September 30, 2004 amounted to $250,697, associated with the net issuance of 30,369 shares; 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, 2004, all options were granted 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 by 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, 2004, 27,569 shares have been issued under the Purchase Plan.

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

Stock Options Granted to Consultants

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 vests over a two-year period commencing in March 2003. We have recorded an expense of $43,432 and $30,881 for the fiscal years ended September 30, 2004 and 2003, respectively, associated with this option and have recorded an offsetting credit to additional paid-in capital. This option will be remeasured at every balance sheet date until completion of services. Vesting will conclude in the third quarter of fiscal 2005.

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 and $24,158 for the fiscal years ended September 30, 2003 and 2002, respectively, 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 $40,433, $41,946 and $42,059, for the fiscal years 2004, 2003 and 2002, respectively.

I. Common Stock Transactions:

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:

Preferred stock may be issued from time to time in one or more series. The rights, preferences, restrictions, qualifications and limitations of such stock shall be determined by the Board of Directors. There were no preferred shares issued or outstanding as of September 30, 2004 and 2003.

K. Segment Information:

We have determined that we conduct our operations in one business segment. In fiscal 2004, 2003 and 2002, revenues from customers and licensees outside of the United States, principally in Europe and Japan, amounted to 21%, 13% and 20%, 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.

Total product sales for the last three years are as follows:

Product Sales Revenue

	Years Ended September 30,		
	2004	2003	2002
Feridex I.V.®	$ 431,823	$ 337,440	$ 701,648
GastroMARK®	336,366	263,004	264,172
Total	$ 768,189	$ 600,444	$ 965,820

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. 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. 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 2005, 2006 and 2007. Equipment rental expenses for the years ended September 30, 2004, 2003 and 2002 amounted to $25,423, $14,619 and $16,708, respectively. Future minimum lease and service payments associated with noncancellable agreements for fiscal year 2005, fiscal year 2006 and fiscal year 2007 are estimated to be $37,000, $19,000 and $3,000 respectively.

We previously leased laboratory, office and warehouse space under an agreement that expired in fiscal 2003. Rental expenses for the years ended September 30, 2004, 2003 and 2002 amounted to $0, $4,836 and $205,710, respectively. There were no future minimum lease payments made in fiscal 2004, since all of these leases previously expired.

Purchase Order Commitments

We entered into an agreement with an FDA-approved manufacturer to reserve manufacturing capacity in exchange for payments amounting to approximately $101,000, which we are committed to making in the first quarter of fiscal year 2005.

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, 2004 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 agreements, Berlex paid a $5,000,000 non-refundable license fee in fiscal 1995 and an additional $5,000,000 non-refundable license fee in October 1996 upon the FDA's marketing approval of *Feridex I.V*. In addition, we receive payments for manufacturing the product and royalties on sales. Under the terms of the agreements, 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 molecular imaging agent consisting of iron oxide nanoparticles for use in conjunction with MRI to aid in the differentiation of cancerous from non-cancerous lymph nodes. In addition, we granted Cytogen the exclusive right to market and sell ferumoxytol for oncology imaging applications 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 manufacturing and distribution 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, Eiken paid us a license fee of $1,500,000 and agreed to pay royalties based upon products shipped for resale. 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 1990, we entered into a second manufacturing and distribution agreement with Eiken granting Eiken the exclusive right to manufacture and distribute *GastroMARK* and *Combidex* in Japan. In addition, for a period of 180 days after we file an Investigational New Drug Application for any future Advanced Magnetics MRI contrast agent, Eiken has a right of first refusal to elect to manufacture and distribute such product in Japan. Upon execution of our second manufacturing and distribution agreement with Eiken, it paid us a license fee of $1,000,000. Additionally, Eiken agreed to pay us royalties on sales of all products shipped for resale by Eiken under the agreement. The agreement is perpetual but terminable upon certain specified events. Due to market conditions in Japan, Eiken subsequently decided not to market *GastroMARK* or *Combidex* and rights to these products in Japan have reverted back to us. Additionally, Eiken has decided not to exercise its option to develop ferumoxytol for marketing in Japan.

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 their 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, as amended, Guerbet paid us license fees of $250,000 upon execution of the agreement and $250,000 on the first anniversary of execution of the agreement. In addition, 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 their 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 rights to ferumoxytol, and accordingly, we retain the rights to manufacture and sell ferumoxytol worldwide for all applications other than oncology imaging. Under the terms of this second distribution agreement, Guerbet paid us a license fee in 1989 of $700,000. In addition, 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. Mallinckrodt currently has rights to *GastroMARK* in the United States only. Under the terms of the agreement, we reserved the right to sell *GastroMARK* through our own direct sales personnel. Mallinckrodt paid $1,350,000 in license fees and a $500,000 non-refundable milestone payment upon FDA marketing approval of *GastroMARK*. In addition, 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 and Schering AG of Berlin, Germany that require us to make payments in accordance with these agreements upon the attainment of particular milestones relating to *Feridex I.V.* and *GastroMARK*. We are also required under these agreements 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 2004, 2003 or 2002. Future milestone payments under these agreements are not to exceed $400,000. Royalty payments under these agreements were less than $105,000 for each of the prior three fiscal years.

In each of November and December 2004, we paid liquidated damages of approximately $43,000 as a result of our failure to meet certain contractual obligations, such failure which was subsequently remedied. There is no assurance that we will not be obligated to pay additional liquidated damages if we fail to meet our contractual obligations in the future.

M. Related Party Transactions:

During the fiscal year 2002 we paid $153,990 to the law firm of White & McNamara, P.C. for its services as our outside legal counsel. Rachel Konforty, who joined us as General Counsel and Assistant Secretary in October 2002 and who is the daughter of Jerome Goldstein, our Chairman of the Board, Chief Executive Officer, President and Treasurer, is a former associate of White & McNamara, P.C. 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. Lisa Gordon, also the daughter of Jerome

Goldstein, 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 $151,666, $138,763 and $112,740 for services rendered during the fiscal years ended September 30, 2004, 2003 and 2002, respectively. Marlene Kaplan Goldstein, wife of Jerome Goldstein and a co-founder of the Company, served part-time as our General Counsel through October 2002, when she resigned. Ms. Goldstein remains our Secretary. We made salary payments to Ms. Goldstein of $65,400 during the fiscal year ended September 30, 2002. Ms. Konforty, Ms. Gordon and Ms. Goldstein were also eligible during those years 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 Chairman of the Board, Chief Executive Officer, President and Treasurer, and his wife Marlene Kaplan Goldstein, was established with a trust for the benefit of the family members of our Chief Executive Officer and spouse as beneficiary. The intent of the policy was to provide liquidity to the estate of the Chief Executive Officer 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.

N. Consolidated Quarterly Financial Data—Unaudited:

The following table provides quarterly data for the fiscal years ended September 30, 2004, and 2003.

	(Unaudited)			
	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
Other income	57,177	52,441	49,844	10,085
Net loss	$ (2,210,812)	$ (777,687)	$ (566,001)	$ (940,700)
Loss per share—basic	$ (0.28)	$ (0.10)	$ (0.07)	$ (0.12)
Loss per share—diluted	$ (0.28)	$ (0.10)	$ (0.07)	$ (0.12)

	Fiscal 2003 Quarters Ended			
	September 30	June 30	March 31	Dec. 31, 2002
License fees	$ 555,223	$ 894,097	$ 785,817	$ 1,406,915
Royalties	55,000	102,990	228,131	148,879
Product sales	168,485	431,959	—	—
Total revenues	778,708	1,429,046	1,013,948	1,555,794
Cost of product sales	48,621	150,940	—	—
Operating expenses	1,490,144	1,361,381	2,034,148	1,343,709
Other (income) expenses*	(1,975,521)	(747,707)	(247,930)	577,606
Income (loss) before income taxes	$ 1,215,464	$ 664,432	$ (772,270)	$ (365,521)
Income taxes (refund)	—	—	(124,752)	—
Net income (loss)	$ 1,215,464	$ 664,432	$ (647,518)	$ (365,521)
Earnings (loss) per share—basic	$ 0.16	$ 0.10	$ (0.10)	$ (0.05)
Earnings (loss) per share—diluted	$ 0.15	$ 0.10	$ (0.10)	$ (0.05)

* In the first fiscal quarter of 2003 there was a write-down of marketable securities of $644,310 which was included in other income.

O. Recently Issued and Proposed Accounting Pronouncements:

In March 2004, the FASB issued a proposed Statement, "Share-Based Payment", that addresses the accounting for share-based payment transactions in which an enterprise receives employee 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. The proposed Statement would eliminate the ability to account for share-based compensation transactions using APB 25, and generally would require instead that such transactions be accounted for using a fair-value-based method. In October 2004, the FASB delayed the effective date of its proposed Statement, "Share-Based Payment". The proposed Statement's effective date would be applicable for awards that are granted, modified, or settled in cash in interim or annual periods beginning after June 15, 2005. The FASB recently decided to include in the proposed Statement two transition methods: one that provides for prospective application and one that provides for retrospective application.

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, 2004. 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, 2004.

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, 2004.

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, 2004.

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, 2004.

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, 2004.

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, 2004 and 2003

   Statements of Operations—for the years ended September 30, 2004, 2003 and 2002

   Statements of Comprehensive Income (Loss)—for the years ended September 30, 2004, 2003 and 2002

   Statements of Stockholders' Equity—for the years ended September 30, 2004, 2003 and 2002

   Statements of Cash Flows—for the years ended September 30, 2004, 2003 and 2002

   Reconciliation of Net Income (Loss) to Net Cash Used in Operating Activities—for the years ended September 30, 2004, 2003 and 2002

   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	Securities Purchase Agreement dated as of July 2, 2003 among the Company and the Purchasers identified on the signature pages thereto (incorporated herein by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-3 (No. 333-107517)).
4.4	Registration Rights Agreement dated as of July 2, 2003 among the Company and the Purchasers identified on the signature pages thereto (incorporated herein by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-3 (No. 333-107517)).
4.5	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)).
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	Contrast Agent Agreement between the Company and Eiken Chemical Co., Ltd. dated March 27, 1990 (incorporated herein by reference to Exhibit 10.8 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	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).
10.11	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).
10.12	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).
10.13	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).
10.14	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).
10.15	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).
10.16	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).

10.17	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).
10.18	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).
10.19*	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)).
10.20++*	Specimen of Stock Option Grant in connection with 1992 Non-Employee Director Stock Plan.
10.21++*	Specimen of Stock Option Grant in connection with 1993 Non-Employee Director Stock Plan.
10.22++*	Specimen of Stock Option Grant in connection with 1993 Stock Plan.
10.23++*	Specimen of Stock Option Grant in connection with 2000 Stock Plan (employees).
10.24++*	Specimen of Stock Option Grant in connection with 2000 Stock Plan (non-employees).
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 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 Exexcutive Officer, President and Treasurer

Date: December 10, 2004

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, President and Treasurer (principal executive and financial officer)	December 10, 2004
/s/ MICHAEL N. AVALLONE Michael N. Avallone	Vice President—Finance and Chief Financial Officer (principal accounting officer)	December 10, 2004
/s/ SHELDON L. BLOCH Sheldon L. Bloch	Director	December 10, 2004
/s/ MICHAEL D. LOBERG Michael D. Loberg, Ph.D.	Director	December 10, 2004
/s/ EDWARD B. ROBERTS Edward B. Roberts, Ph.D.	Director	December 10, 2004
/s/ BRIAN J. G. PEREIRA Brian J. G. Pereira, MD	Director	December 10, 2004

/s/ MARK SKALETSKY		
Mark Skaletsky	Director	December 10, 2004
/s/ THEODORE I. STEINMAN, MD		
Theodore I. Steinman, MD	Director	December 10, 2004

EXHIBIT 10.20

SPECIMEN OF STOCK OPTION GRANT IN CONNECTION WITH 1992 NON-EMPLOYEE DIRECTOR STOCK PLAN

STOCK OPTION GRANT

1. GRANT OF OPTION

Advanced Magnetics, Inc., a Delaware corporation (the "Company"), hereby grants to _____ (the "Director"), an option to purchase _____ shares of Common Stock, $0.01 par value per share, of the Company as hereinafter set forth, pursuant and subject to the terms and provisions of the Company's 1992 NON-EMPLOYEE DIRECTOR STOCK OPTION PLAN (the "Director Plan").

All terms which are defined in the Director Plan shall have the same meanings herein.

2. VESTING OF OPTION

This Option shall be exercisable in cumulative installations, as follows:

Date Exercised	Number of Shares Exercisable
On or before _____	_____
After _____ and on or before	_____
After _____and on or before	_____
After _____and on or before	_____
After _____and on or before	_____
After _____	_____

3. TERM OF OPTION

This Option shall TERMINATE in _____ YEARS on _____.

4. EXERCISE PRICE

The EXERCISE PRICE of this Option shall be _____ ($_____) per share.

5. EXERCISE AND PAYMENT

(a) METHOD OF PAYMENT. This Option shall be exercisable by delivery to the Company of written notice of exercise, specifying the number of shares for which this Option is being exercised (subject to Section 2 hereof), together with payment to the Company for the total exercise price thereof in cash, by check, by Common Stock of the Company already owned by the person or persons exercising the Option or by some combination thereof, PROVIDED, HOWEVER, that there shall be no such exercise at any one time as to fewer than one hundred (100) shares or all of the remaining share(s) then purchasable by the person or persons exercising the option, if fewer than one hundred (100) shares.

(b) VALUATION OF SHARES TENDERED IN PAYMENT OF PURCHASE PRICE. For the purposes hereof, the fair market value of any share of the Company's Common Stock which may be delivered to the Company in exercise of this Option shall be determined in accordance with Section 5 of the Director Plan.

(c) DELIVERY OF SHARES TENDERED IN PAYMENT OF PURCHASE PRICE. If this Option is exercised by delivery of shares of Common Stock of the Company, the certificate or certificates representing the shares of Common Stock of the Company to be delivered shall be duly executed in blank by the owner of the shares or shall be accompanied by a stock power duly executed in blank suitable for purposes of transferring such shares to the Company. Fractional shares of Common Stock of the Company will not be accepted in payment of the purchase price of shares acquired upon exercise of this Option.

6. NON-TRANSFERABILITY

This Option shall not be assignable or transferable other than by will or the laws of descent and distribution or pursuant to a qualified domestic relations order (as defined by the Internal Revenue Code of 1986, as amended, or Title I of the Employment Retirement Income Security Act, or thereunder, and shall be exercisable during the holder's lifetime only by him or her.

7. EFFECT OF TERMINATION OF EMPLOYMENT OR DEATH

In the event that the Director ceases to be an employee of the Board for any reason, other than death or permanent disability, any then unexercised portion of this Option shall, to the extent not then vested, immediately terminate and become void; any portion of this Option which is then vested but has not been exercised at the time the Director so ceases to be a member of the Board may be exercised, to the extent it is then vested, by the holder (or by the holder's personal representative, heir or legatee, in the event of the holder's death) within 90 days of the date the Director ceased to be a member of the Board; and this Option shall terminate after such 90 days have expired.

In the event the Director ceases to be a member of the board by reason of his death or permanent disability, this Option shall be immediately and automatically accelerated and become fully vested and any unexercised portion or portions of this Option shall be exercisable by the holder (or by the holder's personal representative, heir or legatee, in the event of death) until the scheduled expiration date of this Option.

8. WITHHOLDING TAXES

The Director acknowledges and agrees that the Company has the right to deduct from payments of any kind otherwise due to the Director any federal, state or local taxes of any kind required by law to be withheld with respect to exercise of this Option.

9. PLAN PROVISIONS

This Option and the rights of the Director hereunder shall be subject to and governed by the terms and provisions of the Director Plan, including without limitation the provisions of Section 5 thereof, and any terms stated herein that are not inconsistent with the terms of the Director Plan.

10. DIRECTOR REPRESENTATION

The Director hereby represents that he or she has read the Director Plan, attached hereto as EXHIBIT A.

11. EMPLOYEE REPRESENTATION; STOCK CERTIFICATE LEGEND

Because the Director is an "affiliate" of the Company (as defined in Rule 144 promulgated under the Securities Act of 1933), all stock certificates representing shares of Common Stock issued pursuant to this Option shall have affixed thereto legends substantially in the following form:

> "The shares represented by this certificate have not been registered under the Securities Act of 1933, as amended (the "Act") and may not be sold, transferred or assigned unless such shares are registered under the Act or an opinion of counsel, satisfactory to the corporation, is obtained to the effect that such sale, transfer or assignment is exempt from the registration requirements of the Act."

12. NOTICE

Any notice required to be given under the terms of this Option shall be properly addressed as follows: to the Company at its principal executive offices, and to the Employee at his or her address set forth below, or at such other address as either of such parties may hereafter designate in writing to the other.

13. ENFORCEABILITY

This Option shall be binding upon the Director, any direct or indirect transferee, and the estates, personal representatives and beneficiaries of the Director and any direct or indirect transferee.

14. EFFECTIVE DATE

The effective DATE of this Option is _____.

IN WITNESS WHEREOF, this Option has been executed by a duly authorized officer of the Company as of the effective date.

Advanced Magnetics, Inc.

By: ----------

Director's Acceptance

The undersigned hereby accepts this Option and agrees to the terms and provisions set forth in this Option and in the Plan (a copy of which has been delivered to him/her).

(Signature of Director)

(Print Name of Director)

Address: ----------

Date: ----------

EXHIBIT 10.21

SPECIMEN OF STOCK OPTION GRANT IN CONNECTION WITH 1993 NON-EMPLOYEE DIRECTOR STOCK PLAN

STOCK OPTION GRANT

1. GRANT OF OPTION

Advanced Magnetics, Inc., a Delaware corporation (the "Company"), hereby grants to _____(the "Director"), an option to purchase _____ shares of Common Stock, $0.01 par value per share, of the Company as hereinafter set forth, pursuant and subject to the terms and provisions of the Company's 1993 STOCK PLAN (the "Plan").

All terms which are defined in the Plan shall have the same meanings herein.

2. VESTING OF OPTION

This Option shall be exercisable in cumulative installations, as follows:

Date Exercised	Number of Shares Exercisable
On or _____ AFTER _____and on or BEFORE	_____
AFTER _____ and on or BEFORE	_____
AFTER _____and on or BEFORE	_____
AFTER _____	_____

3. TERM OF OPTION

This Option shall TERMINATE in _____ YEARS on _____.

4. EXERCISE PRICE

The EXERCISE PRICE of this Option shall be _____ ($_____) per share.

5. EXERCISE AND PAYMENT

(a) METHOD OF PAYMENT. This Option shall be exercisable by delivery to the Company of written notice of exercise, specifying the number of shares for which this Option is being exercised (subject to Section 2 hereof), together with payment to the Company for the total exercise price thereof in cash, by check or, subject to the consent of the Company, by Common Stock of the Company owned by the Director or by some combination thereof.

(b) VALUATION OF SHARES TENDERED IN PAYMENT OF PURCHASE PRICE. For the purposes hereof, the fair market value of any share of the Company's Common Stock which may be delivered to the Company in exercise of this Option shall be determined in good faith by the Board of Directors of the Company.

(c) DELIVERY OF SHARES TENDERED IN PAYMENT OF PURCHASE PRICE. If the Company permits the Director to exercise Options by delivery of shares of Common Stock of the Company, the certificate or certificates representing the shares of Common Stock of the Company to be delivered

shall be duly executed in blank by the Director or shall be accompanied by a stock power duly executed in blank suitable for purposes of transferring such shares to the Company. Fractional shares of Common Stock of the Company will not be accepted in payment of the purchase price of shares acquired upon exercise of this Option.

6. EFFECT OF TERMINATION OF DIRECTORSHIP OR DEATH

This Option shall not be assignable or transferable either voluntarily or by operation of law, except as set forth in this Section 6.

In the event that the Director during his or her lifetime ceases to be a director of the Company or of any Subsidiary for any reason, other than death or disability, any unexercised portion of this Option which was otherwise exercisable on the date of termination of his or her directorship shall expire unless exercised within three months of that date, but in no event after the expiration of the term hereof.

In the event of the death or disability of the Director (i) while an director of the Company or any Subsidiary, or (ii) during the three-month period following termination of his or her directorship for any reason other than death or disability, this Option shall be exercisable for the number of shares otherwise exercisable on the date of death or disability, by the Director or his or her personal representatives, heirs or legatees, as the case may be, at any time prior to the expiration of one (1) year from the date of the death or disability of the Director, but in no event after the expiration of the term hereof.

7. DIRECTORSHIP

Nothing contained in this Option or in the Plan shall be construed as giving the Director any right to be retained as a director of the Company or any of its Subsidiaries.

8. WITHHOLDING TAXES

The Director acknowledges and agrees that the Company has the right to deduct from payments of any kind otherwise due to the Director any federal, state or local taxes of any kind required by law to be withheld with respect to exercise of this Option.

9. PLAN PROVISIONS

Except as otherwise expressly provided herein, this Option and the rights of the Director hereunder shall be subject to and governed by the terms and provisions of the Plan, including without limitation the provisions of Section 4 thereof. Exhibit 10.20

10. DIRECTOR REPRESENTATION; STOCK CERTIFICATE LEGEND

The Director hereby represents that he or she has received and read the Prospectus filed with the Securities and Exchange Commission as a part of the Registration Statement on Form S-8, which registered the shares under the Plan.

If the Director is an "affiliate" of the Company (as defined in Rule 144 promulgated under the Securities Act of 1933), all stock certificates representing shares of Common Stock issued to such Director pursuant to this Option shall have affixed thereto legends substantially in the following form:

"The shares represented by this certificate have not been registered under the Securities Act of 1933, as amended (the "Act") and may not be sold, transferred or assigned unless such shares are registered under the Act or an opinion of counsel, satisfactory to the

corporation, is obtained to the effect that such sale, transfer or assignment is exempt from the registration requirements of the Act."

11. NOTICE

Any notice required to be given under the terms of this Option shall be properly addressed as follows: to the Company at its principal executive offices, and to the Director at his or her address set forth below, or at such other address as either of such parties may hereafter designate in writing to the other.

12. NON-QUALIFIED STOCK OPTION

It is understood that this Option is not intended to qualify as an "incentive stock option" as defined in Section 422 of the Internal Revenue Code.

13. ENFORCEABILITY

This Option shall be binding upon the Director, his or her estate, and his or her personal representatives and beneficiaries.

14. EFFECTIVE DATE

The effective DATE of this Option is _____.

IN WITNESS WHEREOF, this Option has been executed by a duly authorized officer of the Company as of the effective date.

Advanced Magnetics, Inc.

By: ----------

Director's Acceptance

The undersigned hereby accepts this Option and agrees to the terms and provisions set forth in this Option and in the Plan (a copy of which has been delivered to him/her).

(Signature of Director)

(Print Name of Director)

Address: ----------

Date: ----------

EXHIBIT 10.22

SPECIMEN OF STOCK OPTION GRANT IN CONNECTION WITH 1993 STOCK PLAN

STOCK OPTION GRANT

1. GRANT OF OPTION

Advanced Magnetics, Inc., a Delaware corporation (the "Company"), hereby grants _____ (the "Employee"), an option to purchase _____ SHARES of Common Stock, $0.01 par value per share, of the Company as hereinafter set forth, pursuant and subject to the terms and provisions of the Company's 1993 STOCK PLAN (the "Plan").

All terms which are defined in the Plan shall have the same meanings herein.

2. VESTING OF OPTION

This Option shall be exercisable in cumulative installations, as follows:

Date Exercised	Number of Shares Exercisable
AFTER _____ and on or BEFORE _____	_____
AFTER _____ and on or BEFORE _____	_____
AFTER _____ and on or BEFORE _____	_____
AFTER _____	_____

3. TERM OF OPTION

This Option shall TERMINATE in _____ YEARS on _____.

4. EXERCISE PRICE

The EXERCISE PRICE of this Option shall be _____ ($_____) per share.

5. EXERCISE AND PAYMENT

(a) METHOD OF PAYMENT. This Option shall be exercisable by delivery to the Company of written notice of exercise, specifying the number of shares for which this Option is being exercised (subject to Section 2 hereof), together with payment to the Company for the total exercise price thereof in cash, by check, by Common Stock of the Company owned by the Employee or by some combination thereof.

(b) VALUATION OF SHARES TENDERED IN PAYMENT OF PURCHASE PRICE. For the purposes hereof, the fair

market value of any share of the Company's Common Stock which may be delivered to the Company in exercise of this Option shall be determined in good faith by the Board of Directors of the Company.

(c) DELIVERY OF SHARES TENDERED IN PAYMENT OF PURCHASE PRICE. If the Company permits the employee to exercise Options by delivery of shares of Common Stock of the Company, the certificate or certificates representing the shares of Common Stock of the Company to be delivered

shall be duly executed in blank by the Employee or shall be accompanied by a stock power duly executed in blank suitable for purposes of transferring such shares to the Company. Fractional shares of Common Stock of the Company will not be accepted in payment of the purchase price of shares acquired upon exercise of this Option.

(d) USE OF STATUTORY OPTION STOCK. Notwithstanding the foregoing, "statutory option stock" (as defined below) may not be tendered in payment of the exercise price of this Option if the stock to be so tendered has not, at the time of tender, been held by the Employee for the applicable minimum statutory holding period required to receive the tax benefits afforded under Section 421(a) of the Code with respect to such stock. As used above, the term "statutory option stock" means stock acquired through the exercise of a qualified stock option, incentive stock option, restricted stock option or an option granted under an employee stock purchase plan. The tender of statutory option stock in payment of the exercise price of this Option shall be accompanied by written proof (in form satisfactory to the Company) that such stock has been held by the Employee for the applicable minimum statutory holding period.

6. EFFECT OF TERMINATION OF EMPLOYMENT OR DEATH

This Option shall not be assignable or transferable either voluntarily or by operation of law, except as set forth in this Section 6.

In the event that the Employee during his or her lifetime ceases to be an employee of the Company or of any Subsidiary for any reason, other than death or disability, any unexercised portion of this Option which was otherwise exercisable on the date of termination of employment shall expire unless exercised within three months of that date, but in no event after the expiration of the term hereof.

In the event of the death or disability of the Employee (i) while an employee of the Company or any Subsidiary, or (ii) during the three-month period following termination of his or her employment for any reason other than death or disability, this Option shall be exercisable for the number of shares otherwise exercisable on the date of death or disability, by the Employee or his or her personal representatives, heirs or legatees, as the case may be, at any time prior to the expiration of one (1) year from the date of the death or disability of the Employee, but in no event after the expiration of the term hereof.

7. EMPLOYMENT

Nothing contained in this Option or in the Plan shall be construed as giving the Employee any right to be retained in the employ of the Company or any of its Subsidiaries.

8. WITHHOLDING TAXES

The Employee acknowledges and agrees that the Company has the right to deduct from payments of any kind otherwise due to the Employee any federal, state or local taxes of any kind required by law to be withheld with respect to exercise of this Option.

9. PLAN PROVISIONS

Except as otherwise expressly provided herein, this Option and the rights of the Employee hereunder shall be subject to and governed by the terms and provisions of the Plan, including without limitation the provisions of Section 5 thereof.

10. EMPLOYEE REPRESENTATION; STOCK CERTIFICATE LEGEND

The Employee hereby represents that he or she has received and read the Prospectus filed with the Securities and Exchange Commission as a part of the Registration Statement on Form S-8, which registered the shares under the Plan.

If the Employee is an "affiliate" of the Company (as defined in Rule 144 promulgated under the Securities Act of 1933), all stock certificates representing shares of Common Stock issued to such Employee pursuant to this Option shall have affixed thereto legends substantially in the following form:

> "The shares represented by this certificate have not been registered under the Securities Act of 1933, as amended (the "Act") and may not be sold, transferred or assigned unless such shares are registered under the Act or an opinion of counsel, satisfactory to the corporation, is obtained to the effect that such sale, transfer or assignment is exempt from the registration requirements of the Act."

11. NOTICE

Any notice required to be given under the terms of this Option shall be properly addressed as follows: to the Company at its principal executive offices, and to the Employee at his or her address set forth below, or at such other address as either of such parties may hereafter designate in writing to the other.

12. QUALIFICATION UNDER SECTION 422A

It is understood and intended that this Option shall qualify as an "INCENTIVE STOCK OPTION" as defined in Section 422A of the Internal Revenue Code. Accordingly, the Employee understands that in order to obtain the benefits of an incentive stock option under Section 421 of the Code, NO SALE or other disposition may be made of any shares acquired upon exercise of this Option WITHIN THE ONE (1) YEAR PERIOD beginning on the day after the day of the transfer of such shares to him or her, NOR WITHIN THE TWO (2) YEAR PERIOD beginning on the DAY AFTER the grant of this Option. If the Employee intends to dispose or does dispose (whether by sale, exchange, gift, transfer or otherwise) of any such shares within said periods, he or she will NOTIFY THE COMPANY within THIRTY (30) DAYS after such disposition.

13. ENFORCEABILITY

This Option shall be binding upon the Employee, his or her estate, and his or her personal representatives and beneficiaries.

14. EFFECTIVE DATE

The EFFECTIVE DATE of this Option is _____.

IN WITNESS WHEREOF, this Option has been executed by a duly authorized officer of the Company as of the effective date.

Advanced Magnetics, Inc.

By: _____

Employee's Acceptance

The undersigned hereby accepts this Option and agrees to the terms and provisions set forth in this Option and in the Plan (a copy of which has been delivered to him/her).

(Signature of Employee)

Address:

Date: -----------------------------

EXHIBIT 10.23

SPECIMEN OF STOCK OPTION GRANT IN CONNECTION WITH 2000 STOCK PLAN (EMPLOYEES)

STOCK OPTION GRANT

1. GRANT OF OPTION

Advanced Magnetics, Inc., a Delaware corporation (the "Company"), hereby grants to _____ (the "Employee"), an option to purchase _____ shares of Common Stock, $0.01 par value per share, of the Company as hereinafter set forth (the "Option"), pursuant and subject to the terms and provisions of the Company's 2000 STOCK PLAN (the "Plan").

All terms which are defined in the Plan shall have the same meanings herein.

2. VESTING OF OPTION

This Option shall be exercisable in cumulative installations, as follows:

Date Exercised	Number of Shares Exercisable
On or BEFORE _____	_____
AFTER _____ and on or BEFORE _____	_____
AFTER _____ and on or BEFORE _____	_____
AFTER _____ and on or BEFORE _____	_____
AFTER _____	

3. TERM OF OPTION

This Option shall TERMINATE in _____ YEARS on _____.

4. EXERCISE PRICE

The EXERCISE PRICE of this Option shall be _____ per share.

5. EXERCISE AND PAYMENT

(a) METHOD OF PAYMENT. This Option shall be exercisable by delivery to the Company of written notice of exercise, specifying the number of shares for which this Option is being exercised (subject to Section 2 hereof), together with payment to the Company for the total exercise price thereof in cash, by check or by Common Stock of the Company owned by the Employee or by some combination thereof.

(b) VALUATION OF SHARES TENDERED IN PAYMENT OF PURCHASE PRICE. For the purposes hereof, the fair market value of any share of the Company's Common Stock which may be delivered to the Company in exercise of this Option shall be determined in good faith by the Board of Directors of

the Company.

(c) DELIVERY OF SHARES TENDERED IN PAYMENT OF PURCHASE PRICE. If the Company permits the Employee to exercise Options by delivery of shares of Common Stock of the Company, the certificate or certificates representing the shares of Common Stock of the Company to be delivered

shall be duly executed in blank by the Employee or shall be accompanied by a stock power duly executed in blank suitable for purposes of transferring such shares to the Company. Fractional shares of Common Stock of the Company will not be accepted in payment of the purchase price of shares acquired upon exercise of this Option.

(d) USE OF STATUTORY OPTION STOCK. Notwithstanding the foregoing, "statutory option stock" (as defined below) may not be tendered in payment of the exercise price of this Option if the stock to be so tendered has not, at the time of tender, been held by the Employee for the applicable minimum statutory holding period required to receive the tax benefits afforded under Section 421(a) of the Code with respect to such stock. As used above, the term "statutory option stock" means stock acquired through the exercise of a qualified stock option, incentive stock option, restricted stock option or an option granted under an employee stock purchase plan. The tender of statutory option stock in payment of the exercise price of this Option shall be accompanied by written proof (in form satisfactory to the Company) that such stock has been held by the Employee for the applicable minimum statutory holding period.

6. EFFECT OF TERMINATION OF EMPLOYMENT OR DEATH

This Option shall not be assignable or transferable either voluntarily or by operation of law, except as set forth in this Section 6.

In the event that the Employee during his or her lifetime ceases to be an employee of the Company or of any subsidiary for any reason, other than death or disability, any unexercised portion of this Option which was otherwise exercisable on the date of termination of employment shall expire unless exercised within three months of that date, but in no event after the expiration of the term hereof.

In the event of the death or disability of the Employee (i) while an employee of the Company or any subsidiary, or (ii) during the three-month period following termination of his or her employment for any reason other than death or disability, this Option shall be exercisable for the number of shares otherwise exercisable on the date of death or disability, by the Employee or his or her personal representatives, heirs or legatees, as the case may be, at any time prior to the expiration of one (1) year from the date of the death or disability of the Employee, but in no event after the expiration of the term hereof.

7. EMPLOYMENT

Nothing contained in this Option or in the Plan shall be construed as giving the Employee any right to be retained in the employ of the Company or any of its subsidiaries.

8. WITHHOLDING TAXES

The Employee acknowledges and agrees that the Company has the right to deduct from payments of any kind otherwise due to the Employee any federal, state or local taxes of any kind required by law to be withheld with respect to exercise of this Option.

9. PLAN PROVISIONS

Except as otherwise expressly provided herein, this Option and the rights of the Employee hereunder shall be subject to and governed by the terms and provisions of the Plan, including without limitation the provisions of Section 4

thereof.

10. EMPLOYEE REPRESENTATION; STOCK CERTIFICATE LEGEND

The Employee hereby represents that he or she has received and read the Prospectus filed with the Securities and Exchange Commission as a part of the Registration Statement on Form S-8, which registered the shares under the Plan.

If the Employee is an "affiliate" of the Company (as defined in Rule 144 promulgated under the Securities Act of 1933), all stock certificates representing shares of Common Stock issued to such Employee pursuant to this Option shall have affixed thereto legends substantially in the following form:

> "The shares represented by this certificate have not been registered under the Securities Act of 1933, as amended (the "Act") and may not be sold, transferred or assigned unless such shares are registered under the Act or an opinion of counsel, satisfactory to the corporation, is obtained to the effect that such sale, transfer or assignment is exempt from the registration requirements of the Act."

11. NOTICE

Any notice required to be given under the terms of this Option shall be properly addressed as follows: to the Company at its principal executive offices, and to the Employee at his or her address set forth below, or at such other address as either of such parties may hereafter designate in writing to the other.

12. QUALIFICATION UNDER SECTION 422A

It is understood and intended that this Option shall qualify as an "incentive stock option" as defined in Section 422A of the Internal Revenue Code. Accordingly, the Employee understands that in order to obtain the benefits of an incentive stock option under Section 421 of the Code, no sale or other disposition may be made of any shares acquired upon exercise of this Option within the one (1) year period beginning on the day after the day of the transfer of such shares to him or her, nor within the two (2) year period beginning on the day after the grant of this Option. If the Employee intends to dispose or does dispose (whether by sale, exchange, gift, transfer or otherwise) of any such shares within said periods, he or she will notify the Company within thirty (30) days after such disposition.

13. ENFORCEABILITY

This Option shall be binding upon the Employee, his or her estate, and his or her personal representatives and beneficiaries.

14. EFFECTIVE DATE

The effective DATE of this Option is _____.

IN WITNESS WHEREOF, this Option has been executed by a duly authorized officer of the Company as of the effective date.

Advanced Magnetics, Inc.

By: _____

Employee's Acceptance

The undersigned hereby accepts this Option and agrees to the terms and provisions set forth in this Option and in the Plan (a copy of which has been

delivered to him/her).

(Signature of Employee)

(Print Name of Employee)

Address: ---

Date: ---

EXHIBIT 10.24

SPECIMEN OF STOCK OPTION GRANT IN CONNECTION WITH 2000 STOCK PLAN
(NON-EMPLOYEES)

STOCK OPTION GRANT

1. GRANT OF OPTION

Advanced Magnetics, Inc., a Delaware corporation (the "Company"), hereby grants to _____ (the "Director"), an option to purchase _____ shares of Common Stock, $0.01 par value per share, of the Company as hereinafter set forth (the "Option"), pursuant and subject to the terms and provisions of the Company's 2000 STOCK PLAN (the "Plan").

All terms which are defined in the Plan shall have the same meanings herein.

2. VESTING OF OPTION

This Option shall be exercisable in cumulative installations, as follows:

Date Exercised	Number of Shares Exercisable
AS OF _____	_____
AFTER _____ and on or BEFORE	_____
AFTER _____ and on or before_____	_____
AFTER _____ and on or BEFORE	_____
AFTER _____	_____

3. TERM OF OPTION

This Option shall TERMINATE in _____ YEARS on _____.

4. EXERCISE PRICE

The EXERCISE PRICE of this Option shall be _____ per share.

5. EXERCISE AND PAYMENT

(a) METHOD OF PAYMENT. This Option shall be exercisable by delivery to the Company of written notice of exercise, specifying the number of shares for which this Option is being exercised (subject to Section 2 hereof), together with payment to the Company for the total exercise price thereof in cash, by check or, subject to the consent of the Company, by Common Stock of the Company owned by the Director or by some combination thereof.

(b) VALUATION OF SHARES TENDERED IN PAYMENT OF PURCHASE PRICE. For the purposes hereof, the fair market value of any share of the Company's Common Stock which may be delivered to the

Company in exercise of this Option shall be determined in good faith by the Board of Directors of the Company.

(c) DELIVERY OF SHARES TENDERED IN PAYMENT OF PURCHASE PRICE. If the

Company permits the Director to exercise Options by delivery of shares of Common Stock of the Company, the certificate or certificates representing the shares of Common Stock of the Company to be delivered shall be duly executed in blank by the Director or shall be accompanied by a stock power duly executed in blank suitable for purposes of transferring such shares to the Company. Fractional shares of Common Stock of the Company will not be accepted in payment of the purchase price of shares acquired upon exercise of this Option.

6. EFFECT OF TERMINATION OF DIRECTORSHIP OR DEATH

This Option shall not be assignable or transferable either voluntarily or by operation of law, except as set forth in this Section 6.

In the event that the Director during his or her lifetime ceases to be a director of the Company or of any subsidiary for any reason, other than death or disability, any unexercised portion of this Option which was otherwise exercisable on the date of termination of his or her directorship shall expire unless exercised within three months of that date, but in no event after the expiration of the term hereof.

In the event of the death or disability of the Director (i) while an director of the Company or any subsidiary, or (ii) during the three-month period following termination of his or her directorship for any reason other than death or disability, this Option shall be exercisable for the number of shares otherwise exercisable on the date of death or disability, by the Director or his or her personal representatives, heirs or legatees, as the case may be, at any time prior to the expiration of one (1) year from the date of the death or disability of the Director, but in no event after the expiration of the term hereof.

7. DIRECTORSHIP

Nothing contained in this Option or in the Plan shall be construed as giving the Director any right to be retained as a director of the Company or any of its subsidiaries.

8. WITHHOLDING TAXES

The Director acknowledges and agrees that the Company has the right to deduct from payments of any kind otherwise due to the Director any federal, state or local taxes of any kind required by law to be withheld with respect to exercise of this Option.

9. PLAN PROVISIONS

Except as otherwise expressly provided herein, this Option and the rights of the Director hereunder shall be subject to and governed by the terms and provisions of the Plan, including without limitation the provisions of Section 4 thereof.

10. DIRECTOR REPRESENTATION; STOCK CERTIFICATE LEGEND

The Director hereby represents that he or she has received and read the Prospectus filed with the Securities and Exchange Commission as a part of the Registration Statement on Form S-8, which registered the shares under the Plan.

If the Director is an "affiliate" of the Company (as defined in Rule 144 promulgated under the Securities Act of 1933), all stock certificates representing shares of Common Stock issued to such Director pursuant to

this Option shall have affixed thereto legends substantially in the following form:

"The shares represented by this certificate have not been registered

under the Securities Act of 1933, as amended (the "Act") and may not be sold, transferred or assigned unless such shares are registered under the Act or an opinion of counsel, satisfactory to the corporation, is obtained to the effect that such sale, transfer or assignment is exempt from the registration requirements of the Act."

11. NOTICE

Any notice required to be given under the terms of this Option shall be properly addressed as follows: to the Company at its principal executive offices, and to the Director at his or her address set forth below, or at such other address as either of such parties may hereafter designate in writing to the other.

12. NON-QUALIFIED STOCK OPTION

It is understood that this Option is not intended to qualify as an "incentive stock option" as defined in Section 422 of the Internal Revenue Code.

13. ENFORCEABILITY

This Option shall be binding upon the Director, his or her estate, and his or her personal representatives and beneficiaries.

14. EFFECTIVE DATE

The effective DATE of this Option is _____.

IN WITNESS WHEREOF, this Option has been executed by a duly authorized officer of the Company as of the effective date.

Advanced Magnetics, Inc.

By: ----------

Director's Acceptance

The undersigned hereby accepts this Option and agrees to the terms and provisions set forth in this Option and in the Plan (a copy of which has been delivered to him/her).

(Signature of Director)

(Print Name of Director)

Address: ----------

Date: ----------

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 Nos. 107517 and 333-119682) and in the Registration Statements on Form S-8 (File Nos. 33-72700, 33-62522, 33-8697, 33-13953, 33-40744, 33-46963, 333-28417, and 333-82292) of Advanced Magnetics, Inc. of our report dated November 26, 2004 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
December 13, 2004

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) 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

c) 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 10, 2004

/s/ Jerome Goldstein

Jerome Goldstein

Chairman of the Board of Directors,
President, 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) 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

c) 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 10, 2004

/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, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jerome Goldstein, Chairman of the Board of Directors, President, Chief Executive Officer and Treasurer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 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,
President, Chief Executive Officer
and Treasurer
December 10, 2004

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, 2004 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. Section 1350, as adopted pursuant to Section 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 10, 2004