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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended September 30, 2003

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). **YES** ☐ **NO** ☒

As of December 9, 2003, there were 7,775,095 shares of the registrant's Common Stock, par value $.01 per share, outstanding. The aggregate market value of the registrant's voting stock held by non-affiliates as of March 31, 2003 was approximately $19,121,334.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a Definitive Proxy Statement for its 2003 Annual Meeting of Stockholders, scheduled to be held on February 3, 2004, pursuant to regulation 14A within 120 days of the end of the fiscal year ended September 30, 2003. Portions of such Proxy Statement are incorporated by reference in Part III hereof.

ADVANCED MAGNETICS, INC.
FORM 10-K
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PART I

Except for the historical information contained herein, the matters discussed in this Annual Report on Form 10-K are 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. 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 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., a Delaware corporation, is the premier developer of superparamagnetic iron oxide nanoparticles used in pharmaceutical products. As a leader in our field, we are dedicated to the development and commercialization of our proprietary nanoparticle technology for use in therapeutic iron compounds for the treatment of chronic anemia and novel imaging agents for use in conjunction with magnetic resonance imaging to aid in the diagnosis of cancer and other diseases. Ferumoxytol, the next-generation product in our development pipeline, has completed Phase II clinical studies for use as an iron replacement therapeutic in chronic kidney disease patients receiving erythropoietin. Phase II clinical trials of ferumoxytol for use as a contrast agent in magnetic resonance angiography, also known as MRA, are currently ongoing. In June 2000, we received an approvable letter, subject to certain conditions, from the U.S. Food and Drug Administration, the FDA, for Combidex®, our contrast agent to aid in the diagnosis of metastatic lymph nodes. We are currently discussing the outstanding issues from the approvable letter with the FDA in an effort to bring *Combidex* to market. Our liver contrast agent, Feridex I.V.®, is approved and marketed in Europe, Japan, the United States, Argentina, South Korea and Israel. Our oral contrast agent, GastroMARK®, used for delineating the bowel in magnetic resonance imaging, is approved and marketed in Europe and the United States.

Advanced Magnetics was incorporated in Delaware in November 1981. Our principal offices are located at 61 Mooney Street, Cambridge, Massachusetts 02138, and our telephone number is (617) 497-2070.

Ferumoxytol and the Treatment of Chronic Anemia

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 or kidney failure as well as in many patients receiving chemotherapy. There are approximately 290,000 chronic kidney disease patients on dialysis in the United States, the majority of whom suffer from anemia and receive erythropoietin and iron replacement therapy to manage their condition. Additionally, there are over 8 million people in the United States suffering from moderate or severe chronic kidney disease, who are not yet on dialysis. Some of these patients suffer from anemia and would benefit from receiving erythropoietin and 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 chronic kidney disease often develop anemia. To increase red blood cell production, anemic chronic kidney disease 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 chronic kidney disease 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

For most patients receiving erythropoietin, oral iron supplements do not adequately replenish the body's iron stores. Oral iron is 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. Intravenous iron replacement products allow for 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. In comparison to IV iron replacement products already on the market, we believe that ferumoxytol will afford greater flexibility in both the rate of administration and the amount of iron that can be given to patients in a single dose. As a result, we expect that ferumoxytol will be a more effective and desirable form of iron replacement therapy for patients suffering from chronic anemia. Ferumoxytol has completed Phase II clinical studies for use as an iron replacement therapeutic. We currently anticipate that Phase III studies in iron replacement therapy will begin in 2004.

The Role of *Combidex* in Contrast-enhanced MRI

Magnetic resonance imaging, commonly referred to as MRI, is a non-invasive method to visualize internal structures, abnormalities or anatomical changes in order to diagnose disease and injury. Contrast 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 a contrast agent that localizes to and causes contrast enhancement of the lymph nodes. We believe that MRI exams of lymph nodes using *Combidex* as part of staging cancer will provide increased accuracy in the evaluation of lymph nodes as metastatic or non-metastatic, allowing for improved patient diagnosis and staging and providing a cost-effective way to assess medical treatments and to improve patient outcomes. There are no MRI contrast agents designed specifically for imaging lymph nodes currently on the market. At the present time, we continue to work with the FDA to obtain final approval of *Combidex*. We have granted exclusive rights to market and sell *Combidex* in the United States to Cytogen Corporation. In western Europe and Brazil we have granted such rights to Guerbet S.A. under the tradename Sinerem™.

The Utility of Ferumoxytol in Contrast-enhanced MRA and Cardiovascular Disease

There are no approved contrast agents for use in MRA. However, contrast-enhanced MRA is done off-label with some of the gadolinium-based contrast agents available today and is 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, 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.

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 will allow physicians not only to image the vascular system to diagnose a variety of vascular diseases, including blood flow restrictions, but may also allow physicians to distinguish vulnerable plaque from stable plaque. Ferumoxytol is currently in Phase II studies for use in contrast-enhanced MRA and in exploratory studies for use in vulnerable plaque imaging. We currently anticipate that Phase III clinical studies for ferumoxytol for use in contrast-enhanced MRA could begin before the end of 2004.

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, manufacture the nanoparticles in controlled sizes and 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 IV iron replacement therapy. In the field of MRI, when these nanoparticles are used as MRI contrast agents and placed in a magnetic field, they become strongly magnetic, but lose their magnetism once the field is removed. The properties of our iron oxide nanoparticles result 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 marketing partners and current U.S. and foreign status for each of our products and product candidates.

OUR PRODUCTS

Product	Applications	Marketing Partners	U.S. Status	Foreign Status
ferumoxytol	Iron replacement therapy.	None.	Phase II clinical trials complete. Phase III clinical trials expected to begin in 2004.	

	Magnetic resonance angiography.	None.	Phase II clinical trials underway.	
Combidex	Diagnosis of metastatic lymph nodes.	Cytogen (United States), Guerbet (western Europe and Brazil).	Approvable Letter received June 2000, subject to certain conditions.	EU Dossier filed December 1999. Additional clinical trials in process.
Feridex I.V.	Diagnosis of liver lesions.	Berlex (United States), Eiken (Japan), Guerbet (western Europe and Brazil).	Approved and marketed.	Approved and marketed in Japan and most EU countries.
GastroMARK	Marking of the bowel in abdominal imaging.	Guerbet (western Europe and Brazil), Mallinckrodt (United States).	Approved and marketed.	Approved and marketed in several EU countries.

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

Ferumoxytol. If approved by the FDA, we believe that ferumoxytol would be effective in iron replacement therapy for patients receiving erythropoietin because ferumoxytol consists of intravenously administered bio-available iron, allowing for more efficient replenishment of the body's iron stores without the common side effects associated with oral iron supplements and greater flexibility in both the administration and the amount of iron that can be given to a patient in comparison to other IV iron replacement products currently on the market. Ferumoxytol has completed Phase II clinical studies as an iron replacement therapeutic for chronic kidney disease patients receiving erythropoietin. We anticipate that Phase III clinical trials for ferumoxytol in iron replacement therapy will begin in 2004.

Ferumoxytol is also a blood pool agent which means that, among other things, it is a true intravascular contrast agent that remains in the blood stream for an extended period of time. As a blood pool agent with a long blood half-life as compared to currently approved MRI contrast agents, it may be useful as a contrast agent in a wide range of applications in MRA. Ferumoxytol is currently in Phase II clinical studies for use in MRA. We anticipate that Phase III clinical trials for ferumoxytol in MRA could begin before the end of 2004.

We do not currently have a marketing partner for ferumoxytol in iron replacement therapy or MRA applications. We have granted exclusive rights to market ferumoxytol for oncology imaging applications in the United States to Cytogen. See "Licensing, Marketing and Supply Arrangements."

Combidex. We believe that *Combidex* will be useful in the diagnostic imaging of lymph nodes. Lymph nodes are frequently the site for metastases of different types of cancer, particularly breast cancer and prostate cancer. Effective imaging of lymph nodes could play a role in 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. Since CT and MRI without contrast, the imaging modalities currently used for imaging lymph nodes, cannot distinguish between inflamed nodes and cancerous nodes, the current practice is to assume that enlarged nodes are cancerous and to perform a biopsy to establish their true status. As part of this practice, nodes less than ten millimeters in size are often assumed to be normal. We believe that *Combidex* will enable doctors using MRI to have improved diagnostic confidence in differentiating between normal and diseased lymph nodes, irrespective of node size, because 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 have granted exclusive rights to market and sell *Combidex* in the United States to Cytogen and in western Europe and Brazil to Guerbet. 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, has been marketing *Feridex I.V.* in the United States since October 1996. *Feridex I.V.* was approved in August 1994 by the EU's Committee for Proprietary Medicinal Products and most of the member states of the EU have since issued local approvals to market the product. Guerbet has been marketing the product in Europe since late 1994. Eiken received approval for marketing the product in Japan in

July 1997 and has been marketing the product 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* improves visualization of adjacent abdominal tissues, such as the pancreas.

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. See "Licensing, Marketing and Supply Arrangements."

Licensing, Marketing and Supply Arrangements

BERLEX. 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. 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. In August 2000, we entered into a license and marketing agreement and a supply agreement with Cytogen. Under the terms of these agreements, we granted Cytogen the exclusive right to market and sell *Combidex* in the United States. In addition, we granted Cytogen the exclusive right to market and sell ferumoxytol for oncology imaging applications in the United States. In fiscal 2002 we decided not to develop ferumoxytol for that application. 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 of these agreements, 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 applications and we do not anticipate achieving these milestones. Cytogen has agreed to pay us for manufacturing and supplying the products and royalties on sales, if any. 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. 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 sales. The agreement terminates on the later of (i) the expiration of the last to expire technology patent 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 this agreement, Eiken paid us a license fee of $1,000,000. Additionally, Eiken agreed to pay us royalties on sales of all products sold 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 has been appointed the exclusive distributor of *Feridex I.V.* in western Europe and Brazil (under the tradename Endorem™). Guerbet is responsible for conducting clinical trials and securing the necessary regulatory approvals in the countries in its territory. Under the terms of this agreement, Guerbet paid us license fees and is obligated to pay royalties based on sales. 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 *Endorem*. The agreement terminates on the later of (i) the expiration of the last to expire technology patent 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 opted to exercise its rights to manufacture and sell *Combidex* (under the tradename Sinerem™) in western Europe and Brazil, but, in our opinion, it failed to meet its contractual obligations with respect to the exercise of its option to acquire rights to ferumoxytol, and, accordingly, rights to manufacture and sell this product in those countries have reverted back to us. The Company and Guerbet have asked an arbitrator to decide our respective rights with respect to ferumoxytol. Under the terms of this second distribution agreement, Guerbet paid us a license fee in 1989. 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 the contrast agents. The agreement is perpetual but terminable upon certain specified events.

MALLINCKRODT. 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. 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. 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 the product sales of *Combidex*.

We are 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 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 2003, 2002 or 2001. Future milestone payments under these agreements are not to exceed $400,000. Royalty payments under these agreements were less than $125,000 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 as prescribed by the FDA. 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 at this facility. 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 bottling of *Combidex*.

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 letting third parties 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 have been granted 29 U.S. patents, have several patent applications pending, and have filed counterpart patent applications in several foreign countries. In addition, we are a party to various license agreements, including nonexclusive cross-licensing arrangements covering MRI technology with Nycomed Imaging A.S. of Oslo, Norway and Schering AG of Berlin, Germany. 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. 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.

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 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 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.

Iron Replacement Therapy Products

There are several IV iron replacement therapy products on the market and in various phases of clinical testing in the United States and abroad. Watson Pharmaceuticals, Inc. has two products, INFeD®, iron dextran injection, and Ferrlecit®, sodium ferric gluconate complex in sucrose injection. *INFeD* is approved for the treatment of iron deficiency anemia. *Ferrlecit* is approved for the treatment of anemia in chronic hemodialysis patients receiving erythropoietin. American Regent Laboratories, Inc. has two products, Dexferrum®, iron dextran injection, for the treatment of iron deficiency anemia, and Venofer®, iron sucrose injection, for the treatment of anemia in chronic hemodialysis patients receiving erythropoietin. 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 an IV iron replacement product for use in hemodialysis patients receiving erythropoietin. We do not know the current development status of this product in the United States or Europe.

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. *Resovist* has received approval in some EU and non-EU countries and Japan. Clinical trials are proceeding in the United States. *Primovist* is in Phase III development in Europe for liver imaging. Schering is also in Phase III development in Europe with Supravist® (SHU 555 C) for use as an MRI and MRA contrast agent. Nycomed has received marketing approval in the United States and Europe for its MnDPDP product, Teslascan®, for MRI of liver lesions. Bracco S.p.A. has received marketing approval in Europe for Gadolinium BOPTA (MultiHance)®, a chelated gadolinium compound for MRI of liver lesions, and we believe Bracco has filed for approval in the United States as well. To our knowledge, there are no approved products or drug candidates in human clinical development for the contrast-enhanced imaging of lymph nodes other than *Combidex*. Although we are unaware of any such products, those products may exist and could negatively effect the marketing of our products.

In the area of oral contrast agents, Pharmacyclics, Inc. filed a New Drug Application in late 1995 for GADOLITE®, its gadolinium-based product candidate, which is currently not approved by the FDA. Bracco received marketing 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 from Oncomembrane Inc. We do not know how, or if, Bracco and Oncomembrane are planning to market these products.

In the area of MRA contrast agents, Epix Medical, Inc. is developing MS-325, a gadolinium-based contrast agent. MS-325 has completed Phase III human clinical trials for use in MRA, excluding cardiac imaging. MS-325 is licensed to Schering AG. Guerbet is developing Vistarem® (P-792), a gadolinium-based contrast agent that is in Phase III development in Europe and the United States. Schering AG has two MRA agents in development: Gadovist®, gadolinium D3-butrol, for MRA which has been submitted for approval in Europe; 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. Ferropharm GmbH's VSOP-C184, a citrate-coated iron oxide, is in Phase I clinical studies. Nycomed has discontinued the development of Clariscan®, an iron oxide-based MRA contrast agent.

Resources of Our Competitors

Many of these companies 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 Investigational New Drug Application, also known as 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 a New Drug Application, also known as an NDA; (e) approval and validation of manufacturing facilities used in production of the pharmaceutical product; and (f) review and approval of the New Drug Application 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 a New Drug Application to the FDA for approval. In member countries of the European Union, or EU, the equivalent of a New Drug Application is referred to as a Dossier, and is filed with the Committee for Proprietary Medicinal Products, known as the CPMP, the EU equivalent of the FDA. 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 New Drug Application 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 a New Drug Application 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 such 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 a New Drug Application to be granted by the FDA. Among the conditions for NDA approval is the requirement that a prospective manufacturer's manufacturing procedures conform to current Good Manufacturing Practices, or 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 product for use in the United States, foreign manufacturing establishments must comply with current Good Manufacturing Practices 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, or 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.

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 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 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 payers 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

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. Two companies, Cytogen and Berlex, accounted for approximately 64% and 14%, respectively, of our revenues in fiscal 2001. No other company accounted for more than 10% of our total revenues in fiscal 2003, 2002 or 2001. All of the revenue attributable to Cytogen and a significant portion of the revenue attributable to Berlex in fiscal 2003, fiscal 2002 and fiscal 2001, was deferred revenue that was recognized in those fiscal years.

Employees

As of December 9, 2003, we had 22 full-time employees, 14 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. 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 2003, 2002 and 2001 from customers and licensees outside of the United States, principally in Europe and Japan, amounted to 13%, 20% 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 incurred research and development expenses of $4,458,980, $4,029,115 and $3,622,102 in each of the last three fiscal years, respectively.

ITEM 2. PROPERTIES:

Our principal operations are located in a company-owned building of approximately 25,000 square feet in Cambridge, Massachusetts. We believe this facility is 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 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 State 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.

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, 2003.

Executive Officers of the Registrant:

Jerome Goldstein, 64, 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.

Paula M. Jacobs, 59, joined us in January 1986 as Vice President-Development. From 1981 to 1986, Dr. Jacobs was employed at Seragen, Inc., first as Production Manager and later as General Manager of the Research Products Division.

Dennis Lawler, 49, joined us in February 1989 as Director of Quality Control and has been Vice President of Quality Control since January 1997. Prior to February 1989, Mr. Lawler was employed at CIS-US, first as Senior Quality Control Analyst, then as a Production Manager and then as a Plant Manager.

Jerome M. Lewis, 54, joined us in April 1986 as a Senior Scientist and has been Vice President of Scientific Operations since February 1991. Prior to April 1986, Dr. Lewis was employed as a senior scientist by Petroferm Ltd., a biotechnology company.

James A. Matheson, 59, joined us in May 1996 as Vice President of Finance. Prior to May 1996, Mr. Matheson was Controller of Diatech Diagnostics, Inc.

Mark C. Roessel, 53, joined us in January 1982 as Director of Regulatory Affairs and has been Vice President of Regulatory Affairs since January 1995. Prior to January 1982, Mr. Roessel was Compliance Manager of the Clinical Assay Division of Baxter International, Inc.

PART II

ITEM 5. MARKET FOR THE COMPANY'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS:

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 2002.

		First	Second	Third	Fourth
2003	High	5.14	4.80	12.20	13.74
	Low	3.97	4.04	4.20	8.35
2002	High	4.10	4.24	4.22	5.25
	Low	3.00	3.45	3.65	3.50

On December 9, 2003, there were approximately 250 stockholders of record and we believe that the number of beneficial holders of common stock was approximately 2,460. The last reported sale price of our common stock on December 9, 2003 was $14.19 per share. We have never declared or paid a cash dividend on our capital 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.

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.

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, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other financial information included elsewhere in this Annual Report on Form 10-K.

SELECTED FINANCIAL DATA

	For the years ended September 30,				
	2003	2002	2001	2000*	1999
Statement of Operations Data:					
Revenues:					
License fees	$ 3,642,052	$ 4,020,617	$ 4,640,198	$ 1,124,049	$ —
Royalties	535,000	725,000	700,000	825,000	680,000
Product sales	600,444	965,820	633,480	1,253,537	1,966,059
Contract research and development	—	—	—	106,003	581,429
Total revenues	4,777,496	5,711,437	5,973,678	3,308,589	3,227,488
Costs and Expenses:					
Cost of product sales	199,561	214,357	204,399	239,228	454,642
Contract research and development expenses	—	—	—	3,195	37,056
Company-sponsored research and development expenses	4,458,980	4,029,115	3,622,102	4,623,468	7,952,331
Selling, general and administrative expenses	1,770,402	1,712,234	1,667,066	3,013,796	3,694,038
Total costs and expenses	6,428,943	5,955,706	5,493,567	7,879,687	12,138,067
Other Income (Expense):					
Interest and dividend income	112,730	255,928	697,162	827,780	646,611
Gains and (losses) on sales of securities and derivative instruments, net	2,777,003	610,378	(579,418)	(62,450)	3,555,957
Write-down of marketable securities†	(644,310)	(2,331,956)	(4,659,800)	—	—
Other income, net	148,129	3,647	258,122	—	265,593
Total other income (expense)	2,393,552	(1,462,003)	(4,283,934)	765,330	4,468,161
Income (loss) before provision for income taxes and cumulative effect of accounting change	742,105	(1,706,272)	(3,803,823)	(3,805,768)	(4,442,418)
Income tax (benefit) provision	(124,752)	—	25,362	—	—
Income (loss) before cumulative effect of accounting change	866,857	(1,706,272)	(3,829,185)	(3,805,768)	(4,442,418)
Cumulative effect of accounting change*	—	—	—	(7,457,717)	—
Net income (loss)	$ 866,857	$ (1,706,272)	$ (3,829,185)	$ (11,263,485)	$ (4,442,418)
Earnings (loss) per share—basic:					
Income (loss) per share before cumulative effect of accounting change	$ 0.13	$ (0.26)	$ (0.57)	$ (0.56)	$ (0.66)
Cumulative effect of accounting change	—	—	—	(1.11)	—
Basic	$ 0.13	$ (0.26)	$ (0.57)	$ (1.67)	$ (0.66)
Earnings (loss) per share—diluted:					
Income (loss) per share before cumulative effect of accounting change	$ 0.12	$ (0.26)	$ (0.57)	$ (0.56)	$ (0.66)
Cumulative effect of accounting change	—	—	—	(1.11)	—
Diluted	$ 0.12	$ (0.26)	$ (0.57)	$ (1.67)	$ (0.66)
Weighted average shares outstanding used to compute earnings (loss) per share:					
Basic	6,914,323	6,636,798	6,701,113	6,758,825	6,766,934
Diluted	7,143,455	6,636,798	6,701,113	6,758,825	6,766,934

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

* In fiscal 2000, we adopted SAB 101. 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.

	At September 30,

	2003	2002	2001	2000	1999
Balance sheet data:					
Working capital	$ 22,579,478	$ 14,233,904	$ 18,734,388	$ 25,706,905	$ 22,020,107
Total assets	$ 29,365,613	$ 22,484,002	$ 27,448,667	$ 35,667,591	$ 27,816,359
Long-term liabilities—deferred revenue	$ 5,265,669	$ 7,774,131	$ 11,444,384	$ 15,977,599	—
Stockholders' equity	$ 20,918,075	$ 10,650,267	$ 11,512,294	$ 14,305,632	$ 27,054,709

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

This Annual Report on Form 10-K, including without limitation, "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains certain projections, estimates and other forward-looking statements which involve a number of risks and uncertainties. While this outlook represents management's current judgment on the future direction of our business, actual results could differ materially from those anticipated or projected in any forward-looking statements, as a result of a variety of factors, including those set forth in the section below entitled "Certain Factors That May Affect Future Results" and elsewhere in this Annual Report on Form 10-K.

Overview

Since our inception in November 1981, we have focused our efforts on developing our core superparamagnetic iron oxide nanoparticle technology for various applications, including for use as therapeutic iron compounds for the treatment of chronic anemia and as contrast agents for utilization in magnetic resonance imaging, also known as MRI. We have funded our operations with proceeds of financings, cash from license fees from corporate partners, including proceeds from the sale of securities received from marketing partners, and income earned on invested cash. Our success will depend, in part, on our ability to obtain FDA approval of Combidex®, successfully develop ferumoxytol as an iron replacement therapeutic and as an MRA contrast agent, enter into strategic partnerships for the development and marketing of ferumoxytol or develop a marketing and sales capability internally, maintain and scale up our manufacturing capabilities, retain key employees, and successfully respond to technological and other changes in the marketplace.

Our operating results may continue to vary significantly from quarter to quarter or from year to year depending on a number of factors, including: the variable nature of our product sales to our marketing partners; uneven demand for our products by end users; regulatory approval of our product candidates; the discovery of different applications for our existing products and product candidates; and the acceptance of our products within the medical community. Our current planned expense levels are based in part upon expectations as to future revenue. Consequently, profits may vary significantly from quarter to quarter or year to year based on the timing of revenue. 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.

A substantial portion of our expenses consists of research and development expenditures. We may rely to a greater degree on contract research and development providers in the future as the human clinical development of ferumoxytol for use in iron replacement therapy moves into Phase III clinical trials and expect that research and development expenses will continue to be a significant portion of our total expenses.

Results of Operations

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.

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 Laboratories, Inc. and $2,904,297 of license fee revenue from Cytogen Corporation 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.

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 based on costs incurred and expected remaining expenditures related to this agreement. The entire amount of the license fee was booked as deferred revenue upon signing the agreement. $2,904,297 of that deferred revenue was recognized as revenue in fiscal 2003 and approximately $3,282,862 was recognized in fiscal 2002. 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. 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 2003 and 2002 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.

Deferred revenue consisted of the following at September 30, 2003 and 2002:

	Cytogen	Berlex	Total
At September 30, 2002:			
Short term	$ 2,857,806	$ 737,755	$ 3,595,561
Long term	3,164,187	4,609,944	7,774,131
Total	$ 6,021,993	$ 5,347,699	$ 11,369,692
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

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

Product sales for the fiscal year ended September 30, 2003 were $600,444 compared to $965,820 for the fiscal year ended September 30, 2002. This decrease is a result of the variable nature of our product sales to our marketing partners from quarter to quarter based on uneven demand and the batch size in which our products are manufactured and shipped.

Costs and Expenses

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. We have different gross margins on the sales of each of our products. The lower gross margin in fiscal 2003 is due to reduced sales of our higher gross margin product.

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. We expect selling, general and administrative expenses to continue increasing slightly on a going-forward basis due to

overall increases in the use of our professional advisors as a result of changes in the regulatory environment.

Company-sponsored 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 company-sponsored research and development programs related to the clinical development of ferumoxytol in iron replacement therapy and MRA. Company-sponsored research and development expenses include external expenses, such as costs of clinical trials, 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. We expect company-sponsored research and development expenses to increase in fiscal 2004 as a result of the initiation of Phase III clinical studies of ferumoxytol for use in iron replacement therapy.

Our product candidate, ferumoxytol, has completed Phase II clinical trials for use in iron replacement therapy and is in Phase II clinical trials for use in 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. In August 2000, we entered into a license and marketing agreement with Cytogen, which covers ferumoxytol for oncology imaging and *Combidex*. At the end of fiscal 2000, we adopted SAB 101 and determined to account for the revenue associated with the Cytogen agreement over the development period based on costs incurred and expected remaining expenditures related to the agreement. As a result, since the end of fiscal 2000, we have tracked our internal research and development expenses in relation to those projects covered by the Cytogen agreement and not by specific research and development projects. Since the end of fiscal 2000 and through the year ended September 30, 2003, we incurred aggregate external research and development expenses of approximately $2,000,000 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 for all current applications, including costs related to ongoing and future pre-clinical and clinical trial activities, is currently estimated to range from approximately $10,000,000 to $15,000,000. Phase III clinical trials for ferumoxytol in iron replacement therapy are currently expected to begin in 2004 and Phase III clinical studies for ferumoxytol in MRA could begin before the end of 2004.

In June 2000, we received an approvable letter, subject to certain conditions, from the FDA for *Combidex*, our contrast agent to aid in the diagnosis of metastatic lymph nodes. We are currently discussing the outstanding issues from the approvable letter with the FDA in an effort to obtain marketing approval for *Combidex*. 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 not incurred any additional external research and development expenses since fiscal 2000 related to *Combidex*. We have, however, 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. We do not anticipate substantial additional pre-approval clinical trial expenses related to *Combidex*.

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.

Other Income (Expense)

Other income (expense) consisted of the following in the fiscal years ended September 30, 2003 and 2002:

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

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. 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 CEO 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 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. There was no income tax provision for the fiscal year ended September 30, 2003 due to sufficient net loss carry-forwards. There was 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

In fiscal 2000, we adopted SAB 101. 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. 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.

Net Earnings (losses)

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

Fiscal 2002 Compared to Fiscal 2001

Revenues

Total revenues for the fiscal year ended September 30, 2002 were $5,711,437 compared to $5,973,678 for the fiscal year ended September 30, 2001.

License fee revenues for the fiscal year ended September 30, 2002 were $4,020,617, consisting of $737,755 of license fee revenue associated with the license and marketing agreement signed in 1995 with Berlex Laboratories, Inc. and $3,282,862 of license fee revenue from Cytogen Corporation related to a license and marketing agreement signed in fiscal 2000. License fee revenues for the fiscal year ended September 30, 2001 were $4,640,198, consisting of $786,651 in revenue from Berlex and $3,853,547 in revenue from Cytogen.

Royalties for the fiscal year ended September 30, 2002 were $725,000 as compared to $700,000 in fiscal 2001. The increase in royalties is primarily the result of increased volume of product sales of *GastroMARK* by our United States distributor, Mallinckrodt Inc. Our royalty revenues are entirely dependent on sales of our products by our marketing partners.

Product sales for the fiscal year ended September 30, 2002 were $965,820 compared to $633,480 for the fiscal year ended September 30, 2001. This increase is a result of the variable nature of our product sales to our marketing partners from quarter to quarter based on uneven demand and the batch size in which our products are manufactured and shipped.

Costs and Expenses

The cost of product sales for the fiscal year ended September 30, 2002 was $214,357 compared to $204,399 for the fiscal year ended September 30, 2001. The cost of product sales for fiscal 2002 was slightly higher than in fiscal 2001 because of increased product sales and the related increase in costs associated with producing more of our products. Cost of product sales as a percentage of product sales was 22% in fiscal 2002 compared with 32% for fiscal 2001. We have different gross margins on the sales of each of our products. The increase in gross margin in 2002 compared with fiscal 2001 is due to a higher proportion of sales in fiscal 2002 being of the higher margin products.

Selling, general and administrative expenses for the fiscal year ended September 30, 2002 of $1,712,234 increased slightly when compared to fiscal 2001 expenses of $1,667,066.

Company-sponsored research and development expenses for the fiscal year ended September 30, 2002 were $4,029,115, an increase of $407,013 compared to $3,622,102 for the fiscal year ended September 30, 2001. The increase was primarily attributable to an increase in external company-sponsored research and development programs related to the pre-clinical development of ferumoxytol in MRA and iron replacement therapy.

Other Income (Expense)

Interest and dividend income was $255,928 and net gains and losses on sales of securities and derivative instruments were $610,378 for the fiscal year ended September 30, 2002 compared to $697,162 and $(579,418) respectively, for the fiscal year ended September 30, 2001. Interest income for the fiscal year ended September 30, 2002 was $116,312 compared to $631,386 for the fiscal year ended September 30, 2001. The decrease was primarily due to a reduction in interest-bearing cash equivalents and marketable securities because of increased cash used in operations and a reduction in the rate of return on our interest-bearing cash equivalents due to lower interest rates. Dividend income of

$139,616 for the year ended September 30, 2002 was $73,840 more than the $65,776 for the fiscal year ended September 30, 2001. This increase is primarily due to increased holdings of dividend earning securities during fiscal 2002. Included in net gains and losses on sales of securities for fiscal 2001 was $147,557 in net gains on derivative activity, principally the sale of covered call options. There was also a gain on the sale of certain capital assets of $3,647 during the fiscal year ended September 30, 2002. Other income in the year ended September 30, 2001 included amounts for the settlement of a claim against an investor and gains from the sale of certain capital assets.

As of September 30, 2002, we determined that the decline in the carrying value of Cytogen common stock and two other securities below their original basis was an other-than-temporary decline and recorded a write-down of securities in "Other income (expense)" of $2,331,956 for the fiscal year ended September 30, 2002 and established a new cost basis for the 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 of and business outlook of the companies that issued the securities, including industry and sector performance, and overall market conditions and trends. In fiscal 2001, we determined that the decline in the carrying value of Cytogen common stock below its original basis was an other-than-temporary decline and accordingly recorded a write-down of securities in "other income (expense)" of $4,659,800 and established a new cost basis for this security 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 Cytogen common stock was less than cost basis, and overall market conditions and trends.

Income Taxes

There was no income tax provision or benefit for the fiscal year ended September 30, 2002. The income tax provision of $25,362 in fiscal 2001 reflects a change in estimate of the fiscal 2000 alternative minimum tax.

Cumulative Effect of Accounting Change

In fiscal 2000, we adopted SAB 101. For each of the years ended September 30, 2002 and September 30, 2001, we recognized $735,516 in revenue that was included in the cumulative effect adjustment as of October 1, 1999.

Net Losses

For the reasons stated above, in the fiscal year ended September 30, 2002, we recorded a net loss of $(1,706,272), or $(0.26) per share and in the fiscal year ended September 30, 2001, we recorded a net loss of $(3,829,185), or $(0.57) per share.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through cash generated from operations, financings, investment activities and through corporate partnership agreements.

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 is the result of a financing completed in July of 2003 which brought net proceeds of $9,484,999 to the Company, and the sale of all of our marketable securities partially offset by cash used in our operating activities.

Net cash used in operating activities in fiscal 2003 was $4,932,070, and we believe that our cash and cash equivalents as of September 30, 2003 will be sufficient to cover at least two years of future operating cash flow needs. 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.

The money market account we use for the maintenance of our cash and cash equivalents is a money market mutual fund that is not insured by the Federal Deposit Insurance Corporation. Any decline in value of this money market mutual fund would result in a substantial reduction in our total assets and cash available to support our operating and research and development expenses and could force us to seek alternative sources of financing.

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 $6,474,098 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 to increased company-sponsored 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. 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 we have recently generated cash through the private placement 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 in the manner we anticipate, we could be forced to obtain alternative sources of financing or to curtail our development activity.

Cash provided by investing activities was $10,570,085 for the fiscal year ended September 30, 2003 compared to $941,870 for the fiscal year ended September 30, 2002. Cash provided by investing activities in the fiscal year ended September 30, 2003 included proceeds from the sale of marketable securities of $12,094,577, offset by the purchase of marketable securities of $1,291,425. 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.

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. There was no cash used in financing activities during the fiscal years ended September 30, 2003 and 2002. Cash provided by financing activities was $34,436 from the issuance of our common stock during the fiscal year ended September 30, 2002.

Capital expenditures in the fiscal year ended September 30, 2003 were $167,089 compared to $36,934 in the fiscal year ended September 30, 2002. The capital expenditures in fiscal 2003 related primarily to a scale-up in production facilities for the manufacture of ferumoxytol, while in fiscal 2002 they related to the continuation of our efforts to upgrade laboratory, production and computer equipment. We have no current commitment for any significant expenditures on property, plant and equipment.

We have classified $761,747 as a short-term other asset as of September 30, 2003. This amount is the surrender value of a cash value life insurance policy. This amount was received on October 29, 2003.

Our future capital requirements will depend on many factors, including, but not limited to: continued scientific progress in our research and development programs; the magnitude of our research and development programs; progress with clinical trials for our therapeutic and diagnostic products; the magnitude of product sales; the time involved in obtaining regulatory approvals; the costs involved in filing, prosecuting and enforcing patent claims; competing technological and market developments; and our ability to establish additional development and marketing arrangements or to raise additional capital through other financing activities to provide funding for research and development activities, including the management of clinical trials and engagement in efforts to obtain regulatory approvals, and to manufacture and market certain of our products.

Contractual Obligations

We currently have no long-term debt obligations, capital lease obligations, purchase obligations or other long-term liabilities reflected on our balance sheet. Our future commitments are as follows:

	Payment due by period				
Contractual Obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Operating Lease Obligations	$ 23,821	$ 18,991	$ 4,830	—	—

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 to the Financial Statements.

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."

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 our Company, these critical accounting policies are principally the policies of revenue recognition associated with license fees and policies to determine the existence of an other-than-temporary decline in the fair value of our marketable securities below cost basis.

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 based on the ratio of development expenses incurred to our estimate of total expected 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 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. License revenue is not recognized unless collectibility is reasonably assured.

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 marketable securities. 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 no marketable securities at September 30, 2003, 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 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 issuer of the securities, 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. 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.

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 is a comparison of the asset carrying value to the undiscounted future operating cash flows. 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 Accounting Pronouncements

In November 2002, the Financial Accounting Standards Board ("FASB") Emerging Issues Task Force reached consensus with respect to Issue 00-21 ("EITF 00-21"), "Accounting for Revenue Arrangements with Multiple Deliverables." EITF 00-21 addresses the accounting for multiple-element revenue arrangements. Specifically, EITF 00-21 addresses how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting and how arrangement consideration should be measured and allocated to the separate units of accounting. EITF 00-21 is

effective for all revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of EITF 00-21 did not have a material impact on our financial position or results of operations.

In January 2003, FASB issued FASB Interpretation No. 46 ("FIN 46"), Consolidation of Variable Interest Entities. FIN 46 requires that if an entity has a controlling financial interest in a variable interest entity, the assets, liabilities and results of activities of the variable interest entity

should be included in the consolidated financial statements of the entity. FIN 46 requires that its provisions are effective immediately for all arrangements entered into after January 31, 2003. We do not have any financial interests in variable interest entities created after January 31, 2003. For those arrangements entered into prior to January 31, 2003, FIN 46 provisions are required to be adopted by us in the second quarter of fiscal 2004. The adoption of FIN 46 is not expected to have a material impact on our financial position or results of operations.

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 our Company.

We may not be able to obtain the necessary regulatory approvals in order to market and sell our products; 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 require many years and 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 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.

One of our product candidates, ferumoxytol, has completed Phase II clinical trials for use in iron replacement therapy. Phase II clinical trials for use as a contrast agent in MRA are currently ongoing. Before applying for FDA approval to market ferumoxytol, we must conduct larger-scale human clinical trials that further demonstrate the safety and efficacy of ferumoxytol to the satisfaction of the FDA and other regulatory authorities. 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.

Although we have filed a New Drug Application and received an "approvable" letter from the FDA for *Combidex* for lymph node metastases, final approval remains subject to the satisfaction of certain conditions imposed by the FDA and labeling must be resolved. The New Drug Application for *Combidex* may not be approved, or, if approved, it may not be approved for the indication that we are seeking. If we are unable to obtain approval for this indication or if the FDA requires labeling that imposes limitations on the use of *Combidex*, our ability to market the product to the medical community may be hindered. Any failure to successfully market and sell *Combidex* would reduce the amount of cash generated from operations available to fund research and development activities which could force us to seek other financing alternatives.

We may also be required to demonstrate that *Combidex* or ferumoxytol represent 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 that we may be unable to fund and therefore we could be forced to curtail our development activity.

In addition, 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.

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.

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 seriously hinder our ability to generate revenue through royalties or direct sales of our products.

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

The development of new pharmaceutical products is highly uncertain and subject to a variety of inherent risks of failure, including the following:

- 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,
- Other parties may claim proprietary rights to our product technology that prevent us from marketing our products, and
- Our products may not be widely adopted or commercially successful.

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. 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. 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 product being tested, but which can nevertheless adversely affect clinical trial results or approvals by

the FDA. Clinical testing of pharmaceutical products is itself subject to approvals by various governmental regulatory 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 could negatively affect our future prospects and stock price.

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 programs may not be completed successfully. Any delays or failures in the development of our current or future product candidates will delay or prevent generation of revenue from such product candidates and may damage our ability to become profitable.

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. Two companies were responsible for approximately 84% of our revenue during the fiscal year ended September 30, 2003. Cytogen represented approximately 61% of our revenue in the fiscal year ended September 30, 2003, all of which represented 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 conduct clinical testing, to obtain regulatory approvals and to manufacture and market our products. We may not be able to derive any revenues from these arrangements. If any of our collaborators breaches its agreement with us or otherwise fails to perform, such event could impair our revenue and impose 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 other 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 future clinical trials for ferumoxytol, 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 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 in the company 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 launch would be delayed and the commercialization of ferumoxytol severely impaired.

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 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,
- market demand for *Feridex I.V.* and *GastroMARK*,
- the timing and likelihood of FDA approval of *Combidex* or ferumoxytol,
- market acceptance of *Combidex* or ferumoxytol, if approved,

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

- the extent of reimbursement for the cost of our products from government health administration authorities, private health insurers and other third-party payors, and

- a significant portion of our operating expenses is relatively fixed in nature due to our administrative, research and development and manufacturing costs which could affect our ability to quickly compensate for a revenue shortfall.

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.

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 $4.03 and $15.24 in the fifty-two week period prior to December 9, 2003. 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. In fiscal 2002, our shares had an average daily trading volume of approximately 3,000 shares. As of December 9, 2003, this average daily trading volume had increased to approximately 36,000 shares. Bulk sales, including sales pursuant to our Registration Statement on Form S-3 recently filed and declared effective on August 20, 2003, or purchases of our stock in a short period of time could cause the market price for our shares to decline or fluctuate drastically.

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 products. 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 two years. Thereafter, we may require additional funds to continue our research and

development, commence future pre-clinical and clinical trials, seek regulatory approvals, establish commercial-scale manufacturing capabilities and market and sell our products. We may seek such financing through arrangements with collaborative partners or through public or private sales of our securities, including equity securities. We may not be able to obtain financing on acceptable terms, if at all. Any additional equity financings could be dilutive to our 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 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 treatment 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 our 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. Although on the market since 1996 and 1997, respectively, *Feridex I.V.* and *GastroMARK* represent an alternative technology platform for physicians to adopt. *Combidex*, if approved, may also represent a new technology and ferumoxytol, if approved, may represent an alternative to existing products, 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* and for ferumoxytol for oncology applications. 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. We also may not be able to enter into marketing and sales agreements with others on acceptable terms, if at all. Furthermore, we, or our corporate partners, may not be successful in marketing and selling 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 dependent on our executive officers and senior scientists, as well as our ability to attract and retain qualified scientific and technical personnel for the research and development activities conducted or sponsored by us. Our product development efforts could be delayed or curtailed if we lose the services of any of these people. 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 limit our ability to expand our business.

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 Massachusetts facility. We intend to, pending FDA approval, manufacture *Combidex* formulated drug product at our Massachusetts 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*. 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. In addition, 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. 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. As a result, 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. 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 and become profitable.

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. We generally obtain raw materials from one vendor only, even where multiple sources are available, to maintain quality control and enhance working relationships with suppliers. If we cannot obtain sufficient quantities of these raw materials on commercially reasonable terms, or in a timely manner, we would be unable to manufacture our products on a timely and cost-effective basis, which would hinder our ability to generate revenues from sales of our products and impede our development efforts with respect to our product candidates.

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 which 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 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 IV 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 IV iron therapy products may receive greater market acceptance than ferumoxytol.

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. For example, many cardiac 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.

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. We also cannot be sure that we will develop additional proprietary products that are patentable. 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, invalidated or circumvented. 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, manufacturing 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 breach, 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.

Our success is dependent on third-party reimbursement.

In both the United States and foreign markets, our ability to commercialize our products may 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. 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 the government or third-party payors do not approve our products and related treatments 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, and our ability to generate revenue may be impaired. Even if third-party payors make reimbursement available, these payors' reimbursement policies may negatively impact us and our corporate partners' ability to sell our products on a profitable basis.

In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to reform the health care system. The trend toward managed healthcare in

the United States, the growth of organizations such as health maintenance organizations, and 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, legislation and regulations affecting the pricing of pharmaceuticals may change 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 an agency adopts these proposals they could limit our ability to price our products at desired levels.

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 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 and by-laws, and in order to attract competent candidates, we are obligated to indemnify our officers and directors against certain claims arising from their service to Advanced Magnetics. Currently, we do not maintain liability insurance to cover such potential claims against our officers and directors. As a result of our indemnification obligations, any such 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.

We are subject to various federal, state and local environmental laws and regulations that govern our operations, including the handling and disposal of nonhazardous 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, as well as 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:

Although we did not hold any marketable securities at September 30, 2003, we have historically owned financial instruments sensitive to market risks as part of our investment portfolio. None of these market-risk sensitive instruments were held for trading purposes. Our investment portfolio contained instruments that were subject to a decline in equity markets. However, now that we have sold all of such securities, we are no longer subject to such risks. The proceeds from the sale of the securities along with all of our other cash are being held in bank deposit accounts or money market mutual funds. Due to the current low interest rate environment, we do not believe we are exposed to any material risks as a consequence of potential interest rate fluctuations.

ITEM 8. FINANCIAL STATEMENTS:

Our Financial Statements and related Report of Independent Auditors are presented in the following pages. The financial statements included in this Item 8 are as follows:

Report of Independent Auditors

Financial Statements:

Balance Sheets—September 30, 2003 and 2002

Statements of Operations—for the years ended September 30, 2003, 2002 and 2001

Statements of Comprehensive Income—for the years ended September 30, 2003, 2002 and 2001

Statements of Stockholders' Equity—for the years ended September 30, 2003, 2002 and 2001

Statements of Cash Flows—for the years ended September 30, 2003, 2002 and 2001

Reconciliation of Net Income (Loss) to Net Cash Used in Operating Activities—for the years ended September 30, 2003, 2002 and 2001

Notes to Financial Statements

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REPORT OF INDEPENDENT AUDITORS

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

In our opinion, the accompanying balance sheets and the related statements of operations, comprehensive income, stockholders' equity and cash flows present fairly, in all material respects, the financial position of Advanced Magnetics, Inc. at September 30, 2003 and September 30, 2002, and the results of its operations and its cash flows for each of the three years in the period ended September 30, 2003 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 auditing standards generally accepted in the United States of America, which 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.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
November 11, 2003

Advanced Magnetics, Inc.

Balance Sheets

	September 30,	
	2003	2002
ASSETS		
Current assets:		
Cash and cash equivalents	$ 23,901,126	$ 8,557,819
Marketable securities	—	9,011,325
Accounts receivable—Trade	366,261	205,485
Inventories	267,761	132,672
Prepaid expenses	464,452	386,207
Other assets	761,747	—
Total current assets	25,761,347	18,293,508
Property, plant and equipment:		
Land	360,000	360,000
Buildings and improvements	4,628,295	4,617,996
Laboratory equipment	6,933,871	6,792,298
Furniture and fixtures	793,552	778,335
	12,715,718	12,548,629
Less—accumulated depreciation and amortization	(9,111,452)	(8,905,774)
Net property, plant and equipment	3,604,266	3,642,855
Other assets	—	547,639
Total assets	$ 29,365,613	$ 22,484,002

LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 118,282	$ 80,603
Accrued expenses	601,616	383,440
Deferred revenues	2,461,971	3,595,561
Total current liabilities	3,181,869	4,059,604
Deferred revenues	5,265,669	7,774,131
Total liabilities	8,447,538	11,833,735
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 7,758,107 shares as of September 30, 2003 and 6,644,642 shares as of September 30, 2002	77,581	66,446
Additional paid-in capital	53,619,640	43,888,960
Accumulated deficit	(32,779,146)	(33,646,003)
Accumulated other comprehensive income (loss)	—	340,864
Total stockholders' equity	20,918,075	10,650,267
Total liabilities and stockholders' equity	$ 29,365,613	$ 22,484,002

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

Advanced Magnetics, Inc.

Statements of Operations

	For the years ended September 30,		
	2003	2002	2001
Revenues:			
License fees	$ 3,642,052	$ 4,020,617	$ 4,640,198
Royalties	535,000	725,000	700,000
Product sales	600,444	965,820	633,480
Total revenues	4,777,496	5,711,437	5,973,678
Costs and expenses:			
Cost of product sales	199,561	214,357	204,399
Company-sponsored research and development expenses	4,458,980	4,029,115	3,622,102
Selling, general and administrative expenses	1,770,402	1,712,234	1,667,066
Total costs and expenses	6,428,943	5,955,706	5,493,567
Other income (expense):			
Interest and dividend income	112,730	255,928	697,162
Gains and losses on sales of securities and derivative instruments, net	2,777,003	610,378	(579,418)
Write-down of marketable securities	(644,310)	(2,331,956)	(4,659,800)
Other income, net	148,129	3,647	258,122

Total other income (expense)	2,393,552	(1,462,003)	(4,283,934)
Income (loss) before provision for (benefit from) income taxes	742,105	(1,706,272)	(3,803,823)
Provision for (benefit from) income taxes	(124,752)	—	25,362
Net income (loss)	$ 866,857	$ (1,706,272)	$ (3,829,185)
Earnings (loss) per share:			
Basic	$ 0.13	$ (0.26)	$ (0.57)
Diluted	$ 0.12	$ (0.26)	$ (0.57)
Weighted average shares outstanding used to compute earnings (loss) per share:			
Basic	6,914,323	6,636,798	6,701,113
Diluted	7,143,455	6,636,798	6,701,113

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

Advanced Magnetics, Inc.

Statements of Comprehensive Income

	For the years ended September 30,		
	2003	2002	2001
Net income (loss)	$ 866,857	$ (1,706,272)	$ (3,829,185)
Other comprehensive income:			
Unrealized gains (losses) on securities	1,791,830	(935,927)	(3,765,324)
Reclassification adjustment for (gains) losses included in net income	(2,132,694)	1,721,578	5,239,218
Total other comprehensive income (loss)	(340,864)	785,651	1,473,894
Comprehensive income (loss)	$ 525,993	$ (920,621)	$ (2,355,291)

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

Advanced Magnetics, Inc.

Statements of Stockholders' Equity

For the years ended September 30, 2003, 2002 and 2001

Common Stock		Additional Paid-in Capital	Retained Earnings (Deficit)	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Shares	Amount				

Balance at September 30, 2000	6,773,932	$ 67,739	$ 44,267,120	$ (28,110,546)	$ (1,918,681)	$ 14,305,632
Shares issued in connection with employee stock purchase plan	4,663	47	14,828	—	—	14,875
Common shares repurchased	(144,700)	(1,447)	(451,475)	—	—	(452,922)
Other comprehensive income	—	—	—	—	1,473,894	1,473,894
Net loss	—	—	—	(3,829,185)	—	(3,829,185)
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

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

Advanced Magnetics, Inc.

Statements of Cash Flows

	For the years ended September 30,		
	2003	2002	2001
Cash flows from operating activities:			
Cash received from customers	$ 514,675	$ 1,103,044	$ 1,198,034
Cash paid to suppliers and employees	(6,474,099)	(6,189,861)	(5,956,859)
Dividends and interest received	112,730	226,208	464,124
Royalties received	641,743	700,261	723,214
Income taxes refunded (paid)	124,752	—	(94,752)
Other income	148,129	—	200,000
Net cash used in operating activities	(4,932,070)	(4,160,348)	(3,466,239)
Cash flows from investing activities:			
Proceeds from sales of marketable securities	12,094,579	6,728,059	13,196,124
Proceeds from notes and bonds maturing	—	—	12,000,000

Purchase of marketable securities	(1,291,425)	(5,733,208)	(13,821,980)
Purchase of notes and bonds	—	—	(11,766,961)
Capital expenditures	(167,089)	(36,934)	(80,808)
Proceeds from sale of fixed assets	—	48,000	61,000
(Increase) decrease in other assets	(65,979)	(64,047)	(61,966)
Net cash provided by (used in) investing activities	10,570,086	941,870	(474,591)
Cash flows from financing activities:			
Proceeds from the exercise of stock options	185,532	9,181	—
Proceeds from the issuance of common stock under the Employee Stock Purchase Plan	34,760	25,255	14,875
Net proceeds from the issuance of common stock and warrants to purchase common stock	9,484,999	—	—
Purchase of treasury stock	—	—	(452,922)
Net cash provided by (used in) financing activities	9,705,291	34,436	(438,047)
Net increase (decrease) in cash and cash equivalents	15,343,307	(3,184,042)	(4,378,877)
Cash and cash equivalents at beginning of year	8,557,819	11,741,861	16,120,738
Cash and cash equivalents at end of year	$ 23,901,126	$ 8,557,819	$ 11,741,861
Supplemental data:			
Non-cash operating activities:			
Stock dividend received	—	$ 29,720	—

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,		
	2003	2002	2001
Net income (loss)	$ 866,857	$ (1,706,272)	$ (3,829,185)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Depreciation and amortization	205,678	88,423	493,933
Gains of disposal of property, plant and equipment	—	(3,647)	(58,122)
Non-cash license fee revenue	(3,642,052)	(4,020,617)	(4,582,541)
Non-cash expense associated with stock options	36,524	24,158	—
Net realized (gains) losses on sales of marketable securities	(2,777,003)	(610,378)	579,418
Write-down of marketable securities	644,310	2,331,956	4,659,800
Stock dividend received	—	(29,720)	—
Accretion of U.S. Treasury Notes discount	—	—	(233,038)
Changes in operating assets and liabilities:			
Accounts receivable	(160,776)	112,485	321,770
Inventories	(135,089)	(45,251)	4,035
Prepaid expenses	(78,245)	(219,464)	20,738
Accounts payable and accrued expenses	255,855	(82,021)	(914,310)
Other assets—short term	(761,747)	—	—
Other assets—long term	613,618	—	—
Deferred revenues	—	—	71,263
Total adjustments	(5,798,927)	(2,454,076)	362,946

Net cash used in operating activities	$ (4,932,070)	$ (4,160,348)	$ (3,466,239)

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 for the treatment of chronic anemia and novel imaging agents for use in conjunction with magnetic resonance imaging to aid in the diagnosis of cancer and other diseases.

We are subject to risks common to companies in the industry including, but not limited to, development by us or our competitors of new technological innovations, uncertainty of product development and commercialization, dependence on key personnel and collaborative relationships, market acceptance of products, uncertainties related to third-party reimbursement, product liability, protection of proprietary technology, and compliance with FDA and other government agencies and regulations.

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 marketable securities having a maturity of less than three months at the date acquired. Substantially all of the cash and cash equivalents at September 30, 2003 and 2002 were held in a money market account. The money market account is a money market mutual fund that is not insured by the Federal Deposit Insurance Corporation.

Marketable Securities

We held no marketable securities at September 30, 2003. Our portfolio at September 30, 2002 consisted of securities classified as available-for-sale, which are recorded at fair market value. The fair value of marketable securities are based on quoted market prices. Net unrealized gains and losses on marketable securities (excluding other than temporary losses) are recorded as a separate component of stockholders' equity entitled "Accumulated other comprehensive income (loss)." Interest income is accrued as earned. 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.

Marketable securities 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).

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. 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 is a comparison of the asset carrying value to the undiscounted future cash flows. 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.

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 leasehold improvements—over the life of the lease.

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 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. 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 our 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.

Revenue is not recognized unless collectibility is reasonably assured. At September 30, 2003 and 2002 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" ("APB 25") and related interpretations in accounting for qualifying options granted to our employees under our plans and apply Statement of Financial Accounting Standards No. 123 "Accounting for Stock Issued to Employees" ("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, our pro forma net income (loss) and pro forma earnings (loss) per share for the fiscal year ending September 30, 2003, 2002 and 2001 would have been as follows:

	Fiscal Year Ended September 30,		
	2003	2002	2001
Reported net income (loss)	$ 866,857	$ (1,706,272)	$ (3,829,185)
Pro forma stock compensation expense	(330,817)	(297,244)	(207,529)
Pro forma net income (loss)	$ 536,040	$ (2,003,516)	$ (4,036,714)
Reported earnings (loss) per share:			
Basic	$ 0.13	$ (0.26)	$ (0.57)
Diluted	$ 0.12	$ (0.26)	$ (0.57)
Pro forma earnings per share:			
Basic	$ 0.08	$ (0.30)	$ (0.60)
Diluted	$ 0.08	$ (0.30)	$ (0.60)

The fair value of each option granted during 2003, 2002 and 2001 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 2003 and 2002 and expected life of 5.0 years in 2001; (2) expected volatility of 64.1% in 2003 and 2002, and 64.6% in 2001; (3) an average risk-free interest rates of 3.42% in 2003, 4.26% in 2002, 5.05% in 2001; and (4) no dividend yield.

The assumptions used for awards under our 2003 Employee Stock Purchase Plan were the same as those listed above, except that an expected life of 0.5 years was used for each period. The weighted average grant date fair value of stock awards granted during the years ended September 30, 2003, 2002 and 2001 was $3.74, $2.24 and $1.88 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

There was 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. There was 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. 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 MRI contrast agents. We perform ongoing credit evaluations of our customers and generally do not require collateral. 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. Two companies, Cytogen and Berlex, accounted for approximately 64% and 14% respectively, of our revenues in fiscal 2001. No other company accounted for more than 10% of our total revenues in fiscal 2003, 2002 or 2001. All of the revenue attributable to Cytogen and a significant portion of the revenue attributable to Berlex in fiscal 2003, fiscal 2002 and fiscal 2001, was deferred revenue.

In fiscal 2003, 2002 and 2001, revenues from customers and licensees outside of the United States, principally in Europe and Japan, amounted to 13%, 20% and 20%, respectively, of our total revenues.

Certain raw materials used in our products are procured from a single source. We generally obtain raw materials from one vendor only, even where multiple sources are available, to maintain quality control and enhance working relationships with suppliers. The failure of a supplier, including a subcontractor, to deliver on schedule could delay or interrupt our delivery of products and thereby adversely affect our revenue and results of operations.

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 per share were as follows:

	Fiscal Year Ended September 30,		
	2003	2002	2001
Net income (loss) (A)	$ 866,857	$ (1,706,272)	$ (3,829,185)
Weighted average common shares outstanding (B)	6,914,323	6,636,798	6,701,113
Common stock equivalents	229,132	—	—
Sum of weighted average common shares outstanding and common stock equivalents (C)	7,143,445	6,636,798	6,701,111
Earnings (loss) per share:			
Basic (A/B)	$ 0.13	$ (0.26)	$ (0.57)
Diluted (A/C)	$ 0.12	$ (0.26)	$ (0.57)

Options to purchase a total of 763,097 and 701,700 shares of common stock that were outstanding for fiscal 2002 and 2001, respectively,

were excluded from the computation of diluted earnings per share because such options were anti-dilutive as we had a net loss in these periods. Warrants to purchase 261,780 shares of common stock at an exercise price of $15.50 have not been 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 SEC Staff Accounting Bulleting No. 101. For each of the years ended September 30, 2003, 2002 and 2001, we recognized $735,516 in revenue that was included in the cumulative effect adjustment as of October 1, 1999.

C. Marketable Securities:

At September 30, 2003, we held no marketable securities. The cost and fair value of the marketable securities portfolio at September 30, 2002 are as follows:

	2002 Cost	2002 Fair Value
Common stock	$ 8,670,461	$ 9,011,325

At September 30, 2002, net unrealized holding gains were $340,864, consisting of gross unrealized holding gains of $1,317,141 and gross unrealized holding losses of $976,277. At September 30, 2002, the net unrealized holding gains and losses (excluding other-than-temporary losses) were recorded as a separate component of stockholders' equity, entitled "Accumulated other comprehensive income (loss)." There were no open derivative contracts at September 30, 2003 or 2002.

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. During the year ended September 30, 2001, gross realized gains and gross realized losses on the sale of marketable securities were $2,066,851 and $2,646,269, respectively, resulting in a net realized loss of $579,418. During the year ended September 30, 2001, we realized $147,557 in net gains on trading in covered call options on domestic equity instruments. Our objective for issuing the written covered call option in the fiscal year ended September 30, 2001 was to generate additional income from our marketable securities portfolio. Our strategy for achieving this objective was to issue a covered call option that entailed minimal risk and afforded an opportunity for potential gain with respect to our marketable securities portfolio.

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 and fiscal 2001 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 and $4,659,800 write-down of the shares in such years, respectively, 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 (losses) on sales of securities and derivative instruments and write-down of marketable securities consist of the following:

	For the years ended September 30, 2003	2002	2001
Interest income	$ 38,880	$ 116,312	$ 631,386
Dividend income	73,850	139,616	65,776
Total	$ 112,730	$ 255,928	$ 697,162
Net gains (losses) on sales of securities and derivative instruments	$ 2,777,003	$ 610,378	$ (579,418)
Write-down of marketable securities	$ (644,310)	$ (2,331,956)	$ (4,659,800)

D. Inventories:

Our inventories consisted entirely of raw materials of $267,761 at September 30, 2003 and $132,672 at September 30, 2002.

E. Accrued Expenses and Deferred Revenue:

Accrued expenses consist of the following at September 30:

	2003	2002
Clinical trials	$ 226,098	$ —
Professional fees	141,501	156,975
Salaries and other compensation	118,915	101,318
Accrued vacation	89,852	84,897
License and royalty fees	15,000	30,000
Other	10,250	10,250
Totals	$ 601,616	$ 383,440

Deferred revenue consisted of the following at September 30, 2003 and 2002:

	Cytogen	Berlex	Total
At September 30, 2002:			
Short term	$ 2,857,806	$ 737,755	$ 3,595,561
Long term	3,164,187	4,609,944	7,774,131
Total	$ 6,021,993	$ 5,347,699	$ 11,369,692
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.

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 the alternative minimum taxes paid during fiscal 2000. We were eligible for this refund due to a change in tax law. There were no income tax provisions or benefits for fiscal 2002. Due to the uncertainty of the realizability of deferred tax assets, a full valuation allowance has been recorded as of September 30, 2003 and September 30, 2002 against these assets. The valuation allowance balance as of September 30, 2000 was $15,977,605. There was a current federal income tax provision for the year ended September 30, 2001 of $25,362 which was comprised solely of alternative minimum tax.

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,		
	2003	2002	2001
Statutory U.S. federal tax rate	34.0%	34.0%	34.0%
State taxes, net of federal benefit	6.3%	6.3%	6.3%
Permanent items	(2.9%)	1.7%	0.4%
Tax refund	(16.8%)		
Valuation allowance	(37.4%)	(42.0%)	(41.3%)
	(16.8%)	0.00%	(0.6%)

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

	2003	2002	2001
Assets			
Net operating loss carry-forwards	$ 9,890,625	$ 8,398,229	$ 6,514,907
Research and experimentation tax credit carry-forward	3,622,578	3,357,280	3,173,364
Deductible intangibles	59,511	69,713	79,915
Deferred revenue	3,111,921	4,578,575	6,197,677

Write-down of marketable securities	—	2,815,580	1,876,501
Capital loss carry-forward	1,034,055	—	—
Other	248,134	344,884	507,130
Liabilities			
Property, plant and equipment depreciation	(117,584)	(113,441)	(45,777)
Other	(42,727)	(817,711)	(775,597)
	17,806,513	18,633,109	17,528,120
Valuation allowance	(17,806,513)	(18,633,109)	(17,528,120)
Net deferred taxes	$ —	$ —	$ —

At September 30, 2003, we had unused net operating loss ("NOL") carryforwards for federal income tax purposes of approximately $26,281,137 which begin to expire in fiscal 2010. We also have unused state NOL carry-forwards of approximately $15,231,875 which begin to expire in fiscal 2004. We also have federal research and experimentation credits of approximately $3,107,112 which expire in fiscal 2004.

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. Options to purchase 276,000 shares have been granted under the 2000 Stock Plan as of September 30, 2003, 3,500 of which have expired and 4,000 of which have been exercised. The number of shares available for future grants as of September 30, 2003 was 727,500.

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.

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.

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.

Stock option activity for the years ended September 30, 2003, 2002 and 2001 is as follows:

	2003		2002		2001	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of year	753,097	$ 5.89	701,700	$ 6.56	479,506	$ 8.97
Granted	179,000	$ 6.11	115,000	$ 3.60	299,500	$ 3.21
Exercised	(52,000)	$ 3.49	(3,000)	$ 3.06	—	$ —
Expired	(17,250)	$ 4.90	(50,603)	$ 10.62	(77,306)	$ 8.53
Outstanding at end of year	862,847	$ 6.10	763,097	$ 5.89	701,700	$ 6.56
Options exercisable at year-end	516,222	$ 6.99	431,472	$ 7.62	321,341	$ 9.52
Weighted average fair value of options granted during the year	$ 3.74		$ 2.24		$ 1.88	

The following table summarizes information about stock options outstanding and exercisable at September 30, 2003:

	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
$3.05–$4.58	436,250	6.8	$ 3.39	255,625	$ 3.42
$4.59–$6.86	141,000	8.1	$ 5.18	30,500	$ 5.02
$6.87–$10.29	71,500	8.5	$ 8.76	16,000	$ 9.63
$10.30–$12.13	214,097	3.7	$ 11.33	214,097	$ 11.33
$3.05–$12.13	862,847	6.4	$ 6.10	516,222	$ 6.99

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, 2003, 10,345 shares have been issued under the Purchase Plan.

The weighted average fair value for each purchase right granted during fiscal 2003, 2002 and 2001 under our 2003 Employee Stock Purchase Plan and the predecessor plan in effect since 1997 was $0.97, $1.23 and $1.17, respectively, and was estimated using the Black-Scholes option-pricing model.

Stock Options Granted to Consultants

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.

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 $30,881 for the fiscal year ended September 30, 2003, 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.

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 $41,946, $42,059 and $45,690, for 2003, 2002 and 2001, 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.

K. Segment Information:

We have determined that we conduct our operations in one business segment. In fiscal 2003, 2002 and 2001, revenues from customers and licensees outside of the United States, principally in Europe and Japan, amounted to 13%, 20% 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:

	2003	2002	2001
Feridex I.V.	$ 337,440	$ 701,648	$ 264,774
GastroMARK	263,004	264,172	368,706
	$ 600,444	$ 965,820	$ 633,480

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 State 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

We leased laboratory, office and warehouse space under an agreement that expired in fiscal 2003. Rental expenses for the years ended September 30, 2003, 2002 and 2001 amounted to $4,836, $205,710 and $228,899, respectively. There are no future minimum lease payments for fiscal 2004, since all leases have expired.

We lease equipment under several agreements that expire in 2004, 2005 and 2006. Equipment rental expenses for the years ended September 30, 2003, 2002 and 2001 amounted to $14,619, $16,708 and $25,346, respectively. Future minimum lease payments for fiscal 2004 are $18,991 and $4,860 thereafter.

Guarantor Arrangements

In November 2002, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 45 ("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, 2003 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 certain of our 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

To facilitate the marketing and distribution of our contrast agents, we have entered into strategic relationships with certain established pharmaceutical companies. These companies, both in the United States and abroad, include: (i) Guerbet S.A., a leading European producer of contrast agents, in Western Europe and Brazil; (ii) Eiken Chemical Co., Ltd., one of Japan's leading medical diagnostics

manufacturers, in Japan; (iii) Berlex Laboratories, Inc., a leading marketer of MRI contrast agents, in the United States; (iv) Cytogen Corporation, a U.S. marketer of oncology products, in the United States; and (v) Mallinckrodt Inc., a unit of Tyco, Inc. and a leading manufacturer of contrast agents, in the United States, Canada and Mexico.

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. 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.

In August 2000, we entered into a license and marketing agreement and a supply agreement with Cytogen. Under the terms of these agreements, we granted Cytogen the exclusive right to market and sell *Combidex* in the United States. In addition, we granted Cytogen the exclusive right to market and sell ferumoxytol for oncology imaging applications in the United States. However, given current market conditions and the cost of seeking regulatory approval, we do not intend to pursue the development of ferumoxytol for oncology imaging applications. 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 of these agreements, 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 and will 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 these milestones. Cytogen has agreed to pay us for manufacturing and supplying the products and royalties on sales, if any. 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.

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 sales. The agreement terminates on the later of (i) the expiration of the last to expire technology patent 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 this agreement, Eiken paid us a license fee of $1,000,000. Additionally, Eiken agreed to pay us royalties on sales of all products sold 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.

In 1987, we entered into a supply and distribution agreement with Guerbet. Under this agreement, Guerbet has been appointed the exclusive distributor of *Feridex I.V.* in western Europe and Brazil (under the tradename Endorem™). Guerbet is responsible for conducting clinical trials and securing

the necessary regulatory approvals in the countries in its territory. Under the terms of this agreement, Guerbet paid us license fees and is obligated to pay royalties based on sales. 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 *Endorem*. The agreement terminates on the later of (i) the expiration of the last to expire technology patent 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 in western Europe and

Brazil to manufacture and sell *GastroMARK* (under the tradename Lumirem™) and the option to acquire such rights to any future Advanced Magnetics MRI contrast agents. Guerbet has opted to exercise its rights to manufacture and sell *Combidex* (under the tradename Sinerem™) in western Europe and Brazil, but, in our opinion, it failed to meet its contractual obligations with respect to the exercise of its option to acquire rights to manufacture and sell ferumoxytol in western Europe and Brazil, and, accordingly, rights to manufacture and sell this product in those countries have reverted back to us. The Company and Guerbet have asked an arbitrator to decide our respective rights with respect to ferumoxytol. Under the terms of this second distribution agreement, Guerbet paid us a license fee in 1989. 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 the contrast agents. The agreement is perpetual but terminable upon certain specified events.

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. 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.

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 the product sales of *Combidex*.

We are 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 also 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 2001, 2002 or 2003. Future milestone payments under these agreements are not to exceed $400,000. Royalty payments under these agreements were less than $125,000 for each of the prior three fiscal years.

M. Related Party Transactions:

We paid approximately $42,440, $37,340 and $445 to Ingalls & Snyder LLC during the fiscal years ended September 30, 2003, 2002 and 2001, respectively. We paid approximately $73,740 to Fahnestock & Co. during the fiscal year ended 2001. Leslie Goldstein, a shareholder and former member of our Board of Directors and the brother of Jerome Goldstein, our President, Chairman of the Board and CEO, was employed by SRG Associates, a division of Fahnestock & Co. Inc., and is now employed by Ingalls & Snyder LLC, as an investment analyst and advisor. During the fiscal year 2002 we paid approximately $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 in 2002 and who is the daughter of Jerome Goldstein, is a former associate of White & McNamara, P.C. We made salary payments to Ms. Konforty of approximately $103,995 for services rendered during the fiscal year ended September 30, 2003. Lisa Gordon, also the daughter of Jerome Goldstein, joined the Company as

Director of Business Development and Investor Relations in May 2001. We made salary payments to Ms. Gordon of approximately $138,763, $112,740 and $66,500 for services rendered during the fiscal years ended September 30, 2003, 2002 and 2001, respectively. Marlene Kaplan Goldstein, wife of Jerome Goldstein and a co-founder of the Company, served part-time as our general counsel through October 11, 2002, when she resigned. Ms. Goldstein remains Secretary of the Company. We made salary payments to Ms. Goldstein of approximately $65,400 and $62,370 during the fiscal years ended September 30, 2002 and 2001, respectively. 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.

During fiscal 1991, a split-dollar life insurance policy on the lives of Jerome Goldstein, our CEO, and his wife Marlene Goldstein, was established with a trust for the benefit of the family members of our CEO and spouse as beneficiary. The intent of the policy was to provide liquidity to the estate of the CEO and his spouse, whose primary assets at the time were holdings of common stock in the Company, 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 the Company on October 29, 2003 as a reimbursement for the premiums we paid and the remainder was be remitted to the trust. At September 30, 2003 and 2002, the cash surrender value of the life insurance policy was $761,747 and $547,639, and is presented in current and non-current other assets, respectively. 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, 2003, and 2002.

Quarterly Financial Data
(Unaudited)

	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.

	Fiscal 2002 Quarters Ended			
	September 30	June 30	March 31	Dec. 31, 2001
License fees	$ 785,752	$ 935,236	$ 1,408,772	$ 890,857
Royalties	150,000	175,000	200,000	200,000
Product sales	89,673	26,400	436,220	413,527
Total revenues	1,025,425	1,136,636	2,044,992	1,504,384
Cost of product sales	29,255	2,657	110,434	72,011
Operating expenses	1,166,173	1,594,130	1,649,899	1,331,147
Other (income) expenses*	2,207,645	(334,597)	(136,511)	(274,534)
Net income (loss)	$ (2,377,648)	$ (125,554)	$ 421,170	$ 375,760
Earnings (loss) per share—basic	$ (0.36)	$ (0.02)	$ 0.06	$ 0.06
Earnings (loss) per share—diluted	$ (0.36)	$ (0.02)	$ 0.06	$ 0.06

* In the fourth fiscal quarter of 2002 there was a write-down of marketable securities of $2,331,956 which was included in other income.

O. Recently Issued Accounting Pronouncements:

In November 2002, the Financial Accounting Standards Board ("FASB") Emerging Issues Task Force reached consensus with respect to Issue 00-21 ("EITF 00-21"), "Accounting for Revenue Arrangements with Multiple Deliverables." EITF 00-21 addresses the accounting for multiple-element revenue arrangements. Specifically, EITF 00-21 addresses how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting and how arrangement consideration should be measured and allocated to the separate units of accounting. EITF 00-21 is effective for all revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of EITF 00-21 did not have a material impact on our financial position or results of operations.

In January 2003, FASB issued FASB Interpretation No. 46 (FIN 46), Consolidation of Variable Interest Entities. FIN 46 requires that if an entity has a controlling financial interest in a variable interest entity, the assets, liabilities and results of activities of the variable interest entity should be included in the consolidated financial statements of the entity. FIN 46 requires that its provisions are effective immediately for all arrangements entered into after January 31, 2003. We do not have any financial interests in variable interest entities created after January 31, 2003. For those arrangements entered into prior to January 31, 2003, FIN 46 provisions are required to be adopted by us in the second quarter of fiscal 2004. The adoption of FIN 46 is not expected to have a material impact on the Company s financial position or results of operations.

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)) with the participation of our management, have concluded that, as of the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures are operating in an effective manner 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.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT:

The information concerning our directors required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of our fiscal year ended September 30, 2003, under the heading "Proposal I: Election of Directors."

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 Commission not later than 120 days after the close of our fiscal year ended September 30, 2003, under the heading "Information about Directors and Officers: Section 16(a) Beneficial Ownership Reporting Compliance."

The information required by this item with respect to our Code of Ethics is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of our fiscal year ended September 30, 2003, under the heading "Information about Directors and Officers: Code of Ethics."

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 Commission not later than 120 days after the close of our fiscal year ended September 30, 2003, under the heading "Executive Officers."

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

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 Commission not later than 120 days after the close of our fiscal year ended September 30, 2003, under the headings "Stock Ownership" and "Equity Compensation Plan Information."

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 Commission within 120 days after the close of our fiscal year ended September 30, 2003, under the heading "Certain Relationships and Related Transactions."

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 Commission not later than 120 days after the close of our fiscal year ended September 30, 2003, under the heading "Independent Public Accountants."

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K:

(a) The following documents are filed as part of this Annual Report on Form 10-K:

1. Financial Statements.

Balance Sheets—September 30, 2003 and 2002

Statements of Operations—for the years ended September 30, 2003, 2002 and 2001

Statements of Comprehensive Income—for the years ended September 30, 2003, 2002 and 2001

Statements of Stockholders' Equity—for the years ended September 30, 2003, 2002 and 2001

Statements of Cash Flows—for the years ended September 30, 2003, 2002 and 2001

Reconciliation of Net Income (Loss) to Net Cash Used in Operating Activities—or the years ended September 30, 2003, 2002 and 2001

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 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 Advanced Magnetics, Inc. and the Purchasers identified on the signature pages thereto (incorporated 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 Advanced Magnetics, Inc. and the Purchasers identified on the signature pages thereto (incorporated 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 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 the exhibits 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 the exhibits 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 the exhibits 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).
23.1++	Consent of PricewaterhouseCoopers LLP, independent auditors.
31.1++	Certification Pursuant to Rule 13a-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) 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 Securities and Exchange Commission and are incorporated herein by reference, as indicated.

(b) Reports on Form 8-K:

We filed a Current Report on Form 8-K on July 2, 2003 under Item 5 to disclose a press release that announced the publication of clinical data in the *New England Journal of Medicine* showing that magnetic resonance imaging with Combidex®, the Company's investigational iron oxide nanoparticle used to aid in the diagnosis of metastatic lymph nodes, allows for the noninvasive assessment of lymph nodes in patients with prostate cancer.

We filed a Current Report on Form 8-K on July 9, 2003 under Item 5 to disclose a copy of our press release that announced the private placement of $10,000,000 worth of the Company's Common Stock on July 2, 2003.

We filed a Current Report on Form 8-K on July 17, 2003 to furnish to the SEC under Item 12 of Form 8-K a copy of our quarterly earnings release for the fiscal quarter ended June 30, 2003.

(c) *Exhibits*. We hereby file as exhibits to this Form 10-K those exhibits listed in Item 15(a)(3) above.

(d) *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 11, 2003

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 11, 2003

/s/ JAMES A. MATHESON James A. Matheson	Vice President of Finance (principal accounting officer)	December 11, 2003
/s/ SHELDON L. BLOCH Sheldon L. Bloch	Director	December 11, 2003
/s/ MICHAEL D. LOBERG Michael D. Loberg, Ph.D.	Director	December 11, 2003
/s/ EDWARD B. ROBERTS Edward B. Roberts, Ph.D.	Director	December 11, 2003
/s/ GEORGE M. WHITESIDES George M. Whitesides, Ph.D.	Director	December 11, 2003

QuickLinks

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Exhibit 23.1

Consent of Independent Auditors

We hereby consent to the incorporation by reference in the Registration Statement on Form S-3 (File No. 107517) 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 11, 2003 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
December 11, 2003

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Exhibit 23.1

Consent of Independent Auditors

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Exhibit 31.1

CERTIFICATIONS

I, Jerome Goldstein, certify that:

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

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

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

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

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

   b) [Paragraph omitted in accordance with SEC transition instructions contained in SEC Release No. 34-47986.]

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

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

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

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

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

Date: December 11, 2003

/s/ JEROME GOLDSTEIN

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

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Exhibit 31.1

CERTIFICATIONS

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Exhibit 31.2

CERTIFICATIONS

I, James A. Matheson, 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 quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

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

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

   b) [Paragraph omitted in accordance with SEC transition instructions contained in SEC Release No. 34-47986.]

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

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

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

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

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

Date: December 11, 2003

/s/ JAMES A. MATHESON

James A. Matheson
Vice President of Finance
(principal financial officer)

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Exhibit 31.2

CERTIFICATIONS

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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, 2003 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. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(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 11, 2003

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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

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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, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James A. Matheson, Vice President of Finance of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(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/ JAMES A. MATHESON

James A. Matheson
Vice President of Finance
December 11, 2003

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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