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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the Fiscal Year Ended September 30, 2002

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 (State or other jurisdiction of incorporation or organization)	**04-2742593** (I.R.S. Employer Identification No.)
61 Mooney Street **Cambridge, Massachusetts** (Address of principal executive offices)	**02138** (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 10, 2002, there were 6,657,642 shares of the registrant's Common Stock, $.01 par value per share, outstanding. The aggregate market value of the registrant's voting stock held by non-affiliates as of December 10, 2002 was approximately $27,484,290.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a Definitive Proxy Statement for its 2002 Annual Meeting of Stockholders, scheduled to be held on February 4, 2003, pursuant to regulation 14A within 120 days of the end of the fiscal year ended September 30, 2002. Portions of such Proxy Statement are incorporated by reference in Part III hereof.

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 dedicated to the development and commercialization of therapeutic iron compounds for treating anemia as well as novel imaging agents to aid in the diagnosis of cancer and cardiovascular disease. Code 7228, the lead product in our development pipeline, is currently in Phase II clinical studies for use as an iron replacement therapeutic in chronic kidney disease patients receiving erythropoietin. Code 7228 is also in Phase II clinical studies for use in magnetic resonance angiography, also known as MRA. 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 lymph node disease. 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, China and Israel. Our oral contrast agent, GastroMARK®, used for delineating the bowel in magnetic resonance imaging, also known as MRI, procedures, 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.

Iron Replacement Therapy

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 275,000 kidney failure 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.

Anemia

Cells in the body need oxygen, which is carried from the lungs to the tissues throughout the body by red blood cells. Specifically, hemoglobin, a protein found in red blood cells, binds to oxygen to transport it throughout the body. Anemia is a condition in which the body does not have enough red

blood cells, and therefore does not have enough hemoglobin to transport the amount of oxygen the body needs. If the body's tissues receive less oxygen than the body needs, it can lead to fatigue and weakness. Normal red blood cell production requires both erythropoietin and an adequate supply of iron.

The Body's Iron Stores

The average adult has from 2 to 4 grams of iron stored in the body. Approximately $^{2}/_{3}$ of this iron is in the hemoglobin and $^{1}/_{3}$ is in storage, including in the bone marrow, the spleen and the liver. Unlike many other dietary nutrients, unused amounts of which are excreted by the body, the body conserves iron, losing approximately 1 mg of the body's iron stores daily. This level of iron loss can be supplemented through dietary intake for most adults. When the body needs additional iron beyond normal requirements, as a result of conditions such as bleeding, pregnancy or disease, the body accesses its iron stores because it is difficult to absorb the extra iron it needs through dietary intake.

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, chronic kidney disease patients suffering from anemia 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.

Chemotherapy and Anemia

Chemotherapy helps eliminate cancer cells, but it can also eliminate healthy cells, such as blood cells, which may decrease red blood cell levels and cause anemia. In addition, for some cancer patients undergoing chemotherapy treatments, the kidneys are affected by the chemotherapy and, like chronic kidney disease patients, do not produce enough erythropoietin to stimulate sufficient red blood cell production. In recent years, some oncologists have started giving cancer patients recombinant erythropoietin therapy to treat their chemotherapy-induced anemia. As with chronic kidney disease patients, some cancer patients receiving erythropoietin will also eventually need iron replacement therapy to maintain healthy body iron stores and effectively treat their anemia.

Code 7228 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 Code 7228 will afford greater flexibility in both the administration and the amount of iron that can be given to patients. As a result, Code 7228 could prove to be a more effective and desirable form of iron replacement therapy for patients suffering from chronic anemia.

MRI Contrast Agents

Diagnostic Imaging

Diagnostic imaging is a non-invasive method to visualize internal structures, abnormalities or anatomical changes in order to diagnose disease and injury. Today, the most widely accepted imaging techniques include x-rays, ultrasound, nuclear medicine, computed tomography, also known as CT, positron emission tomography, and MRI. Since the introduction of x-rays, doctors have sought increasingly more accurate and detailed non-invasive visualization of soft tissue for diagnostic purposes. The choice of diagnostic imaging technique to be used in any particular circumstance depends upon a variety of factors, including the particular disease or condition to be studied, image quality, availability of imaging machines, availability of contrast agents, cost and managed health care policies. There is no one imaging technique that is considered superior to all others for most or all diagnostic applications.

Magnetic Resonance Imaging

Introduced in the 1980's, MRI is the diagnostic imaging technique of choice for the central nervous system and is widely used for the imaging of ligaments and tendons. MRI provides high-quality spatial resolution and does not use radiation. In MRI procedures, the patient is placed within the core of a large magnet where radio frequency signals are transmitted into the patient's body producing signals that are processed by a computer to create cross-sectional images.

MRI Contrast Agents

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. Consequently, contrast agents, which may be administered intravenously or orally, are widely used when available. MRI contrast agents currently marketed in the United States are used primarily in imaging the central nervous system. The availability of effective contrast agents often determines the choice of imaging technique for a particular procedure. We believe that the availability of effective MRI contrast agents in addition to those presently available would allow MRI to be used for a wider range of applications, such as the diagnosis and staging of cancer, and would increase the use of MRI as a diagnostic imaging technique, in turn generating additional demand for MRI contrast agents.

Currently available imaging techniques can be of limited usefulness in visualizing certain soft-tissue structures, such as the liver and the lymphatic system, which are among the principal sites where metastases of many common cancers, including colon, prostate and breast cancer, are discovered. Contrast enhanced computed tomography, also known as CECT, is currently the primary imaging technique used to confirm a preliminary or suspected diagnosis of liver cancer. We believe that MRI exams of the liver produced with contrast agents provide more diagnostic information and permit the identification of smaller abnormalities than images produced by CECT or MRI studies without contrast agents. Our product *Feridex I.V.* was the first organ-specific MRI contrast agent designed specifically for the liver and is marketed in the United States, Europe, Japan, Argentina, South Korea, China and Israel.

Additionally, we believe that MRI exams of lymph nodes using a contrast agent could provide increased confidence in the evaluation of lymph nodes as part of the staging of metastatic disease. As a result, MRI contrast agents could allow for improved patient diagnosis and staging and may be a cost-effective way to assess medical treatments and to improve patient outcomes. There are no MRI contrast agents designed specifically for the lymphatic system currently available. An MRI contrast agent that localizes to and causes contrast enhancement of the lymph nodes, such as *Combidex*, could allow for more accurate disease diagnosis.

To facilitate the marketing and distribution of our MRI contrast agents, we have entered into strategic relationships with certain established pharmaceutical companies. These marketing and distribution partners, 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 U.S. 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 and distributor of contrast agents, in the United States, Canada and Mexico.

Our Core Technology

Our core technology is based on the characteristic properties of extremely small, polysaccharide-coated superparamagnetic iron oxide particles. Our core competencies include the ability to design such particles for particular applications, manufacture the particles in controlled sizes and cover the particles 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 particles 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 particles 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 particles 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 particles 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
Code 7228	Iron replacement therapy.	None.	Phase II clinical trials underway in iron replacement therapy.	
	Magnetic resonance angiography.	None.	Phase II clinical trials underway in magnetic resonance angiography.	
Combidex	Diagnosis of lymph node disease.	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."

Code 7228. If approved by the FDA, we believe that Code 7228 would be effective in iron replacement therapy for patients receiving erythropoietin because Code 7228 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. Code 7228 is also a blood pool agent, an agent that stays in the blood stream for an extended period of time, which may make Code 7228 useful as a contrast agent for MRA. Code 7228 is currently in Phase II clinical studies for use in iron replacement therapy and in Phase II clinical studies for use in MRA. In addition, Code 7228 may be useful for the detection of metastatic and primary tumors, including breast cancer, and may also improve tumor border delineation. However, given current market conditions and the cost of seeking regulatory approval, we do not intend to pursue development of Code 7228 for these indications.

We do not currently have a marketing partner for Code 7228 in iron replacement therapy or MRA applications. We have granted exclusive rights to market Code 7228 for oncology 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 licensing 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 Code 7228 for oncology 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 Code 7228 for oncology 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 Code 7228 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 Code 7228 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 did not meet its contractual obligations with respect to the exercise of its option to acquire rights to Code 7228,

and, accordingly, rights to manufacture and sell this product in those countries have reverted back to us. 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 2000, 2001 or 2002. 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 Code 7228 finished product for use in human clinical trials at our Cambridge, Massachusetts 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 28 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 Code 7228 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. Watson has announced that it is planning to conduct clinical trials for both *INFeD* and *Ferrlecit* in chemotherapy 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 Eovist®, gadolinium EOB-DTPA, a chelated gadolinium compound. We believe that Schering has filed for EU and Japanese approval of *Resovist* and that *Resovist* has received approval in some EU and non-EU countries. Clinical trials are proceeding in the United States. *Eovist* is believed to be in Phase III trials in Europe. 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 may have 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 is in Phase III human clinical trials for use in MRA imaging. MS-325 is licensed to Schering AG.

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 Code 7228 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 intended for therapeutic use or 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 payers. 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

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. Three companies, Berlex, Guerbet and Eiken, accounted for approximately 33%, 27% and 17% respectively, of our revenues in fiscal 2000. No other company accounted for more than 10% of our total revenues in fiscal 2002, 2001 or 2000. All of the revenue attributable to Cytogen and a significant portion of the revenue attributable to Berlex in fiscal 2002 and fiscal 2001, was deferred revenue.

Employees

As of December 10, 2002, we had 23 full-time employees, 15 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 2002, 2001 and 2000 from customers and licensees outside of the United States, principally in Europe and Japan, amounted to 20%, 20% and 49% 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 $4,029,115, $3,622,102, and $4,623,468 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 to the Company, 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, 2002.

Executive Officers of the Registrant:

Jerome Goldstein, 63, 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, 58, 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, 48, 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, 53, 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, 58, 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, 52, 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 2002 and 2001.

		Fiscal Quarter			
		First	Second	Third	Fourth
2002	High	4.10	4.24	4.22	5.29
	Low	3.00	3.41	3.65	3.50
2001	High	3.875	3.375	4.87	5.05
	Low	2.25	2.25	2.80	2.86

On December 10, 2002, there were approximately 245 stockholders of record. We believe that the number of beneficial holders of common stock is approximately 1,900. The last reported sale price of our common stock on December 10, 2002 was $4.50 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.

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,				
	2002	2001	2000*	1999	1998
Statement of Operations Data:					

Revenues:					
License fees	$ 4,020,617	$ 4,640,198	$ 1,124,049	$ —	$ —
Royalties	725,000	700,000	825,000	680,000	980,542
Product sales	965,820	633,480	1,253,537	1,966,059	1,399,871
Contract research and development	—	—	106,003	581,429	399,897
Total revenues	5,711,437	5,973,678	3,308,589	3,227,488	2,780,310
Costs and Expenses:					
Cost of product sales	214,357	204,399	239,228	454,642	237,945
Contract research and development expenses	—	—	3,195	37,056	6,514
Company-sponsored research and development expenses	4,029,115	3,622,102	4,623,468	7,952,331	8,961,796
Selling, general and administrative expenses	1,712,234	1,667,066	3,013,796	3,694,038	3,701,410
Total costs and expenses	5,955,706	5,493,567	7,879,687	12,138,067	12,907,665
Other Income (Expense):					
Interest and dividend income	255,928	697,162	827,780	646,611	1,150,010
Net gains and (losses) on sales of securities and derivative instruments	610,378	(579,418)	(62,450)	3,555,957	2,473,826
Write-down of marketable securities	(2,331,956)	(4,659,800)	—	—	—
Other income	3,647	258,122	—	265,593	—
Total other income (expense)	(1,462,003)	(4,283,934)	765,330	4,468,161	3,623,836
Income (loss) before provision for income taxes, minority interest in subsidiary and cumulative effect of accounting change	(1,706,272)	(3,803,823)	(3,805,768)	(4,442,418)	(6,503,519)
Minority shareholder interest in subsidiary	—	—	—	—	(194,178)
Income tax (benefit) provision	—	25,362	—	—	—
Income (loss) before cumulative effect of accounting change	(1,706,272)	(3,829,185)	(3,805,768)	(4,442,418)	(6,309,341)
Cumulative effect of accounting change*	—	—	(7,457,717)	—	—
Net income (loss)	$ (1,706,272)	$ (3,829,185)	$ (11,263,485)	$ (4,442,418)	$ (6,309,341)
Basic and diluted operating income (loss) per share	$ (0.26)	$ (0.57)	$ (0.56)	$ (0.66)	$ (0.93)
Cumulative effect of accounting change per share	—	—	(1.11)	—	—
Basic and diluted net income (loss) per share	$ (0.26)	$ (0.57)	$ (1.67)	$ (0.66)	$ (0.93)
Weighted average shares outstanding:					
Basic	6,636,798	6,701,113	6,758,825	6,766,934	6,752,863
Diluted	6,636,798	6,701,113	6,758,825	6,766,934	6,752,863

* In fiscal 2000, we changed our method of accounting for revenue from licensing arrangements. See Note B in the Notes to the Financial Statements.

	At September 30,				
	2002	2001	2000	1999	1998
Balance sheet data:					
Working capital	$ 14,233,904	$ 18,734,388	$ 25,706,905	$ 22,020,107	$ 27,278,502
Total assets	$ 22,484,002	$ 27,448,667	$ 35,667,591	$ 27,816,359	$ 34,114,708
Stockholders' equity	$ 10,650,267	$ 11,512,294	$ 14,305,632	$ 27,054,709	$ 32,919,398

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 particle 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 primarily with cash from license fees from corporate partners, including proceeds from the sale of securities received from marketing partners, proceeds of financings, and income earned on invested cash. Our success will depend, in part, on our ability to obtain FDA approval of Combidex®, successfully develop Code 7228 as an iron replacement therapeutic and as an MRA contrast agent, enter into strategic partnerships for the development and marketing of Code 7228 and any future product candidates, 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 timing of payments from corporate partners; our introduction of new products; regulatory approval of our product candidates; the discovery of different applications for our existing products and product candidates; the timing and size of orders from our customers; 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 expenses. We may rely to a greater degree on contract research and development providers in the future as the human clinical development of Code 7228 moves into Phase III studies and expect that research and development expenses will continue to be a significant portion of our total expenses.

Results of Operations

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.

In August 2000, we entered into a license and marketing agreement with Cytogen, which covers Code 7228 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 and in proportion to the development costs incurred relative to our estimated total development costs for the products subject to this agreement. The entire amount of the license fee was booked as deferred revenue upon signing the agreement. Approximately $3,300,000 of that deferred revenue was recognized as revenue in fiscal 2002 and approximately $3,800,000 was recognized in fiscal 2001. Recognition of the remainder of the deferred revenue is expected to occur when future expenses are incurred related to the development of *Combidex* and Code 7228. While we believe that Code 7228 would be efficacious in the area of oncology, based upon the costs of clinical development and the anticipated additional revenue realizable from Code 7228 in oncology indications, we have chosen to focus our resources on the development of Code 7228 in the areas of iron replacement therapy and MRA. This change in business strategy is expected to result in adjustments to the amounts and timing of revenue recognition related to the Cytogen agreement that may include recognition of amounts over a shorter period and in proportion to a lower cost base.

In February 1995, we entered into a licensing 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. Approximately $738,000 of deferred revenue was recognized as license fee revenue in fiscal 2002 and approximately $735,500 was recognized in fiscal 2001 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 term of the agreement.

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. While product sales increased in 2002, they continue to remain at lower levels than we experienced in the months immediately following the initial product launches and we expect them to continue on a downward trend overall.

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. The increase is primarily the result of increased sales activity in the marketplace and the timing of orders for our contrast agents. As noted above, with the exception of fiscal 2002, product sales have been on a downward trend and we expect them to continue on this trend overall.

	Product Sales	
	2002	2001
Feridex I.V.	$ 701,648	$ 264,774

GastroMARK	264,172	368,706
	$ 965,820	$ 633,480

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. This decrease in cost of product sales on a percentage basis is largely the result of our having sold more *Feridex I.V.* in fiscal 2002, which has a lower cost of sales than *GastroMARK* in bulk form. The majority of sales in fiscal 2001 were for *GastroMARK* in bulk form.

Selling, general and administrative expenses for the fiscal year ended September 30, 2002 of $1,712,234 remained flat when compared to fiscal 2001 expenses of $1,667,066. We expect selling, general and administrative expenses to increase in the near future and on a going forward basis due to anticipated higher professional fees associated with legal and accounting services related to complying with the provisions of the Sarbanes-Oxley Act of 2002.

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 Code 7228 in MRA and iron replacement therapy. 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 continue at current levels as clinical trials progress for Code 7228 in iron replacement therapy and in MRA.

Our product candidate, Code 7228, is currently in Phase II clinical trials for use in iron replacement therapy and 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 Code 7228. In August 2000, we entered into a license and marketing agreement with Cytogen, which covers Code 7228 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 and in proportion to the development costs incurred related to the products subject to this agreement. As a result, since the end of fiscal 2000, we have tracked our internal research and development expenses in relation to the Cytogen agreement and not by specific research and development projects. Since the end of fiscal 2000 and through the year ended September 30, 2002, we incurred aggregate external research and development expenses of approximately $1,450,000 related to pre-clinical activities and clinical trials in connection with Code 7228. The estimated cost of the external efforts necessary to complete development of Code 7228 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 Code 7228 in iron replacement therapy and Phase III clinical studies for Code 7228 in MRA are currently expected to begin in fiscal 2003 or fiscal 2004. Based upon the anticipated additional product revenue realizable from Code 7228 in oncology and costs associated with clinical trials and obtaining regulatory approval, we do not intend to pursue the development of Code 7228 in oncology.

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 lymph node disease. 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)

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 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.

We employ a methodology in evaluating whether a decline in the fair value of the marketable securities in our portfolio below cost basis is other than temporary that considers available evidence regarding such marketable securities as described below in the discussion of our "Critical Accounting Policies." In accordance with this methodology, we are presently monitoring a decline in the value of certain other marketable securities in our portfolio. Currently, we believe that this decline in value is being driven primarily by overall market conditions rather than company-specific events. If, in the future, we determine that this decline is other than temporary, a write-down will be recorded and a new cost basis in the securities will be established. 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.

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. 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, 2002 and September 30, 2001, we recognized $727,582 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.

Fiscal 2001 Compared to Fiscal 2000

Revenues

Total revenues for the fiscal year ended September 30, 2001 were $5,973,678 compared to $3,308,589 for the fiscal year ended September 30, 2000.

License fee revenues for the fiscal year ended September 30, 2001 were $4,640,198, consisting of $786,651 in revenue associated with the license and marketing agreement signed in 1995 with Berlex and $3,853,547 of license fee revenue associated with the license and marketing agreement signed in fiscal 2000 with Cytogen. License fee revenues for the fiscal year ended September 30, 2000 were $1,124,049, consisting of $735,575 in revenue from Berlex and $388,474 of license fee revenue from Cytogen.

Royalties for the fiscal year ended September 30, 2001 were $700,000 as compared to $825,000 in fiscal 2000. The decrease in royalties was primarily the result of decreases in sales of *Feridex I.V.* by our Japanese distributor, Eiken, and our U.S. distributor, Berlex.

Product sales for the fiscal year ended September 30, 2001 were $633,480 compared to $1,253,537 for the fiscal year ended September 30, 2000. The decrease was primarily the result of reduced sales activity in the marketplace and the timing of orders for our contrast agents.

	Product Sales	
	2001	2000
Feridex I.V.	$ 264,774	$ 969,869
GastroMARK	368,706	283,668
	$ 633,480	$ 1,253,537

There were no contract research and development revenues during the fiscal year ended September 30, 2001 compared to $106,003 in the fiscal year ended September 30, 2000. The decrease primarily reflects the completion of certain development activities, the costs of which were reimbursed under an agreement with Guerbet and the completion of work under a grant from the National Institutes of Health in September 2000.

Costs and Expenses

The cost of product sales for the fiscal year ended September 30, 2001 was $204,399 compared to $239,228 for the fiscal year ended September 30, 2000. The cost of product sales for fiscal 2001 was 32% of product sales and for fiscal 2000 was 19% of product sales. The decrease on an absolute basis is primarily attributable to the decline in product sales, while the increase in the percentage basis is largely the result of most product sales in fiscal 2001 being of *GastroMARK* in bulk form, which has a

higher cost of sales than *Feridex I.V.* No contract-sponsored research and development costs were incurred during fiscal 2001, compared to $3,195 in fiscal 2000. Such contract-sponsored research and development costs incurred during fiscal 2000 were primarily related to the provision of development services to Guerbet. The decrease in costs reflects the completion of such services during fiscal 2000.

Selling, general and administrative expenses for the fiscal year ended September 30, 2001 were $1,667,066 compared to expenses of $3,013,796 for the fiscal year ended September 30, 2000. Selling, general and administrative expenses during the fiscal year ended September 30, 2000 included expenses of approximately $815,750 related to a proposed and subsequently terminated merger with Cytogen and the signing of a license and marketing agreement with Cytogen, and approximately $326,630 in severance expenses and accruals related to the closing of our clinical development office in Princeton, New Jersey. These costs did not recur in fiscal 2001.

Company-sponsored research and development expenses for the fiscal year ended September 30, 2001 were $3,622,102, a decrease of $1,001,366 compared to $4,623,468 for the fiscal year ended September 30, 2000. The decrease was primarily attributable to a reduction in external company-sponsored research and development programs related to the clinical development of *Combidex* and the decision to close our Princeton, New Jersey office during the last month of fiscal 2000.

Other Income (Expense)

Interest and dividend income was $697,162 and net gains and losses on sales of securities were $(579,418) for the fiscal year ended September 30, 2001 compared to $827,870 and $(62,450) respectively, for the fiscal year ended September 30, 2000. Interest income for the fiscal year ended September 30, 2001 was $631,386 compared to $729,805 for the fiscal year ended September 30, 2000. The decrease was primarily due to a reduction in interest-bearing cash equivalents and marketable securities. Dividend income of $65,776 for the year ended September 30, 2001 was $32,199 less than the $97,975 for the fiscal year ended September 30, 2000. This decrease was primarily due to reduced holdings of dividend earning securities during the last fiscal year. Included in net gains and losses on sales of securities for fiscal 2001 is $147,557 in net gains on derivative activity, principally the sale of covered call options. 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.

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 for the fiscal year ended September 30, 2001 and established a new cost basis for Cytogen common stock 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

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

Cumulative Effect of Accounting Change

In fiscal 2000, we adopted SAB 101. For each of the years ended September 30, 2001 and September 30, 2000, we recognized $727,582 in revenue that was included in the cumulative effect adjustment as of October 1, 1999.

Net Losses

In the fiscal year ended September 30, 2001, we recorded a net loss of $(3,829,185), or $(0.57) per share. In the fiscal year ended September 30, 2000, we recorded a net loss from operations of ($3,805,768), or ($0.56) per share, together with a charge related to the cumulative effect of a change

in accounting principle of ($7,457,717), or ($1.11) per share, for a total net loss of ($11,263,485), or ($1.67) per share.

Liquidity and Capital Resources

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

At September 30, 2002, our cash and cash equivalents totaled $8,557,819, compared with $11,741,861 at September 30, 2001. In addition,

we had marketable securities of $9,011,325 at September 30, 2002, including $294,400 in shares of Cytogen common stock, as compared to $10,912,382 on September 30, 2001, which included $1,987,200 in shares of Cytogen common stock. The decrease in cash and cash equivalents is the result of an increase in cash used in operating activities, partially offset by an increase in net cash provided by investing and financing activities. The decrease in our marketable securities balance primarily represents the sale of certain holdings in our portfolio and the write-down of certain marketable securities.

Net cash used in operating activities in fiscal 2002 was approximately $4,000,000, and we believe that our cash and cash equivalents as of September 30, 2002, together with anticipated cash flow generated from operations, will be sufficient to cover approximately two years of future operating cash flow needs. Our long-term liquidity is, however, dependent both on our cash and cash equivalents and our marketable securities portfolio, as well as cash generated from operations and future strategic partnerships.

The money market account utilized by the Company 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 for daily operations. Our marketable securities portfolio is subject to certain equity market risks. A substantial decline in any of our holdings in particular, or in the industries in which these securities are concentrated, or in the market for domestic stocks generally, could cause a significant decrease in the value of our overall investment portfolio. Any such decline in the value of our marketable securities portfolio would cause a substantial reduction in our total assets which would decrease the 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 $4,160,348 in the fiscal year ended September 30, 2002 compared to net cash used in operating activities of $3,466,239 in the fiscal year ended September 30, 2001. Cash used in operating activities increased in 2002 principally due to increased company-sponsored research and development expenditures. We anticipate cash used in operating activities will continue at the same levels for the near future since we expect to incur continued research and development expenses and other costs, including costs related to clinical studies, in order to commercialize products based upon our core superparamagnetic iron oxide particle technology, including Code 7228 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 not be able to secure similar arrangements in the future. Any failure to do so could force us to seek alternative sources of financing or curtail our development activity.

Cash provided by investing activities was $941,870 for the fiscal year ended September 30, 2002 compared to $474,591 used in investing activities in the fiscal year ended September 30, 2001. 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 used in investing activities in the fiscal year ended September 30, 2001 included proceeds from the sale of marketable securities of $13,196,124 and United States Treasury Notes of $12,000,000 offset by the purchase of marketable securities of $13,821,980 and United States Treasury Notes of $11,766,961.

Cash provided by financing activities was $34,436 from the issuance of our common stock during the fiscal year ended September 30, 2002. Cash used in financing activities was $438,047 for the fiscal year ended September 30, 2001 and included proceeds of $14,875 from the issuance of our common stock offset by our purchase of 144,700 shares of our common stock on the open market for $452,922. In November 2000, our Board of Directors authorized the purchase of up to 1,000,000 shares of our common stock on the open market at prevailing market prices. There was no cash used to purchase our common stock during the fiscal year ended September 30, 2002.

Capital expenditures in the fiscal year ended September 30, 2002 were $36,934 compared to $80,808 in the fiscal year ended September 30, 2001. The capital expenditures in both years 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.

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 to provide funding for research and development activities and to conduct clinical trials, obtain regulatory approvals, and manufacture and market certain of our products.

Although we believe that funds for future needs can be generated from existing cash balances and cash generated from investing activities, future strategic partnerships and operations, we will consider, from time to time, various financing alternatives and may seek to raise additional capital through equity or debt financing. If we are unable to fund our future needs in the manner we anticipated, we may be required to pursue such other financing alternatives, which may not be available on terms acceptable to us, if at all.

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.

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. 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 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.

With any accounting policy that applies judgments and estimates, actual results could significantly differ from those estimates.

In compliance with Section 202 of the Sarbanes-Oxley Act of 2002, on November 21, 2002 the Audit Committee of our Board of Directors preapproved the continuing provision of certain non-audit services of PricewaterhouseCoopers LLP, the Company's independent auditor. Such services primarily include tax and tax-related services.

Impact of Recently Issued Accounting Pronouncements

In June 2001, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standard No. 142, ("SFAS 142"), "Goodwill and Other Intangible Assets." Under this statement, goodwill will not be amortized and is to be reviewed for impairment and charged to expense only in the period in which goodwill's recorded value exceeds its fair value. Additionally, entities will be required to review goodwill and indefinite-lived intangible assets for impairment on an annual basis. The provisions of SFAS 142 are required to be applied in fiscal years beginning after December 15, 2001 (fiscal year 2003 for the Company). Adoption of this standard is not expected to have a material impact on our financial position or results of operations.

In June 2001, the FASB issued Statement of Financial Accounting Standard No. 143, ("SFAS 143"), "Accounting for Obligations Associated with the Retirement of Long-Lived Assets." The objectives of SFAS 143 were to establish accounting standards for the recognition and measurement of an asset retirement obligation and its associated asset retirement cost. The provisions of SFAS 143 shall be effective for financial statements issued for fiscal years beginning after June 15, 2002 (fiscal year 2003 for the Company). Adoption of this standard is not expected to have a material impact on our financial position or results of operations.

In October 2001, the FASB issued Statement of Financial Accounting Standard No. 144, ("SFAS 144"), "Accounting for the Impairment or Disposal of Long-Lived Assets." SFAS 144 applies to all long-lived assets (including discontinued operations). SFAS 144 is effective for financial statements issued for fiscal years beginning after December 15, 2001 (fiscal year 2003 for the Company). Adoption of this standard is not expected to have a material impact on our financial position or results of operations.

In May 2002, the FASB issued Statement of Financial Accounting Standard No. 145, ("SFAS 145"), "Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13 and Technical Corrections as of April 2002." Under this statement, debt extinguishments used as part of an entity's risk management strategy should not be classified as extraordinary items in the statement of operations. Additionally, this statement rescinded certain pronouncements that were no longer required, as well as requiring sale-leaseback accounting for certain lease modifications that have economic effects that are similar to sale-leaseback transactions. This statement is effective for

transactions entered into after May 15, 2002 and for financial statements issued after May 15, 2002. The Company's adoption of this standard has had no effect on our financial position or results of operations.

In July 2002, the FASB issued Statement of Financial Accounting Standard No. 146 ("SFAS 146"), "Accounting for Costs Associated with Exit or Disposal Activities." SFAS 146 addresses significant issues relating to the recognition, measurement, and reporting of costs associated with exit and disposal activities, including restructuring activities, and nullifies the guidance in Emerging Issues Task Force (EITF) Issue No. 94-3 (EITF-94-3), "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)." The provisions of SFAS 146 are effective for exit or disposal activities initiated after December 31, 2002. At the present time, adoption of this standard 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 need to obtain the necessary regulatory approvals in order to market and sell our products

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 U.S. Food and Drug Administration, 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, Code 7228, is currently in Phase II clinical trials as a compound for use in iron replacement therapy and as a contrast agent for Magnetic Resonance Angiography. Before applying for FDA approval to market Code 7228, we must conduct larger-scale human clinical trials that further demonstrate the safety and efficacy of Code 7228 to the satisfaction of the FDA and other regulatory authorities. We may not be able to successfully complete these clinical trials for Code 7228, 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, an NDA, and received an "approvable" letter from the FDA for *Combidex* for lymph node indications, 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. In addition, we may also be required to demonstrate that our product candidates 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. Final regulatory approvals may not be obtained for *Combidex* or Code 7228 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.

Regulatory approvals may entail limitations on the indicated uses of our products and impose labeling requirements which may adversely impact our ability to market our products. Even if

regulatory approval is obtained, 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 are unsure about 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. Code 7228 is currently in Phase II clinical studies for more than one indication and will require significant development efforts, including human clinical testing, prior to approval for commercial sale. Additionally, while we have filed a New Drug Application for *Combidex* and received an "approvable" letter for its principal indication, which is the diagnosis of lymph node disease, significant additional development efforts, including additional human clinical testing, may be required prior to approval for commercial sale.

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. In addition, the results from pre-clinical testing and early clinical trials of products under development by us 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. Clinical trials for our products may not 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 this limited number of strategic partners for a significant portion of our revenue. Three companies were responsible for approximately 89% of our revenue during the fiscal year ended September 30, 2002, with Cytogen representing approximately 58% of our revenue in fiscal 2002, 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 or profits from these arrangements. If any of our collaborators breaches its agreement with us or otherwise fails to perform, such event could impair our revenue and impose additional costs. 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 our competitors. Furthermore, we may not be able to enter into future collaborative relationships in connection with the development, commercialization and marketing of our product candidates. Due to the high cost of our research and development activities, in particular the anticipated cost of future clinical trials for Code 7228, our inability to secure strategic partners in connection with these efforts could limit our ability to continue developing such product candidates. Any delay in, or termination of, any of our research and development projects due to insufficient funds, would reduce our potential revenues. 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.

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 Code 7228 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. We may not be successful 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.

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

For a variety of reasons, many of which are out of 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 payers, including insurance companies.

For example, even if we obtain regulatory approval to sell our products, physicians and health care payers 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 seem more cost-effective than our products. Physicians, patients, third-party payers or the medical community in general may not accept and use any 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* still represent a new technology platform for physicians to adopt. *Combidex* and Code 7228, if approved, may also represent new technologies or may represent alternatives 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.

Our success depends on our ability to maintain the proprietary nature of our technology

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 or limit our development of our product candidates.

In the future, we may be required to obtain additional licenses to patents or other proprietary rights of others. 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.

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 policies and decisions

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 payers. 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 payers 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 payers make reimbursement available, these payers' 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 sales of our products. 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 need to maintain 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 Code 7228 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, cGMP, regulations prescribed by the FDA. We may not be able to continue to operate at commercial scale in compliance with cGMP regulations. Failure to operate in compliance with cGMP regulations and other applicable manufacturing requirements of various regulatory agencies could delay our development efforts and impede product sales due to the unavailability of 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 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 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 the area of iron therapeutics, there are several iron replacement therapy products on the market with which Code 7228 will compete, if approved. These products have already received regulatory marketing approval. We may not be able to successfully complete Phase II clinical trials for Code 7228 for iron replacement therapy, or, if completed, may not be able to obtain regulatory approval. In addition, developments by others may render our products or product candidates or technologies obsolete or noncompetitive. Furthermore, our collaborators or customers may choose to use competing technologies or products.

We may need substantial additional capital to grow and operate our business and we are uncertain about obtaining future financing

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. It is possible that we may need additional financing to satisfy our capital and operating requirements relating to the development, manufacturing and marketing of 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, 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 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 the Company. 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.

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 ability to attract and retain qualified scientific and technical personnel for the research and development activities conducted or sponsored by us. Furthermore, our possible expansion into areas and activities requiring additional expertise, such as product distribution and marketing and sales, may require the addition of new management personnel and the development of additional expertise by existing management personnel. There is intense competition for qualified personnel in the areas of our activities, and we may not be able to continue to attract and retain the qualified personnel necessary for the development of our business. The failure to attract and retain such personnel or to develop such expertise could impose limits on our business operations.

Our stock price is volatile

The market prices for securities of biopharmaceutical and pharmaceutical companies, including ours, have historically been highly volatile. Fluctuations in operating results may cause the market price of our common stock to be volatile. In addition, the market prices for securities of biopharmaceutical and pharmaceutical companies have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of such companies. Various factors and events, including announcements by us or our competitors concerning 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 and dividend policy.

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

We own financial instruments that are sensitive to market risks as part of our investment portfolio. This investment portfolio is used to preserve our capital until it is required to fund operations, including our research and development activities, and includes shares of Cytogen common stock received as a license fee. None of these market-risk sensitive instruments are held for trading purposes. Our investment portfolio contains instruments that are subject to a decline in equity markets.

Equity Market Risk—Our investment portfolio includes marketable securities classified as available for sale and cash and cash equivalents. Marketable securities include publicly-traded stocks of domestic issuers. Assuming a decline of 20% in the market for domestic stocks generally, our equity investments may be expected to decline a corresponding 20%, resulting in a hypothetical reduction of the value of our total assets (as of September 30, 2002) of approximately 8%. For purposes of evaluating our exposure to equity market risk for the fiscal year ended September 30, 2001, we had assumed a decline of 15% in the market for domestic stocks generally. Assuming this 15% decline in the market for domestic stocks generally, and a corresponding decline in the value of our equity investments, our total assets as of September 30, 2002 would decline approximately 6% as compared to our total assets as of September 30, 2001 which would decline by approximately the same percentage. The increase in our exposure to equity market risk relates primarily to the increase in the hypothetical percentage reduction in the value of domestic stocks generally. Our choice to use a 20% estimate in the decline of equity securities is strictly for estimation and evaluation purposes only and was changed from last year's estimate of 15% as we believe 20% is closer to relevant recent market performance and therefore better reflects reasonably possible near-term changes in the market for equity securities. The value of our assets may rise or fall by a greater or smaller amount depending on actual general market performance and the value of individual securities owned by us. We manage our equity market risk exposure by maintaining a significant portion of our assets in cash and cash equivalents. At September 30, 2002, approximately 42% of our marketable securities consisted of holdings in the common stock of three companies in the home-building industry, one of which was approximately 33% of the total market value of our marketable securities portfolio. Furthermore, at September 30, 2002 approximately 23% and 14% of our marketable securities portfolio consisted of holdings in the common stocks of companies in the financial services industry and the insurance industry, respectively. In addition to publicly-traded stocks, we held significant cash and cash equivalents in our investment portfolio at September 30, 2002 and 2001. These positions are intended to reduce our equity market risk. A significant decrease in the value of our overall investment portfolio could have a material adverse effect on our results of operations and financial condition and could require us to seek cash from alternative sources.

ITEM 8. FINANCIAL STATEMENTS:

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

Report of Independent Accountants

Financial Statements:

Balance Sheets—September 30, 2002 and 2001

Statements of Operations—for the years ended September 30, 2002, 2001 and 2000

Statements of Comprehensive Income—for the years ended September 30, 2002, 2001 and 2000

Statements of Stockholders' Equity—for the years ended September 30, 2002, 2001 and 2000

Statements of Cash Flows—for the years ended September 30, 2002, 2001 and 2000

Reconciliation of Net Income (Loss) to Net Cash Used in Operating Activities—for the years ended September 30, 2002, 2001 and 2000

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Report of Independent Accountants

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, 2002 and September 30, 2001, and the results of its operations and its cash flows for each of the three years in the period ended September 30, 2002 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.

As discussed in Note B to the financial statements, in fiscal 2000 the Company changed its method of accounting for revenue from license agreements.

PricewaterhouseCoopers LLP

Advanced Magnetics, Inc.

Balance Sheets

	September 30,	
	2002	2001
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,557,819	$ 11,741,861
Marketable securities	9,011,325	10,912,382
Accounts receivable	205,485	317,970
Inventories	132,672	87,421
Prepaid expenses	386,207	166,743
Total current assets	18,293,508	23,226,377
Property, plant and equipment:		
Land	360,000	360,000
Buildings	4,617,996	4,654,047
Laboratory equipment	6,792,298	6,846,193
Furniture and fixtures	778,335	792,484
	12,548,629	12,652,724
Less—accumulated depreciation and amortization	(8,905,774)	(8,914,026)
Net property, plant and equipment	3,642,855	3,738,698
Other assets	547,639	483,592
Total assets	$ 22,484,002	$ 27,448,667
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 80,603	$ 163,942
Accrued expenses	383,440	382,122
Deferred revenues	3,595,561	3,945,925
Total current liabilities	4,059,604	4,491,989
Long-term liabilities:		
Deferred revenues	7,774,131	11,444,384
Total liabilities	11,833,735	15,936,373
Commitments and contingencies		
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 6,644,642 shares as of September 30, 2002 and 6,633,895 shares as of September 30, 2001	66,446	66,339
Additional paid-in capital	43,888,960	43,830,473
Retained deficit	(33,646,003)	(31,939,731)
Accumulated other comprehensive income (loss)	340,864	(444,787)
Total stockholders' equity	10,650,267	11,512,294
Total liabilities and stockholders' equity	$ 22,484,002	$ 27,448,667

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

Advanced Magnetics, Inc.

Statements of Operations

	For the years ended September 30,		
	2002	2001	2000
Revenues:			
License fees	$ 4,020,617	$ 4,640,198	$ 1,124,049
Royalties	725,000	700,000	825,000
Product sales	965,820	633,480	1,253,537
Contract research and development	—	—	106,003
Total revenues	5,711,437	5,973,678	3,308,589
Costs and expenses:			
Cost of product sales	214,357	204,399	239,228
Contract research and development expenses	—	—	3,195
Company-sponsored research and development expenses	4,029,115	3,622,102	4,623,468
Selling, general and administrative expenses	1,712,234	1,667,066	3,013,796
Total costs and expenses	5,955,706	5,493,567	7,879,687
Other income (expense):			
Interest and dividend income	255,928	697,162	827,780
Net gains and losses on sales of securities and derivative instruments	610,378	(579,418)	(62,450)
Write-down of marketable securities	(2,331,956)	(4,659,800)	—
Other income	3,647	258,122	—
Total other income (expense)	(1,462,003)	(4,283,934)	765,330
Income (loss) before cumulative effect of accounting change and provision for income taxes	(1,706,272)	(3,803,823)	(3,805,768)
Provision for income taxes	—	25,362	—
Income (loss) before cumulative effect of accounting change	(1,706,272)	(3,829,185)	(3,805,768)
Cumulative effect of accounting change (Note B)	—	—	(7,457,717)
Net income (loss)	$ (1,706,272)	$ (3,829,185)	$ (11,263,485)
Basic and diluted income (loss) before cumulative effect of accounting change per share	$ (0.26)	$ (0.57)	$ (0.56)
Cumulative effect of accounting change per share	—	—	(1.11)
Basic and diluted net income (loss) per share	$ (0.26)	$ (0.57)	$ (1.67)
Weighted average shares outstanding:			
Basic	6,636,798	6,701,113	6,758,825
Diluted	6,636,798	6,701,113	6,758,825

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

Advanced Magnetics, Inc.

Statements of Comprehensive Income

	For the years ended September 30,		
	2002	2001	2000
Net income (loss)	$ (1,706,272)	$ (3,829,185)	$ (11,263,485)

Other comprehensive income:			
Unrealized gains (losses) on securities	(935,927)	(3,765,324)	(1,610,010)
Reclassification adjustment for (gains) losses included in net income	1,721,578	5,239,218	62,450
Other comprehensive income (loss)	785,651	1,473,894	(1,547,560)
Comprehensive income (loss)	$ (920,621)	$ (2,355,291)	$ (12,811,045)

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

Advanced Magnetics, Inc.

Statements of Stockholders' Equity

For the years ended September 30, 2000, 2001 and 2002

	Common Stock		Additional Paid-in Capital	Retained Earnings (Deficit)	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance at September 30, 1999	6,752,027	$ 67,521	$ 44,205,370	$ (16,847,061)	$ (371,121)	$ 27,054,709
Shares issued in connection with the exercise of stock options	5,250	52	20,956	—	—	21,008
Shares surrendered in connection with the exercise of stock options	(2,488)	(25)	(17,967)	—	—	(17,992)
Shares issued in connection with employee stock purchase plan	19,143	191	58,761	—	—	58,952
Other comprehensive income (loss)	—	—	—	—	(1,547,560)	(1,547,560)
Net loss	—	—	—	(11,263,485)	—	(11,263,485)
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 (loss)	—	—	—	—	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 (loss)	—	—	—	—	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

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

Advanced Magnetics, Inc.

Statements of Cash Flows

	For the years ended September 30,		
	2002	2001	2000
Cash flows from operating activities:			
Cash received from customers	$ 1,103,044	$ 1,198,034	$ 1,615,566
Cash paid to suppliers and employees	(6,189,861)	(5,956,859)	(6,624,397)
Dividends and interest received	226,208	464,124	827,782
Royalties received	700,261	723,214	593,541
Income taxes (paid) refunded	—	(94,752)	—
Other income	—	200,000	—
Net cash used in operating activities	(4,160,348)	(3,466,239)	(3,587,508)
Cash flows from investing activities:			
Proceeds from sales of marketable securities	6,728,059	13,196,124	4,433,874
Proceeds from notes and bonds maturing	—	12,000,000	—
Purchase of marketable securities	(5,733,208)	(13,821,980)	(1,744,075)
Purchase of notes and bonds	—	(11,766,961)	—
Capital expenditures	(36,934)	(80,808)	(36,333)
Proceeds from sale of fixed assets	48,000	61,000	—
(Increase) decrease in other assets	(64,047)	(61,966)	(59,824)
Net cash provided by (used in) investing activities	941,870	(474,591)	2,593,642
Cash flows from financing activities:			
Proceeds from issuances of common stock	34,436	14,875	61,968
Purchase of treasury stock	—	(452,922)	—
Net cash (used in) provided by financing activities	34,436	(438,047)	61,968
Net (decrease) increase in cash and cash equivalents	(3,184,042)	(4,378,877)	(931,898)
Cash and cash equivalents at beginning of year	11,741,861	16,120,738	17,052,636
Cash and cash equivalents at end of year	$ 8,557,819	$ 11,741,861	$ 16,120,738
Supplemental data:			
Non-cash operating activities:			
Marketable securities received in licensing and marketing agreements	—	—	$ 13,546,875
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,		
	2002	2001	2000
Net income (loss)	$ (1,706,272)	$ (3,829,185)	$ (11,263,485)

Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Non-cash license fee revenue	(4,020,617)	(4,582,541)	(1,116,056)
Stock dividend received	(29,720)	—	—
Non-cash expense associated with stock options	24,158	—	—
Cumulative effect of accounting change	—	—	7,457,717
Depreciation	88,423	493,933	554,434
Accretion of U. S. Treasury Notes discount	—	(233,038)	—
(Increase) decrease in accounts receivable	112,485	321,770	8,462
(Increase) decrease in inventories	(45,251)	4,035	(10,976)
(Increase) decrease in prepaid expenses	(219,464)	20,738	8,174
Gains of disposal of fixed assets	(3,647)	(58,122)	—
Increase (decrease) in accounts payable and accrued expenses	(82,021)	(914,310)	698,724
Increase (decrease) in deferred revenues	—	71,263	13,048
Increase (decrease) in income taxes payable	—	—	—
Net realized (gains) losses on sales of marketable securities	(610,378)	579,418	62,450
Write-down of marketable securities	2,331,956	4,659,800	—
Total adjustments	(2,454,076)	362,946	7,675,977
Net cash used in operating activities	$ (4,160,348)	$ (3,466,239)	$ (3,587,508)

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, a Delaware corporation, is a biopharmaceutical company engaged in the development and manufacture of compounds utilizing our proprietary colloidal superparamagnetic particle technology and polysaccharide technology. The products we develop are iron therapeutic compounds for the treatment of chronic anemia and diagnostic imaging agents for use in conjunction with magnetic resonance imaging, also known as MRI, 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 regulations.

Business Segments

Prior to the divestiture of our majority-owned subsidiary, Kalisto Biologicals, Inc. in July 1999, we had two business segments under the "management approach" as defined in FASB Statement of Financial Accounting Standard No. 131 "Disclosures About Segments of an Enterprise and Related Information" ("SFAS 131"). We no longer have separate business segments.

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 significantly 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, 2002 and 2001 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 and Derivative Activities

Our portfolio at September 30, 2002 and 2001 consists of securities classified as available-for-sale, which are recorded at fair market value. The fair values 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)." All derivatives are recognized on the balance sheet at their fair value. Derivative instruments entered into by us are primarily trading instruments and the changes in the fair value of these instruments are reported in current-period earnings. There were no open derivative contracts at September 30, 2002 and 2001. 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.

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.

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 recognized based on the ratio of development expenses incurred to our estimate of total expected development expenses. 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. Milestone payments, which are not refundable, are recognized as revenue on a retrospective basis. Accordingly, upon achievement of the milestone, a portion of the milestone payment equal to the percentage of collaboration completed through that date would be recognized. The remainder would be recognized as services are performed over the remaining term of the collaboration.

Other Income

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. Other income in the year ended September 30, 2001 includes amounts for the settlement of a claim against an investor and gains from the sale of certain capital assets.

Income Taxes

There was no provision for income taxes for fiscal 2002. The provision for income taxes for fiscal 2001 includes federal and state income taxes currently payable (including alternative minimum taxes) and deferred income taxes arising from the recognition of certain income and expenses in different periods for financial and tax reporting purposes.

Income (Loss) per Share

The weighted average common and common equivalent shares used in the computation of basic and diluted earnings per share is presented below. Aggregate options of 763,097 (weighted average exercise price of $5.89), 701,700 (weighted average exercise price of $6.56), and 479,506 (weighted average exercise price of $8.97) for 2002, 2001 and 2000, respectively, have not been included in the calculation of weighted average shares since their effect would be anti-dilutive, given the net loss in those years.

The following table summarizes income (loss) per share:

	For the years ended September 30,		
	2002	2001	2000
Numerator:			
Net income (loss)	$ (1,706,272)	$ (3,829,185)	$ (11,263,485)
Denominator:			
Weighted average number of common shares issued and outstanding	6,636,798	6,701,113	6,758,825

Assumed exercise of options reduced by the number of shares which could have been purchased with the proceeds of those options	—	—	—
Weighted average common and common equivalent shares	6,636,798	6,701,113	6,758,825
Basic and diluted net income (loss) per share	$ (0.26)	$ (0.57)	$ (1.67)

Reclassifications

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

B. Cumulative Effect of Accounting Change:

In fiscal 2000, we adopted SEC Staff Accounting Bulleting No. 101, commonly referred to as SAB 101. The effect of applying this change in accounting principle was a cumulative charge of $7,457,717, or $1.11 per share, in fiscal 2000. 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 retroactively to October 1, 1999, each payment is recorded as deferred revenue to be recognized over the remaining term of the related agreement. For each of the years ended September 30, 2002, 2001 and 2000, we recognized $727,582 in revenue that was included in the cumulative effect adjustment as of October 1, 1999.

C. Marketable Securities:

The cost and fair value of the marketable securities portfolio at September 30 are as follows:

	2002 Cost	2002 Fair Value	2001 Cost	2001 Fair Value
Common stock	$ 8,670,461	$ 9,011,325	$ 11,357,169	$ 10,912,382
	$ 8,670,461	$ 9,011,325	$ 11,357,169	$ 10,912,382

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, 2001, net unrealized holding losses were $444,787 consisting of $1,268,455 in gross unrealized holding gains and $1,713,242 of gross unrealized holding losses. At September 30, 2002 and 2001, the net unrealized holding gains and losses (excluding other-than-temporary losses) have been recorded as a separate component of stockholders' equity, entitled "Accumulated other comprehensive income (loss)." At September 30, 2002, approximately 42% of our marketable securities consisted of holdings in the common stock of three companies in the home-building industry, one of which was approximately 33% of the total market value of our marketable securities portfolio. Furthermore, at September 30, 2002 approximately 23% and 14% of our marketable securities portfolio consisted of holdings in the common stocks of companies in the financial services industry and the insurance industry, respectively. At September 30, 2001, over 40% of our marketable securities consisted of holdings in the common stock of two companies, including $1,987,200 in the common stock of Cytogen. There were no open derivative contracts at September 30, 2002 or 2001.

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 and derivative instruments 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. During the year ended September 30, 2000, gross realized gains and gross realized losses on the sale of marketable securities were $101,325 and $163,775, respectively, resulting in a net realized loss of $62,450.

In fiscal 2002 and 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,

	2002	2001	2000
Interest income	$ 116,312	$ 631,386	$ 729,805
Dividend income	139,616	65,776	97,975
Total	$ 255,928	$ 697,162	$ 827,780
Net gains (losses) on sales of securities and derivative instruments	$ 610,378	$ (579,418)	$ (62,450)
Write-down of marketable securities	$ (2,331,956)	$ (4,659,800)	—

D. Inventories:

Our inventories consisted entirely of raw materials of $132,672 at September 30, 2002 and $87,421 at September 30, 2001.

E. Commitments:

We lease laboratory, office and warehouse space under an agreement expiring in fiscal 2003. Rental expenses for the years ended September 30, 2002, 2001 and 2000 amounted to $205,710, $228,899 and $326,347, respectively. Future minimum lease payments for fiscal 2003 amount to $12,800.

F. Accrued Expenses:

Accrued expenses consist of the following at September 30:

	2002	2001
Salaries and other compensation	$ 101,318	$ 91,651
Accrued vacation	84,897	84,640
License and royalty fees	30,000	30,204
Professional fees	156,975	158,450
Other	10,250	17,177
Totals	$ 383,440	$ 382,122

G. Income Taxes:

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using statutory rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized.

There was no income tax provision or benefit for the year ended September 30, 2002. 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. There was no income tax provision or benefit for the year ended September 30, 2000.

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,		
	2002	2001	2000
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	1.7%	0.4%	0.2%
Valuation allowance	(42.0%)	(41.3%)	(40.5%)
	0.0%	(0.6%)	0.0%

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

	2002	2001	2000
Assets			
Net operating loss carry-forwards	$ 8,398,229	$ 6,514,907	$ 4,649,480
Research and experimentation tax credit carry-forward	3,357,280	3,173,364	3,041,904
Deductible intangibles	69,713	79,915	90,116
Deferred revenue	4,578,575	6,197,677	8,014,368
Write-down of marketable securities	2,815,580	1,876,501	—

Other	344,884	507,130	403,165
Liabilities			
Property, plant and equipment depreciation	(113,441)	(45,777)	(135,586)
Other	(817,711)	(775,597)	(85,842)
	18,633,109	17,528,120	15,977,605
Valuation allowance	(18,633,109)	(17,528,120)	(15,977,605)
Net deferred taxes	$ —	$ —	$ —

Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, we have placed a valuation allowance against our otherwise recognizable net deferred tax assets. Realization of favorable tax attributes is, therefore, reflected as a tax benefit in the provision for income taxes.

At September 30, 2002, we had unused net operating loss ("NOL") carryforwards for federal income tax purposes of approximately $21,893,825 which begin to expire in fiscal 2008. We also have unused state NOL carry-forwards of approximately $15,220,548 which begin to expire in fiscal 2003. We also have federal research and experimentation credits of approximately $2,912,833 which expire in fiscal 2004.

H. 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 87,000 shares have been granted under the 2000 Stock Plan as of September 30, 2002, 2,000 of which have expired. The number of shares available for future grants as of September 30, 2002 was 915,000.

Our 1993 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 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. The maximum term of the options under the 1993 Stock Plan is ten years, with limited exceptions. The number of shares available for future grants at September 30, 2002 was 51,903. We currently do not intend to grant any additional options under the 1993 Stock Plan.

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.

We apply Accounting Principles Board Opinion No. 25 "Accounting for Stock Issued to Employees" and related interpretations in accounting for our stock option plans and follow the disclosure provisions of SFAS 123, "Accounting for Stock-Based Compensation," referred to as SFAS 123.

Stock option activity for the years ended September 30, 2002, 2001 and 2000 is as follows:

	2002		2001		2000	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of year	701,700	$ 6.56	479,506	$ 8.97	473,833	$ 9.47
Granted	115,000	$ 3.60	299,500	$ 3.21	47,500	$ 3.50
Exercised	(3,000)	$ 3.06	—	$ —	(5,250)	$ 4.00
Expired	(50,603)	$ 10.62	(77,306)	$ 8.53	(36,577)	$ 9.12
Outstanding at end of year	763,097	$ 5.89	701,700	$ 6.56	479,506	$ 8.97
Options exercisable at year-end	431,472	$ 7.62	321,341	$ 9.52	288,411	$ 9.65
Weighted average fair value of options granted during the year		$ 2.24		$ 1.88		$ 1.90

The fair value of each option granted during 2002, 2001 and 2000 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 2002 and expected life of and 5.0 years in 2001 and 2000; (2) expected volatility of 64.1% in 2002, 64.6% in 2001, and 55.2% in 2000; (3) risk-free interest rates of 3.84% and 4.67% in 2002, 4.68%, 4.98%, 4.71% and 5.81% in 2001, and 6.12% in 2000; and (4) no dividend yield.

The following table summarizes information about stock options outstanding and exercisable at September 30, 2002:

	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	505,000	7.7	$ 3.39	197,125	$ 3.47
$4.59–$6.86	21,000	8.8	$ 4.79	5,250	$ 4.79
$6.87–$10.29	20,000	6.1	$ 9.63	12,000	$ 9.63
$10.30–$12.13	217,097	4.7	$ 11.34	217,097	$ 11.34
$3.05–$12.13	763,097	6.8	$ 5.89	431,472	$ 7.62

Employee Stock Purchase Plan

Our 1997 Employee Stock Purchase Plan provides for the issuance of up to 150,000 shares of common stock to our employees. Under the terms of the 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. The fifth and last offering under the Purchase Plan ended on May 31, 2002 and 7,747 shares of common stock were purchased by eligible employees at a price of approximately $3.26 per share. As of September 30, 2002, 39,696 shares have been issued under the Purchase Plan. On May 2, 2002, our Board of Directors adopted, subject to the approval of our shareholders, the 2003 Employee Stock Purchase Plan which would, if approved, provide for the issuance of up to 100,000 shares of the Company's common stock to our employees.

Had we adopted SFAS 123, the weighted average fair value for each purchase right granted during fiscal 2002, 2001 and 2000 would have been $1.23, $1.17, and $1.56, respectively.

Pro Forma Disclosures

Had compensation costs for our 2002, 2001 and 2000 grants for stock-based compensation plans been determined consistent with SFAS 123, our net income (loss) and net income (loss) per share would approximate the pro forma amounts below:

		2002	2001	2000
Net income (loss)	As reported	$ (1,706,272)	$ (3,829,185)	$ (11,263,485)
	Pro forma	$ (2,003,516)	$ (4,036,714)	$ (11,840,095)
Basic and diluted net income (loss) per share	As reported	$ (0.26)	$ (0.57)	$ (1.67)
	Pro forma	$ (0.30)	$ (0.60)	$ (1.75)

The effects of applying SFAS 123 in this pro-forma disclosure are not indicative of future amounts. SFAS 123 does not apply to awards prior to fiscal 1996, and additional awards in future years are anticipated.

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 vests over a two-year period commencing in October 2001. We have recorded an expense of $24,158 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 fourth quarter of fiscal 2003.

I. 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 $42,059, $45,690, and $64,524 for 2002, 2001 and 2000, respectively.

J. Common Stock Transactions:

In November 1997, the Board of Directors extended the authorization granted in May 1996 to purchase 250,000 shares of our common stock in the aggregate 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, 2002, we had purchased 266,900 shares for $2,027,166. All shares have been retired.

K. 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.

L. Business Customers:

Our operations are located solely within the United States. We are focused principally on developing and manufacturing iron replacement therapeutics and MRI contrast agents. Since July 1999, our revenues have been attributable to one principal business segment. We perform ongoing credit evaluations of our customers and generally do not require collateral. 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. Three companies, Berlex, Guerbet and Eiken, accounted for approximately 33%, 27% and 17% respectively, of our revenues in fiscal 2000. No other company accounted for more than 10% of our total revenues in fiscal 2002, 2001 or 2000. All of the revenue attributable to Cytogen and a significant portion of the revenue attributable to Berlex in fiscal 2002 and fiscal 2001, was deferred revenue.

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

	2002	2001	2000
Feridex I.V.	$ 701,648	$ 264,774	$ 969,869
GastroMARK	264,172	368,706	283,668
	$ 965,820	$ 633,480	$ 1,253,537

In fiscal 2002, 2001 and 2000, revenues from customers and licensees outside of the United States, principally in Europe and Japan, amounted to 20%, 20%, and 49%, respectively, of our total revenues.

M. 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 to us, 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.

N. 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 licensing 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 Code 7228 for oncology 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 Code 7228 for oncology 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 Code 7228 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.

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 Code 7228 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 has not met its contractual obligations with respect to the exercise of its option to acquire rights to manufacture and sell Code 7228 in western Europe and Brazil, and, accordingly, rights to manufacture and sell this product in those countries have reverted back to us. 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 2000, 2001 or 2002. 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.

O. Related Party Transactions:

We paid approximately $73,737 and $16,600 in trading commissions on our marketable securities to Fahnestock & Co. Inc. during the fiscal years ended September 30, 2001 and 2000, respectively, and approximately $37,340 and $445 to Ingalls & Snyder LLC during the fiscal years ended September 30, 2002 and 2001, respectively. 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 fiscal years 2002 and 2001, we paid approximately $153,990 and $26,800, respectively, to the law firm of White & McNamara, P.C. for its services as our outside legal counsel. Rachel Konforty, a shareholder of our Company and the daughter of Jerome Goldstein, is a former associate of White & McNamara, P.C. and, on September 30, 2002, joined us as general counsel. Lisa Gordon, also the daughter of Jerome Goldstein, served the Company as Director of Corporate Strategy and Investor Relations through May 2000, after which time she provided the Company with consulting services in the area of Investor Relations. In May 2001, Ms. Gordon rejoined us as Director of Business Development and Investor Relations. We made salary and consulting fee payments to Ms. Gordon of approximately $112,740, $66,500 and $46,440 for services rendered during the fiscal years ended September 30, 2002, 2001 and 2000, 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, $62,370 and $57,430 during the fiscal years ended September 30, 2002, 2001 and 2000, respectively. Ms. Gordon and Ms. Goldstein were also eligible during those years for employee benefits plans and programs available generally to all salaried employees.

P. Consolidated Quarterly Financial Data—Unaudited:

The following table provides quarterly data for the fiscal years ended September 30, 2002, and 2001.

Quarterly Financial Data
(Unaudited)

	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	(124,311)	(334,597)	(136,511)	(274,534)
Write-down of marketable securities	2,331,956	—	—	—
Income taxes	—	—	—	—
Net income (loss)	$ (2,377,648)	$ (125,554)	$ 421,170	$ 375,760
Net income (loss) per share	$ (0.36)	$ (0.02)	$ 0.06	$ 0.06

	Fiscal 2001 Quarters Ended			
	September 30	June 30	March 31	Dec. 31, 2000
License fees	$ 1,447,929	$ 1,143,902	$ 964,707	$ 1,083,660
Royalties	100,000	200,000	200,000	200,000
Product sales	191,519	127,002	49,915	265,044
Total revenues	1,739,448	1,470,904	1,214,622	1,548,704
Cost of product sales	78,904	53,606	25,474	46,415
Operating expenses	1,605,278	1,221,261	1,304,255	1,158,374
Other (income) expenses	(55,934)	(533,306)	(672,711)	886,085
Write-down of marketable securities	4,659,800	—	—	—
Income taxes	—	25,362	—	—
Net income (loss)	$ (4,548,600)	$ 703,981	$ 557,604	$ (542,170)
Net income (loss) per share	$ (0.68)	$ 0.11	$ 0.08	$ (0.08)

Q. Recently Issued Accounting Pronouncements:

In June 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standard No. 142,

("SFAS 142"), "Goodwill and Other Intangible Assets." Under this statement, goodwill will not be amortized and is to be reviewed for impairment and charged to expense only in the period in which goodwill's recorded value exceeds its fair value. Additionally, entities will be required to review goodwill and indefinite-lived intangible assets for impairment on an annual basis. The provisions of SFAS 142 are required to be applied in fiscal years beginning after December 15, 2001. At the present time, adoption of this standard is not expected to have a material impact on our financial position or results of operations.

In June 2001, the FASB issued Statement of Financial Accounting Standard No. 143, ("SFAS 143"), "Accounting for Obligations Associated with the Retirement of Long-Lived Assets." The objectives of SFAS 143 were to establish accounting standards for the recognition and measurement of

an asset retirement obligation and its associated asset retirement cost. The provisions of SFAS 143 shall be effective for financial statements issued for fiscal years beginning after June 15, 2002. At the present time, adoption of this standard is not expected to have a material impact on our financial position or results of operations.

In October 2001, the FASB issued Statement of Financial Accounting Standard No. 144, ("SFAS 144"), "Accounting for the Impairment or Disposal of Long-Lived Assets." SFAS 144 applies to all long-lived assets (including discontinued operations). SFAS 144 is effective for financial statements issued for fiscal years beginning after December 15, 2001. At the present time, adoption of this standard is not expected to have a material impact on our financial position or results of operations.

In May 2002, the FASB issued Statement of Financial Accounting Standard No. 145, ("SFAS 145"), "Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13 and Technical Corrections as of April 2002." Under this statement, debt extinguishments used as part of an entity's risk management strategy should not be classified as extraordinary items in the statement of operations. Additionally, this statement rescinded certain pronouncements that were no longer required, as well as requiring sale-leaseback accounting for certain lease modifications that have economic effects that are similar to sale-leaseback transactions. This statement is effective for transactions entered into after May 15, 2002 and for financial statements issued after May 15, 2002. The Company's adoption of this standard has had no effect on our financial position or results of operations.

In July 2002 the FASB issued Statement of Financial Accounting Standard No. 146 ("SFAS 146"), "Accounting for Costs Associated with Exit or Disposal Activities." SFAS 146 addresses significant issues relating to the recognition, measurement, and reporting of costs associated with exit and disposal activities, including restructuring activities, and nullifies the guidance in Emerging Issues Task Force (EITF) Issue No. 94-3 (EITF-94-3), "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)". The provisions of SFAS 146 are effective for exit or disposal activities initiated after December 31, 2002. At the present time, adoption of this standard is not expected to have a material impact on our financial position or results of operations.

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

Not applicable.

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, 2002, 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.

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, 2002, under the headings "How are the Company's Directors Compensated?" and "How Were the Company's Executive Officers Compensated in Fiscal Year 2002?"

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, 2002, under the headings of "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, 2002, under the heading "Certain

Relationships and Related Transactions."

ITEM 14. CONTROLS AND PROCEDURES:

(a) Evaluation of disclosure controls and procedures. Our Chief Executive Officer and our Vice President of Finance, after evaluating the effectiveness of our "disclosure controls and procedures" (as defined in the Securities Exchange Act of 1934 Rules 13a-14(c) and 15-d-14(c)) as of a date (the "Evaluation Date"), within 90 days before the filing date of this Annual Report on Form 10-K, have concluded that, as of the Evaluation Date, our disclosure controls and procedures were adequate and designed to ensure that material information relating to us and our consolidated subsidiaries would be made known to them.

(b) Changes in internal controls. There were no significant changes in our internal controls or, to our knowledge, in other factors that could significantly affect our disclosure controls and procedures subsequent to the Evaluation Date.

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, 2002 and 2001

   Statements of Operations—for the years ended September 30, 2002, 2001 and 2000

   Statements of Comprehensive Income—for the years ended September 30, 2002, 2001 and 2000

   Statements of Stockholders' Equity—for the years ended September 30, 2002, 2001 and 2000

   Statements of Cash Flows—for the years ended September 30, 2002, 2001 and 2000

   Reconciliation of Net Income (Loss) to Net Cash Used in Operating Activities—for the years ended September 30, 2002, 2001 and 2000

   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.
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*	1997 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, 1996, 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 accountants.
99.1++	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
99.2++	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: Not applicable.

(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 12, 2002

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 12, 2002
/s/ JAMES A. MATHESON James A. Matheson	Vice President of Finance (principal accounting officer)	December 12, 2002
/s/ SHELDON L. BLOCH Sheldon L. Bloch	Director	December 12, 2002
/s/ MICHAEL D. LOBERG Michael D. Loberg, Ph.D.	Director	December 12, 2002
/s/ EDWARD B. ROBERTS Edward B. Roberts, Ph.D.	Director	December 12, 2002
/s/ GEORGE M. WHITESIDES George M. Whitesides, Ph.D.	Director	December 12, 2002

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 annual 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 annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual 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 annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

a) designed such disclosure controls and procedures 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 annual report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

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

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: December 12, 2002

/s/ JEROME GOLDSTEIN

Jerome Goldstein
Chairman of the Board of Directors,
President, Chief Executive Officer and Treasurer

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 annual 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 annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual 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 annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

a) designed such disclosure controls and procedures 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 annual report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

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

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any

corrective actions with regard to significant deficiencies and material weaknesses.

Date: December 12, 2002

/s/ JAMES A. MATHESON

James A. Matheson
Vice President of Finance

QuickLinks

EXHIBIT 23.1

CONSENT OF INDEPENDENT ACCOUNTANTS

We hereby consent to the incorporation by reference 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 21, 2002 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
December 12, 2002

EXHIBIT 99.1

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, 2002 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jerome Goldstein, Chairman of the Board of Directors, President, Chief Executive Officer and Treasurer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(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 12, 2002

EXHIBIT 99.2

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, 2002 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. Section 1350, as adopted pursuant to Section 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 12, 2002