

ADVANCED MAGNETICS INC  
Form 424B5  
June 02, 2005

Use these links to rapidly review the document  
[TABLE OF CONTENTS Prospectus Supplement](#)  
[TABLE OF CONTENTS](#)

Filed Pursuant to Rule 424(b)(5)  
Registration No. 333-119682

PROSPECTUS SUPPLEMENT  
(TO PROSPECTUS DATED DECEMBER 16, 2004)

**290,525 Units**

## **Each Unit Consisting of Five Shares of Common Stock and a Warrant to Purchase One Share of Common Stock**

We are offering 290,525 units, consisting of five shares of our common stock and a warrant to purchase one share of our common stock at an exercise price of \$13.00 per share. The warrants will be exercisable at any time on or prior to June 1, 2008. This prospectus supplement and the accompanying prospectus also relate to the offering of shares of our common stock upon exercise, if any, of the warrants. Our common stock is listed on the American Stock Exchange, or AMEX, under the trading symbol "AVM." The last sale price of our common stock as reported on the AMEX on May 31, 2005 was \$8.95 per share.

There will be no trading market for the units. The shares of common stock and warrants comprising the units will separate immediately upon completion of this offering and prior to any trading of the common stock and warrants. An aggregate of 1,452,625 shares of our common stock and warrants to purchase an additional 290,525 shares of our common stock will be issued in connection with this offering. We are not listing the warrants on an exchange or any trading system and we do not expect that a trading market for the warrants will develop.

**Investing in our securities involves risks. Please read "Risk Factors" beginning on page S-5 of this prospectus supplement and page 3 of the accompanying prospectus.**

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	Per Unit	Total
Offering price of units, before expenses	\$47.50	\$13,799,937.50

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We expect that all of the units will be sold to affiliates of Great Point Partners, LLC and to Dr. Brian J.G. Pereira, one of the members of our Board of Directors. We expect the total offering expenses to be approximately \$212,500.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined whether this prospectus supplement or the accompanying prospectus is accurate or complete. Any representation to the contrary is a criminal offense.

June 1, 2005



TABLE OF CONTENTS

Prospectus Supplement

	<u>Page</u>
<u>About this Prospectus Supplement</u>	S-1
<u>Where You Can Find More Information</u>	S-1
<u>Cautionary Note Regarding Forward-Looking Statements</u>	S-2
<u>Prospectus Supplement Summary</u>	S-3
<u>Risk Factors</u>	S-5
<u>Use of Proceeds</u>	S-18
<u>Price Range of Common Stock and Dividend Policy</u>	S-18
<u>Description of the Securities We Are Offering</u>	S-19
<u>Plan of Distribution</u>	S-19
<u>Dilution</u>	S-20
<u>Legal Matters</u>	S-21
<u>Experts</u>	S-21

Prospectus

About this Prospectus	1
<u>Cautionary Note Regarding Forward-Looking Statements</u>	1
<u>Our Company</u>	2
<u>Risk Factors</u>	3
<u>Ratio of Earnings to Combined Fixed Charges and Preference Stock Dividends</u>	3
<u>Use of Proceeds</u>	3
<u>Description of Our Common Stock</u>	4
<u>Description of Our Preferred Stock</u>	4
<u>Description of Our Warrants</u>	5
<u>Description of Certain Provisions of Delaware Law and Our Certificate of Incorporation and By-Laws</u>	6
<u>Plan of Distribution</u>	8
<u>Validity of the Offered Securities</u>	10
<u>Experts</u>	10
<u>Documents Incorporated by Reference</u>	10
<u>Where you Can Find More Information</u>	11

### **ABOUT THIS PROSPECTUS SUPPLEMENT**

This prospectus supplement is part of a registration statement that we have filed with the U.S. Securities and Exchange Commission, or SEC, using a "shelf" registration process. Under this process, we are offering to sell units consisting of five shares of our common stock and a warrant to purchase one share of our common stock using this prospectus supplement and the accompanying prospectus. The prospectus supplement describes the specific terms of this offering of common stock and warrants to purchase common stock. The accompanying prospectus gives more general information, some of which may not apply to this offering. You should read both this prospectus supplement and the accompanying prospectus in addition to the information contained in the documents we refer to under the heading "Where You Can Find More Information." If the description of this offering varies between the prospectus supplement and the accompanying prospectus, you should rely on the information in the prospectus supplement.

You should rely on the information contained in or incorporated by reference into this prospectus supplement and the accompanying prospectus. We have not authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer of the units in any jurisdiction where the offer is not permitted. You should not assume that the information contained in this prospectus supplement or the accompanying prospectus is accurate as of any date other than the date on the front cover of the respective documents or that the information we previously filed with the SEC and incorporated by reference is accurate as of any date other than the date of the document incorporated by reference. Our business, prospects, financial condition and results of operations may have changed since that date.

### **WHERE YOU CAN FIND MORE INFORMATION**

We file reports, proxy statements and other information with the SEC. You may read and copy the reports, proxy statements and other information that we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for information about the operation of its Public Reference Room and for its prescribed rates to obtain copies of such material. The SEC also maintains an Internet site that contains reports, proxy and information statements and other information regarding registrants, like us, that file electronically with the SEC. The address of the SEC's Internet site is <http://www.sec.gov>. Our Internet site is <http://www.advancedmagnetics.com>. Information contained on these Internet sites is not a part of this prospectus supplement.

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and other filings with the SEC are available, free of charge, through our website, shortly after those reports or filings are electronically filed with or furnished to the SEC. Information on our website or any other website is not incorporated by reference into this prospectus supplement or the accompanying prospectus and does not constitute a part of this prospectus supplement or the accompanying prospectus.

This prospectus supplement is part of a registration statement we filed with the SEC relating to the securities we may offer. As permitted by SEC rules, this prospectus supplement does not contain all of the information we have included in the registration statement and the accompanying exhibits and schedules we filed with the SEC. You may refer to the registration statement, exhibits and schedules for more information about us and the securities. The registration statement, exhibits and schedules are available at the SEC's public reference room or through its Internet site.

The SEC allows us to "incorporate by reference" the information we have filed with it, which means that we can disclose important information by referring you to those documents. The information we incorporate by reference is an important part of this prospectus supplement, and later information that we file with the SEC will automatically update and supersede this information. We incorporate by reference into this prospectus supplement and the accompanying prospectus the

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documents listed below and any future filings (excluding information furnished pursuant to items 2.02 and 7.01 of Form 8-K) we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act subsequent to the date of this prospectus supplement and prior to the termination of the offering:

Our Annual Report on Form 10-K for the fiscal year ended September 30, 2004,

Our Quarterly Report on Form 10-Q for the quarter ended December 31, 2004,

Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2005,

The section entitled "Description of Registrant's Securities to be Registered" contained in our Registration Statement on Form 8-A as filed on September 24, 1991, and

Our Current Reports on Form 8-K filed with the SEC on October 19, 2004, November 10, 2004, January 18, 2005, February 2, 2005, March 3, 2005, March 24, 2005, April 19, 2005 and June 1, 2005.

We will provide without charge to each person, including any beneficial owner, to whom this prospectus supplement is delivered, upon the written or oral request of that person, a copy of any and all of the information that has been incorporated in this prospectus supplement by reference other than exhibits unless those exhibits are specifically incorporated by reference into the documents. Requests for these copies should be directed to our Chief Financial Officer at the following address and telephone number: Advanced Magnetics, Inc., 61 Mooney Street, Cambridge, MA 02138, (617) 497-2070.

### **CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

We have made and incorporated by reference statements in this document that constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and federal securities laws. This section provides a "safe harbor" for forward-looking statements to encourage companies to provide prospective information about themselves so long as they identify these statements as forward-looking and provide meaningful cautionary statements identifying important factors that could cause actual results to differ from the projected results. All statements other than statements of historical fact we make in this prospectus supplement or in any document incorporated by reference are forward-looking statements. These statements are based on management's beliefs and assumptions and on information currently available to management and use words such as "expect," "anticipate," "intend," "plan," "believe," "estimate," or similar expressions. Forward-looking statements include information concerning possible or assumed future results of operations, future product development and related clinical trials and statements regarding future research and development. Forward-looking statements reflect our current expectations and are subject to various known and unknown risks, uncertainties and other factors. Our actual results could differ materially from those anticipated in these forward-looking statements. Important factors that could cause these differences include, among others, those set forth below. Please read carefully the information discussed under "Risk Factors" in this prospectus supplement as well as other factors which may be described from time to time in our filings with the SEC, including our Annual Report on Form 10-K for the fiscal year ended September 30, 2004, and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2005.

These cautionary statements should not be construed by you to be exhaustive and they are made only as of the date of this prospectus supplement. You should not rely upon forward-looking statements except as statements of our present intentions and of our present expectations, which may or may not occur. You should read these cautionary statements as being applicable to all forward-looking statements wherever they appear. We assume no obligation, except as specifically required by law and the rules of the SEC, to update the forward-looking statements or the reasons why actual results could differ from those projected in the forward-looking statements to reflect events or circumstances after the date hereof.

**PROSPECTUS SUPPLEMENT SUMMARY**

This summary highlights information appearing in other sections of this prospectus supplement or the accompanying prospectus. It may not contain all of the information that you should consider before making an investment in the units. You should read the entire prospectus supplement, the accompanying prospectus and the documents incorporated by reference carefully, including the financial statements and the notes to those financial statements contained in those documents. References in this prospectus supplement to the terms "Advanced Magnetix," "company," "we," "our" or "us" or other similar terms mean Advanced Magnetix, Inc.

**Our Business**

Advanced Magnetix is a developer of superparamagnetic iron oxide nanoparticles used in pharmaceutical products. We are dedicated to the development and commercialization of our proprietary nanoparticle technology for use in therapeutic iron compounds to treat anemia as well as novel imaging agents to aid in the diagnosis of cardiovascular disease and cancer. We have two approved products, Feridex I.V.® and GastroMARK®, and two product candidates, *Combidex*® and ferumoxytol. *Combidex* is our investigational functional molecular imaging agent consisting of iron oxide nanoparticles for use in conjunction with magnetic resonance imaging, also known as MRI, to aid in the differentiation of cancerous from normal lymph nodes. Ferumoxytol is in Phase III multi-center clinical trials for use as an iron replacement therapeutic in chronic kidney disease patients, whether or not on dialysis. Exploratory Phase II clinical trials of ferumoxytol for use as a contrast agent in magnetic resonance angiography, also known as MRA, are currently ongoing.

In June 2000, *Combidex* received an approvable letter, subject to certain conditions, from the U.S. Food and Drug Administration, also known as the FDA. In September 2004, we submitted a complete response to the approvable letter, which was accepted by the FDA and assigned a user fee goal date of March 30, 2005. On March 3, 2005, the FDA's Oncologic Drugs Advisory Committee voted to not recommend approval of the proposed broad indication for *Combidex*. Subsequently, in March 2005, we received an approvable letter from the FDA with respect to *Combidex*, subject to certain conditions. We have formally requested a meeting with the FDA to discuss next steps in the regulatory process for *Combidex*. Until such next steps are determined, we cannot predict with certainty the timing or costs of the efforts that would be necessary to satisfy the conditions specified for approval of *Combidex* in the approvable letter, or our ability to complete those efforts in a timely or cost-effective manner, if at all.

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

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

**The Offering**

Securities offered by Advanced Magnetics

We are offering 290,525 units. Each unit consists of five shares of our common stock and a warrant to purchase one share of our common stock. An aggregate of 1,452,625 shares of our common stock and warrants to purchase an additional 290,525 shares of our common stock will be issued in connection with this offering. This prospectus supplement and the accompanying prospectus also relate to the offering of shares of our common stock upon exercise, if any, of the warrants.

Common stock outstanding after the offering

9,502,738 shares.

Warrant Terms

Each warrant is exercisable for the purchase of one share of our common stock at an exercise price of \$13.00 per share. The warrants will be exercisable at any time on or prior to June 1, 2008.

Use of Proceeds

We intend to use the net proceeds from this offering for development of our products, working capital and general corporate purposes.

Risk Factors

Investing in our common stock involves risk. Please read "Risk Factors" beginning on page S-5 of this prospectus supplement and page 3 of the accompanying prospectus.

American Stock Exchange symbol

AVM

The number of shares outstanding after this offering is based on 8,050,113 shares of our common stock outstanding as of May 31, 2005. This number excludes 889,328 shares of our common stock currently issuable upon exercise of outstanding stock options and 261,780 shares of our common stock currently issuable upon exercise of outstanding warrants at an exercise price of \$15.50 per share.

## RISK FACTORS

The following should be considered carefully with the information provided elsewhere in this prospectus supplement, the accompanying prospectus and the documents we incorporate by reference in reaching a decision regarding an investment in our common stock.

### Risks Related to the Offering

*The price of our common stock may fluctuate which may cause our common stock to trade at a substantially lower price than the price which you paid for the common stock underlying the units.*

The trading price of our common stock and the price at which we may sell securities in the future is subject to substantial fluctuations in response to various factors, including any of the following: our ability to successfully accomplish our business strategy; the trading volume in our stock; changes in governmental regulations; actual or anticipated variations in our quarterly or annual financial results; our involvement in litigation; general market conditions; announcements by us and our competitors; our liquidity; our ability to raise additional funds; and other events. The price of our common stock could decrease materially as a result of such events.

The market price of our common stock has been, and may continue to be, volatile. This price has ranged between \$24.25 and \$6.00 in the fifty-two week period through May 31, 2005. The stock market has from time to time experienced extreme price and volume fluctuations, particularly in the biotechnology sector, which have often been unrelated to the operating performance of particular companies. Various factors and events, including announcements by us or our competitors concerning results of regulatory actions, technological innovations, new products, clinical trial results, agreements with collaborators, governmental regulations, developments in patent or other proprietary rights, or public concern regarding the safety of products developed by us or others, may have a significant impact on the market price of our common stock. Thus, as a result of events both within and beyond our control, our stock price could fluctuate significantly or lose value rapidly. As of May 31, 2005, our shares had an average 90 calendar day trading volume of approximately 79,000 shares. Bulk sales or substantial purchases of our stock in a short period of time could cause the market price for our shares to decline or fluctuate drastically.

*If securities analysts downgrade our stock or cease coverage of us, the price of our stock could decline.*

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. Currently, only one financial analyst publishes reports about us and our business. We do not control this or any other analyst. Furthermore, there are many large, well-established, publicly traded companies active in our industry and market, which may mean that it is less likely that we will receive widespread analyst coverage. If the analyst who covers us downgrades our stock, our stock price would likely decline rapidly. If this analyst ceases coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

*Future sales of our common stock could adversely affect our stock price*

Substantial sales of our common stock in the public market following this offering, or the perception by the market that those sales could occur, may lower our stock price or make it difficult for us to raise additional equity capital in the future. These potential sales could include sales of shares of our common stock by our directors and officers, who beneficially owned approximately 15.2% of the outstanding shares of our common stock as of May 31, 2005.



## Risks Related to Our Business

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

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

Our ability to complete our clinical trials for ferumoxytol in iron replacement therapy in a timely manner is also subject to a number of uncertainties, many of which are out of our control. For example, the completion rate of our clinical trials depends, in large part, on patient enrollment. We rely on third-party clinical trial sites to find suitable patients for our clinical trial programs for ferumoxytol in iron replacement therapy. If these third parties do not find suitable patients in the timeframe for which we have planned, we will not be able to complete our clinical trials according to our expected schedule. Any such delays would significantly impair or delay our ability to generate future revenues from product sales of ferumoxytol in iron replacement therapy. In addition, clinical trials are often conducted with patients in the most advanced stages of disease. During the course of treatment, these patients can die or suffer adverse medical effects for reasons that may not be related to the investigational product being tested, but which can nevertheless adversely affect clinical trial results for ferumoxytol in iron replacement therapy or approvals by the United States Food and Drug Administration, also known as the FDA. Any unexpected results from our clinical sites for ferumoxytol in iron replacement therapy could hinder our ability to complete our Phase III studies in a timely manner, if at all. Any such delays, among others, could result in an increase in development costs for ferumoxytol in iron replacement therapy, a delay in making regulatory submissions, and a delay in the commercialization of our iron replacement therapy product.

Clinical testing of pharmaceutical products is itself subject to approvals by various governmental regulatory authorities. We conduct our Phase III clinical trials for ferumoxytol in iron therapy in accordance with specific protocols, which are filed with the FDA or other relevant authorities. We may not be permitted by regulatory authorities to continue these clinical trials if such protocols are not approved or if the FDA determines that there are flaws in the design of the protocols or the trials during the course of the studies. Any deficiency in the design or oversight of our Phase III clinical studies by us could delay or prevent us from obtaining regulatory approval and could significantly increase the costs of such clinical trials and negatively affect our future prospects and stock price. We may also be required to demonstrate that ferumoxytol in iron replacement therapy represents an improved form of treatment over existing therapies in order to receive regulatory approval and we may be unable to do so without conducting further clinical studies, if at all. If, upon completion of our current Phase III clinical trial program, the FDA requires us to perform additional studies, we could

incur significant additional costs and experience significant delays in our efforts to obtain regulatory approval for ferumoxytol in iron replacement therapy. Any such requirement could also result in delays in, or the prevention of, our ability to make regulatory submissions and delays in, or the prevention of, the commercialization of our products. Any such delays would significantly impair or delay our ability to generate future revenues from product sales of ferumoxytol in iron replacement therapy.

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

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

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

We rely on third-party contract research organizations for a variety of activities in our iron replacement therapy development program, including monitoring of our clinical sites, collection and analysis of data, drafting study reports and assisting in regulatory submissions. We also rely on third-party service providers in our iron therapy replacement development program for clinical laboratory testing and randomization of clinical trial subjects. In addition to our internal research and development costs, we currently estimate that the future cost of the external efforts necessary to complete development of ferumoxytol as an iron replacement therapeutic will be in the range of approximately \$10,500,000 to \$11,500,000 over the next thirteen months. These external costs could increase, however, if we experience significant delays in our clinical development program due to slow enrollment, unexpected results from our clinical sites that affect our ability to complete the studies in a timely manner, inadequate performance or errors by third-party contract research and development service providers or any deficiencies in the design or oversight of these studies by us. In addition, if any of these third-party contract research and development service providers should fail to perform or should perform inadequately or in violation of current Good Clinical Practices, our regulatory submissions could be delayed or the data in support of such submissions tainted, which could negatively impact the timing or possibility of obtaining regulatory approval for ferumoxytol in iron replacement therapy. Such delays could also result in increased costs associated with our iron replacement therapy development program. Any delay in, or failure to obtain regulatory approval of, ferumoxytol in iron replacement therapy in a timely manner would significantly impair or delay our ability to generate future revenues from product sales.

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

Prior to marketing, every product candidate must undergo an extensive regulatory approval process in the United States and in every other country in which we intend to test and market our product candidates and products. This regulatory process includes testing and clinical trials of product candidates to demonstrate safety and efficacy and can take many years and require the expenditure of substantial resources. Data obtained from pre-clinical trials and clinical trials may not support our expected results in one or more indications or may be subject to varying interpretations. Unexpected or

unfavorable data obtained from pre-clinical testing and clinical trials can delay, limit or prevent regulatory approval by the FDA or similar regulatory bodies in foreign countries. In addition, changes in FDA or foreign regulatory approval policies or requirements may occur or new regulations may be promulgated which may result in a delay or failure to receive FDA or foreign regulatory approval. Delays and related costs in obtaining regulatory approvals could delay our product commercialization and revenue and consume our resources, both financial and managerial.

In 2004, we initiated Phase III multi-center clinical studies for one of our product candidates, ferumoxytol, for use in iron replacement therapy. Before applying for FDA approval to market ferumoxytol for use in iron replacement therapy, large-scale Phase III human clinical trials that demonstrate the safety and efficacy of ferumoxytol in iron replacement therapy to the satisfaction of the FDA and other regulatory authorities must be completed. These clinical trials, and the support from third-party contract research and development service providers necessary for us to conduct them, will entail the expenditure of significant corporate resources, both financial and managerial. We may not be able to successfully complete these clinical trials for ferumoxytol iron replacement therapy, or, if completed, we may not obtain the desired results or, even if we do, we may not be able to obtain regulatory approval or obtain regulatory approval of the desired scope.

Exploratory Phase II clinical trials of ferumoxytol for use as a contrast agent in magnetic resonance angiography, also known as MRA, are currently ongoing. Before applying for FDA approval to market ferumoxytol as a contrast agent, we need to first successfully complete our Phase II program for ferumoxytol as a contrast agent in MRA. We then need to determine an appropriate indication for ferumoxytol in MRA, develop a regulatory strategy for its approval, and conduct and complete large-scale Phase III human clinical trials that demonstrate the safety and efficacy of ferumoxytol as a contrast agent to the satisfaction of the FDA and other regulatory authorities. These clinical trials, and the support from third-party contract research and development service providers necessary for us to conduct them, will entail the expenditure of significant corporate resources, both financial and managerial. We do not currently possess the financial or human resources necessary to conduct Phase III clinical trials for ferumoxytol as a contrast agent in MRA. Therefore, we may not be able to successfully complete these clinical trials for ferumoxytol as a contrast agent in MRI or, if completed, we may not obtain the desired results or, even if we do, we may not be able to obtain regulatory approval or obtain regulatory approval of the desired scope.

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

In June 2000, we received an approvable letter, subject to certain conditions, for *Combidex*<sup>®</sup>, our investigational functional molecular imaging agent consisting of iron oxide nanoparticles for use in conjunction with magnetic resonance imaging, also known as MRI, to aid in the differentiation of cancerous from normal lymph nodes. In September 2004, we submitted a complete response to the approvable letter, which was accepted by the FDA, and assigned a user fee goal date of March 30, 2005. On March 3, 2005, the FDA's Oncologic Drugs Advisory Committee voted to not recommend approval of the proposed broad indication for *Combidex*. Subsequently, in March 2005, we received an approvable letter from the FDA with respect to *Combidex*, subject to certain conditions. We have formally requested a meeting with the FDA to discuss next steps in the regulatory process for *Combidex*. Although we have received an approvable letter from the FDA, final approval of *Combidex* remains subject to the satisfaction of certain conditions imposed by the FDA and final labeling must be resolved. We may be unable to address the conditions imposed in the approvable letter to the

satisfaction of the FDA or we may be unable to satisfy these conditions in a timely manner and/or without the expenditure of significant additional resources, both financial and managerial. If we are unable to successfully address the concerns of the FDA in a timely manner, the New Drug Application for *Combidex* may not be approved, or, if approved, may be approved for a limited or truncated indication. If we are unable to obtain approval or are unable to obtain approval for our requested indication or if the FDA requires labeling that imposes limitations on the use of *Combidex*, our partners' ability to market the product to the medical community may be prevented or hindered. Any failure to successfully market and sell *Combidex* or any delay in these efforts, would reduce the amount of cash generated from operations available to fund research and development or other activities. We may not be able to replenish our cash needs by seeking financing alternatives or otherwise.

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

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

the timing and magnitude of external research and development expenses, in particular, those related to our Phase III clinical trials for ferumoxytol in iron therapy;

the timing and likelihood of FDA approval of *Combidex*, including the magnitude of potential costs we may incur, if any, to satisfy the conditions specified by the FDA for approval of *Combidex*;

the timing of our recognition of deferred revenue, which is affected by fluctuations in our activities under our license and marketing agreement with Cytogen Corporation, or Cytogen;

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

uneven demand for our products by end users which affects the royalties we receive from our marketing partners;

the magnitude of the non-cash accounting charge we will record as an expense in a given period following our adoption of Statement of Financial Accounting Standards Number 123R ("SFAS 123R"); and

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

As a result of these and other factors, our quarterly operating results could fluctuate, and this fluctuation could cause the market price of our common stock to decline. Results from one quarter should not be used as an indication of future performance.

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

Our strategy for the development, commercialization and marketing of our product candidates has been to enter into strategic relationships with various corporate partners, licensees and other collaborators. We rely on a limited number of marketing and distribution partners to market and sell our approved products, Feridex I.V.® and GastroMARK®, both in the United States and in foreign countries, and we depend on these strategic partners for a significant portion of our revenue. Three companies were responsible for approximately 92% of our revenue during the six-month period ended March 31, 2005. Berlex Laboratories, Inc. represented approximately 45% of our revenue, Guerbet represented approximately 20% of our revenue, and Cytogen, represented approximately 27% of our revenue in the six-month period ended March 31, 2005. The majority of our revenue for the quarter ended March 31, 2005, including all of the Cytogen revenue, constituted recognition of deferred

revenue. A decrease in revenue from any of our significant marketing or distribution partners could seriously impair our overall revenues. In some cases, we have granted exclusive rights to these partners. If these partners are not successful in marketing our products, or if these partners fail to meet minimum sales requirements or projections, our ability to generate revenue would be substantially harmed. For example, to date, we have not generated significant revenues on royalties from the sale of our approved products by our marketing partners. In addition, we might incur further costs in an attempt to enforce our contractual rights, renegotiate agreements, find new partners or market our own products. In some cases, we are dependent upon some of our collaborators to manufacture and market our products. We may not be able to derive any revenues from these arrangements. If any of our collaborators breaches its agreement with us or otherwise fails to perform, such event could impair our revenue and impose additional costs on us. In addition, many of our corporate partners have considerable discretion in electing whether to pursue the development of any additional products and may pursue technologies or products either on their own or in collaboration with competitors. Given these and other risks, our current and future collaborative efforts may not be successful. Failure of these efforts would materially adversely impact our ability to generate revenue from product sales, thereby decreasing the amount of cash from operations available to support our development efforts for ferumoxytol as an iron therapeutic and as a contrast agent for MRI.

Due to the high cost of our research and development activities, in particular the anticipated cost of clinical trials for ferumoxytol in iron replacement therapy, our inability to secure strategic partners or alternative strategic arrangements could limit our ability to continue developing ferumoxytol or force us to raise additional capital through alternative means which may not be available to us on acceptable terms or within an acceptable timeframe, if at all. Any delay in, or termination of, any of our research and development projects due to insufficient funds resulting from lack of revenue from strategic partners or alternative capital raising or strategic arrangements would reduce our potential revenues. In addition, if, in the future, we are unable to enter into collaborative agreements related to ferumoxytol in either iron replacement therapy or MRI, or choose not to enter into collaborative agreements, we would need to develop an internal sales and marketing department, including a direct sales force, or contract for these services from a third party, in order to market and sell ferumoxytol since we do not have the necessary sales and marketing expertise at this time. If we are unable to successfully recruit and retain the necessary sales and marketing personnel, to obtain the financing to support these efforts, if necessary, or to contract with third parties for these services on acceptable terms, if at all, our product marketing efforts and potential product launches would be delayed and the commercialization of ferumoxytol in both iron replacement therapy and MRI would be severely impaired. Any delay in the product launch of ferumoxytol in iron replacement therapy or MRI would delay any potential revenue from these product candidates.

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

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

impact on our ability to generate additional revenues, our ability to achieve profitability, and on the future prospects for our business.

In addition, although we have dedicated significant resources to our research and development efforts, we may not develop new applications for our existing technology or expand the indications for our current products or product candidates for development into future product candidates. We are not currently conducting or sponsoring research to expand our development pipeline. Any failure by us to develop and commercialize additional products and product candidates will place greater pressure on the performance of our existing products and product candidates and will materially adversely affect our ability to increase revenues, our ability to achieve profitability, and the future prospects of our business.

***We may need additional capital to achieve our business objectives.***

We have expended and will continue to expend substantial funds to complete the research, development, clinical trials, regulatory approvals and other activities necessary to achieve final commercialization of our product candidates, *Combidex* and ferumoxytol as an iron replacement therapeutic and as a contrast agent in MRI. In particular, we anticipate that the high levels of expenditures related to our research and development activities will continue due to the conduct of Phase III clinical studies for ferumoxytol in iron replacement therapy and that our cash-burn rate will continue to increase in the near term. Our near-term capital requirements will also depend on additional factors, including, but not limited to, the progress of, and our ability to successfully complete, our clinical trials for ferumoxytol in iron replacement therapy in a timely manner; our ability to establish additional development and/or marketing arrangements, to enter into alternative strategic relationships and/or to raise additional capital, if necessary, on terms and within a timeframe acceptable to us, if at all; the costs we may incur, if any, to satisfy the conditions specified by the FDA for approval of *Combidex*; and the magnitude of product sales and royalties for our marketed products. We estimate that our existing cash resources, combined with cash we currently expect to receive from other sources, including the net proceeds we expect to receive from this offering, will be sufficient to finance our operations, including projected operating expenses and research and development costs related to the Phase III clinical trials for ferumoxytol in iron replacement therapy, for approximately the next eighteen months. Thereafter, we may require additional funds or need to establish alternative strategic arrangements to continue our research and development activities, including our iron replacement therapy development program, to conduct future clinical trials for ferumoxytol in new indications, to expand our commercial-scale manufacturing capabilities and to market and sell our products. We may seek needed funding through arrangements with collaborative partners or through public or private equity or debt financings. We may not be able to obtain financing or to secure alternative strategic arrangements on acceptable terms or within an acceptable timeframe, if at all. Any additional equity financings or alternative strategic arrangements could be dilutive to our stockholders. In addition, the terms of any debt financing could greatly restrict our ability to raise additional capital and may provide rights and preferences to the investors in any such financing which are not available to current stockholders.

***Our success depends on our ability to attract and retain key employees.***

Because of the specialized nature of our business, we are highly reliant on our executive officers, senior scientists, clinical staff, and manufacturing and quality control personnel, including our Chief Executive Officer, Jerome Goldstein. If we are unable to attract and retain qualified scientific and technical personnel for the development activities conducted or sponsored by us, including our Phase III clinical trials for ferumoxytol in iron replacement therapy, or we fail to hire qualified people or lose the services of our key personnel, our product development efforts could be delayed or curtailed. If we fail to attract and retain key members of our manufacturing or quality control departments, our ability

to manufacture our products, or to manufacture our products in a timely manner, could be hindered and our product sales and development efforts delayed. Furthermore, our possible expansion into areas and activities requiring additional expertise, such as late-stage clinical development and marketing and sales, may require the addition of new management personnel or the development of additional expertise by existing management personnel, which would increase our projected research and development costs and accelerate our need for additional financing. There is intense competition for qualified personnel in the areas of our activities, and we may not be able to continue to attract and retain the qualified personnel necessary for the development of our business. The failure to attract and retain such personnel or to develop such expertise could impose significant limits on our business operations and hinder our ability to successfully and efficiently complete our development projects.

***We lack marketing and sales experience.***

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

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

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

the establishment and demonstration in the medical community of the clinical efficacy and safety of our products;

our products' potential advantage over existing treatments or diagnostic methods; and

reimbursement policies of government and third-party payors, including insurance companies.

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

To date, we have not generated significant revenues on royalties from the sale of our approved products by our marketing partners and these products have not achieved broad market acceptance. *Feridex I.V.* and *GastroMARK*, approved in 1996 and 1997, respectively, represented an alternative

technology platform for physicians to adopt in MRI. *Feridex I.V.* sales have decreased from their peak based on changes in MRI technology and competition in the market, and we expect product sales of *Feridex I.V.* to remain at current low levels overall. *Combidex*, if approved, will represent a shift in the diagnostic process that physicians could use to stage and monitor cancer patients that may not be adopted by physicians. In addition, ferumoxytol, if approved in iron replacement therapy, will represent an alternative to existing products or procedures that might not be adopted by the medical community. If our approved products or future products are not adopted by physicians, revenues will be delayed or fail to materialize.

***An inability to obtain raw materials and our reliance on a sole source supplier could adversely impact our business.***

We currently purchase the raw materials used to manufacture our products from third-party suppliers. We do not, however, have any long-term supply contracts with these third parties. Certain raw materials used in our products are procured from a single source with no qualified alternative supplier. If any of these third-party suppliers should cease to produce the raw materials used in our products, we would be unable to manufacture our products until we were able to qualify an alternative source. The qualification of an alternative source may require repeated testing of the new materials and generate greater expenses to us if materials that we test do not perform in an acceptable manner. In addition, we sometimes obtain raw materials from one vendor only, even where multiple sources are available, to maintain quality control and enhance working relationships with suppliers, which could make us susceptible to price inflation by the sole supplier, thereby increasing our production costs. As a result of the high quality standards imposed on our raw materials, we may not be able to obtain raw materials of the quality required to manufacture our products from an alternative source on commercially reasonable terms, or in a timely manner, if at all. Any delay in or failure to obtain sufficient quantities of raw materials would prevent us from manufacturing our products. In addition, even if we are able to obtain raw materials from an alternative source, if these raw materials are not available in a timely manner or on commercially reasonable terms, we would be unable to manufacture our products on a timely and cost-effective basis. Any such difficulty in obtaining raw materials would hinder our ability to generate revenues from sales of our products or reduce the revenues realized from such sales and could impede our development efforts with respect to our product candidates.

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

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

***We may not be successful in competing with other companies or our technology may become obsolete.***

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



successfully develop efficacious products, obtain timely regulatory approvals, manufacture products at commercially acceptable costs, market our products alone or with our partners, gain satisfactory market acceptance or otherwise successfully compete in the future.

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

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

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

We currently have only one manufacturing facility at which we produce limited quantities of ferumoxytol. Although we are currently testing scale-up for production of ferumoxytol, some aspects of our manufacturing processes may not be easily scalable to allow for production in larger volumes, resulting in higher than anticipated material, labor and overhead costs per unit. Additionally, manufacturing and quality control problems may arise as we increase our level of production. We may not be able to increase our manufacturing capacity in a timely and cost-effective manner, and we may experience delays in manufacturing ferumoxytol. Furthermore, if we fail to attract and retain key members of our manufacturing or quality control departments, we may be unable to manufacture our products and product candidates in a timely manner, which could delay our product sales and development efforts.

If we are unable to consistently manufacture our products on a timely basis because of these or other factors, we will not be able to meet anticipated demand. As a result, we may lose sales and fail to generate increased revenue.

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

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

***Our success is dependent on third-party reimbursement.***

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

In the United States, there have been, and we expect there will continue to be, a number of federal and state proposals to reform the health care system. Significant uncertainty exists as to the reimbursement status of newly-approved healthcare products and products which have competitors for their approved indications. If Medicare or third-party payors do not approve our therapeutic products, MRI products and/or related MRI procedures for reimbursement, or for adequate levels of reimbursement, the adoption of our products may be limited. Sales may suffer as some physicians or their patients will opt for a competing product that is approved for sufficient reimbursement or may forgo the treatment or MRI procedure instead of paying out-of-pocket for costs associated with the treatment or procedure and contrast agent and our ability to generate revenue may be impaired. Even if third-party payors make reimbursement available, these payors' reimbursement policies may be insufficient, which may negatively impact us and our corporate partners' ability to sell our products on a profitable basis.

Health care reform is an area of continuing national and international attention and a priority of many government officials. Future changes could impose limitations on the prices that can be charged in the United States and elsewhere for our products or the amount of reimbursement available for our products from government agencies or third-party private payors. The increasing use of managed care organizations, health maintenance organizations and the growing trend in capitated coverage as well as continued legislative proposals to reform healthcare and government insurance programs could

significantly influence the purchase of healthcare services and products, resulting in lower prices and reduced demand for our products which could harm our ability to profit from product sales. In addition, recent and possible future legislation and regulations affecting the pricing of pharmaceuticals may change reimbursement in ways adverse to us that may affect the marketing of our current or future products. While we cannot predict the likelihood of adoption of any of these legislative or regulatory proposals, if the government or a private third-party payor adopts these proposals they could limit our ability to price our products at desired levels.

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

We rely on a combination of patents, trademarks, copyrights and trade secrets in the conduct of our business. The patent positions of pharmaceutical and biopharmaceutical firms are generally uncertain and involve complex legal and factual questions. We may not be successful or timely in obtaining any patents for which we submit applications. The breadth of the claims obtained in our patents may not provide significant protection for our technology. The degree of protection afforded by patents for licensed technologies or for future discoveries may not be adequate to protect our proprietary technology. The patents issued to us may not provide us with any competitive advantage. In addition, there is a risk that others will independently develop or duplicate similar technology or products or circumvent the patents issued to us.

Moreover, patents issued to us may be contested or invalidated. Future patent interference proceedings involving either our patents or patents of our licensors may harm our ability to commercialize our products. Claims of infringement or violation of the proprietary rights of others may be asserted against us. If we are required to defend against such claims or to protect our own proprietary rights against others, it could result in substantial costs to us and distraction of our management. An adverse ruling in any litigation or administrative proceeding could prevent us from marketing and selling our products, limit our development of our product candidates or harm our competitive position and result in additional significant costs. In addition, any successful claim of infringement asserted against us could subject us to monetary damages or injunction preventing us or our marketing partners from making or selling products. We also may be required to obtain licenses to use the relevant technology, and licenses may not be available on commercially reasonable terms, if at all.

In the future, we may be required to obtain additional licenses to patents or other proprietary rights of others in order to commercialize our products or continue with our development efforts. Such licenses may not be available on acceptable terms, if at all. The failure to obtain such licenses could result in delays in marketing our products or our inability to proceed with the development, manufacture or sale of our products or product candidates requiring such licenses. In addition, the termination of any of our existing licensing arrangements could impair our revenues and impose additional costs which could limit our ability to sell our products commercially.

The laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States. In countries where we do not have or have not applied for patents on our products, we will be unable to prevent others from developing or selling similar products. In addition, in jurisdictions outside the United States where we have patent rights, we may be unable to prevent unlicensed parties from selling or importing products or technologies derived elsewhere using our proprietary superparamagnetic iron oxide nanoparticle technology.

We also rely upon unpatented trade secrets and improvements, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our corporate partners, collaborators, employees and consultants. These agreements, however, may be breached. We may not have adequate remedies for any such breaches, and our trade secrets might otherwise become known or be independently

discovered by our competitors. In addition, we cannot be certain that others will not independently develop substantially equivalent or superseding proprietary technology, or that an equivalent product will not be marketed in competition with our products, thereby substantially reducing the value of our proprietary rights.

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

We maintain product liability insurance coverage for claims arising from the use of our products and product candidates in clinical trials and commercial use. However, coverage is becoming increasingly expensive and costs may continue to increase significantly particularly as our Phase III clinical trial activities for ferumoxytol in iron replacement therapy continue, and we may not be able to maintain insurance at a reasonable cost. Furthermore, our insurance may not provide sufficient coverage amounts to protect us against liability that could deplete our capital resources. We also may not be able to obtain commercially reasonable product liability insurance for any product approved for marketing in the future. Our insurance coverage and our resources may not be sufficient to satisfy any liability or cover costs resulting from product liability claims. A product liability claim or series of claims brought against us could reduce or eliminate our resources, whether or not the plaintiffs in such claims ultimately prevail. In addition, pursuant to our certificate of incorporation, by-laws and contractual agreements with our directors, and in order to attract competent candidates, we are obligated to indemnify our officers and directors against certain claims arising from their service to us. We maintain directors and officers' liability insurance to cover such potential claims against our officers and directors. However, this insurance may not be adequate for certain claims and deductibles apply. As a result of our indemnification obligations and in instances where insurance coverage is not available or insufficient, any liability claim or series of claims brought against our officers or directors could deplete or exhaust our resources, regardless of the ultimate disposition of such claims.

***We are subject to environmental laws and potential exposure to environmental liabilities.***

Because we use certain hazardous materials in the production of our products, we are subject to various federal, state and local environmental laws and regulations that govern our operations, including the handling and disposal of non-hazardous and hazardous wastes, and emissions and discharges into the environment. Failure to comply with these laws and regulations could result in costs for corrective action, penalties or the imposition of other liabilities. We also are subject to laws and regulations that impose liability and clean-up responsibility for releases of hazardous substances into the environment. Under certain of these laws and regulations, a current or previous owner or operator of property may be liable for the costs of remediating the release or spill of hazardous substances or petroleum products on or from its property, without regard to whether the owner or operator knew of, or caused, the contamination, and such owner or operator may incur liability to third parties impacted by such contamination. The presence of, or failure to remediate properly the release or spill of, these substances could adversely affect the value of, and our ability to transfer or encumber, our real property.

**USE OF PROCEEDS**

We expect to receive net proceeds of approximately \$13.59 million after deducting the estimated offering expenses of approximately \$212,500, payable by us. We intend to use the net proceeds from this offering for development of our products, working capital and general corporate purposes.

**PRICE RANGE OF COMMON STOCK AND DIVIDEND POLICY**

As of May 31, 2005, there were 8,050,113 shares of our common stock outstanding, held by approximately 220 holders. This number does not include any beneficial owners for whom shares of common stock may be held in "nominee" or "street" name. Our common stock is traded on the AMEX under the symbol "AVM." The following table sets forth, for the periods indicated, the high and low closing price per share of our common stock, as reported on the AMEX. The last reported sale price of common stock on the AMEX on May 31, 2005 was \$8.95 per share.

	<u>High</u>	<u>Low</u>
<b>2003</b>		
First Quarter	\$ 5.14	\$ 3.97
Second Quarter	4.80	4.04
Third Quarter	12.20	4.20
Fourth Quarter	13.74	8.35
<b>2004</b>		
First Quarter	\$ 15.24	\$ 8.70
Second Quarter	13.35	9.70
Third Quarter	15.49	8.00
Fourth Quarter	16.43	13.01
<b>2005</b>		
First Quarter	\$ 15.72	\$ 12.11
Second Quarter	23.55	6.65
Third Quarter (through May 31, 2005)	10.11	7.73

We have never declared or paid a cash dividend on our common stock. We currently anticipate that we will retain all of our earnings for use in the development of our business and do not anticipate paying any cash dividends in the foreseeable future.

## DESCRIPTION OF THE SECURITIES WE ARE OFFERING

In this offering, we are offering a maximum of 290,525 units, consisting of 1,452,625 shares of common stock and warrants to purchase 290,525 shares of common stock. Each unit consists of five shares of common stock and a warrant to purchase one share of common stock at an exercise price of \$13.00 per share. The warrants will be exercisable at any time on or prior to June 1, 2008. This prospectus supplement and the accompanying prospectus also relate to the offering of shares of our common stock upon exercise, if any, of the warrants.

### Common Stock

The material terms and provisions of our common stock and each other class of our securities which qualifies or limits our common stock are described in the section entitled "Description of Registrant's Securities to be Registered" contained in our Registration Statement on Form 8-A as filed on September 24, 1991, which is incorporated by reference into the accompanying prospectus.

### Warrants

The material terms and provisions of the warrants being offered pursuant to this prospectus supplement and the accompanying prospectus are summarized below. A copy of the form of warrant to be issued to each investor in this offering is on file with the Securities and Exchange Commission as Exhibit 4.1 to our Form 8-K dated June 1, 2005, which is incorporated by reference into the accompanying prospectus.

*Exercisability.* The warrants will be exercisable at any time on or prior to June 1, 2008. The warrants will be exercisable, at the option of each holder, upon the surrender of the warrants to us and the payment in cash by the holder of the exercise price of the shares being acquired upon exercise of the warrants, or with our prior consent, upon the surrender of shares of our common stock equal in value to the exercise price of the warrant.

*Exercise Price.* The exercise price per share of common stock purchasable upon exercise of the warrants is \$13.00 per share of common stock being purchased. The exercise price and the number of underlying warrant shares is subject to appropriate adjustment in the event of stock splits, stock dividends or similar events affecting our common stock.

*Transferability; Lack of Trading Market for Warrants.* Subject to compliance with applicable federal and state securities laws, the Warrants may be transferred by a holder with respect to any or all of the shares purchasable thereunder. However, we are not listing the warrants on an exchange or any trading system and we do not expect that a trading market for the warrants will develop.

*No Rights as Stockholders.* The warrant holders do not have the rights or privileges of holders of common stock, including, without limitation, the right to vote, to receive dividends and other distributions, to receive any notice of, or to attend, meetings of stockholders or any other proceedings of Advanced Magnetics.

## PLAN OF DISTRIBUTION

We are offering the units to selected investors at a price of \$47.50 per unit. We expect that all of the units will be sold to affiliates of Great Point Partners, LLC and to Dr. Brian J.G. Pereira, one of the members of our Board of Directors.

There is no requirement that any minimum number of units or dollar amount of units be sold in this offering, and there can be no assurance that we will sell all or any of the units being offered.

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There will be no trading market for the units. The shares of common stock and warrants comprising the units will separate immediately upon completion of this offering and prior to any trading of the common stock and warrants. We are not listing the warrants on an exchange or any trading system and we do not expect that a trading market for the warrants will develop.

We will pay all of the expenses incurred in this offering. Our estimated expenses of the offering are approximately \$212,500. This assumes that all 290,525 units offered by this prospectus supplement are sold in this offering.

The transfer agent for our common stock is American Stock Transfer and Trust Company.

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

### DILUTION

Our net tangible book value on March 31, 2005 was approximately \$12,027,771, or approximately \$1.50 per share. "Net tangible book value" is total assets minus the sum of liabilities and intangible assets. "Net tangible book value per share" is net tangible book value divided by the total number of shares outstanding.

Assuming we sell all of the 290,525 units offered by this prospectus supplement at the offering price of \$47.50 per unit (although the warrants are being sold for value, solely for purposes of presenting the maximum amount of dilution to the purchasers, we are attributing a purchase price of \$9.50 per share to the common stock included in the units and are not attributing any value to the warrants) and after deducting estimated offering expenses of approximately \$212,500, our pro forma net tangible book value on March 31, 2005 would have been approximately \$25,615,209, or approximately \$2.70 per share. The adjustments made to determine pro forma net tangible book value per share are the following:

An increase in total assets to reflect the net proceeds of the offering assuming we sell the maximum number of units offered hereby as described under "Use of Proceeds."

The addition of the number of shares of our common stock offered by this prospectus supplement (excluding shares that may be issued upon the exercise of the warrants included in the units) to the number of shares outstanding, assuming we sell the maximum number of units offered hereby.

The following table illustrates the pro forma increase in net tangible book value per share after giving effect to the offering of \$1.20 per share and the dilution (the difference between the offering price per share and net tangible book value per share) to new investors:

Offering price per share	\$	9.50
Net tangible book value per share as of March 31, 2005	\$	1.50
Increase in net tangible book value per share attributable to the offering	\$	1.20
Pro forma net tangible book value per share as of March 31, 2005, after giving effect to the offering		2.70
Dilution per share to new investors in the offering	\$	6.80

The number of shares of our common stock to be outstanding after the offering is based on 8,050,113 shares outstanding as of May 31, 2005 and excludes:

up to 290,525 shares of common stock issuable upon the exercise of the warrants with an exercise price of \$13.00 per share included in the units offered by this prospectus supplement;

889,328 shares of common stock issuable upon the exercise of outstanding stock options with a weighted average exercise price of \$8.84 per share;





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392,875 shares of common stock available for future grant under our stock option plans;

261,780 shares of common stock issuable upon the exercise of outstanding warrants with an exercise price of \$15.50 per share; and

72,531 shares of common stock available for sale under our employee stock purchase plan.

### **LEGAL MATTERS**

The validity of the common stock and certain other legal matters will be passed upon for us by Sullivan & Worcester, LLP, Boston, Massachusetts.

### **EXPERTS**

The consolidated financial statements incorporated in this Prospectus Supplement by reference to the Annual Report on Form 10-K for the year ended September 30, 2004 have been so incorporated in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

S-21

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PROSPECTUS

**\$50,000,000**

**Common Stock  
Preferred Stock  
Warrants**

We may offer and sell, from time to time, in one or more offerings:

common stock,

preferred stock, and

warrants

The securities we offer will have an aggregate public offering price of up to \$50,000,000. We may offer and sell these securities separately or together in units with other securities described in this prospectus.

We will indicate the particular securities we offer and their specific terms in a supplement to this prospectus. In each case we would describe the type and amount of securities we are offering, the initial public offering price and the other terms of the offering.

Our common stock is listed on the American Stock Exchange under the symbol "AVM." We will make applications to list any shares of common stock sold pursuant to a supplement to this prospectus on the AMEX. We have not determined whether we will list any of the other securities we may offer on any exchange or over-the-counter market. If we decide to seek listing of any securities, the supplement will disclose the exchange or market.

**Investing in our securities involves risks. See "Risk Factors" on page 3.**

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Our principal executive office is at 61 Mooney Street, Cambridge, Massachusetts, and our telephone number is (617) 497-2070.

The date of this prospectus is December 16, 2004

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TABLE OF CONTENTS

	<u>Page</u>
<u>About This Prospectus</u>	1
<u>Cautionary Note Regarding Forward-Looking Statements</u>	1
<u>Our Company</u>	2
<u>Risk Factors</u>	3
<u>Ratio of Earnings to Combined Fixed Charges and Preference Stock Dividends</u>	3
<u>Use of Proceeds</u>	3
<u>Description of Our Common Stock</u>	4
<u>Description of Our Preferred Stock</u>	4
<u>Description of Our Warrants</u>	5
<u>Description of Certain Provisions of Delaware Law and Our Certificate of Incorporation and By-Laws</u>	6
<u>Plan of Distribution</u>	8
<u>Validity of the Offered Securities</u>	10
<u>Experts</u>	10
<u>Documents Incorporated by Reference</u>	10
<u>Where You Can Find More Information</u>	11

### ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement we filed with the Securities and Exchange Commission, or the SEC, using a "shelf" registration process. Under this shelf process, we may sell any combination of the securities described in this prospectus from time to time in one or more offerings up to a total amount of proceeds of \$50,000,000.

This prospectus provides you only with a general description of the securities we may offer. Each time we sell securities, we will provide a prospectus supplement containing specific information about the terms of that offering. The prospectus supplement may also add to, update or change information contained in this prospectus. You should read both this prospectus and any prospectus supplement together with additional information described under the headings "Where You Can Find More Information" and "Documents Incorporated By Reference."

You should rely only on the information incorporated by reference or provided in this document or any applicable prospectus supplement. We have not authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We will not make an offer of these securities in any jurisdiction where it is unlawful. You should assume that the information in this prospectus, as well as the information we have previously filed with the SEC and incorporated by reference in this prospectus, is accurate only as of the date of the documents containing the information.

*References in this prospectus to the terms "Advanced Magnetics," "company," "we," "our" or "us" or other similar terms mean Advanced Magnetics, Inc.*

### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

We have made and incorporated by reference statements in this document that constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and federal securities laws. This section provides a "safe harbor" for forward-looking statements to encourage companies to provide prospective information about themselves so long as they identify these statements as forward-looking and provide meaningful cautionary statements identifying important factors that could cause actual results to differ from the projected results. All statements other than statements of historical fact we make in this prospectus or in any document incorporated by reference are forward-looking statements. These statements are based on management's beliefs and assumptions and on information currently available to management and use words such as "expect," "anticipate," "intend," "plan," "believe," "estimate," or similar expressions. Forward-looking statements include information concerning possible or assumed future results of operations, future product development and related clinical trials and statements regarding future research and development. Forward-looking statements reflect our current expectations and are subject to various known and unknown risks, uncertainties and other factors. Our actual results could differ materially from those anticipated in these forward-looking statements. Important factors that could cause these differences include, among others, those set forth below. For a more detailed discussion of some, but not all, of these factors, please read carefully the information discussed under "Risk Factors" in the applicable prospectus supplement to be provided with this prospectus as well as other factors which may be described from time to time in our filings with the SEC, including our Annual Report on Form 10-K for the fiscal year ended September 30, 2004.

the timing and results of our product development program for our product candidates, including uncertainties relating to our ability to successfully complete the clinical development of our product candidates,

the timing and results of regulatory interactions regarding the clinical development of our product candidates and uncertainties relating to our ability to obtain regulatory approval to market and sell our product candidates,

our ability to continue to operate at commercial scale in compliance with applicable manufacturing requirements,

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uncertainties relating to the variable nature of our product sales cycles,

our ability to compete successfully against our competitors and the acceptance of our products in the marketplace, and

other trends in competitive or economic conditions affecting our financial condition or results of operations not presently contemplated.

These cautionary statements should not be construed by you to be exhaustive and they are made only as of the date of this prospectus. You should not rely upon forward-looking statements except as statements of our present intentions and of our present expectations, which may or may not occur. You should read these cautionary statements as being applicable to all forward-looking statements wherever they appear. We assume no obligation, except as specifically required by law and the rules of the SEC, to update the forward-looking statements or the reasons why actual results could differ from those projected in the forward-looking statements to reflect events or circumstances after the date hereof.

## OUR COMPANY

*This overview highlights information contained in certain documents incorporated by reference into this prospectus. This overview does not contain all of the information that you should consider before investing in our securities. You should read the entire prospectus and any applicable prospectus supplement carefully, including the "Risk Factors" section and the financial statements and the notes to those statements incorporated herein or therein by reference, before making an investment decision.*

Advanced Magnetix is a developer of superparamagnetic iron oxide nanoparticles used in pharmaceutical products. We are dedicated to the development and commercialization of our proprietary nanoparticle technology for use in therapeutic iron compounds to treat anemia as well as novel imaging agents to aid in the diagnosis of cardiovascular disease and cancer. *Combidex*® is our investigational molecular imaging agent consisting of iron oxide nanoparticles for use in conjunction with magnetic resonance imaging, also known as MRI, to aid in the differentiation of cancerous from non-cancerous lymph nodes. *Combidex* received an approvable letter, subject to certain conditions, from the U.S. Food and Drug Administration, the FDA, in June 2000. In September 2004, we submitted a complete response to the approvable letter, which was accepted by the FDA and assigned a user fee goal date of March 30, 2005. *Ferumoxytol*, the next-generation product in our development pipeline, is currently in Phase III multi-center clinical trials for use as an iron replacement therapeutic in anemic chronic kidney disease patients, whether or not on dialysis. Exploratory Phase II clinical trials of *ferumoxytol* for use as a contrast agent in magnetic resonance angiography, also known as MRA, are currently ongoing. Our liver contrast agent, *Feridex I.V.*®, is approved and marketed in Europe, Japan, the United States and other countries. Our oral contrast agent, *GastroMARK*®, used for delineating the bowel in MRI, is approved and marketed in Europe, the United States and other countries.

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

## RISK FACTORS

An investment in our securities involves a high degree of risk. In addition to the other information included in, or incorporated by reference into, this prospectus, you should carefully consider the risk factors included in our Annual Report on Form 10-K for the fiscal year ended September 30, 2004 starting on page 33 of such report under the heading "Certain Factors That May Affect Future Results," and in any applicable prospectus supplement when determining whether or not to purchase the securities offered under this prospectus and the prospectus supplement.

### RATIO OF EARNINGS TO COMBINED FIXED CHARGES AND PREFERENCE STOCK DIVIDENDS

The following table sets forth our ratio of earnings to combined fixed charges and preference stock dividends for the periods indicated:

Fiscal Year Ended September 30,				
2000	2001	2002	2003	2004
(a)	(b)	(c)	157.9x	(d)

- (a) Earnings in fiscal 2000 were inadequate to cover combined fixed charges and preference dividends. The coverage deficiency was approximately \$3.8 million.
- (b) Earnings in fiscal 2001 were inadequate to cover combined fixed charges and preference dividends. The coverage deficiency was approximately \$3.8 million.
- (c) Earnings in fiscal 2002 were inadequate to cover combined fixed charges and preference dividends. The coverage deficiency was approximately \$1.7 million.
- (d) Earnings in fiscal 2004 were inadequate to cover combined fixed charges and preference dividends. The coverage deficiency was approximately \$4.5 million.

The ratios above were computed by dividing earnings by combined fixed charges and preference dividends. We did not pay or accrue any preference dividends for the periods presented. For this purpose, earnings consist of (a) pre-tax income (loss) from continuing operations (which excludes the cumulative effect of accounting change) before adjustment for minority interests in consolidated subsidiaries or income (loss) from equity investees, and (b) fixed charges, including estimated interest associated with certain facility, equipment and vehicle leases. Fixed charges consist of that portion of rental expense associated with certain facility, equipment and vehicle leases considered to be a reasonable estimate of the interest factor.

## USE OF PROCEEDS

Unless otherwise described in a prospectus supplement, we intend to use the net proceeds from the sale of the offered securities for general corporate purposes, which may include, but are not limited to, working capital, ongoing research and development activities and capital expenditures. Pending any specific utilization, the proceeds from the sale of the offered securities may be invested in a manner designed to ensure levels of liquidity which correspond to our current and foreseeable cash needs. Such investments may include, but not be limited to, short-term investments, including government bonds, or other interest-bearing investments.

### DESCRIPTION OF OUR COMMON STOCK

We are authorized to issue up to 15,000,000 shares of common stock, \$.01 par value per share.

This section describes the general terms of our common stock that we may offer from time to time. For more detailed information, a holder of our common stock should refer to our certificate of incorporation and our by-laws, copies of which are filed with the SEC as exhibits to the registration statement of which this prospectus is a part.

Holders of our common stock are entitled to one vote per share and vote together as a single class on all matters to be voted on by our stockholders. Pursuant to our certificate of incorporation, there are no cumulative voting rights in the election of directors. The approval of corporate actions may also require the approval of the holders of any series of our preferred stock. See "Description of Our Preferred Stock."

Our common stock will be the only type of our capital stock entitled to vote in the election and removal of directors and other matters presented to our stockholders from time to time, unless we issue voting preferred stock or our certificate of incorporation or the law requires otherwise.

Our common stockholders will be entitled to receive dividends and distributions declared by our board of directors, or board, to the extent permitted by outstanding series of preferred stock and by our certificate of incorporation. If a dividend is declared, it will be distributed pro rata to our common stockholders on a per share basis.

If we are liquidated or dissolved, our common stockholders will be entitled to receive our assets and funds available for distribution to common stockholders in proportion to the number of shares they hold. Our common stockholders may not receive any assets or funds until our creditors have been paid in full and the preferential or participating rights of our preferred stockholders, if any, have been satisfied.

Holders of our common stock will not have any preemptive, subscription or conversion rights with respect to shares of our common stock. We may issue additional shares of our common stock, if authorized by our board, without the common stockholders' approval, unless required by Delaware law or a stock exchange on which our securities are traded. The issuance of additional shares could have the effect of diluting any earnings per share and the book value per share of outstanding shares of common stock. If we receive the appropriate payment, shares of our common stock that we issue will be fully paid and nonassessable.

Reference is made to the applicable prospectus supplement relating to the common stock offered by that prospectus supplement for specific terms, including:

amount and number of shares offered,

the initial offering price, if any, and market price, and

information with respect to dividends.

### DESCRIPTION OF OUR PREFERRED STOCK

We are authorized to issue up to 2,000,000 shares of preferred stock, \$.01 par value per share.

This section describes the general terms and provisions of our preferred stock that we may offer from time to time. The applicable prospectus supplement will describe the specific terms of the shares of preferred stock offered through that prospectus supplement. We will file a copy of the certificate of designation that contains the terms of each new series of preferred stock with the SEC each time we issue a new series of preferred stock, and these certificates of designation will be incorporated by reference into the registration statement of which this prospectus is a part. Each certificate of

designation will establish the number of shares included in a designated series and fix the designation, powers, privileges, preferences and rights of the shares of each series as well as any applicable qualifications, limitations or restrictions. A holder of our preferred stock should refer to the applicable certificate of designation, our certificate of incorporation and the applicable prospectus supplement for more specific information.

Our board has been authorized, subject to limitations provided in our certificate of incorporation, to provide for the issuance of shares of our preferred stock in multiple series. As of the date of this prospectus, no series has been designated and no shares of our preferred stock are currently outstanding.

With respect to each series of our preferred stock, our board has the authority to fix, among other things, the following terms:

the designation of the series,

the number of shares within the series,

whether the dividends are cumulative and, if cumulative, the dates from which dividends are cumulative,

the rate of any dividends, any conditions upon which dividends are payable, and the dates of payment of dividends,

whether the shares are redeemable, the redemption price and the terms of redemption,

the amount payable to a holder for each share owned if we are dissolved or liquidated,

whether the shares are convertible or exchangeable, the price or rate of exchange, and the applicable terms and conditions,

any restrictions on issuance of shares in the same series or any other series, and

the voting rights, if any, of the shares of the series.

Holders of our preferred stock will not have preemptive rights with respect to shares of our preferred stock. In addition, rights with respect to shares of our preferred stock will be subordinate to the rights of our general creditors. If we receive the appropriate payment, shares of our preferred stock that we issue will be fully paid and nonassessable. The issuance of preferred stock could discourage an unsolicited acquisition proposal.

We currently plan to retain American Stock Transfer & Trust Company as the registrar and transfer agent of any series of our preferred stock.

#### **DESCRIPTION OF OUR WARRANTS**

This section describes the general terms and provisions of our warrants to acquire our securities that we may issue from time to time. The applicable prospectus supplement will describe the specific terms of the warrants offered through that prospectus supplement.

We may issue warrants for the purchase of our common stock or preferred stock. We may issue warrants independently or together with other securities, and they may be attached to or separate from the other securities. Each series of warrants will be issued under a separate warrant agreement that we will enter into with American Stock Transfer & Trust Company, or another bank or trust company, as warrant agent, as detailed in the applicable prospectus supplement. The warrant agent will act solely as our agent in connection with the warrants and will not assume any obligation, or agency or trust relationship, with you. We will file a copy of the warrant and warrant agreement with the SEC each time we issue a series of warrants, and these warrants and warrant agreements will be incorporated by





reference into the registration statement of which this prospectus is a part. A holder of our warrants should refer to the provisions of the applicable warrant agreement and prospectus supplement for more specific information.

The prospectus supplement relating to a particular issue of warrants will describe the terms of those warrants, including, where applicable:

the offering price,

the number of warrants offered,

the securities underlying the warrants,

the exercise price, the amount of securities you will receive upon exercise, the procedure for exercise of the warrants and the circumstances, if any, that will cause the warrants to be automatically exercised,

the rights, if any, we have to redeem the warrants,

the date on which the warrants will expire,

U.S. federal income tax consequences,

the name of the warrant agent, and

any other terms of the warrants.

After your warrants expire they will become void. All warrants will be issued in registered form. The prospectus supplement may provide for the adjustment of the exercise price of the warrants.

Warrants may be exercised at the appropriate office of the warrant agent or any other office indicated in the applicable prospectus supplement. Before the exercise of warrants, holders will not have any of the rights of holders of the securities purchasable upon exercise and will not be entitled to payments made to holders of those securities.

The warrant agreements may be amended or supplemented without the consent of the holders of the warrants to which they apply to effect changes that are not inconsistent with the provisions of the warrants and that do not materially and adversely affect the interests of the holders of the warrants. However, any amendment that materially and adversely alters the rights of the holders of warrants will not be effective unless the holders of at least a majority of the applicable warrants then outstanding approve the amendment. Every holder of an outstanding warrant at the time any amendment becomes effective, by continuing to hold the warrant, will be bound by the applicable warrant agreement as amended. The prospectus supplement applicable to a particular series of warrants may provide that certain provisions of the warrants, including the securities for which they may be exercisable, the exercise price and the expiration date, may not be altered without the consent of the holder of each warrant.

#### **DESCRIPTION OF CERTAIN PROVISIONS OF DELAWARE LAW AND OUR CERTIFICATE OF INCORPORATION AND BY-LAWS**

We are organized as a Delaware corporation. The following is a summary of our certificate of incorporation and by-laws and certain provisions of the Delaware General Corporation Law, or the DGCL. Because it is a summary, it does not contain all the information that may be important to you. If you want more information, you should read our entire certificate of incorporation and by-laws, copies of which are filed with the SEC as exhibits to the registration statement of which this prospectus is a part, see "Where You Can Find More Information," or refer to the provisions of the DGCL.



### **Classification of Directors**

Our by-laws provide that, except as otherwise required by specific provisions of the certificate of incorporation relating to the rights of holders of any class or series of preferred stock to elect additional directors under specified circumstances, the number of our directors may be fixed from time to time by a resolution adopted by a majority of our board but must not be less than one. Our board is not classified into classes. A director may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors, subject to the rights of any series of preferred stock then outstanding.

### **Special Meetings**

Except as otherwise required by law and subject to the rights of holders of any class or series of preferred stock, special meetings of the stockholders may only be called by our President or by our board. No business other than that stated in the notice of meeting may be transacted at any special meeting of stockholders.

### **Limitation of Liability and Indemnification**

Our certificate of incorporation provides that we shall indemnify our directors and officers to the fullest extent that Delaware law permits. Our certificate of incorporation also provides that we, by action of our board, may provide indemnification to our employees and agents with the same scope and effect as the indemnification of our officers and directors. Delaware law permits a corporation to indemnify any director, officer, employee or agent made or threatened to be made a party to any pending or completed proceeding if the person acted in good faith and in a manner that the person reasonably believed to be in the best interests of the corporation and, with respect to any criminal proceeding, had no reasonable cause to believe that his or her conduct was unlawful.

Our certificate of incorporation limits the liability of our directors to the fullest extent permitted by the DGCL. The DGCL provides that directors will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except liability for:

any breach of their duty of loyalty to the corporation or its stockholders,

acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law,

unlawful payments of dividends or unlawful stock repurchases or redemptions, or

any transaction from which the director derived an improper personal benefit.

The effect of this provision may be to reduce the likelihood of derivative litigation against directors for breach of their duty of care, even though the action, if successful, might otherwise have benefited us and our stockholders. This provision has no effect on any non-monetary remedies that may be available to us or our stockholders, nor does it relieve us or our officers or directors from compliance with federal or state securities laws.

Each of our directors is party to an indemnification agreement that provides specific contractual assurance that the indemnification protection promised by certificate of incorporation and by-laws will be available.

As permitted by our certificate of incorporation, we have purchased and maintain insurance on behalf of our directors and officers for any expense, liability or loss incurred by them arising out of their actions in that capacity if we would have the power to indemnify such person against such expense, liability or loss under the DGCL.

### **Section 203 of the Delaware General Corporation Law**

Section 203 of the DGCL prohibits a defined set of transactions between a Delaware corporation, such as us, and an "interested stockholder." An interested stockholder is defined as a person who, together with any affiliates or associates of such person, beneficially owns, directly or indirectly, 15% or more of the outstanding voting stock of a Delaware corporation. This provision may prohibit business combinations between an interested stockholder and a corporation for a period of three years after the date the interested stockholder becomes an interested stockholder. The term "business combination" is broadly defined to include mergers, consolidations, sales or other dispositions of assets having a total value in excess of 10% of the consolidated assets of the corporation, and some other transactions that would increase the interested stockholder's proportionate share ownership in the corporation.

This prohibition is effective unless:

either the business combination or the transaction that resulted in the interested stockholder becoming an interested stockholder is approved by our board prior to the time the interested stockholder becomes an interested stockholder,

the interested stockholder owns at least 85% of our voting stock, other than stock held by directors who are also officers or by qualified employee stock plans, upon completion of the transaction in which it becomes an interested stockholder, or

the business combination is approved by a majority of our board and by the affirmative vote of 66<sup>2</sup>/<sub>3</sub>% of the outstanding voting stock that is not owned by the interested stockholder.

In general, the prohibitions do not apply to business combinations with persons who were interested stockholders prior to the corporation becoming subject to Section 203.

### **Stock Exchange Listing**

Our common stock is listed on the American Stock Exchange. The trading symbol for our common stock on this exchange is "AVM."

### **Transfer Agent**

American Stock Transfer & Trust Company is the transfer agent for our common stock.

### **PLAN OF DISTRIBUTION**

We may sell the securities in and outside the United States (a) through underwriters or dealers, (b) directly to purchasers, including our affiliates, (c) through agents or (d) through a combination of any of these methods. The applicable prospectus supplement will include the following information:

the terms of the offering,

the names of any underwriters or agents,

the name or names of any managing underwriter or underwriters,

the purchase price of the securities,

the net proceeds from the sale of the securities,

any delayed delivery arrangements,

any underwriting discounts, commissions and other items constituting underwriters' compensation,

any initial public offering price,

any discounts or concessions allowed or reallocated or paid to dealers, and

any commissions paid to agents.

The sale of the securities may be effected in transactions (a) on any national or international securities exchange or quotation service on which the securities may be listed or quoted at the time of sale, (b) in the over-the-counter market, (c) in transactions otherwise than on such exchanges or in the over-the-counter market or (d) through the writing of options.

The distribution of offered securities may be effected from time to time in one or more transactions at a fixed price or prices, which may be changed, at market prices prevailing at the time of sale, at prices related to the market prices, or at negotiated prices.

#### **Sale Through Underwriters or Dealers**

If underwriters are used in the sale of any of these securities, the underwriters will acquire the securities for their own account. The underwriters may resell the securities from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. Underwriters may offer securities to the public either through underwriting syndicates represented by one or more managing underwriters or directly by one or more firms acting as underwriters. Unless we inform you otherwise in any prospectus supplement, the obligations of the underwriters to purchase the securities will be subject to certain conditions, and the underwriters will be obligated to purchase all the offered securities if they purchase any of them. We may grant underwriters an option to purchase additional securities to cover over-allotments, if any, in connection with the distribution. The underwriters may change from time to time any initial public offering price and any discounts or concessions allowed or reallocated or paid to dealers.

During and after an offering through underwriters, the underwriters may purchase and sell the securities in the open market. These transactions may include overallotment and stabilizing transactions and purchases to cover syndicate short positions created in connection with the offering. The underwriters may also impose a penalty bid, which means that selling concessions allowed to syndicate members or other broker-dealers for the offered securities sold for their account may be reclaimed by the syndicate if the offered securities are repurchased by the syndicate in stabilizing or covering transactions. These activities may stabilize, maintain or otherwise affect the market price of the offered securities, which may be higher than the price that might otherwise prevail in the open market. If commenced, the underwriters may discontinue these activities at any time.

Some or all of the securities that we offer through this prospectus may be new issues of securities with no established trading market. Any underwriters to whom we sell these securities for public offering and sale may make a market in those securities, but they will not be obligated to and they may discontinue any market making at any time without notice. Accordingly, we cannot assure you of the liquidity of, or continued trading markets for, any securities that we offer.

If dealers are used in the sale of securities, we will sell the securities to them as principals. They may then resell those securities to the public at varying prices determined by the dealers at the time of resale. We will include in the prospectus supplement the names of the dealers and the terms of the transaction.

#### **Direct Sales and Sales Through Agents**

We may sell the securities directly, and not through underwriters or agents. We may also sell the securities through agents designated from time to time. In the prospectus supplement, we will name any agent involved in the offer or sale of the offered securities, and we will describe any commissions payable to the agent. Unless we inform you otherwise in the prospectus supplement, any agent will agree to use its reasonable best efforts to solicit purchases for the period of its appointment.

We may sell the securities directly to institutional investors or others who may be deemed to be underwriters within the meaning of the Securities Act of 1933, as amended, or the Securities Act, with respect to any sale of those securities. We will describe the terms of any such sales in the prospectus supplement.

We may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement indicates, in connection with those derivatives, the third parties may sell securities covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use securities pledged by us or borrowed from us or others to settle those sales or to close out any related open borrowings of stock, and may use securities received from us in settlement of those derivatives to close out any related open borrowings of stock. The third party in such sale transactions will be an underwriter and, if not identified in this prospectus, will be identified in the applicable prospectus supplement (or a post-effective amendment).

#### **Delayed Delivery Contracts**

If we so indicate in the prospectus supplement, we may authorize agents, underwriters or dealers to solicit offers from certain types of institutions to purchase securities from us at the public offering price under delayed delivery contracts. These contracts would provide for payment and delivery on a specified date in the future. The contracts would be subject only to those conditions described in the prospectus supplement. The prospectus supplement will describe the commission payable for solicitation of those contracts.

#### **General Information**

We may have agreements with the agents, dealers and underwriters to indemnify them against certain civil liabilities, including liabilities under the Securities Act, or to contribute with respect to payments that the agents, dealers or underwriters may be required to make. Agents, dealers and underwriters may be customers of, engage in transactions with or perform services for us in the ordinary course of their businesses.

### **VALIDITY OF THE OFFERED SECURITIES**

Certain legal matters with respect to the securities offered hereby have been passed upon by Sullivan & Worcester LLP, Boston, Massachusetts. As of the date of this prospectus, certain attorneys with the firm of Sullivan & Worcester LLP beneficially own an aggregate of approximately 1,700 shares of our common stock.

### **EXPERTS**

The financial statements incorporated in this prospectus and elsewhere in this registration statement by reference to our Annual Report on Form 10-K for the year ended September 30, 2004 have been so incorporated in reliance on the report of PricewaterhouseCoopers LLP, independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

### **DOCUMENTS INCORPORATED BY REFERENCE**

The SEC allows us to "incorporate by reference" the information we file with it, which means that we can disclose important information to you by referring you to those documents. The information we incorporate by reference is considered part of this prospectus. Statements in this prospectus regarding the contents of any contract or other document may not be complete. You should refer to the copy of the contract or other document filed as an exhibit to the registration statement. Later information filed



with the SEC will update and supersede information we have included or incorporated by reference in this prospectus.

We incorporate by reference the documents listed below, which have been filed with the SEC:

1. Our Annual Report on Form 10-K for the fiscal year ended September 30, 2004,
2. Our Current Report on Form 8-K as filed on October 19, 2004, and
3. The section entitled "Description of Registrant's Securities to be Registered" contained in our Registration Statement on Form 8-A as filed on September 24, 1991.

We also incorporate by reference any filings made after the date of the initial filing of the registration statement of which this prospectus forms a part including filings made prior to the effectiveness of the registration statement, made with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 until the offering of the securities made by this prospectus is completed or terminated.

We will provide without charge to each person, including any beneficial owner, to whom this prospectus is delivered, upon the written or oral request of that person, a copy of any and all of the information that has been incorporated in this prospectus by reference other than exhibits unless those exhibits are specifically incorporated by reference into the documents. Requests for these copies should be directed to our Chief Financial Officer at the following address and telephone number: Advanced Magnetics, Inc., 61 Mooney Street, Cambridge, MA 02138, (617) 497-2070.

#### **WHERE YOU CAN FIND MORE INFORMATION**

We file reports, proxy statements and other information with the SEC. You may read and copy the reports, proxy statements and other information that we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for information about the operation of its Public Reference Room and for its prescribed rates to obtain copies of such material. The SEC also maintains an Internet site that contains reports, proxy and information statements and other information regarding registrants, like us, that file electronically with the SEC. The address of the SEC's Internet site is <http://www.sec.gov>. Our Internet site is <http://www.advancedmagnetics.com>. Information contained on these Internet sites is not a part of this prospectus.

This prospectus provides you with a general description of the common stock, preferred stock and warrants being registered. This prospectus is part of a registration statement that we have filed with the SEC. To see more detail, you should read the registration statement and the exhibits and schedules filed with, or incorporated by reference into, our registration statement.