SPECTRUM PHARMACEUTICALS INC
Form 424B3
September 21, 2004

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Filed pursuant to Rule 424(b)(3)
Registration Statement No. 333-115759

PROSPECTUS

UP TO 4,502,010 SHARES OF

SPECTRUM PHARMACEUTICALS, INC.

COMMON STOCK

Our common stock is traded on the NASDAQ National Market under the symbol SPPI. On September 16, 2004, the closing price of our common stock was $6.63.

This prospectus relates to the sale of up to 4,502,010 shares of our common stock by the selling stockholders named in this prospectus. The shares of our common stock and the securities which are exercisable for the shares of our common stock which are being offered by this prospectus were issued to the selling stockholders pursuant to a financing transaction and consulting agreements. See Issuance of Common Stock to Selling Stockholders on page 12. We will not receive any of the proceeds from the sale of these shares.

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 2.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of the prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is September 17, 2004

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ABOUT SPECTRUM PHARMACEUTICALS, INC.

We are a pharmaceutical company engaged in the business of acquiring, developing and commercializing proprietary drug products, or drug products with respect to which we have patent rights, either directly or through licenses, which have a primary focus on the treatment of cancer and related disorders as well as generic drug products for various indications. Spectrum Pharmaceuticals, Inc. is a Delaware corporation which was originally incorporated in Colorado as Americus Funding Corporation in December 1987, became NeoTherapeutics, Inc. in August 1996, was reincorporated in Delaware in June 1997, and was renamed Spectrum Pharmaceuticals, Inc. in December 2002.

Our business strategy has two principal components: first, what we refer to as our oncology strategy, to acquire rights to clinical-stage oncology, or anti-cancer, drug candidates and either alone, or through alliances with other companies, develop and eventually commercialize those drugs; and second, what we refer to as our generic drug strategy, to seek to generate revenues from the sale of generic versions of drugs whose patent protection has expired or expires in the near term. Prior to August 2002, when we announced a shift in our strategic focus, we were primarily engaged in the discovery and development of neurology drugs as well as functional genomics research.

Our oncology strategy focuses on the acquisition, or in-licensing, and continued development of clinical-stage, novel drugs for the treatment and supportive care of cancer patients. We currently have four drug candidates in clinical development: satraplatin, EOquin , elsamitrucin and SPI-153 (formerly D-63153). Of these product candidates, satraplatin is being co-developed by a third-party pharmaceutical company under an exclusive license, and the others are being developed by us. We also plan to continue to pursue acquisitions, or in-licensing, of additional clinical-stage cancer drugs from other companies and institutions. We believe that this method of drug development is a cost effective business strategy. However, to date our oncology strategy has not produced any marketable products. We intend, either alone, or through alliances with other companies, to market our oncology drug candidates if our clinical trials are successful and we obtain regulatory approval of our drug candidates.

Our generic drug strategy is to identify and acquire distribution rights for selected generic drugs both directly and through alliances with third party companies, apply our expertise and experience to further develop and pursue regulatory approval for those drugs, then either directly or through third party alliances, market and distribute those generic drugs into retail and institutional channels. During 2003, we filed with the United States Food and Drug Administration (FDA) three Abbreviated New Drug Applications (ANDA) for the generic drugs ciprofloxacin, carboplatin and fluconazole. In September 2004, we received approval from the FDA of our ANDA for ciprofloxacin and filed a new ANDA for an opthalmic product. We intend to file several additional ANDAs during 2004 and beyond. We have entered into product supply alliances for the manufacture of these generic drug candidates and we have entered into a distribution alliance for our lead generic drug candidate, ciprofloxacin. We intend to enter into additional supply and distribution alliances in the future.

We have incurred losses in every year of our existence and expect to continue to incur significant operating losses for the next several years. We have never generated revenues from product sales and we may never generate revenue because all of our drug candidates are currently either in clinical trials or under review by the FDA and our clinical trials may fail or we may not receive approval of the FDA except ciprofloxacin. In addition, even if our current drug candidates receive FDA approval, they may not become commercially viable or achieve market acceptance.

The pharmaceutical marketplace in which we operate is highly competitive, and includes many large, well-established companies pursuing treatments for the applications we are pursuing. See Risk Factors below.

This prospectus relates to the sale of up to 4,502,010 shares of our common stock by the stockholders identified under the heading Selling Stockholders below. Approximately 3.2 million shares were issued and sold in a private placement transaction to select institutional investors at a price of $7.75 per share for aggregate proceeds of

approximately $25 million. In addition, purchasers of the common stock received warrants to purchase up to approximately 1.1 million shares of common stock at an exercise price of $10.00 per share, which are first exercisable in April 2005. Pursuant to an investor rights agreement entered into with the investors, the company is required to file a registration statement of which this prospectus forms a part covering the privately placed common stock and the common stock issuable upon exercise of the warrants. In addition, the company is registering 155,000 shares of its common stock issuable upon exercise of warrants issued to two consultants.

Our executive offices are located at 157 Technology Drive, Irvine, California 92618. Our telephone number is (949) 788-6700. Our web site address is www.spectrumpharm.com. Information contained in our web site does not constitute part of this prospectus.

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RISK FACTORS

An investment in our common stock involves a high degree of risk. Our business, financial condition, operating results and prospects can be impacted by a number of factors, any one of which could cause our actual results to differ materially from recent results or from our anticipated future results. As a result, the trading price of our common stock could decline, and you could lose a part or all of your investment. You should carefully consider the risks described below with all of the other information included in this prospectus and the incorporated documents before making an investment decision.

Our losses will continue to increase as we expand our development efforts, and our efforts may never result in profitability.

Our cumulative losses since our inception in 1987 through June 30, 2004 were in excess of $150 million, almost all of which consisted of research and development and general and administrative expenses. We lost approximately $10 million in 2003, $18 million in 2002 and $28 million in 2001, and approximately $4.7 million in the first six months of 2004. We expect to continue to incur losses in the future, particularly as we continue to invest in the development of our oncology drug candidates, and expand the scope of our generics operations. We recently received approval to market our first generic drug product, ciprofloxacin, in the United States, however, we currently do not sell any products or services and we may never achieve revenues from sales of products or become profitable. Even if we eventually generate revenues from sales, we nevertheless may continue to incur operating losses over the next several years.

Our business does not generate the cash needed to finance our ongoing operations and therefore, we will need to raise additional capital.

Our business does not generate cash from operations needed to finance our ongoing operations. We have relied primarily on raising capital through the sale of our securities, and/or out-licensing our drug candidates and technology, to meet our financial needs. We believe our existing cash and investment securities will allow us to fund our current planned operations; however, over the long-term, we will likely need to continue to raise funds through public or private financings, including equity financings and through other arrangements, to continue operating and growing our business. If we are successful in generating revenues and profits from the sale of generic drugs, we expect to use such resources to help to reduce this reliance on raising funds through the sale of our securities.

We may not be able to raise additional capital on favorable terms, if at all. Accordingly, we may be forced to significantly change our business plans and restructure our operations to conserve cash, which would likely involve out-licensing or selling some or all of our intellectual, technological and/or tangible property not presently contemplated and at terms that we believe would not be favorable to us and/or reducing the scope and nature of our currently planned research and drug development activities. An inability to raise additional capital would also impact our ability to expand operations.

Clinical trials may fail to demonstrate the safety and efficacy of our oncology drug candidates, which could prevent or significantly delay obtaining regulatory approval.

Prior to receiving approval to commercialize each of our existing four oncology drug candidates, satraplatin, EOquin, elsamitrucin and SPI-153, and any drug candidates we acquire in the future, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA, and other regulatory authorities in the United States and other countries that each of the products is both safe and effective. For each current and future product candidate, we will need to demonstrate the efficacy and monitor its safety throughout the process. All of our drug candidates are in various stages of clinical trials. If these trials are unsuccessful, our business

and reputation would be harmed and our stock price would be adversely affected.

All of our product candidates are prone to the risks of failure inherent in drug development. The results of pre-clinical studies and early-stage clinical trials of our product candidates do not necessarily predict the results of later-stage clinical trials. Later-stage clinical trials may fail to demonstrate that a product candidate is safe and effective despite having progressed through initial clinical testing. Even if we believe the data collected from clinical trials of our drug candidates are promising, such data may not be sufficient to support approval by the FDA or any other United States or foreign regulatory approval. Pre-clinical and clinical data can be interpreted in different ways. Accordingly, FDA officials could interpret such data in different ways than we or our partners do, which could delay, limit or prevent regulatory approval. The FDA, other regulatory authorities, our institutional review boards, our contract research organization, or we may suspend or terminate our clinical trials for our drug candidates. Any failure or significant delay in completing clinical trials for our product candidates, or in receiving regulatory approval for the sale of any drugs resulting from our drug candidates, may severely harm our business and reputation. Even if we receive FDA and other regulatory approvals, our product candidates may later exhibit adverse effects that may limit or prevent their widespread use, may cause FDA to revoke, suspend or limit their approval, or may force us to withdraw products derived from those candidates from the market.

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Our oncology drug candidates, their target indications, and status of development are summarized in the following table:

Drug Candidate	Target Indication	Development Status
Satraplatin	Hormone Refractory Prostate Cancer	Phase 3 clinical trial
EOquin	Superficial Bladder Cancer	Phase 2 clinical trial
	Radiation Sensitization	Pre-clinical
Elsamitrucin	Refractory non-Hodgkin s Lymphoma	Phase 2 clinical trial
SPI-153	Hormone Dependent Cancers and Benign Proliferative Disorders	Phase 2 clinical trial

Our oncology drug candidates may not be more effective, safer or more cost efficient than competing drugs and otherwise may not have any competitive advantage, which could hinder our ability to successfully commercialize our drug candidates.

Oncology drugs produced by other companies are currently on the market for each cancer type we are pursuing. Even if one or more of our oncology drug candidates ultimately received FDA approval, our drug candidates may not have better efficacy in treating the target indication than a competing drug, may not have a more favorable side-effect profile than a competing drug, may not be more cost efficient to manufacture or apply, or otherwise may not demonstrate a competitive advantage over competing therapies. Accordingly, even if FDA approval is obtained for one or more of our drug candidates, they may not gain acceptance by the medical field or become commercially successful.

The development of our lead drug candidate, satraplatin, depends on the efforts of a third party and, therefore, its eventual success or commercial viability is largely beyond our control.

In September 2002, we entered into a co-development and license agreement with GPC Biotech AG for the development and commercialization of our lead drug candidate, satraplatin. GPC Biotech has agreed to fully fund development and commercialization expenses for satraplatin. We will not have control over the drug development process and therefore, the success of our lead drug candidate will depend upon the efforts of GPC Biotech. GPC Biotech may not be successful in the clinical development of the drug, the achievement of any milestones such as the acceptance of a New Drug Application, or an NDA, filing by the FDA or the eventual commercialization of satraplatin.

Our efforts to acquire or in-license and develop additional oncology drug candidates may fail, which would limit our ability to grow our oncology business.

The long-term success of our oncology strategy depends in part on obtaining clinical stage drug candidates in addition to our existing portfolio of satraplatin, EOquin, elsamitrucin and SPI-153. We are actively seeking to acquire, or in-license, additional clinical stage oncology drug candidates that demonstrate the potential to be both medically and commercially viable. We have certain criteria that we are looking for in an oncology drug candidate acquisition and therefore, we may not be successful in locating and acquiring, or in-licensing, additional desirable drug candidates on acceptable terms.

Price and other competitive pressures may make the marketing and sale of our generic drugs not commercially feasible and not profitable.

The generic drug market in the United States is extremely competitive, characterized by many participants and constant downward price pressure on generic drug products. Consequently, margins are continually reduced and it is necessary to continually introduce new products to achieve and maintain profitability. We have only obtained regulatory approval of one of our generic drug candidates. While we have entered into agreements with third parties to manufacture the drug products for us, given the price volatility of the generic market, we believe it is imprudent to enter into definitive agreements on transfer prices with the manufacturers of our generic drug product candidates prior to FDA approval, and we do not expect to do so until we receive FDA approval and are ready to begin selling the generic drug products. We have not yet entered into an agreement on price with the manufacturer of our only approved generic product, ciprofloxacin. Our ability to compete effectively in the generic drug market depends largely on our ability to obtain transfer price agreements that ensure a supply of our generic drug products at favorable prices. Even if we obtain regulatory approval to market one or more generic drug candidates in the United States, we may not be able to complete a transfer

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price arrangement with the manufacturers of the drug candidates that will allow us to market any generic drug products in the United States on terms favorable to us, or at all.

Also, if we fail to obtain approval of our ANDAs from the FDA in a timely manner, preferably before the patent and any additional exclusivity granted by the FDA to the branded drug product expire, our profitability will be significantly affected due to the significant price erosion caused by the typically large number of the generic companies entering the market. The U.S. patent for Cipro®, the branded form of our generic drug candidate ciprofloxacin, expired in December 2003. The FDA granted pediatric exclusivity to Cipro which expired in June 2004. We received approval from the FDA of our ANDA for ciprofloxacin in September 2004, however, twelve other companies have previously received FDA approval to market generic versions of ciprofloxacin. The patent and all exclusivities for our ophthalmic product have previously expired, and a number of other companies are currently selling their own generic versions of the product. In addition, we did not obtain approval of our ANDA for fluconazole prior to the expiration in July 2004 of patent and exclusivities granted by the FDA to the branded product, and we may not obtain approval of our ANDA for our other generic product candidate, carboplatin, prior to when the patent and/or any exclusivities granted by the FDA to the branded drug products expires in October 2004. Consequently, our ability to achieve a profit may be significantly harmed.

We may face opposition from the producers of the branded versions of the generic drugs for which we obtain approval. Branded pharmaceutical companies have aggressively sought to prevent generic competition, including the extensive use of litigation.

In addition, many branded pharmaceutical companies increasingly have used state and federal legislative and regulatory means to delay generic competition. These efforts have included:

- pursuing new patents for existing products which may be granted just before the expiration of one patent, which could extend patent protection for a number of years or otherwise delay the launch of generics;
- using the citizen petition process, a process by which any person can submit a petition to the Commissioner of the FDA to issue, amend or revoke a regulation or order or take or refrain from taking any other administrative action, to request amendments to FDA standards;
- seeking changes to the United States Pharmacopoeia, an organization which publishes industry recognized compendia of drug standards; and
- attaching patent extension amendments to non-related federal legislation.

We are a small company relative to our principal competitors and our limited financial resources may limit our ability to develop and market our oncology drug candidates and our generic drug candidates.

Many companies, both public and private, including well-known pharmaceutical companies and smaller niche-focused companies, are developing products to treat all of the diseases we are pursuing, or distributing generic drug products directly competitive to the generic drugs we intend to market and distribute. Many of these companies have substantially greater financial, research and development, manufacturing, marketing and sales experience and resources than us. As a result, our competitors may be more successful than us in developing their products, obtaining regulatory approvals and marketing their products to consumers.

The success of our generic drug strategy depends significantly upon our ability to identify generic drugs that we believe represent desirable market opportunities and that our products suppliers based in India and other countries can produce for us cost-effectively. In addition, we must be able to expand our distribution channel relationships in the United States because we currently have no internal manufacturing and an alliance with only one distributor.

However, since we are new generic competitor and the marketplace is made up of many well-established companies, we may not be able to successfully compete.

As a new generic competitor, we will be competing against established generic companies such as Teva Pharmaceuticals, Sandoz, Barr Laboratories, Mylan, Watson Pharmaceuticals, Inc., Genpharm, Dr. Reddy s, American Pharmaceutical Partners, Bedford Laboratories and others. These companies may have greater economies of scale in the production of their products and in certain cases may produce their own product supplies, or can procure product supplies on more favorable terms which may provide significant cost and supply advantages to customers in the retail prescription market. Since price is the primary basis for competition among generic versions of a given drug, any ability by our competitors to reduce production costs can provide them with a significant competitive advantage, and our ability to compete will be largely dependent on our ability to obtain supplies of our generic drug product manufacturers at favorable prices. For those products which we intend to develop as generic equivalents to certain branded

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products, we expect that the market will be competitive and will be largely dominated by the competitors listed above who will target many if not all of the same products for development as Spectrum.

Spectrum currently has three generic drug candidates approved or under review at the FDA and one for which an ANDA has been filed with the FDA but not yet accepted for review. For ciprofloxacin, our first generic product candidate filed with FDA, and for which we obtained approval in September 2004, there are currently twelve generic manufacturers approved to sell versions of ciprofloxacin, which include Teva, Technilab, West Ward, Eon Labs, Carlsbad Technology, IVAX, Sandoz, Genpharm, Ranbaxy, Dr. Reddy s, Mylan and Novopharm. The pediatric exclusivity for Diflucan, the branded form of fluconazole, our second generic product filed with the FDA, expired on July 29, 2004. The market is very competitive with versions from generic drug manufacturers such as Taro Pharmaceutical Industries, Mylan, Sandoz, Ranbaxy, IVAX, Novopharm, Genpharm, Gedeon Richter, Teva, Torpharm, Roxane and Pliva approved by the FDA for sale in the U.S., with sales by some or all of these companies expected to launch at the expiration of pediatric exclusivity. We have not yet obtained approval from the FDA for fluconazole and can give no estimate for when approval is likely to come, if at all. Carboplatin, our third generic drug ANDA filed with FDA, is the generic equivalent of Bristol Meyers Squibb s brand Paraplatin, for which the patent expires in October 2004. The FDA has granted tentative approval for carboplatin to five generic companies, including Sicor, Pharmachemie, APP, Bedford and Mayne. The tentative approvals are expected to be changed to full approval status by FDA provided that no change in labeling or indications are granted by the FDA during the exclusivity period. Teva Pharmaceuticals, through an agreement with Bristol Meyers Squibb, is currently selling Bristol Meyers Squibb s branded drug as a generic drug. We have not yet obtained approval from the FDA for carboplatin and can give no estimate for when approval is likely to come, if at all. In September 2004, we filed our fourth generic drug ANDA with the FDA for an ophthalmic product. The patent and all exclusivities for our ophthalmic product have previously expired, and a number of other companies are currently selling their own generic versions of the product.

In our oncology program, we have four oncology drug candidates currently in clinical trials. Our lead compound satraplatin, being developed by our co-development partner, GPC Biotech, is in a phase 3 clinical trial for hormone-refractory prostate cancer and our second and third compounds, EOquin and elsamitrucin are in phase 2 clinical studies for superficial bladder cancer and Non-Hodgkin s lymphoma, respectively. In August 2004 we acquired rights to SPI-153, which has previously been in phase 2 clinical trials for hormone-dependent cancers and benign, proliferative disorders. We plan to expand the development of SPI-153 by initiating additional trials in one or more indications as soon as feasible. We may not be successful in any or all of these studies; or if successful, and if approved by FDA, we may encounter direct competition from other companies who may be developing products for similar or the same indications as our oncology drug candidates. Companies active in the areas of oncology include Bristol Meyers Squibb, Pfizer, Novartis, Genentech, Roche and others who are more established and are currently marketing products for the treatment of various forms of cancer including the forms our oncology drug candidates target.

Any oncology product for which we obtain FDA approval must compete for market acceptance and market share. For example, cisplatin and carboplatin are the most prevalent platinum-based derivatives used in chemotherapy and are the primary treatment for many of the cancer types we are pursuing. Our drug candidate, satraplatin, if the FDA approves it for sale, would likely compete against these drugs directly. Unless satraplatin is shown to have better efficacy and is as cost effective, if not more cost effective, than cisplatin and carboplatin, it may not gain acceptance by the medical field and therefore may never be successful commercially. Competition for branded drugs is less driven by price and is more focused on innovation in treatment of disease, advanced drug delivery and specific clinical benefits over competitive drug therapies.

Our oncology competitors that have products on the market or in research and development that are in the same clinical focus as us include Astra Zeneca, Amgen, Inc., Bayer AG, Eli Lilly and Co., Novartis Pharmaceuticals Corporation, Bristol-Myers Squibb Company, Glaxo SmithKline, Biogen-IDEC Pharmaceuticals, Inc., Guilford

Pharmaceuticals, Inc., Cephalon, Inc., Aventis Pharmaceuticals Inc., Pfizer, Inc., Chiron Corp., Genta Inc., Imclone Systems Incorporated, MGI Pharma, Inc., and SuperGen, Inc., among others. Many of our competitors are large and well capitalized companies such as Eli Lilly and Co. and Bristol-Myers Squibb focusing on a wide range of diseases and drug indications, and have substantially greater financial, research and development, human and other resources than we do. Furthermore, large pharmaceutical companies have significantly more experience than we do in pre-clinical testing, human clinical trials and regulatory approval procedures, among other things.

Technologies under development by these and other pharmaceutical companies could result in treatments for diseases and disorders for which we are developing our own treatments. Several other companies are engaged in research and development of compounds that are similar to our research. In the event that one or more of these programs is successful, the market for some of our drug candidates could be reduced or eliminated.

We may not be successful in establishing additional generic drug supply relationships, which would limit our ability to grow our generic drug business.

Long-term success of our generic drug strategy depends in part on our ability to expand and enhance our existing relationships and establish new relationships for supplying generic drug products. We do not presently intend to focus our research and development efforts on developing active pharmaceutical ingredients or the dosage form for generic drugs. In addition, we currently have no capacity to manufacture generic drug products and do not intend to spend our capital resources to develop the capacity to do so.

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Therefore, we must rely on relationships with other companies to supply our generic drug products. We may not be successful in expanding or enhancing our existing relationships or in securing new relationships. If we fail to expand our existing relationships or secure new relationships, our ability to expand our generic drug business will be harmed.

We may not be successful in expanding our generic drug distribution capabilities in the United States, our only target market for generic drugs, which would limit our ability to grow our generic drug business.

Many of our competitors have substantial, established direct and indirect distribution channels. We have not yet undertaken the marketing and distribution of a generic drug product and we currently have no direct sales and marketing organization and our limited sales and marketing resources are devoted to establishing and enhancing our third party distribution relationships. We have established a relationship with a distributor for the distribution of ciprofloxacin; however, we have not commenced distribution of ciprofloxacin. The long-term success of our generic drug strategy will depend in part on our generic drug distribution capabilities in the U.S., our only target market for generic drugs. We may not be successful in expanding our existing distribution channel, establishing new, additional distribution channels or establishing a direct generic drug marketing capability sufficient to effectively and successfully compete in the generic drug market.

Our supply of generic drug products will be dependent upon the production capabilities of our supply sources, may limit our ability to meet demand for our products and ensure regulatory compliance.

We have no internal manufacturing capacity for our generic drug product candidates, and therefore, we have entered into agreements with third-party manufacturers to supply us with our generic drug products, subject to further agreement on pricing for particular drug products. Consequently, we will be dependent on our manufacturing partners for our supply of generic drug products. Most of these manufacturing facilities are located outside the United States. The manufacture of generic drug products, including the acquisition of compounds used in the manufacture of the finished generic drug product, may require considerable lead times. Further, sales of a new generic drug product may be difficult to forecast. Also, we will have little or no control over the production process. Accordingly, while we do not currently anticipate shortages of supply, there could arise circumstances in which market demand for a particular generic product could outstrip the ability of our supply source to timely manufacture and deliver the product, thereby causing us to lose sales.

Reliance on a third-party manufacturers entails risks to which we would not be subject if we manufactured products ourselves, including reliance on the third party for regulatory compliance and adhering to FDA s current Good Manufacturing Practices or cGMP requirements, the possible breach of the manufacturing agreement by the third party because of factors beyond our control and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us. Before we can obtain marketing approval for our product candidates, our supplier s manufacturing facilities must pass an FDA pre-approval inspection. In order to obtain approval, all of the facility s manufacturing methods, equipment and processes must comply with cGMP requirements. The cGMP requirements govern all areas of record keeping, production processes and controls, personnel and quality control. One of our generic drug manufacturing partners in India, J.B. Chemicals & Pharmaceuticals, Limited, has received FDA approval to manufacture tablet dosage forms of drug products, including ciprofloxacin and fluconazole, our first two generic drug product candidates, at its pharmaceutical manufacturing facility in India for marketing in the United States. However, additional inspections and review of these facilities may be required in the future. Any failure of our third party manufacturers or us to comply with applicable regulations, including an FDA pre-approval inspection and cGMP requirements, could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delay, suspension or withdrawal of approvals, license revocation, seizures or recalls of product, operation restrictions and criminal prosecutions, any of which could significantly and adversely affect our business.

We are dependent on third parties for clinical testing, manufacturing and marketing our proposed products. If we are not able to secure favorable arrangements with such third parties, our business and financial condition could be harmed.

We may not conduct clinical trials ourselves, and we will not manufacture any of our proposed products for commercial sale nor do we have the resources necessary to do so. In addition, we do not have the capability to market our drug products ourselves. We intend to contract with larger pharmaceutical companies or contract research organizations to conduct such activities. In connection with our efforts to secure corporate partners, we may seek to retain certain co-promotional and/or co-marketing rights to certain of our drug candidates, so that we may promote our products to selected medical specialists while our corporate partner promotes these products to the medical market generally.

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We may not be able to enter into any partnering arrangements on this or any other basis. If we are not able to secure adequate partnering arrangements, our business and financial condition could be harmed. In addition, we will have to hire additional employees or consultants, since our current employees have limited experience in these areas. Sufficient employees with relevant skills may not be available to us. Any increase in the number of our employees would increase our expense level, and could have an adverse effect on our financial position.

In addition, we, or our potential corporate partners, may not successfully introduce our proposed products or our proposed products may not achieve acceptance by patients, health care providers and insurance companies. Further, it is possible that we may not be able to secure arrangements to manufacture and market our proposed products at prices that would permit us to make a profit. To the extent that clinical trials are conducted by corporate partners, we may not be able to control the design and conduct of these clinical trials.

Our limited experience at managing and conducting clinical trials ourselves may delay the trials and increase our costs.

We may manage and conduct some future clinical trials ourselves rather than hiring outside clinical trial contractors. While some of our management has had experience at conducting clinical trials, we have limited experience in doing so as a company. If we move forward with self-conducted clinical trials, our limited experience may delay the completion of our clinical trials and increase our costs.

Rapid technological advancement may render our oncology drug candidates or generic product candidates obsolete before we recover expenses incurred in connection with their development. As a result, certain drug candidates and generic products may never become profitable.

The pharmaceutical industry is characterized by rapidly evolving technology. Technologies under development by other pharmaceutical companies could result in treatments for diseases and disorders for which we are developing our own treatments. Several other companies are engaged in research and development of compounds that are similar to our research. A competitor could develop a new technology, product or therapy that has better efficacy, a more favorable side-effect profile or is more cost effective than one or more of our drug candidates or generic products and thereby cause our drug candidate or generic product to become commercially obsolete. Some drug candidates and generic products may become obsolete before we recover the expenses incurred in their development. As a result, such products may never become profitable.

Competition for patients in conducting clinical trials may prevent or delay product development and strain our limited financial resources.

Many pharmaceutical companies are conducting clinical trials in patients with the cancer types that our drug candidates target. As a result, we must compete with them for clinical sites, physicians and the limited number of patients who fulfill the stringent requirements for participation in clinical trials. Also, due to the confidential nature of clinical trials, we do not know how many of the eligible cancer patients may be enrolled in competing studies and consequently not available to us. Our clinical trials may be delayed or terminated due to the inability to enroll enough patients to complete our clinical trials. Patient enrollment depends on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites and the eligibility criteria for the study. The delay or inability to meet planned patient enrollment may result in increased costs and delays or termination of the trial, which could have a harmful effect on our ability to develop products.

We may not be successful in obtaining regulatory approval to market and sell any of our oncology or generic drug candidates.

Before our drug candidates can be marketed and sold, regulatory approval must be obtained from the FDA and comparable foreign regulatory agencies. We must demonstrate to FDA and other regulatory authorities in the United States and abroad that our product candidates satisfy rigorous standards of safety and efficacy. We will need to conduct significant additional research, pre-clinical testing and clinical testing, before we can file applications with the FDA for approval of our product candidates. The process of obtaining FDA and other regulatory approvals is time consuming, expensive, and difficult to design and implement. The review and approval, or denial, process for an application can take years. The FDA, or comparable foreign regulatory agencies, may not timely, or ever, approve an application. Among the many possibilities, the FDA may require substantial additional testing or clinical trials or find our drug candidate is not sufficiently safe or effective in treating the targeted disease. This could result in the denial or delay of product approval. Our product development costs will increase if we experience delays in testing or approvals. Further, a competitor may develop a competing drug or therapy that impairs or eliminates the commercial feasibility of our drug candidates.

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In order to obtain approval for our generic drug candidates, we will need to scientifically demonstrate that our drug product is safe and bioequivalent to the innovator drug. Bioequivalency may be demonstrated by comparing the generic drug candidate to the innovator drug product in dosage form, strength, route of administration, quality, performance characteristics and intended use. We plan to use our management s experience with the regulatory approval process in the United States to prepare, file and prosecute appropriate Abbreviated New Drug Applications, or ANDAs, for our current and future generic drug candidates. During 2003 we filed three ANDAs for ciprofloxacin, carboplatin and fluconazole. In September 2004, we received approval from the FDA for ciprofloxacin and filed an ANDA for an opthalmic product. We intend to file additional ANDAs during 2004 and beyond. The FDA may not agree that our safety and bioequivalency studies provide sufficient support for approval. This could result in denial or delay of FDA approval of our generic products. Generic drugs generally have a relatively short window in which they can be profitable before other manufacturers introduce competing products that impose downward pressure on prices and reduce market share for other versions of the generic drug. Consequently, delays in obtaining FDA approval may also significantly impair our ability to compete.

Our failure to comply with extensive governmental regulation to which we are subject may delay or prevent approval of our product candidates and may subject us to penalties.

The FDA and comparable agencies in foreign countries impose many requirements on the introduction of new drugs through lengthy and detailed clinical testing and data collection procedures, and other costly and time consuming compliance procedures. These requirements apply to every stage of the clinical trial process and make it difficult to estimate when any of our drug candidates will be available commercially, if at all. While we believe that we are currently in compliance with applicable FDA regulations, if we, our partners, or contract research organizations fail to comply with the regulations applicable to our clinical testing, the FDA may delay, suspend or cancel our clinical trials, or the FDA might not accept the test results. The FDA, an institutional review board at our clinical trial sites, our third-party investigators, any comparable regulatory agency in another country**,** or we**,** may suspend clinical trials at any time if the trials expose subjects participating in such trials to unacceptable health risks. Further, human clinical testing may not show any current or future product candidate to be safe and effective to the satisfaction of the FDA or comparable regulatory agencies or the data derived from the clinical tests may be unsuitable for submission to the FDA or other regulatory agencies.

Once we submit a drug candidate for commercial sale approval, the FDA or other regulatory agencies may not issue their approvals on a timely basis, if at all. If we are delayed or fail to obtain these approvals, our business and prospects may be significantly damaged. Even if we obtain regulatory approval for our product candidates, we, our partners, our manufacturers, and other contract entities will continue to be subject to extensive requirements by a number of national, foreign, state and local agencies. These regulations will impact many aspects of our operations, including testing, research and development, manufacturing, safety, effectiveness, labeling, storage, quality control, adverse event reporting, record keeping, approval, advertising and promotion of our future products. Failure to comply with applicable regulatory requirements could, among other things, result in:

fines;

changes in advertising;

revocation or suspension of regulatory approvals of products;

product recalls or seizures;

delays, interruption, or suspension of product distribution, marketing and sale;

civil or criminal sanctions; and

refusals to approve new products.

The later discovery of previously unknown problems with our products may result in restrictions of the product candidate, including withdrawal from manufacture. In addition, the FDA may revisit and change its prior determinations with regard to the safety and efficacy of our future products. If the FDA s position changes, we may be required to change our labeling or to cease manufacture and marketing of the challenged products. Even prior to any formal regulatory action, we could voluntarily decide to cease the distribution and sale or recall any of our future products if concerns about their safety or effectiveness develop.

In their regulation of advertising, the FDA and the Federal Trade Commission from time to time issue correspondence alleging that some advertising or promotional practices are false, misleading or deceptive. The FDA has the power to impose a wide array of

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sanctions on companies for such advertising practices, and the receipt of correspondence from the FDA alleging these practices could result in any of the following:

- incurring substantial expenses, including fines, penalties, legal fees and costs to comply with the FDA s requirements;
- changes in the methods of marketing and selling products;
- taking FDA-mandated corrective action, which may include placing advertisements or sending letters to physicians, rescinding previous advertisements or promotions; and
- disruption in the distribution of products and loss of sales until compliance with the FDA s position is obtained.

If we were to become subject to any of the above requirements, it could be damaging to our reputation, and our business condition could be adversely affected.

Physicians may prescribe pharmaceutical products for uses that are not described in a product s labeling or differ from those tested by us and approved by the FDA. While such off-label uses are common and the FDA does not regulate physicians choice of treatments, the FDA does restrict a manufacturer s communications on the subject of off-label use. Companies cannot actively promote FDA-approved pharmaceutical products for off-label uses, but they may disseminate to physicians articles published in peer-reviewed journals. If our promotional activities fail to comply with the FDA s regulations or guidelines, we may be subject to warnings from, or enforcement action by, the FDA.

Legislative or regulatory reform of the healthcare system and pharmaceutical industry may hurt our ability to sell our products profitably or at all.

In both the United States and certain foreign jurisdictions, there have been and may continue to be a number of legislative and regulatory proposals to change the healthcare system and pharmaceutical industry in ways that could impact upon our ability to sell our products profitably. For example, sales of our products will depend in part on the availability of reimbursement from third-party payers such as government health administration authorities, private health insurers, health maintenance organizations including pharmacy benefit managers and other health care-related organizations. Both the federal and state governments in the United States and foreign governments continue to propose and pass new legislation, rules and regulations designed to contain or reduce the cost of health care. As an example, the Medicare Prescription Drug and Improvement Act of 2003, the Medicare Act, was recently enacted. This legislation provides a new Medicare prescription drug benefit beginning in 2006 and mandates other reforms. Also, the passage of the Medicare Modernization Act in 2003 reduces reimbursement for certain drugs used in the treatment of cancer. Although we cannot predict the full effects on our business of the implementation of this new legislation, it is possible that the new benefit, which will be managed by private health insurers, pharmacy benefit managers and other managed care organizations, will result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce the prices charged for prescription drugs. This could harm our ability to market our products and generate revenues.

It is also possible that other proposals will be adopted. As a result of the new Medicare prescription drug benefit, or any other proposals, we may determine to change our current manner of operation which could harm our ability to operate our business efficiently. Existing regulations that affect the price of pharmaceutical and other medical products may also change before any of our products are approved for marketing. Cost control initiatives could decrease the price that we receive for any of our products we are developing. In addition, third-party payers are increasingly challenging the price and cost-effectiveness of medical products and services. Significant uncertainty exists as to the reimbursement status of newly approved pharmaceutical products. Our products may not be considered

cost effective, or adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize a return on our investments.

In addition, new court decisions, FDA interpretations, and legislative changes have modified the rules governing eligibility for and the timing of 180-day market exclusivity periods, a period of marketing exclusivity that the FDA may grant to a abbreviated new drug application (ANDA) applicant who is the first to file a legal challenge to patents of branded drugs. It is difficult to predict the effects such changes may have on our business. Any changes in FDA regulations, procedures, or interpretations may make ANDA approvals of generic drugs more difficult or otherwise limit the benefits available to us through the granting of 180-day marketing exclusivity. If

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we are not able to exploit the 180-day exclusivity period for one of our generic product candidates for any reason, our product may not gain market share, which could materially adversely affect our results of operations.

Additional government regulations, legislation, or policies may be enacted which could prevent or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of adverse government action that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we might not be permitted to market our products and our business could suffer.

Intellectual property rights are complex and uncertain and therefore may subject us to infringement claims.

The patent positions related to our drug portfolio candidates that we have in-licensed from third parties and those related to our generic drug candidate portfolio are inherently uncertain and involve complex legal and factual issues. Although we are not aware of any infringement by any of our drug candidates on the rights of any third party, there may be third party patents or other intellectual property rights relevant to our drug candidates of which we are not aware. Third parties may assert patent or other intellectual property infringement claims against us with respect to our drug candidates or our generic drug products. This could draw us into costly litigation as well as result in the loss of our use of the intellectual property that is critical to our business strategy.

Intellectual property litigation is increasingly common and increasingly expensive and may result in restrictions on our business and substantial costs, even if we prevail.

Patent and other intellectual property litigation is becoming more common in the pharmaceutical industry. Litigation is sometimes necessary to defend against or assert claims of infringement, to enforce our patent rights, to protect trade secrets or to determine the scope and validity of proprietary rights of third parties. No third party has asserted that we are infringing upon their patent rights or other intellectual property, nor are we aware that we are infringing upon any third party s patent rights or other intellectual property. We may, however, be infringing upon a third party s patent rights or other intellectual property, and litigation asserting such claims might be initiated in which we would not prevail or we would not be able to obtain the necessary licenses on reasonable terms, if at all. All such litigation, whether meritorious or not, as well as litigation initiated by us against third parties, is time consuming and very expensive to defend or prosecute and to resolve.

If our competitors prepare and file patent applications in the United States that claim technology we also claim, we may have to participate in interference proceedings required by the Patent and Trademark Office to determine priority of invention, which could result in substantial costs, even if we ultimately prevail. Results of interference proceedings are highly unpredictable and may result in us having to try to obtain licenses in order to continue to develop or market certain of our drug candidates.

We also rely on trade secret protection and contractual protections for our unpatented, confidential and proprietary technology. Trade secrets are difficult to protect. While we enter into proprietary information agreements with our employees, consultants and others, these agreements may not successfully protect our trade secrets or other confidential and proprietary information.

We may be subject to product liability claims, and may not have sufficient product liability insurance to cover any such claims, which may expose us to substantial liabilities.

We may be exposed to product liability claims from patients who participate in our clinical trials, or, if we are able to obtain FDA approval for one or more of our potential products, from consumers of our products. Although we currently carry product liability insurance in the amount of $25 million in the aggregate, it is possible that this coverage will be insufficient to protect us from future claims.

Further, we may not be able to maintain our existing insurance or obtain or maintain additional insurance on acceptable terms for our clinical and commercial activities or that such additional insurance would be sufficient to cover any potential product liability claim or recall. Failure to maintain sufficient insurance coverage could have a material adverse effect on our business, prospects and results of operations if claims are made that exceed our coverage.

The loss of key personnel could significantly hinder our growth strategy and might cause our business to fail.

Our success depends upon the contributions of our key management and scientific personnel, especially Dr. Rajesh C. Shrotriya, our Chairman, President and Chief Executive Officer and Dr. Luigi Lenaz, the President of our Oncology division. Dr. Shrotriya has been President since 2000 and Chief Executive Officer since 2002, and has spearheaded the major changes in our business strategy

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and coordinated structural reorganization. Dr. Lenaz has been President of our Oncology Division since 2000 and has played a key role in the identification and development of our oncology drug candidates. The loss of the services of Dr. Shrotriya, Dr. Lenaz or any other key personnel could delay or preclude us from achieving our business objectives. Dr. Shrotriya has an employment agreement with us that will expire on December 31, 2004, with automatic one-year renewals thereafter unless we, or Dr. Shrotriya, gives notice of intent not to renew at least 90 days in advance of the renewal date. Dr. Lenaz has an employment agreement with us that will expire on July 1, 2005, with automatic one year renewals thereafter unless Dr. Lenaz or we give notice of intent not to renew at least 90 days in advance of the renewal date.

We also may need substantial additional expertise in marketing and other areas in order to achieve our business objectives. Competition for qualified personnel among pharmaceutical companies is intense, and the loss of key personnel, or the delay or inability to attract and retain the additional skilled personnel required for the expansion of our business, could significantly damage our business.

There are a substantial number of shares of our common stock eligible for future sale in the public market. The sale of these shares could cause the market price of our common stock to fall. Any future equity issuances by us may have dilutive and other effects on our existing stockholders.

As of September 9, 2004, there were approximately 14 million shares of our common stock outstanding, and in addition, security holders held options, warrants and preferred stock which, if exercised or converted, would obligate us to issue up to approximately 10 million additional shares of common stock. A substantial number of those shares, when we issue them upon conversion or exercise, will be available for immediate resale in the public market. The market price of our common stock could fall as a result of such resales due to the increased number of shares available for sale in the market.

We have financed our operations, and for the foreseeable future we expect to continue to finance a substantial portion of our operating cash requirements, primarily by issuing and selling our common stock or securities convertible into or exercisable for shares of our common stock. Any issuances by us of equity securities may be at or below the prevailing market price of our common stock and may have a dilutive impact on our other stockholders. These issuances would also cause our net income, if any, to decrease or our loss per share to decrease in future periods. As a result, the market price of our common stock could drop.

The market price and volume of our common stock fluctuate significantly and could result in substantial losses for individual investors.

The stock market from time to time experiences significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These broad market fluctuations may cause the market price and volume of our common stock to decrease. In addition, the market price and volume of our common stock is highly volatile. Factors that may cause the market price and volume of our common stock to decrease include fluctuations in our results of operations, timing and announcements of our technological innovations or new products or those of our competitors, FDA and foreign regulatory actions, developments with respect to patents and proprietary rights, public concern as to the safety of products developed by us or others, changes in health care policy in the United States and in foreign countries, changes in stock market analyst recommendations regarding our common stock, the pharmaceutical industry generally and general market conditions. In addition, the market price and volume of our common stock may decrease if our results of operations fail to meet the expectations of stock market analysts and investors. While a decrease in market price could result in direct economic loss for an individual investor, low trading volume could limit an individual investor s ability to sell our common stock, which could result in substantial economic loss as well. During 2003, the price of our common stock ranged between $1.66 and $10.37, and the daily trading volume was as high as 3,338,000 shares and as low as 1,300 shares. During 2004, the price of our common

stock has ranged between $4.21 and $9.97, and the daily trading volume has been as high as 1,391,800 shares and as low as 39,300 shares.

Provisions of our charter, bylaws and stockholder rights plan may make it more difficult for someone to acquire control of us or replace current management even if doing so would benefit our stockholders, which may lower the price an acquirer or investor would pay for our stock.

Provisions of our certificate of incorporation, as amended, and bylaws may make it more difficult for someone to acquire control of us or replace our current management. These provisions include:

the ability of our board of directors to amend our bylaws without stockholder approval;

the inability of stockholders to call special meetings;

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the ability of members of the board of directors to fill vacancies on the board of directors;

the inability of stockholders to act by written consent, unless such consent is unanimous;

the establishment of advance notice requirements for nomination for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

These provisions may make it more difficult for stockholders to take certain corporate actions and could delay, discourage or prevent someone from acquiring our business or replacing our current management, even if doing so would benefit our stockholders. These provisions could limit the price that certain investors might be willing to pay for shares of our common stock.

In December 2000, we adopted a stockholder rights plan pursuant to which we distributed rights to purchase units of our Series B junior participating preferred stock. The rights become exercisable upon the earlier of ten days after a person or group of affiliated or associated persons has acquired 20% or more of the outstanding shares of our common stock or ten business days after a tender offer has commenced that would result in a person or group beneficially owning 20% or more of our outstanding common stock. These rights could delay or discourage someone from acquiring our business, even if doing so would benefit our stockholders. We currently have no stockholders who own 20% or more of the outstanding shares of our common stock.

The use of hazardous materials in our research and development efforts imposes certain compliance costs on us and may subject us to liability for claims arising from the use or misuse of these materials.

Our research and development efforts involved and may involve the use of hazardous materials, including biological materials, chemicals and radioactive materials. We are subject to federal, state and local laws and regulations governing the storage, use and disposal of these materials and some waste products. We believe that our safety procedures for the storage, use and disposal of these materials comply with the standards prescribed by federal, state and local regulations. However, we cannot completely eliminate the risk of accidental contamination or injury from these materials. If there were to be an accident, we could be held liable for any damages that result, which could exceed our financial resources. We currently maintain insurance coverage for injuries resulting from the hazardous materials we use, and for pollution clean up and removal, however, future claims may exceed the amount of our coverage. Currently the costs of complying with federal, state and local regulations are not significant, and consist primarily of waste disposal expenses.

FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference into this prospectus contain forward-looking statements that are based on current expectations, estimates and projections about our industry, management s beliefs, and assumptions made by management. Words such as anticipates, expects, intends, plans, believes, seeks, and variations of such words and similar expressions are intended to identify such forward-looking statements. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict; therefore, actual results may differ materially from those expressed or forecasted in any forward-looking statements. The risks and uncertainties include those noted in Risk Factors above and in the documents incorporated by reference.

We undertake no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except to the extent that we are required to do so by law. We also may make additional disclosures in our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K that we may file from time to time with the Securities and Exchange Commission, or SEC. Please also note

that we provide a cautionary discussion of risks and uncertainties under the section entitled Risk Factors in our Annual Report on Form 10-K. These are factors that we think could cause our actual results to differ materially from expected results. Other factors besides those listed here could also adversely affect us. This discussion is provided as permitted by the Private Securities Litigation Reform Act of 1995.

ISSUANCE OF COMMON STOCK TO THE SELLING STOCKHOLDERS

On April 21, 2004, we completed a financing pursuant to which we issued to certain of the selling stockholders (i) 3,220,005 shares of our common stock for $7.75 per share, and (ii) five-year warrants to purchase up to 1,127,005 shares of our common stock at an exercise price of $10.00, in consideration for cash in the aggregate amount of $24,955,000. The warrants are not exercisable for one year from the date of issuance. Pursuant to the investor rights agreement which we entered into in connection with the financing, we have filed a registration statement, of which this prospectus forms a part, in order to permit these selling stockholders or their transferees to resell to the public the shares of common stock they have or may acquire.

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We entered into a financial advisory agreement as of February 26, 2004 with SG Cowen Securities Corporation (or SG Cowen), whereby we agreed, among other fees, to (i) pay SG Cowen a placement fee consisting of cash in an amount equal to 7% of the gross proceeds of the securities sold in a transaction with parties which SG Cowen identified to us, (ii) pay warrants to purchase 1% of the securities sold in the transaction; and (iii) reimburse SG Cowen for reasonable out-of-pocket expenses incurred in connection with the engagement. Pursuant to our agreement with SG Cowen, in connection with the sale of our securities to certain selling stockholders in the financing described above, we paid a cash fee of $750,000 to SG Cowen and SG Cowen agreed to waive its right to receive any warrants.

Also, in connection with the financing, we paid Rodman and Renshaw, Inc. (or Rodman) approximately $230,000 as a finder s fee in respect of certain investors in the financing who were introduced to us by Rodman.

We may also pay a finder s fee or issue warrants to SCO Financial Group LLC (or SCO) in respect of certain investors in the financing originally introduced to us by SCO under a financial advisory agreement we entered into with SCO on February 1, 2003. We are currently in negotiations with SCO regarding the amount of this fee and/or warrants and the termination of the financial advisory agreement. We may be liable for a cash fee of up to 7% of the gross proceeds of the common stock sold in the financing to those certain investors and may have to issue warrants to purchase up to 10% of the number of shares of our common stock sold to such investors. We are not able to determine the amount of the fee and/or warrants at this time.

Also issued on April 21, 2004, we issued a five year warrant to purchase up to 25,000 shares of our common stock, at an exercise price of $11.50 per share, to Anna Kazanchyan, our investor relations consultant, in consideration of her assistance with the financing. The warrant is not exercisable for one year from the date of issuance.

In addition, we issued a five-year warrant, dated September 17, 2003, to purchase up to 130,000 shares of our common stock, at an exercise price of $4.90, to John Moore, a consultant to the company, for his services.

USE OF PROCEEDS

The proceeds from the sale of the common stock under this prospectus will belong to the selling stockholders. While we will not receive any proceeds from this offering, if the warrants that were issued to the selling stockholders to purchase up to 1,282,005 shares of our common stock are all exercised, we will receive estimated proceeds of $12 million. If we do receive any proceeds from the exercise of the warrants, we will likely use such proceeds for general corporate purposes.

DILUTION

The net tangible book value of our common stock on June 30, 2004 was approximately $37.1 million, or approximately $2.67 per share. Net tangible book value per share represents the amount of our total tangible assets, less our total liabilities and the aggregate liquidation preference of our preferred stock outstanding, divided by the total number of shares of our common stock outstanding. The number of shares of our common stock outstanding may be increased by shares issued upon conversion of preferred stock, payment of dividends, exercise of warrants or exercise of options, and, to the extent warrants and options are exercised for cash, the net tangible book value of our common stock may increase. If all the warrants for which the shares of our common stock that are issuable upon exercise of the warrants which are being offered pursuant to this prospectus were exercised for cash and including the approximately $25 million raised pursuant to the sale of shares of our common stock that are being offered for resale pursuant to this prospectus (less estimated costs associated with the financing and the warrants), the net tangible book value of our common stock would be approximately $48.6 million, or approximately $3.20 per share, excluding the

effect of any other transactions occurring after June 30, 2004, other than the original issuance of the common stock included in this registration statement. Since we will not receive any of the proceeds from the sale of common stock under this prospectus, the net tangible book value of our common stock will not be increased as a result of such sales, nor will the number of shares outstanding be affected by such sales. Consequently, there will be no change in net tangible book value per share of our common stock as a result of any sales made under this prospectus. However, any dilution to new investors will represent the difference between the amount per share paid by purchasers of shares of our common stock in this offering and the net tangible book value per share of our common stock at the time of the purchase.

SELLING STOCKHOLDERS

The selling stockholders may sell up to 4,502,010 shares of our common stock pursuant to this prospectus. The shares of our common stock offered by this prospectus were issued or may be issued to the selling stockholders in connection with the financing

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transaction and a consulting agreement described above under Issuance of Common Stock to the Selling Stockholders. We have no other material relationship with the selling stockholders except for Anna Kazanchyan and John Moore, who both provide investor relations consulting services to us.

The following table sets forth information regarding ownership of our common stock by the selling stockholders as of September 9, 2004. There were 14,185,452 shares of our common stock outstanding as of September 9, 2004.

	Shares of Common Stock Owned Before Offering		Number of Shares of Common Stock Offered Hereby(3)	Shares of Common Stock Beneficially Owned Following the Offering(4)	
Investor	**Number(1)**	**% of Class(2)**		**Number**	**% of Class**
BayStar Capital II LP (6)(9)	211,600	1.48	65,000	146,600	1.02
Bristol Investment Fund, Ltd. (10)	113,227	*	113,227	0	*
Cranshire Capital, L.P. (7)(8)(11)	638,732	4.38	261,290	377,442	2.59
C.S.L. Associates L.P. (12)	54,000	*	54,000	0	*
Galleon Captain s Offshore, Ltd.(13)	159,773	1.12	159,773	0	*
Galleon Captain s Partners, L.P. (13)	42,728	*	42,728	0	*
Galleon HealthCare Offshore, Ltd. (13)	740,560	5.18	473,040	267,520	1.87
Galleon HealthCare Partners, L.P.(13)	102,860	*	66,960	35,900	*
J.W. Focused Growth Fund, LP (14)	17,853	*	6,097	11,756	*
J. Wild Fund, LP (14)	17,111	*	6,967	10,144	*
LEBA Investments, LP(15)	37,000	*	27,000	10,000	*
Mulligan BioCapital AG (16)	206,193	1.45	174,193	32,000	*
North Sound Legacy Fund LLC (5)(6)(7)(8)(17)	124,195	*	37,125	87,070	*
North Sound Legacy Institutional Fund LLC (5)(6)(7)(8)(17)	1,526,798	9.99	534,600	992,198	6.49
North Sound Legacy International LTD (5)(6)(7)(8)(17)	2,128,840	13.68	913,275	1,215,565	7.81
Off Sands Point, LTD(18)	90,000	*	84,375	5,625	*
Omicron Master Trust (6)(7)(8)(19)	909,862	6.11	261,290	648,572	4.35
ProMed Offshore Fund, Ltd. (7)(20)	26,772	*	20,156	6,616	*
ProMed Partners, L.P. (7)(20)	167,904	1.18	124,484	43,420	*
ProMed Partners, II, L.P. (20)	50,790	*	34,790	16,000	*
Sands Point Partners, LP (18)	90,000	*	84,375	5,625	*
Sargon Capital International Fund Ltd (21)	22,750	*	22,750	0	*
Schottenfeld Qualified Associates, LP (22)	219,676	1.55	69,676	150,000	1.06
SDS Capital Group, SPC, Ltd. (5)(7)(23)	1,548,295	9.97	270,000	1,278,295	8.23

Wheaten HealthCare Partners LP (24)	34,838	*	34,838	0	*
Xmark Fund, Ltd. (7)(25)	638,481	4.41	198,005	440,476	3.04
Xmark Fund, L.P. (7)(25)	545,902	3.79	206,996	338,906	2.35
Kazanchyan, Anna (26)	32,870	*	25,000	7,870	*
Moore, John (27)	191,800	1.34	130,000	61,800	*

*** less than 1%**

1) Includes all shares of common stock which may be issued to the selling stockholder without regard to any limits on beneficial ownership that may be contained in the terms of warrants or preferred stock held by the selling stockholder. The shares of common stock issuable upon exercise of the warrants issued to the selling stockholders other than John Moore in connection with the April 21, 2004 financing are included in the number of shares of common stock beneficially held by such selling stockholders although such warrants are not exercisable until April 21, 2005. The selling stockholders (other than Anna Kazanchyan and John Moore) own warrants which provide that the number of shares of our common stock that may be acquired by any holder of the warrants upon exercise of the warrants is limited to the extent necessary to ensure that, following such exercise, the number of shares of our common stock then beneficially owned by such holder and any other persons or entities whose beneficial ownership of common stock would be aggregated with the holder s for purposes of the Exchange Act, does not exceed 4.99% of the total number of shares of our common stock then outstanding. This limit may be waived by the holder on not less than 61 days advance notice.

2) For the purposes of calculating the percent of class beneficially owned by a holder, shares of common stock which may be

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issued to that holder are deemed to be outstanding without regard to any limits on beneficial ownership that may be contained in the terms of warrants or preferred stock held by the selling stockholder.

3) Includes shares of common stock issuable upon exercise of the warrants issued to the selling stockholders other than John Moore in connection with the April 21, 2004 financing that are not exercisable until April 21, 2005, which shares may be offered for resale under this Prospectus.

4) Assumes the sale by the selling stockholders of all of the shares of common stock available for resale under this Prospectus.

5) This selling stockholder owns shares of our Series D 8% cumulative convertible voting preferred stock. Pursuant to the terms of the certificate of designation for the Series D preferred stock, the number of shares of our common stock that may be acquired by any holder of Series D preferred stock upon any conversion of the preferred stock or that shall be entitled to voting rights is limited to the extent necessary to ensure that, following such conversion, the number of shares of our common stock then beneficially owned by such holder and any other persons or entities whose beneficial ownership of common stock would be aggregated with the holder s for purposes of the Securities and Exchange Act of 1934, as amended, does not exceed 4.95% of the total number of shares of our common stock then outstanding.

6) This selling stockholder owns shares of our Series E preferred stock. Pursuant to the terms of the certificate of designation of the Series E preferred stock, the number of shares of our common stock that may be acquired by any holder of our Series E preferred stock upon any conversion of the Series E preferred stock or that shall be entitled to voting rights is limited to the extent necessary to ensure that, following such conversion, the number of shares of our common stock then beneficially owned by such holder and any other persons or entities whose beneficial ownership of common stock would be aggregated with the holder s for purposes of the Exchange Act, does not exceed 4.95% of the total number of shares of our common stock then outstanding.

7) This selling stockholder owns warrants which provide that the number of shares of our common stock that may be acquired by any holder of the warrants upon exercise of the warrants is limited to the extent necessary to ensure that, following such exercise, the number of shares of our common stock then beneficially owned by such holder and any other persons or entities whose beneficial ownership of common stock would be aggregated with the holder s for purposes of the Exchange Act, does not exceed 4.95% of the total number of shares of our common stock then outstanding.

8) This selling stockholder owns warrants which provide that the number of shares of our common stock that may be acquired by any holder of the warrants upon exercise of the warrants is limited to the extent necessary to ensure that, following such exercise, the number of shares of our common stock then beneficially owned by such holder and any other persons or entities whose beneficial ownership of common stock would be aggregated with the holder s for purposes of the Exchange Act, does not exceed 9.95% of the total number of shares of our common stock then outstanding.

9) BayStar Capital Management, LLC is the General Partner of BayStar Capital II, L.P. Bay East, L.P., Lawrence Goldfarb, and Steven M. Lamar are the three Managing Members of the General Partner, and acting together exercise shared voting and investment control over the securities beneficially owned by BayStar Capital II, L.P. Steve Derby is the General Partner Bay East, L.P. Shares of common stock beneficially owned before and after the offering includes 140,000 shares issuable upon conversion of outstanding shares of preferred stock.