AVANIR PHARMACEUTICALS Form S-3/A January 27, 2004 As filed with the Securities and Exchange Commission on January 27, 2004

Registration No. 333-111680

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 1 to

FORM S-3

REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933

AVANIR PHARMACEUTICALS

(Exact name of Registrant as specified in its charter)

California

(State or other jurisdiction of incorporation or organization)

33-0314804

(I.R.S. Employer Identification No.)

11388 Sorrento Valley Road, Suite 200, San Diego, California 92121 (858) 622-5200

(Address, including zip code, and telephone number, including area code, of Registrant s principal executive offices)

Gerald J. Yakatan, Ph.D.
President and Chief Executive Officer
11388 Sorrento Valley Road, Suite 200, San Diego, California 92121 (858) 622-5200

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copy to:

Alan Jacobs, Esq.
Heller Ehrman White & McAuliffe LLP
4350 La Jolla Village Drive, 7th Floor
San Diego, California 92122-1246
Telephone: (858) 450-8400
Facsimile: (858) 450-8499

Approximate date of commencement of proposed sale to the public: From time to time as soon as practicable after this Registration Statement becomes effective.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. o

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act of 1933, please check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering: o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act of 1933, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering: o

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box: o

Table of Contents

CALCULATION OF REGISTRATION FEE

		Proposed Maximum Offering Price	Proposed Maximum	
Title of Securities	Amount to be	per	Aggregate Offering	Amount of
to be Registered	Registered (1)	Share (2)	Price (2)	Registration Fee (3)
Class A Common Stock, no par value	8,773,175	\$ 1.46	\$12,808,835	\$1,036.23

- (1) In accordance with Rule 416 under the Securities Act of 1933, Common Stock offered hereby shall also be deemed to cover additional securities to be offered or issued to prevent dilution resulting from stock splits, stock dividends or similar transactions. Each share of Class A Common Stock includes certain purchase rights issued pursuant to that certain Rights Agreement, dated as of March 5, 1999, between the Registrant and American Stock Transfer & Trust Company.
- (2) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, based on the average of the high and low prices of Registrant s Common Stock on the American Stock Exchange on December 26, 2003, which is within 5 days from the date of initial filing of this Registration Statement on December 31, 2003.
- (3) Registration fee of \$1,017 was previously paid in connection with the initial filing of this Registration Statement on December 31, 2003.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission (the SEC), acting pursuant to said Section 8(a), may determine.

Table of Contents

Prospectus

AVANIR PHARMACEUTICALS

5,382,316 Shares of Class A Common Stock and

3,390,859 Shares of Class A Common Stock Issuable upon Exercise of Warrants

This prospectus may be used only in connection with the resale, from time to time, of up to 5,382,316 shares of our Class A common stock, no par value, held by the selling security holders identified in this prospectus and up to an additional 3,390,859 shares of our Class A common stock that may be acquired by the selling security holders upon the exercise of our stock purchase warrants. Information on the selling security holders, and the times and manner in which they may offer and sell shares of our Class A common stock under this prospectus, is provided under Selling Security Holders and Plan of Distribution in this prospectus. We will not receive any proceeds from the sale of these shares by the selling security holders under this prospectus. We will receive proceeds upon cash exercise of the warrants, to the extent the warrants are exercised.

Our address is 11388 Sorrento Valley Road, Suite 200, San Diego, California 92121, and our telephone number is (858) 622-5200. In this prospectus, Avanir, the Company, the Registrant, we, us and our refer to Avanir Pharmaceuticals.

Our common stock trades on the American Stock Exchange under the symbol AVN. On January 26, 2004, the closing price for our Class A common stock, as reported on the American Stock Exchange, was \$2.24 per share.

Investing in our Class A common stock involves certain risks. See Risk Factors beginning on Page 2 of this prospectus for the risks you should consider. You should read the entire prospectus carefully before you make your investment decision.

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.

The date of this prospectus is January 27, 2004

TABLE OF CONTENTS

ABOUT AVANIR PHARMACEUTICALS

PROSPECTUS SUMMARY

RISK FACTORS

SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

USE OF PROCEEDS

SELLING SECURITY HOLDERS

PLAN OF DISTRIBUTION

LEGAL MATTERS

EXPERTS

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

WHERE YOU CAN FIND MORE INFORMATION

SIGNATURES

EXHIBIT INDEX

EXHIBIT 5.1

EXHIBIT 23.2

Table of Contents

TABLE OF CONTENTS

	Page
About Avanir Pharmaceuticals	1
Prospectus Summary	1
Risk Factors	2
Special Note Regarding Forward Looking Statements	7
Use of Proceeds	7
Selling Security Holders	8
Plan of Distribution	9
Legal Matters	10
Experts	10
Incorporation of Certain Information by Reference	11
Where You Can Find More Information	11

ii

Table of Contents

ABOUT AVANIR PHARMACEUTICALS

AVANIR Pharmaceuticals, based in San Diego and incorporated in California in 1988, is a drug discovery and development company focused on treatments for central nervous system disorders and inflammatory diseases. The Company s lead product candidate, Neurodex , is in a Phase III clinical trial for pseudobulbar affect, also known as emotional lability, and in Phase II clinical development for neuropathic pain. An internally discovered small molecule, AVP-13358, is being developed as a potential treatment of asthma and is in Phase I clinical development. AVANIR has established itself as a company that is capable of developing a drug through all preclinical and clinical phases of development and experienced in preparing and submitting new drug applications. The Company s first commercialized product, Abreva®, has been approved by the U.S. Food and Drug Administration (FDA) and is marketed in North America by GlaxoSmithKline Consumer Healthcare (GlaxoSmithKline). Abreva is the leading over-the-counter (OTC) product for the treatment of cold sores.

AVANIR s preclinical research and drug discovery programs are focused primarily on small molecules that can be taken orally as therapeutic treatments. Using its proprietary Xenerex technology, AVANIR is also conducting research to develop injectable human monoclonal antibody products for infectious diseases, such as anthrax and cytomegalovirus, and for other therapeutic applications.

Partnering, licensing and research collaborations have been, and will continue to be, an important part of AVANIR s business development strategy. We intend to partner with pharmaceutical companies that can help fund AVANIR s research in exchange for sharing in the rights to commercialize new drugs resulting from this research. We have licensed and continue to seek licensees for docosanol 10% cream and other potential products in our pipeline. Research collaborations also represent an important way to achieve our development goals, by sharing in the risks and the opportunities that come from such development efforts.

AVANIR s offices and research facilities are located at 11388 Sorrento Valley Road, San Diego, California 92121. Our telephone number is (858) 622-5200 and our e-mail address is info@Avanir.com. Additional information about AVANIR can be found on our website, at www.avanir.com, and in our periodic and current reports filed with the Securities and Exchange Commission (SEC). Copies of our current and periodic reports filed with the SEC are available at the SEC Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549, and online at www.sec.gov and our website at www.avanir.com.

PROSPECTUS SUMMARY

This prospectus relates to resale of up to 8,773,175 shares of Class A common stock, which includes 3,390,859 shares of Class A common stock issuable upon the exercise of warrants held by the security holders listed under Selling Security Holders. The selling security holders may sell their shares of common stock in the open market at prevailing market prices or in private transactions at negotiated prices. They may sell the shares directly, or may sell them through underwriters, brokers or dealers. Underwriters, brokers or dealers may receive discounts, concessions or commissions from the selling security holders or from the purchasers, and this compensation might be in excess of the compensation customary in the type of transaction involved. See the section of this prospectus entitled Plan of Distribution. In this prospectus, we refer to our Class A common stock simply as common stock and refer to the common stock purchase warrants described above as the warrants.

We will not receive any proceeds from the potential sale of the 5,382,316 shares offered by the selling security holders. We will receive proceeds upon the exercise of the warrants to the extent they are exercised. The warrants have an exercise price of \$1.75 per share.

Table of Contents

RISK FACTORS

You should carefully consider the following risks and uncertainties before you invest in our common stock. Investing in our common stock involves risk. If any of the following risks or uncertainties actually occurs, our business, financial condition or results of operations could be materially adversely affected. The following are not the only risks and uncertainties we face. Additional risks and uncertainties of which we are unaware or which we currently believe are immaterial could also materially adversely affect our business, financial condition or results of operations. In any case, the trading price of our common stock could decline, and you could lose all or part of your investment. See also, Special Note Regarding Forward-Looking Statements.

We expect that we will need to raise additional capital to fund ongoing operations. If we cannot raise additional capital, we may be forced to curtail operations. If we succeed in raising additional capital, it may affect our stock price and future revenues.

In order to maintain sufficient cash and investments for future operations, we will need to raise additional capital. We expect to seek to raise additional capital over the next twelve months through various alternatives, including licensing or sales of our technologies and drug candidates and sale of shares of our Class A common stock.

If we raise capital through licensing or sales of one or more of our technologies and drug candidates, then we may lose an opportunity for product sales if a product is successfully developed, approved by the FDA and marketed. If we license any of our technologies or drug candidates, then the development of the product or technology will no longer be in our control. A licensee might not ever reach any of the milestones in a license agreement and we would not earn any additional payments in such an event. Further, if we sell any of our technologies or drug candidates, there can be no assurance that the sales price will cover our investment in such technology or drug candidate.

If we raise capital by issuing additional shares of Class A common stock at a price per share less than the then-current market price per share, then the value of the shares of Class A common stock outstanding will be diluted or reduced. Further, even if we were to sell shares of common stock at prices equal to or higher than the current market price, the issuance of additional shares may depress the market price of our common stock and dilute your voting rights in the Company.

We may not be able raise capital on terms that we find acceptable, if at all. If we are unable to raise additional capital to fund future operations, then we might have to reduce operations or defer or abandon one or more of our clinical or preclinical research programs. Any of these actions could be expected to have an adverse effect on our stock price.

AVANIR and its licensees may not be successful in obtaining regulatory approval of docosanol 10% cream immediately as an over-the-counter (OTC) product in the rest of the world or in licensing, marketing and selling the product in foreign countries.

AVANIR and its licensees face a wide variety of risks in foreign countries in obtaining regulatory approval and in marketing and selling docosanol 10% cream, including:

Regulatory approval requirements differ by country, and obtaining approvals to market the drug in foreign countries may be difficult to obtain, may require additional costly and time consuming clinical trials, or may require prescription status first before obtaining sufficient experience to warrant approval as an OTC product;

Building product awareness of a new drug, whether prescription or OTC, among customers or retail store decision makers may require a substantial amount of product promotion, which does not guarantee success;

Consumers may not perceive that docosanol 10% cream is superior to existing and potentially new OTC products for oral herpes;

Acceptance of docosanol 10% cream in the OTC consumer market may not be widespread; and

2

Table of Contents

Potential price erosion could occur due to competitive products and responses to our product s introduction.

Developing and testing a drug candidate is a very expensive and time-consuming process that may not ultimately lead to a marketable product.

We may spend millions of dollars in preclinical studies researching the potential safety and efficacy of our drug candidates. If any such drug candidate fails to demonstrate the desired safety and efficacy, we may abandon the development of the compound, in which event we would not recover our expenditures incurred to date for that compound. If a compound appears to be safe and effective in preclinical studies, we may decide to proceed with human clinical trials. The full complement of clinical trials required to obtain regulatory approval for a new drug may involve several million dollars. Because of the Company s limited financial resources, we may be required to license the compound to a pharmaceutical company with greater financial resources in order to complete development of the drug. There is no assurance that we will be able to find a large pharmaceutical company interested in licensing the drug or, if we do locate such a licensee, that the proposed license terms will be acceptable to the Company. In the event that we are unable to find a large pharmaceutical partner or licensee on acceptable terms, we may be forced to abandon one or more of our drug candidates.

We expect our quarterly operating results to fluctuate significantly from period-to-period for a number of reasons.

Future operating results will continue to be subject to significant quarterly fluctuations based on a variety of factors, including:

Limited rights to future Abreva royalties In December 2002 we sold to Drug Royalty USA the rights to a substantial portion of our future royalty revenues from sales of Abreva by GlaxoSmithKline. We will not receive any future royalty payments unless and until annual Abreva sales exceed \$62 million, at which time we will receive one-half of the stated royalty rate on any excess sales. We expect that any royalty payments on these excess sales, if any, would occur only once a year, after the end of each calendar year.

Concentration of significant customers, suppliers and industries Milestone payments, royalties earned, and revenues recognized from the sale of rights to royalties from a single licensee (GlaxoSmithKline) accounted for approximately 73% and 95% of our fiscal 2003 and 2002 revenues, respectively. We have now received all of the milestone payments from GlaxoSmithKline for North America. With the sale of our Abreva royalty rights to Drug Royalty USA, future royalty payments from GlaxoSmithKline will come exclusively from our remaining 50% share of Abreva royalties on contract sales in excess of \$62 million a year. Additionally, we purchase our raw materials from a sole foreign supplier that has been approved for manufacture by the FDA. Any disturbances or delays in the manufacture of the raw materials could seriously and adversely affect our business.

Achievement of milestones under license agreements may be outside our control Recognition of revenue under several of our license agreements may depend solely on the efforts and performance of our licensees in reaching milestones outside of our control. Such milestones may include specific events, such as regulatory approval, product launch, the passage of time, or reaching a sales threshold.

Acquisitions/alliances If, in the future, we acquire technologies, products, or businesses, or we form alliances with companies requiring technology investments or commitments, we will face a number of risks to our business. The risks that we may encounter include those associated with integrating operations, personnel, and technologies acquired or licensed, and the potential for unknown liabilities of the acquired business. Our business and operating results on a quarterly basis could be adversely affected if any of our acquisition or alliance activities are not successful.

Foreign sales of docosanol 10% cream and other potential products are subject to various foreign trade risks.

Our license agreement with GlaxoSmithKline is for the United States and Canada only. We also have exclusive license agreements for docosanol 10% cream for Israel, South Korea, Italy and Egypt. We are holding discussions with other potential licensees for marketing and selling docosanol 10% cream in other countries not already licensed. However, we may not finalize any license or distribution arrangements for other territories on a timely

3

Table of Contents

basis or on favorable terms, if at all. Further, our foreign licensees expose us to various foreign trade risks relating to development and marketing of docosanol 10% cream. We may arrange for contracts in the future for the manufacture, marketing and distribution of docosanol 10% cream overseas by foreign licensees, which will be substantially outside our control. Even if we are able to obtain experienced licensees in foreign markets, specific risks that could impact significantly our ability to deliver products abroad include:

difficulties in obtaining regulatory approval of docosanol 10% cream in foreign countries;

changes in the regulatory and competitive environments in foreign countries;

changes in a specific country s or region s political or economic conditions;

difficulty in finding foreign partners with sufficient capital to effectively launch, market and promote the product;

shipping delays;

difficulties in managing operations across disparate geographic areas;

fluctuations in foreign currency exchange rates;

prices of competitive products;

difficulties associated with enforcing agreements through foreign legal systems;

trade protection measures, including customs duties and export quotas; and

foreign tax withholding laws.

Our research and development programs face intense competition and rapid technological change. If we fail to develop products that keep pace with competitive products and new technologies, our products and technologies could become obsolete.

The biotechnology industry is highly competitive and subject to significant and rapid technological change. We compete with hundreds of companies that develop and market products and technologies in similar areas as our research. Each competitor may have specific expertise and technologies that are better than ours. Many of these companies, either alone or together with their research partners, have substantially greater financial resources, larger research and development staffs, and substantially greater experience than we do.

Our failure or inability to comply with government regulations regarding the development, production, testing, manufacturing and marketing of our products may adversely affect our operations.

Governmental authorities in the U.S., including the FDA, and other countries highly regulate the development, production, testing, manufacturing and marketing of pharmaceutical products. The clinical testing and regulatory approval process can take a number of years and requires the expenditure of substantial resources. Failure to obtain, or delays in obtaining, these approvals will adversely affect our business operations, including our ability to commence marketing of any proposed products. We may find it necessary to use a significant portion of our financial resources for research and development and the clinical trials necessary to obtain these approvals for our proposed products. We will continue to incur costs of development without any assurance that we will ever obtain regulatory approvals for any of our products under development. Additionally, we cannot predict the extent to which adverse governmental regulation might arise from future U.S. or foreign legislative or administrative action. Moreover, we cannot predict with accuracy the effects of any future changes in the regulatory approval process and in the domestic health care system for which we develop our products. Future changes could affect adversely the time frame required for regulatory review, our financial resources, and the sale prices of our proposed products, if approved for sale.

4

Table of Contents

Unsuccessful or lengthy research and development programs for proposed new products could negatively affect our business.

The drug development process is lengthy and capital intensive. Our drug development programs are exposed to all of the risks inherent in product development based on innovative technologies, including unanticipated development problems and the possible lack of funding or collaborative partners. Any of a number of problems in the development process could result in the abandonment or substantial change in the development of a specific product. Our Phase III clinical trial of Neurodex for the treatment of pseudobulbar affect in multiple sclerosis patients may experience setbacks or failures for reasons we have not anticipated. Our Phase I clinical trial of our lead compound for treating allergy and asthma may not demonstrate the efficacy of, or have the safety profile necessary for, a proposed product for human use. Unsuccessful clinical trial results for our proposed products could affect materially and adversely our future business operations and financial condition.

Our financial results could be affected by potential changes in the accounting rules governing the recognition of stock-based compensation expense.

We measure compensation expense for our employee stock compensation plans under the intrinsic value method of accounting prescribed by Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees. In addition, we provide pro forma disclosures of our operating results in our Notes to Consolidated Financial Statements as if the fair value method of accounting had been applied in accordance with SFAS No. 123, Accounting for Stock-based Compensation. Had we accounted for our compensation expense under the fair value method of accounting prescribed by SFAS No. 123, the charges would have been significantly higher, by approximately \$1,554,000, \$2,176,000, and \$1,540,000 during fiscal 2003, 2002, and 2001, respectively. Currently, the U.S. Congress, the Securities and Exchange Commission and the Financial Accounting Standards Board are considering changes to accounting rules concerning the recognition of stock option compensation expense. If one or more of these proposals are implemented, we and other companies may be required to measure compensation expense using the fair value method, which would adversely affect our results of operations by reducing our income or increasing our losses by an amount equal to the difference in the two measurement methods.

Business interruptions could adversely affect our business.

Our operations are vulnerable to interruption by fire, earthquake, power loss, telecommunications failure, and other events beyond our control. For example, during 2001 and again in 2003, we experienced blackouts, where there were periods of time lasting several hours in which our utility provider was unable to provide us with electrical power. The loss of electrical power or blackouts for any significant periods of time could adversely affect our ability to conduct experiments and could also harm our vendors. Further, we could lose valuable data made to date in experiments currently underway. We have mitigated the severity of power losses by installing on our premises emergency power equipment, which we have used on several occasions to supply electricity in the areas that we consider to be the most critical to our operations. However, the emergency power unit does not cover all of our electrical needs and, further, it might not operate properly in the event of a power loss.

Our inability to attract and retain key management and scientific personnel could negatively affect our business.

Our success depends on the performance of a small core staff of key management and scientific employees with biotech experience. Given our small staff size and programs currently under development, we depend substantially on our ability to hire, train, retain and motivate high quality personnel, especially our scientists and management team in this field. If we were to lose one or more of our key scientists, then we would likely lose some portion of our institutional knowledge and technical know-how, potentially causing a substantial delay in one or more of our development programs until adequate replacement personnel could be hired and trained.

Our future success also depends on our continuing ability to identify, hire, train and retain highly qualified, technical, sales, marketing and customer service personnel. We presently employ approximately 63 people. Further, we might hire additional people over the next twelve months. Other than our chief executive officer, our executives do not have employment agreements. We do not have key person life insurance policies for any of our executives. The industry in which we compete has a high level of employee mobility and aggressive recruiting of skilled personnel. This type of environment creates intense competition for qualified personnel, particularly in product research and development, sales and marketing, and accounting and finance.

5

Table of Contents

Our patents may be challenged and our pending patents may be denied. Either result would seriously jeopardize our ability to compete in the intended markets for our proposed products.

We rely substantially on the protection of our intellectual property through our ownership or control of issued patents and patent applications. Patents and patent applications owned or controlled by the Company are for docosanol-related products and technologies, Neurodex , compounds capable of regulating the target IgE in controlling symptoms of allergy and asthma, compounds capable of regulating the target MIF in the treatment of several inflammatory diseases, and Xenerex technologies for developing monoclonal antibodies. Because of the competitive nature of the biopharmaceutical industry, we cannot assure you that:

the claims in any pending patent applications will be allowed or that patents will be granted;

present and future competitors will not develop similar or superior technologies independently, duplicate our technologies or design around the patented aspects of our technologies;

our proposed technologies will not infringe other patents or rights owned by others, including licenses that may not be available to us;

any of our issued patents will provide us with significant competitive advantages; or

challenges will not be instituted against the validity or enforceability of any patent that we own or, if instituted, that these challenges will not be successful.

Our inability to obtain or maintain patent protections for our products in foreign markets may negatively affect our financial condition.

The process for the approval of patent applications in foreign countries may differ significantly from the process in the U.S. These differences may delay our plans to market and sell docosanol 10% cream and other products in the international marketplace. Approval in one country does not indicate that approval will be obtained in other countries. The patent authorities in each country administer that country s laws and regulations relating to patents independently of the laws and regulations of any other country and we must seek and obtain the patents separately. Our inability to obtain or maintain patent protections for docosanol 10% cream and other products in foreign markets would severely hamper our ability to generate international sales from our first product and other products still under development.

If we do not protect our technical innovations, then our business may be negatively affected.

We rely substantially on confidentiality agreements to protect our innovations. We cannot assure you that secrecy obligations will be honored, or that others will not independently develop similar or superior technology. Additionally, if our consultants, key employees or other third parties apply technological information independently developed by them or by others to our projects, then disputes may arise as to the ownership rights of these innovations. It is costly to litigate these disputes and an unfavorable result could adversely affect our intellectual property portfolio as well as our business and financial condition.

Developing new pharmaceutical products for human use involves product liability risks, for which we currently have limited insurance coverage.

The testing, marketing, and sale of pharmaceutical products involves the risk of product liability claims by consumers and other third parties. We maintain product liability insurance coverage for our clinical trials in the amount of \$5 million per incident and \$5 million in the aggregate. However, product liability claims can be high in the pharmaceutical industry and our insurance may not sufficiently cover our actual liabilities. If a suit against our business or proposed products is successful, then the lack or insufficiency of insurance coverage could affect materially and adversely our business and financial condition. Furthermore, various distributors of pharmaceutical products require minimum product liability insurance coverage before their purchase or acceptance of products for distribution. Failure to satisfy these insurance requirements could impede our ability to achieve broad distribution of our proposed products.

6

Table of Contents

We could incur significant liabilities as a result of material litigation.

In the ordinary course of business, we face various claims brought by third parties, including claims relating to the safety or efficacy of our products. Any of these claims could subject us to costly litigation and, while we generally believe that we have adequate insurance to cover many different types of liabilities, our insurance carriers may deny coverage or our policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on our operations and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business.

Abreva faces competition from a number of existing and well-established products and the companies that market their products.

We have the opportunity to earn royalties on Abreva product wholesale sales if sales exceed \$62 million a year. Abreva competes with several other products for oral-facial herpes currently on the market in the U.S., as well as other products or potential products that are or may be under development or undergoing FDA review. Most of the competing products are manufactured by companies having substantial financial resources, research and development facilities and manufacturing and marketing experience. Even with Abreva being marketed by one of the world slargest consumer healthcare companies, GlaxoSmithKline, not all competitive responses and the impacts of those responses can be foreseen.

SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

This prospectus contains or incorporates by reference forward-looking statements that involve risks and uncertainties. The statements contained or incorporated by reference in this prospectus that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 (the 1933 Act) and Section 21E of the Securities Exchange Act of 1934 (the 1934 Act"), including without limitation statements regarding our expectations, beliefs, intentions or strategies regarding the future. All forward-looking statements included in this document are based on information available to us on the date hereof, and all forward-looking statements in documents incorporated by reference are based on information available to us as of the date of such documents. We assume no obligation to update any such forward-looking statements. Our actual results may differ materially from those discussed in the forward-looking statements as a result of certain factors, including those set forth above under Risk Factors and elsewhere in this prospectus and in the documents incorporated by reference into this prospectus. In evaluating our business, prospective investors should carefully consider these factors in addition to the other information set forth in this prospectus and incorporated herein by reference.

USE OF PROCEEDS

The selling security holders identified below will receive all of the proceeds from the sale of the shares offered by this prospectus and we will receive no proceeds from this offering, with the exception of proceeds received upon the exercise of the warrants to the extent they are exercised by the selling security holders. We intend to use any proceeds we receive from the exercise of the warrants for general corporate purposes.

7

Table of Contents

SELLING SECURITY HOLDERS

The following table sets forth the names of each of the selling security holders, the number of shares of common stock beneficially owned by each selling security holder immediately prior to the date of this prospectus, the number of shares subject to currently exercisable warrants, the number of shares that may be offered pursuant to this prospectus, and the number of shares of common stock that will be beneficially owned by each of the selling security holders after the offering is completed. This information is based upon information provided to us by each selling security holder with respect to itself only. For purposes of this table, beneficial ownership is determined in accordance with Securities and Exchange Commission rules, and includes voting power and investment power with respect to shares. Under these rules, shares issuable upon the exercise of currently exercisable warrants are considered outstanding for purposes of calculating the percentage owned by a person, but not for purposes of calculating the percentage owned by any other person. The percent of shares held is based on a total of 71,208,750 shares of common stock outstanding as of December 15, 2003 and the total shares and percent owned for each selling security holder includes shares issuable upon exercise of warrants.

	Securities Beneficially Owned Prior to Offering				Shares Beneficially Owned After the Offering	
Selling Security Holders	Shares	Shares underlying Warrants	Total	Percent	Number	Percent
Alexandra Global Master Fund Ltd.	671,141	402,685	1,073,826	1.5%		
Alpha Capital A.G	167,785	100,671	268,456	*		
Gamma Opportunity Capital Partners,						
L.P.	167,785	100,671	268,456	*		
Benjamin Partners Inc. Savings Plan						
F/B/O Jeffrey Benison	187,900	30,000	217,900	*	137,900	*
Bristol Investment Fund, Ltd.	201,342	120,805	322,147	*		
Capital Ventures International	671,140	268,456	939,596	1.3%	402,684	*
Cityplatz Ltd.	167,785	100,671	268,456	*		
Clarion Capital Corporation	134,228	80,537	214,765	*		
Clarion Offshore Fund, Ltd.	67,114	40,268	107,382	*		
Clarion Partners, L.P.	67,114	40,268	107,382	*		
Elliot Associates, L.P.	165,883	64,430	230,313	*	58,500	*
Elliot International, L.P.	247,574	96,644	344,218	*	86,500	*
Smithfield Fiduciary LLC	167,786	100,672	268,458	*		
Omicron Master Trust	135,000	81,000	216,000	*		
Perceptive Life Sciences Master Fund,						
Ltd.	1,647,985	533,557	2,181,542	3.0%	1,381,542	1.9%
Portside Growth and Opportunity Fund						
(1)	335,570	201,342	536,912	*		
Promed Offshore Fund, Ltd.	60,420	36,252	96,672	*		
		0				
		8				

Shares Beneficially

Table of Contents

		Securities Beneficially Owned Prior to Offering				Owned After the Offering	
Selling Security Holders	Shares	Shares underlying Warrants	Total	Percent	Number	Percent	
Promed Partners, L.P.	375,822	225,493	601,315	*			
Rodman & Renshaw, Inc. (2)		161,470	161,470	*			
SRG Capital, LLC	67,115	40,269	107,384	*			
TCMP3 Partners	100,000	60,000	160,000	*			
The Tail Wind Fund, Ltd.	335,570	248,321	583,891	*	46,979	*	
Xmark Fund, Ltd.	631,913	379,148	1,011,061	1.4%			
Xmark Fund, L.P.	374,799	224,879	599,678	*			

- * Less than 1%.
- (1) The investment advisor to Portside Growth and Opportunity Fund is Ramius Capital Group, LLC. The Managing Member of Ramius Capital Group, LLC is C4S & Co., the Managing Members of which are Peter Cohen, Thomas Strauss, Morgan Stark and Jeffrey Solomon. As such, Messrs. Cohen, Strauss, Stark and Solomon may be deemed beneficial owners of these shares. Messrs. Cohen, Strauss, Stark and Solomon disclaim beneficial ownership of such securities.
- (2) Represents shares Rodman & Renshaw may acquire upon exercise of a warrant issued by the Company as consideration for certain services. Rodman & Renshaw is not acting as an underwriter and the shares are not being sold in a distribution.

PLAN OF DISTRIBUTION

The Selling Shareholders (defined below) may, from time to time, sell any or all of their shares of our common stock (including without limitation the shares of common stock issuable upon exercise of the warrants) on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The term Selling Shareholder includes pledgees, donees, assignees and successors-in-interest of any Selling Shareholder. The Selling Shareholders may use any one or more of the following methods when selling shares:

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

short sales;

broker-dealers may agree with the Selling Shareholders to sell a specified number of such shares at a stipulated price per share;

a combination of any such methods of sale; and

any other method permitted pursuant to applicable law.

The Selling Shareholders may also sell shares under Rule 144 under the 1933 Act, if available, rather than under this prospectus.

The Selling Shareholders may enter into hedging transactions with third parties, which may in turn engage in short sales of the common stock into which the warrants are exercisable in the course of hedging the position they assume. The Selling Shareholders may also enter into short positions or other derivative transactions relating to the

9

Table of Contents

common stock into which the warrants are exercisable, or interests in the common stock, and deliver the common stock, or interests in the common stock, to close out their short or other positions or otherwise settle short sales or other transactions, or loan or pledge the common stock into which the warrants are exercisable, or interests in the common stock, to third parties that in turn may dispose of these securities.

Broker-dealers engaged by the Selling Shareholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the Selling Shareholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The Selling Shareholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved.

The Selling Shareholders may from time to time pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell shares of common stock from time to time under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the 1933 Act amending the list of selling shareholders to include the pledgee, transferee or other successors in interest as selling shareholders under this prospectus.

The Selling Shareholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The Selling Shareholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be underwriters within the meaning of 1933 Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under 1933 Act. The Selling Shareholders have informed the Company that it does not have any agreement or understanding, directly or indirectly, with any person to distribute the common stock.

We are required to pay all fees and expenses incident to the registration of the shares. We will not receive any proceeds from the sale of the common stock by the Selling Shareholders and we have agreed to indemnify the Selling Shareholders against certain losses, claims, damages and liabilities, including liabilities under 1933 Act.

In order to comply with the securities laws of certain states, if applicable, the shares will be sold in such jurisdictions only through registered or licensed brokers or dealers. In addition, in certain states the shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under the rules and regulations of the 1934 Act, any person engaged in the distribution or the resale of shares may not simultaneously engage in market making activities with respect to our common stock for a period of two business days prior to the commencement of such distribution. The selling security holders will also be subject to applicable provisions of the 1934 Act and regulations under the 1934 Act which may limit the timing of purchases and sales of shares of our common stock by the selling security holders.

LEGAL MATTERS

The legality of the issuance of the common stock being offered hereby is being passed upon by Heller Ehrman White & McAuliffe LLP, San Diego, California.

EXPERTS

The consolidated financial statements of AVANIR Pharmaceuticals incorporated in this prospectus by reference from AVANIR Pharmaceutical's Annual Report on Form 10-K for the year ended September 30, 2003 have been audited by Deloitte & Touche LLP, independent auditors, as stated in their report, which is incorporated herein by reference, and have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

10

Table of Contents

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The following documents previously filed by us with the Securities and Exchange Commission pursuant to the 1934 Act are hereby incorporated by reference in this prospectus and made a part hereof:

- 1. Our Annual Report on Form 10-K for the year ended September 30, 2003;
- 2. Our Current Report on Form 8-K filed December 11, 2003;
- 3. Our Current Report on Form 8-K filed December 17, 2003; and
- 4. The description of our Class A common stock contained in our registration statement on Form S-1 (File No. 33-32742) declared effective by the SEC on May 8, 1990, including any amendment or report filed for the purpose of updating such description.

All other documents we file with the Securities and Exchange Commission pursuant to Section 13(a), 13(c), 14 or 15(d) of the 1934 Act after the date of this prospectus and prior to the termination of the offering shall be deemed to be incorporated by reference into this prospectus and to be a part hereof from the date of filing of such documents. Any statement contained in any document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained herein or in any other subsequently filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as modified or superseded, to constitute a part of this prospectus.

Upon written or oral request, we will provide without charge to each person to whom a copy of the prospectus is delivered a copy of the documents incorporated by reference herein (other than exhibits to such documents unless such exhibits are specifically incorporated by reference herein). You may request a copy of these filings, at no cost, by writing or telephoning us at the following address: Avanir Pharmaceuticals, 11388 Sorrento Valley Road, Suite 200, San Diego, California 92121, Attention: Chief Financial Officer, telephone: (858) 622-5200. We have authorized no one to provide you with any information that differs from that contained in this prospectus. Accordingly, you should not rely on any information that is not contained in this prospectus. You should not assume that the information in this prospectus is accurate as of any date other than the date of the front cover of this prospectus.

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the informational requirements of the 1934 Act and in accordance therewith file reports, proxy statements and other information with the Securities and Exchange Commission. Our filings are available to the public over the Internet at the Securities and Exchange Commission s website at http://www.sec.gov, as well as at our website at http://www.avanir.com. You may also read and copy, at prescribed rates, any document we file with the Securities and Exchange Commission at the Public Reference Room of the Securities and Exchange Commission located at 450 Fifth Street, N.W., Suite 1024, Washington, D.C. 20549. Please call the Securities and Exchange Commission at (800) SEC-0330 for further information on the Securities and Exchange Commission s Public Reference Rooms.

* * *

11

Table of Contents

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The following table sets forth various expenses in connection with the sale and distribution of the securities being registered. All of the amounts shown are estimates except for the Securities and Exchange Commission Registration Fee.

Securities and Exchange Commission registration fee	\$ 1,036
Accounting fees	4,000
Legal fees and disbursements	10,000
Listing fees for additional shares on The American Stock Exchange	22,500
Miscellaneous	2,000
Total:	\$39,536

Item 15. Indemnification of Officers and Directors.

The registrant s Articles of Incorporation, as amended, (the Articles) provide that, to the extent permitted by applicable law, the registrant s directors shall not be personally liable to the registrant or its shareholders for monetary damages for any breach of fiduciary duty as directors of the registrant. The Articles eliminate the personal liability of directors to the fullest extent permitted by the California Corporations Law and, together with the registrant s Bylaws (the Bylaws), provides that the registrant shall fully indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding (whether civil, criminal, administrative or investigative) by reason of the fact that such person is or was a director or officer of the registrant, or is or was serving at the request of the registrant as a director or officer of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise, against expenses (including attorneys fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding. The registrant has also obtained liability insurance for its officers and directors and has entered into indemnification agreements with certain of its executive officers and directors.

Item 16. Exhibits.

The following documents are filed herewith (unless otherwise indicated) and made a part of this registration statement.

Exhibit Number	Description of Exhibit
4.1	Securities Purchase Agreement, dated as of November 25, 2003, among the
	Registrant and the purchasers identified therein *
4.2	Form of Class A Common Stock Warrant *
5.1	Opinion of Heller Ehrman White & McAuliffe LLP
23.1	Consent of Heller Ehrman White & McAuliffe LLP (filed as part of Exhibit 5.1)
23.2	Consent of Deloitte & Touche LLP, Independent Auditors
24.1	Power of Attorney**

^{*} Filed as an exhibit to that Current Report on Form 8-K filed by the registrant on December 11, 2003.

II-1

^{**} Previously filed.

Table of Contents

Item 17. Undertakings.

- A. The undersigned Registrant hereby undertakes:
 - (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement;
- (i) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;
- (2) That, for the purpose of determining any liability under the Securities Act of 1933 (the 1933 Act), each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- B. The undersigned Registrant hereby undertakes that, for purposes of determining any liability under the 1933 Act, each filing of the Registrant s annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (the 1934 Act) (and, where applicable, each filing of an employee benefit plan s annual report pursuant to Section 15(d) of the 1934 Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offering therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

C. Insofar as indemnification for liabilities arising under the 1933 Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the provisions described under Item 14 above, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the 1933 Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted against the Registrant by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the 1933 Act and will be governed by the final adjudication of such issue.

* * *

II-2

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the city of San Diego, state of California, on January 27, 2004.

Avanir Pharmaceuticals

By /s/ Gerald J. Yakatan, Ph.D.

Gerald J. Yakatan, Ph.D. President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement on Form S-3 has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

Signature	Title	Date	
/s/ Gerald J. Yakatan, Ph.D. Gerald J. Yakatan, Ph.D.	President and Chief Executive Officer (Principal Executive Officer)	January 27, 2004	
/s/ Gregory P. Hanson Gregory P. Hanson	Vice President, Finance; Chief Financial Officer; and Secretary (Principal Accounting and Financial Officer)	January 27, 2004	
*	Director	January 27, 2004	
Stephen G. Austin	_		
*	Director	January 27, 2004	
Dennis J. Carlo			
*	Director	January 27, 2004	
Michael W. George	Director	January 27, 2004	
James B. Glavin	- Birector	January 27, 2004	
	Director	January 27, 2004	
Susan Golding	-		
*	Director	January 27, 2004	
Charles A. Mathews			

*	Director	January 27, 2004
Harold F. Oberkfell		
*	Director	January 27, 2004
Kenneth E. Olson	_	
*By: Gregory P. Hanson		
Attorney-in-fact		
	II-3	

Table of Contents

AVANIR PHARMACEUTICALS

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
4.1	Securities Purchase Agreement, dated as of November 25, 2003, among the Registrant and the purchasers identified therein *
4.0	
4.2	Form of Class A Common Stock Warrant *
5.1	Opinion of Heller Ehrman White & McAuliffe LLP
23.1	Consent of Heller Ehrman White & McAuliffe LLP (filed as part of Exhibit 5.1)
23.2	Consent of Deloitte & Touche LLP, Independent Auditors
24.1	Power of Attorney**

^{*} Filed as an exhibit to that Current Report on Form 8-K filed by the registrant on December 11, 2003.

^{**} Previously filed.