

AVANIR PHARMACEUTICALS

Form 424B2

December 14, 2004

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Filed pursuant to Rule 424(b)(2)  
Registration number 333-114389

Prospectus Supplement  
(To Prospectus Dated May 25, 2004)

**2,333,333 Shares**

**Class A Common Stock**

Avanir Pharmaceuticals is offering by this prospectus supplement 2,333,333 shares of Class A common stock at a price of \$3.00 per share.

This is a best efforts offering being made directly by Avanir, without an underwriter or placement agent. We are not required to sell any specific number or dollar amount of securities in this offering, but will use our best efforts to sell the securities offered. We will receive all of the proceeds from any securities sold in this offering. If we sell the maximum number of shares offered by this prospectus supplement, the total gross offering proceeds to us, before offering expenses, will be approximately \$7 million. This offering will continue until the earlier of the sale of all shares offered by this prospectus supplement or December 31, 2004.

Our Class A common stock is listed on the American Stock Exchange under the symbol AVN . The last reported sale price of our Class A common stock on the American Stock Exchange on December 9, 2004 was \$3.24 per share.

**Investing in our Class A common stock involves certain risks. See Risk Factors beginning on page 3 of the accompanying prospectus for certain risks you should consider, as well as the risk factors set forth in our SEC reports incorporated by reference into this prospectus. You should read this prospectus supplement, the accompanying prospectus and the SEC documents incorporated by reference into this 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 supplement or the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

The date of this prospectus supplement is December 10, 2004.

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## Edgar Filing: AVANIR PHARMACEUTICALS - Form 424B2

Unless otherwise mentioned or unless the context requires otherwise, all references in this prospectus supplement and the accompanying prospectus to the company, Avanir, we, us, our, or similar references mean Avanir Pharmaceuticals.

This document is in two parts. The first part is this prospectus supplement, which describes the terms of this offering of our Class A common stock and supplements information contained in the accompanying prospectus and the documents incorporated by reference into the accompanying prospectus. The second part is the accompanying prospectus, which gives more general information about us and the shares of Class A common stock we may offer from time to time under our shelf registration statement. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or any document incorporated by reference therein, on the other hand, the information in this prospectus supplement shall control.

We have not authorized any dealer, salesman or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus supplement and the accompanying prospectus. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus supplement or the accompanying prospectus. This prospectus supplement and the accompanying prospectus do not constitute an offer to sell or the solicitation of an offer to buy Class A common stock, nor do this prospectus supplement and the accompanying prospectus constitute an offer to sell or the solicitation of an offer to buy Class A common stock in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus supplement and the accompanying prospectus is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus supplement and any accompanying prospectus is delivered or Class A common stock is sold on a later date.

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**THE OFFERING**

Class A common stock offered by us      2,333,333 shares

Class A common stock to be  
outstanding after this offering      97,661,241 shares

Use of proceeds      We intend to use the proceeds of this offering primarily for clinical trials, research and development expenses, marketing and sales expenses, general and administrative expenses and for potential acquisitions of, or investments in, complementary businesses, products and technologies. See Use of Proceeds on page 12.

American Stock Exchange symbol      AVN

Except as otherwise noted, the information above and elsewhere in this prospectus supplement regarding outstanding shares of our Class A common stock is based on 95,327,908 shares of Class A common stock outstanding as of December 7, 2004, and excludes the following shares of Class A common stock as of that date: (i) 5,925,540 shares of Class A common stock issuable upon the exercise of stock options outstanding at a weighted average exercise price of \$2.12 per share; (ii) 2,334,656 shares of Class A common stock reserved for future awards under our existing stock plans; and (iii) 5,322,106 shares of Class A common stock issuable upon the exercise of warrants outstanding with a weighted average exercise price of \$1.83 per share.

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The following table sets forth our capitalization as of September 30, 2004:

on an actual basis;

on an as-adjusted basis, to give effect to the sale of 2,333,333 shares of Class A common stock offered by us in this offering, at an offering price of \$3.00 per share in this offering and after deducting the estimated offering expenses of approximately \$50,000 payable by us.

	<b>As of September 30, 2004 (Unaudited)</b>	
	<b>Actual</b>	<b>As Adjusted</b>
Cash, cash equivalents and short-term investments in securities	\$ 22,298,065	\$ 29,248,065
Shareholders' equity:		
Preferred stock - no par value, 10,000,000 shares authorized		
Series C Junior Participating - 1,000,000 shares authorized; no shares issued or outstanding		
Class A Common stock - no par value; 200,000,000 shares authorized; shares issued and outstanding:		
95,305,757 shares actual; 97,639,090 shares as adjusted	\$ 134,687,535	\$ 141,637,535
Accumulated deficit	(124,405,902)	(124,405,902)
Accumulated other comprehensive loss	(84,374)	(84,374)
Total shareholders' equity	10,197,259	17,147,259
<b>TOTAL CAPITALIZATION</b>	<b>\$ 10,197,259</b>	<b>\$ 17,147,259</b>

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**DILUTION**

Our pro forma net tangible book value as of September 30, 2004 was approximately \$7.2 million, or \$0.08 per share of Class A common stock. Pro forma net tangible book value per share is calculated by subtracting our total liabilities from our total tangible assets, which is total assets less intangible assets, and dividing this amount by the number of shares of Class A common stock outstanding. After giving effect to the sale by us of the 2,333,333 shares of Class A common stock offered in this offering, at an offering price of \$3.00 per share and after deducting estimated offering expenses payable by us, our pro forma, as adjusted net tangible book value as of September 30, 2004 would have been approximately \$14.1 million, or \$0.14 per share of Class A common stock. This represents an immediate increase in the pro forma net tangible book value of \$0.06 per share to our existing shareholders and an immediate and substantial dilution in pro forma net tangible book value of \$2.86 per share to new investors. The following table illustrates this per share dilution:

Offering price per share	\$3.00
Pro forma net tangible book value per share as of September 30, 2004	\$0.08
Increase per share attributable to new investors	\$0.06
Pro forma, as adjusted net tangible book value per share after this offering	\$0.14
Dilution per share to new investors	\$2.86

**PLAN OF DISTRIBUTION**

This is a best efforts offering being made directly by Avanir, without an underwriter or placement agent. We are not required to sell any specific number or dollar amount of securities in this offering, but will use our best efforts to sell the securities offered. We will receive all of the proceeds from any securities sold in this offering. If we sell the maximum number of shares offered by this prospectus supplement, the total gross offering proceeds to us, before offering expenses, will be \$7 million.

We expect to enter into a stock purchase agreement with one or more institutional investors for the sale and purchase of the shares offered under this prospectus supplement. Any such stock purchase agreement will contain customary representations and warranties by us and each of the purchasers, and provides that the obligations of the purchasers to purchase the shares will be subject to certain customary conditions precedent.

This offering will continue until the earlier of the sale of all shares offered by this prospectus supplement or December 14, 2004.

**Expenses of the Offering**

We estimate that the net total expenses of the offering will be approximately \$50,000.

**American Stock Exchange Listing**

Our Class A common stock is listed on the American Stock Exchange under the symbol AVN.

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**DESCRIPTION OF SECURITIES**

Holders of Class A common stock are entitled to one vote for each share held on all matters submitted to a vote of shareholders and do not have cumulative voting rights. Holders of Class A common stock are entitled to receive ratably such dividends, if any, as may be declared by the board of directors out of funds legally available therefor, subject to any preferential dividend rights of outstanding preferred stock. Upon the liquidation, dissolution or winding up of our company, the holders of Class A common stock are entitled to receive ratably our net assets available after the payment of all our debts and other liabilities, subject to the prior rights of any outstanding preferred stock. Holders of our Class A common stock have no preemptive, subscription, redemption, conversion or registration rights, nor are they entitled to the benefit of any sinking fund. The outstanding shares of Class A common stock are, and the shares offered by us in this offering will be, when issued and paid for, validly issued, fully paid and nonassessable. The rights, powers, preferences and privileges of holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock which our board of directors may designate and issue in the future.

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**DATED MAY 25, 2004**

**Prospectus**

**\$50,000,000**

**Class A Common Stock**

This prospectus and any accompanying prospectus supplement will allow us to sell shares of our Class A common stock over time in one or more offerings up to a maximum aggregate offering price of \$50,000,000. Each time we offer securities under this prospectus, we will provide you with a supplement to this prospectus. You should read this prospectus and any prospectus supplement, together with additional information described under the heading **Where You Can Find More Information**, before you make your investment decision.

Our Class A common stock trades on the American Stock Exchange under the symbol **AVN**. On May 25, 2004, the closing price for our Class A common stock, as reported on the American Stock Exchange, was \$1.33 per share.

**Investing in our Class A common stock involves certain risks. See **Risk Factors** beginning on Page 3 of this prospectus for certain risks you should consider. You should read the entire prospectus and any accompanying prospectus supplement 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.**

We may sell shares to or through underwriters or dealers, through agents, or directly to investors. For additional information on the methods of sale, you should refer to the section entitled, **Plan of Distribution** in this prospectus.

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**ABOUT THIS PROSPECTUS**

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

This prospectus provides you with a general description of the Class A common stock we may offer. Each time we sell the Class A common stock, we will provide a prospectus supplement containing specific information about the terms of that offering. The prospectus supplement may also add, update or change information in this prospectus or in documents incorporated by reference in this prospectus. To the extent that any statement that we make in a prospectus supplement is inconsistent with statements made in this prospectus or in documents incorporated by reference in this prospectus, the statements made or incorporated by reference in this prospectus will be deemed modified or superseded by those made in the prospectus supplement. You should carefully read both this prospectus and any prospectus supplement, together with the additional information described under the heading *Where You Can Find More Information*, before buying any securities in this offering.

The registration statement containing this prospectus, including exhibits to the registration statement, provides additional information about us and the Class A common stock offered under this prospectus. The registration statement can be read at the SEC website or at the SEC offices mentioned under the heading *Where You Can Find More Information*.

We have not authorized any broker-dealer, salesperson or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus and the accompanying supplement to this prospectus. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus or the accompanying prospectus supplement. This prospectus and the accompanying supplement to this prospectus do not constitute an offer to sell or the solicitation of an offer to buy common stock, nor do this prospectus and the accompanying supplement to this prospectus constitute an offer to sell or the solicitation of an offer to buy common stock in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation. The information contained in this prospectus and the accompanying prospectus supplement speaks only as of the date set forth on the cover page and may not reflect subsequent changes in our business, financial condition, results of operations and prospects even though this prospectus and any accompanying prospectus supplement is delivered or common stock is sold on a later date.

**ABOUT AVANIR PHARMACEUTICALS**

We are a drug discovery and development company focused primarily on novel treatments for chronic diseases. We have one product that has been approved by the U.S. Food and Drug Administration ( FDA ) for the treatment of cold sores, docosanol 10% cream (sold as Abreva® by our marketing partner, GlaxoSmithKline Consumer Healthcare, in North America), and have several product candidates in clinical development. Our most advanced product candidate, Neurodex™, is in Phase III clinical development for the treatment of pseudobulbar affect ( PBA ), also known as pathological laughing or crying. Neurodex is also in Phase II clinical development for the treatment of neuropathic pain. A potential product for allergy and asthma, AVP-13358, is in Phase I clinical development. We also have preclinical research programs targeting inflammatory diseases, atherosclerosis, and cancer. Our preclinical research and drug discovery programs are focused primarily on small molecules that can be taken orally as therapeutic treatments. Using our proprietary Xenorex™ technology, we are also conducting research to develop injectable human monoclonal antibody products for infectious diseases, such as anthrax and cytomegalovirus, and for other therapeutic applications.

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The following graph illustrates the development status of our product candidates.

The continued development of our product candidates, and the potential launch of a new drug, will require substantial additional capital. We intend to partner with pharmaceutical companies that can help fund our research and potential product launch in exchange for sharing in the rights to commercialize new drugs. We have licensed certain rights to docosanol 10% cream and continue to seek licensees for that product and potential products in our pipeline. Research collaborations also represent an important way to achieve our development goals by sharing the risks and the opportunities that come from such development efforts.

We expect that our development and operational costs will continue to exceed revenues from existing sources at least until the end of 2005. We will have to raise significant amounts of additional capital to finance our research and development activities and operations if we are unable to enter into partnership or collaborative arrangements with pharmaceutical companies that will share our drug development costs. The offering that may be made pursuant to this prospectus could satisfy some portion of our capital needs. If we are unable to raise capital as needed to fund our operations, or if we are unable to enter into collaborative arrangements, then we may need to slow the rate of development of some of our programs or sell the rights to one or more our drug candidates.

Our 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](mailto:info@Avanir.com). Additional information about Avanir can be found on our website, at [www.avanir.com](http://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](http://www.sec.gov) and our website at [www.avanir.com](http://www.avanir.com).

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**RISK FACTORS**

Investing in our securities involves significant risk, including the risks identified below. We have organized the following risk factors into three categories: Risks Related to the Offering, Risks Related to Our Business, and Risks Related to Our Industry. You should carefully consider the following risks and uncertainties before you invest in our securities. If any of the following risks or uncertainties actually occurs, our business, financial condition or results of operations could be materially adversely affected. Additional risks and uncertainties of which we are unaware or that 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 Class A common stock could decline, and you could lose all or part of your investment. See also Note Regarding Forward-Looking Statements.

**Risks Relating to the Offering**

*We expect to complete our Phase III clinical trial soon for Neurodex and any negative results in this trial could harm our stock price.*

In March 2004, we announced that we had completed enrollment in our Phase III clinical trial for Neurodex, our late-stage candidate for the treatment of pseudobulbar affect. We expect to announce preliminary data from this trial later in 2004. Neurodex is our most developed drug candidate and we believe it represents the most immediate opportunity to produce significant revenue for the Company. If the clinical trial data are negative or inconclusive, then we may be required to conduct one or more additional clinical trials and may not be able to seek regulatory approval to market the compound. If this were to happen, we expect our stock price would be negatively affected.

*Assuming favorable results from our Phase III trial for Neurodex in Multiple Sclerosis patients with PBA, we must submit our results to the FDA for review and approval prior to U.S. commercialization. Any delay in the regulatory review or approval process may harm our prospects and could harm our stock price.*

Assuming positive results from our Phase III trial of Neurodex in patients suffering from PBA with Multiple Sclerosis, we will have to seek FDA approval prior to commercialization in the United States. Any delays in our submission or in the FDA's review or approval would delay market launch and increase our cash requirements and could increase the volatility of our stock price and result in additional operating losses.

The process of obtaining FDA approval often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. FDA's review and approval of the actual NDA application is expensive and uncertain. If we submit an NDA for Neurodex, the FDA must decide whether to accept or reject the submission for filing. The FDA's official filing of an NDA begins the application's substantive review. The FDA may refuse to file an NDA for review for many reasons, including if the submission contains insufficient data to demonstrate efficacy and safety. We cannot be certain that our NDA submission would be accepted for filing and reviewed by the FDA or that we would be able to respond to any requests during the review period in a timely manner without delaying potential action on our request for approval. We also cannot be certain that Neurodex will receive a favorable recommendation from any FDA advisory committees or be approved for marketing by the FDA. Even if the FDA grants us marketing approval for Neurodex, we cannot be certain that we will be able to obtain the labeling claims necessary or desirable for the promotion of the product. In addition, delays in approvals or rejections of marketing applications may be based upon many factors, including regulatory requests for additional analyses, reports, data and/or studies, regulatory questions regarding data and results, changes in regulatory policy during the period of product development and/or the emergence of new information regarding our products or other products.

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***Our stock price is highly volatile and you may not be able to resell your shares at or above the price you pay for them.***

The market price of our Class A common stock has been, and is likely to continue to be, highly volatile. The following factors, among others, could have a significant impact on the market price of our Class A common stock:

- our success or failure in entering into license and/or co-promotion arrangements for our products and product candidates;
- unfavorable or delayed announcements by us regarding clinical trial results or results of operations, or favorable announcements by our competitors;
- delays in meeting goals or performance milestones by us or our marketing partners;
- comments made by securities analysts, including changes in, or failure to achieve, financial estimates or milestones;
- announcements of financing transactions and/or future sales of equity or debt securities;
- announcements by us of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- sales of our Class A common stock by our directors, officers or significant shareholders; and
- market and economic conditions.

In addition, the market for biotechnology and pharmaceutical stocks has experienced significant price and volume fluctuations that are frequently unrelated to operating performance. This price volatility is often more pronounced for companies with a low stock price and a small market capitalization, such as ours. These broad market and industry factors might seriously harm the market price of our Class A common stock, regardless of our operating performance.

A significant decline in our stock price could also result in our Class A common stock being delisted from the American Stock Exchange and could initiate litigation, including a securities class action lawsuit. Such a lawsuit against us could result in substantial costs, potential liabilities and the diversion of management's attention and resources.

***We may sell additional shares of capital stock in the future, which could dilute your investment.***

Our Amended and Restated Articles of Incorporation authorize the issuance of up to 200,000,000 shares of Class A common stock and up to 10,000,000 shares of preferred stock. Currently, there are approximately 71,000,000 shares of Class A common stock outstanding. We intend to seek to raise additional capital to continue meeting our financial needs and anticipate that we will do so, at least in part, through the sale of equity securities. Our Board of Directors is able to issue a substantial number of additional shares of Class A common stock without shareholder approval. Potential investors should be aware that any such stock issuance will reduce the proportionate ownership and voting power of existing shareholders and may result in a reduction of the market price of the outstanding shares of our Class A common stock.

***The Board of Directors has the authority to effect a reverse stock split within a stated range until March 18, 2005. If implemented, the reverse stock split may negatively affect the price and liquidity of our Class A common stock.***

At our 2004 Annual Meeting of Shareholders, the Board of Directors received the authority to implement, within its discretion and for a period of one year, a reverse split of our Class A common stock within a range of 1:2 to 1:12.5. If the Board of Directors were to effect a reverse stock split, the bid price of the Class A common stock may not continue at a level in proportion to the reduction in the number of outstanding shares resulting from the reverse stock split. For example, if the Board of Directors decided to implement a reverse stock split at a ratio of 1-for-5, that the post-split market price of our Class A common stock may not

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be at least five times greater than the pre-split price. Accordingly, the total market capitalization of our Class A common stock after a reverse stock split, if implemented, could be lower than the total market capitalization before the proposed reverse stock split. Additionally, the liquidity of our Class A common stock could be affected adversely by the reduced number of shares outstanding after the reverse stock split.

***Management will have broad discretion as to the use of the proceeds from this offering, and the use of the proceeds may not yield positive results.***

We have not designated the amount of net proceeds we will use for any particular purpose. As a result, our management will have broad discretion as to the application of the net proceeds. We have eight significant research and development programs under development, and the use of offering proceeds on any one of these programs may not yield positive results. Accordingly, the use of net proceeds from this offering may not increase our market value or make us profitable.

***Provisions in our charter documents and our shareholder rights plan could prevent or delay a change of control in a transaction that offers our shareholders a premium for their stock.***

Certain provisions of our charter documents may have an anti-takeover effect and could discourage a third party from acquiring control of us without approval of our board of directors. Additionally, we adopted a Shareholder Rights Plan in 1999 for the purpose of requiring bidders to negotiate with our Board of Directors before attempting a takeover of our company. Although the Shareholder Rights Plan is intended to prevent coercive or low offers, it could have the effect of discouraging, delaying or preventing a third party from acquiring us in a transaction that may otherwise offer a premium over our then-current stock price.

## **Risks Relating to Our Business**

***We have a history of losses and we may never achieve or maintain profitability.***

To date, we have experienced significant operating losses in funding the research, development and clinical testing of our drug candidates and we expect to continue to incur substantial operating losses through at least 2005. As of December 31, 2003, our accumulated deficit was approximately \$102.5 million. To achieve profitability, we would need to generate significant additional revenue with positive gross margins. Although we are seeking to negotiate revenue-generating licenses and/or co-promotion arrangements for docosanol 10% cream, Neurodex and other product candidates, we may not be successful in doing so, and any such arrangements may not generate the anticipated revenue. Additionally, our sales and marketing and general and administrative expenses are expected to increase over the next several quarters. These increases in expenses may not be offset by new or increased revenue, and, as a result, we may not achieve or maintain profitability.

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

The drug development process is lengthy and capital-intensive. Since September 1998, we have spent approximately \$55 million in preclinical and clinical studies researching the safety and efficacy of our drug candidates and potential drug candidates. If any of our drug candidates fail 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 tens-of-millions of dollars. Because of our 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. We may be unable 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.

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***We expect that we will need to raise additional capital to fund ongoing operations through at least 2005. If we are unable to raise additional capital, we may be forced to curtail operations. If we succeed in raising additional capital through a licensing or financing transaction, it may affect our stock price and future revenues.***

In order to maintain sufficient cash and investments to fund future operations, we will need to raise additional capital, including through this offering. We expect to seek to raise additional capital over the next 12 to 24 months through various alternatives, including licensing or sales of our technologies and drug candidates and through the 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 that product or technology may 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, the sales price may not 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 may 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 Class A 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.

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

Historically, we have had only limited recurring revenue. As a result, operating results have been, and will continue to be, subject to significant quarterly fluctuations based on a variety of factors, including:

*Co-promotion or License Arrangements* We are currently seeking co-promotion or licensing partners for docosanol 10% cream and Neurodex, as well as for our compounds targeting IgE (allergy and asthma), MIF (inflammation) and apolipoprotein A1 (cholesterol). It is difficult to predict whether any of these discussions will result in a partnering or license arrangement and what the financial terms of such an arrangement might be. If we do enter into any such arrangements, the recognition of revenue under that arrangement may depend on the efforts and performance of our licensees or partners in reaching milestones that are 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.

*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 wholesale 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

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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.

*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, to the extent they exist in the future, are not successful.

***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.***

Currently, docosanol 10% cream is approved for sale in the United States, Canada, Korea, Israel and Sweden and we are currently seeking regulatory approval in various other countries in the European Union and intend to seek approval in Japan. 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

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

***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. 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 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 potential revenues on foreign sales 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, including related to terrorism;

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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 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 biotechnology 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. 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.

***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 82 issued patents and 213 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 inflammatory diseases, compounds targeting apolipoprotein A1 for the treatment of cholesterol, and Xenorex 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.

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***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.

***We are dependent on third parties to manufacture our drug and drug-candidate compounds. The failure of these third parties to perform successfully could harm our business.***

We have utilized, and intend to continue utilizing, third parties to manufacture docosanol 10% cream, Neurodex and our other drug candidates. We have no experience in manufacturing and do not have any manufacturing facilities. Currently, we have only a single supplier for docosanol 10% cream and we do not have any long-term supply agreements in place with this manufacturer. Although we and GlaxoSmithKline maintain a strategic reserve of docosanol 10% cream to mitigate against a short-term supply disruption, any sustained disruption of our supply could result in shipping and sales delays and additional costs that could harm our operations.

***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.

***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's largest consumer healthcare companies, GlaxoSmithKline, not all competitive responses and the impacts of those responses can be foreseen.

***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 electrical power outages lasting several hours. The loss of electrical power 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 emergency power equipment, which we have used on several occasions to supply electricity in the

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areas that we consider to be the most critical to our operations. However, the emergency power units do not cover all of our electrical needs and, further, they might not operate properly in the event of a power loss.

***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. Recently, the Financial Accounting Standards Board proposed changes to accounting rules concerning the recognition of stock option compensation expense. If these proposals are implemented, we and other companies would 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.

## **Risks Relating to Our Industry**

***The pharmaceutical industry is highly competitive and most of our competitors are larger and have greater resources. As a result, we face significant competitive hurdles.***

The pharmaceutical and biotechnology industries are 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. For example, docosanol 10% cream faces worldwide competition from the following products:

OTC monograph preparations, including Carmex®, Zilactin®, Campho®, Orajel®, Herpecin® and others;

Zovirax® acyclovir (oral and topical) and Valtrex® valacyclovir (oral) prescription products marketed by Biovail Corporation and GlaxoSmithKline, respectively, and

Famvir® famciclovir (oral) and Denavir® penciclovir (topical) prescription products marketed by Novartis.

Our competitors may have specific expertise and technologies that are better than ours and 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. Accordingly, our competitors may develop superior products or may develop competing products more rapidly. If we commence commercial sales of our products, we will also be competing with respect to manufacturing efficiencies and marketing capabilities, areas in which we have limited or no direct experience.

***Our industry is highly regulated and 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 of the 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

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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, or the costs of on-going compliance regulations after marketing approval has been obtained. 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.

*Companies in our industry must protect their intellectual property rights and operate without infringing on or misappropriating the proprietary rights of others. Our inability to do so could be costly and could significantly affect our business prospects.*

Biotechnology companies such as Avanir rely heavily on intellectual property rights to protect their innovations. Although we attempt to protect these rights by regularly filing patent applications and requiring all employees to sign confidentiality agreements, we cannot assure you that patents will issue, 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 to our projects technological information independently developed by them or by others, then disputes may arise as to the ownership rights of these innovations. Even if we successfully preserve our intellectual property rights, other biotechnology or pharmaceutical companies may allege that our technology infringes on their rights. Intellectual property litigation is costly, and, even if we were to prevail in such a dispute, the cost of such litigation would adversely affect our business, financial condition and results of operations. Litigation is also time consuming and would divert management's attention and resources away from our operations and other activities. If we were not to prevail in any litigation, in addition to any damages we would have to pay, we could be required to stop the infringing activity or obtain a license. Any required license might not be available to us on acceptable terms. Some licenses might be non-exclusive, and our competitors could have access to the same technology licensed to us. If we were to fail to obtain a required license or were unable to design around a competitor's patent, we would be unable to sell or continue to develop some of our products, which would have a material adverse affect on our business, financial condition and results of operations.

*Companies in our industry are frequently subjected to product liability claims, which can be very costly to defend against.*

In the ordinary course of business, biotechnology and pharmaceutical companies face various claims brought by third parties, including claims relating to the safety or efficacy of 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.

**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,

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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**

We will retain broad discretion over the use of the net proceeds from the sale of our Class A common stock offered hereby. Except as described in any prospectus supplement, we currently anticipate using the net proceeds from the sale of our Class A common stock hereby primarily to fund clinical trials and for research and development, marketing and general and administrative expenses. The amounts and timing of the expenditures may vary significantly depending on numerous factors, such as the progress of our research and development efforts, regulatory approval status of Neurodex, technological advances and the competitive environment for our products. We may also use a portion of the net proceeds to acquire or invest in complementary businesses, products and technologies. Although we have no specific agreements, commitments or understandings with respect to any acquisition, we evaluate acquisition opportunities and engage in related discussions with other companies from time to time.

Pending the use of the net proceeds, we intend to invest the net proceeds in short-term, interest-bearing, investment-grade securities.

### **PLAN OF DISTRIBUTION**

We may sell the Class A common stock:

to or through one or more underwriters or dealers;

directly to purchasers, through agents; or

through a combination of any of these methods of sale.

We may distribute the Class A common stock:

from time to time in one or more transactions at a fixed price or prices, which may be changed from time to time;

at market prices prevailing at the times of sale;

at prices related to such prevailing market prices; or

at negotiated prices.

We will describe the method of distribution of the Class A common stock in the applicable prospectus supplement.

We may determine the price or other terms of the Class A common stock offered under this prospectus by use of an electronic auction. We will describe how any auction will determine the price or any other terms, how potential investors may participate in the auction and the nature of the obligations of the underwriter, dealer or agent in the applicable prospectus supplement.

Underwriters, dealers or agents may receive compensation in the form of discounts, concessions or commissions from us or our purchasers (as their agents in connection with the sale of the Class A common stock). In addition, underwriters may sell common stock to or through dealers, and those dealers may receive compensation in the form of discounts, concessions or commissions from the underwriters and/or commissions from the purchasers for whom they act as agent. These underwriters, dealers or agents may be considered to be underwriters under the 1933 Act. As a result, discounts, concessions or commissions on resale received by the underwriters, dealers or agents may be treated as underwriting discounts and commissions. Each applicable prospectus supplement will identify any such underwriter, dealer or agent, and describe any compensation received by them from us. Any initial public offering price and any discounts or concessions allowed or reallocated or paid to dealers may be changed from time to time.

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We may enter into agreements that provide for indemnification against certain civil liabilities, including liabilities under the 1933 Act, or for contribution with respect to payments made by the underwriters, dealers or agents and to reimburse these persons for certain expenses.

We may grant underwriters who participate in the distribution of the Class A common stock an option to purchase additional shares of common stock to cover over-allotments, if any, in connection with the distribution. Underwriters or agents and their associates may be customers of, engage in transactions with, or perform services for us in the ordinary course of business.

In connection with the offering of the Class A common stock, certain underwriters and selling group members and their respective affiliates, may engage in transactions that stabilize, maintain or otherwise affect the market price of the Class A common stock. These transactions may include stabilization transactions effected in accordance with Rule 104 of Regulation M promulgated by the SEC pursuant to which these persons may bid for or purchase common stock for the purpose of stabilizing its market price.

The underwriters in an offering of the Class A common stock may also create a short position for their account by selling more common stock in connection with the offering than they are committed to purchase from us. In that case, the underwriters could cover all or a portion of the short position by either purchasing common stock in the open market or by exercising any over-allotment option granted to them by us. In addition, any managing underwriter may impose penalty bids under contractual arrangements with other underwriters, which means that they can reclaim from an underwriter (or any selling group member participating in the offering) for the account of the other underwriters, the selling concession for the Class A common stock that are distributed in the offering but subsequently purchased for the account of the underwriters in the open market. Any of the transactions described in this paragraph or comparable transactions that are described in any accompanying prospectus supplement may result in the maintenance of the price of the Class A common stock at a level above that which might otherwise prevail in the open market. None of the transactions described in this paragraph or in an accompanying prospectus supplement are required to be taken by any underwriters and, if they are undertaken, may be discontinued at any time.

## **LEGAL MATTERS**

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

## **EXPERTS**

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

With respect to the unaudited interim financial information which is incorporated herein by reference, Deloitte & Touche LLP have applied limited procedures in accordance with professional standards for a review of such information. However, as stated in their report included in the Company's Quarterly Report on Form 10-Q and incorporated by reference herein, they did not audit and they do not express an opinion on that interim financial information. Accordingly, the degree of reliance on their reports on such information should be restricted in light of the limited nature of the review procedures applied. Deloitte & Touche LLP are not subject to the liability provisions of Section 11 of the Securities Act of 1933 for their reports on the unaudited interim financial information because those reports are not reports or a part of the registration statement prepared or certified by an accountant within the meaning of Sections 7 and 11 of the Act.

## **INCORPORATION OF CERTAIN INFORMATION BY REFERENCE**

The SEC allows us to incorporate by reference into this prospectus the information contained in other documents we file with the SEC, which means that we can disclose important information to you by referring

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you to those 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 in or omitted from this prospectus, 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 so modified or superseded, to constitute a part of this prospectus. We incorporate by reference the documents listed below and any future filings we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act until the offering is completed:

1. Our Annual Report on Form 10-K for the year ended September 30, 2003;
2. Our Definitive Proxy Statement on Schedule 14A, filed January 28, 2004;
3. Our Quarterly Reports on Form 10-Q for the quarters ended December 31, 2003 and March 31, 2004;
4. Our Current Report on Form 8-K filed April 6, 2004;

5. The description of our Class A common stock contained in our registration statement on Form 8-A (File No. 001-15803) filed with the SEC on April 13, 2000, 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 [www.sec.gov](http://www.sec.gov), as well as at our website at [www.avanir.com](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.

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**2,333,333 Shares**

**Class A Common Stock**

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**PROSPECTUS SUPPLEMENT**

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**December 10, 2004**

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