AVANIR PHARMACEUTICALS, INC. Form 424B5 July 30, 2009

#### **Table of Contents**

PROSPECTUS SUPPLEMENT (To Prospectus dated May 6, 2009)

Filed Pursuant to 424(b)(5) Registration No. 333-158665

## 12,500,000 Shares Common Stock

We have entered into a sales agreement with Cantor Fitzgerald & Co. relating to shares of our common stock offered by this prospectus supplement and the accompanying prospectus. In accordance with the terms of the sales agreement, we may offer and sell an aggregate of up to 12,500,000 shares of our common stock, \$0.0001 par value per share, from time to time through Cantor Fitzgerald & Co. acting as agent and/or principal. The gross proceeds from this offering may be up to \$35,000,000.

Our common stock is listed on the NASDAQ Global Market under the symbol AVNR. The last reported sale price of our common stock on the NASDAQ Global Market on July 29, 2009 was \$2.35 per share.

Sales of our common stock, if any, under this prospectus supplement and the accompanying prospectus may be made in sales deemed to be at-the-market equity offerings as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including sales made directly on or through the NASDAQ Global Market, the existing trading market for our common stock, sales made to or through a market maker other than on an exchange or otherwise, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices, and/or any other method permitted by law.

Cantor Fitzgerald & Co. will be entitled to compensation at a fixed commission rate of 4.0% of the gross sales price per share sold, up to aggregate gross proceeds of \$10 million, and, thereafter, at a fixed commission rate of 3.0% of the gross sales price per share sold. In connection with the sale of the common stock on our behalf, Cantor Fitzgerald & Co. may be deemed to be an underwriter within the meaning of the Securities Act of 1933, as amended, and the compensation of Cantor Fitzgerald & Co. may be deemed to be underwriting commissions or discounts.

Before buying shares of our common stock, you should carefully consider the risk factors described in Risk Factors beginning on page S-3 of this prospectus supplement.

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

The date of this prospectus supplement is July 30, 2009.

## TABLE OF CONTENTS

# PROSPECTUS SUPPLEMENT

	Page
About This Prospectus Supplement	S-1
Offering Summary	S-2
Risk Factors	S-3
<u>Use of Proceeds</u>	S-12
<u>Dilution</u>	S-12
<u>Plan of Distribution</u>	S-13
PROSPECTUS	
	Page
About This Prospectus	1
About Avanir Pharmaceuticals, Inc.	3
Risk Factors	3
Note Regarding Forward-Looking Statements	3
Description of Securities	4
<u>Use of Proceeds</u>	4
Ratio of Earnings to Fixed Charges	4
<u>Plan of Distribution</u>	5
<u>Legal Matters</u>	6
<u>Experts</u>	6
Incorporation of Certain Information by Reference	6
Where You Can Find More Information	7

#### **Table of Contents**

#### ABOUT THIS PROSPECTUS SUPPLEMENT

Unless expressly stated otherwise, all references in this prospectus supplement and the accompanying prospectus to the Company, Avanir, we, us, our, or similar references mean Avanir Pharmaceuticals, Inc. and its subsidiaries consolidated basis.

This document is in two parts. The first part is this prospectus supplement, which describes the terms of this offering of our 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 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, salesperson 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 should 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 common stock, nor do this prospectus supplement and the accompanying 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 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 common stock is sold on a later date.

S-1

#### **Table of Contents**

#### OFFERING SUMMARY

Common stock offered by us pursuant to this

prospectus supplement

Manner of offering

Up to 12,500,000 shares

Common stock to be outstanding after this offering

90,744,987 shares

through our agent, Cantor Fitzgerald & Co. See Plan of

At-the-market offering that may be made from time to time

Distribution on page S-13.

Offering price and proceeds Variable at-the-market pricing, with aggregate gross

proceeds of up to \$35,000,000

Use of proceeds We intend to use the net proceeds from this offering to

provide additional working capital. See Use of Proceeds on

page S-12.

NASDAQ Global Market symbol AVNR

Risk factors This investment involves a high degree of risk. See Risk

Factors beginning on page S-3 of this prospectus

supplement.

The number of shares of common stock to be outstanding after this offering assumes the issuance of the full 12,500,000 shares that may be offered hereunder and is based on 78,244,987 shares outstanding as of June 30, 2009 and excludes the following securities outstanding as of that date: (i) options representing the right to purchase a total of 2,204,438 shares of common stock at a weighted average exercise price of \$2.16 per share, (ii) options representing the right to purchase a total of 2,031,218 shares of common stock at an exercise price of \$0.88 per share upon attainment of pre-determined performance milestones, (iii) restricted stock units representing a total of 2,279,912 shares of common stock issuable upon vesting, (iv) restricted stock units representing a total of 536,868 vested shares of common stock issuable to directors, and (v) warrants representing the right to purchase a total of 12,240,437 shares of common stock at a weighted average exercise price of \$1.43 per share.

Our principal executive offices are located at 101 Enterprise, Suite 300, Aliso Viejo, California 92656. Our telephone number is (949) 389-6700 and our e-mail address is info@avanir.com.

S-2

#### RISK FACTORS

Before making an investment decision, you should carefully consider the risks described in this prospectus supplement, together with all of the other information incorporated by reference into this prospectus supplement and the accompanying prospectus, including from our most recent annual report on Form 10-K and subsequent quarterly reports on Form 10-Q. The following risks are presented as of the date of this prospectus supplement and we expect that these will be updated from time to time in our periodic and current reports filed with the SEC, which will be incorporated herein by reference. Please refer to these subsequent reports for additional information relating to the risks associated with investing in our common stock.

Our business, financial condition or results of operations could be materially adversely affected by any of these risks. The trading price of our securities could decline due to any of these risks, and you may lose part or all of your investment. This prospectus supplement, the accompanying prospectus and the incorporated documents also contain forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks mentioned below. Forward-looking statements included in this prospectus supplement 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 disclaim any intent to update any forward-looking statements.

## **Risks Relating to Our Business**

We need additional positive clinical data from the confirmatory Phase III trial for Zenvia for PBA and there can be no assurance that the FDA will approve Zenvia.

In October 2006, we received an approvable letter from the FDA for our NDA submission for Zenvia in the treatment of patients with PBA. The approvable letter raised certain safety and efficacy concerns. Based on discussions with the FDA, we were able to successfully resolve the outstanding efficacy concern of the original dose formulation that was tested in earlier clinical trials. However, the safety concerns require additional clinical development to resolve. To address the safety concerns, we agreed to re-formulate Zenvia and conduct one additional confirmatory Phase III clinical trial using a new low quinidine dose formulation. The goal of the study is to demonstrate an improved safety profile and significant efficacy using a low-dose quinidine formulation. We have completed patient enrollment and expect top-line safety and efficacy data from the blinded phase to be available in August 2009. It is possible that the efficacy will be so reduced at low quinidine dose formulations that we will not be able to satisfy the FDA s efficacy requirements. It is also possible that the FDA will continue to have safety concerns relating to potential cardiac risks associated with Zenvia in light of the findings from our recently completed Advanced Cardiac Safety Study, the results of which were summarized in our quarterly report on Form 10-Q filed on May 8, 2009. Management believes data generated in these studies suggest an improved cardiac safety margin of the new low-dose formulation of Zenvia compared to the dose previously tested. However, the FDA approval decision for Zenvia is expected to depend to a significant degree on the agency s overall assessment of benefits versus potential risks, including the risks assessed in these studies. Accordingly, there can be no assurance that the FDA will approve Zenvia for commercialization.

Additionally, although we have a Special Protocol Assessment (SPA) from the FDA for our confirmatory Phase III trial for Zenvia for PBA, there can be no assurance that the terms of the SPA will ultimately be binding on the FDA. An SPA is intended to serve as a binding agreement with the FDA on the adequacy of the design of a planned clinical trial. Even where an SPA has been granted, however, additional data may subsequently become available that causes the FDA to reconsider the previously agreed upon SPA and the FDA may have subsequent safety or efficacy concerns that override this agreement. For example, it is possible that we will not obtain enough data on cardiac risks through our ongoing Phase III trials to satisfy FDA safety concerns, which could necessitate further clinical trials. Additionally, the expansion in the planned number of patients enrolled in the ongoing PBA Phase III trial, may result in the FDA requesting other amendments to the trial design that could add to the trial s cost and/or time, as well as degree of difficulty in reaching clinical endpoints. As a result, even with an SPA, we cannot be certain that the trial results will be found to be adequate enough to demonstrate the safety and efficacy required for product approval.

The FDA's safety concerns regarding Zenvia for the treatment of PBA are expected to extend to other clinical indications that we are pursuing, including DPN pain. Due to these concerns, any future development of Zenvia for

other indications is expected to use an alternative low-dose quinidine formulation, which may negatively affect efficacy.

S-3

#### **Table of Contents**

We have successfully completed a single Phase III trial for Zenvia in the treatment of DPN pain. In recent communications regarding the continued development of Zenvia for this indication, the FDA has expressed that the safety concerns and questions raised in the PBA approvable letter would be expected to necessitate the testing of a low-dose quinidine formulation in the DPN pain indication as well. Additionally, based on feedback we have received from the FDA on the proposed continued development of Zenvia for this indication, it is possible that two large well controlled Phase III trials would be needed to support an NDA filing for this indication. However, due to our limited capital resources and current focus on gaining approval for the PBA indication, we do not expect that we will be able to conduct the trials needed for this indication without additional capital or a development partner for Zenvia. Moreover, although we achieved positive results in our initial Phase III trial, an alternative low quinidine dose formulation may not yield the same levels of efficacy as seen in the earlier trials or as predicted based on our subsequent PK study. Any decrease in efficacy may be so great that the drug does not demonstrate a statistically significant improvement over placebo. Additionally, any alternative low quinidine dose formulation that we develop may not sufficiently satisfy the FDA s safety concerns. If this were to happen, we may not be able to pursue the development of Zenvia for other indications or may need to undertake significant additional clinical trials, which would be costly and cause potentially substantial delays.

Even if Zenvia receives marketing approval from the FDA, the approval may not be on the terms that we seek and could limit the marketability of the drug.

Even if the FDA approves Zenvia for marketing in one or more indications, any side effects associated with this product candidate could cause the approval to be granted on terms less favorable than those we are seeking. This may, in turn, limit our ability to enter into licensing, partnering or collaboration arrangements with respect to Zenvia and to commercialize Zenvia and generate revenues from its sales. In addition to the confirmatory Phase III trial in PBA, we recently completed additional pre-clinical and clinical cardiac safety studies designed to enhance our response to the FDA s approvable letter and to support planned label discussions with the FDA. Although we believe these studies showed an improvement in the cardiac safety margin with the low dose of quinidine that we are currently testing, it did show QTc prolongation of a duration that is above the FDA s threshold of concern (5 ms mean increase) in approving new drugs. As a result, we could face one or more of the following risks:

regulatory authorities may require the addition of labeling statements, such as a black box warning, which is the strongest type of warning that the FDA can require for a drug and is generally reserved for warning prescribers about adverse drug reactions that can cause serious injury or death;

regulatory authorities may withdraw approval of the product after its initial approval;

product labeling may be amended to restrict use in certain populations;

physicians may be required to conduct additional tests prior to dispensing product or monitor patients taking Zenvia:

we may be required to conduct additional studies either post-marketing or before approval; and

Zenvia may not be approved by the FDA for commercialization as the FDA may perceive that the benefit does not outweigh the potential risk, particularly if the efficacy is marginal at the new lower dose currently being tested

Any of these events could prevent us from achieving or maintaining market acceptance of our product, even if it receives marketing approval, or could substantially increase the cost of commercialization, which in turn could impair our ability to generate revenues from the product candidate.

We have limited capital resources and will need to raise additional funds to support our operations.

We have experienced significant operating losses in funding the research, development and clinical testing of our drug candidates, accumulating losses totaling \$271 million as of June 30, 2009, and we expect to continue to incur substantial operating losses for the foreseeable future. As of June 30, 2009, we had approximately \$26.6 million in

cash and cash equivalents and restricted investments in marketable securities. Additionally, we currently do not have any meaningful sources of recurring revenue or cash flow.

S-4

#### **Table of Contents**

In light of our current capital resources, lack of near-term revenue opportunities and substantial long-term capital needs, we will need to raise additional capital in the future to finance our long-term operations until we expect to be able to generate meaningful amounts of revenue from product sales. Based on our current loss rate and existing capital resources as of the date of this prospectus supplement, we estimate that we have sufficient funds to sustain our operations at their current levels through the anticipated timing of the FDA approval decision for Zenvia in PBA in the second half of calendar year 2010. Although we expect to be able to raise additional capital, there can be no assurance that we will be able to do so or that the available terms of any financing would be acceptable to us. If we are unable to raise additional capital to fund future operations, then we may be unable to fully execute our development plans for Zenvia. This may result in significant delays in the development of Zenvia and may force us to further curtail our operations.

Any transactions that we may engage in to raise capital could dilute our stockholders and diminish certain commercial prospects.

Although we believe that we will have adequate capital reserves to fund operations through the anticipated timing of the FDA approval decision for Zenvia in PBA, we expect that we will need to raise additional capital in the future. We may do so through various financing alternatives, including licensing or sales of our technologies, drugs and/or drug candidates, selling shares of common or preferred stock (including through the financing facility to which this prospectus supplement relates), through the acquisition of other companies, or through the issuance of debt. Each of these financing alternatives carries certain risks. Raising capital through the issuance of common stock may depress the market price of our stock. Any such financing will dilute our existing stockholders and, if our stock price is relatively depressed at the time of any such offering, the levels of dilution would be greater. In addition, debt financing, to the extent available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as making capital expenditures or entering into licensing transactions. If we seek to raise capital through licensing transactions or sales of one or more of our technologies, drugs or drug candidates, as we have previously done with certain investigational compounds and docosanol 10% cream, then we will likely need to share a significant portion of future revenues from these drug candidates with our licensees. Additionally, the development of any drug candidates licensed or sold to third parties will no longer be in our control and thus we may not realize the full value of any such relationships.

We may or may not sell shares under the financing facility to which this prospectus supplement relates, depending on the volume and price of our common stock, as well as our capital needs and potential alternative sources of capital, such as a development partner for Zenvia. If we actively sell shares under this facility, a significant number of shares of common stock (up to approximately 16% of our total shares outstanding) could be issued in a short period of time, although we would attempt to structure the volume and price thresholds in a way that minimizes market impact. Notwithstanding these control efforts, these sales, or the perceived risk of dilution from potential sales of stock through this facility, may depress our stock price or cause holders of our common stock to sell their shares, or it may encourage short selling by market participants, which could contribute to a decline in our stock price. A decline in our stock price might impede our ability to raise capital through the issuance of additional shares of common stock or other equity securities, and may cause our stockholders to lose part or all of the value of their investment in our stock.

We have licensed out or sold most of our non-core drug development programs and related assets and these and other possible future dispositions carry certain risks.

We have entered into agreements for the licensing out or sale of our non-core assets, including FazaClo, macrophage migration inhibitory factor (MIF), our anthrax antibody program, and other antibodies in our infectious disease program, as well as docosanol in major markets worldwide. We are considering a suitable license or development partner for Zenvia for PBA and/or other indications. These transactions involve numerous risks, including:

diversion of management s attention from normal daily operations of the business;

disputes over earn-outs, working capital adjustments or contingent payment obligations;

insufficient proceeds to offset expenses associated with the transactions; and

the potential loss of key employees following such a transaction.

S-5

#### **Table of Contents**

Transactions such as these may result in disputes regarding representations and warranties, indemnities, earn-outs, and other provisions in the transaction agreements. If disputes are resolved unfavorably, our financial condition and results of operations may be adversely affected and we may not realize the anticipated benefits from the transactions.

Disputes relating to these transactions can lead to expensive and time-consuming litigation and may subject us to unanticipated liabilities or risks, disrupt our operations, divert management s attention from day-to-day operations, and increase our operating expenses.

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

We have invested in an extensive patent portfolio and we rely substantially on the protection of our intellectual property through our ownership or control of issued patents and patent applications. 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;

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

our technologies will not infringe on 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;

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; or

we will be able to secure additional worldwide intellectual property protection for our Zenvia patent portfolio. Even if we successfully secure our intellectual property rights, third parties, including other biotechnology or pharmaceutical companies, may allege that our technology infringes on their rights or that our patents are invalid. Intellectual property litigation is costly, and even if we were to prevail in such a dispute, the cost of litigation could 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 to lose 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, or at all. 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 effect on our business, financial condition and results of operations.

We currently have only a limited term of patent coverage and exclusivity protection for Zenvia in the U.S., which could result in the introduction of generic competition within a few years of product launch.

Our PBA related patents for Zenvia in the U.S. expire at various times from 2011 through 2012 and our DPN pain patent for Zenvia expires in 2016 (we have longer patent protection for Zenvia in certain European markets). Depending upon the timing, duration and specifics of FDA approval, if any, of Zenvia, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. If Zenvia is approved, the Hatch-Waxman Amendments may permit a patent restoration term of up to five years for one of our patents covering Zenvia as compensation for the patent term lost during product development and the regulatory review process. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. We intend to

S-6

#### **Table of Contents**

apply for patent term restoration. However, because Zenvia is not a new chemical entity, but is a combination of two previously approved products, it is uncertain whether Zenvia will be granted any patent term restoration under the U.S. Patent and Trademark Office guidelines. In addition, the patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years after the product s approval date.

Market exclusivity provisions under the Federal Food, Drug and Cosmetic Act, or the FDCA, also may delay the submission or the approval of certain applications for competing product candidates. The FDCA provides three years of non-patent marketing exclusivity for an NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving abbreviated NDAs for drugs containing the original active agent.

Once the three-year FDCA exclusivity period has passed and after the patents (including the patent restoration term, if any) that cover Zenvia expire, generic drug companies would be able to introduce competing versions of the drug. Although we have filed additional new patent applications for Zenvia, there can be no assurance that these patents will issue or that any patents will have claims that are broad enough to prevent generic competition. In January 2009, the U.S. Patent and Trademark Office ( USPTO ) issued an office action on one of the Zenvia applications. We recently amended the claims in an effort to address the objections made by the USPTO examiner and filed a request for continued examination ( RCE ). Although revisions to a patent application like this are common during a patent prosecution process, there is no guarantee that our amended claims will be accepted by the USPTO. If we are unsuccessful in strengthening our patent portfolio on a timely basis to secure sufficient protection against generic competition, our long-term revenues from Zenvia sales may be less than expected and we are likely to have greater difficulty finding a development partner or licensee for Zenvia.

If we fail to obtain regulatory approval in foreign jurisdictions, we would not be able to market our products abroad and our revenue prospects would be limited.

We may seek to have our products or product candidates marketed outside the United States. In order to market our products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and jurisdictions and can involve additional testing. The time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval processes may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. For example, our development partner in Japan encountered significant difficulty in seeking approval of docosanol in that country and was forced to abandon efforts to seek approval in that country. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. The failure to obtain these approvals could materially adversely affect our business, financial condition and results of operations.

We face challenges retaining members of management and other key personnel.

The industry in which we compete has a high level of employee mobility and aggressive recruiting of skilled employees. This type of environment creates intense competition for qualified personnel, particularly in clinical and regulatory affairs, research and development and accounting and finance. Because we have a relatively small organization, the loss of any executive officers, including the Chief Executive Officer, key members of senior management or other key employees, could adversely affect our operations. For example, if we were to lose one or more of the senior members of our clinical and regulatory affairs team, the pace of clinical development for Zenvia could be slowed significantly. We have experienced employee turnover and the loss of key employees could adversely affect our business and cause significant disruption in our operations.

## **Risks Relating to Our Industry**

There are a number of difficulties and risks associated with clinical trials and our trials may not yield the expected results.

#### **Table of Contents**

There are a number of difficulties and risks associated with conducting clinical trials. For instance, we may discover that a product candidate does not exhibit the expected therapeutic results, may cause harmful side effects or have other unexpected characteristics that may delay or preclude regulatory approval or limit commercial use if approved. It typically takes several years to complete a late-stage clinical trial and a clinical trial can fail at any stage of testing. If clinical trial difficulties or failures arise, our product candidates may never be approved for sale or become commercially viable.

In addition, the possibility exists that:

the results from earlier clinical trials may not be predictive of results that will be obtained from subsequent clinical trials, particularly larger trials;

institutional review boards or regulators, including the FDA, may hold, suspend or terminate our clinical research or the clinical trials of our product candidates for various reasons, including noncompliance with regulatory requirements or if, in their opinion, the participating subjects are being exposed to unacceptable health risks;

subjects may drop out of our clinical trials;

our preclinical studies or clinical trials may produce negative, inconsistent or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials;

trial results derived from top-line data, which is based on a preliminary analysis of efficacy and safety data related to primary and secondary endpoints, may change following a more comprehensive review of the complete data set derived from a particular clinical trial or may change due to FDA requests to analyze the data differently; and

the cost of our clinical trials may be greater than we currently anticipate.

It is possible that earlier clinical and pre-clinical trial results may not be predictive of the results of subsequent clinical trials. If earlier clinical and/or pre-clinical trial results cannot be replicated or are inconsistent with subsequent results, our development programs may be cancelled or deferred. In addition, the results of these prior clinical trials may not be acceptable to the FDA or similar foreign regulatory authorities because the data may be incomplete, outdated or not otherwise acceptable for inclusion in our submissions for regulatory approval.

Additionally, the FDA has substantial discretion in the approval process and may reject our data or disagree with our interpretations of regulations or our clinical trial data or ask for additional information at any time during their review. For example, the use of different statistical methods to analyze the efficacy data from our Phase III trial of Zenvia in DPN pain results in significantly different conclusions about the efficacy of the drug. Although we believe we have legitimate reasons to use the methods that we have adopted as outlined in our SPA with the FDA, the FDA may not agree with these reasons and may disagree with our conclusions regarding the results of these trials.

Although we would work to be able to fully address any such FDA concerns, we may not be able to resolve all such matters favorably, if at all. Disputes that are not resolved favorably could result in one or more of the following: delays in our ability to submit an NDA;

the refusal by the FDA to accept for file any NDA we may submit;

requests for additional studies or data;

delays of an approval;

the rejection of an application; or

the approval of the drug, but with adverse labeling claims that could adversely affect the commercial market. S-8

#### **Table of Contents**

If we do not receive regulatory approval to sell our product candidates or cannot successfully commercialize our product candidates, we would not be able to generate meaningful levels of sustainable revenues.

The pharmaceutical industry is highly competitive and most of our competitors have larger operations 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, we expect that Zenvia will face competition from antidepressants, atypical anti-psychotic agents and other agents in the treatment of PBA and from a variety of pain medications and narcotic agents for the treatment of DPN pain.

Our competitors may have specific expertise and development technologies that are better than ours and many of these companies, which include large pharmaceutical companies, either alone or together with their research partners, have substantially greater financial resources, larger research and development capabilities and substantially greater experience than we do. Accordingly, our competitors may successfully develop competing products. We are also competing with other companies and their products with respect to manufacturing efficiencies and marketing capabilities, areas where we have limited or no direct experience.

If we fail to comply with regulatory requirements, regulatory agencies may take action against us, which could significantly harm our business.

Marketed products, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for these products, are subject to continual requirements and review by the FDA and other regulatory bodies. Even if we receive regulatory approval for one of our product candidates, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product.

In addition, regulatory authorities subject a marketed product, its manufacturer and the manufacturing facilities to ongoing review and periodic inspections. We will be subject to ongoing FDA requirements, including required submissions of safety and other post-market information and reports, registration requirements, current Good Manufacturing Practices ( cGMP ) regulations, requirements regarding the distribution of samples to physicians and recordkeeping requirements.

The cGMP regulations also include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. We rely on the compliance by our contract manufacturers with cGMP regulations and other regulatory requirements relating to the manufacture of products. We are also subject to state laws and registration requirements covering the distribution of our products. Regulatory agencies may change existing requirements or adopt new requirements or policies. We may be slow to adapt or may not be able to adapt to these changes or new requirements.

We rely on insurance companies to mitigate our exposure for business activities, including developing and marketing pharmaceutical products for human use.

The testing, marketing and sale of pharmaceutical products involves the risk of product liability claims by consumers and other third parties. Although we maintain product liability insurance coverage, product liability claims can be high in the pharmaceutical industry and our insurance may not sufficiently cover our actual liabilities. If product liability claims were made against us, it is possible that our insurance carriers may deny, or attempt to deny, coverage in certain instances. If a lawsuit against us 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 and the imposition of higher insurance requirements could

S-9

#### **Table of Contents**

impose additional costs on us. Additionally, we are potentially at risk if our insurance carriers become insolvent. Although we have historically obtained coverage through well rated and capitalized firms, the ongoing financial crisis may affect our ability to obtain coverage under existing policies or purchase insurance under new policies at reasonable rates.

#### **Risks Related to Reliance on Third Parties**

Because we depend on clinical research centers and other contractors for clinical testing and for certain research and development activities, the results of our clinical trials and such research activities are, to a certain extent, beyond our control.

The nature of clinical trials and our business strategy of outsourcing a substantial portion of our research require that we rely on clinical research centers and other contractors to assist us with research and development, clinical testing activities, patient enrollment and regulatory submissions to the FDA. As a result, our success depends partially on the success of these third parties in performing their responsibilities. Although we pre-qualify our contractors and we believe that they are fully capable of performing their contractual obligations, we cannot directly control the adequacy and timeliness of the resources and expertise that they apply to these activities. Additionally, the current global economic slowdown may affect our development partners and vendors, which could adversely affect our ability to complete our trials within projected time periods. If our contractors do not perform their obligations in an adequate and timely manner, the pace of clinical development, regulatory approval and commercialization of our drug candidates could be significantly delayed and our prospects could be adversely affected.

We depend on third parties to manufacture, package and distribute compounds for our drugs and drug candidates. 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, package and distribute Zenvia and the Active Pharmaceutical Ingredient (API) for docosanol 10% cream and to provide clinical supplies of our drug candidates. We have no experience in manufacturing and do not have any manufacturing facilities. Currently, we have sole suppliers for the API for docosanol and Zenvia, and a sole manufacturer for the finished form of Zenvia. In addition, these materials are custom and available from only a limited number of sources. Any material disruption in manufacturing could cause a delay in shipments and possible loss of sales. We do not have any long-term agreements in place with our current docosanol supplier or Zenvia supplier. If we are required to change manufacturers, we may experience delays associated with finding an alternate manufacturer that is properly qualified to produce supplies of our products and product candidates in accordance with FDA requirements and our specifications. Any delays or difficulties in obtaining APIs or in manufacturing, packaging or distributing Zenvia could delay our clinical trials of this product candidate for PBA and/or DPN pain. The third parties we rely on for manufacturing and packaging are also subject to regulatory review, and any regulatory compliance problems with these third parties could significantly delay or disrupt our commercialization activities. Additionally, the ongoing economic crisis creates risk for us if any of these third parties suffer liquidity or operational problems. If a key third party vendor becomes insolvent or is forced to lay off workers assisting with our projects, our results and development timing could suffer.

We generally do not control the development of compounds licensed to third parties and, as a result, we may not realize a significant portion of the potential value of any such license arrangements.

Under our license arrangement for our MIF compound, we have no direct control over the development of this drug candidate and have only limited, if any, input on the direction of development efforts. These development efforts are ongoing by our licensing partner and if the results of their development efforts are negative or inconclusive, it is possible that our licensing partner could elect to defer or abandon further development of these programs. We similarly rely on licensing partners to obtain regulatory approval for docosanol in foreign jurisdictions. Because much of the potential value of these license arrangements is contingent upon the successful development and commercialization of the licensed technology, the ultimate value of these licenses will depend on the efforts of licensing partners. If our licensing partners do not succeed in developing the licensed technology for whatever reason, or elect to discontinue the development of these programs, we may be unable to realize the potential value of these arrangements. If we were to license Zenvia to a third party or a development partner, it is likely that much of the long-term success of that drug will similarly depend on the efforts of the licensee.

#### **Table of Contents**

We expect to rely entirely on third parties for international registration, sales and marketing efforts.

In the event that we attempt to enter into international markets, we expect to rely on collaborative partners to obtain regulatory approvals and to market and sell our product(s) in those markets. We have not yet entered into any collaborative arrangement with respect to marketing or selling Zenvia, with the exception of one such agreement relating to Israel. We may be unable to enter into any other arrangements on terms favorable to us, or at all, and even if we are able to enter into sales and marketing arrangements with collaborative partners, we cannot assure you that their sales and marketing efforts will be successful. If we are unable to enter into favorable collaborative arrangements with respect to marketing or selling Zenvia in international markets, or if our collaborators efforts are unsuccessful, our ability to generate revenues from international product sales will suffer.

## **Risks Relating to Our Stock**

Our stock price has historically been volatile and we expect that this volatility will continue for the foreseeable future.

The market price of our common stock has been, and is likely to continue to be, highly volatile. This volatility can be attributed to many factors independent of our operating results, including the following:

announcements by us regarding our non-compliance with continued listing standards on the NASDAQ Stock Market:

comments made by securities analysts, including changes in their recommendations;

short selling activity by certain investors, including any failures to timely settle short sale transactions;

announcements by us of financing transactions, including the facility to which this prospectus supplement relates, and/or future sales of equity or debt securities;

sales of our common stock by our directors, officers or significant stockholders;

lack of volume of stock trading leading to low liquidity; and

market and economic conditions.

If a substantial number of shares is sold into the market at any given time, particularly following any significant announcements or large swings in our stock price (whether sales are through the Controlled Equity Offering facility or from an existing stockholder), there may not be sufficient demand in the market to purchase the shares without a decline in the market price for our common stock. Moreover, continuous sales into the market of a number of shares in excess of the typical trading volume for our common stock, or even the availability of such a large number of shares, could depress the trading market for our common stock over an extended period of time.

Additionally, our stock price has been volatile as a result of announcements of regulatory actions and decisions relating to our product candidates, including Zenvia, and periodic variations in our operating results. We expect that our operating results will continue to vary from quarter-to-quarter. Our operating results and prospects may also vary depending on the status of our partnering arrangements.

As a result of these factors, we expect that our stock price may continue to be volatile and investors may be unable to sell their shares at a price equal to, or above, the price paid. Additionally, any significant drops in our stock price, such as the one we experienced following the announcement of the Zenvia approvable letter, could give rise to stockholder lawsuits, which are costly and time consuming to defend against and which may adversely affect our ability to raise capital while the suits are pending, even if the suits are ultimately resolved in favor of the Company.

S-11

#### **Table of Contents**

The trading price for our common stock has been volatile and we have previously had difficulty satisfying the continued listing standards for the NASDAQ Global Market.

Our common stock is currently listed on the NASDAQ Global Market. On June 3, 2009 we regained compliance with the \$1.00 minimum bid price requirement for continued listing on the NASDAQ Global Market. If we fail to comply with the \$1.00 minimum bid price requirement for continued listing, we will be given an initial cure period of 180 calendar days to regain compliance. If we fail to comply with the listing standards following the initial cure period, our common stock listing may be moved to the NASDAQ Capital Market, which is a lower tier market, or our common stock may be delisted and traded on the over-the-counter bulletin board network. Moving our listing to the NASDAQ Capital Market could adversely affect the liquidity of our common stock and the delisting of our common stock would significantly affect the ability of investors to trade our securities and could significantly negatively affect the value of our common stock. In addition, the delisting of our common stock could further depress our stock price and materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Delisting from NASDAQ could also have other negative results, including the potential loss of confidence by suppliers and employees, the loss of institutional investor interest and fewer business development opportunities.

### **USE OF PROCEEDS**

We anticipate using the net proceeds from the sale of our securities offered by this prospectus supplement for general working capital. 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.

## **DILUTION**

Our pro forma net tangible book value as of June 30, 2009 was approximately \$15.2 million, or \$0.19 per share of 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 common stock outstanding. After giving effect to the sale by us of the full 12,500,000 shares of common stock that may be offered in this offering at an assumed offering price of \$2.35 per share, which is the closing price of our common stock on the NASDAQ Global Market as of July 29, 2009, and after deducting estimated offering commissions and expenses payable by us, our pro forma, as-adjusted net tangible book value as of June 30, 2009 would have been approximately \$43.5 million, or \$0.48 per share of common stock. This represents an immediate increase in the pro forma net tangible book value of \$0.29 per share to our existing shareholders and an immediate and substantial dilution in pro forma net tangible book value of \$1.87 per share to new investors. The following table illustrates this hypothetical per share dilution:

Assumed offering price per share	\$2.35
Pro forma net tangible book value per share as of June 30, 2009	\$0.19
Increase per share attributable to new investors	\$0.29
Pro forma, as-adjusted net tangible book value per share after this offering	\$0.48
Dilution per share to new investors	\$1.87

The foregoing dilution information assumes an offering price equal to the closing price for our common stock as of the date of this prospectus supplement. The actual price at which we sell shares in this offering may be higher or lower than this assumed price. For each \$1.00 increase or decrease in the assumed offering price, the per-share dilution would be \$0.87 more and \$0.87 less, respectively, than the figures in the above table.

S-12

#### PLAN OF DISTRIBUTION

We have entered into a Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co. ( Cantor ) under which we may issue and sell up to 12,500,000 shares of our common shares from time to time through Cantor acting as agent and/or principal, with gross offering proceeds of up to \$35,000,000. The form of the sales agreement will be filed as an exhibit to a report filed under the Exchange Act and incorporated by reference in this prospectus supplement. The sales, if any, of shares made under the sales agreement will be made on the NASDAQ Global Market by means of ordinary brokers—transactions at market prices, in block transactions or as otherwise agreed by Cantor and us. We may instruct Cantor not to sell common stock if the sales cannot be effected at or above the price designated by us from time to time. We or Cantor may suspend the offering of common stock upon notice and subject to other conditions. As an agent, Cantor will not engage in any transactions that stabilize the price of our common shares.

We will pay Cantor commissions for its services in acting as agent in the sale of common stock. Cantor will be entitled to compensation at a fixed commission rate of 4.0% of the gross sales price per share sold, up to aggregate gross proceeds of \$10 million, and, thereafter, at a fixed commission rate of 3.0% of the gross sales price per share sold. We estimate that the total expenses for the offering, excluding compensation payable to Cantor under the terms of the sales agreement, will be approximately \$100,000, which includes certain expense reimbursements payable to Cantor.

Settlement for sales of common stock will occur on the third business day following the date on which any sales are made, or on some other date that is agreed upon by us and Cantor in connection with a particular transaction, in return for payment of the net proceeds to us. There is no arrangement for funds to be received in an escrow, trust or similar arrangement.

Cantor will act as sales agents on a reasonable efforts basis. In connection with the sale of the common stock on our behalf, Cantor may, and will with respect to sales effected in an at the market offering, be deemed to be an underwriter within the meaning of the Securities Act of 1933, as amended (the Securities Act ) and the compensation of Cantor may be deemed to be underwriting commissions or discounts. We have agreed to provide indemnification and contribution to Cantor against certain civil liabilities, including liabilities under the Securities Act. We have also agreed to reimburse Cantor for certain other specified expenses.

The offering pursuant to the sales agreement will terminate upon the earlier of (i) the sale of all common shares subject to the agreement, or (ii) termination of the sales agreement as permitted therein.

Cantor and its affiliates may in the future provide various investment banking, commercial banking and other financial services for us and our affiliates, for which services they may in the future receive customary fees. To the extent required by Regulation M, Cantor will not engage in any market making activities involving our common stock while the offering is ongoing under this prospectus supplement.

Pursuant to an agreement with Cantor, Trout Capital LLC will be entitled to receive compensation from Cantor of up to 20.0% of the net discount and fees paid to Cantor in accordance with the terms of the Sales Agreement. Although Trout Capital LLC, a member of the Financial Industry Regulatory Authority (FINRA), is not offering or selling common shares on our behalf pursuant to this prospectus supplement, the fee received by Trout Capital LLC pursuant to the agreement may be deemed by FINRA to be compensation received by a FINRA member in connection with the offering. Outside of the aforementioned agreement with Cantor, Trout Capital LLC has no other relationship with Cantor.

\* \* \*

S-13

#### **PROSPECTUS**

## \$35,000,000 AVANIR Pharmaceuticals, Inc.

Common Stock Preferred Stock Debt Securities Warrants

We may offer and sell an indeterminate number of shares of our common stock and preferred stock, debt securities and warrants from time to time under this prospectus. We may offer these securities separately or as units, which may include combinations of the securities. We will describe in a prospectus supplement the securities we are offering and selling, as well as the specific terms of the securities.

We may offer these securities in amounts, at prices and on terms determined at the time of offering. We may sell the securities directly to you, through agents we select, or through underwriters and dealers we select. If we use agents, underwriters or dealers to sell the securities, we will name them and describe their compensation in a prospectus supplement.

Our common stock trades on the NASDAQ Global Market under the symbol AVNR. On April 17, 2009, the closing price for our common stock, as reported on the NASDAQ Global Market, was \$0.58 per share.

Investing in our securities involves certain risks. See Risk Factors beginning on Page 3 of this prospectus and in the applicable prospectus supplement for certain 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 May 6, 2009

## **Table of Contents**

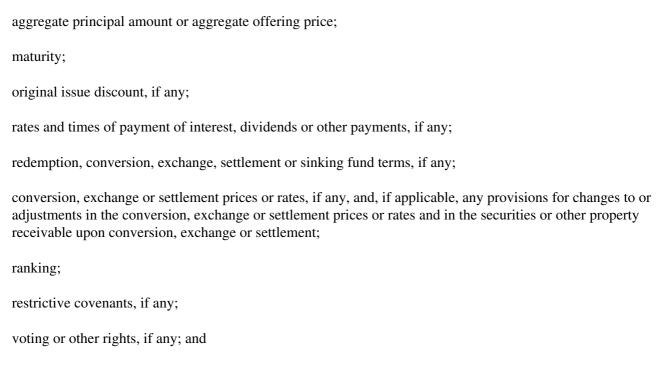
## **TABLE OF CONTENTS**

	Page
About This Prospectus	1
About Avanir Pharmaceuticals, Inc.	3
Risk Factors	3
Note Regarding Forward Looking Statements	3
<u>Description of Securities</u>	4
<u>Use of Proceeds</u>	4
Ratio of Earnings to Fixed Charges	4
Plan of Distribution	5
<u>Legal Matters</u>	6
<u>Experts</u>	6
Incorporation of Certain Information by Reference	6
Where You Can Find More Information	7

#### ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission (SEC), utilizing a shelf registration process. Under the shelf registration process, we may offer shares of our common stock and preferred stock, various series of debt securities and warrants to purchase any of such securities with a total value of up to \$35,000,000 from time to time under this prospectus at prices and on terms to be determined by market conditions at the time of offering. This prospectus provides you with a general description of the securities we may offer. Each time we offer a type or series of securities, we will provide a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities, including, to the extent applicable:

designation or classification;



important federal income tax considerations.

A prospectus supplement may include a discussion of risks or other special considerations applicable to us or the offered securities. A prospectus supplement may also add, update or change information in this prospectus. If there is any inconsistency between the information in this prospectus and the applicable prospectus supplement, you must rely on the information in the prospectus supplement. Please carefully read both this prospectus and the applicable prospectus supplement together with additional information described under the heading Where You Can Find More Information. This prospectus may not be used to offer or sell any securities unless accompanied by a prospectus supplement.

The registration statement containing this prospectus, including exhibits to the registration statement, provides additional information about us and the common stock offered under this prospectus. The registration statement can be read at the SEC website or at the SEC s public reading room 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 securities, nor do this prospectus and the accompanying supplement to this prospectus constitute an offer to sell or the solicitation of an offer to buy securities 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,

1

#### **Table of Contents**

financial condition, results of operations and prospects even though this prospectus and any accompanying prospectus supplement is delivered or securities are sold on a later date.

We may sell the securities directly to or through underwriters, dealers or agents. We, and our underwriters or agents, reserve the right to accept or reject all or part of any proposed purchase of securities. If we do offer securities through underwriters or agents, we will include in the applicable prospectus supplement:

the names of those underwriters or agents;

applicable fees, discounts and commissions to be paid to them;

details regarding over-allotment options, if any; and

the net proceeds to us.

Common Stock. We may issue shares of our common stock from time to time. Holders of our common stock are entitled to one vote per share for the election of directors and on all other matters that require stockholder approval. Subject to any preferential rights of any outstanding preferred stock, in the event of our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in the assets remaining after payment of liabilities and the liquidation preferences of any outstanding preferred stock. Our common stock does not carry any redemption rights or any preemptive rights enabling a holder to subscribe for, or receive shares of, any class of our common stock or any other securities convertible into shares of any class of our common stock.

**Preferred Stock.** We may issue shares of our preferred stock from time to time, in one or more series. Under our certificate of incorporation, our board of directors has the authority, without further action by stockholders, to designate up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges, qualifications and restrictions granted to or imposed upon the preferred stock, including dividend rights, conversion rights, voting rights, rights and terms of redemption, liquidation preference and sinking fund terms, any or all of which may be greater than the rights of the common stock.

If we issue preferred stock, we will fix the rights, preferences, privileges, qualifications and restrictions of the preferred stock of each series that we sell under this prospectus and applicable prospectus supplements in the certificate of designations relating to that series. If we issue preferred stock, we will incorporate by reference into the registration statement of which this prospectus is a part the form of any certificate of designations that describes the terms of the series of preferred stock we are offering before the issuance of the related series of preferred stock. We urge you to read the prospectus supplement related to any series of preferred stock we may offer, as well as the complete certificate of designations that contains the terms of the applicable series of preferred stock.

**Debt Securities**. We may issue debt securities from time to time, in one or more series, as either senior or subordinated debt or as senior or subordinated convertible debt. The senior debt securities will rank equally with any other unsubordinated debt that we may have and may be secured or unsecured. The subordinated debt securities will be subordinate and junior in right of payment, to the extent and in the manner described in the instrument governing the debt, to all or some portion of our indebtedness. Any convertible debt securities that we issue will be convertible into or exchangeable for our common stock or other securities of ours. Conversion may be mandatory or at your option and would be at prescribed conversion rates.

If we issue debt securities, they will be issued under one or more documents called indentures, which are contracts between us and a trustee for the holders of the debt securities. We urge you to read the prospectus supplement related to the series of debt securities being offered, as well as the complete indenture that contains the terms of the debt securities (which will include a supplemental indenture). If we issue debt securities, indentures and forms of debt securities containing the terms of debt securities being offered will be incorporated by reference into the registration statement of which this prospectus is a part from reports we would subsequently file with the SEC.

*Warrants*. We may issue warrants for the purchase of common stock, preferred stock and/or debt securities in one or more series, from time to time. We may issue warrants independently or together with common stock, preferred stock and/or debt securities, and the warrants may be attached to or separate from those securities.

## **Table of Contents**

If we issue warrants, they will be evidenced by warrant agreements or warrant certificates issued under one or more warrant agreements, which are contracts between us and an agent for the holders of the warrants. We urge you to read the prospectus supplement related to any series of warrants we may offer, as well as the complete warrant agreement and warrant certificate that contain the terms of the warrants. If we issue warrants, forms of warrant agreements and warrant certificates relating to warrants for the purchase of common stock, preferred stock and debt securities will be incorporated by reference into the registration statement of which this prospectus is a part from reports we would subsequently file with the SEC.

## ABOUT AVANIR PHARMACEUTICALS, INC.

Avanir Pharmaceuticals, Inc., a Delaware corporation originally incorporated in California in August 1988 and reincorporated in Delaware in March 2009, is a pharmaceutical company focused on developing, acquiring and commercializing novel therapeutic products for the treatment of chronic diseases. Our product candidates address therapeutic markets that include the central nervous system and inflammatory diseases. Our lead product candidate, Zenvia<sup>tm</sup> (dextromethorphan hydrobromide/quinidine sulfate), is currently in Phase III clinical development for the treatment of pseudobulbar affect (PBA) and diabetic peripheral neuropathic pain (DPN pain). Our first commercialized product, docosanol 10% cream, (sold as Abreva® by our marketing partner GlaxoSmithKline Consumer Healthcare in North America) is the only over-the-counter treatment for cold sores that has been approved by the FDA. Our inflammatory disease program, which targets macrophage migration inhibitory factor (MIF), is currently partnered with Novartis. Our infectious disease program has historically been focused primarily on monoclonal antibodies. In 2008, we sold our rights to substantially all of these monoclonal antibodies to two biotechnology companies. As of June 30, 2008, we ceased all future research and development work related to our infectious disease program and remain eligible to receive additional milestone payments and royalties related to the program.

For additional information about our company, please refer to other documents we have filed with the SEC and that are incorporated by reference into this prospectus, as listed under the heading Incorporation of Certain Information by Reference.

Our offices are located at 101 Enterprise, Suite 300, Aliso Viejo, California 92656. Our telephone number is (949) 389-6700 and our e-mail address is info@avanir.com. Additional information about Avanir can be found on our website, at <a href="www.avanir.com">www.avanir.com</a>, and in our periodic and current reports filed with the SEC. Copies of our current and periodic reports filed with the SEC are available at the SEC Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549, and online at <a href="www.sec.gov">www.sec.gov</a> and our website at <a href="www.avanir.com">www.avanir.com</a>. No portion of our website is incorporated by reference into this prospectus.

#### **RISK FACTORS**

Before making an investment decision, you should carefully consider the risks described under Risk Factors in the applicable prospectus supplement, together with all of the other information appearing in this prospectus or incorporated by reference into this prospectus and any applicable prospectus supplement, in light of your particular investment objectives and financial circumstances. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. The trading price of our securities could decline due to any of these risks, and you may lose all or part of your investment. This prospectus and the incorporated documents also contain forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks mentioned above.

## NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains or incorporates by reference forward-looking statements and readers are cautioned that our actual results may differ materially from those discussed in the forward-looking statements. These forward-looking statements include, without limitation, statements regarding the progress and timing of clinical trials, the safety and efficacy of our product candidates, the goals of our development activities, estimates of the potential markets for our product candidates, projected cash needs and our expected future revenues, operations and expenditures. These statements relate to future events or our future financial performance and involve known and

#### **Table of Contents**

unknown risks, uncertainties and other factors that could cause our actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements. These risks and uncertainties include, among others:

risks relating to the uncertainty around the conduct of clinical trials generally and, more specifically, around our ongoing and future clinical trials for Zenvia for both PBA and DPN pain;

risks of delay in meeting our development plans, including delays in patient enrollment in our clinical trials;

risks relating to our lack of profitability, our significant historical operating losses and our ability to obtain additional funding to continue to operate our business, which funding may not be available on commercially reasonable terms, or at all;

risks relating to our patent portfolio and the patent portfolios of competitors;

risks relating to turnover in senior management and our reliance on key employees;

risks around our reliance on third parties to conduct our clinical trials and manufacture our product candidates; and

competitive risks in our industry.

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, including under the caption, Risk Factors. 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 disclaim any intent to update any forward-looking statements.

#### **DESCRIPTION OF SECURITIES**

We may offer shares of our common stock and preferred stock, various series of debt securities and warrants to purchase any such securities with a total value of up to \$35,000,000 from time to time under this prospectus at prices and on terms to be determined by market conditions at the time of offering. Each time we offer a type or series of securities, we will provide a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities.

#### **USE OF PROCEEDS**

We will retain broad discretion over the use of the net proceeds from the sale of our securities offered hereby. Except as described in any prospectus supplement, we currently anticipate using the net proceeds from the sale of our securities hereby primarily to fund the development and commercialization of Zenvia for PBA and DPN pain, for our ongoing and future clinical trials and for general and administrative expenses. We may also use a portion of the net proceeds to pay off outstanding indebtedness and/or 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.

## RATIO OF EARNINGS TO FIXED CHARGES

If we offer debt securities and/or preference equity securities under this prospectus, then we will, at that time, provide a ratio of earnings to fixed charges and/or ratio of combined fixed charges and preference dividends to earnings, respectively, in the applicable prospectus supplement for such offering.

4

#### **Table of Contents**

#### PLAN OF DISTRIBUTION

We may sell the securities covered by this prospectus from time to time in one or more offerings. Registration of the securities covered by this prospectus does not mean, however, that those securities will necessarily be offered or sold.

We may sell the securities separately or together:

through one or more underwriters or dealers in a public offering and sale by them;

directly to investors; or

through agents.

We may sell the securities 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 securities and the terms of the offering in the prospectus supplement.

Any discounts or concessions allowed or re-allowed or paid to dealers may be changed from time to time.

If underwriters are used in the sale of any securities, the securities will be acquired by the underwriters for their own account and may be resold from time to time in one or more transactions described above. The securities may be either offered to the public through underwriting syndicates represented by managing underwriters, or directly by underwriters. Generally, the underwriters obligations to purchase the securities will be subject to conditions precedent and the underwriters will be obligated to purchase all of the securities if they purchase any of the securities. We may use underwriters with whom we have a material relationship. We will describe in the prospectus supplement, naming the underwriter, the nature of any such relationship.

We may authorize underwriters, dealers or agents to solicit offers by certain purchasers to purchase the securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. The contracts will be subject only to those conditions set forth in the prospectus supplement, and the prospectus supplement will set forth any commissions we pay for solicitation of these contracts.

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

Underwriters, dealers and agents may be entitled to indemnification by us against certain civil liabilities, including liabilities under the Securities Act, or to contribution with respect to payments made by the underwriters, dealers or agents, under agreements between us and the underwriters, dealers and agents.

\_

#### **Table of Contents**

We may grant underwriters who participate in the distribution of securities an option to purchase additional securities to cover over-allotments, if any, in connection with the distribution.

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 securities. These underwriters, dealers or agents may be considered to be underwriters under the Securities Act. As a result, discounts, commissions or profits on resale received by the underwriters, dealers or agents may be treated as underwriting discounts and commissions. The 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 re-allowed or paid to dealers may be changed from time to time.

Unless otherwise specified in the related prospectus supplement, all securities we offer, other than common stock, will be new issues of securities with no established trading market. Any underwriters may make a market in these securities, but will not be obligated to do so and may discontinue any market making at any time without notice. Any common stock sold pursuant to a prospectus supplement will be listed for trading on the NASDAQ Stock Market or other principal market for our common stock. We may apply to list any series of debt securities, preferred stock or warrants on an exchange, but we are not obligated to do so. Therefore, there may not be liquidity or a trading market for any series of securities.

Any underwriter may engage in over-allotment transactions, stabilizing transactions, short-covering transactions and penalty bids in accordance with Regulation M under the Exchange Act. Over-allotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Short covering transactions involve purchases of the securities in the open market after the distribution is completed to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the securities originally sold by the dealer are purchased in a covering transaction to cover short positions. Those activities may cause the price of the securities to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time. We make no representation or prediction as to the direction or magnitude of any effect that such transactions may have on the price of the securities. For a description of these activities, see the information under the heading Underwriting or Plan of Distribution in the applicable prospectus supplement.

Underwriters, broker-dealers or agents who may become involved in the sale of the common stock may engage in transactions with and perform other services for us in the ordinary course of their business for which they receive compensation.

#### **LEGAL MATTERS**

The legality of the issuance of the securities being offered hereby and the binding nature of any debt securities or warrants being offered hereby is being passed upon by Goodwin Procter LLP, San Francisco, California.

## **EXPERTS**

The consolidated financial statements incorporated in this prospectus by reference from Avanir Pharmaceuticals, Inc. s predecessor California corporation s Annual Report on Form 10-K for the year ended September 30, 2008 have been audited by KMJ Corbin & Company LLP, independent registered public accounting firm, 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.

## 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 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 that 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

Table of Contents

33

#### **Table of Contents**

incorporate by reference the documents listed below which have been filed by us or our predecessor California corporation (the Predecessor Registrant ) 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 Predecessor Registrant s Annual Report on Form 10-K for the year ended September 30, 2008, as amended;
- 2. Our Predecessor Registrant s Definitive Proxy Statement on Schedule 14A filed with the SEC on January 9, 2009:
- 3. Our Predecessor Registrant s Quarterly Report on Form 10-Q for the period ended December 31, 2008;
- 4. Our Predecessor Registrant s Current Reports on Form 8-K filed with the SEC on November 12, 2008 and February 25, 2009 and our Current Reports on Form 8-K filed with the SEC on March 25, 2009 and April 2, 2009; and
- 5. The description of our common stock contained in our registration statement on Form 8-A/A (File No. 001-15803) filed with the SEC on March 25, 2009, including any amendment or report filed for the purpose of updating such description.

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, Inc., 101 Enterprise, Suite 300, Aliso Viejo, California 92656, Attention: Investor Relations, telephone: (949) 389-6700. 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 <a href="https://www.sec.gov">www.sec.gov</a>, as well as at our website at <a href="https://www.sec.gov">www.sec.gov</a>, as well as at our website at <a href="https://www.sec.gov">www.sec.gov</a>, as well as at our website at <a href="https://www.sec.gov">www.sec.gov</a>, as well as at our website at <a href="https://www.sec.gov">www.sec.gov</a>, as well as at our website at <a href="https://www.sec.gov">www.sec.gov</a>, as well as at our website at <a href="https://www.sec.gov">www.sec.gov</a>, as well as at our website at <a href="https://www.sec.gov">www.sec.gov</a>, as well as at our website at <a href="https://www.sec.gov">www.sec.gov</a>, as well as at our website at <a href="https://www.sec.gov">www.sec.gov</a>, as well as at our website at <a href="https://www.sec.gov">www.sec.gov</a>, as well as at our website at <a href="https://www.sec.gov">www.sec.gov</a>, as well as at our website at <a href="https://www.sec.gov">www.sec.gov</a>, as well as at our website at <a href="https://www.sec.gov">www.sec.gov</a>, as well as at our website at <a href="https://www.sec.gov">www.sec.gov</a>, as well as at our website at <a href="https://www.sec.gov">www.sec.gov</a>, as well as at our website at <a href="https://www.sec.gov">www.sec.gov</a>, as well as at our website at <a href="https://www.sec.gov">www.sec.gov</a>, as well as at our website at <a href="https://www.sec.gov">www.sec.gov</a>, as well as at our website at <a href="https://www.sec.gov">www.sec.gov</a>, as well as at our website at <a href="https://www.sec.gov">www.sec.gov</a>, as well as at our website at <a href="https://www.sec.gov">www.sec.gov</a>, as well as at our website at <a href="https://www.sec.gov">www.sec.gov</a>, as well as at our websi

\* \* \*

7