AVANIR PHARMACEUTICALS, INC. Form 424B5 September 22, 2014 <u>Table of Contents</u>

#### Filed Pursuant to Rule 424(b)(5) Registration No. 333-198878

The information in this preliminary prospectus supplement is not complete and may be changed. This preliminary prospectus supplement and the accompanying prospectus do not constitute an offer to sell these securities and we are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

#### SUBJECT TO COMPLETION, DATED SEPTEMBER 22, 2014

#### **PROSPECTUS SUPPLEMENT**

(To Prospectus dated September 22, 2014)

#### \$200,000,000

#### **Common Stock**

We are offering shares of our common stock. Our common stock trades on The NASDAQ Global Market under the symbol AVNR. On September 19, 2014, the last reported sale price of our common stock on the NASDAQ Global Market was \$11.04 per share.

Investing in our common stock involves a high degree of risk. See <u>Risk Factors</u> beginning on Page S-10 of this prospectus supplement, as well as the section captioned Item 1A Risk Factors in our most recently filed annual report on Form 10-K or subsequently filed quarterly report on Form 10-Q which are incorporated by reference into this prospectus supplement, for certain risks you should consider. You should read the entire prospectus and the documents incorporate by reference 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 and the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	PER SHARE	TOTAL
Public Offering Price	\$	\$
Underwriting Discounts and Commissions <sup>(1)</sup>	\$	\$
Proceeds to Avanir Pharmaceuticals, Inc., Before Expenses	\$	\$

(1) See Underwriting for additional disclosure regarding underwriting discounts, commissions and estimated offering expenses.

Delivery of the shares of common stock is expected to be made on or about underwriters an option for a period of 30 days to purchase up to an additional . We have granted the shares of our common stock. If

the underwriters exercise the option in full, the total underwriting discount payable by us will be \$ and the total proceeds to us, before expenses, will be \$

Joint Book-Running Managers

#### J.P. Morgan Deutsche Bank Securities BofA Merrill Lynch

Prospectus Supplement dated September , 2014.

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#### NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements in this prospectus supplement and the documents incorporated herein by reference that are not historical facts are hereby identified as forward-looking statements for the purpose of the safe harbor provided by Section 21E of the Exchange Act and Section 27A of the Securities Act. Readers are cautioned that our actual results may differ materially from those discussed in the forward-looking statements. Terms such as intend, estimate, anticipate, b plan, goal and expect and similar expressions as they relate to us identify forward-looking statements. These forward-looking statements include, without limitation, statements regarding sales of NUEDEXTA, the safety and efficacy of NUEDEXTA and our product candidates, including AVP-923 and AVP-786, the goals of our development activities, estimates of the potential markets for NUEDEXTA and our product candidates, projected cash needs and our expected future cash, revenues, operations and expenditures. These statements relate to future events or our future financial performance and involve known and 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 that we may not become profitable as a result of the commercialization of NUEDEXTA;

risks relating to our ability to raise PBA awareness among patients and physicians;

risks that we may not be able to obtain reimbursement and third-party payor coverage;

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 estimates of the potential market size of PBA;

risks relating to the occurrence of adverse safety events with NUEDEXTA;

risks relating to our ability to build or maintain the necessary sales, marketing and supply chain management capabilities for NUEDEXTA;

risks relating to our patent portfolio, including our core patents covering NUEDEXTA, which are currently being challenged by generic drug companies;

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

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risks relating to our loan agreement with Oxford Finance and Silicon Valley Bank, which contains certain covenants that could adversely affect our operations;

risks relating to our ability to conduct clinical trials and receive approval for additional indications for AVP-923 and for approval of NUEDEXTA in Europe;

risks around our reliance on third parties to conduct our clinical trials and manufacture and distribute 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 supplement and incorporated herein by reference. 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.

#### 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 of 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.

#### **PROSPECTUS SUMMARY**

#### **Our Company**

We are a biopharmaceutical company focused on acquiring, developing and commercializing novel therapeutic products for the treatment of central nervous system disorders. Our lead product, NUEDEXTA® (referred to as AVP-923 during clinical development) is a first-in-class dual *N-methyl-D-aspartate* (NMDA) receptor antagonist and sigma-1 agonist. NUEDEXTA 20/10mg (dextromethorphan hydrobromide 20 mg/quinidine sulfate 10 mg) is approved in the United States for the treatment of pseudobulbar affect (PBA). It is also approved for the symptomatic treatment of PBA in the European Union in two dose strengths, NUEDEXTA 20/10 mg and NUEDEXTA 30/10 mg. We commercially launched NUEDEXTA in the United States in February 2011 and we are currently assessing plans regarding the potential commercialization of NUEDEXTA in the European Union.

We are studying the clinical utility of AVP-923 in other mood/behavior disorders and movement disorders, including the potential treatment of agitation in patients with Alzheimer's disease and the potential treatment of levodopa-induced dyskinesia in Parkinson's disease (LID). Our Phase II LID study is supported by a grant from the Michael J. Fox Foundation. Our Phase II study of agitation in Alzheimer's disease was recently completed and, on September 15, 2014, we announced positive results for this study (see AVP-923 for the Treatment of Agitation in Patients with Alzheimer's Disease, below).

We are also developing AVP-786, a next generation drug product containing deuterium-modified dextromethorphan and quinidine for the potential treatment of neurologic and psychiatric disorders. We completed pharmacokinetic studies with AVP-786 and, based on these data, we believe that we have identified a formulation of AVP-786 to move forward into clinical studies. This AVP-786 formulation contains significantly less quinidine than used in AVP-923. In June 2013, the U.S. Food and Drug Administration (FDA) agreed to an expedited development pathway for AVP-786, requiring only a limited non-clinical package as part of the Investigational New Drug (IND) application. We initiated a Phase 2 study for AVP-786 as an adjunctive therapy to antidepressants for the treatment of Major Depressive Disorder (MDD) during August 2014.

We are also developing a novel Breath Powered intranasal delivery system containing low-dose sumatriptan powder for the acute treatment of migraine, AVP-825. If approved, this product would be the first and only fast-acting dry-powder nasal delivery form of sumatriptan. AVP-825 is licensed from OptiNose AS (OptiNose). Under the terms of the agreement, we assumed responsibility for regulatory, manufacturing, supply-chain and commercialization activities for the investigational product. In March 2014, the FDA accepted our New Drug Application (NDA) of AVP-825 and the Prescription Drug User Fee Act (PDUFA) date is November 26, 2014.

We entered into a multi-year agreement with Merck Sharp & Dohme Corp. (Merck) to co-promote Merck s type 2 diabetes therapies JANUVIA® (sitagliptin) and the sitagliptin family of products in the long-term care institutional setting in the United States beginning October 1, 2013. The term of the agreement will continue for three years following the launch date of the co-promotion activities, unless terminated earlier pursuant to the terms of the agreement. Under the terms of the agreement, we will be compensated via a (i) fixed monthly fee and (ii) performance fee based on the amount of the products sold by us above a predetermined baseline. A significant majority of the fee is performance-based. Over the three years of the agreement, Avanir could receive up to \$50.0 million in compensation, including revenue earned in the first contract year.

We have developed and licensed certain intellectual property rights relating to NUEDEXTA and our existing drug candidates (AVP-923, AVP-786 and AVP-825) and we continue to actively seek to acquire rights to other complementary products and technologies, particularly following our successful defense of the patents underlying

NUEDEXTA. As a result, we intend to seek to in-license or acquire through other means, such as mergers, stock purchases or asset purchases, complementary products and technologies, as well as sales and marketing infrastructure and other assets or resources. There can be no assurance, however, that we will be successful in acquiring any additional assets, or that we will receive the anticipated benefits of any such acquisitions.

The following chart illustrates the status of research and development activities for our products and product candidates that are commercialized or under development.

In addition to the research and development programs identified above, Avanir has provided unrestricted research grants to support several investigator-initiated studies with AVP-923. Current studies planned or ongoing include potential treatment of behavioral symptoms of adults with autism spectrum disorder, potential treatment of bulbar function (impaired speech, swallowing, and saliva control) associated with amyotrophic lateral sclerosis ( ALS ) and potential treatment of treatment resistant-depression.

#### NUEDEXTA for the Treatment of Pseudobulbar Affect

NUEDEXTA is the first and only FDA and European Medicines Agency (EMA)-approved treatment for PBA. PBA occurs secondary to a variety of otherwise unrelated neurological conditions, and is characterized by involuntary, sudden, and frequent episodes of laughing and/or crying. PBA episodes typically occur out of proportion or incongruent to the patient s underlying emotional state.

NUEDEXTA is an innovative combination of two well-characterized components: dextromethorphan hydrobromide, the ingredient that is pharmacologically active in the central nervous system, and quinidine sulfate, a metabolic inhibitor enabling dextromethorphan to reach therapeutic plasma concentrations. NUEDEXTA acts on sigma-1 and NMDA receptors in the brain, although the mechanism by which NUEDEXTA exerts therapeutic effects in patients with PBA is unknown.

Studies to support the effectiveness of NUEDEXTA were performed in patients with PBA and underlying ALS and Multiple Sclerosis (MS). The primary outcome measure, the number of laughing and crying episodes, was significantly lower in the NUEDEXTA cohort compared with placebo. The secondary outcome measure, the Center for Neurologic Studies Lability Scale (CNS-LS), demonstrated a significantly greater mean decrease in CNS-LS score from baseline for the NUEDEXTA cohort compared with placebo. NUEDEXTA has not been studied in other types of emotional lability that can commonly occur, for example, in Alzheimer s disease and other dementias.

A copy of the NUEDEXTA safety information has been filed with our Annual Report on Form 10-K for the year ended September 30, 2013.

We launched NUEDEXTA in the United States in February 2011 with a specialty sales force calling primarily on physicians that care for patients where PBA is most commonly observed. This includes patients with underlying MS, ALS, Parkinson s disease (PD), Alzheimer s disease, traumatic brain injury and stroke. Our commercial efforts focus on the outpatient setting where patients typically receive prescription medications through retail and mail-order pharmacies and the institutional setting where patients typically receive prescription medications through an institutional pharmacy.

The table below shows total net product sales and dispensed units (capsules) for NUEDEXTA during the past four quarterly periods.

	Three Months Ended September 30, December 31, March 31, June 30,			
	2013	2013	2014	2014
Net product sales	\$20,233,418	\$ 23,299,027	\$24,379,159	\$26,540,131
Percentage growth over same quarter in the previous year	63 %	57 %	47 %	39 %
Total dispensed units (capsules)	2,568,626	2,798,569	2,868,468	3,039,450
Percentage growth over same quarter in the previous year A VP 923 for the Treatment of Agita	62 %	62 %	56 %	30 %

AVP-923 for the Treatment of Agitation in Patients with Alzheimer s Disease

Alzheimer s disease is generally characterized by cognitive decline, impaired performance of daily activities, and behavioral disturbances. Behavioral and psychiatric symptoms develop in as many as 60% of community-dwelling dementia patients and in more than 80% of patients with dementia living in nursing homes; as the disease progresses the risk of such complications approaches 100%. Dementia-related behavioral symptoms, including agitation, can be extremely distressing to the individual, the family, and caregivers. These behavioral disturbances have been associated with more rapid cognitive decline, institutionalization, and increased caregiver burden.

On September 15, 2014, Avanir announced positive results from a Phase II clinical study of AVP-923 in the treatment of agitation in Alzheimer's patients. The objectives of this proof-of-concept study were to evaluate the safety, tolerability, and efficacy of AVP-923 for the treatment of agitation in Alzheimer's patients. The trial was a multicenter, randomized, double-blind, placebo-controlled study that enrolled approximately 220 Alzheimer's patients in the United States utilizing a Sequential Parallel Comparison Design (SPCD) intended to reduce placebo response rates. Eligible patients were initially randomized 3:4 to receive either AVP-923 (dose escalated from DM 20mg/Q 10mg to DM 30mg/Q 10mg) or placebo. At the end of week five, patients who initially received placebo were stratified according to their response to treatment and subsequently re-randomized 1:1 to receive either AVP-923 or placebo for the remainder of the study (an additional five weeks of treatment). The primary efficacy measure was the agitation/aggression domain of the Neuropsychiatric Inventory (NPI). The primary endpoint follows a standard analysis of SPCD by combining the change from baseline to week five (stage 1: full analysis population) and change from week five to week ten (stage 2) on the NPI agitation/aggression domain (patients who were considered

non-responders to placebo during the initial five weeks). Secondary outcome measures include global assessments of disease severity, other neuropsychiatric symptoms, cognition, activities of daily living, quality of life and caregiver strain.

Treatment with AVP-923 was associated with significantly reduced agitation as measured by the primary endpoint, the agitation/aggression domain score of the NPI compared to placebo (p=0.00008). The reduction in agitation was observed in both stage 1 (p=0.0002) and stage 2 (p=0.021) of the SPCD. In addition, improvements were also seen in secondary endpoints including the NPI total score (p=0.014), clinical global impression of change-agitation (p=0.0003), patient global impression of change (p=0.001) and measures of caregiver burden ( $p\pm0.05$ ). The complete set of primary and secondary endpoints in the study is set forth below. In the study, AVP-923 showed a statistically significant improvement over placebo in the primary endpoint and in a majority of the secondary endpoints.

#### **Primary Endpoint**

Agitation/Aggression domain of NPI Secondary Endpoints

Total NPI NPI-4A (agitation/aggression; irritability/lability; aberrant motor behavior; anxiety)

NPI-4D (agitation/aggression; irritability/lability; aberrant motor behavior; disinhibition) ADCS-ADL ADCS-CGIC (agitation and overall) PGIC-agitation MMSE ADAS-Cog\* Quality of Life-AD (Patient, Caregiver) Cornell Depression Scale Caregiver Strain Index Caregiver Distress NPI (measured for agitation/aggression, total NPI, NPI4-A, NPI4-D)

\* Exploratory endpoint, not a secondary endpoint

As a result of the successful study, we intend to request an end of Phase II meeting with the FDA and a meeting with the EMA to discuss next steps in the clinical program. We also expect to discuss with the FDA the possibility of transitioning the Phase II study results in AVP-923 to AVP-786, and thereby proceed with the development of AVP-786 for this indication.

#### AVP-923 for the Treatment of Levodopa-Induced Dyskinesia

LID occurs in most patients with PD, after several years of treatment, generally in association with other motor response complications, such as wearing-off or on-off fluctuations. Dyskinesia may be as disabling as the parkinsonism itself, and current treatment options are limited and are not always effective.

This proof-of-concept, double blind, randomized, crossover study will compare AVP-923 (45mg DM/10mg Q) with placebo for treatment of LID. The study will enroll approximately 16 PD patients across three study centers in the U.S. and Canada. Study participants will receive, in a random order, a two-week treatment with AVP-923 and a two-week placebo treatment, separated by a two-week break. At the end of each two-week treatment period, patients will receive a two-hour levodopa infusion to test the drug effect on dyskinesia. Patients will be carefully monitored throughout the six-week study for side effects, PD symptoms and general health status. The results of this study will help inform future development of AVP-923 for LID. This study is being funded through a grant awarded by the Michael J. Fox Foundation.

#### AVP-923 for the Treatment of Diabetic Neuropathic Pain

Diabetic peripheral neuropathic pain ( DPN pain ), which arises from nerve injury, can result in a chronic and debilitating form of pain that has historically been poorly diagnosed and treated. It is often described as burning, tingling, stabbing, or pins and needles in the feet, legs, hands or arms. An estimated 3.5 million people in the United States experience DPN pain according to the American Diabetes Association. DPN pain currently is most commonly treated with antidepressants, anticonvulsants, opioid analgesics and local anesthetics. Most of these treatments have limited effectiveness or undesirable side effects resulting in a high degree of unmet medical need. The global neuropathic pain market was approximately \$2.4 billion in 2010 and is expected to grow to \$3.6 billion by 2020 among the seven largest markets, consisting of the United States, Japan, France, Germany, Italy, Spain and the United Kingdom.

Avanir previously completed a Phase III clinical trial for AVP-923 in the treatment of patients with DPN pain. In April 2007, we announced positive top-line data from our first Phase III clinical trial of AVP-923 for the treatment of patients with DPN pain. The most commonly reported adverse events from this Phase III study were dizziness, nausea, diarrhea, fatigue and somnolence, which were mild to moderate in nature. Given the results of our Phase II

study (PRIME) for the treatment of central neuropathic pain in MS, we are continuing to evaluate our options for this program, including the use of AVP-786 in the advancement of this program.

#### AVP-786 for the Treatment of Neurologic and Psychiatric Disorders

AVP-786 is a novel investigational drug product consisting of a combination of deuterium-modified dextromethorphan (a new chemical entity, or NCE) and the metabolic inhibitor quinidine. The compound was developed through incorporation of deuterium into molecular positions of dextromethorphan, resulting in strengthened molecular bonds which reduce susceptibility to enzyme cleavage. This AVP-786 formulation contains significantly less quinidine than used in AVP-923. In June 2013, the FDA agreed to an expedited development pathway for AVP-786, requiring only a limited non-clinical package as part of the IND application. We are currently studying AVP-786 in MDD and intend to study AVP-786 in agitation in patients with Alzheimer s disease and potentially other disorders of the nervous system.

#### AVP-786 for the Adjunctive Treatment to Antidepressants for Major Depressive Disorder

Major depressive disorder is a condition in which patients exhibit depressive symptoms, such as a depressed mood or a loss of interest or pleasure in daily activities consistently for at least a two-week period, and demonstrate impaired social, occupational, educational or other important functioning. An estimated 16.1 million people in the United States suffer from MDD in a given year, with as many as two-thirds of patients who are diagnosed with MDD do not experience adequate improvement with initial antidepressant therapy.

In August 2014, we initiated patient enrollment in a Phase 2 study for AVP-786 as adjunctive therapy to antidepressants for the treatment of MDD. This multicenter, randomized, double-blind, placebo-controlled proof-of-concept Phase II study will evaluate the efficacy and safety of AVP-786 in patients suffering from MDD who have had an inadequate response to commonly prescribed antidepressants, including selective serotonin reuptake inhibitors and serotonin-norepinephrine reuptake inhibitors. The study is expected to enroll approximately 200 patients in the United States. The study will utilize innovative methodologies to reduce the placebo response, which is commonly observed in depression trials. Eligible patients will be randomized to receive either AVP-786 or placebo for 10 weeks. The main efficacy measure is the Montgomery-Asberg Depression Rating Scale total score, a standard clinical measure of depression. Secondary outcome measures include assessments of disease severity, activities of daily living, and quality of life. Pharmacokinetics and standard safety assessments will also be conducted.

#### AVP-825 for the Acute Treatment of Migraine

Migraine represents an area of significant unmet medical need. According to the Centers for Disease Control and Prevention, over 37 million people in the United States suffer from migraine headaches. The triptan class of medications is generally considered the standard of care with over 13 million prescriptions written annually. Sumatriptan is the class leader with a market share of over 50%, making it the most commonly prescribed migraine drug in the U.S. An online survey of over 2,500 frequent migraine sufferers revealed that 66% were dissatisfied with their treatments. As a result, many migraine sufferers are seeking fast-acting, well-tolerated treatment options.

AVP-825 is an investigational drug-device combination product consisting of low-dose sumatriptan powder for the acute treatment of migraine. The powder is delivered intranasally utilizing a novel Breath Powered delivery technology. If approved, AVP-825 would be the first and only fast-acting dry-powder intranasal form of sumatriptan. In March 2014, the FDA accepted our NDA of AVP-825 and the PDUFA date is November 26, 2014. In June 2014, the Company completed a Phase 3b clinical trial comparing the efficacy and safety of the investigational product AVP-825 22mg to sumatriptan 100mg tablets for the acute treatment of migraines in adults ( the COMPASS study ). The COMPASS study met the primary endpoint for the sum of pain intensity difference at 30 minutes post dose, showing that migraine sufferers achieved greater pain relief within 30 minutes of treatment with 22 mg of the investigational product AVP-825 compared with 100 mg sumatriptan tablet (p<0.0001). In addition, AVP-825 treated

migraine sufferers achieved pain freedom in a greater proportion of migraine attacks at 15, 30, 45, 60 and 90 minutes post dose compared with those treated with sumatriptan tablet (p<0.05). In these topline data, several additional secondary endpoints relating to pain relief were also met.

The overall safety profile of AVP-825, an investigational product, was consistent with that observed in previous trials, with less than 2% of subjects experiencing an adverse event leading to treatment discontinuation. There were no serious adverse events in the study. Nasal discomfort and abnormal product taste were more common with AVP-825 administration; these adverse events were deemed mild in nearly 90% of cases.

#### **General Information**

Avanir was incorporated in California in August 1988 and was reincorporated in Delaware in March 2009. Our principal executive offices are located at 30 Enterprise, Suite 400, Aliso Viejo, California 92656. Our telephone number is (949) 389-6700 and our e-mail address is *info@avanir.com*. Our Internet website address is *www.avanir.com*. We make our periodic and current reports available on our Internet website, free of charge, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. No portion of our website is incorporated by reference into this prospectus. The public may read and copy the materials we file with the SEC at the SEC s Public Reference Room, located at 100 F Street, NE, Washington, D.C. 20549. The public may obtain information regarding the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The public may also read and copy the materials we file with the SEC by visiting the SEC s website, *www.sec.gov*.

#### THE OFFERING

Common stock offered by us pursuant to this prospectus supplement	shares
Common stock to be outstanding after this offering	shares
Option to purchase additional shares	We have granted the underwriters an option for a period of 30 days from the date of this prospectus supplement to purchase up to additional shares.
Use of proceeds	General corporate purposes, which include, but are not limited to, funding NUEDEXTA commercial activities, funding our ongoing and future clinical trials, funding the commercial launch of AVP-825, if approved and for general and administrative expenses. We may also use a portion of the net proceeds to pay off outstanding indebtedness, if any, and/or acquire or invest in complementary businesses, products and technologies or to fund the development of any such complementary businesses, products or technologies that we may acquire in a stock-based acquisition. See Use of Proceeds on page S-31.
NASDAQ Global Market symbol	AVNR
Risk factors	This investment involves a high degree of risk. See Risk Factors beginning on page S-9 of this prospectus supplement, as well as the other information included or incorporated by reference into this prospectus supplement, for a discussion of risk factors that you should read and consider before investing in our common stock.
If the underwriters option to purc	hase additional shares is exercised in full, we will issue and sell an additional

If the underwriters option to purchase additional shares is exercised in full, we will issue and sell an additional shares of our common stock and will have shares outstanding after the offering.

The number of shares of common stock to be outstanding after this offering is based on 171,831,324 shares outstanding as of June 30, 2014 and excludes the following securities outstanding as of that date:

options representing the right to purchase a total of 9,902,248 shares of common stock at a weighted average exercise price of \$3.06 per share;

restricted stock units representing a total of 2,769,875 shares of common stock issuable upon vesting; and restricted stock units representing a total of 1,108,873 vested shares of common stock issuable to directors.

#### **RISK FACTORS**

An investment in our common stock involves a high degree of risk. Before deciding whether to invest in our common stock, you should consider carefully the risks described below, together with other information in this prospectus supplement, the information and documents incorporated by reference in this prospectus supplement, and in any free writing prospectus that we have authorized for use in connection with this offering. If any of these risks actually occurs, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment.

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**

Our near-term prospects depend on reaching profitability from the commercialization of NUEDEXTA in the United States. If we are unable to continue to increase NUEDEXTA revenues, including through raising PBA awareness among patients and physicians, driving higher rates of physician adoption and obtaining reimbursement and third party payer coverage, our ability to generate significant revenue or achieve profitability will be adversely affected.

Although NUEDEXTA has been approved for marketing, our ability to generate significant revenue in order to reach profitability in the near term is entirely dependent upon our ability to continue the successful commercialization of NUEDEXTA. To continue to be successful we must:

maintain successful sales, marketing and educational programs for our targeted physicians and other health care providers;

raise patient and physician awareness of PBA and encourage physicians to screen patients for the condition;

minimize employee turnover in the increasing competitive market for sales and marketing employees in the CNS space;

obtain adequate reimbursement for NUEDEXTA from a broad range of payers; and

maintain and defend our patent protection and maintain regulatory exclusivity for NUEDEXTA.

Supplying the market for NUEDEXTA requires us to manage relationships with an increasing number of collaborative partners, suppliers and third-party contractors. If we are unable to successfully maintain the required sales and marketing infrastructure, as well as successfully manage an increasing number of relationships, including with suppliers, manufacturers, distributors, insurance carriers and prescribers, we will have difficulty growing our business. In addition, pharmacies, institutions and prescribers may rely on third-party medical information systems to interpret the NUEDEXTA approved product label and guide utilization of NUEDEXTA. If these information systems load incorrect information or misinterpret the approved product label, it may result in lower adoption or utilization than expected. For example, because NUEDEXTA contains quinidine, which is a known pro-arrhythmic drug at antiarrhythmic doses exceeding 600 mg per day, it is possible that medical information systems may incorrectly identify NUEDEXTA as contraindicated or otherwise inappropriate for a patient, even in situations where the risks are substantially less than perceived.

In addition, we may enter into co-promotion or out-licensing arrangements with other pharmaceutical or biotechnology partners for NUEDEXTA where necessary to reach customers in domestic or foreign market segments and when deemed strategically and economically advantageous. To the extent that we enter into co-promotion or other licensing arrangements, our product revenues may be lower than if we directly marketed and sold NUEDEXTA, and some or all of the revenues we receive will depend upon the efforts of third parties, which may not be successful. If we are unable to accomplish any of these key objectives, we may not be able to generate significant product revenue or become profitable.

### We have a history of net losses and an accumulated deficit, and we may be unable to generate sufficient revenue to achieve or maintain profitability in the future.

We have experienced significant net losses and negative cash flows from operations and we expect our negative cash flow from operations to continue until we are able to generate substantially higher revenues from sales of NUEDEXTA. As of June 30, 2014, we had an accumulated deficit of approximately \$536.9 million. We have incurred these losses principally from costs incurred in funding the research, development and clinical testing of our drug candidates, from our general and administrative expenses and from our commercialization activities for NUEDEXTA. We may continue incurring net losses for the foreseeable future and we expect our operating losses to continue for the foreseeable future as we continue to grow NUEDEXTA sales, invest in the development of AVP-923 and AVP-786, seek to commercialize NUEDEXTA in the European Union (EU), and seek FDA approval and subsequently commercialize AVP-825.

Our ability to generate revenue and achieve profitability in the near term is dependent on our ability, alone or with partners, to successfully manufacture and market NUEDEXTA for the treatment of patients with PBA in the United States. We expect to continue to spend substantial amounts on the ongoing marketing of NUEDEXTA domestically for the treatment of PBA, invest in Europe to commercialize NUEDEXTA, and seek regulatory approvals for use of NUEDEXTA in other geographic markets and indications. As a result, we may be unable to generate sufficient revenue from product sales to become profitable or generate positive cash flows.

## Certain of our key issued patents may be challenged and our pending patent applications may be denied. An adverse outcome affecting either issued patents or patent applications would adversely affect our ability to generate significant product revenue or become profitable.

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. The degree of patent protection that will ultimately be afforded to us in the U.S. and in other important markets remains uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts and lawmakers in these countries. If we cannot prevent others from exploiting claims in our patent portfolio, we will not derive the benefit from it that we currently expect. Further, we may incur substantial expense from litigation to protect our patent portfolio.

On September 16, 2011, the Leahy-Smith America Invents Act (the America Invents Act ), was signed into law. The final substantive provisions of the America Invents Act, including the first-to-file system, became effective on March 16, 2013. The America Invents Act includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications are being filed and prosecuted and may also affect patent litigation. For example, the America Invents Act enacted proceedings involving post-issuance patent review procedures, such as *inter partes* review, covered business method reviews, and post grant reviews. These proceedings are conducted before the Patent Trial and Appeal Board. Each proceeding has different eligibility criteria and different patentability challenges that can be raised. Because the standard of review for certain of these proceedings may differ from the standard in patent litigation, the success of the Company in defending its patents in a court proceeding does

not necessarily preclude a subsequent challenge of the same patents under the America Invents Act. As a result, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The validity, enforceability and scope of our core patents may also be challenged as a result of abbreviated new drug application ( ANDA ) filings from generic drug companies or through post-grant proceedings before the U.S. Patent and Trademark Office outside of the auspices of the America Invents Act. An adverse outcome in any future challenge to the validity, enforceability or scope of our patent portfolio could significantly reduce revenues from any future products. More broadly, investors should be aware that the pharmaceutical industry is highly competitive.

Our ability to compete in this space involves various risks relating to our intellectual property, including:

our patents may be found to be invalid and unenforceable or insufficiently broad to block the introduction of a generic form;

the claims in any of our pending patent applications may not be allowed and/or our patent applications may not be granted;

we or our licensors or partners might not have been the first to invent or file, as appropriate, subject matters covered by our issued patents or pending patent applications or the pending patent applications or issued patents of our licensors or partners;

competitors may develop similar or superior technologies independently, duplicate our technologies, or design around the patented aspects of our technologies;

others may be able to make products that are similar to our product candidates but that are not covered by the claims of our patents, or for which we are not licensed under our license agreements;

others may independently develop similar or alternative products without infringing our intellectual property rights;

we may not develop additional proprietary products that are patentable;

our issued patents may not cover our competitors products and the issued patents of our licensors or partners may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;

our issued patents and the issued patents of our licensors or partners may be vulnerable to legal challenges as a result of changes in applicable law;

the patents of others may have an adverse effect on our business;

any of our issued patents may not provide us with significant competitive advantages; and

we may not be able to secure additional worldwide intellectual property protection for our patent portfolio.

The existence of a patent will not necessarily prevent other companies from developing similar or therapeutically equivalent products or protect us from claims of third parties that our products infringe their issued patents, which may require licensing and the payment of significant fees or royalties. Competitors may successfully challenge our patents, produce similar products that do not infringe our patents, or manufacture products in countries where we have not applied for patent protection or that do not respect our patents. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents, our licensed patents or in third party patents.

If our employees, consultants, advisors and partners develop inventions or processes independently, or jointly with us, that may be applicable to our products under development, disputes may arise about ownership or proprietary rights to those inventions and processes. Enforcing a claim that a third party illegally obtained and is using any of our inventions is expensive and time-consuming, and the outcome is unpredictable. In addition, our competitors may independently develop equivalent knowledge, methods and know-how.

Our research and development collaborators may have rights to publish data and other information to which we have rights. In addition, we sometimes engage individuals or entities to conduct research that may be relevant to our business. While the ability of these individuals or entities to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to contractual limitations, these contractual provisions may be insufficient or inadequate to protect our trade secrets and may impair our patent rights. If we do not apply for patent protection prior to such publication, or if we cannot otherwise maintain the confidentiality of our innovations and other confidential information, then our ability to obtain patent protection or protect our proprietary information may be jeopardized. Moreover, a dispute may arise with our research and development collaborators over the ownership of rights to jointly developed intellectual property. Such disputes, if not successfully resolved, could lead to a loss of rights and possibly prevent us from pursuing certain new products or product candidates.

An adverse outcome with respect to any of these risks could adversely affect our ability to generate significant product revenue or become profitable.

We have received notices of ANDA filings for NUEDEXTA submitted by six generic drug companies. These ANDA filings assert that a generic form of NUEDEXTA would not infringe our FDA Orange Book listed patents and/or those patents are invalid. Although we have prevailed on certain of these matters at the district court level, this decision has been appealed. The litigation has been costly and time consuming and, depending on the outcome of any appeal, we may face competition from lower cost generic or follow-on products in the future.

NUEDEXTA is approved under the provisions of the Federal Food, Drug and Cosmetic Act (FDCA), which renders it susceptible to potential competition from generic manufacturers via the Hatch-Waxman Act and ANDA process. Generic manufacturers pursuing ANDA approval are not required to conduct costly and time-consuming clinical trials to establish the safety and efficacy of their products; rather, they are permitted to rely on the innovator s data regarding safety and efficacy. Additionally, generic drug companies generally do not expend significant sums on sales and marketing activities, instead relying on physicians or payers to substitute the generic form of a drug for the branded form. Thus, generic manufacturers can sell their products at prices much lower than those charged by the innovative pharmaceutical or biotechnology companies who have incurred substantial expenses associated with the research and development of the drug product and who must spend significant sums marketing a new drug.

The ANDA procedure includes provisions allowing generic manufacturers to challenge the innovator s patent protection by submitting Paragraph IV certifications to the FDA in which the generic manufacturer claims that the innovator s patent is invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of the generic product. A patent owner who receives a Paragraph IV certification may choose to sue the generic applicant for patent infringement. In recent years, generic manufacturers have used Paragraph IV certifications extensively to challenge the applicability of patents listed in the FDA s Approved Drug Products List with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book, on a wide array of innovative therapeutic products. We expect this trend to continue and to affect drug products with even relatively modest revenues.

We have received Paragraph IV certification notices from six separate companies contending that our patents listed in the Orange Book (U.S. Patents 7,659,282, 8,227,484 and RE 38,115, which expire in August 2026, July 2023 and January 2016, respectively) are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of a generic form of NUEDEXTA. In response to these notices, we filed suit against all of the generic drug companies to defend our patent rights. We have entered into settlement agreements with five of the companies to resolve pending patent litigation in response to their ANDAs seeking approval to market generic versions of NUEDEXTA capsules. The settlement agreements grant the five companies the right to begin selling a generic version of NUEDEXTA on July 30, 2026, or earlier under certain circumstances. The parties also filed stipulations and orders of dismissal with the United States District Court for the District of Delaware which conclude the litigation with respect to the five companies. On April 30, 2014, the United States District Court for the District of Delaware issued an Order finding our latest to expire patents to be valid and infringed. On May 14, 2014, the Court issued a Judgment in favor of Avanir and a permanent injunction enjoining Par from manufacturing, using, offering to sell, or selling a generic version of NUEDEXTA during the terms of the 282 Patent and 484 Patent. The Judgment also ordered that the FDA shall not approve Par s generic product earlier than the latest date of expiration of the 282 Patent and 484 Patent, August 13, 2026. On September 11, 2014, Par filed a Notice of Appeal in the United States Court of Appeals for the Federal Circuit pertaining to the district court s Order.

We intend to continue to vigorously enforce our intellectual property rights relating to any future challenges to our NUEDEXTA product. Our existing patents could be invalidated, found unenforceable or found not to cover a generic form of NUEDEXTA. If an ANDA filer were to receive FDA approval to sell a generic version of NUEDEXTA

and/or prevail in any patent litigation, NUEDEXTA would become subject to increased competition and our revenue would be adversely affected.

#### There can be no assurance that the FDA will approve AVP-825 for the acute treatment of migraine.

A Phase II and Phase III clinical trial of AVP-825 for the acute treatment of migraine have been completed and we have filed an NDA with previously completed studies with the reference drug, sumatriptan, utilizing the FDA s 505(b)(2) pathway. The FDA and other regulatory authorities will have substantial discretion in evaluating the results of the Phase III clinical trial and our NDA filing.

It is possible that the FDA may require us to conduct additional non-clinical, clinical or chemical manufacturing control-related studies before we gain approval for AVP-825. Prior to approving a new drug, the FDA generally requires that the efficacy of the drug be demonstrated in two adequate and well-controlled clinical trials. In some situations, the FDA approves drugs on the basis of a single well-controlled clinical trial and / or on the basis of referencing data generated previously with the reference drug under the 505(b)(2) application process. If the FDA determines that the clinical trials already conducted do not demonstrate a clinically meaningful benefit and an acceptable safety profile, or do not reflect an acceptable risk-benefit profile or if the FDA requires us to conduct additional clinical trials in order to gain approval, we may incur significant additional development costs and commercialization of AVP-825 would be prevented or delayed and our business would be adversely affected. AVP-825 is classified as a new drug-device combination which requires additional conditions to be satisfied for FDA approval beyond what is required for other drug products.

In addition, this Breath Powered intranasal device has not been previously reviewed or approved by the FDA and therefore, it is possible that other issues may arise during the review process which could delay or preclude the approval and require additional capital investment. In addition, we have limited experience obtaining FDA approval for drug-device combinations.

We established a joint steering committee, a joint intellectual property committee and joint development committee which will give OptiNose input on matters related to development of AVP-825 and intellectual property related to the product. As a result, our success depends partially on the success of OptiNose in performing its responsibilities and enforcing their intellectual property rights.

## There can be no assurance that we will be able to successfully manufacture, distribute and commercialize AVP-825, including adequate sales, marketing, distribution and manufacturing capabilities. If we are unable to successfully commercialize AVP-825, our ability to generate significant revenue and achieve product launch timelines may be adversely affected.

We are primarily responsible for the manufacturing and distribution of AVP-825. We will utilize third parties to manufacture, package and distribute AVP-825. We have limited experience with the manufacturing and regulatory approval of nasal delivery devices. We have no experience in manufacturing AVP-825 in commercial quantities. Currently, we have sole suppliers for AVP-825 drug product and device components. Any delays or difficulties, including the purchase of manufacturing equipment, entering into manufacturing and supply agreements, obtaining API or in the manufacturing, packaging or distribution of AVP-825, could negatively affect our sales revenues as well as delay FDA approval or launch timing.

If AVP-825 is approved by the FDA, our ability to generate significant revenue is entirely dependent upon our ability to commercialize AVP-825 successfully. Our future results could be impacted by important factors which include, but are not limited to, commercial market estimates, reliance on market research, competition in the migraine segment, effect of healthcare reform, ability to secure reasonable pricing and patent protection. If we are unable to generate revenues from AVP-825, including through raising awareness among patients and physicians of the benefits of using the device for the acute treatment of migraine, driving higher rates of physician adoption and obtaining reimbursement and third party payer coverage, our ability to generate significant revenue or achieve profitability will be adversely affected.

We may not be able to adequately build or maintain necessary sales, marketing, supply chain management or reimbursement capabilities on our own or enter into arrangements with third parties to perform these functions in a timely manner or on acceptable terms. Additionally, maintaining sales, marketing and distribution capabilities may be more expensive than we anticipate, requiring us to divert capital from other intended purposes or preventing us from

building our sales, marketing and distribution capabilities to the desired levels. To be successful we must:

recruit and retain adequate numbers of effective sales personnel;

effectively train our sales personnel on AVP-825;

reach an adequate number of health care providers which treat migraine;

manage geographically dispersed sales and marketing operations;

obtain adequate reimbursement for AVP-825 from a broad range of payers;

effectively compete with existing and newly developed migraine products or therapies; and

rely on OptiNose to maintain and defend the patent protection and maintain regulatory exclusivity for AVP-825.

The commercialization of AVP-825 requires us to manage relationships with an increasing number of collaborative partners, suppliers and third-party contractors. If we are unable to successfully establish and maintain the required infrastructure, either internally or through third parties, and successfully manage an increasing number of relationships, we will have difficulty growing our business. In addition, we may enter into co-promotion or out-licensing arrangements with other pharmaceutical or biotechnology partners where necessary to reach customers when deemed strategically and economically advisable. To the extent that we enter into co-promotion or other licensing arrangements, our product revenues are likely to be lower than if we directly marketed and sold AVP-825, and some or all of the revenues we receive will depend upon the efforts of third parties, which may not be successful. If we are unable to develop and maintain adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate significant product revenue or become profitable.

### Our co-promotion agreement with Merck may be terminated with or without cause, which could negatively impact our business.

The co-promotion agreement with Merck may be terminated with cause at any time or without cause upon 90 days written notice at any time after the first year anniversary of the launch date. If the agreement were to be terminated, with or without cause, our business could be negatively impacted, including failure to achieve profitability for the co-promote activity and damage to our reputation.

# We are developing AVP-786, a next generation drug product containing deuterium-modified dextromethorphan for neuropsychiatric disorders including agitation in patients with Alzheimer s disease. It is possible that studies of AVP-786 may not produce similar results to those observed in studies of AVP-923 or favorable results. Future studies utilizing AVP-786 carry certain risks.

We have licensed exclusive, worldwide rights to develop and commercialize deuterium-modified dextromethorphan compounds for the potential treatment of neurologic and psychiatric disorders, as well as certain rights to other deuterium-modified dextromethorphan compounds. The goal of the AVP-786 program is to deliver therapeutically effective levels of deuterium-modified dextromethorphan, but with a reduction in the need for an enzyme inhibitor such as quinidine. Although we believe that a drug product containing deuterium-modified dextromethorphan will allow us to significantly reduce the level of quinidine, we are not certain that the reduction in quinidine will result in improved safety.

We completed pharmacokinetic studies with AVP-786 and, based on these data, we believe that we have identified a formulation of AVP-786 to move forward into clinical studies. In June 2013, the FDA Division of Neurology agreed to an expedited development pathway for AVP-786, requiring only a limited non-clinical package as part of the Investigational New Drug application. To date, we have had no discussions with the EMA regarding AVP-786. Although the FDA has agreed to allow us to reference the extensive data generated during the AVP-923 development

programs in support of the AVP-786 development programs and regulatory filings, there can be no assurance that:

the FDA will continue to allow us to reference data generated during the AVP-923 development programs in this fashion;

the FDA will allow us to continue on an expedited development pathway for AVP-786 for additional indications including agitation in patients with Alzheimer s disease;

the FDA will allow us to advance directly into a phase III program with AVP-786 for the treatment of agitation in patients with Alzheimer s disease;

the EMA will allow us to reference data generated during the AVP-923 development program;

we will be successful developing this investigational drug; or

we will obtain regulatory approval domestically or internationally. In addition, our initial discussions regarding the development of AVP-786 have been with the FDA s Division of Neurology. There can be no assurance that other divisions at the FDA will agree with the expedited development plan discussed with the Division of Neurology.

Additionally, we established a joint steering committee and a joint patent committee which will give Concert Pharmaceuticals input on development and patent prosecution for a period of time. As a result, our success depends partially on the success of Concert Pharmaceuticals in performing its responsibilities.

## PBA is a new market and estimates vary significantly over the potential market size and our anticipated revenues over the near and long term.

NUEDEXTA is being made available to patients to treat PBA, an indication for which there was no previously established pharmaceutical market. Industry sources and equity research analysts have a wide divergence of estimates for our drug s market potential, including estimates of underlying neurologic condition prevalence, severity of PBA prevalence among these conditions, rates of physician adoption of our drug for treatment of PBA among these populations, health plan reimbursement rates, and patient adherence and compliance rates within each underlying neurological condition. Small differences in these assumptions can lead to widely divergent estimates of the market potential of our product. Additionally, although our approved product label is indicated to treat PBA, without regard to the underlying neurological condition, it is possible that physicians, the FDA s Office of Prescription Drug Promotion (OPDP), payers or others may interpret the label more narrowly than the FDA s Division of Neurology Products approval for a broad PBA label and believe that PBA secondary to certain conditions, such as Alzheimer s disease, is not an indicated use. If such misinterpretations are widespread, the actual market size may be smaller than we have estimated. Accordingly, investors are cautioned not to place undue reliance on any particular estimates of equity research analysts or industry sources.

## Significant safety or drug interaction problems could arise with respect to NUEDEXTA, which could result in restrictions in NUEDEXTA s label, recalls, withdrawal of NUEDEXTA from the market, an adverse impact on potential sales of NUEDEXTA, or cause us to alter or terminate current or future NUEDEXTA clinical development programs, any of which would adversely impact our future business prospects.

Discovery of previously unknown safety or drug interaction problems with an approved product may result in a variety of adverse regulatory actions. Under the Food and Drug Administration Amendments Act of 2007, the FDA has broad authority to force drug manufacturers to take any number of actions if previously unknown safety or drug interaction problems arise, including, but not limited to: (i) requiring manufacturers to conduct post-approval clinical studies to assess known risks or signals of serious risks, or to identify unexpected serious risks; (ii) mandating labeling changes to a product based on new safety information; or (iii) requiring manufacturers to implement a Risk Evaluation Mitigation Strategy, or REMS, where necessary to assure safe use of the drug. In addition, previously unknown safety or drug interaction problems could result in product recalls, restrictions on the product s permissible uses, or withdrawal of the product from the market.

The combination of dextromethorphan and quinidine has never been marketed for the treatment of any condition until the approval of NUEDEXTA for the treatment of PBA. NUEDEXTA has only been studied in a limited number of patients in clinical trials. The data submitted to the FDA and the EMA were obtained in controlled clinical trials of limited duration. In connection with the approval of NUEDEXTA, the FDA and EMA have required that we conduct certain post-approval studies, which include clinical and non-clinical studies. New safety or drug interaction issues may arise from these studies or as NUEDEXTA is used over longer periods of time by a wider group of patients. For example, elderly patients may be more prone to have multiple risk factors for adverse events such as certain cardiac conditions, hepatic or renal insufficiency, or multi-drug treatment regimens. In addition, as

we conduct other clinical trials for AVP-923 in other indications, new safety or drug interaction problems may be identified which could negatively impact both our ability to successfully complete these studies and the use and/or regulatory status of NUEDEXTA for the treatment of PBA. New safety or drug interaction issues may result in product liability lawsuits and may require us to, among other things, provide additional warnings and/or restrictions on the NUEDEXTA prescribing information, including a boxed warning, directly alert healthcare providers of new safety information, narrow our approved indications, or alter or terminate current or planned trials for additional uses of AVP-923, any of which could have a significant adverse impact on potential sales of NUEDEXTA and our ability to achieve or maintain profitability.

In addition, if we are required to conduct additional post-approval clinical studies, implement a REMS, or take other similar actions, such requirements or restrictions could have a material adverse impact on our ability to generate revenues from sales of NUEDEXTA, and/or require us to expend significant additional funds.

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

We have experienced significant operating losses due to costs associated with funding the research, development, clinical testing and commercialization of NUEDEXTA and our drug candidates. We expect to continue to incur substantial operating losses for the foreseeable future as we continue to expand our commercialization efforts for NUEDEXTA in the U.S. and in European markets, continue to develop AVP-923 and AVP-786, and seek FDA approval and subsequently commercialize AVP-825. Although we had approximately \$87.6 million in cash and cash equivalents, restricted cash and cash equivalents, and restricted investments as of June 30, 2014, we currently do not have sufficient revenue from NUEDEXTA or other sources of recurring revenue or cash flow from operations to sustain our operations and it is possible that we may not be able to achieve profitability with our current capital resources.

In light of our substantial long-term capital needs, we may need to partner our rights to NUEDEXTA (either in the U.S. or outside the U.S.) or raise additional capital in the future to finance our long-term operations, until we are able to generate sufficient revenue from product sales to fund our operations. Based on our current loss rate and existing capital resources as of the date of this report, we estimate that we have sufficient funds to sustain our operations at their current and anticipated levels over the next 12 months, which includes the costs associated with the ongoing commercialization of NUEDEXTA for the treatment of PBA in the U.S. and European markets, seeking FDA approval and subsequently commercialize AVP-825. Although we expect to be able to raise additional capital if needed, 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, we may experience significant delays or cutbacks in the commercialization of NUEDEXTA and may be forced to further curtail our operations.

If we raise additional capital, 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, through the acquisition of other companies, or through the issuance of debt securities. 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 may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as encumbering our assets, making capital expenditures or entering into certain licensing transactions.

Our Loan Agreement with Oxford and SVB contains certain covenants that could adversely affect our operations and, if an event of default were to occur, we could be forced to repay the outstanding indebtedness sooner than planned and possibly at a time when we do not have sufficient capital to meet this obligation. The occurrence of any of these events could cause a significant adverse impact on our business, prospects and stock price.

Pursuant to our Loan Agreement with Oxford and SVB, we have pledged all of our assets, other than our patents and other intellectual property rights, and have agreed that we may not sell or assign rights to our patents and other intellectual property without the prior consent of Oxford and SVB. The Loan Agreement also requires us to maintain a minimum sales level relative to projected NUEDEXTA revenues, measured on a trailing three-month basis, or maintain cash and cash equivalents in accounts subject to control agreements in favor of the collateral agent equal to at least 1.5 times the outstanding amount of obligations under the Loan Agreement. The failure to satisfy both of these tests would result in an event of default, which could accelerate our repayment obligations. Additionally, the Loan Agreement contains affirmative and negative covenants that, among other things, restrict our ability to:

incur additional indebtedness or guarantees;

incur liens;

make investments, loans and acquisitions;

consolidate or merge;

sell assets, including capital stock of subsidiaries;

alter the business of the Company;

engage in transactions with affiliates; and

enter into agreements limiting dividends and distributions of certain subsidiaries. The Loan Agreement also includes events of default, including, among other things, payment defaults; breaches of representations, warranties or covenants; certain bankruptcy events; the occurrence of certain material adverse changes; and a commercial, generic version of NUEDEXTA (for the treatment of PBA) becoming available. Upon the occurrence of an event of default and following any cure periods (if applicable), a default interest rate of an additional 5.0% per annum may be applied to the outstanding loan balances, and the lenders may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement.

These terms of the Loan Agreement could prevent us from taking certain actions without the consent of our lenders and, if an event of default should occur, we could be required to immediately repay the outstanding indebtedness. If we are unable to repay this debt, the lenders would be able to foreclose on the secured collateral, including our cash

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accounts, and take other remedies permitted under the security agreement. Even if we are able to repay the indebtedness on an event of default, the repayment of these sums may significantly reduce our working capital and impair our ability to operate as planned. The occurrence of any of these events could cause a significant adverse impact on our business, prospects and stock price.

### We are party to a co-promotion agreement for our institutional sales force that could have negative business implications.

We entered into a multi-year agreement involving our institutional sales team. This co-promote agreement involves certain financial and operating risks, including:

promotional efforts being diverted to the co-promote product which could result in a negative impact on NUEDEXTA revenues;

increased compliance risk which could harm our reputation;

dependence on our partner for reimbursement from third party payers; and

if we are unable to generate significant revenue or achieve profitability for the co-promote activity. If any of these risks occurred, it could adversely affect our business, financial condition and operating results.

## We are party to a license agreement with obligations that could require significant capital infusions and could involve many financial and operating risks.

In July 2013, we entered into an exclusive license agreement for the development and commercialization of a Breath Powered intranasal delivery system containing low-dose sumatriptan powder for the acute treatment of migraine, now named AVP-825. The licensed territories are the United States, Canada and Mexico. Our obligations pursuant to this license agreement could require significant capital infusions and could involve many financial and operating risks, including, but not limited to, the following:

we may have to issue debt or equity securities to meet our obligations under this license agreement, which would dilute our stockholders and could adversely affect the market price of our common stock, and we may issue securities or rights with contingent payment obligations, which could have variable accounting treatment and negative accounting consequences;

our obligations pursuant to this license agreement may result in a negative impact on our results of operations and, as such, delay profitability;

we may encounter difficulties in assimilating and integrating AVP-825 into our existing business, including related technologies, personnel or operations;

our obligations pursuant to this license agreement may require significant capital infusions and AVP-825 may not generate sufficient value to justify the acquisition cost;

focus on integrating AVP-825 into our existing business may disrupt our ongoing business, divert resources, increase our expenses and distract our management; and

we have little or no prior experience in the migraine market and our assumptions surrounding the market, including revenue forecasts, may not be accurate.

If any of these risks occurred, it could adversely affect our business, financial condition and operating results.

We are seeking partners to market NUEDEXTA in the EU, and we will be substantially dependent on any such marketing partners in those countries to successfully commercialize NUEDEXTA. We may not be successful in establishing a partnership, but even if we are successful in establishing a partnership or decide to launch ourselves, we may be unable to generate NUEDEXTA revenue in the European market, including through raising PBA awareness among patients and physicians, driving higher rates of physician adoption and obtaining reimbursement and third party payer coverage, our ability to generate significant revenue or achieve profitability in the European market will be adversely affected.

NUEDEXTA has been approved for marketing in the EU and our ability to generate significant revenue in the EU is entirely dependent upon our ability to successfully commercialize NUEDEXTA. To be successful in the EU we must:

maintain successful sales, marketing and educational programs for our targeted physicians and other health care providers;

raise patient and physician awareness of PBA and encourage physicians to screen patients for the condition;

obtain adequate reimbursement for NUEDEXTA from a broad range of payers; and

maintain and defend our patent protection and maintain regulatory exclusivity for NUEDEXTA. Our prospects to successfully commercialize NUEDEXTA in the EU will depend, among other things, on our ability to establish successful arrangements with international distribution and marketing partners. Consummation of NUEDEXTA partnering arrangements is subject to the negotiation of complex contractual relationships and we may not be able to negotiate such agreements on a timely basis, if at all, or on terms acceptable to us. Where we are successful in entering into these third party arrangements, our revenues from NUEDEXTA sales will be lower than if we commercialized directly, as we will be required to share the revenues with our licensing, commercialization and development partners. If our commercialization efforts with our partners are unsuccessful or we are unable to launch NUEDEXTA in certain countries, we may realize little or no revenue from sales in the EU despite having received marketing approval. In the event that we are unsuccessful in obtaining a partner, we may establish a NUEDEXTA sales and marketing sales infrastructure in the EU.

We have entered into a number of agreements providing for the acquisition or divestiture of drug products and clinical assets and we expect to enter into additional such agreements in the future. We may not realize the anticipated value of these transactions and we may become involved in disputes with the counterparties, both of which could harm our business operations and prospects.

We have entered into agreements relating to the acquisition or divestiture of certain assets, including FazaClo, our anthrax antibody program, and other antibodies in our infectious disease program, as well as docosanol in the U.S. and other markets worldwide. We have also licensed certain intellectual property rights from CNS, AVP-786 from Concert Pharmaceuticals and AVP-825 from OptiNose AS. All of these transactions and agreements involve numerous risks, including:

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

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

threatened or actual loss of potentially material contractual rights;

inability to effectively integrate an acquired business or asset or to achieve the efficiencies or synergies we anticipate;

insufficient proceeds to offset expenses associated with the transactions; and

the potential loss of key employees following such a transaction.

Further, from time to time, we have been and will continue to be engaged in discussions with potential licensing or development partners for NUEDEXTA for the treatment of PBA and/or AVP-923/AVP-786 for other indications and we may choose to pursue a partnership or license involving NUEDEXTA and/or AVP-923/AVP-786 if the terms are attractive. We also regularly review potential acquisition opportunities for complementary products and technologies and may seek to acquire rights to other drugs or technologies, as well as other complementary assets.

Transactions such as these carry significant risks where a large portion of the total value to Avanir and our stockholders is contingent upon post-closing events, such as regulatory, commercialization or sales milestones. In certain circumstances, we may not have control over whether these milestones are met and, if they are not met, then a potentially large portion of the value of the transaction may not be realized. Disputes may also develop over these and other terms, such as representations and warranties, indemnities, earn-outs, the scope of intellectual property rights and related obligations, and other provisions in the underlying 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. Further, stockholders may not support the terms of any such transactions and our stock price may decline upon announcing any planned acquisition or divestiture.

# The FDA s safety concerns regarding our prior formulation of NUEDEXTA, known as AVP-923, for the treatment of PBA extend to other clinical indications that we have been pursuing, including DPN pain. Due to these concerns, any future development of AVP-923 or AVP-786 for other indications is expected to use an alternative lower-dose quinidine formulation, which may negatively affect efficacy.

We have completed a single Phase III trial for AVP-923 in the treatment of DPN pain. In communications regarding the continued development of AVP-923 for this indication, the FDA has stated that certain safety concerns and questions raised in the PBA approvable letter issued in 2006 necessitate the testing of a low-dose quinidine formulation for the DPN pain indication. Additionally, based on feedback we have received from the FDA on the proposed continued development of AVP-923 for DPN pain, we believe it is likely that two additional large well-controlled Phase III trials would be needed to support a supplemental NDA filing for this indication. Due to our

limited capital resources, we do not expect that we will be able to conduct the trials needed for this indication without additional capital, a development partner for AVP-923 for DPN pain, or a commercialization partner for NUEDEXTA. Moreover, although we achieved positive results in our initial Phase III trial, an alternative low-dose quinidine formulation may not yield the same levels of efficacy as seen in the earlier trials or as predicted based on our subsequent pharmacokinetic study. Any decrease in efficacy may be so great that the drug does not demonstrate a statistically significant improvement over placebo or an active comparator. Additionally, any alternative low-dose quinidine formulation that we develop may not sufficiently satisfy the FDA safety concerns. If this were to happen, we may not be able to pursue the development of AVP-923 or AVP-786 for DPN pain or other indications and symptoms of agitation in patients with Alzheimer s disease, or may need to undertake significant additional clinical trials, which would be costly and cause potentially substantial delays.

Given the results of our Phase II study (PRIME) for the treatment of central neuropathic pain in MS, we are continuing to evaluate our options for this program, including the use of AVP-786 in the advancement of this program.

# If our products infringe the intellectual property rights of others, we may incur damages and be required to incur the expense of obtaining a license.

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. In addition, a third party may claim that we or our manufacturing or commercialization partners are using inventions covered by the third party s patent rights, or that we or such partners are infringing, misappropriating or otherwise violating other intellectual property rights, and may go to court to stop us from engaging in our normal operations and activities, including making or selling our products. 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 could 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 rely on market research to evaluate the commercial acceptance of NUEDEXTA and AVP-825.

Based on the results of our market research, we believe that physicians are likely to continue to support the use and adoption of NUEDEXTA for the treatment of PBA. In addition, we believe that physicians are likely to support and adopt the use of AVP-825 for the acute treatment of migraine, if approved by the FDA. We conduct market research in accordance with Good Marketing Research Practices; however, research findings may not be indicative of the response we might receive from a broader sample of physicians. Moreover, these results are based on physicians impressions formed from a description of the product or their actual experience from having prescribed the product, which could result in different impressions or intended behaviors compared to other physicians in our target audience. If the actual use and adoption rates of NUEDEXTA and AVP-825 (if approved by the FDA) are significantly lower than market research or other data suggest, our financial condition and results of operations could be adversely affected.

# It is unclear whether we would be eligible for patent term extension in the U.S. and supplementary protection certificates in Europe and we therefore do not know whether our patent term can be extended.

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Market exclusivity provisions under the FDCA 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 (ANDA) for drugs containing the original active agent.

If the patents that cover NUEDEXTA expire or have been invalidated, generic drug companies would be able to introduce competing versions of the drug. If we are unsuccessful in defending our patents against generic competition, our long-term revenues from NUEDEXTA sales may be significantly less than expected, we may have greater difficulty finding a development partner or licensee for NUEDEXTA and the costs to defend the patents would be significant.

In Europe, based on the European Commission s Article 14(11) of Regulation (EC) No. 726/2004, NUEDEXTA qualifies for ten years of regulatory data protection. Similar to the U.S., market exclusivity provisions provide for a maximum five-year extension for certain patents through the granting of Supplementary Protection Certificates. Although all countries in the European Union are required to provide Supplementary Protection Certificates that come into force after expiry of the patent upon which they are based, no unified cross-recognition exists. Applications for Supplementary Protection Certificates must be filed with each country s patent office and approved on a country-by-country basis. Although we believe that NUEDEXTA will qualify for this extension and we have applied for Supplementary Protection Certificates, we cannot assure you that NUEDEXTA will be granted any Supplementary Protection Certificates nor, if a Supplementary Protection Certificate is granted, that the term of the extension will be five years.

# We may be unable to protect our unpatented proprietary technology and information.

In addition to our patented intellectual property, we also rely on trade secrets and confidential information. We may be unable to effectively protect our rights to such proprietary technology or information. Other parties may independently develop or gain access to equivalent technologies or information and disclose it for others to use. Disputes may arise about inventorship and corresponding rights to know-how and inventions resulting from the joint creation or use of intellectual property by us and our corporate partners, licensees, scientific and academic collaborators and consultants. In addition, confidentiality agreements and material transfer agreements we have entered into with these parties and with employees and advisors may not provide effective protection of our proprietary technology or information or, in the event of unauthorized use or disclosure, may not provide adequate remedies. If we fail to protect our trade secrets and confidential information, our business and results of operations could be adversely affected.

# We face challenges recruiting and 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 commercial, clinical and regulatory affairs, research and development and accounting and finance. Because we have a relatively small management team, 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.

# Our operations might be interrupted by the occurrence of a natural disaster or other catastrophic event.

Our principal operations are located in Aliso Viejo, California. We depend on our facilities and on our partners, contractors and vendors for the continued operation of our business. Natural disasters or other catastrophic events, interruptions in the supply of natural resources, political and governmental changes, wildfires and other fires, floods, explosions, actions of animal rights activists, earthquakes and civil unrest could disrupt our operations or those of our partners, contractors and vendors. Even though we believe we carry commercially reasonable business interruption and liability insurance, and our contractors may carry liability insurance that protect us in certain events, we might suffer losses as a result of business interruptions that exceed the coverage available under our and our contractors insurance policies or for which we or our contractors do not have coverage. Any natural disaster or catastrophic event could have a significant negative impact on our operations and financial results. However, we have a disaster recovery plan in place for our information technology infrastructure that generally allows us to have our critical systems operational in as little as four hours of triggering the disaster recovery plan, depending on the severity of the disaster. Moreover, any such event could adversely impact the commercialization of NUEDEXTA and our research and development programs.

# We may become involved in litigation and administrative proceedings that may materially affect us.

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From time to time, we may become involved in various legal proceedings relating to matters incidental to the ordinary course of our business, including contracts and license agreements that we have entered into or may enter

into, intellectual property, commercial, employment, class action, whistleblower and other litigation and claims, and governmental and other regulatory investigations and proceedings. Litigation may also arise as a result of a decline in the market price of our securities or as a result of disclosures we make with the Securities and Exchange Commission in our periodic reports and documents that are provided to our stockholders. Although we are not currently aware of litigation or administrative proceedings that will have a material effect on us, such matters can be time-consuming, divert management s attention and resources and may cause us to incur significant expenses. Furthermore, because legal actions are inherently unpredictable, there can be no assurance that the results of any legal actions will not have a material adverse effect on our business, results of operations or financial condition.

# **Risks Relating to Our Industry**

# The pharmaceutical industry is highly competitive and most of our competitors have larger operations and 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 areas similar to those in which we are performing our research. For example, we expect that NUEDEXTA may face competition from off-label use of other agents in the treatment of PBA, even though none of these agents has proven to be safe and effective for the treatment of PBA. Additionally, NUEDEXTA may face direct competition from a generic form of NUEDEXTA, if approved, as described above.

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.

Further, AVP-825, if approved, will have to compete with existing and any newly developed migraine products or therapies. There are also likely to be numerous competitors developing new products to treat migraine, which could render AVP-825 obsolete or non-competitive.

# 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, the EMA and other regulatory bodies. In addition, regulatory authorities subject a marketed product, its manufacturer and the manufacturing facilities to ongoing review and periodic inspections. We are 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. If we fail to comply with any of these requirements, we may be subject to action by regulatory agencies, which could negatively affect our business.

Regulatory agencies may also 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.

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

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 non-clinical 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;

the cost of our clinical trials may be greater than we currently anticipate and clinical trials may take longer than expected to enroll patients and complete, particularly for progressive diseases such as MS where our drug candidates are primarily aimed at treating associated symptoms and not the underlying disease itself; and

there could be a delay in initiating our clinical trials.

It is possible that earlier clinical and non-clinical trial results may not be predictive of the results of subsequent clinical trials. If earlier clinical and/or non-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, disagree with our interpretations of regulations, draw different conclusions from our clinical trial data or ask for additional information at any time during their review.

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 filing any NDA we may submit;

requests for additional studies or data;

delays in obtaining an approval;

the rejection of an application; or

the approval of the drug, but with restrictive labeling that could adversely affect the commercial market. If we do not receive regulatory approval to sell our product candidates or cannot successfully commercialize our product candidates, we may not be able to generate sufficient revenues or achieve or maintain profitability.

# We face uncertainty related to healthcare reform, pricing, coverage and reimbursement, which could reduce our revenue.

In the United States, President Obama signed in March 2010 the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, PPACA), which is expected to substantially change the way health care is financed by both governmental and private payers. PPACA provides for changes to extend medical benefits to those who currently lack insurance coverage, encourages improvements in the quality of health care items and services, and significantly impacts the U.S. pharmaceutical industry in a number of ways, further listed below. By extending coverage to a larger population, PPACA may substantially change the structure of the health insurance system and the methodology for reimbursing medical services, drugs and devices. These structural changes, as well as other changes that may be made as part of deficit and debt reduction efforts in Congress, could entail modifications to the existing system of private payers and government programs, such as Medicare, Medicaid and State Children s Health Insurance Program, as well as the creation of a government-sponsored healthcare insurance source, or some combination of both. Such restructuring of the coverage of medical care in the United States could impact the extent of coverage and reimbursement for prescribed drugs, including our product candidates, biopharmaceuticals, and medical devices. We expect that the PPACA, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry in general and on our ability to maintain or increase our product sales, successfully commercialize our product candidates or could limit or eliminate our future spending on development projects. Some of the specific PPACA provisions, among other things:

Establish annual, non-deductible fees on any entity that manufactures or imports certain branded prescription drugs and biologics;

Increase minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program;

Extend manufacturers Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations or extension of statutory rebates to a broader patient population;

Establish a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research;

Require manufacturers to participate in a coverage gap discount program, under which they must agree to offer 50 percent point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer s outpatient drugs to be covered under Medicare Part D; and

Revised the definition of average manufacturer price by changing the classes of purchasers included in the calculation, and expanded the entities eligible for discounted 340B pricing.

A significant portion of our sales of NUEDEXTA come from patients who are covered under a third-party reimbursement plan. Any adverse change in reimbursement policies affecting these patients, including a change in

co-payments or a transition to a co-insurance plan for NUEDEXTA, for example, if a third-party payor placed NUEDEXTA in a specialty tier, may have a material and adverse impact on our business.

If future coverage and reimbursement for NUEDEXTA, products that we co-promote or any other approved product candidates, if any, is substantially less than we project, or rebate obligations associated with them are substantially increased, our business could be materially and adversely impacted.

Sales of NUEDEXTA for treatment of patients with PBA will depend in part on the availability of coverage and reimbursement from third-party payers such as government insurance programs, including Medicare and Medicaid, private health insurers, health maintenance organizations and other health care related organizations. Accordingly, coverage and reimbursement may be uncertain. Adoption of NUEDEXTA by the medical community may be limited if third-party payers will not offer coverage. Cost control initiatives may decrease coverage and payment levels for NUEDEXTA and, in turn, the price that we will be able to charge. We are unable to predict all changes to the coverage or reimbursement methodologies that will be applied by private or government payers to NUEDEXTA. Any denial of private or government payer coverage of NUEDEXTA could harm our business and reduce our revenue.

In addition, both the federal and state governments in the United States and foreign governments continue to propose and pass new legislation affecting coverage and reimbursement policies, which are designed to contain or reduce the cost of health care, as well as hold public hearings on these matters. Further federal and state proposals

and healthcare reforms are likely, which could limit the prices that can be charged for our products and the product candidates that we develop and may further limit our commercial opportunity. There may be future changes that result in reductions in current coverage and reimbursement levels for our products and product candidates, if approved and commercialized, and we cannot predict the scope of any future changes or the impact that those changes would have on our operations.

# We may be subject to regulatory and investigative proceedings, which may find that our policies and procedures do not fully comply with complex and changing regulations.

While we have established policies and procedures that we believe will be sufficient to ensure that we operate in substantial compliance with applicable laws, regulations and requirements, the criteria are often vague and subject to change and interpretation. We may become the subject of regulatory, enforcement or other investigations or proceedings, and our relationships, business structure, and interpretations of applicable laws and regulations may be challenged. The defense of any such challenge could result in substantial cost and a diversion of management s time and attention. In addition, any such challenge could require significant changes to how we conduct our business and could have a material adverse effect on our business, regardless of whether it ultimately is successful. If we fail to comply with any applicable laws, or a determination is made that we have failed to comply with these laws, our financial condition and results of operations could be adversely affected.

# 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 are seeking to have our products or product candidates marketed outside the United States. In order to market our products in the EU 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, and may not qualify or be accepted for accelerated review in foreign countries. 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 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 rely on insurance companies to mitigate our exposure for business activities, including developing and marketing pharmaceutical products for human use.

The conduct of our business, including the testing, marketing and sale of pharmaceutical products, involves the risk of liability claims by consumers, stockholders, and other third parties including products in which we co-promote. Although we maintain various types of insurance, including product liability and director and officer liability, claims can be high and our insurance may not sufficiently cover our actual liabilities. If 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 materially and adversely affect 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 products and the imposition

of higher insurance requirements could impose additional costs on us. Additionally, we are potentially at risk if our insurance carriers become insolvent. Although we have historically obtained coverage through highly rated and capitalized firms, there can be no assurance that we will be able to maintain coverage under existing policies at the current rates or purchase insurance under new policies at reasonable rates.

# If we market products in a manner that violates health care fraud and abuse laws, we may be subject to civil and criminal penalties, which may adversely affect our business, financial condition and results of operations.

We are subject to healthcare fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

the federal healthcare programs Anti-Kickback Statute (as amended by the PPACA, which modified the intent requirement of the Anti-Kickback Statute so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it to have committed a violation), which prohibits, among other things, persons from soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or

fraudulent and, under the PPACA, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation; HIPAA, as amended by the Health Information Technology and Clinical Health Act and its implementing regulations, which imposes certain requirements relating to the privacy, security, and transmission of individually identifiable health information; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payer, including commercial insurers. In addition, the compliance environment is changing as some states mandate implementation of commercial compliance programs to ensure compliance with these laws.

The PPACA also imposes new reporting and disclosure requirements on drug manufacturers for any transfer of value made or distributed to prescribers and other healthcare providers and such information will be made publicly available in a searchable format. Drug manufacturers are required to submit reports disclosing any investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of \$150,000 per year (and up to an aggregate of \$1 million per year for knowing failures ), for all payments, transfers of value or ownership or investment interests not reported in an annual submission. PPACA also requires pharmaceutical manufacturers and distributors to provide the U.S. Department of Health and Human Services with an annual report on the drug samples they provide to physicians. There has also been a recent trend of increased federal and state regulation of payments made to physicians. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

If our operations are found to be in violation of any of the laws described above or any other domestic or foreign laws or governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from governmental health care programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Even if we are not found to be in violation of any of the laws described above or any other domestic or foreign laws or governmental regulations that apply to us, any action against us for violation of these laws could cause us to incur significant legal expenses and divert our management s attention from the operation of our business.

# We may incur significant liability if it is determined that we are promoting the off-label use of drugs.

We have taken numerous steps to ensure compliance is a high priority throughout the organization and we believe that our communications regarding our products are in compliance with the relevant regulatory requirements. However, the FDA or another regulatory authority may disagree.

Responding to government investigations, defending any claims raised, and any resulting fines, restitution, damages and penalties, settlement payments or administrative actions, as well as any related actions brought by stockholders or other third parties, could have a material impact on our reputation, business and financial condition and divert the attention of our management from operating our business. Our distribution and contracting partners may also be the subject of regulatory investigations involving, or remedies or sanctions for, off-label promotion of products we have licensed to them, or for which they provide vendor support services, which may have an adverse impact on sales of such licensed products, or indemnification obligations, which may, in turn, have a material adverse effect on our business, financial condition and results of operations and could cause the market value of our common shares to decline. The risks of a regulatory investigation are increased by the practice of some stock market participants to publicly issue reports alleging compliance violations.

Companies may not promote approved drugs for off-label uses that is, uses that are not described in the product s labeling and that differ from those approved by the FDA or other applicable regulatory agencies. Physicians may prescribe approved drug products for off-label uses and such off-label uses are common across medical specialties. Although the FDA and other regulatory agencies do not regulate a physician s choice of treatments for a given medical condition, the FDA and other regulatory agencies do restrict communications by pharmaceutical companies and their sales representatives regarding information concerning approved products for off-label use. The FDA and other regulatory agencies approved products for off-label uses and their sales representatives regarding information concerning approved products for off-label use. The FDA and other regulatory agencies approved products for off-label uses and their sales representatives for which marketing authorization has not been obtained. A company that is found to have promoted an approved product for off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific exchange with health care professionals concerning their products.

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

# 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 NUEDEXTA and the active pharmaceutical ingredient (API) for docosanol 10% cream and to provide clinical supplies of our drug candidates. We will also utilize third parties to manufacture, package and distribute AVP-825 and AVP-786. We have no experience in manufacturing and do not have any manufacturing facilities. Currently, we have sole suppliers for the API for docosanol and NUEDEXTA, and a sole manufacturer for the finished form of NUEDEXTA. In addition, these materials are custom-made and available from only a limited number of sources. In particular, there may be a limited supply source for APIs in NUEDEXTA. Although we maintain a significant supply of APIs on hand, any sustained disruption in this supply could adversely affect our operations and revenues. 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 NUEDEXTA API suppliers. 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 NUEDEXTA could negatively affect our sales revenues, as well as delay our clinical trials of AVP-923 or AVP-786 for future indications. 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, macro-economic conditions may adversely affect these third parties, causing them to 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.

#### 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, macro-economic

conditions may affect our development partners and vendors, which could adversely affect their ability to timely perform their tasks. 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 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 typical out-license arrangement we have no direct control over the development of drug candidates and have only limited, if any, input on the direction of development efforts. These development efforts are made 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 NUEDEXTA 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.

#### 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, in some instances 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 NUEDEXTA, 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 NUEDEXTA 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 our operating results, as well as many factors independent of our operating results, including the following:

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 and/or future sales of equity or debt securities;

sales of our common stock by our directors, officers or significant stockholders, including sales effected pursuant to predetermined trading plans adopted under the safe-harbor afforded by Rule 10b5-1;

negative opinions that are misleading and inaccurate regarding our business, management or future prospects published by certain market participants intent on putting downward pressure on our stock price;

regulatory developments in the U.S. and foreign countries, including the passage of laws, rules or regulations relating to healthcare and reimbursement or the public announcement of inquiries relating to these subjects;

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

market and economic conditions.

If a substantial number of shares are sold into the market at any given time, particularly following any significant announcements or large swings in our stock price (whether sales are under our existing shelf registration statements, from an existing stockholder, or the result of warrant or stock options exercised), 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.

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 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 our favor. We have, from time to time, been a party to such suits and although none have been material to date, there can be no assurance that any such suit will not have an adverse effect on us.

# If our internal controls over financial reporting are not considered effective, our business and stock price could be adversely affected.

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to evaluate the effectiveness of our internal controls over financial reporting as of the end of each fiscal year, and to include a management report assessing the effectiveness of our internal controls over financial reporting in our annual report on Form 10-K for that fiscal year. Section 404 also requires our independent registered public accounting firm to attest to, and report on, management s assessment of our internal controls over financial reporting.

Our management, including our chief executive officer and principal financial officer, does not expect that our internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system s objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud involving a company have been, or will be, detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and we cannot assure you that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become ineffective because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. We cannot assure you that we or our independent registered public accounting firm will not identify a material weakness in our internal controls in the future. A material weakness in our internal controls over financial reporting would require management and our independent registered public accounting firm to consider our internal controls as ineffective. If our internal controls over financial reporting are not considered effective, we may experience a loss of public confidence, which could have an adverse effect on our business and on the market price of our common stock.

# Because we do not expect to pay dividends in the foreseeable future, you must rely on stock appreciation for any return on your investment.

We have paid no cash dividends on our common stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future, and payment of cash dividends, if any, will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. In addition, under the terms of our Loan Agreement, we are precluded from paying cash dividends without the prior written consent of the lenders. Accordingly, the success of your investment in our common stock will likely depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value or even maintain the price at which you purchased your shares, and you may not realize a return on your investment in our common stock.

# Our corporate governance documents and Delaware law may delay or prevent an acquisition of us that stockholders may consider favorable, which could decrease the value of our common stock.

Our certificate of incorporation and bylaws and Delaware law contain provisions that could make it more difficult for a third party to acquire us without the consent of our board of directors. These provisions include restrictions on the ability of our stockholders to remove directors and supermajority voting requirements for stockholders to amend our organizational documents and a classified board of directors. In addition, our board of directors has the right to issue preferred stock without stockholder approval, which could be used to dilute the stock ownership of a potential hostile acquirer. Delaware law, for instance, also imposes some restrictions on mergers and other business combinations between any holder of 15% or more of our outstanding common stock and us. Although we believe these provisions protect our stockholders from coercive or otherwise unfair takeover tactics and thereby provide for an opportunity to receive a higher bid by requiring potential acquirers to negotiate with our board of directors, these provisions apply even if the offer may be considered beneficial by some stockholders.

#### **Risks Related to this Offering**

# There may be future sales or other dilution of our equity, which may adversely affect the market price of our common stock.

We are generally not restricted from issuing additional common stock, including any securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. The market price of our common stock could decline as a result of sales of common stock or securities that are convertible into or exchangeable for, or that represent the right to receive, common stock after this offering or the perception that such sales could occur.

# We have broad discretion in how we use the net proceeds of this offering, and we may not use these proceeds effectively or in ways with which you agree.

We have not designated any portion of the net proceeds from this offering to be used for any particular purpose. Our management will have broad discretion as to the application of the net proceeds of this offering and could use them for purposes other than those contemplated at the time of this offering. Our stockholders may not agree with the manner in which our management chooses to allocate and spend the net proceeds. Moreover, our management may use the net proceeds for corporate purposes that may not increase the market price of our common stock.

# Purchasers will experience immediate dilution in the book value per share of the common stock purchased in the offering.

Because the price per share of our common stock being offered is substantially higher than the book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. Based on the public offering price of \$ per share, if you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of \$ per share in the net tangible book value of the common stock. See Dilution on page S-32 for a more detailed discussion of the dilution you will incur in this offering.

In addition to this offering, subject to market conditions and other factors, we may pursue additional equity financings in the future, including future public offerings or future private placements of equity securities. Further, the exercise of outstanding options and warrants could result in further dilution to investors and any additional shares issued in connection with acquisitions will result in dilution to investors. In addition, the market price of our common stock could fall as a result of resales of any of these shares of common stock due to an increased number of shares available for sale in the market.

# **USE OF PROCEEDS**

General corporate purposes, which include, but are not limited to, funding NUEDEXTA commercial activities, funding our ongoing and future clinical trials, funding the commercial launch of AVP-825, if approved and for general and administrative expenses. We may also use a portion of the net proceeds to pay off outstanding indebtedness, if any, and/or acquire or invest in complementary businesses, products and technologies or to fund the development of any such complementary businesses, products or technologies that we may acquire in a stock-based acquisition.

# DILUTION

If you invest in our common stock, your interest will be diluted immediately to the extent of the difference between the public offering price per share and the adjusted net tangible book value per share of our common stock after this offering.

The net tangible book value of our common stock as of June 30, 2014, was approximately \$66.7 million, or approximately \$0.39 per share. Net tangible book value per share represents the amount of our total tangible assets, excluding goodwill and intangible assets, less total liabilities, divided by the total number of shares of our common stock outstanding. Dilution per share to new investors represents the difference between the amount per share paid by purchasers for each share of common stock in this offering and the net tangible book value per share of our common stock immediately following the completion of this offering.

After giving effect to the sale of shares of our common stock in this offering at the public offering price of \$ per share and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of June 30, 2014 would have been approximately \$ million, or \$ per share. This represents an immediate increase in net tangible book value of \$ per share to existing stockholders and immediate dilution in net tangible book value of \$ per share to new investors purchasing our common stock in this offering. The following table illustrates this dilution on a per share basis:

Assumed public offering price per share		\$
Net tangible book value per share as of June 30, 2014	\$ 0.39	
Increase per share attributable to the offering	\$	
As-adjusted net tangible book value per share after this offering		\$
Dilution per share to new investors		\$

If the underwriters exercise in full their option to purchase additional shares of common stock at the public offering price of \$ per share, the as adjusted net tangible book value after this offering would be \$ per share, representing an increase in net tangible book value of \$ per share to existing stockholders and immediate dilution in net tangible book value of \$ per share to new investors purchasing our common stock in this offering.

The number of shares of common stock to be outstanding after this offering is based on 171,831,324 shares outstanding on June 30, 2014 and excludes as of that date:

options representing the right to purchase a total of 9,902,248 shares of common stock at a weighted average exercise price of \$3.06 per share;

restricted stock units representing a total of 2,769,875 shares of common stock issuable upon vesting; and

restricted stock units representing a total of 1,108,873 vested shares of common stock issuable to directors. To the extent that outstanding options or warrants are exercised, investors purchasing our common stock in this offering will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

#### UNDERWRITING

We are offering the shares of common stock described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC, Deutsche Bank Securities Inc. and Merrill Lynch, Pierce, Fenner & Smith Incorporated are acting as joint book-running managers of the offering and as representatives of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover of this prospectus, the number of shares of common stock listed next to its name in the following table:

Number of shares

The underwriters are committed to purchase all the shares of common stock offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the shares of common stock directly to the public at the public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of \$ per share. Any such dealers may resell shares to certain other brokers or dealers at a discount of up to \$ per share from the public offering price. After the public offering of the shares, the offering price and other selling terms may be changed by the underwriters. Sales of shares made outside of the United States may be made by affiliates of the underwriters.

The underwriters have an option to buy up to an additional shares of our common stock. The underwriters have 30 days from the date of this prospectus to exercise this option to purchase additional shares. If any shares are purchased with this option to purchase additional shares, the underwriters will purchase shares in approximately the same proportion as shown in the table above. If any additional shares of common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriting fee is equal to the public offering price per share of common stock less the amount paid by the underwriters to us per share of common stock. The underwriting fee is \$ per share. The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters option to purchase additional shares.

Paid by us

	Without exercise of option to purchase additional shares	With full exercise of option to purchase additional shares
Per Share	\$	\$
Total	\$	\$

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately \$\$. We have agreed to reimburse the underwriters for all expenses relating to the clearance of this offering with the Financial Industry Regulatory Authority.

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

We have agreed that we will not (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, or file with the Securities and Exchange Commission a registration statement under the Securities Act of 1933, as amended (the Securities Act ), relating to, any shares of our common stock or any securities convertible into or exercisable or exchangeable for shares of our common stock, or publicly disclose the intention to make any offer, sale, pledge, disposition or filing, or (ii) enter into any swap or other arrangement that transfers all or a portion of the economic consequences associated with the ownership of any shares of our common stock or any such other securities (regardless of whether any of these transactions are to be settled by the delivery of shares of our common stock or such other securities, in cash or otherwise), in each case without the prior written consent of J.P. Morgan Securities LLC, Deutsche Bank Securities Inc. and Merrill Lynch, Pierce, Fenner & Smith Incorporated for a period of 60 days after the date of this prospectus, other than (i) the shares of our common stock to be sold hereunder, (ii) any shares of our common stock issued upon the exercise of options granted under our stock-based compensation plans and those of our subsidiaries, (iii) subject to certain conditions, any shares of our common stock issued or to be issued in connection with any business combination, acquisition, in-license or strategic investment.

Our directors and executive officers have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each of these persons or entities, with limited exceptions, for a period of 60 days after the date of this prospectus, may not, without the prior written consent of J.P. Morgan Securities LLC, Deutsche Bank Securities Inc. and Merrill Lynch, Pierce, Fenner & Smith Incorporated, (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock (including without limitation, common stock or such other securities which may be deemed to be beneficially owned by such directors, executive officers and shareholders in accordance with the rules and regulations of the Securities and Exchange Commission and securities which may be issued upon exercise of a stock option or warrant), or publicly disclose the intention to make any offer, sale, pledge or disposition, (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of our common stock or such other securities, in cash or otherwise or (3) make any demand for or exercise any right with respect to the registration of any shares of our common stock or any securities.

Notwithstanding the foregoing, if (1) during the last 17 days of the 60-day restricted period, we issue an earnings release or material news or a material event relating to our company occurs; or (2) prior to the expiration of the 60-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the [60]-day period, the restrictions described above shall continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933, as amended.

Our common stock is listed on The NASDAQ Global Market under the symbol AVNR.

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling shares of common stock in the open market for the purpose of preventing or retarding a decline in the market price of the common stock while this offering is in progress. These stabilizing transactions may include making short sales of the common stock, which involves the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering, and purchasing shares of common stock on the open market to cover positions created by short sales. Short sales may be covered shorts, which are short positions

in an amount not greater than the underwriters option to purchase additional shares referred to above, or may be naked shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their option to purchase additional shares, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the option to purchase additional shares. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the common stock, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase common stock in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common stock or preventing or retarding a decline in the market price of the common stock, and, as a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on The NASDAQ Global Market, in the over-the-counter market or otherwise.

In addition, in connection with this offering certain of the underwriters (and selling group members) may engage in passive market making transactions in our common stock on The NASDAQ Global Market prior to the pricing and completion of this offering. Passive market making consists of displaying bids on The NASDAQ Global Market no higher than the bid prices of independent market makers and making purchases at prices no higher than these independent bids and effected in response to order flow. Net purchases by a passive market maker on each day are generally limited to a specified percentage of the passive market maker s average daily trading volume in the common stock during a specified period and must be discontinued when such limit is reached. Passive market making may cause the price of our common stock to be higher than the price that otherwise would exist in the open market in the absence of these transactions. If passive market making is commenced, it may be discontinued at any time.

# **Selling Restrictions**

# General

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

# **United Kingdom**

Each underwriter has represented and agreed that:

(1) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the FSMA) received by it in connection with the issue or sale of our common shares in circumstances in which Section 21(1) of the FSMA does not apply to us; and

(2) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to our common shares in, from or otherwise involving the United Kingdom.

# European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a Relevant Member State ), an offer to the public of any shares which are the subject of the offering contemplated by this prospectus (the Shares ) may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any Shares may be made at any time under the following exemptions

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under the Prospectus Directive, if they have been implemented in that Relevant Member State:

(1) to any legal entity which is a qualified investor as defined in the Prospectus Directive;

(2) to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives for any such offer; or

(3) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of Shares shall result in a requirement for the publication by us or any underwriter of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an offer to the public in relation to any Shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any Shares to be offered so as to enable an investor to decide to purchase any Shares, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression Prospectus Directive means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State, and the expression 2010 PD Amending Directive means Directive 2010/73/EU.

# Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or the SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, the Company, the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or the CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

# Notice to Prospective Investors in the Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority (DFSA). This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

# Notice to Prospective Investors in Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission ( ASIC ), in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the Corporations Act ), and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure Act.

Any offer in Australia of the shares may only be made to persons (the Exempt Investors ) who are sophisticated investors (within the meaning of section 708(8) of the Corporations Act), professional investors (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708

of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

# Hong Kong

The shares may not be offered or sold by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), or (ii) to professional investors within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a prospectus within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), and no advertisement,

invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to

professional investors within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

# Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the SFA), (ii) to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 by a relevant person which is: (a) a corporation (which is not an accredited investor) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor, shares, debentures and units of shares and debentures of that corporation or the beneficiaries rights and interest in that trust shall not be transferable for 6 months after that corporation or that trust has acquired the shares under Section 275 except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA; (2) where no consideration is given for the transfer; or (3) by operation of law.

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### Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (the Financial Instruments and Exchange Law) and each underwriter has agreed that it will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Law and any other applicable laws, regulations and ministerial guidelines of Japan.

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# LEGAL MATTERS

Gibson, Dunn & Crutcher LLP of San Francisco, California, will issue an opinion with respect to the validity of the issuance of the securities being offered hereby. Latham & Watkins LLP is counsel to the underwriters in connection with this offering.

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# PROSPECTUS

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. Each time we sell securities pursuant to this prospectus, 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 or sales agreement prospectus.

Our common stock trades on The NASDAQ Global Market under the symbol AVNR .

Investing in our securities involves certain risks. See <u>Risk Factors</u> beginning on Page 2 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 September 22, 2014.

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## **ABOUT THIS PROSPECTUS**

References in this prospectus to Avanir, the Company, we, us, and our refer to Avanir Pharmaceuticals, Inc. and subsidiaries, on a consolidated basis.

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or 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 such securities 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:

the type and amount of securities that we propose to sell;

the initial public offering price of the securities;

the names of any underwriters or agents through or to which we will sell the securities;

any compensation of those underwriters or agents; and

information about any securities exchanges or automated quotation systems on which the securities will be listed or traded.

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 and the applicable prospectus supplement in their entirety together with additional information described under the heading Where You Can Find More Information in this prospectus. This prospectus may not be used to offer or sell any securities unless accompanied by a prospectus supplement.

Wherever references are made in this prospectus to information that will be included in a prospectus supplement, to the extent permitted by applicable law, rules or regulations, we may instead include such information or add, update or change the information contained in this prospectus by means of a post-effective amendment to the registration statement of which this prospectus is a part, through filings we make with the SEC that are incorporated by reference into this prospectus or by any other method as may then be permitted under applicable law, rules or regulations.

# ABOUT AVANIR PHARMACEUTICALS, INC.

Avanir is a biopharmaceutical company focused on acquiring, developing and commercializing novel therapeutic products for the treatment of central nervous system disorders. The Company s lead product NUEDEXT® (referred to as AVP-923 during clinical development) is a first-in-class dual *N-methyl-D-aspartate* receptor antagonist and sigma-1 agonist. NUEDEXTA, 20/10 mg, was approved in the United States in October 2010 for the treatment of pseudobulbar affect (PBA). It is also approved for the treatment of PBA in the European Union in two dose strengths, NUEDEXTA 20/10 mg and NUEDEXTA 30/10 mg. The Company commercially launched NUEDEXTA in the United States in February 2011 and it is currently assessing plans regarding the potential commercialization of NUEDEXTA in the European Union.

We are developing and commercializing a number of other therapeutic products for the treatment of central nervous disorders. Additionally, we have partnered programs in other therapeutic areas that may generate future revenue for us.

Avanir was incorporated in California in August 1988 and was reincorporated in Delaware in March 2009.

Our offices are located at 30 Enterprise, Suite 400, 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 www.avanir.com, 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 www.sec.gov and our website at www.avanir.com. No portion of our website is incorporated by reference into this prospectus.

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.

# **RISK FACTORS**

Investing in our securities involves risk. Before you decide whether to purchase any of our securities, in addition to the other information, documents or reports included in or incorporated by reference into this prospectus and any accompanying prospectus supplement or other offering materials, you should carefully consider the risk factors in the section entitled Risk Factors in any prospectus supplement as well as our most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q, which are incorporated by reference into this prospectus and any prospectus supplement in their entirety, as the same may be amended, supplemented or superseded from time to time by our filings under the Exchange Act of 1934 (the Exchange Act ). For more information, see the section entitled Where You Con Find More Information.

Where You Can Find More Information. These risks could materially and adversely affect our business, results of operations and financial condition and could result in a partial or complete loss of your investment.

# **USE OF PROCEEDS**

We intend to use the net proceeds we receive from the sale of securities by us as set forth in the applicable prospectus supplement.

# **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 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.

**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.

We are authorized to issue 300,000,000 shares of common stock, par value \$0.0001 per share, of which 171,832,565 shares were issued and outstanding as of July 31, 2014.

Our common stock is listed on the NASDAQ Global Market under the symbol AVNR . The transfer agent and registrar for the common stock is American Stock Transfer & Trust Company, LLC. Its address is 59 Maiden Lane, Plaza Level, New York, NY 10038.

**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 pursuant to this prospectus, we will fix the rights, preferences, privileges, qualifications and restrictions of each series of such preferred stock in the certificate of designations relating to that series. If we issue preferred stock pursuant to this prospectus, 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**. The paragraphs below describe the general terms and provisions of the debt securities we may issue. When we offer to sell a particular series of debt securities, we will describe the specific terms of the securities in a supplement to this prospectus, including any additional covenants or changes to existing covenants relating to such series. The prospectus supplement also will indicate whether the general terms and provisions described in this prospectus apply to a particular series of debt securities. You should read the actual indenture if you do not fully understand a term or the way we use it in this prospectus.

If we issue debt securities at a discount from their principal amount, then, for purposes of calculating the aggregate initial offering price of the offered securities issued under this prospectus, we will include only the initial offering price of the debt securities and not the principal amount of the debt securities.

We have summarized below the material provisions of the indenture, or indicated which material provisions will be described in the related prospectus supplement. The prospectus supplement relating to any particular securities offered will describe the specific terms of the securities, which may be in addition to or different from the general terms summarized in this prospectus. We have included the form of the indenture as an exhibit to our registration statement of which this prospectus is a part, and it is incorporated into this prospectus by reference. Because the summary in this prospectus and in any prospectus supplement does not contain all of the information that you may find useful, you should read the documents relating to the securities that are described in this prospectus or in any applicable prospectus supplement. Please read Where You Can Find More Information in this prospectus to find out how you can obtain a copy of those documents. References below to an indenture are references to the indenture, as supplemented, under which a particular series of debt securities is issued. As used under this caption, the term debt securities includes the debt securities being offered by this prospectus and all other debt securities issued by us under the indenture.

### General

The indenture:

does not limit the amount of debt securities that we may issue;

allows us to issue debt securities in one or more series;

does not require us to issue all of the debt securities of a series at the same time; and

allows us to reopen a series to issue additional debt securities without the consent of the holders of the debt securities of such series.

The prospectus supplement for each offering of debt securities will provide the following terms, where applicable:

the title of the debt securities and whether they are senior, senior subordinated or subordinated debt securities;

the aggregate principal amount of the debt securities being offered and any limit on their aggregate principal amount, and, if the series is to be issued at a discount from its face amount, the method of computing the accretion of such discount;

the price at which the debt securities will be issued, expressed as a percentage of the principal and, if other than the full principal amount thereof, the portion of the principal amount thereof payable upon declaration of acceleration of the maturity thereof or, if applicable, the portion of the principal amount of such debt securities that is convertible into common stock or preferred stock or the method by which any such portion shall be determined;

if convertible, the terms on which such debt securities are convertible, including the initial conversion price or rate or the method of calculation, how and when the conversion price or exchange ratio may be adjusted, whether conversion or exchange is mandatory, at the option of the holder or at our option, the conversion or exchange period, and any other provision in relation thereto, and any applicable limitations on the ownership or transferability of common stock or preferred stock received on conversion;

the date or dates, or the method for determining the date or dates, on which the principal of the debt securities will be payable;

the fixed or variable interest rate or rates of the debt securities, or the method by which the interest rate or rates is determined;

the date or dates, or the method for determining the date or dates, from which interest will accrue;

the dates on which interest will be payable;

the record dates for interest payment dates, or the method by which we will determine those dates;

the persons to whom interest will be payable;

the basis upon which interest will be calculated if other than that of a 360-day year of twelve 30-day months;

Any collateral securing the performance of our obligations under the debt securities;

the place or places where the principal of, premium, if any, and interest on, the debt securities will be payable;

where the debt securities may be surrendered for registration of transfer or conversion or exchange;

where notices or demands to or upon us in respect of the debt securities and the applicable indenture may be served;

any provisions regarding our right to redeem or purchase debt securities or the right of holders to require us to redeem or purchase debt securities;

any right or obligation we have to redeem, repay or purchase the debt securities pursuant to any sinking fund or analogous provision;

the currency or currencies (including any composite currency) in which the debt securities are denominated and payable if other than United States dollars, and the currency or currencies (including any composite currency) in which principal, premium, if any, and interest, if any, will be payable, and if such payments may be made in a currency other than that in which the debt securities are denominated, the manner for determining such payments, including the time and manner of determining the exchange rate between the currency in which such securities are denominated and the currency in which such securities or any of them may be paid, and any additions to, modifications of or deletions from the terms of the debt securities to provide for or to facilitate the issuance of debt securities denominated or payable in a currency other than U.S. dollars;

whether the amount of payments of principal of, premium, if any, or interest on, the debt securities may be determined according to an index, formula or other method and how such amounts will be determined;

whether the debt securities will be in registered form, bearer form or both, and the terms of these forms;

whether the debt securities will be issued in whole or in part in the form of a global security and, if applicable, the identity of the depositary for such global security;

any provision for electronic issuance of the debt securities or issuance of the debt securities in uncertificated form;

whether and upon what terms the debt securities of such series may be defeased or discharged, if different from the provisions set forth in the indenture for the series to which the supplemental indenture or authorizing resolution relates;

any provisions granting special rights to holders of securities upon the occurrence of such events as specified in the applicable prospectus supplement;

any deletions from, modifications of, or additions to our events of default or covenants or other provisions set forth in the indenture for the series to which the supplemental indenture or authorizing resolution relates; and

any other material terms of the debt securities, which may be different from the terms set forth in this prospectus.

We may issue debt securities at a discount below their principal amount and provide for less than the entire principal amount thereof to be payable upon declaration of acceleration of the maturity of the debt securities. We

refer to any such debt securities throughout this prospectus as original issue discount securities. The applicable prospectus supplement will describe the United States federal income tax consequences and other relevant considerations applicable to original issue discount securities.

Neither the Delaware General Corporation Law nor our governing instruments define the term substantially all as it relates to the sale of assets. Additionally, Delaware cases interpreting the term substantially all rely upon the facts and circumstances of each particular case. Consequently, to determine whether a sale of substantially all of our assets has occurred, a holder of debt securities must review the financial and other information that we have disclosed to the public.

The applicable prospectus supplement will also describe any material covenants to which a series of debt securities will be subject and the applicability of those covenants to any of our subsidiaries to be restricted thereby, which are referred to herein as restricted subsidiaries. The applicable prospectus supplement will also describe provisions for restricted subsidiaries to cease to be restricted by those covenants.

# **Events of Default**

Unless the applicable prospectus supplement states otherwise, when we refer to events of default as defined in the indentures with respect to any series of debt securities, we mean:

our failure to pay interest on any debt security of such series when the same becomes due and payable and the continuance of any such failure for a period of 30 days;

our failure to pay the principal or premium of any debt security of such series when the same becomes due and payable at maturity, upon acceleration, redemption or otherwise;

our failure or the failure of any restricted subsidiary to comply with any of its agreements or covenants in, or provisions of, the debt securities of such series or the indenture (as they relate thereto) and such failure continues for a period of 60 days after our receipt of notice of the default from the trustee or from the holders of at least 25 percent in aggregate principal amount of the then outstanding debt securities of that series (except in the case of a default with respect to the provisions of the indenture regarding the consolidation, merger, sale, lease, conveyance or other disposition of all or substantially all of the assets of us (or any other provision specified in the applicable supplemental indenture or authorizing resolution), which will constitute an event of default with notice but without passage of time); or

certain events of bankruptcy, insolvency or reorganization occur with respect to Avanir or any restricted subsidiary of Avanir that is a significant subsidiary (as defined in the indenture).

If an event of default occurs and is continuing with respect to debt securities of any series outstanding, then the trustee or the holders of 25% or more in principal amount of the outstanding debt securities of that series will have the right to declare the principal amount of all the debt securities of that series to be due and payable immediately. However, the holders of at least a majority in principal amount of outstanding debt securities of such series may rescind and annul such declaration and its consequences, except an acceleration due to nonpayment of principal or interest on such series, if the rescission would not conflict with any judgment or decree and if all existing events of default with

respect to such series have been cured or waived.

The indenture also provides that the holders of at least a majority in principal amount of the outstanding debt securities of any series, by notice to the trustee, may, on behalf of all holders, waive any existing default and its consequences with respect to such series of debt securities, other than any event of default in payment of principal or interest.

The indenture will require the trustee to give notice to the holders of debt securities within 90 days after the trustee obtains knowledge of a default that has occurred and is continuing. However, the trustee may withhold notice to the holders of any series of debt securities of any default, except a default in payment of principal or interest, if any, with respect to such series of debt securities, if the trustee considers it in the interest of the holders of such series of debt securities to do so.

The holders of a majority of the outstanding principal amount of the debt securities of any series will have the right to direct the time, method and place of conducting any proceedings for any remedy available to the trustee with respect to such series, subject to limitations specified in the indenture.

### Amendment, Supplement and Waiver

Without notice to or the consent of any holder, we and the trustee may amend or supplement the indenture or the debt securities of a series:

to cure any ambiguity, omission, defect or inconsistency;

to comply with the provisions of the indenture regarding the consolidation, merger, sale, lease, conveyance or other disposition of all or substantially all of our assets;

to provide that specific provisions of the indenture shall not apply to a series of debt securities not previously issued or to make a change to specific provisions of the indenture that only applies to any series of debt securities not previously issued or to additional debt securities of a series not previously issued;

to create a series and establish its terms;

to provide for uncertificated debt securities in addition to or in place of certificated debt securities;

to release a guarantor in respect of any series which, in accordance with the terms of the indenture applicable to such series, ceases to be liable in respect of its guarantee;

to add a guarantor subsidiary in respect of any series of debt securities;

to secure any series of debt securities;

to add to the covenants of Avanir for the benefit of the holders or surrender any right or power conferred upon Avanir;

to appoint a successor trustee with respect to the securities;

to comply with requirements of the SEC in order to effect or maintain the qualification of the indenture under the Trust Indenture Act;

to make any change that does not adversely affect the rights of holders; or

to conform the provisions of the indenture to the final offering document in respect of any series of debt securities.

The indenture will provide that we and the trustee may amend or supplement any provision of the debt securities of a series or of the indenture relating to such series with the written consent of the holders of at least a majority in principal amount of the outstanding debt securities of such series. However, without the consent of each holder of a debt security the terms of which are directly amended, supplemented or waived, an amendment, supplement or waiver may not:

reduce the amount of debt securities of such series whose holders must consent to an amendment, supplement or waiver;

reduce the rate of or extend the time for payment of interest, including defaulted interest;

reduce the principal of or extend the fixed maturity of any debt security or alter the provisions with respect to redemptions or mandatory offers to repurchase debt securities of a series in a manner adverse to holders;

make any change that adversely affects any right of a holder to convert or exchange any debt security into or for shares of our common stock or other securities, cash or other property in accordance with the terms of such security;

modify the ranking or priority of the debt securities of the relevant series;

release any guarantor of any series from any of its obligations under its guarantee or the indenture otherwise than in accordance with the terms of the indenture;

make any change to any provision of the indenture relating to the waiver of existing defaults, the rights of holders to receive payment of principal and interest on the debt securities, or to the provisions regarding amending or supplementing the indenture or the debt securities of a particular series with the written consent of the holders of such series, except to increase the percentage required for modification or waiver or to provide for consent of each affected holder of debt securities of such series;

waive a continuing default or event of default in the payment of principal of or interest on the debt securities; or

make any debt security payable at a place or in money other than that stated in the debt security, or impair the right of any holder of a debt security to bring suit as permitted by the indenture.

The holders of a majority in aggregate principal amount of the outstanding debt securities of such series may, on behalf of all holders of debt securities of that series, waive any existing default under, or compliance with, any provision of the debt securities of a particular series or of the indenture relating to a particular series of debt securities, other than any event of default in payment of interest or principal.

#### Defeasance

The indenture will permit us to terminate all our respective obligations under the indenture as they relate to any particular series of debt securities, other than the obligation to pay interest, if any, on and the principal of the debt securities of such series and certain other obligations, at any time by:

depositing in trust with the trustee, under an irrevocable trust agreement, money or government obligations in an amount sufficient to pay principal of and interest, if any, on the debt securities of such series to their maturity or redemption; and

complying with other conditions, including delivery to the trustee of an opinion of counsel to the effect that holders will not recognize income, gain or loss for federal income tax purposes as a result of our exercise of such right and will be subject to federal income tax on the same amount and in the same manner and at the same times as would have been the case otherwise.

The indenture will also permit us to terminate all of our respective obligations under the indenture as they relate to any particular series of debt securities, including the obligations to pay interest, if any, on and the principal of the debt securities of such series and certain other obligations, at any time by:

depositing in trust with the trustee, under an irrevocable trust agreement, money or government obligations in an amount sufficient to pay principal and interest, if any, on the debt securities of such series to their maturity or redemption; and

complying with other conditions, including delivery to the trustee of an opinion of counsel to the effect that (A) we have received from, or there has been published by, the Internal Revenue Service a ruling, or (B) since the date such series of debt securities were originally issued, there has been a change in the applicable federal income tax law, in either case to the effect that, and based thereon such opinion of counsel shall state that, holders will not recognize income, gain or loss for federal income tax purposes as a result of our exercise of such right and will be subject to federal income tax on the same amount and in the same manner and at the same times as would have been the case otherwise.

In addition, the indenture will permit us to terminate substantially all our respective obligations under the indenture as they relate to a particular series of debt securities by depositing with the trustee money or

government obligations sufficient to pay all principal and interest on such series at its maturity or redemption date if the debt securities of such series will become due and payable at maturity within one year or are to be called for redemption within one year of the deposit.

# Transfer and Exchange

A holder will be able to transfer or exchange debt securities only in accordance with the indenture. The registrar may require a holder, among other things, to furnish appropriate endorsements and transfer documents, and to pay any taxes and fees required by law or permitted by the indenture.

### **Concerning the Trustee**

The indenture will contain limitations on the rights of the trustee, should it become our creditor, to obtain payment of claims in specified cases or to realize on property received in respect of any such claim as security or otherwise. The indenture will permit the trustee to engage in other transactions; however, if it acquires any conflicting interest, it must eliminate such conflict or resign.

The indenture will provide that in case an event of default occurs and is not cured, the trustee will be required, in the exercise of its power, to use the degree of care of a prudent person in similar circumstances in the conduct of such person s own affairs. The trustee shall be under no obligation to exercise any of the rights or powers vested in it by the Indenture at the request or direction of any of the holders pursuant to the Indenture, unless such holders shall have offered to the trustee security or indemnity satisfactory to the trustee against the costs, expenses and liabilities which might be incurred by it in compliance with such request or direction.

#### No Recourse Against Others

The indenture will provide that there is no recourse under any obligation, covenant or agreement in the applicable indenture or with respect to any debt security against any of our or our successor s past, present or future stockholders, employees, officers or directors.

# Governing Law

The laws of the State of New York will govern the indenture and the debt securities.

<u>Warrants</u>. 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.

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.

# 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 any securities issued pursuant to this prospectus, and the terms of any offering pursuant to this prospectus, in the applicable 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 applicable 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 applicable 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 such prospectus supplement, and such 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.

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

Unless otherwise specified in the applicable 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 Global 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 Gibson, Dunn & Crutcher LLP, San Francisco, California. The legality of the securities for any underwriters, dealers or agents will be passed upon by counsel as may be specified in the applicable prospectus supplement.

#### **EXPERTS**

Our consolidated financial statements incorporated in this prospectus by reference from our Annual Report on Form 10-K for the year ended September 30, 2013, and the effectiveness of our internal control over financial reporting, have been audited by KMJ Corbin & Company LLP, an independent registered public accounting firm, as stated in their reports, which are incorporated herein by reference, and have been so incorporated in reliance upon the reports 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 incorporate by reference the documents listed below which have been filed by us:

- 1. Our Annual Report on Form 10-K for the year ended September 30, 2013;
- 2. Portions of our Definitive Proxy Statement on Schedule 14A filed with the SEC on December 30, 2013 that have been incorporated by reference into our Annual Report on Form 10-K for the year ended September 30, 2013;
- 3. Our Quarterly Reports on Form 10-Q for the periods ended December 31, 2013, March 31, 2014 and June 30, 2014;
- 4. Our Current Reports on Form 8-K filed with the SEC on November 15, 2013, December 10, 2013, January 10, 2014, February 19, 2014, March 19, 2014, May 5, 2014, May 7, 2014 and September 15, 2014 (in each case, not including any information furnished under Items 2.02 or 7.01 of Form 8-K, including the related exhibits, which information is not incorporated by reference herein); 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.

All documents we file with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, except as to any portion of any report or documents that is not deemed filed under such provisions, (1) on or after the date of filing of the registration statement containing this prospectus and prior to the effectiveness of the registration statement and (2) on or after the date of this prospectus until the earlier of the date on which all of the securities registered hereunder have been sold or the registration statement of which this prospectus is a part has been withdrawn, shall be deemed incorporated by reference in this prospectus and to be a part of this prospectus from the date of filing of those documents.

Nothing in this prospectus shall be deemed to incorporate information furnished but not filed with the SEC pursuant to Item 2.02 or 7.01 of Form 8-K.

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., 30 Enterprise, Suite 400, 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 Exchange Act and in accordance therewith file reports, proxy statements and other information with the SEC. Our filings are available to the public over the Internet at the SEC s website at *www.sec.gov*, as well as at our website at *www.avanir.com*. You may also read and copy, at prescribed rates, any document we file with the SEC at the Public Reference Room of the SEC located at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at (800) SEC-0330 for further information on the SEC s Public Reference Rooms.

\* \* \*

\$200,000,000

**Common Stock** 

# **PROSPECTUS SUPPLEMENT**

Joint Book-Running Managers

J.P. Morgan

**Deutsche Bank Securities** 

**BofA Merrill Lynch** 

September , 2014