AVANIR

pharmaceuticals

2010 Annual Report

Making a Difference for Those Suffering with a Significant, Unmet Medical Need

To our valued Stockholders,

It would be an understatement to say that 2010 has been a landmark year for AVANIR, with the FDA approval of NUEDEXTA™, marking the first and only therapy to treat patients with pseudobulbar affect (PBA), a neurologic condition causing involuntary, sudden and frequent episodes of laughing and crying. October 29, 2010 marked a significant milestone for the many patients with a broad range of neurologic conditions in the U.S. also suffering from the debilitating episodes of PBA, including those patients with multiple sclerosis (MS), ALS (Lou Gehrig's disease), brain injury, stroke, Alzheimer's disease, Parkinson's disease and others. On behalf of all my colleagues at AVANIR, our deepest gratitude goes to all of the patients and investigators who have contributed to our success through participation in our studies, as well as our dedicated employees who invested more than 10 years of research and development to gain the approval of NUEDEXTA.

The achievement of FDA approval for NUEDEXTA seemed, at one time, like a far and distant dream. However, AVANIR persevered over the five years it took from the initial application to gain approval from the FDA to where we are today — planning for the commercial launch of NUEDEXTA in early 2011. The past year was also highlighted by important accomplishments, such as key Phase III STAR Trial data presentations to support NUEDEXTA at prestigious medical conferences, the announcement of favorable safety and efficacy results from the open label extension trial, to the FDA submission of our complete response to the October 2006 approvable letter.

It was also five years ago that I had the privilege to join the dedicated team at AVANIR Pharmaceuticals. Though it has been a long road, it has been and continues to be a rewarding and fulfilling experience. I am honored and committed to oversee our company's transition toward becoming a commercial enterprise and supporting the launch of NUEDEXTA in the first calendar quarter of 2011. It is long overdue for the more than one million patients who suffer from PBA to receive a treatment that is not only safe and effective, but the first indicated specifically for their condition.

Fulfilling an Educational Gap: Launch Preparation for a First-in-Class Treatment for PBA

Another great accomplishment for AVANIR in 2010 has been the significant transition that has been made to broaden our focus from clinical and regulatory success to market development and commercial readiness. With its first-in-class approval, our efforts have been accelerated in order to ensure a successful launch and long-term commercial use of NUEDEXTA. And since we are developing a new market and therapeutic category, we expect to educate a large number of physicians, patients and caregivers in order to change established behaviors and ensure that patients suffering from PBA are appropriately diagnosed and treated.

Leading up to the FDA's decision, we brought on a team of experienced sales professionals to begin educating health care practitioners about PBA and the impact it has on patients' lives. As expected, our team members have been finding a high level of interest from clinicians in treating PBA. Through physician dialogue, we have discovered that they do not believe current therapies are very effective and therefore are interested in identifying a new therapeutic option for these patients.

Just as it is important that clinicians know about the approval of NUEDEXTA, irrespective of underlying neurologic disease or injury giving rise to PBA, it is equally important to ensure clinicians make the correct diagnosis of PBA. In order to carry this out, we have expanded our team following approval, and I'm pleased we have filled all 75 planned sales territories and all 7 sales management positions. I'm even more pleased at the caliber of individuals we were able to attract to our sales teams. The average AVANIR sales representative has more than six years of pharmaceutical sales tenure, with approximately 75 percent of our sales force having prior experience selling CNS therapies to neurologists and psychiatrists in their new AVANIR territories.

Additionally, we have built out our managed market team with nine account managers and a director of trade relations who are calling on key Medicare Part D Plans, commercial plans and drug wholesalers. Furthermore, we staffed our medical affairs organization with five talented medical science liaisons who have been building relationships with advocacy groups, and with national and regional opinion leaders over the past year.

Looking Ahead to 2011 & Beyond

Subsequent to the end of the fiscal year, we strengthened our balance sheet by raising net proceeds of $83.2 million in a public offering of common stock. We believe the size of the offering, favorable financial terms and strong investor syndicate, including several large, long-only institutional investors, demonstrate the high level of interest and excitement about AVANIR in the financial community.

With a strong balance sheet, a high-performing commercial team and a clinical development team with a track record of proven success, our priorities for fiscal year 2011 are clear. We expect to be able to fully fund the commercialization of NUEDEXTA, the additional clinical development of NUEDEXTA for follow-on indications and further development of our European regulatory strategy.

In summary, 2010 has been a transformational year for AVANIR. After years of hard work and perseverance, we now have the opportunity to deliver on our promise to help the many neurologic patients in the U.S. suffering from PBA. We are confident that we have the right strategy, resources and the commercial expertise to successfully launch NUEDEXTA in February of 2011.

On behalf of AVANIR, I extend our gratitude to you, our stockholders, for your continued support, putting us in a strong position to achieve our goals and realize our mission of becoming a leading developer and marketer of innovative therapies to dramatically improve the lives of patients with CNS disorders.

Sincerely,

Keith Katkin
President and Chief Executive Officer

December 2010

Note: Please review the enclosed Annual Report on Form 10-K for the year ended September 30, 2010, including the information under Item 1A, captioned "Risk Factors," for more important information regarding AVANIR and risks associated with forward-looking statements contained in this letter and in our annual report. These forward-looking statements include our expectations around the timing, costs and ultimate success of the launch of NUEDEXTA, physician and patient adoption of the drug, the NUEDEXTA safety profile in patients once commercialized, our ability to successfully obtain European approval for NUEDEXTA and develop NUEDEXTA for other indications, and other expressed or implied forward-looking statements contained in this letter and the accompanying annual report. These forward-looking statements are based on our current expectations and assumptions and many factors could cause our actual results to differ materially from those indicated in these forward-looking statements.

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended September 30, 2010

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File No. 1-15803

AVANIR Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**33-0314804**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
101 Enterprise Suite 300, Aliso Viejo, California	**92656**
(Address of principal executive offices)	*(Zip Code)*

(949) 389-6700

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, $.0001 par value	**The NASDAQ Global Market**

Securities registered pursuant to Section 12(g) of the Act:

Title of Each Class to be so Registered	Name of Each Exchange on Which Each Class is to be Registered
Preferred Share Purchase Rights	N/A

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15 (d) of the Act. YES ☐ NO ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☑ NO ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES ☐ NO ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☑

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☑ Non-accelerated filer ☐ Smaller reporting company ☐
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☑

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of March 31, 2010 was approximately $158.3 million, based upon the closing price on the NASDAQ Global Market reported for such date. Shares of common stock held by each officer and director and by each person who is known to own 10% or more of the outstanding Common Stock have been excluded in that such persons may be deemed to be affiliates of the Company. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

120,982,441 shares of the registrant's Common Stock were issued and outstanding as of December 1, 2010.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required to be disclosed in Part III of this report is incorporated by reference from the registrant's definitive Proxy Statement for the 2011 Annual Meeting of Stockholders, which will be held on February 8, 2011 and which proxy statement will be filed not later than 120 days after the end of the fiscal year covered by this report.

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PART I

Item 1. *Business*

This Annual Report on Form 10-K contains forward-looking statements concerning future events and performance of our Company. When used in this report, the words "intend," "estimate," "anticipate," "believe," "plan," "goal" and "expect" and similar expressions as they relate to AVANIR Pharmaceuticals, Inc. are included to identify forward-looking statements. These forward-looking statements are based on our current expectations and assumptions and many factors could cause our actual results to differ materially from those indicated in these forward-looking statements. Risks that could cause actual results to differ significantly from our forward-looking statements include, but are not limited to, risks relating to our product sales, capital resources, commercial market estimates, safety of NUEDEXTA, future development efforts, patent protection, effects of healthcare reform, reliance on third parties, and other risks set forth below under Item 1A, "Risk Factors." We disclaim any intent to update or announce revisions to any forward-looking statements to reflect actual events or developments.

References in this report to AVANIR, the Company, we, our and us refer to AVANIR Pharmaceuticals, Inc. and its subsidiaries, on a consolidated basis. "AVANIR" and "NUEDEXTA" are trademarks of AVANIR Pharmaceuticals, Inc. or its subsidiaries in the U.S. and/or other countries. Other trademarks or service marks appearing in this report may be trademarks or service marks of other owners.

Executive Overview

AVANIR is a pharmaceutical company focused on developing and commercializing novel therapeutic products for the treatment of central nervous system disorders. In October 2010, the U.S. Food and Drug Administration ("FDA") approved NUEDEXTA™ (formerly referred to as AVP-923 or its previously proposed trade name Zenvia), a unique proprietary combination of dextromethorphan/quinidine, for the treatment of pseudobulbar affect ("PBA"). NUEDEXTA has also successfully completed a Phase III trial for the treatment of patients with diabetic peripheral neuropathic pain ("DPN pain"). We plan to commercially launch NUEDEXTA in the second quarter of fiscal 2011.

In addition to our focus on products for the central nervous system, we also have a number of partnered programs in other therapeutic areas that may generate future revenue for us. Our first commercialized product, docosanol 10% cream, (sold in the United States and Canada as Abreva® by our marketing partner GlaxoSmithKline Consumer Healthcare) is the only over-the-counter treatment for cold sores that has been approved by the FDA. In 2008, we out-licensed all of our monoclonal antibodies and we remain eligible to receive milestone payments and royalties related to the sale of these assets. AVANIR was incorporated in California in August 1988 and was reincorporated in Delaware in March 2009.

Drug Candidates and Marketed Products

NUEDEXTA for the treatment of PBA

NUEDEXTA™ is the first and only FDA-approved treatment for PBA, which 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 (20 mg), the ingredient active in the central nervous system, and quinidine sulfate (10 mg), a metabolic inhibitor enabling therapeutic dextromethorphan concentrations. NUEDEXTA acts on sigma-1 and N-Methyl-D-aspartic acid, or 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 in PBA were performed in patients with amyotrophic lateral sclerosis, or ALS, and multiple sclerosis, or MS. NUEDEXTA has not been shown to be safe and effective in other types of emotional lability that can commonly occur, for example, in Alzheimer's disease and other

dementias. The primary outcome measure, laughing and crying episodes, was significantly lower in the NUEDEXTA cohort compared to 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 to placebo.

NUEDEXTA safety information

NUEDEXTA can interact with other medications causing significant changes in blood levels of those medications and/or NUEDEXTA. NUEDEXTA is contraindicated in patients receiving drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine and pimozide) and should not be used concomitantly with other drugs containing quinidine, quinine, or mefloquine. NUEDEXTA is contraindicated in patients taking monoamine oxidase inhibitors (MAOIs) or in patients who have taken MAOIs within the preceding 14 days. NUEDEXTA is contraindicated in patients with a known hypersensitivity to its components.

NUEDEXTA may cause serious side effects, including possible changes in heart rhythm. NUEDEXTA is contraindicated in patients with a prolonged QT interval, congenital long QT syndrome or a history suggestive of torsades de pointes, in patients with heart failure as well as patients with, or at risk of, complete atrioventricular (AV) block, unless the patient has an implanted pacemaker. NUEDEXTA causes dose-dependent QTc prolongation. When initiating NUEDEXTA in patients at risk of QT prolongation and torsades de pointes, electrocardiographic (ECG) evaluation of QT interval should be conducted at baseline and 3-4 hours after the first dose.

The most common adverse reactions in patients taking NUEDEXTA are diarrhea, dizziness, cough, vomiting, weakness, swelling of feet and ankles, urinary tract infection, flu, elevated liver enzymes, and flatulence.

NUEDEXTA may cause dizziness. Precautions to reduce the risk of falls should be taken, particularly for patients with motor impairment affecting gait or a history of falls.

PBA indication and market

PBA is a distinct neurologic syndrome that is characterized by a lack of control of emotional expression, typically involving episodes of involuntary or exaggerated motor expression of emotion such as laughing, crying or other emotional displays.

There are an estimated 18 to 20 million people in the United States who suffer from the underlying neurological conditions that can give rise to PBA. These underlying neurologic conditions include but are not limited to ALS, MS, Alzheimer's disease, Parkinson's disease, stroke and traumatic brain injury. Extrapolating from the epidemiologic medical literature, physician estimates and an AVANIR-sponsored patient survey, which surveyed a total of 2,464 patients and caregivers of patients with underlying neurologic conditions associated with PBA (including ALS, Alzheimer's disease/dementias, MS, Parkinson's disease, stroke and traumatic brain injury), we estimate that approximately 10% of people in the United States who suffer from neurological disease or injury suffer from moderate to severe PBA, with many more suffering from mild PBA.

Other than NUEDEXTA, there are no approved therapies indicated to treat PBA. Currently, some physicians treat PBA using a range of drugs off-label, including: selective serotonin reuptake inhibitors/serotonin-norepinephrine reuptake inhibitors, or SSRIs/SNRIs, antidepressants and atypical antipsychotics. According to our market research, physicians are generally only moderately satisfied with these off-label therapies as a treatment for PBA. We conducted this market research through an Internet-based survey of 215 physicians, consisting of Neurologists, Internal Medicine/Geriatrics, Psychiatrists and Physical Medicine and Rehabilitation specialists.

We believe that NUEDEXTA represents a more attractive treatment option for patients suffering from PBA. In our Phase III STAR trial that was completed in 2009 with patients suffering from either ALS or MS as the underlying neurological condition, patients treated with NUEDEXTA reported an average overall 80% reduction in episodes at the end of the 12-week study compared to baseline, with an average 50% reduction in episodes in the first week of treatment. Over the course of the 12-week study, patients receiving NUEDEXTA experienced significantly lower PBA episode rates versus placebo ($P<0.0001$). Over the final two weeks of the STAR trial, one-half of patients treated with NUEDEXTA achieved episode-free remission.

Our market research, conducted pursuant to the physician survey described above, indicates that 85% of surveyed physicians within targeted physician specialties would likely or very likely prescribe NUEDEXTA to treat their patients suffering from PBA. Of the surveyed physicians, the highest use was expected to be in PBA patients who have underlying conditions of either stroke or traumatic brain injury, but physicians expect to treat all PBA patient populations with NUEDEXTA. Among those physicians expressing an intent to prescribe NUEDEXTA, 78% indicated that NUEDEXTA would likely be used as a first-line therapy or an add-on therapy.

NUEDEXTA Commercialization Strategy

We intend to market NUEDEXTA initially to approximately 14,000 physicians who primarily specialize in psychiatry and neurology. Our commercialization strategy for NUEDEXTA includes the following elements: increase awareness of PBA, promote trial and adoption of NUEDEXTA, increase brand awareness of NUEDEXTA and minimize payment and distribution barriers.

AVP-923 for the Treatment of Neuropathic Pain Indications

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 neuropathic pain market is continuing to grow rapidly, and in 2006, was estimated to be worth $2.6 billion in sales among the seven largest markets, consisting of the United States, Japan, France, Germany, Italy, Spain and the United Kingdom.

AVANIR has successfully 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 primary endpoint of the trial was based on the daily diary entries for the Pain Rating Scale as defined in the SPA with the FDA. In the trial, two doses of AVP-923, 45/30 mg DMQ dosed twice daily ("AVP-923 45/30") and 30/30 mg DMQ dosed twice daily ("AVP-923 30/30"), were compared to placebo based on daily patient diary entries for the Pain Rating Scale. Both AVP-923 treatment groups had lower pain ratings than placebo patients ($p < 0.0001$ in both cases). In the AVP-923 45/30 patient group, average reductions were significantly greater than placebo patients at Days 30, 60, and 90 ($p < 0.0001$ at each time point). In the AVP-923 30/30 patient group, average reductions were also significantly greater than placebo patients at Days 30 and 60 ($p < 0.0001$) and Day 90 ($p=0.007$).

AVP-923 also demonstrated statistically significant improvements in a number of key secondary endpoints including the Pain Relief Ratings Scale and the Pain Intensity Ratings Scale. The secondary endpoints compared the baseline value to the average rating values at each study visit after randomization. The average pain relief reductions, as measured on the Pain Relief Rating Scale, were greater for the AVP-923 45/30 patient group ($p=0.0002$) and for the AVP-923 30/30 patient group ($p=0.0083$), compared with placebo. In addition, the DMQ 45, but not the DMQ 30, patient group demonstrated statistically significant improvements in the Pain Intensity Rating Scale compared with placebo ($p=0.029$). Although not powered to detect differences in the secondary endpoint of the Peripheral Neuropathy Quality of Life Scale Composite score and thus not achieving statistical significance, the AVP-923 45/30 patients showed a greater improvement than placebo patients ($p=0.05$) and the AVP-923 30/30 patients showed a trend towards greater improvement than placebo patients ($p=0.08$).

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. A higher number of patients in the AVP-923 45/30 and AVP-923 30/30 treatment groups (25.2% and 21.0%, respectively) discontinued due to an adverse event than compared to placebo (11.4%). There were no statistically significant differences in serious adverse event with 7.6%, 4.8% and 4.1% reported in the AVP-923 45/30, AVP-923 30/30 and placebo groups, respectively, and no deaths occurred during the study.

Due to safety concerns raised by the FDA in our October 2006 approvable letter for AVP-923, we conducted a formal pharmacokinetic ("PK") study to identify a lower quinidine dose formulation that may have similar efficacy to the doses tested in the Phase III study. In May 2008, we reported a positive outcome of the formal PK study and announced that we identified alternative lower quinidine dose formulations of AVP-923 for the next DPN pain phase III clinical trial. The new dose is intended to deliver similar efficacy and improved safety/tolerability versus the formulations previously tested in DPN pain.

In September 2008, we submitted our Phase III protocol and related program questions for AVP-923 in the treatment of patients with DPN pain to the FDA under the SPA process. In subsequent communications regarding the continued development of AVP-923 for DPN pain, the FDA has indicated that it may be necessary to test a lower quinidine dose formulation in the DPN pain indication, such as the formulation that was identified in our PK study. Additionally, based on feedback from the FDA, we believe that it is likely that two large well controlled Phase III trials utilizing a new lower quinidine dose formulation would be needed to support a New Drug Application ("NDA") filing for this indication. Due to our limited capital resources and focus on the commercialization of NUEDEXTA, we do not expect that we will be able to initiate the trials needed for this indication without additional capital or a development partner for AVP-923. Accordingly, we are evaluating our options to fund this program, including the potential for a development partner.

AVP-923 for the Treatment of MS Pain

In September 2009, we reported on secondary efficacy endpoints from the double-blind phase of the AVP-923 STAR trail in PBA, including an endpoint measuring reduction of pain in patients with underlying MS. AVP-923 30/10 mg demonstrated statistically significant relief of MS-related pain compared to placebo in the subset of MS patients with moderate-to-severe pain. Based on these data and the previous proof of concept pain data in MS patients with PBA, we are conducting a strategic assessment of the optimal clinical development path for AVP-923 to obtain an MS pain indication.

Other Programs

Docosanol 10% Cream — Cold Sore Treatment

Docosanol 10% cream is a topical treatment for cold sores. In 2000, we received FDA approval for marketing docosanol 10% cream as an over-the-counter product. Since that time, docosanol 10% cream has been approved by regulatory agencies in Asia, North America, and Europe. In March 2000, we granted a subsidiary of GlaxoSmithKline, SB Pharmco Puerto Rico, Inc. ("GSK"), the exclusive rights under a license to market docosanol 10% cream in the United States and Canada ("GSK License Agreement"). GSK markets the product under the name Abreva® in these markets. Under the terms of the GSK License Agreement, GSK is responsible for all sales and marketing activities and the manufacturing and distribution of docosanol 10% cream. Under the GSK license agreement, the Company received a total of $25 million in milestone payments from GSK and the Company was entitled to receive an 8% royalty on net sales of Abreva by GSK.

In November 2002, the Company sold to Drug Royalty USA an undivided interest in the Company's rights to receive future Abreva royalties under the GSK License Agreement for $24.1 million (the "Drug Royalty Agreement"). Under the Drug Royalty Agreement, Drug Royalty USA has the right to receive royalties from GSK on sales of Abreva until December 2013. The Company retained the right to receive 50% of all royalties (a net of 4%) under the GSK License Agreement for annual net sales of Abreva in the U.S. and Canada in excess of $62 million. From the effective date of the GSK License Agreement up to the 2002 sale of the Company's royalty rights to Drug Royalty USA, Inc. ("DRC") the Company received a total of approximately $5.9 million in royalty payments from GSK attributed to the 8% royalty on net sales by GSK.

Under the terms of our docosanol license agreements, our partners are generally responsible for all regulatory approvals, sales and marketing activities, and manufacturing and distribution of the product in the licensed territories. The terms of the license agreements typically provide for us to receive a data transfer fee, potential milestone payments and royalties on product sales. We purchase the active pharmaceutical ingredient ("API"), docosanol, from a large supplier in Western Europe and have, on occasion, sold material to our licensees. We

currently store our API in the United States. Any material disruption in manufacturing could cause a delay in shipments and possible loss of sales.

Xenerex Human Antibody Technology — Anthrax/Other Infectious Diseases

In March 2008, we entered into an Asset Purchase and License Agreement with Emergent Biosolutions for the sale of our anthrax antibodies and license to use our proprietary Xenerex Technology platform, which was used to generate fully human antibodies to target antigens. Under the terms of the Agreement, we completed the remaining work under our NIH/NIAID grant ("NIH grant") and transferred all materials to Emergent. Under the terms of the agreement, we are eligible to receive milestone payments and royalties on any product sales generated from this program. In connection with the sale of the anthrax antibody program, we also ceased all ongoing research and development work related to other infectious diseases on June 30, 2008.

In September 2008, we entered into an Asset Purchase Agreement with a San Diego based biotechnology company for the sale of our non-anthrax related antibodies as well as the remaining equipment and supplies associated with the Xenerex Technology platform. In connection with this sale, we received an upfront payment of $210,000 and are eligible to receive future royalties on potential product sales, if any.

Competition

The pharmaceutical industry is characterized by rapidly evolving technology and intense competition. A large number of companies of all sizes, including major pharmaceutical companies and specialized biotechnology companies, engage in activities similar to our activities. Many of our competitors have substantially greater financial and other resources available to them. In addition, colleges, universities, governmental agencies and other public and private research organizations continue to conduct research and are becoming more active in seeking patent protection and licensing arrangements to collect royalties for use of technologies that they have developed. Some of our competitors' products and technologies are in direct competition with ours. We also must compete with these institutions in recruiting highly qualified personnel.

NUEDEXTA for Pseudobulbar Affect. Although NUEDEXTA is the first product to be marketed for the treatment of PBA, we are aware that physicians may prescribe other products in an off-label manner for the treatment of this disorder. For example, NUEDEXTA may face competition from the following products:

- Antidepressants, including Prozac®, Celexa®, Zoloft®, Paxil®, Elavil® and Pamelor® and others;
- Atypical antipsychotic agents, including Zyprexa®, Risperdal®, Seroquel, Abilify®, Geodon® and others; and
- Miscellaneous agents, including Symmetrel®, Lithium and others.

While it is also possible that compounding pharmacies could combine the components of NUEDEXTA in an unauthorized fashion, it is inconsistent with the policies of the Pharmacy Compounding Accreditation Board.

AVP-923 for DPN pain. We anticipate that AVP-923 for the treatment of DPN pain, if further developed by us and approved by the FDA for marketing, would compete with other drug products that are currently prescribed by physicians, including those identified below. Additionally, many other companies are developing drug candidates for this indication and we expect competition for AVP-923, if approved to treat DPN pain, to be intense. Current approved competitors include:

- Cymbalta®;
- Lyrica®;
- Narcotic products; and
- Off-label uses of non-narcotic products, such as the anticonvulsants phenytoin, carbamazepine and topamax, and the antidepressant amitriptyline.

Docosanol 10% cream. Abreva faces intense competition in the U.S. and Canada from the following established products:

- Over-the-counter preparations, including Carmex®, Zilactin®, Campho®, Orajel®, Herpecin® and others;
- Zovirax® acyclovir (oral and topical) and Valtrex® valacyclovir (oral) prescription products marketed by Biovail Corporation and GSK, respectively; and
- Famvir® famciclovir (oral) and Denavir® penciclovir (topical) prescription products marketed by Novartis.

Manufacturing

We currently have no manufacturing or production facilities and, accordingly, rely on third parties for clinical production of our products and product candidates. We obtain the API for NUEDEXTA from one of several available commercial suppliers. Further, we licensed to various pharmaceutical companies the exclusive rights to manufacture and distribute docosanol 10% cream.

Patents and Proprietary Rights

As of September 30, 2010, we owned or had the rights to 136 issued patents (41U.S. and 95 foreign) and 60 pending applications (5 U.S. and 55 foreign). Patents and patent applications owned or licensed by us include NUEDEXTA and other technologies, including but not limited to docosanol-related products and technologies and MIF inhibitor technologies.

	United States			Foreign		
Description	**Issued**	**Expiration**	**Pending**	**Issued**	**Expiration**	**Pending**
NUEDEXTA	8	Up to 2026	5	50	Up to 2023	32
Other	33	—	0	45	—	23
Total	**41**		**5**	**95**		**55**

In June 2008, the European Patent Office ("EPO") granted a new patent which extends the period of commercial exclusivity for NUEDEXTA into 2023. The new European patent expands the available NUEDEXTA dose ranges under prior patent protection and encompasses a range of indications, including PBA, DPN pain, and other neurologic conditions.

In February 2010, the United States Patent and Trademark Office ("USPTO") granted a new patent which extends the period of commercial exclusivity for NUEDEXTA into 2025. Subsequent to February 2010, the period of commercial exclusively for NUEDEXTA was extended an additional year to 2026. The new U.S. patent expands the available NUEDEXTA dose ranges under prior patent protection and encompasses our current clinical development programs in PBA and other neurologic conditions. A divisional application containing claims in support of the DPN pain program was filed and is pending with the USPTO.

In addition to this newly allowed U.S. patent, we have exclusive rights under a royalty-bearing license granted from the Center for Neurologic Study ("CNS") to a family of patents and patent applications that claim methods of treating PBA, chronic pain, as well as other neurologic conditions, using combinations of dextromethorphan and quinidine, the two active agents in NUEDEXTA.

Information regarding the status of our various research and development programs, and the amounts spent on major programs through the last two fiscal years, can be found in Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Government Regulations

The FDA and comparable regulatory agencies in foreign countries extensively regulate the manufacture and sale of the pharmaceutical products that we have developed or are currently developing. The FDA has established guidelines and safety standards that are applicable to the nonclinical evaluation and clinical investigation of therapeutic products and stringent regulations that govern the manufacture and sale of these products. The process

of obtaining regulatory approval for a new therapeutic product usually requires a significant amount of time and substantial resources. The steps typically required before a product can be tested in humans include:

- Animal pharmacology studies to obtain preliminary information on the safety and efficacy of a drug; and
- Nonclinical evaluation *in vitro* and *in vivo* including extensive toxicology studies.

The results of these nonclinical studies may be submitted to the FDA as part of an Investigational New Drug ("IND") application. The sponsor of an IND application may commence human testing of the compound 30 days after submission of the IND, unless notified to the contrary by the FDA.

The clinical testing program for a new drug typically involves three phases:

- Phase I investigations are generally conducted in healthy subjects. In certain instances, subjects with a life-threatening disease, such as cancer, may participate in Phase I studies that determine the maximum tolerated dose and initial safety of the product;
- Phase II studies are conducted in limited numbers of subjects with the disease or condition to be treated and are aimed at determining the most effective dose and schedule of administration, evaluating both safety and whether the product demonstrates therapeutic effectiveness against the disease; and
- Phase III studies involve large, well-controlled investigations in diseased subjects and are aimed at verifying the safety and effectiveness of the drug.

Data from all clinical studies, as well as all nonclinical studies and evidence of product quality, typically are submitted to the FDA in a NDA. Although the FDA's requirements for clinical trials are well established and we believe that we have planned and conducted our clinical trials in accordance with the FDA's applicable regulations and guidelines, these requirements, including requirements relating to testing the safety of drug candidates, may be subject to change or new interpretation. Additionally, we could be required to conduct additional trials beyond what we had planned due to the FDA's safety and/or efficacy concerns or due to differing interpretations of the meaning of our clinical data. (See Item 1A, "Risk Factors").

The FDA's Center for Drug Evaluation and Research must approve a NDA for a drug before it may be marketed in the U.S. If we begin to market our proposed products for commercial sale in the U.S., any manufacturing operations that may be established in or outside the U.S. will also be subject to rigorous regulation, including compliance with current good manufacturing practices. We also may be subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substance Control Act, the Export Control Act and other present and future laws of general application.

Regulatory obligations continue post-approval, and include the reporting of adverse events when a drug is utilized in the broader commercial population. Promotion and marketing of drugs is also strictly regulated, with penalties imposed for violations of FDA regulations, the Lanham Act (trademark statute), and other federal and state laws, including the federal anti-kickback statute.

We currently intend to continue to seek, directly or through our partners, approval to market our products and product candidates in foreign countries, which may have regulatory processes that differ materially from those of the FDA. We anticipate that we will rely upon pharmaceutical or biotechnology companies to license our proposed products or independent consultants to seek approvals to market our proposed products in foreign countries. We cannot assure you that approvals to market any of our proposed products can be obtained in any country. Approval to market a product in any one foreign country does not necessarily indicate that approval can be obtained in other countries.

Product Liability Insurance

We maintain product liability insurance on our products and clinical trials that provides coverage in the amount of $10 million per incident and $10 million in the aggregate. We may increase our product liability insurance coverage when we commence marketing NUEDEXTA.

Executive Officers and Key Employees of the Registrant

Information concerning our executive officers and key employees, including their names, ages and certain biographical information can be found in Part III, Item 10 under the caption, "Executive Officers and Key Employees of the Registrant." This information is incorporated by reference into Part I of this report.

Employees

As of December 1, 2010, we employed 128 persons, including 14 engaged in research and development activities, including clinical development, medical and regulatory affairs, and 114 in selling, general and administrative functions such as human resources, finance, accounting, business development, sales, marketing, and investor relations. Of the selling, general and administrative positions, approximately 94 are field based.

Financial Information about Segments

We operate in a single accounting segment — the development and commercialization of novel treatments that target the central nervous system. Refer to Note 15, "Segment Information" in the Notes to the Consolidated Financial Statements.

General Information

Our principal executive offices are located at 101 Enterprise, Suite 300, Aliso Viejo, California 92656. Our telephone number is (949) 389-6700 and our e-mail address is *info@avanir.com*. Our Internet website address is *www.avanir.com.* No portion of our website is incorporated by reference into this Annual Report on Form 10-K.

You are advised to read this Annual Report on Form 10-K in conjunction with other reports and documents that we file from time to time with the Securities and Exchange Commission ("SEC"). In particular, please read our Quarterly Reports on Form 10-Q and any Current Reports on Form 8-K that we may file from time to time. You may obtain copies of these reports after the date of this annual report directly from us or from the SEC at the SEC's Public Reference Room at 100 F Street, N.E. Washington, D.C. 20549. In addition, the SEC maintains information for electronic filers (including AVANIR) at its website at www.sec.gov. The public may obtain information regarding the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. 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.

Item 1A. ***Risk Factors***

This Annual Report on Form 10-K contains forward-looking information based on our current expectations. Because our actual results may differ materially from any forward-looking statements that we make or that are made on our behalf, this section includes a discussion of important factors that could affect our actual future results, including, but not limited to, our product sales, capital resources, commercial market estimates, safety of NUEDEXTA, future development efforts, patent protection, effects of healthcare reform, reliance on third parties, and other risks set forth below.

Risks Relating to Our Business

Our near-term prospects are dependent on NUEDEXTA. If we are unable to successfully commercialize NUEDEXTA, including successfully maintaining adequate sales, marketing or distribution capabilities or entering into agreements with third parties to perform some of these functions, we will not be able to commercialize NUEDEXTA effectively and 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 the near to medium term is entirely dependent upon our ability to commercialize NUEDEXTA. As we prepare for the launch of NUEDEXTA, we may not be able to adequately build or maintain the 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 NUEDEXTA;
- establish and maintain successful sales and marketing and education programs for our targeted physicians;
- manage geographically dispersed sales and marketing operations; and
- maintain and defend our patent protection and maintain regulatory exclusivity for NUEDEXTA.

The commercialization of NUEDEXTA 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 in domestic or foreign market segments and 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 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 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.

We have a history of net losses and an accumulated deficit, and we may never 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 significant revenues from sales of NUEDEXTA. As of September 30, 2010, we had an accumulated deficit of approximately $304.7 million. We have incurred these losses principally from costs incurred in funding the research, development and clinical testing of our drug candidates and from our general and administrative expenses. We may continue incurring net losses for the foreseeable future and we expect our operating losses to increase for at least the short term as we increase our total expenditures in preparation for the commercial launch of NUEDEXTA.

Our ability to generate revenue and achieve profitability is dependent on our ability, alone or with partners, to successfully manufacture and market NUEDEXTA for the treatment of patients with PBA. We expect to continue to spend substantial amounts on preparing for the commercial launch of NUEDEXTA in PBA, as well as seeking regulatory approvals for use of NUEDEXTA in other geographic markets and indications. As a result, we may never generate sufficient revenue from product sales to become profitable or generate positive cash flows.

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

Our drug is being made available to patients to treat PBA, an indication for which there is no established pharmaceutical market. Industry sources and equity research analysts have a wide divergence of estimates for the near- and long-term market potential of our product. A variety of assumptions directly impact the 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, drug pricing assumptions, and patient adherence and compliance rates within each underlying neurologic condition. Small differences in these assumptions can lead to widely divergent estimates of the market potential of our product. Accordingly, investors are cautioned not to place undue reliance on any particular estimates of equity research analysts or industry sources.

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

We have experienced significant operating losses in funding the research, development and clinical testing of our drug candidates and we expect to continue to incur substantial operating losses for the foreseeable future as we commence commercial operations. Although we had approximately $122.3 million in cash and cash equivalents and restricted investments in marketable securities as of December 1, 2010, we currently do not have any meaningful sources of recurring revenue or cash flow from operations and 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 (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 expect to be able to generate meaningful amounts of revenue from product sales. Based on our current loss rate and existing capital resources as of the date of this report, we estimate that we have sufficient funds to sustain our operations at their current and anticipated levels through at least the next 24 months, which includes the planned launch of NUEDEXTA for PBA in the first calendar quarter of fiscal 2011. Although we expect to be able to raise additional capital, there can be no assurance that we will be able to do so or that the available terms of any financing would be acceptable to us. If we are unable to raise additional capital to fund future operations, then we may be unable to fully execute our development and commercialization plans for NUEDEXTA. This may result in significant delays or cutbacks in the commercialization of NUEDEXTA and may force us to further curtail our operations or seek to raise additional capital.

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. Each of these financing alternatives carries certain risks. Raising capital through the issuance of common stock may depress the market price of our stock. Any such financing will dilute our existing stockholders and, if our stock price is relatively depressed at the time of any such offering, the levels of dilution would be greater. In addition, debt financing, to the extent available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as making capital expenditures or entering into licensing transactions. If we seek to raise capital through licensing transactions or sales of one or more of our technologies, drugs or drug candidates, as we have previously done with certain investigational compounds and docosanol 10% cream, then we will likely need to share a significant portion of future revenues from these drug candidates with our licensees. Additionally, the development of any drug candidates licensed or sold to third parties will no longer be in our control and thus we may not realize the full value of any such relationships.

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. NUEDEXTA has only been studied in a limited number of patients in clinical studies and the data submitted to the FDA as part of our New Drug Application was obtained in controlled clinical trials of limited duration. In connection with the approval of NUEDEXTA, the FDA has required that we conduct certain post-approval studies, which include both non-clinical studies and a pediatric development plan. 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. In addition, as we conduct other clinical trials for NUEDEXTA in other indications, new safety 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 package insert, 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 NUEDEXTA, any of which could have a significant adverse impact on potential sales of NUEDEXTA.

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, or require us to expend significant additional funds.

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

We have entered into agreements for the out-licensing or sale of our non-core 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. As a result, we do not currently have a diversified pipeline of product candidates and our long-term success is currently dependent on NUEDEXTA. From time to time, we have been and will continue to be engaged in discussions with potential licensing or development partners for NUEDEXTA for PBA and/or other indications and we may choose to pursue a partnership or license involving NUEDEXTA, if the terms are attractive. However, these transactions involve numerous risks, including:

- diversion of management's attention from normal daily operations of the business;
- disputes over earn-outs, working capital adjustments or contingent payment obligations;
- insufficient proceeds to offset expenses associated with the transactions; and
- the potential loss of key employees following such a transaction.

Transactions such as these carry significant risks where a large portion of the total consideration is contingent upon post-closing events, such as commercialization or sales milestones. We may not exercise 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, and other provisions in the transaction agreements. If disputes are resolved unfavorably, our financial condition and results of operations may be adversely affected and we may not realize the anticipated benefits from the transactions.

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

The FDA's safety concerns regarding our prior formulation of 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 for other indications is expected to use an alternative lower-dose quinidine formulation, which may negatively affect efficacy.

We have successfully 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 expressed that the safety concerns and questions raised in the PBA approvable letter necessitate the testing of a low-dose quinidine formulation in the DPN pain indication as well. Additionally, based on feedback we have received from the FDA on the proposed continued development of AVP-923 for this indication, we believe it is likely that two 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 or a development 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's safety concerns. If this were to happen, we may not be able to pursue the development of AVP-923 for other indications or may need to undertake significant additional clinical trials, which would be costly and cause potentially substantial delays.

We rely on market research to evaluate the potential commercial acceptance of NUEDEXTA.

Based on the results of our market research, we believe that physicians are likely to support the use and adoption of NUEDEXTA for the treatment of PBA. We conducted market research in accordance with Good Marketing Research Practices and we concluded that they may not be indicative of the response we might receive from a broader selection of physicians. Moreover, these results are based on physicians' impressions formed from a description of the product, and not actual results from prescription of the product, which could result in different responses from those same or other physicians.

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

We have invested in an extensive patent portfolio and we rely substantially on the protection of our intellectual property through our ownership or control of issued patents and patent applications. Because of the competitive nature of the biopharmaceutical industry, we cannot assure you that:

- the claims in any pending patent applications will be allowed or that patent applications will be granted;
- competitors will not develop similar or superior technologies independently, duplicate our technologies, or design around the patented aspects of our technologies;
- our technologies will not infringe on other patents or rights owned by others, including licenses to other intellectual property that may not be available to us;
- any of our issued patents will provide us with significant competitive advantages;
- challenges will not be instituted against the validity or enforceability of any patent that we own or have licensed, and, if challenged, that we will be successful in defending ourselves against these challenges; or
- we will be able to secure additional worldwide intellectual property protection for our NUEDEXTA patent portfolio.

Even if we successfully secure our intellectual property rights, third parties, including other biotechnology or pharmaceutical companies, may allege that our technology infringes on their rights or that our patents are invalid or not enforceable. Intellectual property litigation is costly, and even if we were to prevail in such a dispute, the cost of litigation could adversely affect our business, financial condition, and results of operations. Litigation is also time consuming and would divert management's attention and resources away from our operations and other activities. If we were to lose any litigation, in addition to any damages we would have to pay, we could be required to stop the infringing activity or obtain a license. Any required license might not be available to us on acceptable terms, or at all. Some licenses might be non-exclusive, and our competitors could have access to the same technology licensed to us. If we were to fail to obtain a required license or were unable to design around a competitor's patent, we would be unable to sell or continue to develop some of our products, which would have a material adverse effect on our business, financial condition and results of operations.

It is unclear whether we would be eligible for patent-term restoration in the U.S. under applicable law and we therefore do not know whether our patent-term can be extended.

Some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. Due to receipt of approval for NUEDEXTA, the Hatch-Waxman Amendments permit a patent restoration term of up to five years for one of our patents covering NUEDEXTA as compensation for the patent term lost during product development and the regulatory review process. The patent term restoration period is generally one-half the time between the

effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application with a maximum of five years. We intend to apply for patent term restoration. However, because NUEDEXTA is not a new chemical entity, but is a combination of two previously approved products, it is uncertain whether NUEDEXTA will be granted any patent term restoration under the U.S. Patent and Trademark Office guidelines. In addition, the patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years after the product's approval date.

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

Once the three-year FDCA exclusivity period has passed and after the patents (including the patent restoration term, if any) that cover 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 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.

NUEDEXTA may face competition from lower cost generic or follow-on products.

NUEDEXTA is approved under the provisions of the FDCA, which renders it susceptible to potential competition from generic manufacturers via the ANDA procedure. 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. 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.

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 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 implicate drug products with even relatively modest revenues.

If an ANDA filer were to receive approval to sell a generic version of NUEDEXTA, NUEDEXTA would become subject to increased competition and our revenue would be adversely affected. Additionally, it is possible that compounding pharmacies could formulate a generic version of NUEDEXTA in violation of our patent rights, which could also adversely affect our revenues.

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

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

We face challenges 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 organization, the loss of any executive officers, including the Chief Executive Officer, key members of senior management or other key employees, could adversely affect our operations. For example, if we were to lose one or more of the senior members of our sales and marketing team, the success of the NUEDEXTA launch could be adversely affected.

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. Moreover, any such event could impact the commercialization of NUEDEXTA and our research and development programs.

Future acquisitions could disrupt our business and harm our financial condition.

In order to augment our product pipeline or otherwise strengthen our business, we may decide to acquire additional businesses, products and technologies. As we have limited experience in evaluating and completing acquisitions, our ability as an organization to make such acquisitions is unproven. Acquisitions could require significant capital infusions and could involve many risks, including, but not limited to, the following:

- we may have to issue convertible debt or equity securities to complete an acquisition, which would dilute our stockholders and could adversely affect the market price of our common stock;
- an acquisition may negatively impact our results of operations because it may require us to amortize or write down amounts related to goodwill and other intangible assets, or incur or assume substantial debt or liabilities, or it may cause adverse tax consequences, substantial depreciation or deferred compensation charges;
- we may encounter difficulties in assimilating and integrating the business, products, technologies, personnel or operations of companies that we acquire;

- certain acquisitions may impact our relationship with existing or potential partners who are competitive with the acquired business, products or technologies;
- acquisitions may require significant capital infusions and the acquired businesses, products or technologies may not generate sufficient value to justify acquisition costs;
- an acquisition may disrupt our ongoing business, divert resources, increase our expenses and distract our management;
- acquisitions may involve the entry into a geographic or business market in which we have little or no prior experience; and
- key personnel of an acquired company may decide not to work for us.

If any of these risks occurred, it could adversely affect our business, financial condition and operating results. We cannot assure you that we will be able to identify or consummate any future acquisitions on acceptable terms, or at all. If we do pursue any acquisitions, it is possible that we may not realize the anticipated benefits from such acquisitions or that the market will not view such acquisitions positively.

Risks Relating to Our Industry

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

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

In addition, the possibility exists that:

- the results from earlier clinical trials may not be predictive of results that will be obtained from subsequent clinical trials, particularly larger trials;
- institutional review boards or regulators, including the FDA, may hold, suspend or terminate our clinical research or the clinical trials of our product candidates for various reasons, including noncompliance with regulatory requirements or if, in their opinion, the participating subjects are being exposed to unacceptable health risks;
- subjects may drop out of our clinical trials;
- our preclinical studies or clinical trials may produce negative, inconsistent or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials;
- trial results derived from top-line data, which is based on a preliminary analysis of efficacy and safety data related to primary and secondary endpoints, may change following a more comprehensive review of the complete data set derived from a particular clinical trial or may change due to FDA requests to analyze the data differently; and
- the cost of our clinical trials may be greater than we currently anticipate.

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

Additionally, the FDA has substantial discretion in the approval process and may reject our data or disagree with our interpretations of regulations or draw different conclusions from our clinical trial data or ask for additional

information at any time during their review. For example, the use of different statistical methods to analyze the efficacy data from our Phase III trial of AVP-923 in DPN pain results in significantly different conclusions about the efficacy of the drug. Although we believe we have legitimate reasons to use the methods that we have adopted as outlined in our SPA with the FDA, the FDA may not agree with these reasons and may disagree with our conclusions regarding the results of these trials.

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

- delays in our ability to submit an NDA;
- the refusal by the FDA to accept for 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 adverse labeling claims 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 would not be able to generate meaningful levels of sustainable revenues.

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

The pharmaceutical and biotechnology industries are highly competitive and subject to significant and rapid technological change. We compete with hundreds of companies that develop and market products and technologies in areas similar to those in which we are performing our research. For example, we expect that NUEDEXTA will face competition from antidepressants, atypical anti-psychotic agents and other agents in the treatment of PBA. Additionally, NUEDEXTA may face challenges from "generic" drug companies, 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.

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

Marketed products, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for these products, are subject to continual requirements and review by the FDA and other regulatory bodies. In addition, regulatory authorities subject a marketed product, its manufacturer and the manufacturing facilities to ongoing review and periodic inspections. We will be subject to ongoing FDA requirements, including required submissions of safety and other post-market information and reports, registration requirements, current Good Manufacturing Practices ("cGMP") regulations, requirements regarding the distribution of samples to physicians and recordkeeping requirements.

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

We face uncertainty related to healthcare reform, pricing 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 Affordability Reconciliation Act (collectively, "PPACA"), which is expected to substantially change the way health care is financed by both governmental and private payors. 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 could entail modifications to the existing system of private payors 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 reimbursement for prescribed drugs, including our product candidates, biopharmaceuticals, and medical devices. 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, beginning 2011;
- 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;
- 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, beginning 2011; and
- Increase the number of entities eligible for discounts under the Public Health Service pharmaceutical pricing program, effective January 2010.

If future reimbursement for NUEDEXTA 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 payors 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 payors 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 payors to NUEDEXTA. Any denial of private or government payor coverage or inadequate reimbursement for procedures performed using 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. Further federal and state proposals and healthcare reforms are likely, which could limit the prices that can be charged for 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, if commercialized, and we cannot predict the scope of any future changes or the impact that those changes would have on our 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. 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 proposed 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, the ongoing financial crisis may affect our ability to obtain coverage under existing policies 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 or criminal penalties.

We are also 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 Law, which prohibits, among other things, persons from knowingly and willfully 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 payors that are false or fraudulent;
- 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; 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 payor, including commercial insurers.

If our operations are found to be in violation of any of the laws described above or any other 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. Further, the recently enacted PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the PPACA provides that 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. Moreover, some states, such as California, Massachusetts and Vermont, mandate implementation of commercial compliance programs to ensure compliance with these laws. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians for marketing, including the tracking and reporting of gifts, compensation, and other remuneration 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.

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, effective March 30, 2013. Such information will be made publicly available in a searchable format beginning September 30, 2013. In addition, drug manufacturers will also be required to report and disclose any investment interests held by physicians and their immediate family members during the preceding calendar year. 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. Finally, under PPACA, effective April 1, 2012, pharmaceutical manufacturers and distributors must provide the U.S. Department of Health and Human Services with an annual report on the drug samples they provide to physicians.

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

Companies may not promote 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, TPD or other applicable regulatory agencies. Physicians may prescribe drug products for off-label uses, and such off-label uses are common across medical specialties. Although the FDA, TPD and other regulatory agencies do not regulate a physician's choice of treatments, the FDA, TPD and other regulatory agencies do restrict communications by pharmaceutical companies or their sales representatives on the subject of off-label use. The FDA, TPD and other regulatory agencies actively enforce regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained. A company that is found to have improperly promoted 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, TPD and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional speech concerning their products. Although we believe that all of our communications regarding all of our products are in compliance with the relevant regulatory requirements, the FDA, TPD or another regulatory authority may disagree, and we may be subject to significant liability, including civil and administrative remedies, as well as criminal sanctions. In addition, management's attention could be diverted from our business operations and our reputation could be damaged. Our distribution partners may also be the subject of regulatory investigations involving, or remedies or sanctions for, off-label uses of products we have licensed to them, which may have an adverse impact on sales of such licensed products, 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.

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 API for docosanol 10% cream and to provide clinical supplies of our drug candidates. We have no experience in manufacturing and do not have any manufacturing facilities. Currently, we have sole suppliers for the API for docosanol and NUEDEXTA, and a sole manufacturer for the finished form of NUEDEXTA. In addition, these materials are custom and available from only a limited number of sources. Any material disruption in manufacturing could cause a delay in shipments and possible loss of sales. We do not have any long-term agreements in place with our current docosanol supplier or NUEDEXTA supplier. If we are required to change manufacturers, we may experience delays associated with finding an alternate manufacturer that is properly qualified to produce supplies of our products and product candidates in accordance with FDA requirements and our specifications. Any delays or difficulties in obtaining APIs or in manufacturing, packaging or distributing NUEDEXTA could delay our clinical trials of this product candidate for DPN pain, MS-related pain or other potential 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, the ongoing economic crisis creates risk for us if any of these third parties suffer liquidity or operational problems. If a key third party vendor becomes insolvent or is forced to lay off workers assisting with our projects, our results and development timing could suffer.

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

The nature of clinical trials and our business strategy of outsourcing a substantial portion of our research require that we rely on clinical research centers and other contractors to assist us with research and development, clinical testing activities, patient enrollment and regulatory submissions to the FDA. As a result, our success depends partially on the success of these third parties in performing their responsibilities. Although we pre-qualify our contractors and we believe that they are fully capable of performing their contractual obligations, we cannot directly control the adequacy and timeliness of the resources and expertise that they apply to these activities. Additionally, the current global economic slowdown may affect our development partners and vendors, which could adversely affect 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 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, 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 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;
- regulatory developments in the U.S. and foreign countries;
- 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.

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

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

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, and we again became subject to these requirements starting with the year ended September 30, 2010.

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. Furthermore, we may in the future become subject to contractual restrictions on, or prohibitions against, the payment of dividends. 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, rights agreement 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. We have also adopted a stockholder rights agreement intended to deter hostile or coercive attempts to acquire us. Under the agreement, if a person becomes an "acquiring person," each holder of a right (other than the acquiring person) will be entitled to purchase, at the then-current exercise price, such number of shares of our preferred stock which are equivalent to shares of common stock having twice the exercise price of the right. If we are acquired in a merger or other business combination transaction after any such event, each holder of a right will then be entitled to purchase, at the then-current exercise price, shares of the acquiring company's common stock having a value of twice the exercise price of the right. Our stockholder rights agreement could make it more difficult for a third party to acquire, or could discourage a third party from acquiring, us or a large block of our common stock without the support of our board of directors. Therefore, the agreement makes an acquisition much more costly to a potential acquirer.

Item 1B. *Unresolved Staff Comments*

None.

Item 2. *Properties*

Our headquarters and commercial and administrative offices are located in Aliso Viejo, California, where we currently occupy approximately 17,000 square feet. The Aliso Viejo office lease expires in June 2011. With the organizational growth anticipated following the October 2010 FDA approval of NUEDEXTA, we have determined that we will need to increase our current office space capacity. We may or may not renew the Aliso Viejo office lease as we identify other suitable properties.

We lease approximately 30,370 square feet in two buildings in San Diego. The terms of the leases for the San Diego facilities end in January 2013. The San Diego buildings are sublet through January 2013.

Item 3. *Legal Proceedings*

In the ordinary course of business, we may face various claims brought by third parties and we may, from time to time, make claims or take legal actions to assert our rights, including intellectual property rights as well as claims

relating to employment matters and the safety or efficacy of our products. Any of these claims could subject us to costly litigation and, while we generally believe that we have adequate insurance to cover many different types of liabilities, our insurance carriers may deny coverage, may be inadequately capitalized to pay on valid claims, or our policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on our consolidated operations, cash flows and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business. Management believes the outcome of currently pending claims or lawsuits will not likely have a material effect on our operations or financial position.

Item 4. ***Removed and Reserved***

PART II

Item 5. ***Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

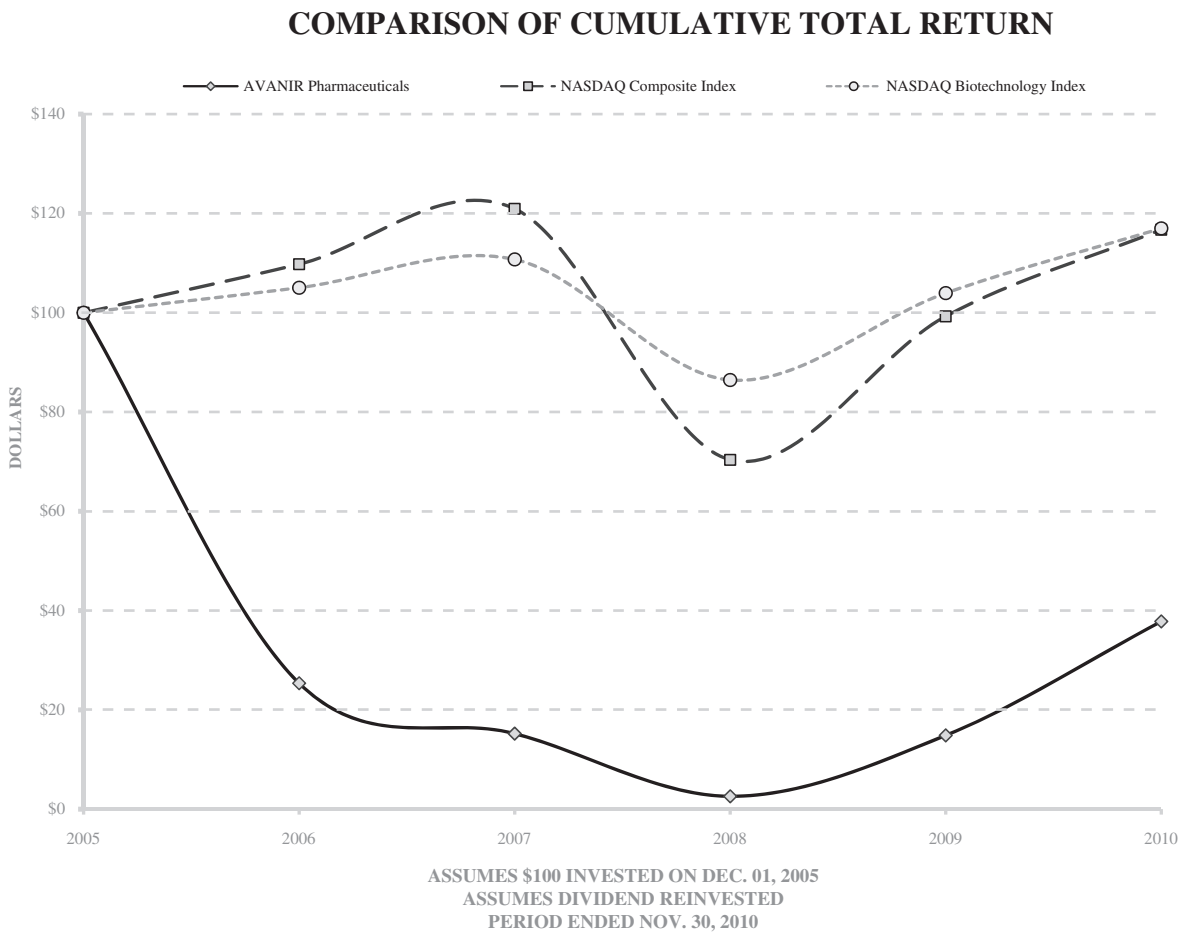
The following table sets forth the high and low prices for our common stock in each of the quarters over the past two fiscal years, as quoted on the NASDAQ Global Market.

	Common Stock Price			
	Fiscal 2010		Fiscal 2009	
	High	Low	High	Low
First Quarter	$2.68	$1.65	$0.70	$0.23
Second Quarter	$2.72	$1.67	$0.68	$0.25
Third Quarter	$3.45	$2.20	$2.62	$0.39
Fourth Quarter	$3.73	$2.63	$4.09	$1.75

On December 1, 2010, the closing sales price of our common stock was $4.18 per share.

As of November 27, 2010, we had approximately 29,344 stockholders, including 371 holders of record and an estimated 28,973 beneficial owners. We have not paid any dividends on our common stock since our inception and do not expect to pay dividends on our common stock in the foreseeable future.

The following graph compares the cumulative 5-year return provided stockholders on AVANIR Pharmaceutical, Inc.'s common stock relative to the cumulative total returns of the NASDAQ Composite index and the NASDAQ Biotechnology index. An investment of $100 (with reinvestment of all dividends) is assumed to have been made in our common stock and in each of the indexes on October 1, 2005 and its relative performance is tracked through November 30, 2010.



Information About Our Equity Compensation Plans

Information regarding our equity compensation plans is incorporated by reference in Item 12 of Part III of this annual report on Form 10-K.

Item 6. ***Selected Financial Data***

The selected consolidated financial data set forth below at September 30, 2010 and 2009, and for the fiscal years ended September 30, 2010, 2009, and 2008, are derived from our audited consolidated financial statements included elsewhere in this report. This information should be read in conjunction with those consolidated financial statements, the notes thereto, and with "Management's Discussion and Analysis of Financial Condition and Results of Operations." The selected consolidated financial data set forth below at September 30, 2008, 2007 and 2006, and for the years ended September 30, 2007 and 2006, are derived from our audited consolidated financial statements that are contained in reports previously filed with the SEC, not included herein. The quarterly consolidated financial data are derived from unaudited consolidated financial statements included in our Quarterly Reports on Form 10-Q. All share and per share information herein (including shares outstanding, earnings per share and warrant and stock option exercise prices) reflect the retrospective adjustment for a one-for-four reverse stock split implemented in January 2006.

The following tables include selected consolidated financial data for each of our last five fiscal years and quarterly data for the last two fiscal years and include adjustments to reflect the classification of our FazaClo Business as discontinued operations.

Summary Financial Information

	Fiscal Years Ended September 30,				
Statement of Operations Data:	**2010**	**2009**	**2008**	**2007**	**2006**
Net revenues	$ 2,895,474	$ 4,176,509	$ 6,958,568	$ 9,224,561	$ 15,185,852
Operating expenses	$ 29,794,558	$ 26,017,815	$ 24,709,901	$ 33,945,900	$ 59,369,701
Operating loss	$(27,096,724)	$(21,924,665)	$(18,962,458)	$(29,368,855)	$(51,677,459)
Loss before discontinued operations and cumulative effect of change in accounting principle	$(26,694,148)	$(21,996,016)	$(15,912,672)	$(28,381,724)	$(50,234,040)
(Loss) income from discontinued operations	$ —	$ —	$ (1,583,067)	$ 7,448,271	$ (8,702,716)
Cumulative effect of change in accounting principle	$ —	$ —	$ —	$ —	$ (3,616,058)
Net loss	$(26,694,148)	$(21,996,016)	$(17,495,739)	$(20,933,453)	$(62,552,814)
Basic and diluted loss per share:					
Loss before cumulative effect of change in accounting principle and discontinued operations	$ (0.30)	$ (0.28)	$ (0.27)	$ (0.72)	$ (1.64)
(Loss) income from discontinued operations	$ —	$ —	$ (0.03)	$ 0.19	$ (0.28)
Cumulative effect of change in accounting principle	$ —	$ —	$ —	$ —	$ (0.12)
Net loss	$ (0.30)	$ (0.28)	$ (0.30)	$ (0.53)	$ (2.04)
Basic and diluted weighted average number of shares of common stock outstanding	87,614,420	78,844,251	58,901,030	39,643,876	30,634,872
Cash dividends declared per share	$ —	$ —	$ —	$ —	$ —

	Fiscal Years Ended September 30,				
Balance Sheet Data:	**2010**	**2009**	**2008**	**2007**	**2006**
Cash and cash equivalents	$38,771,469	$31,486,012	$41,383,930	$30,487,962	$ 4,898,214
Investments in marketable securities	$ 601,550	$ 468,475	$ 856,597	$ 3,153,436	$19,851,859
Total cash, cash equivalents and investments in marketable securities	$39,373,019	$31,954,487	$42,240,527	$33,641,398	$24,750,073
Working capital (deficit)	$32,967,188	$26,685,567	$37,171,636	$29,336,776	$ (6,969,777)
Total assets	$42,141,198	$34,068,072	$45,906,161	$39,095,893	$71,462,337
Deferred revenues	$ 8,476,831	$ 9,912,367	$12,486,032	$15,320,430	$19,354,175
Notes payable and capital lease obligations	$ —	$ —	$ 25,744	$12,024,592	$14,395,978
Total liabilities	$14,134,642	$14,126,337	$16,905,997	$32,065,659	$77,136,872
Stockholders' equity (deficit)	$28,006,556	$19,941,735	$29,000,164	$ 7,030,234	$ (5,674,535)

Quarterly Statement of Operations Data for Fiscal 2010 (Unaudited):	Fiscal Quarters Ended			
	December 31, 2009	March 31, 2010	June 30, 2010	September 30, 2010
Net revenues	$ 1,484,934	$ 994,494	$ 487,350	$ (71,304)(1)
Operating expenses	$ 6,313,368	$ 7,438,317	$ 6,521,283	$ 9,521,590
Operating loss	$ (4,828,434)	$ (6,443,823)	$ (6,113,933)	$ (9,710,534)
Gross profit (loss)	$ 1,484,934	$ 994,494	$ 407,350	$ (188,944)
Loss from continuing operations	$ (4,822,957)	$ (6,440,462)	$ (5,721,583)	$ (9,709,146)
Net loss	$ (4,822,957)	$ (6,440,462)	$ (5,721,583)	$ (9,709,146)
Basic and diluted net loss per share	$ (0.06)	$ (0.08)	$ (0.06)	$ (0.10)
Basic and diluted weighted average number of common shares outstanding	83,159,376	83,419,640	89,347,783	94,458,530

Quarterly Statement of Operations Data for Fiscal 2009 (Unaudited):	Fiscal Quarters Ended			
	December 31, 2008	March 31, 2009	June 30, 2009	September 30, 2009
Net revenues	$ 1,754,061	$ 811,675	$ 590,925	$ 1,019,848
Operating expenses	$ 7,039,226	$ 5,760,680	$ 5,562,822	$ 7,655,087
Operating loss	$ (5,293,216)	$ (4,950,700)	$ (4,971,897)	$ (6,708,852)
Gross profit	$ 1,746,010	$ 809,980	$ 590,925	$ 946,235
Loss from continuing operations	$ (5,178,716)	$ (4,909,971)	$ (4,955,969)	$ (6,951,360)
Net loss	$ (5,178,716)	$ (4,909,971)	$ (4,955,969)	$ (6,951,360)
Basic and diluted net loss per share	$ (0.07)	$ (0.06)	$ (0.06)	$ (0.09)
Basic and diluted weighted average number of common shares outstanding	78,225,041	78,226,972	78,236,153	80,673,233

(1) In accordance with Staff Accounting Bulletin 108 ("SAB 108"), in the fourth quarter of fiscal 2010, the Company recorded a cumulative non-cash adjustment to correct an immaterial error related to previously recorded deferred royalty revenue related to the GSK license agreement. The total cumulative non-cash adjustment recorded in the fourth quarter was a decrease in revenue of $797,000 which resulted in net revenues of ($71,000) in the fourth fiscal quarter of 2010 and $2.9 million for fiscal 2010.

Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations*

This Annual Report on Form 10-K contains forward-looking statements concerning future events and performance of the Company. When used in this report, the words "intend," "estimate," "anticipate," "believe," "plan" or "expect" and similar expressions are included to identify forward-looking statements. These forward-looking statements are based on our current expectations and assumptions and many factors could cause our actual results to differ materially from those indicated in these forward-looking statements. You should review carefully the factors identified in this report in Item 1A, "Risk Factors". We disclaim any intent to update or announce revisions to any forward-looking statements to reflect actual events or developments. Except as otherwise indicated herein, all dates referred to in this report represent periods or dates fixed with reference to the calendar year, rather than our fiscal year ending September 30.

Executive Overview

We are a pharmaceutical company focused on acquiring, developing and commercializing novel therapeutic products for the treatment of central nervous system disorders. In October 2010, the U.S. Food and Drug Administration ("FDA") approved NUEDEXTA (formerly referred to as AVP-923 or its previously proposed trade name Zenvia), a unique proprietary combination of dextromethorphan/quinidine, for the treatment of pseudobulbar affect ("PBA"). NUEDEXTA has also successfully completed a Phase III trial for the treatment

of patients with diabetic peripheral neuropathic pain ("DPN pain"). We plan to commercially launch NUEDEXTA in the second quarter of fiscal 2011.

In addition to our focus on products for the central nervous system, we also have a number of partnered programs in other therapeutic areas which may generate future revenue for us. Our first commercialized product, docosanol 10% cream, (sold in the United States and Canada as Abreva® by our marketing partner GlaxoSmithKline Consumer Healthcare) is the only over-the-counter treatment for cold sores that has been approved by the FDA. In 2008, we out-licensed all of our monoclonal antibodies and we remain eligible to receive milestone payments and royalties related to the sale of these assets. AVANIR was incorporated in California in August 1988 and was reincorporated in Delaware in March 2009.

The following is a summary of significant accomplishments in fiscal 2010 and subsequent to the end of fiscal 2010 through the date of this filing that have materially affected our operations, financial condition and prospects:

- On February 9, 2010, the United States Patent and Trademark Office (USPTO) issued the Company a new patent, U.S. patent number 7,659,282 titled "*Pharmaceutical Compositions Comprising Dextromethorphan and Quinidine for the Treatment of Neurological Disorders*", for its lead drug candidate NUEDEXTA (dextromethorphan/quinidine), extending the period of patent protection in the United States into late 2025. The new patent provided AVANIR with patent protection for low-dose quinidine formulations of NUEDEXTA used to treat PBA. On October 7, 2010, the USPTO granted our Request for Recalculation further extending the period of patent protection to 2026.
- On April 13, 2010, the Company announced long-term efficacy data from the 12-week double-blind phase and the 12-week open-label extension phase of the confirmatory Phase III STAR trial evaluating NUEDEXTA in the treatment of PBA in patients with underlying multiple sclerosis or amyotrophic lateral sclerosis. The detailed efficacy data were presented at the American Academy of Neurology (AAN) Annual Meeting in Toronto and were selected by the AAN as part of the Late-Breaking Science program.
- On April 30, 2010, the Company submitted its Complete Response to the October 2006 Approvable Letter issued by the FDA for NUEDEXTA for the treatment of PBA.
- On May 6, 2010 the Company announced the pricing of a public offering of 10,000,000 shares of its common stock. Jefferies & Company, Inc. acted as sole book-running manager in this offering. Canaccord Genuity Inc. served as co-manager for the offering.
- On October 29, 2010, the Company announced that the FDA approved NUEDEXTA capsules as the first treatment for PBA.
- On November 22, 2010, the Company completed an underwritten public offering of 20,000,000 shares of its common stock offered at a price of $4.40 per share. Gross offering proceeds resulting from the offering were approximately $88,000,000, before deducting customary underwriting discounts, commissions and offering expenses.

Our principal focus is on the commercial launch of NUEDEXTA for the PBA indication. We believe that cash and cash equivalents and restricted investments of approximately $39.4 million at September 30, 2010, as well as the proceeds raised from the common stock offering completed in November 2010 totaling approximately $83.0 million in net proceeds, will be sufficient to fund our operations, for at least the next 24 months. For additional information about the risks and uncertainties that may affect our business and prospects, please see Item 1A, "Risk Factors."

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these consolidated financial statements requires us to make a number of assumptions and estimates that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reported periods. Significant estimates and assumptions are required in the determination of revenue

recognition in certain royalties. Significant estimates and assumptions are also required in the appropriateness of amounts recognized for inventories, income taxes, contingencies, estimates on the net working capital adjustment and stock-based compensation. We base our estimates on historical experience and various other assumptions that are available at that time and that we believe to be reasonable under the circumstances. Some of these judgments can be subjective and complex. For any given individual estimate or assumption made by us, there may also be other estimates or assumptions that are reasonable. These items are monitored and analyzed by management for changes in facts and circumstances, and material changes in these estimates could occur in the future. Changes in estimates are recorded in the period in which they become known. Actual results may differ from our estimates if past experience or other assumptions do not turn out to be substantially accurate.

Share-Based Compensation

We grant options, restricted stock units and restricted stock awards to purchase our common stock to our employees, directors and consultants under our stock option plans. The benefits provided under these plans are share-based payments that we account for using the fair value method.

The fair value of each option award is estimated on the date of grant using a Black-Scholes-Merton option pricing model ("Black-Scholes model") that uses assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, our expected stock price volatility, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends. Expected volatilities are based on historical volatility of our common stock and other factors. The expected terms of options granted are based on analyses of historical employee termination rates and option exercises. The risk-free interest rates are based on the U.S. Treasury yield in effect at the time of the grant. Since we do not expect to pay dividends on our common stock in the foreseeable future, we estimated the dividend yield to be 0%.

If factors change and we employ different assumptions in calculating the fair value in future periods, the compensation expense that we record may differ significantly from what we have recorded in the current period. There is a high degree of subjectivity involved when using option pricing models to estimate share-based compensation. Because changes in the subjective input assumptions can materially affect our estimates of fair values of our share-based compensation, in our opinion, existing valuation models, including the Black-Scholes and lattice binomial models, may not provide reliable measures of the fair values of our share-based compensation. Consequently, there is a risk that our estimates of the fair values of our share-based compensation awards on the grant dates may bear little resemblance to the actual values realized upon the exercise, early termination or forfeiture of those share-based payments in the future. Certain share-based payments, such as employee stock options, may expire worthless or otherwise result in zero intrinsic value as compared to the fair values originally estimated on the grant date and reported in our financial statements. For awards with a longer vesting period, such as the three-year cliff vesting awards issued to certain officers, the actual forfeiture rate and related expense may not be known for a longer period of time, which can result in more significant accounting adjustments once the awards are either vested or forfeited.

Alternatively, values may be realized from these instruments that are significantly in excess of the fair values originally estimated on the grant date and reported in our financial statements. There is no current market-based mechanism or other practical application to verify the reliability and accuracy of the estimates stemming from these valuation models, nor is there a means to compare and adjust the estimates to actual values. Although the fair value of employee share-based awards is determined using an option-pricing model, the value derived from that model may not be indicative of the fair value observed in a willing buyer/willing seller market transaction.

The application of the fair value method of accounting for share-based compensation may be subject to further interpretation and refinement over time. There are significant differences among valuation models, and there is a possibility that we will adopt different valuation models in the future. This may result in a lack of consistency in future periods and materially affect the fair value estimate of share-based payments. It may also result in a lack of comparability with other companies that use different models, methods and assumptions.

Theoretical valuation models and market-based methods are evolving and may result in lower or higher fair value estimates for share-based compensation. The timing, readiness, adoption, general acceptance, reliability and testing of these methods is uncertain. Sophisticated mathematical models may require voluminous historical

information, modeling expertise, financial analyses, correlation analyses, integrated software and databases, consulting fees, customization and testing for adequacy of internal controls. Market-based methods are emerging that, if employed by us, may dilute our earnings per share and involve significant transaction fees and ongoing administrative expenses. The uncertainties and costs of these extensive valuation efforts may outweigh the benefits to investors.

Share-based compensation expense recognized during a period is based on the value of the portion of share-based payment awards that is ultimately expected to vest amortized using the straight-line attribution method. As share-based compensation expense recognized in the consolidated statements of operations for fiscal 2010, 2009, and 2008 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. The fair value method requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We estimate forfeitures based on our historical experience. Changes to the estimated forfeiture rate are accounted for as a cumulative effect of change in the period the change occurred. During fiscal 2010, we reduced our estimated forfeiture rate on certain restricted stock unit awards from 12.6% to zero percent, as we expect all the awards to vest. This change in the estimated forfeiture rates resulted in an increase in share-based compensation expense of approximately $93,000 with no effect on loss per share for fiscal 2010. In the fourth quarter of fiscal 2009, we reviewed our estimated forfeiture rate considering then recent actual data resulting in a reduction to our estimated forfeiture rate from 30.0% to 12.6% in fiscal 2009. Additionally, we reduced our estimated forfeiture rate on certain restricted stock unit awards from 30.0% to zero percent, as we expected all the awards to vest. These changes in the estimated forfeiture rates during fiscal 2009 resulted in an increase in share-based compensation expense of $935,000 and an increase to the diluted loss per share of $0.01 for fiscal 2009.

Revenue Recognition

General. We recognize revenue when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) our price to the buyer is fixed or determinable; and (4) collectability is reasonably assured.

Certain product sales are subject to rights of return. For products sold where the buyer has the right to return the product, we recognize revenue at the time of sale only if (1) our price to the buyer is fixed or determinable; (2) the buyer has paid us, or the buyer is obligated to pay us and the obligation is not contingent on the resale of the product; (3) the buyer's obligation to us would not be changed in the event of theft or physical destruction or damage of the product; (4) the buyer has economic substance apart from that provided by us; (5) we do not have significant obligations for future performance to directly bring about resale of the product by the buyer; and (6) the amount of future returns can be reasonably estimated.

Revenue Arrangements with Multiple Deliverables. In the past, we have entered into revenue arrangements whereby we deliver to the customer multiple products and/or services. Such arrangements have generally included some combination of the following: antibody generation services; licensed rights to technology, patented products, compounds, data and other intellectual property; and research and development services. We analyze our multiple element arrangements to determine whether the elements can be separated. We perform our analysis at the inception of the arrangement and as each product or service is delivered. If a product or service is not separable, the combined deliverables will be accounted for as a single unit of accounting.

A delivered product or service (or group of delivered products or services) can be separated from other elements when it meets all of the following criteria: (1) the delivered item has value to the customer on a standalone basis; (2) there is objective and reliable evidence of the fair value of the undelivered item; and (3) if the arrangement includes a general right of return relative to the delivered item, delivery, or performance of the undelivered item is considered probable and substantially in our control. If an element can be separated, we allocate revenue based upon the relative fair values of each element. We determine the fair value of a separate deliverable using the price we charge other customers when we sell that product or service separately; however if we do not sell the product or service separately, we use third-party evidence of fair value. We consider licensed rights or technology to have standalone value to our customers if we or others have sold such rights or technology separately or our customers can sell such rights or technology separately without the need for our continuing involvement.

License Arrangements. License arrangements may consist of non-refundable upfront license fees, data transfer fees, or research reimbursement payments and/or exclusive licensed rights to patented or patent pending compounds, technology access fees, various performance or sales milestones and future product royalty payments. Some of these arrangements are multiple element arrangements.

Non-refundable, up-front fees that are not contingent on any future performance by us, and require no consequential continuing involvement on our part, are recognized as revenue when the license term commences and the licensed data, technology and/or compound is delivered. Such deliverables may include physical quantities of compounds, design of the compounds and structure-activity relationships, the conceptual framework and mechanism of action, and rights to the patents or patents pending for such compounds. We defer recognition of non-refundable upfront fees if we have continuing performance obligations without which the technology, right, product or service conveyed in conjunction with the non-refundable fee has no utility to the licensee that is separate and independent of our performance under the other elements of the arrangement. In addition, if we have continuing involvement through research and development services that are required because our know-how and expertise related to the technology is proprietary to us, or can only be performed by us, then such up-front fees are deferred and recognized over the period of continuing involvement.

Payments related to substantive, performance-based milestones in a research and development arrangement are recognized as revenue upon the achievement of the milestones as specified in the underlying agreements when they represent the culmination of the earnings process.

Royalty Revenues. We recognize royalty revenues from licensed products when earned in accordance with the terms of the license agreements. Net sales figures used for calculating royalties include deductions for returned product, pricing allowances, managed care charge backs, cash discounts, freight/warehousing, and miscellaneous write-offs.

Certain royalty agreements require that royalties are earned only if a sales threshold is exceeded. Under these types of arrangements, the threshold is typically based on annual sales. The company recognizes royalty revenue in the period in which the threshold is exceeded.

Revenues from Sale of Royalty Rights. When we sell our rights to future royalties under license agreements and also maintain continuing involvement in earning such royalties, we defer recognition of any upfront payments and recognize them as revenue over the life of the license agreement. We recognize revenue for the sale of an undivided interest of our Abreva license agreement to Drug Royalty USA under the "units-of-revenue method." Under this method, the amount of deferred revenue to be recognized as revenue in each period is calculated by multiplying the following: (1) the ratio of the royalty payments due to Drug Royalty USA for the period to the total remaining royalties that we expect GSK will pay Drug Royalty USA over the term of the agreement by (2) the unamortized deferred revenue amount.

Product Sales — Active Pharmaceutical Ingredient Docosanol ("API Docosanol"). Revenue from sales of our API Docosanol is recorded when title and risk of loss have passed to the buyer and provided the criteria for revenue recognition are met. We sell the API Docosanol to various licensees upon receipt of a written order for the materials. Shipments generally occur fewer than three times a year. Our contracts for sales of the API Docosanol include buyer acceptance provisions that give our buyers the right of replacement if the delivered product does not meet specified criteria. That right requires that they give us notice within 30 days after receipt of the product. We have the option to refund or replace any such defective materials; however, we have historically demonstrated that the materials shipped from the same pre-inspected lot have consistently met the specified criteria and no buyer has rejected any of our shipments from the same pre-inspected lot to date. Therefore, we recognize revenue at the time of delivery without providing any returns reserve.

Cost of Revenues

Cost of revenues includes direct and indirect costs to manufacture product sold, including the write-off of obsolete inventory, reserves against inventory and to provide research and development services. We apply estimates or judgments in the valuation of inventory reserve.

Recognition of Expenses in Outsourced Contracts

Pursuant to management's assessment of the services that have been performed on clinical trials and other contracts, we recognize expenses as the services are provided. Such management assessments include, but are not limited to: (1) an evaluation by the project manager of the work that has been completed during the period, (2) measurement of progress prepared internally and/or provided by the third-party service provider, (3) analyses of data that justify the progress, and (4) management's judgment. Several of our contracts extend across multiple reporting periods, including our largest contract, representing a $7.1 million Phase III clinical trial contract that was entered into in the first fiscal quarter of fiscal 2008. Management bases its assessments on estimates that it considers reasonable in the circumstances. Other estimates could result in different assessments and different expense recognition.

Research and Development Expenses

Research and development expenses consist of expenses incurred in performing research and development activities including salaries and benefits, facilities and other overhead expenses, clinical trials, contract services and other outside expenses. Research and development expenses are charged to operations as they are incurred. Up-front payments to collaborators made in exchange for the avoidance of potential future milestone and royalty payments on licensed technology are also charged to research and development expense when the drug is still in the development stage, has not been approved by the FDA for commercialization and concurrently has no alternative uses.

We assess our obligations to make milestone payments that may become due under licensed or acquired technology to determine whether the payments should be expensed or capitalized. We charge milestone payments to research and development expense when:

- The technology is in the early stage of development and has no alternative uses;
- There is substantial uncertainty regarding the future success of the technology or product;
- There will be difficulty in completing the remaining development; and
- There is substantial cost to complete the work.

Acquired contractual rights. Payments to acquire contractual rights to a licensed technology or drug candidate are expensed as incurred when there is uncertainty in receiving future economic benefits from the acquired contractual rights. We consider the future economic benefits from the acquired contractual rights to a drug candidate to be uncertain until such drug candidate is approved by the FDA or when other significant risk factors are abated.

Effects of Inflation

We believe the impact of inflation and changing prices on net revenues and on operations has been minimal during the past three years.

Results of Operations

We operate our business on the basis of a single reportable segment, which is the business of development, acquisition and commercialization of novel therapeutics for chronic diseases. Our chief operating decision-maker is the Chief Executive Officer, who evaluates our company as a single operating segment.

We categorize revenues by type of revenue in five different categories: 1) royalties and royalty rights, 2) licensing, 3) government research grant services, 4) research and development services and 5) product sales.

All long-lived assets for fiscal 2010 and 2009 are located in the United States.

Comparison of Fiscal 2010 and 2009

Revenues and Cost of Revenues

	Year Ended September 30,			
	2010	2009	$ Change	% Change
REVENUES FROM PRODUCT SALES				
Net revenues	$ —	$ —	$ —	0%
Cost of revenues	197,640	73,135	124,505	170%
Product gross loss	(197,640)	(73,135)	(124,505)	170%
REVENUES AND COST OF RESEARCH SERVICES AND OTHER				
Revenues:				
Revenues from royalties and royalty rights	2,895,474	3,642,675	(747,201)	−21%
Revenues from license agreements	—	533,834	(533,834)	−100%
Revenue from research services and other	2,895,474	4,176,509	(1,281,035)	−31%
Costs:				
Cost of research and development services	—	10,224	(10,224)	−100%
Research services and other gross profit	2,895,474	4,166,285	(1,270,811)	−31%
Total gross profit	$2,697,834	$4,093,150	$(1,395,316)	−34%

Revenues

Revenues were $2.9 million for the fiscal year ended September 30, 2010 compared to $4.2 million for the fiscal year ended September 30, 2009. The decrease in revenues of approximately $1.3 million, or 31%, was primarily attributed to a decrease in the recognition of deferred royalty revenue, as well as a decrease in licensing revenue related to the license agreement with Kobayashi Pharmaceutical Co. Ltd. which was terminated in fiscal 2009.

In the fourth quarter of fiscal 2010, the Company recorded a cumulative non-cash adjustment to correct an immaterial error related to previously recorded deferred royalty revenue related to the GSK license agreement. The total cumulative non-cash adjustment recorded in the fourth quarter was a decrease in revenue of $797,000 which resulted in net revenues of ($71,000) in the fourth fiscal quarter of 2010 and $2.9 million for fiscal 2010.

For the fiscal years ended September 30, 2010 and 2009, we generated no product revenue from the sale of the active pharmaceutical ingredient docosanol.

Potential revenue-generating contracts that remained active as of September 30, 2010 include licensing revenue from our agreement with GSK, potential royalties from our agreements with Azur Pharma and Emergent Biosolutions, Inc. and modest revenue generated from various other licensing agreements. Partnering, licensing and research collaborations have been, and may continue to be, an important part of our business development strategy. We may continue to seek partnerships with pharmaceutical companies that can help fund our operations in exchange for sharing in the success of any licensed compounds or technologies. See Note 12 “Research, License, Supply and other Agreements” and Note 15 “Segment Information” in the Notes to Consolidated Financial Statements.

Cost of Revenues

In fiscal 2010, cost of revenues was $198,000 compared to $83,000 in fiscal 2009. The increase in cost of revenues was attributed to an increase in our inventory obsolescence reserve for docosanol.

Operating Expenses

	Year Ended September 30,			
	2010	2009	$ Change	% Change
OPERATING EXPENSES				
Research and development	$13,322,040	$15,867,049	$(2,545,009)	−16%
Selling, general and administrative	16,472,518	10,150,766	6,321,752	62%
Total Operating Expenses	$29,794,558	$26,017,815	$ 3,776,743	15%

Research and Development Expenses

Research and development expenses decreased by approximately $2.5 million or 16% for the fiscal year ended September 30, 2010 compared to the fiscal year ended September 30, 2009. The decrease is primarily due to a reduction in clinical expenses resulting from the completion of the STAR trial in fiscal 2009 offset by costs incurred in support of the complete response to the FDA approvable letter for NUEDEXTA and other regulatory activities. The complete response was submitted to the FDA in the third fiscal quarter of 2010.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by approximately $6.3 million or 62% for the fiscal year ended September 30, 2010, compared to the fiscal year ended September 30, 2009. The increase is primarily attributed to costs associated with preparation for commercial readiness for the launch of NUEDEXTA.

Share-Based Compensation

The Company re-examines forfeiture rates as they apply to stock-based compensation on an annual basis. We estimate forfeitures based on our historical experience. Changes to the estimated forfeiture rate are accounted for as a cumulative effect of change in the period the change occurred. During fiscal 2010, we reduced our estimated forfeiture rate on certain restricted stock unit awards from 12.6% to zero percent, as we expect all the awards to vest. This change in the estimated forfeiture rates resulted in an increase in share-based compensation expense of approximately $93,000 with no effect on loss per share for fiscal 2010. In the fourth quarter of fiscal 2009, we reviewed our estimated forfeiture rate considering then recent actual data resulting in a reduction to our estimated forfeiture rate from 30.0% to 12.6% in fiscal 2009. Additionally, we reduced our estimated forfeiture rate on certain restricted stock unit awards from 30.0% to zero percent, as we expected all the awards to vest. These changes in the estimated forfeiture rates during fiscal 2009 resulted in an increase in share-based compensation expense of $935,000 and an increase to the diluted loss per share of $0.01 for fiscal 2009. Future estimates may differ substantially from management's current estimates.

Total compensation expense for our share-based payments in the fiscal years ended September 30, 2010 and 2009 was approximately $2.7 million and $2.9 million, respectively. Selling, general and administrative expense in the fiscal years ended September 30, 2010 and 2009 includes share-based compensation expense of approximately $2.2 million for each period. Research and development expense in the fiscal years ended September 30, 2010 and 2009 includes share-based compensation expense of approximately $578,000 and $664,000, respectively. As of September 30, 2010, approximately $4.6 million of total unrecognized compensation costs related to unvested awards is expected to be recognized over a weighted average period of 2.4 years. See Note 11, "Stockholders' Equity -Employee Equity Incentive Plans" in the Notes to Consolidated Financial Statements for further discussion.

Interest Expense and Interest Income

We had no interest expense for the fiscal year ended September 30, 2010, compared to a nominal amount of $517 for the prior fiscal year.

For the fiscal year ended September 30, 2010, interest income was approximately $15,000, compared to approximately $204,000 for the prior fiscal year. The decrease is due to a lower investment yield in fiscal 2010 as compared to the prior fiscal year.

Other, net

Other, net was approximately $391,000 of income in fiscal 2010 compared to expense of approximately $272,000 in fiscal 2009. In fiscal year 2010, the Company recorded approximately $390,000 as Other, net under Other Income (Expenses) in connection with a legal settlement. (See Note 10, "Commitments and Contingencies" in the Notes to Consolidated Financial Statements). In fiscal 2009, the Company recognized a loss on disposal of fixed assets of approximately $266,000.

Net Loss

Net loss was approximately $26.7 million, or $0.30 per share, for the fiscal year ended September 30, 2010, compared to a net loss of approximately $22.0 million, or $0.28 per share for the fiscal year ended September 30, 2009. The increase in net loss is primarily attributed to costs incurred in preparation for the commercial launch of NUEDEXTA and regulatory costs associated with the complete response to the approvable letter and other regulatory activities.

Comparison of Fiscal 2009 and 2008

Revenues and Cost of Revenues

	Year Ended September 30,			
	2009	2008	$ Change	% Change
PRODUCT SALES				
Net revenues	$ —	$ 129,820	$ (129,820)	−100%
Cost of revenues	73,135	21,714	51,421	237%
Product gross (loss) profit	(73,135)	108,106	(181,241)	−168%
REVENUES AND COST OF RESEARCH SERVICES AND OTHER				
Revenues:				
Revenue from royalties and royalty rights	3,642,675	3,616,102	26,573	1%
Revenues from license agreements	533,834	2,205,724	(1,671,890)	−76%
Revenues from government research grant services	—	1,006,922	(1,006,922)	−100%
Revenues from research services and other	4,176,509	6,828,748	(2,652,239)	−39%
Costs:				
Cost of research and development services	10,224	249,281	(239,057)	−96%
Cost of government research grant	—	940,130	(940,130)	−100%
Costs from research services and grants	10,224	1,189,411	(1,179,187)	−99%
Research services and other gross margin	4,166,285	5,639,337	(1,473,052)	−26%
Total gross profit	$4,093,150	$5,747,443	$(1,654,293)	−29%

Revenues

For the fiscal year ended September 30, 2009, we generated no product revenues. In fiscal 2008, we received net product revenues of $130,000. Product revenues for that period were generated from the sale of the active pharmaceutical ingredient docosanol.

Revenues from research services and other were $4.2 million for the fiscal year ended September 30, 2009 compared to $6.8 million for the fiscal year ended September 30, 2008. The decrease in revenues is attributed to a one-time milestone payment received from HBI of $1.5 million in fiscal 2008 that was not repeated in 2009, and a

decline in grant revenue received from the NIH grant of $1.0 million due to the termination of the anthrax antibody program which ended in 2008, and accordingly, there are no comparable revenues in fiscal 2009.

Cost of Revenues

In fiscal 2009, cost of product revenues was $73,000 compared to $22,000 in fiscal 2008. Cost of product revenues in fiscal 2009 was primarily attributed to an inventory reserve amount of $69,000 established for docosanol.

Cost of research services and grants was $10,000 for the fiscal year ended September 30, 2009 compared to $1.2 million for the fiscal year ended September 30, 2008. The decline in cost of revenues is primarily attributable to the completion of the remaining work under the NIH grant and the termination of all future research and development work related to other infectious diseases in June 2008.

Operating Expenses

	Year Ended September 30,			
	2009	2008	$ Change	% Change
OPERATING EXPENSES				
Research and development	$15,867,049	$14,110,743	$1,756,306	12%
General and administrative	10,150,766	10,599,158	(448,392)	−4%
Total Operating Expenses	$26,017,815	$24,709,901	$1,307,914	5%

Research and Development Expenses

Research and development expenses increased by approximately $1.8 million or 12% for the fiscal year ended September 30, 2009 compared to the fiscal year ended September 30, 2008. The increase is primarily due to costs incurred for the confirmatory Phase III trial for the PBA indication of NUEDEXTA.

General and Administrative Expenses

General and administrative expenses decreased by approximately $448,000 or 4% for the fiscal year ended September 30, 2009, compared to the fiscal year ended September 30, 2008. The decrease is primarily attributed to a decrease in our overall general and administrative expenses as a result of the restructuring and the significant organizational changes that we made to our infrastructure. In addition, our general and administrative costs have decreased as a result of our focused efforts to contain costs and negotiate discounts with our principal vendors.

Share-Based Compensation

The Company re-examines forfeiture rates as they apply to stock-based compensation on an annual basis. We estimate forfeitures based on our historical experience. Changes to the estimated forfeiture rate are accounted for as a cumulative effect of change in the period the change occurred. In the fourth quarter of fiscal 2009, we reviewed our estimated forfeiture rate considering recent actual data resulting in a reduction to our estimated forfeiture rate from 30.0% to 12.6%. Additionally, we reduced our estimated forfeiture rate on certain restricted stock unit awards from 30.0% to zero percent, as we expect all the awards to vest. These changes in the estimated forfeiture rates resulted in an increase in share-based compensation expense of approximately $935,000 and an increase to the diluted loss per share of $0.01 for fiscal 2009. Future estimates may differ substantially from the Company's current estimates.

Total compensation expense for our share-based payments in the fiscal year ended September 30, 2009, and 2008 was approximately $2.9 million and $1.6 million (excluding $14,000 included in discontinued operations), respectively. General and administrative expense in the fiscal years ended September 30, 2009 and 2008 includes share-based compensation expense of approximately $2.2 million and $1.1 million, respectively. Research and development expense in the fiscal years ended September 30, 2009 and 2008 includes share-based compensation expense of approximately $664,000 and $491,000, respectively. As of September 30, 2009, approximately $3.0 million of total unrecognized compensation costs related to unvested awards is expected to be recognized

over a weighted average period of 2.4 years. See Note 11, "Stockholders' Equity — Employee Equity Incentive Plans" in the Notes to Consolidated Financial Statements for further discussion.

Interest Expense and Interest Income

For the fiscal year ended September 30, 2009, interest expense was $517, compared to approximately $541,000 for the prior fiscal year. The decrease in interest expense in 2009 is primarily due to a decrease in the balance on notes payable as compared to the prior year, mostly attributed to the accelerated repayment of the remaining outstanding principal in June 2008. The notes payable were issued in connection with the purchase of Alamo Pharmaceuticals, Inc.

For the fiscal year ended September 30, 2009, interest income was approximately $204,000, compared to approximately $1.3 million for the prior fiscal year. The decrease is due to an 18% decrease in the average cash balance of our investment accounts in fiscal 2009 as compared to the prior fiscal year, coupled with a lower investment yield in fiscal 2009.

Other, net

Other, net expense was approximately $272,000 in fiscal 2009 compared to income of approximately $1.2 million in fiscal 2008. In fiscal 2009, the company recognized a loss on disposal of fixed assets of approximately $268,000. In fiscal 2008, the Company received approximately $1.25 million in proceeds resulting from a settlement agreement with a former employee. The proceeds represented court awarded reimbursement of attorney's fees incurred in connection with the Company's defense. The proceeds were recorded as other income in the third fiscal quarter of 2008.

Loss from Discontinued Operations

There was no loss from discontinued operations for the fiscal year ended September 30, 2009. For the fiscal year ended September 30, 2008, approximately a $1.6 million loss from discontinued operations was recorded as a result of the final net working capital adjustment of approximately $1.4 million under our FazaClo asset purchase agreement with Azur, as well as additional trailing costs related to the operations of FazaClo.

Net Loss

Net loss was approximately $22.0 million, or $0.28 per share, for the fiscal year ended September 30, 2009, compared to a net loss of approximately $17.5 million, or $0.30 per share for the fiscal year ended September 30, 2008. The increase in net loss is primarily attributed to the following: 1) non-cash expenses of $1.9 million related to share-based compensation expense and other non-cash expenses, 2) increased spending in research and development and 3) the presence of two non-recurring revenue sources in 2008 totaling $2.5 million. In addition, in fiscal 2008, we recorded a gain on early extinguishment of debt and other income which together totaled approximately $2.2 million.

Liquidity and Capital Resources

We assess our liquidity based on our ability to generate cash to fund future operations. Key factors in the management of our liquidity are: cash required to fund operating activities including expected operating losses and the levels of inventories, accounts payable and capital expenditures; the timing and extent of cash received from milestone payments under license agreements; adequate credit facilities; and financial flexibility to attract long-term equity capital on favorable terms. Historically, cash required to fund on-going business operations has been provided by financing activities and used to fund operations, working capital requirements and investing activities.

Cash, cash equivalents and restricted investments, as well as net cash provided by or used in operating, investing and financing activities, are summarized in the table below.

	September 30, 2010	Increase During Period	September 30, 2009	Increase During Period	September 30, 2008
Cash, cash equivalents and investment in marketable securities	$39,373,019	$7,418,532	$31,954,487	$(10,286,040)	$42,240,527
Cash and cash equivalents	$38,771,469	$7,285,457	$31,486,012	$ (9,897,918)	$41,383,930
Net working capital	$32,967,188	$6,281,621	$26,685,567	$(10,486,069)	$37,171,636

	Year Ended September 30, 2010	Change Between Periods	Year Ended September 30, 2009	Change Between Periods	Year Ended September 30, 2008
Net cash used in operating activities	$(23,799,255)	$ (3,509,095)	$(20,290,160)	$ (3,611,951)	$(16,678,209)
Net cash (used in) provided by investing activities	(346,486)	(703,848)	357,362	(671,629)	1,028,991
Net cash provided by financing activities	31,431,198	21,396,318	10,034,880	(16,510,306)	26,545,186
Net increase (decrease) in cash and cash equivalents	$ 7,285,457	$17,183,375	$ (9,897,918)	$(20,793,886)	$ 10,895,968

Operating activities. Net cash used in operating activities was approximately $23.8 million in fiscal year 2010 compared to approximately $20.3 million in fiscal year 2009. The increase is primarily due to expenses related to the Company's regulatory and commercial readiness activities. Net cash used in operating activities was approximately $16.7 million in fiscal year 2008. The increase from fiscal year 2008 to 2009 was primarily due to expenses related to the confirmatory Phase III trial and additional pre-clinical and clinical studies in support of the response to the approvable letter.

Investing activities. Net cash used in investing activities was approximately $346,000 in fiscal year 2010, compared to approximately $357,000 net cash provided by investing activities in fiscal year 2009. In fiscal year 2010, cash used in investing activities was primarily due to the purchase of property and equipment in support of our commercial readiness activities and investments in securities. In fiscal year 2009, cash provided by investing activities arose primarily from sales and maturities of investments. Net cash provided by investing activities was approximately $1.0 million in fiscal year 2008. In fiscal year 2008, proceeds from sales and maturities of investments of approximately $2.3 million were partially offset by payments of approximately $1.4 million related to the net working capital adjustment from our sale of FazaClo.

Financing activities. Net cash provided by financing activities was approximately $31.4 million in fiscal year 2010 compared to approximately $10.0 million in fiscal year 2009. In fiscal 2010, we raised approximately $32.7 million in gross proceeds (approximately $31.6 million net of offering costs and commissions) from sales of common stock. In fiscal 2009, we raised approximately $10.8 million in gross proceeds (approximately $10.2 million net of offering costs and commissions) from sale of common stock. Net cash provided by financing activities was approximately $26.5 million in fiscal year 2008. In fiscal 2008, we raised gross proceeds of approximately $40.0 million from sales of our common stock through a registered common stock offering in April 2008 (approximately $37.9 million net of offering costs and commissions), offset by $11.3 million to reduce long-term debt.

In April 2009, we filed a shelf registration statement on Form S-3 with the SEC to sell an aggregate of up to $35.0 million in common stock, preferred stock, debt securities and warrants. On May 6, 2009, the registration statement was declared effective. On July 30, 2009 we entered into a financing facility with Cantor Fitzgerald & Co., providing for the sale of up to 12,500,000 shares of our common stock from time to time into the open market at prevailing prices. As of December 1, 2010, 7.6 million shares of common stock had been sold for total gross

proceeds of $21.5 million through this facility under our registration statement. Approximately $13.5 million remains on this shelf registration statement. We may or may not sell additional shares under this facility, depending on the volume and price of our common stock, as well as our capital needs and potential alternative sources of capital, such as a development partner for NUEDEXTA.

In September 2009, we filed a shelf registration statement on Form S-3 with the SEC to sell an aggregate of up to $75.0 million in common stock, preferred stock, debt securities and warrants. On September 23, 2009, the registration statement was declared effective.

In May 2010, we sold an aggregate of 10,000,000 shares of our common stock in an underwritten offering at a public offering price of $2.75 per share, resulting in $27.5 million in gross offering proceeds and approximately $26.6 million in net proceeds to us, after deducting underwriting discounts, commissions and estimated offering expenses. Approximately $34.5 million remains on this shelf registration statement.

In September 2010, we filed a shelf registration statement on Form S-3 with the SEC to sell an aggregate of up to $75.0 million in common stock, preferred stock, debt securities and warrants. As of December 1, 2010, there were no funds remaining on this shelf registration statement.

In November 2010, we completed an underwritten public offering of 20,000,000 shares of our common stock offered at a public offering price of $4.40 per share. Gross offering proceeds resulting from the offering were approximately $88,000,000, with net proceeds of approximately $83.0 million, after deducting offering discounts, costs and commissions.

As of September 30, 2010, we have contractual obligations for trade expenses and operating lease obligations, as summarized in the table that follows. We have no off-balance sheet arrangements.

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating lease obligations(1)	$3,071,409	$1,497,202	$1,574,207	$—	$—
Purchase obligations(2)	4,168,552	4,168,552	—	—	—
Total	$7,239,961	$5,665,754	$1,574,207	$—	$—

(1) Operating lease obligations are exclusive of payments we expect to receive under sublease agreements.

(2) Purchase obligations consist of the total of trade accounts payable and trade related accrued expenses at September 30, 2010, and a $1.3 million contingent contractual commitment for achievement of certain milestones, which approximates our contractual commitments for goods and services in the normal course of our business.

In connection with our acquisition of Alamo, in May 2006, we agreed to pay up to an additional $39,450,000 in revenue-based earn-out payments, based on future sales of FazaClo. These earn-out payments are based on FazaClo sales in the U.S. from the closing date of the acquisition through December 31, 2018 (the "Contingent Payment Period"). We sold the FazaClo product line to Azur in August 2007. (See Note 3, "Sale of FazaClo" in the Notes to Consolidated Financial Statements.) Our future earn-out obligations that would have been payable to the prior owner of Alamo Pharmaceuticals upon the achievement of certain milestones were assumed by Azur, although we may remain liable for these payments if Azur defaults on these obligations.

NUEDEXTA License Milestone Payments. We hold the exclusive worldwide marketing rights to NUEDEXTA for certain indications pursuant to an exclusive royalty-bearing license agreement with the Center for Neurologic Study ("CNS"). We will be obligated to pay CNS up to $400,000 in the aggregate in milestones to continue to develop NUEDEXTA for both PBA and DPN pain, assuming they are both approved for marketing by the FDA. We are not currently developing, nor do we have an obligation to develop, any other indications under the CNS license agreement. We paid a $75,000 milestone upon FDA approval of NUEDEXTA for the treatment of PBA. In addition, we are obligated to pay CNS a royalty on commercial sales of NUEDEXTA with respect to each indication, if the drug is approved by the FDA for commercialization. Under certain circumstances, we may have the obligation to pay CNS a portion of net revenues received if we sublicense NUEDEXTA to a third party. Under

the agreement with CNS, we are required to make payments on achievements of up to a maximum of ten milestones, based upon five specific clinical indications. Maximum payments for these milestone payments could total approximately $1.1 million if we pursued the development of NUEDEXTA for all of the licensed indications. Of the clinical indications that we currently plan to pursue, expected milestone payments could total approximately $400,000. In general, individual milestones range from approximately $75,000 to $125,000 for each accepted new drug application ("NDA") and a similar amount for each approved NDA. In addition we are obligated to pay CNS a royalty ranging from approximately 5% to 8% of net GAAP revenues.

Management Outlook

We believe that cash, cash equivalents and restricted investments of approximately $39.4 million at September 30, 2010 and net proceeds of approximately $83.0 million raised under common stock offering completed in November 2010, will be sufficient to sustain our planned level of operations for at least the next 24 months. However, we cannot provide assurances that our plans will not change, or that changed circumstances will not result in the depletion of capital resources more rapidly than anticipated.

For information regarding the risks associated with our need to raise capital to fund our ongoing and planned operations, please see Item 1A, "Risk Factors."

Recent Authoritative Guidance

See Note 2, "Summary of Significant Accounting Policies" in the Notes to Consolidated Financial Statements for a discussion of recently issued authoritative guidance and its effect, if any, on us.

Item 7A. ***Quantitative and Qualitative Disclosures About Market Risk***

As described below, we are exposed to market risks related to changes in interest rates. Because substantially all of our revenue, expenses, and capital purchasing activities are transacted in U.S. dollars, our exposure to foreign currency exchange rates is immaterial. However, in the future we could face increasing exposure to foreign currency exchange rates if we expand international distribution of docosanol 10% cream and purchase additional services from outside the U.S. Until such time as we are faced with material amounts of foreign currency exchange rate risks, we do not plan to use derivative financial instruments, which can be used to hedge such risks. We will evaluate the use of derivative financial instruments to hedge our exposure as the needs and risks should arise.

Interest Rate Sensitivity

Our investment portfolio consists primarily of cash equivalent fixed income instruments invested in government money market funds. The primary objective of our investments in these securities is to preserve principal. We classify our restricted investments, which are primarily certificates of deposit, as of September 30, 2010 as held-to-maturity. These held-to-maturity securities are subject to interest rate risk. Based on the average duration of our investments as of September 30, 2010 and 2009, an increase of one percentage point in the interest rates would have resulted in increases in interest income of approximately $388,000 and $343,000, respectively.

As of September 30, 2010, $25.2 million of our cash and cash equivalents were maintained in four separate money market mutual funds, and approximately $13.6 million of our cash and cash equivalents were maintained at three major financial institutions in the United States. At times, deposits held with financial institutions may exceed the amount of insurance provided by the Federal Deposit Insurance Corporation. At September 30, 2010, such uninsured deposits totaled approximately $37.7 million. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk.

Financial instruments that potentially subject us to concentrations of credit risk consist principally of cash and cash equivalents. Our cash and cash equivalents are placed at various money market mutual funds and financial institutions of high credit standing.

We perform ongoing credit evaluations of our customers' financial conditions and would limit the amount of credit extended if deemed necessary but usually we have required no collateral.

Item 8. ***Financial Statements and Supplementary Data***

Our consolidated financial statements are annexed to this report beginning on page F-1.

Item 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

None.

Item 9A. ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Vice President, Finance, of the effectiveness of our "disclosure controls and procedures" as of the end of the period covered by this report, pursuant to Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended.

In connection with that evaluation, our CEO and Vice President, Finance concluded that our disclosure controls and procedures were effective and designed to provide reasonable assurance that the information required to be disclosed is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms as of September 30, 2010. For the purpose of this review, disclosure controls and procedures means controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. These disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit is accumulated and communicated to management, including our principal executive officer, principal financial officer and principal accounting officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and related COSO guidance. Based on our evaluation under this framework, our management concluded that our internal control over financial reporting was effective as of September 30, 2010.

Our assessment of the effectiveness of our internal control over financial reporting as of September 30, 2010 has been audited by KMJ Corbin & Company LLP, an independent registered public accounting firm, as stated in their report, which is set forth at F-3.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during our fourth fiscal quarter ended September 30, 2010, that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

Item 9B. ***Other Information***

None.

PART III

Item 10. ***Directors, Executive Officers and Corporate Governance***

The information relating to our directors that is required by this item is incorporated by reference from the information under the captions "Election of Directors," "Corporate Governance," and "Board of Directors and Committees" contained in our definitive proxy statement (the "Proxy Statement"), which will be filed with the Securities and Exchange Commission in connection with our 2011 Annual Meeting of Stockholders.

Additionally, information relating to reporting of insider transactions in Company securities is incorporated by reference from the information under the caption "Section 16(a) Beneficial Ownership Reporting Compliance" in the Proxy Statement.

Executive Officers and Key Employees of the Registrant

The names of our executive officers and other key employees and their ages as of December 1, 2010 are set forth below. Officers are elected annually by the Board of Directors and hold office until their respective successors are qualified and appointed or until their resignation, removal or disqualification.

Executive Officers		
Keith A. Katkin	**39**	**President and Chief Executive Officer**
Randall E. Kaye, M.D.	**48**	**Senior Vice President, Chief Medical Officer**
Christine G. Ocampo, CPA	**38**	**Vice President, Finance, Secretary**
Key Employees		
Eric S. Benevich	**45**	**Vice President, Communications**
Gregory J. Flesher	**40**	**Vice President, Business Development**
Michael McFadden	**43**	**Vice President, U.S. Sales and Managed Markets**

Executive Officers

Keith Katkin. Mr. Katkin joined AVANIR in July of 2005 as Senior Vice President of Sales and Marketing. In March 2007, Mr. Katkin was appointed President and Chief Executive Officer and was elected as a member of the Board of Directors. Prior to joining AVANIR, Mr. Katkin previously served as Vice President, Commercial Development for Peninsula Pharmaceuticals, playing a key role in the management and ultimate sale of the company to Johnson & Johnson in 2005. Additionally, Mr. Katkin's employment experience includes leadership roles at InterMune, Inc., Amgen, Inc., and Abbott Laboratories. Mr. Katkin also served as strategic advisor to Cerexa, a pharmaceutical company that was sold to Forest Laboratories in 2007. Mr. Katkin received a B.S. degree in Business and Accounting from Indiana University and an M.B.A. degree in Finance from the Anderson School of Management at UCLA, graduating with honors. Mr. Katkin became a licensed Certified Public Accountant in 1995.

Randall E. Kaye, M.D. Dr. Kaye joined AVANIR in January 2006 as Vice President of Clinical and Medical Affairs and assumed the role of Senior Vice President Clinical Research and Medical Affairs and Chief Medical Officer in February 2007. Immediately prior to joining AVANIR, from 2004 to 2006, Dr. Kaye was the Vice President of Medical Affairs for Scios Inc., a division of Johnson & Johnson. From 2002 to 2004, Dr. Kaye recruited and managed the Medical Affairs department for InterMune Inc. Previously, Dr. Kaye served for nearly a decade in a variety of Medical Affairs and Marketing positions for Pfizer Inc. Dr. Kaye earned his Doctor of Medicine, Masters in Public Health and Bachelor of Science degrees at George Washington University in Washington, D.C. and was a Research Fellow in Allergy and Immunology at Harvard Medical School.

Christine G. Ocampo, CPA. Ms. Ocampo joined AVANIR in March 2007 as Corporate Controller and was promoted to Vice President, Finance in February 2008. Prior to joining AVANIR, Ms. Ocampo served as Senior Vice President, Chief Financial Officer, Chief Accounting Officer, Treasurer and Secretary of Cardiogenesis Corporation from November 2003 until April 2006. From 2001 to November 2003, Ms. Ocampo served in the role of Vice President and Corporate Controller at Cardiogenesis. Prior to first joining Cardiogenesis in April 1997, Ms. Ocampo held a management position in Finance at Mills-Peninsula Health Systems in Burlingame, CA, and

spent three years as an auditor for Ernst & Young LLP. Ms. Ocampo graduated with a Bachelors of Science in Accounting from Seattle University and became a licensed Certified Public Accountant in 1996.

Key Employees

Eric S. Benevich. Mr. Benevich joined AVANIR in July 2005 as Senior Director of Marketing. In August 2007, he was promoted to Vice President of Communications. Prior to joining AVANIR, Mr. Benevich previously served as the Senior Director of Marketing for Peninsula Pharmaceuticals. Prior to his tenure at Peninsula Pharmaceuticals, Mr. Benevich held several Marketing positions with Amgen Inc., a global biotechnology company. In addition, Mr. Benevich held several commercial roles at Astra Merck in Sales, Market Research and Brand Marketing. Mr. Benevich graduated from Washington State University with a degree in International Business.

Gregory J. Flesher. Mr. Flesher joined AVANIR in June 2006 as Senior Director of Commercial Strategy and in November 2006 assumed the additional responsibility for Business Development and Portfolio Planning. In August 2007 he was promoted to Vice President of Business Development. Prior to joining AVANIR, he served as a Sales Director from 2004 to 2006 and as Director of Pulmonary & Infectious Disease Marketing from 2002 to 2004 at InterMune, Inc., a biopharmaceutical company. Prior to his tenure at InterMune, Mr. Flesher held Oncology and Nephrology marketing positions with Amgen Inc., a global biotechnology company. Mr. Flesher also held roles in global marketing and clinical development at Eli Lilly and Company. Mr. Flesher graduated from Purdue University with a degree in Biology and has completed his doctorate coursework in Biochemistry and Molecular Biology at Indiana University School of Medicine.

Michael McFadden. Mr. McFadden joined AVANIR in May 2010 as Vice President of U.S. Sales and Managed Markets. In this role, Mr. McFadden is responsible for staffing, training and leading the planned NUEDEXTA specialty sales force as well as leading the development of all strategies and activities related to managed markets; including national health plans, pharmacy benefit managers, state Medicaid, trade relations, long term care, government affairs, and contract administration. Mr. McFadden's 20 years of pharmaceutical commercial experience includes the selling and marketing of several successful blockbuster prescription products. Prior to joining AVANIR, Mr. McFadden served in various leadership roles in sales and managed care at Amylin Pharmaceuticals where he was responsible for building and leading sales and managed markets teams and launching two first-in-class diabetes products. Prior to his tenure at Amylin, Mr. McFadden held commercial roles at Pharmacia and Eli Lilly and Company. Mr. McFadden graduated from University of Louisiana at Monroe with a degree in Business Administration.

Code of Ethics

We have adopted a code of Business Conduct and Ethics for directors, officers (including our principal executive officer, principal financial officer, and principal accounting officer and controller), and employees. This code is available on our website at www.avanir.com. Any waivers from or amendments to the code of ethics will be filed with the SEC on Form 8-K. You may also request a printed copy of our code of ethics, without charge, by writing to us at 101 Enterprise, Suite 300, Aliso Viejo, California 92656, Attn: Investor Relations.

Item 11. ***Executive Compensation***

The information required by this item is incorporated by reference to the information under the captions "Executive Compensation" and "Compensation Committee Interlocks and Insider Participation" contained in the Proxy Statement.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

The information required by this item is incorporated by reference to the information under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" contained in the Proxy Statement.

Item 13. ***Certain Relationships and Related Transactions and Director Independence***

The information required by this item is incorporated by reference to the information under the captions "Certain Relationships and Related Party Transactions," "Director Independence" and "Board Committees" contained in the Proxy Statement.

Item 14. ***Principal Accounting Fees and Services***

The information required by this item is incorporated by reference to the information under the caption "Fees for Independent Registered Public Accounting Firm" contained in the Proxy Statement.

PART IV

Item 15. ***Exhibits and Financial Statement Schedules***

(a) Financial Statements and Schedules

See index to the financial statements on page F-1.

(b) Exhibits

The following exhibits are incorporated by reference or filed as part of this report.

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
3.1	Certificate of Incorporation of the Registrant	Current Report on Form 8-K, as Exhibit 3.1	March 25, 2009
3.2	Bylaws of the Registrant	Current Report on Form 8-K, as Exhibit 3.2	March 25, 2009
3.3	Certificate of Ownership and Merger merging AVANIR Pharmaceuticals, a California corporation, with and into AVANIR Pharmaceuticals, Inc., a Delaware corporation	Current Report on Form 8-K, as Exhibit 3.3	March 25, 2009
3.4	Certificate of Designations of Series A Junior Participating Cumulative Preferred Stock	Registration Statement on Form 8-A/A (File No. 001-15803), as Exhibit 3.3	March 25, 2009
4.1	Form of Common Stock Certificate	Current Report on Form 8-K, as Exhibit 4.1	March 25, 2009
4.2	Form of Senior Indenture	Registration Statement on Form S-3 (File No. 333-169175), as Exhibit 4.3	September 8, 2009
4.3	Form of Subordinated Indenture	Registration Statement on Form S-3 (File No. 333-169175), as Exhibit 4.4	September 8, 2009
4.4	Form of Common Stock Warrant, issued in connection with the Subscription Agreement dated March 26, 2008	Current Report on Form 8-K, as Exhibit 10.2	March 27, 2008
4.5	Stockholder Rights Agreement, dated as of March 20, 2009, by and between AVANIR Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, LLC	Registration Statement on Form 8-A/A (File No. 001-15803), as Exhibit 4.2	March 25, 2009
4.6	Form of Rights Certificate with respect to the Stockholder Rights Agreement, dated as of March 20, 2009	Registration Statement on Form 8-A/A (File No. 001-15803), as Exhibit 4.2	March 25, 2009

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
10.1	License Agreement, dated as of March 31, 2000, by and between AVANIR Pharmaceuticals and SB Pharmco Puerto Rico, a Puerto Rico Corporation	Current Report on Form 8-K, as Exhibit 10.1	May 4, 2000
10.2	License Purchase Agreement, dated as of November 22, 2002, by and between AVANIR Pharmaceuticals and Drug Royalty USA, Inc.	Current Report on Form 8-K, as Exhibit 99.1	January 7, 2003
10.3	Standard Industrial Net Lease by and between AVANIR Pharmaceuticals and BC Sorrento, LLC, effective as of September 1, 2000	Quarterly Report on Form 10-Q for the quarter ended June 30, 2000, as Exhibit 10.1	August 14, 2000
10.4	Standard Industrial Net Lease by and between AVANIR Pharmaceuticals and Sorrento Plaza, effective as of May 20, 2002	Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, as Exhibit 10.1	August 13, 2002
10.5	Office lease agreement, dated as of April 28, 2006, by and between RREEF America REIT II Corp. FFF and AVANIR Pharmaceuticals	Annual Report on Form 10-K for the fiscal year ended September 30, 2006, as Exhibit 10.7	December 18, 2006
10.6	License Agreement, dated as of August 1, 2000, by and between AVANIR Pharmaceuticals and IriSys Research & Development, LLC*	Quarterly Report on Form 10-Q for the quarter ended June 30, 2000, as Exhibit 10.2	August 14, 2000
10.7	Exclusive Patent License Agreement, dated as of April 2, 1997, by and between IriSys Research & Development, LLC and the Center for Neurologic Study	Quarterly Report on Form 10-Q for the quarter ended March 31, 2005, as Exhibit 10.1	May 13, 2005
10.8	Amendment to Exclusive Patent License Agreement, dated as of April 11, 2000, by and between IriSys Research & Development, LLC and the Center for Neurologic Study	Quarterly Report on Form 10-Q for the quarter ended March 31, 2005, as Exhibit 10.2	May 13, 2005
10.9	Manufacturing Services Agreement, dated as of January 4, 2006, by and between Patheon Inc. and AVANIR Pharmaceuticals*	Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, as Exhibit 10.1	May 10, 2006
10.10	Amended and Restated 1998 Stock Option Plan	Annual Report on Form 10-K for the fiscal year ended September 30, 2001, as Exhibit 10.2	December 21, 2001
10.11	Amended and Restated 1994 Stock Option Plan	Annual Report on Form 10-K for the fiscal year ended September 30, 2001, as Exhibit 10.4	December 21, 2001
10.12	Amended and Restated 2000 Stock Option Plan	Quarterly Report on Form 10-Q for the quarter ended March 31, 2003, as Exhibit 10.1	May 14, 2003
10.13	Form of Restricted Stock Grant Notice for use with Amended and Restated 2000 Stock Option Plan	Quarterly Report on Form 10-Q for the quarter ended March 31, 2003, as Exhibit 10.2	May 14, 2003

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
10.14	2003 Equity Incentive Plan	Quarterly Report on Form 10-Q for the quarter ended March 31, 2003, as Exhibit 10.3	May 14, 2003
10.15	Form of Non-Qualified Stock Option Award Notice for use with 2003 Equity Incentive Plan	Quarterly Report on Form 10-Q for the quarter ended March 31, 2003, as Exhibit 10.4	May 14, 2003
10.16	Form of Restricted Stock Grant for use with 2003 Equity Incentive Plan	Quarterly Report on Form 10-Q for the quarter ended March 31, 2003, as Exhibit 10.5	May 14, 2003
10.17	Form of Restricted Stock Grant Notice (cash consideration) for use with 2003 Equity Incentive Plan	Quarterly Report on Form 10-Q for the quarter ended March 31, 2003, as Exhibit 10.6	May 14, 2003
10.18	Form of Indemnification Agreement with certain Directors and Executive Officers of the Registrant	Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, as Exhibit 10.1	July 30, 2009
10.19	2005 Equity Incentive Plan	Annual Report on Form 10-K for the fiscal year ended September 30, 2005, as Exhibit 10.21	December 14, 2005
10.20	Form of Stock Option Agreement for use with 2005 Equity Incentive Plan	Current Report on Form 8-K, as Exhibit 10.1	March 23, 2005
10.21	Form of Restricted Stock Unit Grant Agreement for use with 2005 Equity Incentive Plan and 2003 Equity Incentive Plan	Filed herewith	
10.22	Form of Restricted Stock Unit Director Grant Agreement for use with 2005 Equity Incentive Plan and 2003 Equity Incentive Plan	Filed herewith	
10.23	Form of Restricted Stock Purchase Agreement for use with 2005 Equity Incentive Plan	Annual Report on Form 10-K for the fiscal year ended September 30, 2006, as Exhibit 10.35	December 18, 2006
10.24	Form of Change of Control Agreement	Filed herewith	
10.25	Employment Agreement with Randall Kaye, dated as of December 23, 2005	Quarterly Report on Form 10-Q for the quarter ended December 31, 2005, as Exhibit 10.1	February 9, 2006
10.26	Employment Agreement with Keith Katkin, dated as of March 13, 2007	Annual Report on Form 10-K for the fiscal year ended September 30, 2007, as Exhibit 10.44	December 21, 2007
10.27	Bonus Agreement, dated as of September 10, 2007, by and between AVANIR Pharmaceuticals and Keith Katkin	Current Report on Form 8-K, as Exhibit 10.1	December 10, 2007
10.28	Sublease Agreement, dated as of July 2, 2007, by and between AVANIR Pharmaceuticals and Halozyme, Inc. (11388 Sorrento Valley Rd., San Diego, CA)	Annual Report on Form 10-K for the fiscal year ended September 30, 2007, as Exhibit 10.51	December 21, 2007

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
10.29	Sublease Agreement, dated as of July 2, 2007, by and between AVANIR Pharmaceuticals and Halozyme, Inc. (11404 Sorrento Valley Rd., San Diego, CA)	Annual Report on Form 10-K for the fiscal year ended September 30, 2007, as Exhibit 10.52	December 21, 2007
10.30	Third Amendment to Lease, dated as of July 19, 2007, by and between AVANIR Pharmaceuticals and RREEF America REIT II Corp. FFF	Annual Report on Form 10-K for the fiscal year ended September 30, 2007, as Exhibit 10.53	December 21, 2007
10.31	Asset Purchase and License Agreement, dated as of March 6, 2008, by and among AVANIR Pharmaceuticals, Xenerex Biosciences and Emergent Biosolutions, Inc.*	Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, as Exhibit 10.1	May 14, 2008
10.32	Sublease Agreement, dated as of April 21, 2009, by and between AVANIR Pharmaceuticals, Inc. and Halozyme, Inc.	Quarterly Report on Form 10-Q for the quarter ended March 31, 2009, as Exhibit 10.1	May 8, 2009
10.33	Controlled Equity Offering℠ Sales Agreement, dated as of July 30, 2009, by and between AVANIR Pharmaceuticals, Inc. and Cantor Fitzgerald & Co.	Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, as Exhibit 10.2	July 30, 2009
10.34	Amendment #1 to Manufacturing Services Agreement, dated as of January 19, 2010, by and between AVANIR Pharmaceuticals, Inc. and Patheon Inc.	Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, as Exhibit 10.1	May 3, 2010
10.35	Quality Agreement, dated as of January 19, 2010, by and between AVANIR Pharmaceuticals, Inc. and Patheon Inc.*	Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, as Exhibit 10.2	May 3, 2010
10.36	Underwriting Agreement, dated as of May 6, 2010, by and between AVANIR Pharmaceuticals, Inc. and Jefferies & Company, Inc.	Current Report on Form 8-K, as Exhibit 1.1	May 6, 2010
10.37	First Amendment to Offer of Employment, dated as of December 31, 2008, by and between Keith A. Katkin and AVANIR Pharmaceuticals, Inc.	Filed herewith	
21.1	List of Subsidiaries	Filed herewith	
23.1	Consent of Independent Registered Public Accounting Firm	Filed herewith	
31.1	Certification of Chief Executive Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002	Filed herewith	
31.2	Certification of Chief Financial Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002	Filed herewith	

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
32.1	Certification of Chief Executive Officer pursuant to Section 906 of Sarbanes-Oxley Act of 2002	Filed herewith	
32.2	Certification of Chief Financial Officer pursuant to Section 906 of Sarbanes-Oxley Act of 2002	Filed herewith	
99.1	FDA Action Letter received on October 29, 2010	Filed herewith	

* Confidential treatment has been granted with respect to portions of this exhibit pursuant to an application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934. A complete copy of this exhibit, including the redacted terms, has been separately filed with the Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AVANIR PHARMACEUTICALS, INC.

By: /s/ KEITH A. KATKIN
Keith A. Katkin
President and Chief Executive Officer

Date: December 7, 2010

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the date indicated.

Signature	Title	Date
/s/ KEITH A. KATKIN Keith A. Katkin	President and Chief Executive Officer (Principal Executive Officer)	December 7, 2010
/s/ CHRISTINE G. OCAMPO, CPA Christine G. Ocampo, CPA	Vice President, Finance (Principal Financial and Accounting Officer)	December 7, 2010
/s/ CRAIG A. WHEELER Craig A. Wheeler	Director, Chairman of the Board	December 7, 2010
/s/ STEPHEN G. AUSTIN, CPA Stephen G. Austin, CPA	Director	December 7, 2010
/s/ CHARLES A. MATHEWS Charles A. Mathews	Director	December 7, 2010
/s/ DAVID J. MAZZO, PH.D. David J. Mazzo, Ph.D.	Director	December 7, 2010
/s/ DENNIS G. PODLESAK Dennis G. Podlesak	Director	December 7, 2010
/s/ SCOTT M. WHITCUP, M.D. Scott M. Whitcup, M.D.	Director	December 7, 2010

AVANIR Pharmaceuticals, Inc.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
AVANIR Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of AVANIR Pharmaceuticals, Inc. and subsidiaries (the "Company") as of September 30, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity and comprehensive loss and cash flows for each of the three years in the period ended September 30, 2010. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of AVANIR Pharmaceuticals, Inc. and subsidiaries as of September 30, 2010 and 2009, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2010, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of September 30, 2010, based on the criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated December 7, 2010 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ KMJ CORBIN & COMPANY LLP

Costa Mesa, California
December 7, 2010

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON INTERNAL CONTROL OVER FINANCIAL REPORTING

To the Board of Directors and Stockholders of
AVANIR Pharmaceuticals, Inc.

We have audited the internal control over financial reporting of AVANIR Pharmaceuticals, Inc. and subsidiaries (the "Company") as of September 30, 2010, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting included in Item 9A. Our responsibility is to express an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal controls over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness of the internal control over financial reporting to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, AVANIR Pharmaceuticals, Inc. and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of September 30, 2010, based on the criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of AVANIR Pharmaceuticals, Inc. and subsidiaries as of September 30, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity and comprehensive loss and cash flows for each of the three years in the period ended September 30, 2010 and our report dated December 7, 2010 expressed an unqualified opinion on those consolidated financial statements.

/s/ KMJ CORBIN & COMPANY LLP

Costa Mesa, California
December 7, 2010

AVANIR Pharmaceuticals, Inc.

CONSOLIDATED BALANCE SHEETS

	September 30, 2010	September 30, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 38,771,469	$ 31,486,012
Stock subscriptions receivable	580,910	—
Inventories	652,628	114,098
Prepaid expenses	432,705	397,100
Other current assets	52,867	331,717
Current portion of restricted investments in marketable securities	200,000	200,775
Total current assets	40,690,579	32,529,702
Restricted investments in marketable securities, net of current portion	401,550	267,700
Property and equipment, net	449,712	310,677
Non-current inventories	228,207	710,531
Other assets	371,150	249,462
TOTAL ASSETS	$ 42,141,198	$ 34,068,072
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,106,110	$ 1,214,117
Accrued expenses and other liabilities	1,070,061	1,001,599
Accrued compensation and payroll taxes	2,147,371	1,345,859
Current portion of deferred revenues	2,399,849	2,282,560
Total current liabilities	7,723,391	5,844,135
Accrued expenses and other liabilities, net of current portion	334,269	652,395
Deferred revenues, net of current portion	6,076,982	7,629,807
Total liabilities	14,134,642	14,126,337
Commitments and contingencies		
Stockholders' equity:		
Preferred stock — $0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of September 30, 2010 and 2009	—	—
Common stock — $0.0001 par value, 200,000,000 shares authorized; 95,965,572 and 83,084,182 shares issued and outstanding as of September 30, 2010 and 2009, respectively	9,597	8,308
Common stock subscribed but unissued	580,910	—
Additional paid-in capital	332,100,685	297,923,915
Accumulated deficit	(304,684,636)	(277,990,488)
Total stockholders' equity	28,006,556	19,941,735
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 42,141,198	$ 34,068,072

See notes to consolidated financial statements.

AVANIR Pharmaceuticals, Inc.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended September 30,		
	2010	**2009**	**2008**
REVENUES FROM PRODUCT SALES			
Net revenues	$ —	$ —	$ 129,820
Cost of revenues	197,640	73,135	21,714
Product gross (loss) profit	(197,640)	(73,135)	108,106
REVENUES AND COST OF RESEARCH SERVICES AND OTHER			
Revenues from royalties and royalty rights	2,895,474	3,642,675	3,616,102
Revenues from license agreements	—	533,834	2,205,724
Revenues from government research grant services	—	—	1,006,922
Revenue from research services and other	2,895,474	4,176,509	6,828,748
Cost of research and development services	—	10,224	249,281
Cost of government research grant	—	—	940,130
Research services and other gross profit	2,895,474	4,166,285	5,639,337
Total gross profit	2,697,834	4,093,150	5,747,443
OPERATING EXPENSES			
Research and development	13,322,040	15,867,049	14,110,743
Selling, general and administrative	16,472,518	10,150,766	10,599,158
Total operating expenses	29,794,558	26,017,815	24,709,901
Loss from operations	(27,096,724)	(21,924,665)	(18,962,458)
OTHER INCOME(EXPENSES)			
Interest income	15,021	204,190	1,283,302
Interest expense	—	(517)	(540,618)
Gain on early extinguishment of debt	—	—	967,547
Gain on sale of Xenerex antibodies	—	—	120,274
Other, net	390,755	(271,824)	1,222,481
Loss before provision for income taxes	(26,690,948)	(21,992,816)	(15,909,472)
Provision for income taxes	3,200	3,200	3,200
Loss from continuing operations	(26,694,148)	(21,996,016)	(15,912,672)
DISCONTINUED OPERATIONS			
Loss from discontinued operations	—	—	(231,848)
Loss on sale of discontinued operations	—	—	(1,351,219)
Loss from discontinued operations	—	—	(1,583,067)
Net loss	$(26,694,148)	$(21,996,016)	$(17,495,739)
BASIC AND DILUTED NET LOSS PER SHARE:			
Loss from continuing operations	$ (0.30)	$ (0.28)	$ (0.27)
Loss from discontinued operations	—	—	(0.03)
Net loss per share	$ (0.30)	$ (0.28)	$ (0.30)
Basic and diluted weighted average number of common shares outstanding	87,614,420	78,844,251	58,901,030

See notes to consolidated financial statements.

AVANIR Pharmaceuticals, Inc.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS

	Common Stock		Common Stock Subscribed but Unissued		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity	Comprehensive Loss
	Shares	Amount	Shares	Amount					
BALANCE, OCTOBER 1, 2007	43,117,358	$4,312	—	$ —	$245,527,400	$(238,498,733)	$(2,745)	$ 7,030,234	
Net loss	—	—	—	—	—	(17,495,739)	—	(17,495,739)	$(17,495,739)
Issuance of common stock in connection with:									
Sale of stock, net of offering costs	35,007,246	3,500	—	—	37,835,342	—	—	37,838,842	
Vesting of restricted stock units and awards	113,361	11	—	—	260	—	—	271	
Common stock surrendered	(21,979)	(2)	—	—	(29,848)	—	—	(29,850)	
Forfeiture of restricted awards	(2,000)	—	—	—	—	—	—	—	
Share-based compensation expense	—	—	—	—	1,653,661	—	—	1,653,661	
Reclassification adjustment for unrealized gains on investments in marketable securities	—	—	—	—	—	—	2,745	2,745	2,745
BALANCE, SEPTEMBER 30, 2008	78,213,986	7,821	—	—	284,986,815	(255,994,472)	—	29,000,164	$(17,492,994)
Net loss	—	—	—	—	—	(21,996,016)	—	(21,996,016)	$(21,996,016)
Issuance of common stock in connection with:									
Sale of stock, net of offering costs	4,613,350	461	—	—	10,246,419	—	—	10,246,880	
Vesting of restricted stock units	346,294	35	—	—	(35)	—	—	—	
Common stock surrendered	(89,448)	(9)	—	—	(186,247)	—	—	(186,256)	
Share-based compensation expense	—	—	—	—	2,876,963	—	—	2,876,963	
BALANCE, SEPTEMBER 30, 2009	83,084,182	8,308	—	—	297,923,915	(277,990,488)	—	19,941,735	$(21,996,016)
Net loss	—	—	—	—	—	(26,694,148)	—	(26,694,148)	$(26,694,148)
Issuance of common stock in connection with:									
Exercise of stock options	55,836	5	—	—	45,471	—	—	45,476	
Sale of stock, net of offering costs	11,746,160	1,175	180,000	580,910	31,597,209	—	—	32,179,294	
Vesting of restricted stock units	1,185,258	119	—	—	(119)	—	—	—	
Common stock surrendered	(105,864)	(10)	—	—	(212,652)	—	—	(212,662)	
Share-based compensation expense	—	—	—	—	2,746,861	—	—	2,746,861	
BALANCE, SEPTEMBER 30, 2010	95,965,572	$9,597	180,000	$580,910	$332,100,685	$(304,684,636)	$ —	$ 28,006,556	$(26,694,148)

See notes to consolidated financial statements.

AVANIR Pharmaceuticals, Inc.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended September 30,		
	2010	2009	2008
OPERATING ACTIVITIES:			
Net loss	$(26,694,148)	$(21,996,016)	$(17,495,739)
Loss from discontinued operations	—	—	1,583,067
Adjustments to reconcile net loss from continuing operations to net cash used in operating activities:			
Depreciation and amortization	204,998	260,780	445,980
Share-based compensation expense	2,746,861	2,876,963	1,639,756
Amortization of debt discount	—	—	232,776
Gain on extinguishment of debt	—	—	(967,547)
Gain on sale of Xenerex antibodies	—	—	(120,274)
Loss on impairment of assets	—	—	41,048
Loss on disposal of assets	—	266,212	26,852
Changes in operating assets and liabilities:			
Receivables	—	—	72,000
Inventories	(56,206)	508,648	21,714
Prepaid expenses and other assets	121,557	547,169	1,220,915
Accounts payable	761,371	762,271	144,146
Accrued expenses and other liabilities	(249,664)	(1,095,924)	(471,342)
Accrued compensation and payroll taxes	801,512	153,402	780
Deferred revenues	(1,435,536)	(2,573,665)	(2,834,398)
Net cash used in operating activities of continuing operations	(23,799,255)	(20,290,160)	(16,460,266)
Net cash used in operating activities of discontinued operations	—	—	(217,943)
Net cash used in operating activities	(23,799,255)	(20,290,160)	(16,678,209)
INVESTING ACTIVITIES:			
Purchase of investments in securities	(200,000)	—	(527)
Proceeds from sales and maturities of investments in securities	66,925	388,122	2,300,111
Purchase of property and equipment	(213,411)	(33,010)	(134,374)
Proceeds from sale of Xenerex antibodies	—	—	210,000
Proceeds from disposal of assets	—	2,250	5,000
Net cash (used in) provided by investing activities of continuing operations	(346,486)	357,362	2,380,210
Net cash used in investing activities of discontinued operations	—	—	(1,351,219)
Net cash (used in) provided by investing activities	(346,486)	357,362	1,028,991
FINANCING ACTIVITIES:			
Proceeds from issuances of common stock and warrants, net of commissions and offering costs	31,598,384	10,246,880	37,838,842
Proceeds from exercise of stock options	45,476	—	—
Tax withholding payments reimbursed by surrender of restricted stock	(212,662)	(186,256)	(29,579)
Payments on notes and capital lease obligations	—	(25,744)	(11,264,077)
Net cash provided by financing activities	31,431,198	10,034,880	26,545,186
Net increase (decrease) in cash and cash equivalents	7,285,457	(9,897,918)	10,895,968
Cash and cash equivalents at beginning of year	31,486,012	41,383,930	30,487,962
Cash and cash equivalents at end of year	$ 38,771,469	$ 31,486,012	$ 41,383,930
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:			
Interest paid	$ —	$ 517	$ 447,508
Income taxes paid	$ 4,539	$ 6,427	$ 51,108
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:			
Sale of common stock, net of offering costs, for stock subscriptions receivable	$ 580,910	$ —	$ —
Purchase of property and equipment in accounts payable	$ 130,622	$ —	$ —

See notes to consolidated financial statements.

1. Description of Business

AVANIR Pharmaceuticals, Inc. and subsidiaries ("AVANIR", the "Company" or "we") is a pharmaceutical company focused on developing and commercializing novel therapeutic products for the treatment of central nervous system disorders. In October 2010, the U.S. Food and Drug Administration ("FDA") approved NUEDEXTA (formerly referred to as AVP-923 or its previously proposed trade name Zenvia), a unique proprietary combination of dextromethorphan/quinidine, for the treatment of pseudobulbar affect ("PBA"). NUEDEXTA has also successfully completed a Phase III trial for the treatment of patients with diabetic peripheral neuropathic pain ("DPN pain"). We plan to make NUEDEXTA commercially available for prescription in the second quarter of fiscal 2011.

In addition to our focus on products for the central nervous system, we also have a number of partnered programs in other therapeutic areas which may generate future income for us. Our first commercialized product, docosanol 10% cream, (sold in the United States and Canada as Abreva® by our marketing partner GlaxoSmithKline Consumer Healthcare) is the only over-the-counter treatment for cold sores that has been approved by the FDA. In 2008, we licensed all of our monoclonal antibodies and we remain eligible to receive milestone payments and royalties related to the sale of these assets.

The Company's operations are subject to certain risks and uncertainties frequently encountered by companies in the early stages of operations, particularly in the evolving market for small biotech and specialty pharmaceuticals companies. Such risks and uncertainties include, but are not limited to, the occurrence of adverse safety events with NUEDEXTA, that NUEDEXTA may not gain acceptance by the medical field, our dependence on third parties for manufacturing and distribution of NUEDEXTA, that we may not adequately build or maintain the necessary sales, marketing, supply chain management and reimbursement capabilities on our own or enter into arrangements with third parties to perform these functions in a timely manner or on acceptable terms, timing and uncertainty of achieving milestones in clinical trials and in obtaining approvals by the FDA and regulatory agencies in other countries. The Company's ability to generate revenues in the future may depend on market acceptance of NUEDEXTA for the treatment of PBA and the timing and success of reaching clinical development milestones and obtaining regulatory approvals. The Company's operating expenses depend substantially on the level of expenditures for the commercial launch of NUEDEXTA, clinical development activities for AVP-923 and the rate of progress being made on such activities.

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

2. Summary of Significant Accounting Policies

Basis of presentation

The consolidated financial statements include the accounts of AVANIR Pharmaceuticals, Inc. and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated. The Company's fiscal year ends on September 30 of each year. The years ended September 30, 2010, 2009, and 2008 are herein referred to as fiscal 2010, fiscal 2009 and fiscal 2008, respectively.

The Company has evaluated subsequent events through the filing date of this Form 10-K, and determined that no subsequent events have occurred that would require recognition in the consolidated financial statements or disclosure in the notes thereto other than as discussed in the accompanying notes. See Note 16 "Subsequent Events".

On March 27, 2009, the Company effected a change of domicile from California to Delaware. In the change of domicile, AVANIR Pharmaceuticals, a California corporation ("AVANIR California"), merged with and into AVANIR Pharmaceuticals, Inc., a Delaware corporation ("AVANIR Delaware") and a wholly-owned subsidiary of AVANIR California. As a result of the merger, AVANIR Delaware succeeded to the assets and liabilities of AVANIR California. In the merger, each share of AVANIR California Class A common stock, no par value, was converted into one share of AVANIR Delaware common stock, $0.0001 par value, and all options, warrants and purchase rights

issued by AVANIR California and outstanding at the time of the merger were assumed by AVANIR Delaware. Due to the change in the par value of the Company's common stock, the Company attributed $7,824 to stockholders' equity for common stock as of March 31, 2009, which amount is equal to the aggregate par value of the shares of common stock issued and outstanding on that date, and reclassified the balance of $285,814,402 as additional paid-in capital as of that date. No change was made to stockholders' equity for preferred stock as no shares were outstanding as of March 31, 2009. The reclassifications had no effect on total stockholders' equity.

Management estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("GAAP") requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates. Significant estimates made by management include, among others, provisions for uncollectible receivables, valuation of inventories and investments, recoverability of long-lived assets, recognition of deferred revenue, share-based compensation expense, determination of expenses in outsourced contracts, and realization of deferred tax assets.

Cash and cash equivalents

Cash and cash equivalents consist of cash and highly liquid investments with maturities of three months or less at the date of acquisition.

Restricted investments in marketable securities

Restricted investments consist of certificates of deposit and represent amounts pledged to the Company's bank as collateral for letters of credit issued in connection with certain of the Company's lease agreements. These investments are classified as held-to-maturity and are stated at the amortized cost. The restricted amounts that apply to the terms of the leases, which expire in January 2013, were $401,550 and $468,475 for the years ended September 30, 2010 and 2009, respectively. Restricted investments also consist of a $200,000 certificate of deposit related to the Company's credit card agreement.

Concentrations

As of September 30, 2010, $25.2 million of the Company's cash and cash equivalents were maintained in four separate money market mutual funds, and approximately $13.6 million of the Company's cash and cash equivalents were maintained at three major financial institutions in the United States. At times, deposits held with financial institutions may exceed the amount of insurance provided by the Federal Deposit Insurance Corporation ("FDIC"), which provides deposit coverage with limits up to $250,000 per owner. At September 30, 2010, such uninsured deposits totaled approximately $37.7 million. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk.

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. The Company's cash and cash equivalents are placed in various money market mutual funds and at financial institutions of high credit standing.

The Company performs ongoing credit evaluations of customers' financial conditions and would limit the amount of credit extended if deemed necessary but usually has required no collateral.

Inventories

Inventories are stated at the lower of cost or market. Cost is determined on a first-in, first-out ("FIFO") basis. The Company evaluates the carrying value of inventories on a regular basis, based on the price expected to be

obtained for products in their respective markets compared with historical cost. Write-downs of inventories are considered to be permanent reductions in the cost basis of inventories.

The Company also regularly evaluates its inventories for excess quantities and obsolescence (expiration), taking into account such factors as historical and anticipated future sales or use in production compared to quantities on hand and the remaining shelf life of products and active pharmaceutical ingredients on hand. The Company establishes reserves for excess and obsolete inventories as required based on its analyses.

Property and equipment

Property and equipment, net, is stated at cost less accumulated depreciation and amortization. Depreciation and amortization is computed using the straight-line method over the estimated useful life of the asset. Computer equipment and related software are depreciated over three to five years. Office equipment, furniture and fixtures are depreciated over five years. Leasehold improvements are amortized over the useful life or remaining lease term, whichever is shorter.

Capitalization and Valuation of Long-Lived Assets

Long-lived assets are evaluated for impairment whenever events or changes in circumstances indicate that their carrying value may not be recoverable. If the review indicates that a long-lived asset is not recoverable (i.e. the carrying amount is less than the future projected undiscounted cash flows), its carrying amount would be reduced to fair value. Factors management considers important that could trigger an impairment review include the following:

- A significant underperformance relative to expected historical or projected future operating results;
- A significant change in the manner of our use of the acquired asset or the strategy for our overall business; and/or
- A significant negative industry or economic trend.

Based on its analysis, the Company's management believes that no impairment of the carrying value of its long-lived assets existed at September 30, 2010 or 2009.

Deferred rent

The Company accounts for rent expense related to operating leases (excluding leases related to exit activities) by accumulating total minimum rent payments on the leases over their respective periods and recognizing the rent expense on a straight-line basis. The difference between the actual amount paid and the amount recorded as rent expense in each fiscal year is recorded as an adjustment to deferred rent. Deferred rent as of September 30, 2010 and 2009 was $12,148 and $19,516, respectively, and is included in accrued expenses and other liabilities in the accompanying consolidated balance sheets.

Fair value of financial instruments

At September 30, 2010 and 2009, the Company's financial instruments include cash and cash equivalents, restricted investments in marketable securities, accounts payable, accrued expenses and other liabilities, and accrued compensation and payroll taxes. The carrying amount of cash and cash equivalents, accounts payable, accrued expenses and other liabilities, and accrued compensation and payroll taxes approximates fair value due to the short-term maturities of these instruments. The Company's short- and long-term restricted investments in marketable securities are carried at amortized cost which approximates fair value.

Revenue recognition

The Company has historically generated revenues from product sales, collaborative research and development arrangements, and other commercial arrangements such as, royalties, the sale of royalty rights and sales of technology rights. Payments received under such arrangements may include non-refundable fees at the inception of the arrangements, milestone payments for specific achievements designated in the agreements, royalties on sales of products resulting from collaborative arrangements, and payments for the sale of rights to future royalties.

The Company recognizes revenue when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the Company's price to the buyer is fixed or determinable; and (4) collectability is reasonably assured. Certain product sales are subject to rights of return. For products sold where the buyer has the right to return the product, the Company recognizes revenue at the time of sale only if (1) the Company's price to the buyer is substantially fixed or determinable at the date of sale, (2) the buyer has paid the Company, or the buyer is obligated to pay the seller and the obligation is not contingent on resale of the product, (3) the buyer's obligation to the Company would not be changed in the event of theft or physical destruction or damage of the product, (4) the buyer acquiring the product for resale has economic substance apart from that provided by the seller, (5) the Company does not have significant obligations for future performance to directly bring about resale of the product by the buyer, and (6) the amount of future returns can be reasonably estimated. The Company recognizes such product revenues when either it has met all the above criteria, including the ability to reasonably estimate future returns, when it can reasonably estimate that the return privilege has substantially expired, or when the return privilege has substantially expired, whichever occurs first.

Product Sales — Active Pharmaceutical Ingredient Docosanol ("Docosanol"). Revenue from sales of the Company's docosanol is recorded when title and risk of loss have passed to the buyer and provided the criteria for revenue recognition are met. The Company sells the docosanol to various licensees upon receipt of a written order for the materials. Shipments generally occur fewer than three times a year. The Company's contracts for sales of the docosanol include buyer acceptance provisions that give the Company's buyers the right of replacement if the delivered product does not meet specified criteria. That right requires that they give the Company notice within 30 days after receipt of the product. The Company has the option to refund or replace any such defective materials; however, it has historically demonstrated that the materials shipped from the same pre-inspected lot have consistently met the specified criteria and no buyer has rejected any of the Company's shipments from the same pre-inspected lot to date. Therefore, the Company recognizes revenue at the time of delivery without providing any returns reserve.

Multiple Element Arrangements. The Company has, in the past, entered into arrangements whereby it delivers to the customer multiple elements including technology and/or services. Such arrangements have generally included some combination of the following: antibody generation services; licensed rights to technology, patented products, compounds, data and other intellectual property; and research and development services. The Company analyzes its multiple element arrangements to determine whether the elements can be separated. The Company performs its analysis at the inception of the arrangement and as each product or service is delivered. If a product or service is not separable, the combined deliverables will be accounted for as a single unit of accounting.

A delivered element can be separated from other elements when it meets all of the following criteria: (1) the delivered item has value to the customer on a standalone basis; (2) there is objective and reliable evidence of the fair value of the undelivered item; and (3) if the arrangement includes a general right of return relative to the delivered item, delivery, or performance of the undelivered item is considered probable and substantially in the Company's control. If an element can be separated, the Company allocates amounts based upon the relative fair values of each element. The Company determines the fair value of a separate deliverable using the price it charges other customers when it sells that product or service separately; however, if the Company does not sell the product or service separately, it uses third-party evidence of fair value. The Company considers licensed rights or technology to have standalone value to its customers if it or others have sold such rights or technology separately or its customers can sell such rights or technology separately without the need for the Company's continuing involvement.

License Arrangements. License arrangements may consist of non-refundable upfront license fees, data transfer fees, research reimbursement payments, exclusive licensed rights to patented or patent pending compounds, technology access fees, and various performance or sales milestones. These arrangements are often multiple element arrangements.

Non-refundable, up-front fees that are not contingent on any future performance by the Company, and require no consequential continuing involvement on its part, are recognized as revenue when the license term commences and the licensed data, technology and/or compound is delivered. Such deliverables may include physical quantities of compounds, design of the compounds and structure-activity relationships, the conceptual framework and mechanism of action, and rights to the patents or patents pending for such compounds. The Company defers recognition of non-refundable upfront fees if it has continuing performance obligations without which the technology, right, product or service conveyed in conjunction with the non-refundable fee has no utility to the licensee that is separate and independent of the Company's performance under the other elements of the arrangement. In addition, if the Company has required continuing involvement through research and development services that are related to its proprietary know-how and expertise of the delivered technology, or can only be performed by the Company, then such up-front fees are deferred and recognized over the period of continuing involvement.

Payments related to substantive, performance-based milestones in a research and development arrangement are recognized as revenues upon the achievement of the milestones as specified in the underlying agreements when they represent the culmination of the earnings process.

Royalty Arrangements. The Company recognizes royalty revenues from licensed products when earned in accordance with the terms of the license agreements. Net sales amounts generally required to be used for calculating royalties include deductions for returned product, pricing allowances, cash discounts, freight and warehousing. These arrangements are often multiple element arrangements.

Certain royalty arrangements require that royalties are earned only if a sales threshold is exceeded. Under these types of arrangements, the threshold is typically based on annual sales. For royalty revenue generated from the license agreement with GlaxoSmithKline, the Company recognizes royalty revenue in the period in which the threshold is exceeded. For royalty revenue generated from the license agreement with Azur Pharma, the Company recognizes revenue when it has confirmed that the threshold has been exceeded.

When the Company sells its rights to future royalties under license agreements and also maintains continuing involvement in earning such royalties, it defers recognition of any upfront payments and recognizes them as revenues over the life of the license agreement. The Company recognizes revenues for the sale of an undivided interest of its Abreva® license agreement to Drug Royalty USA under the "units-of-revenue method." Under this method, the amount of deferred revenues to be recognized in each period is calculated by multiplying the ratio of the royalty payments due to Drug Royalty USA by GlaxoSmithKline for the period to the total remaining royalties the Company expects GlaxoSmithKline will pay Drug Royalty USA over the remaining term of the agreement by the unamortized deferred revenues.

Cost of revenues

Cost of revenues includes direct and indirect costs to manufacture product sold, including the write-off of obsolete inventory, and to provide research and development services.

Recognition of expenses in outsourced contracts

Pursuant to management's assessment of the services that have been performed on clinical trials and other contracts, the Company recognizes expense as the services are provided. Such management assessments include, but are not limited to: (1) an evaluation by the project manager of the work that has been completed during the period, (2) measurement of progress prepared internally and/or provided by the third-party service provider,

(3) analyses of data that justify the progress, and (4) management's judgment. Several of the Company's contracts extend across multiple reporting periods.

Research and development expenses

Research and development expenses consist of expenses incurred in performing research and development activities including salaries and benefits, facilities and other overhead expenses, clinical trials, contract services and outsource contracts. Research and development expenses are charged to operations as they are incurred. Up-front payments to collaborators made in exchange for the avoidance of potential future milestone and royalty payments on licensed technology are also charged to research and development expense when the drug is still in the development stage, has not been approved by the FDA for commercialization and currently has no alternative uses.

The Company assesses its obligations to make milestone payments that may become due under licensed or acquired technology to determine whether the payments should be expensed or capitalized. The Company charges milestone payments to research and development expense when:

- The technology is in the early stage of development and has no alternative uses;
- There is substantial uncertainty regarding the future success of the technology or product;
- There will be difficulty in completing the remaining development; and
- There is substantial cost to complete the work.

Acquired contractual rights. Payments to acquire contractual rights to a licensed technology or drug candidate are expensed as incurred when there is uncertainty in receiving future economic benefits from the acquired contractual rights. The Company considers the future economic benefits from the acquired contractual rights to a drug candidate to be uncertain until such drug candidate is approved by the FDA or when other significant risk factors are abated.

Share-Based Compensation

The Company grants options, restricted stock units and restricted stock awards to purchase the Company's common stock to employees, directors and consultants under stock option plans. The benefits provided under these plans are share-based payments that the Company accounts for using the fair value method.

The fair value of each option award is estimated on the date of grant using a Black-Scholes-Merton option pricing model ("Black-Scholes model") that uses assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, expected stock price volatility, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends. Expected volatilities are based on historical volatility of common stock and other factors. The expected terms of options granted are based on analyses of historical employee termination rates and option exercises. The risk-free interest rates are based on the U.S. Treasury yield in effect at the time of the grant. Since the Company does not expect to pay dividends on common stock in the foreseeable future, it estimated the dividend yield to be 0%.

Share-based compensation expense recognized during a period is based on the value of the portion of share-based payment awards that is ultimately expected to vest amortized under the straight-line attribution method. As share-based compensation expense recognized in the consolidated statements of operations for fiscal 2010, 2009, and 2008 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. The fair value method requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company estimates forfeitures based on historical experience. Changes to the estimated forfeiture rate are accounted for as a cumulative effect of change in the period the change occurred. During fiscal 2010, the Company reduced the estimated forfeiture rate on certain restricted stock unit awards from 12.6% to zero percent, as management expects all the awards to vest. This change in the estimated

forfeiture rates resulted in an increase in share-based compensation expense of approximately $93,000 with no effect on loss per share for fiscal 2010. In the fourth quarter of fiscal 2009, the Company reviewed the estimated forfeiture rate considering then recent actual data resulting in a reduction to our estimated forfeiture rate from 30.0% to 12.6% in fiscal 2009. Additionally, the Company reduced the estimated forfeiture rate on certain restricted stock unit awards from 30.0% to zero percent, as management expected all the awards to vest. These changes in the estimated forfeiture rates during fiscal 2009 resulted in an increase in share-based compensation expense of $935,000 and an increase to the diluted loss per share of $0.01 for fiscal 2009.

Total compensation expense related to all of the Company's share-based awards for fiscal 2010, 2009 and 2008 was comprised of the following:

	Fiscal 2010	Fiscal 2009	Fiscal 2008
Share-based compensation classified as:			
Selling, general and administrative expense	$2,168,795	$2,213,242	$1,149,018
Research and development expense	578,066	663,721	490,738
Share-based compensation expense related to continuing operations	2,746,861	2,876,963	1,639,756
From discontinued operations	—	—	13,905
Total	$2,746,861	$2,876,963	$1,653,661

	Fiscal 2010	Fiscal 2009	Fiscal 2008
Share-based compensation expense from:			
Stock options	$1,265,945	$ 919,478	$ 666,129
Restricted stock units	1,480,916	1,957,485	848,535
Restricted stock awards	—	—	138,997
Total	$2,746,861	$2,876,963	$1,653,661

Since the Company has a net operating loss carry-forward as of September 30, 2010, 2009, and 2008, no excess tax benefits for the tax deductions related to share-based awards were recognized in the consolidated statements of operations. Additionally, no incremental tax benefits were recognized from stock options exercised in fiscal 2010, 2009, and 2008 that would have resulted in a reclassification from cash flows from operating activities to cash flows from financing activities.

Restructuring expense

The Company records costs and liabilities associated with exit and disposal activities at fair value in the period the liability is incurred. In periods subsequent to initial measurement, changes to a liability are measured using the credit-adjusted risk-free rate applied in the initial period. In fiscal 2009, the Company recorded costs and liabilities for exit and disposal activities related to a relocation plan that was implemented in 2006. Refer to Note 8, "Accrued Expenses and Other Liabilities" for further information.

Advertising expenses

Advertising costs are expensed as incurred, and these costs are included in both research and development expenses and selling, general and administrative expenses. Advertising costs were approximately $1.2 million, $336,000 and $304,000 for fiscal 2010, 2009, and 2008, respectively.

Income taxes

The Company accounts for income taxes and the related accounts under the liability method. Deferred tax assets and liabilities are determined based on the differences between the consolidated financial statement carrying amounts and the income tax bases of assets and liabilities. A valuation allowance is applied against any net deferred tax asset if, based on available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company recognizes any uncertain income tax positions on income tax returns at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained.

The total unrecognized tax benefit resulting in a decrease in deferred tax assets and corresponding decrease in the valuation allowance at September 30, 2010 is $3.4 million. There are no unrecognized tax benefits included in the consolidated balance sheet that would, if recognized, affect the effective tax rate.

The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had $0 accrued for interest and penalties on the Company's consolidated balance sheets at September 30, 2010 and 2009.

The Company is subject to taxation in the U.S. and various state jurisdictions. The Company's tax years for 1992 and forward are subject to examination by the U.S. and California tax authorities due to the carryforward of unutilized net operating losses and research and development credits.

The Company does not foresee material changes to its gross uncertain income tax position liability within the next twelve months.

In July 2010, the Company applied for the Qualifying Therapeutic Discovery Project tax credit ("Therapeutic Credit"). The Therapeutic Credit allows qualifying businesses to claim a credit for 50% of their qualified investment in qualifying projects for tax years 2010 and 2009. In November 2010, the Company received notification from the Internal Revenue Service that it was granted a credit of approximately $244,000 related to the Therapeutic Credit.

Comprehensive Loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on marketable securities. The Company presents an accumulated other comprehensive loss in its consolidated statements of stockholders' equity and comprehensive loss.

Computation of net loss per common share

Basic net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is computed by dividing net loss by the weighted-average number of common and dilutive common equivalent shares outstanding during the period. In the loss periods, the shares of common stock issuable upon exercise of stock options and warrants are excluded from the computation of diluted net loss per share, as their effect is anti-dilutive. There were no restricted shares with right of repurchase excluded from the computation of net loss per share in fiscal 2010, 2009, and 2008.

For fiscal 2010, 2009, and 2008, the following options and warrants to purchase shares of common stock, restricted stock awards and restricted stock units were excluded from the computation of diluted net loss per share, as the inclusion of such shares would be anti-dilutive:

	Fiscal 2010	Fiscal 2009	Fiscal 2008
Stock options	6,364,265	4,217,156	2,672,227
Stock warrants	12,240,437	12,240,437	12,509,742
Restricted stock units(1)	1,679,341	2,505,434	2,432,416

(1) Includes 1,158,138, 692,448, and 173,374 shares of restricted stock in fiscal 2010, 2009, and 2008, respectively, awarded to directors that have vested but are still restricted until the directors resign.

Recent authoritative guidance

Milestone Method of Revenue Recognition. In March 2010, the Financial Accounting Standard Board ("FASB") ratified a consensus of the Emerging Issues Task Force related to the milestone method of revenue recognition. The consensus will codify a method of revenue recognition that has been common practice. Under this method, contingent consideration from research and development activities that is earned upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved. This guidance is effective for annual periods beginning on or after June 15, 2010 but may be early adopted as of the beginning of an annual period. The Company is currently evaluating the effect that this guidance will have on its consolidated financial position, results of operations and cash flows.

Multiple-Deliverable Revenue Arrangements. In September 2009, the FASB issued authoritative guidance regarding multiple-deliverable revenue arrangements. This guidance addresses how to measure and allocate consideration to one or more units of accounting. Specifically, the guidance requires that consideration be allocated among multiple deliverables based on relative selling prices. The guidance establishes a selling price hierarchy of (1) vendor-specific objective evidence, (2) third-party evidence and (3) estimated selling price. This guidance is effective for annual periods beginning on or after June 15, 2010 but may be early adopted as of the beginning of an annual period. The Company is currently evaluating the effect that this guidance will have on its consolidated financial position, results of operations and cash flows.

Determining Whether an Instrument (or an Embedded Feature) is Indexed to an Entity's Own Stock. In June 2008, the FASB issued authoritative guidance on determining whether an instrument (or an embedded feature) is indexed to an entity's own stock. This guidance provides that an entity should use a two-step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument's contingent exercise and settlement provisions. It also clarifies the impact of foreign currency denominated strike prices and market-based employee stock option valuation instruments on the evaluation. The Company adopted this guidance effective October 1, 2009. The adoption of this guidance did not have an impact on the Company's consolidated financial position, results of operations and cash flows.

Noncontrolling Interests in Consolidated Financial Statements. In December 2007, the FASB issued authoritative guidance on noncontrolling interests in consolidated financial statements, which is intended to improve the relevance, comparability and transparency of the financial information that a reporting entity provides in its consolidated financial statements by establishing certain required accounting and reporting standards. This guidance is effective for fiscal years beginning on or after December 15, 2008. The Company adopted this guidance effective October 1, 2009. The adoption of this guidance did not have an impact on the Company's consolidated financial position, results of operations and cash flows.

Fair Value Measurements. In September 2006, the FASB issued authoritative guidance on fair value measurements, which defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. This guidance was effective for fiscal years beginning after November 15, 2007, and

interim periods within those fiscal years. In February 2008, the FASB delayed the effective date of this guidance for non-financial assets and non-financial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), until fiscal years beginning after November 15, 2008, and interim periods within those years. The Company adopted certain provisions of this guidance effective October 1, 2008 and the delayed provisions of this guidance effective October 1, 2009. The adoption of this guidance did not have a material impact on the Company's consolidated financial position, results of operations and cash flows.

3. Sale of FazaClo

In August 2007, the Company sold FazaClo, which was acquired in conjunction with the acquisition of Alamo Pharmaceuticals, Inc. ("Alamo") in May 2006, and its related assets and operations to Azur. In connection with the sale, the Company received approximately $43.9 million in upfront consideration. In addition, the Company could receive up to $2 million in royalties, based on 3% of annualized net product revenues in excess of $17 million. During fiscal 2010, 2009, and 2008, the Company recorded royalty revenues of approximately $516,000, $395,000 and $71,000, respectively, for FazaClo royalties. The Company's earn-out obligations that would have been payable to the prior owner of Alamo upon the achievement of certain milestones were assumed by Azur; however, the Company is contingently liable in the event of default. The Company transferred all FazaClo related business operations to Azur in August 2007.

The financial results relating to FazaClo have been classified as discontinued operations in the accompanying consolidated statements of operations for all periods presented.

A summarized statement of operations for the discontinued operations for fiscal 2008 are as follows:

	Fiscal 2008
OPERATING AND OTHER EXPENSES	
General and administrative expenses	$ 231,848
Loss on sale of FazaClo	1,351,219
NET LOSS	$1,583,067

No loss or income from discontinued operations was recorded in fiscal 2010 and 2009.

The Asset Purchase Agreement (the "Agreement") with Azur provided for an adjustment to the sale price of FazaClo in connection with the final determination of the amount of net working capital (as defined in the Agreement) included as part of the sale ("Net Working Capital Adjustment"). The Agreement also stipulated that an adjustment to net working capital shall only exist if the final Net Working Capital Adjustment is greater than $250,000. As of September 30, 2007, based on the knowledge and information that the Company had at the time, it estimated that the Net Working Capital Adjustment was less than the $250,000 threshold. However, in January 2008, the Company received claims from Azur that the Net Working Capital Adjustment should reduce the sale price of FazaClo by approximately $2.0 million. The Company disputed the amount of Net Working Capital Adjustment claimed by Azur. However, based upon new information and its own analysis, for the quarter ended December 31, 2007, the Company accrued a liability of approximately $868,000 and recognized a charge in its statement of operations as a result of the potential Net Working Capital Adjustment. On August 1, 2008, the independent arbitrator engaged by the Company and Azur determined the Net Working Capital Adjustment to be approximately $1,351,000. As a result, the Company recorded a loss on sale of FazaClo of approximately $1,351,000, which was paid by the Company in the fourth quarter of fiscal 2008, in its statement of operations for the fiscal year ended September 30, 2008. The Net Working Capital Adjustment was considered a change in estimate and represents new information that was not available as of September 30, 2007.

In addition to the loss of approximately $1,351,000 due to the Net Working Capital Adjustment, the Company recognized other costs related to the operations of the FazaClo business of approximately $232,000 during the fiscal year ended September 30, 2008. The Company initially estimated these costs were assumed by Azur.

4. Fair Value of Financial Instruments

The Company measures the fair value of certain of its financial assets on a recurring basis. A fair value hierarchy is used to rank the quality and reliability of the information used to determine fair values. Financial assets and liabilities carried at fair value will be classified and disclosed in one of the following three categories:

- Level 1-Quoted prices in active markets for identical assets and liabilities.
- Level 2-Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets and liabilities, quoted prices in the markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3-Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

As of September 30, 2010, the Company's cash equivalents of approximately $25.2 million are all valued using quoted prices generated by market transactions involving identical assets, or Level 1 as defined by the fair value hierarchy noted above. As of September 30, 2009, the Company's cash equivalents of approximately $31.1 million are all valued using quoted prices generated by market transactions involving identical assets, or Level 1 as defined by the fair value hierarchy.

5. Restricted Investments in Marketable Securities

Restricted investments in marketable securities at September 30, 2010 and 2009 consist of certificates of deposits, which are classified as held-to-maturity. At September 30, 2010, restricted investments in marketable securities totaling $401,550 are recorded as non-current assets in the consolidated balance sheet. The restricted investment consists of an investment certificate of deposit that automatically renews every 30 days and is related to a letter of credit connected to an office lease with an expiration date in 2013. Restricted investments also consist of a $200,000 certificate of deposit related to the Company's corporate credit card agreement. The certificate of deposit automatically renews every three months. At September 30, 2010, restricted investments in marketable securities totaling $200,000 and $401,550 were recorded as current and non-current assets, respectively, in the consolidated balance sheet. At September 30, 2009, restricted investments in marketable securities totaling $200,775 and $267,700 are recorded as current and non-current assets, respectively, in the consolidated balance sheet. Restricted investments of $66,925 and $388,122 matured in fiscal 2010 and 2009, respectively.

6. Inventories

Inventories are comprised of NUEDEXTA product and the active pharmaceutical ingredients of NUEDEXTA, dextromethorphan ("DM") and quinidine ("Q"), as well as the active pharmaceutical ingredient docosanol.

The composition of inventories as of September 30, 2010 and 2009 is as follows:

	September 30, 2010	September 30, 2009
Raw materials	$ 554,465	$ 824,629
Work in progress	326,370	—
Total inventory	880,835	824,629
Less: current portion	(652,628)	(114,098)
Non-current portion	$ 228,207	$ 710,531

As of September 30, 2010, the current portion of inventories represents work in progress inventory of $326,370 and raw material inventory of $326,258 which is expected to be used in manufacturing NUEDEXTA within the next 12 months.

In fiscal 2010, the Company recorded an inventory reserve of approximately $198,000 for docosanol inventory based on estimated usage. In fiscal 2009, the Company recorded an inventory reserve of approximately $456,000 which is primarily comprised of $383,000 for DM and Q supplies that are scheduled to expire in fiscal 2011 and an additional inventory reserve of approximately $69,000 for docosanol inventory.

The following table presents the activity in inventory reserves for the last two fiscal years:

	Balance at September 30, 2009	Additional Reserves	Balance at September 30, 2010
Reserve for excess and obsolete inventory			
Reserve for docosanol	$118,760	$197,640	$316,400
Reserve for DM and Q	383,000	—	383,000
Total	$501,760	$197,640	$699,400

	Balance at September 30, 2008	Additional Reserves	Balance at September 30, 2009
Reserve for excess and obsolete inventory			
Reserve for docosanol	$50,000	$ 68,760	$118,760
Reserve for DM and Q	—	383,000	383,000
Total	$50,000	$451,760	$501,760

The Company recorded no additional reserves in fiscal 2008.

7. Property and Equipment

Property and equipment as of September 30, 2010 and 2009 consist of the following:

	September 30, 2010			September 30, 2009		
	Gross Carrying Value	Accumulated Depreciation	Net	Gross Carrying Value	Accumulated Depreciation	Net
Computer equipment and related software	$1,659,196	$(1,291,068)	$368,128	$1,330,223	$(1,211,096)	$119,127
Leasehold improvements	37,790	(26,470)	11,320	37,790	(18,916)	18,874
Office equipment furniture and fixtures	756,672	(686,408)	70,264	756,672	(583,996)	172,676
Total property and equipment	$2,453,658	$(2,003,946)	$449,712	$2,124,685	$(1,814,008)	$310,677

Depreciation and amortization expense associated with property and equipment was approximately $205,000, $261,000, and $415,000 for fiscal 2010, 2009, and 2008, respectively. In fiscal 2009, manufacturing equipment of approximately $262,000 was disposed as it was determined the equipment was not likely to be used in the packaging process of NUEDEXTA. The loss on disposal is included in other, net on the accompanying consolidated statements of operations.

8. Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities at September 30, 2010 and 2009 are as follows:

	September 30, 2010	September 30, 2009
Accrued research and development expenses	$ 221,956	$ 372,494
Accrued selling, general and administrative expenses	537,347	270,401
Deferred rent	12,148	19,516
Lease restructuring liability(1)	632,879	991,583
Total accrued expenses and other liabilities	1,404,330	1,653,994
Less: Current portion	(1,070,061)	(1,001,599)
Total non-current total accrued expenses and other liabilities	$ 334,269	$ 652,395

(1) In fiscal 2006, the Company relocated all operations other than research and development from San Diego, California to Aliso Viejo, California. In fiscal 2007, the Company subleased a total of approximately 49,000 square feet of laboratory and office space in San Diego and relocated remaining personnel and clinical trial support functions to the Company's offices in Aliso Viejo, California. Restructuring expenses included recognition of the estimated loss due to the exit of the Company's leases of approximately $2.1 million. No further costs were incurred related to these restructuring events in fiscal 2008. In April 2009, the Company entered into a sublease for office space in San Diego, California. Sublease rental payments commenced in September 2009 pursuant to this sublease. In September 2009, the Company recognized a loss of approximately $172,000 related to a lease restructuring liability resulting from a sublease entered into in April 2009 for office buildings subleased in San Diego, California. The lease restructuring loss is included in rent expense in fiscal 2009.

The following table presents the restructuring activities in fiscal 2010:

	Balance at September 30, 2009	Payments/ Reductions	Balance at September 30, 2010
Accrued Restructuring			
Total lease restructuring liability	$ 991,583	$(358,704)	$ 632,879
Less current portion	(358,704)		(298,610)
Non-current portion	$ 632,879		$ 334,269

The following table presents the restructuring activities in fiscal 2009:

	Balance at September 30, 2008	Payments/ Reductions	Balance at September 30, 2009
Accrued Restructuring			
Lease restructuring liability	$1,135,965	$(144,382)	$ 991,583
Less current portion	(316,086)		(358,704)
Total	$ 819,879		$ 632,879

9. Deferred Revenues/Sale of Licenses

The following table sets forth as of September 30, 2010 and 2009 the net deferred revenue balances, which are primarily related to the Company's sale of future Abreva® royalty rights to Drug Royalty USA.

Net deferred revenues as of October 1, 2009	$ 9,912,367
Changes during the period:	
Recognized as revenues during period	(1,435,536)
Net deferred revenues as of September 30, 2010	$ 8,476,831
Classified and reported as:	
Current portion of deferred revenues	$ 2,399,849
Deferred revenues, net of current portion	6,076,982
Total deferred revenues	$ 8,476,831
Net deferred revenues as of October 1, 2008	$12,486,032
Changes during the period:	
Recognized as revenues during period	(2,573,665)
Net deferred revenues as of September 30, 2009	$ 9,912,367
Classified and reported as:	
Current portion of deferred revenues	$ 2,282,560
Deferred revenues, net of current portion	7,629,807
Total deferred revenues	$ 9,912,367

Drug Royalty Agreement — In November 2002, the Company sold to Drug Royalty USA an undivided interest in the Company's rights to receive future Abreva royalties under the license agreement with GlaxoSmithKline for $24.1 million (the "Drug Royalty Agreement" and the "GSK License Agreement," respectively). Under the Drug Royalty Agreement, Drug Royalty USA has the right to receive royalties from GlaxoSmithKline on sales of Abreva

until December 2013. The Company retained the right to receive 50% of all royalties (a net of 4%) under the GSK License Agreement for annual net sales of Abreva in the U.S. and Canada in excess of $62 million. In fiscal 2010, 2009, and 2008, the Company recognized royalties related to the annual net Abreva sales in excess of $62 million in the amount of approximately $942,000, $951,000 and $924,000, respectively, which is included in the consolidated statements of operations as revenues from royalties and royalty rights.

In the fourth quarter of fiscal 2010, the Company recorded a cumulative non-cash adjustment to correct an immaterial error related to previously recorded deferred royalty revenue related to the GSK license agreement. The total cumulative non-cash adjustment recorded in the fourth quarter was a decrease in revenue of $797,000 which resulted in net revenues of ($71,000) in the fourth fiscal quarter of 2010 and $2.9 million for fiscal 2010.

Revenues are recognized when earned, collection is reasonably assured and no additional performance of services is required. The Company classified the proceeds received from Drug Royalty USA as deferred revenue, to be recognized as revenue over the life of the license agreement because of the Company's continuing involvement over the term of the Drug Royalty Agreement. Such continuing involvement includes overseeing the performance of GlaxoSmithKline and its compliance with the covenants in the GSK License Agreement, monitoring patent infringement, adverse claims or litigation involving Abreva, and undertaking to find a new license partner in the event that GlaxoSmithKline terminates the agreement. The Drug Royalty Agreement contains both covenants and events of default that require such performance on the Company's part. Therefore, nonperformance on the Company's part could result in default of the arrangement, and could give rise to additional rights in favor of Drug Royalty USA under a separate security agreement with Drug Royalty USA, which could result in loss of the Company's rights to share in future Abreva royalties if wholesale sales by GlaxoSmithKline exceed $62 million a year. Because of the Company's continuing involvement, the Company recorded the net proceeds of the transaction as deferred revenue, which is being recognized as revenue using the "units-of-revenue method" over the life of the license agreement. Based on a review of the Company's continuing involvement, the Company concluded that the sale proceeds did not meet any of the rebuttable presumptions that would require classification of the proceeds as debt.

Kobayashi Docosanol License Agreement — In January 2006, the Company signed an exclusive license agreement with Kobayashi Pharmaceutical Co., Ltd. ("Kobayashi"), a Japanese corporation, to allow Kobayashi to market in Japan medical products that are curative of episodic outbreaks of herpes simplex or herpes labialis and that contain a therapeutic concentration of the Company's docosanol 10% cream.

In April 2009, the license agreement with Kobayashi was terminated and no termination fees were incurred. In the third quarter of fiscal 2009, the Company recognized approximately $170,000 in revenue which was previously deferred relating to the approximately $860,000 data transfer fee received in March 2006 upon initiation of the agreement.

During fiscal 2009 and 2008, the Company recognized total revenues of approximately $284,000 and $228,000, respectively, related to the Kobayashi agreement.

HBI Docosanol License Agreement — In July 2006, the Company entered into an exclusive license agreement with Healthcare Brands International ("HBI"), pursuant to which the Company granted to HBI the exclusive rights to develop and commercialize docosanol 10% in the following countries: Austria, Belgium, Czech Republic, Estonia, France, Germany, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Russia, Slovakia, Slovenia, Spain, Ukraine and the United Kingdom.

Pursuant to the HBI License Agreement, in fiscal 2008, the Company received £750,000 (or approximately U.S. $1.5 million based on the exchange rate as of September 30, 2008) for each of the first two regulatory approvals for marketing in countries of the Licensed Territory (as defined in the agreement). If there is any subsequent divestiture or sublicense of docosanol by HBI (including through a sale of HBI), or any initial public offering of HBI's securities, the Company will receive an additional payment related to the future value of docosanol under the Agreement. No revenue was received from this agreement in fiscal 2010 and 2009.

HBI will bear all expenses related to the regulatory approval and commercialization of docosanol within the Licensed Territory. HBI also has certain financing obligations, pursuant to which it will be obligated to raise a minimum amount of working capital within certain time periods following execution of the HBI License Agreement.

Emergent Biosolutions License Agreement — In March 2008, the Company entered into an Asset Purchase and License Agreement with Emergent Biosolutions (the "Emergent Agreement") for the sale of the Company's anthrax antibodies and license to use its proprietary Xenerex Technology platform. Under the terms of the definitive agreement, the Company received upfront payments totaling $500,000, of which $250,000 was deferred and recognized in the fourth quarter of fiscal 2008 upon delivery of all materials to Emergent. The Company has the potential to receive up to $1.25 million in milestone payments, as well as royalties on annual net sales if the product is commercialized. Milestone payments of $250,000 and $500,000 are included in the consolidated statements of operations as revenues from license agreements in fiscal 2009 and 2008, respectively. No revenue was received from this agreement in fiscal 2010.

In October 2010, AVP-21D9 for the treatment of inhalation anthrax was granted Orphan Drug Designation and Fast Track Designation. Emergent BioSolutions has initiated a Phase I clinical trial for AVP-21D9.

10. Commitments and Contingencies

Operating lease commitments. The Company leases approximately 12,000 square feet of office space in Aliso Viejo, California. The lease has scheduled rent increases each year and expires in 2011. As of September 30, 2010, the financial commitment for the remainder of the term of the lease is approximately $318,000.

The Company leases approximately 30,370 square feet of office and lab space in San Diego, California. The lease has scheduled rent increases each year and expires in 2013. All 30,370 square feet of office and lab space is subleased through January 14, 2013. The sublease has scheduled rent increases each year. As of September 30, 2010, the financial commitment for the remainder of the term of the lease is approximately $2.8 million (excluding the benefit of approximately $2.2 million of payments to be received from the subleases). The Company delivered an irrevocable standby letter of credit to the lessor in the amount of approximately $402,000, to secure the Company's performance under the lease (see Note 5).

Rent expense, excluding common area charges and other costs, was approximately $1.6 million, $1.5 million and $2.3 million in fiscal 2010, 2009, and 2008, respectively. Sublease rent income totaled approximately $889,000, $907,000 and $888,000 in fiscal 2010, 2009 and 2008, respectively. Future minimum rental payments under non-cancelable operating lease commitments as of September 30, 2010 are approximated as follows:

Year Ending September 30,	Minimum Payments	Less Payments to be Received from Subleases	Net Payments
2011	$1,497,202	$ 961,425	$535,777
2012	1,222,548	997,422	225,126
2013	351,659	281,801	69,858
Total	$3,071,409	$2,240,648	$830,761

Legal contingencies. In the ordinary course of business, the Company may face various claims brought by third parties and the Company may, from time to time, make claims or take legal actions to assert the Company's rights, including intellectual property rights as well as claims relating to employment and the safety or efficacy of products. Any of these claims could subject the Company to costly litigation and, while the Company generally believes that the Company has adequate insurance to cover many different types of liabilities, the Company's insurance carriers may deny coverage or policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on

consolidated operations, cash flows and financial position. Additionally, any such claims, whether or not successful, could damage the Company's reputation and business. Management believes the outcome of currently pending claims and lawsuits will not likely have a material effect on consolidated operations or financial position.

In May 2010, the Company received proceeds from a legal settlement in the amount of approximately $390,000. The proceeds were recorded as Other, net under Other Income (Expenses) in the consolidated statement of operations in the third fiscal quarter of 2010. In September 2007, a court awarded the Company reimbursement of attorney's fees incurred over a four-year period in connection with the enforcement of a settlement agreement entered into with a former employee. In April 2008, the Company received the proceeds from the settlement in the amount of $1.25 million. The proceeds were recorded as other income in the third fiscal quarter of 2008.

In addition, it is possible that the Company could incur termination fees and penalties if it elected to terminate contracts with certain vendors, including clinical research organizations.

Guarantees and Indemnities. The Company indemnifies directors and officers to the maximum extent permitted under the laws of the State of Delaware, and various lessors in connection with facility leases for certain claims arising from such facilities or leases. Additionally, the Company periodically enters into contracts that contain indemnification obligations, including contracts for the purchase and sale of assets, clinical trials, pre-clinical development work and securities offerings. These indemnification obligations provide the contracting parties with the contractual right to have AVANIR pay for the costs associated with the defense and settlement of claims, typically in circumstances where AVANIR has failed to meet its contractual performance obligations in some fashion.

The maximum amount of potential future payments under such indemnifications is not determinable. The Company has not incurred significant costs related to these guarantees and indemnifications, and no liability has been recorded in the consolidated financial statements for guarantees and indemnifications as of September 30, 2010 and 2009.

Center for Neurologic Study ("CNS") — The Company holds the exclusive worldwide marketing rights to NUEDEXTA for certain indications pursuant to an exclusive license agreement with CNS. The Company will be obligated to pay CNS up to $400,000 in the aggregate in milestones to continue to develop for both PBA and DPN pain, assuming they are both approved for marketing by the FDA. The Company is not currently developing, nor does it have an obligation to develop, any other indications under the CNS license agreement. In fiscal 2005, the Company paid $75,000 to CNS under the CNS license agreement, and in fiscal 2011, paid a $75,000 milestone upon FDA approval of NUEDEXTA for the treatment of PBA. In addition, the Company is obligated to pay CNS a royalty on commercial sales of NUEDEXTA with respect to each indication, if and when the drug is approved by the FDA for commercialization for such indications. Under certain circumstances, the Company may have the obligation to pay CNS a portion of net revenues received if we sublicense NUEDEXTA to a third party. Under the agreement with CNS, the Company is required to make payments on achievements of up to a maximum of ten milestones, based upon five specific medical indications. Maximum payments for these milestone payments could total approximately $1.1 million if the Company pursued the development of NUEDEXTA for all of the licensed indications. Of the clinical indications that the Company currently plans to pursue, expected milestone payments could total approximately $400,000. In general, individual milestones range from approximately $75,000 to $125,000 for each accepted new drug application ("NDA") and a similar amount for each approved NDA. In addition the Company is obligated to pay CNS a royalty ranging from approximately 5% to 8% of net GAAP revenues.

11. Stockholders' Equity

Preferred Stock

In March 2009, the Board of Directors approved a stockholder rights plan (the "Plan") that provides for the issuance of Series A junior participating preferred stock to each stockholder of record under certain circumstances. None of the Series A junior participating preferred stock was outstanding on September 30, 2010 and 2009. The

Plan provided for a dividend distribution of one preferred share purchase right (the "Right") on each outstanding share of common stock, payable on shares outstanding as of March 20, 2009 (the "Record Date"). All shares of common stock issued by the Company after the Record Date have been issued with such Rights attached. Subject to limited exceptions, the Rights would become exercisable if a person or group acquires 20% or more of the Company's common stock or announces a tender offer for 20% or more of the Company's common stock (a "Trigger Event").

If and when the Rights become exercisable, each Right will entitle stockholders, excluding the person or group causing the Trigger Event (an "Acquiring Person"), to buy a fraction of a share of Series A junior participating preferred stock at a fixed price. In certain circumstances following a Trigger Event, each Right will entitle its owner, who is not an Acquiring Person, to purchase at the Right's then current exercise price, a number of shares of common stock having a market value equal to twice the Right's exercise price. Rights held by any Acquiring Person would become void and not be exercisable to purchase shares at the discounted purchase price.

The Board of Directors may redeem the Rights at $0.0001 per Right at any time before a person has acquired 20% or more of the outstanding common stock. The Rights will expire on March 20, 2019, subject to a periodic review of the Plan by a committee of independent directors.

Common stock

Fiscal 2010. In May 2010, the Company closed an underwritten securities offering raising $27.5 million in gross proceeds and approximately $26.6 million in net proceeds to the Company after deducting underwriting discounts, commissions and offering expenses. In connection with the offering, 10 million shares of common stock were sold at a public offering price of $2.75 per share. The Company intends to use the net proceeds for general working capital. In addition, the net proceeds may be used for further clinical, regulatory and commercial development of NUEDEXTA, as well as business development activities.

On July 30, 2009, the Company entered into a Controlled Equity Offering Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor"), providing for the sale of up to 12,500,000 shares of common stock from time to time into the open market at prevailing prices. Pursuant to the Sales Agreement, sales of common stock will be made in such quantities and on such minimum price terms as the Company may set from time to time. During fiscal 2010, 1,926,160 shares of common stock were sold under this Sales Agreement at an average price of $3.00 per share raising proceeds of $5.8 million ($5.6 million after offering expenses, including commissions). As of September 30, 2010, a total of 6,539,510 shares of common stock were sold under the Sales Agreement at an average price of $2.53 per share raising gross proceeds of $16.6 million ($15.8 million after offering expenses, including commissions). At September 30, 2010, the Company had not issued 180,000 shares sold in connection with the Sales Agreement. The Company recorded a stock subscription receivable of approximately $581,000 at September 30, 2010 related to the net proceeds in consideration for the 180,000 shares sold. The proceeds were received in October 2010.

During fiscal 2010, the Company issued 1,185,258 shares of common stock in connection with the vesting of restricted stock units. In connection with the vesting, two officers and three employees exercised their option to pay for minimum required withholding taxes associated with the vesting of restricted stock by surrendering 90,606 and 15,258 shares of common stock, respectively, at an average market price of $2.02 and $1.97 per share, respectively.

Also during fiscal 2010, the Company issued 55,836 shares of common stock upon the exercise of outstanding options.

Fiscal 2009. During fiscal 2009, 4,613,350 shares of common stock were issued under the Sales Agreement at an average price of $2.34 per share raising gross proceeds of $10.8 million ($10.2 million after offering expenses, including commissions).

During fiscal 2009, the Company issued 346,294 shares of common stock in connection with the vesting of restricted stock units. In connection with the vesting, two officers and three employees exercised their option to pay for minimum required withholding taxes associated with the vesting of restricted stock by surrendering 77,046 and 12,402 shares of common stock, respectively, at an average market price of $2.08 and $2.13 per share, respectively.

Fiscal 2008. In April 2008, the Company closed a registered securities offering raising $40 million in gross proceeds ($37.8 million after offering expenses) from a select group of institutional investors. In connection with the offering, approximately 35 million shares of common stock were issued at a price of $1.14 per share unit. Additionally, the Company issued warrants to acquire up to approximately 12.2 million common shares at $1.43 per share. The warrants have a 5-year exercise term, but can be called for redemption for a nominal price.

During fiscal 2008, the Company issued 113,361 shares of common stock in connection with the vesting of restricted stock units. In connection with the vesting, two officers exercised their option to pay for minimum required withholding taxes associated with the vesting of restricted stock by surrendering 16,996 shares of common stock at an average market price of $1.42 per share.

Also during fiscal 2008, 2,000 shares of common stock, previously issued as a restricted stock award, were surrendered upon the termination of an employee and 4,983 shares of restricted stock with an average market price of $1.13 per share were surrendered to pay for the minimum required withholding taxes associated with the vesting of restricted stock awards. In addition, the Company issued 20,500 shares of common stock for restricted stock awards which vested in fiscal 2008.

During January 2008, the Company sold and issued a total of 34,568 shares of its common stock for aggregate gross offering proceeds of $44,200 ($42,700 after offering expenses, including underwriting discounts and commissions).

A summary of common stock issued for fiscal 2010, 2009, and 2008 is shown in the table below:

Common Stock Issued and Stock Options Exercised	Date	Common Stock Shares	Gross Amount Received(1)	Average Price per Share(2)
Fiscal year ended September 30, 2010:				
Registered offering of common stock	May-10	10,000,000	$27,500,000	$2.75
Registered offering of common stock	Various	1,746,160	5,188,704	$2.97
Restricted stock units	Various	1,185,258	—	$ —
Stock option exercises	Various	55,836	45,476	$0.81
Total		12,987,254	$32,734,180	
Fiscal year ended September 30, 2009:				
Registered offering of common stock	Aug-09	4,613,350	$10,787,907	$2.34
Restricted stock units	Various	346,294	—	$ —
Total		4,959,644	$10,787,907	
Fiscal year ended September 30, 2008:				
Registered offering of common stock	Apr-08	34,972,678	$40,000,000	$1.14
Private placement of common stock	Jan-08	34,568	44,200	$1.28
Restricted stock awards and restricted stock units	Various	113,361	—	$ —
Total		35,120,607	$40,044,200	

(1) Amount received represents the amount before the cost of financing and after underwriter's discount, if any.

(2) Average price per share has been rounded to two decimal places.

Warrants

In April 2008, in connection with the Company's registered securities offering, warrants were issued to acquire up to 12,240,437 shares of common stock at $1.43 per share. The warrants have a 5-year exercise term, but can be called for redemption for a nominal price. As of September 30, 2010, all these warrants are exercisable and remained outstanding. See Note 16 "Subsequent Events" for additional information related to the warrants.

Employee Equity Incentive Plans

The Company currently has five equity incentive plans (the "Plans"): the 2005 Equity Incentive Plan (the "2005 Plan"), the 2003 Equity Incentive Plan (the "2003 Plan"), the 2000 Stock Option Plan (the "2000 Plan"), the 1998 Stock Option Plan (the "1998 Plan") and the 1994 Stock Option Plan (the "1994 Plan"), which are described below. The 1998 Plan, 1994 Plan and 2000 Plan are expired and the Company no longer grants share-based awards from these plans. All of the Plans were approved by the stockholders, except for the 2003 Equity Incentive Plan, which was approved solely by the Board of Directors. Share-based awards are subject to terms and conditions established by the Compensation Committee of the Company's Board of Directors. The Company's policy is to issue new common shares upon the exercise of stock options, conversion of share units or purchase of restricted stock.

During fiscal 2010, 2009, and 2008, the Company granted share-based awards under both the 2003 Plan and the 2005 Plan. Under the 2003 Plan and 2005 Plan, options to purchase shares, restricted stock units, restricted stock and other share-based awards may be granted to employees and consultants. Under the Plans, as of September 30, 2010, the Company had an aggregate of 14,513,538 shares of common stock reserved for issuance. Of those shares, 8,043,606 were subject to outstanding options and other awards and 6,469,932 shares were available for future grants of share-based awards. The Company may also issue share-based awards outside of the Plans. As of September 30, 2010, there were no options to purchase shares of common stock that were issued outside of the Plans (inducement option grants). None of the share-based awards is classified as a liability as of September 30, 2010.

2005 Equity Incentive Plan. On March 17, 2005, the Company's stockholders approved the adoption of the 2005 Plan that initially provided for the issuance of up to 500,000 shares of common stock, plus an annual increase beginning in fiscal 2006 equal to the lesser of (a) 1% of the shares of common stock outstanding on the last day of the immediately preceding fiscal year, (b) 325,000 shares of common stock, or (c) such lesser number of shares of common stock as the board of directors shall determine. Pursuant to the provisions of annual increases, the number of authorized shares of common stock for issuance under the 2005 Plan increased by 273,417 shares effective November 16, 2005, 317,084 shares effective November 30, 2006, and an additional 325,000 shares effective for each date of December 4, 2007, November 6, 2008 and November 11, 2009 to a total of 2,065,501 shares. In February 2006, the Company's stockholders eliminated the limitation on the number of shares of common stock that may be issued as restricted stock under the 2005 Plan. The 2005 Plan allows the Company to grant options, restricted stock awards and stock appreciation rights to directors, officers, employees and consultants. As of September 30, 2010, 525,632 shares of common stock remained available for issuance under the 2005 Plan.

2003 Equity Incentive Plan. On March 13, 2003, the board of directors approved the adoption of the 2003 Plan that provides for the issuance of up to 625,000 shares of common stock, plus an annual increase beginning January 2004 equal to the lesser of (a) 5% of the number of shares of common stock outstanding on the immediately preceding December 31, or (b) a number of shares of common stock set by the board of directors. Pursuant to the provisions of annual increases, the number of authorized shares of common stock for issuance under the 2003 Plan increased by 1,528,474 shares effective November 30, 2005, 1,857,928 shares effective August 3, 2007, 2,158,220 shares effective February 21, 2008, 3,911,352 shares effective February 19, 2009, and an additional 4,158,905 shares effective February 18, 2010 to a total of 14,239,879 shares. Of the additional 3,911,352 shares effective February 19, 2009, the board of directors provided that no more than 2,346,811 shares would be available to grant in calendar 2009. The 2003 Plan allows the Company to grant options, restricted stock awards and stock

appreciation rights to directors, officers, employees and consultants. As of September 30, 2010, 5,944,300 shares of common stock remained available for issuance under the 2003 Plan.

Stock Options. Stock options are granted with an exercise price equal to the current market price of the Company's common stock at the grant date and have 10-year contractual terms. Options awards typically vest in accordance with one of the following schedules:

a. 25% of the option shares vest and become exercisable on the first anniversary of the grant date and the remaining 75% of the option shares vest and become exercisable quarterly in equal installments thereafter over three years;

b. One-third of the option shares vest and become exercisable on the first anniversary of the grant date and the remaining two-thirds of the option shares vest and become exercisable daily or quarterly in equal installments thereafter over two years;

c. 6.25% vest upon obtainment of a performance target and the remaining option shares vest and become exercisable quarterly in equal installments thereafter over 3.75 years; or

d. Options fully vest and become exercisable at the date of grant.

Performance Stock Options. During fiscal 2008, the Company granted stock options to purchase 2,048,000 shares of common stock from the 2003 Stock Option Plan at $0.88 per share, the current market price of the Company's common stock on the date of grant. The stock options had a performance goal related to the clinical development of NUEDEXTA that determined when vesting began and the actual number of shares awarded ranging from 0% to 115% of target. All performance goals were accomplished in fiscal 2009 and the actual number of shares awarded ranged from 100% to 107.5% of target and 2,031,218 performance options began vesting. The performance stock options are included in the equity compensation tables below.

Certain option awards provide for accelerated vesting if there is a change in control (as defined in the Plans). Summaries of stock options outstanding and changes during fiscal 2010, 2009, and 2008 are presented below.

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value
Outstanding September 30, 2009	4,217,156	$ 1.55		
Granted	2,228,250	$ 1.96		
Exercised	(55,836)	$ 0.81		
Forfeited	(22,805)	$ 1.48		
Expired	(2,500)	$11.62		
Outstanding September 30, 2010	6,364,265	$ 1.69	8.2	$11,915,254
Vested and expected to vest in the future, September 30, 2010	5,638,634	$ 1.73	8.2	$10,634,442
Exercisable, September 30, 2010	1,949,755	$ 2.47	7.3	$ 3,794,197

The weighted average grant-date fair values of options granted during fiscal 2010, 2009, and 2008 were $1.56, $0.40 and $0.70 per share, respectively. The total intrinsic value of options exercised during fiscal 2010 was $116,000 based on the differences in market prices on the dates of exercise and the option exercise prices. There were no stock options exercised in fiscal 2009 or fiscal 2008. As of September 30, 2010, the total unrecognized compensation cost related to options was approximately $4.1 million, which is expected to be recognized over a weighted-average period of 2.8 years, based on the vesting schedules.

The fair value of each option award is estimated on the date of grant using the Black-Scholes model that uses the assumptions noted in the following table. Expected volatilities are based on historical volatility of the Company's common stock and other factors. The expected term of options granted is based on analyses of historical employee termination rates and option exercises. The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant.

Assumptions used in the Black-Scholes model for options granted during fiscal 2010, 2009, and 2008 were as follows:

	2010	2009	2008
Expected volatility	104.6% — 105.3%	100.8% — 101.3%	95.8% — 99.3%
Weighted-average volatility	105.0%	100.8%	98.9%
Average expected term in years	5.6	5.0	5.0 - 6.3
Risk-free interest rate (zero coupon U.S. Treasury Note)	1.7% — 2.7%	1.6% — 2.3%	2.9% — 3.5%
Expected dividend yield	0%	0%	0%

The following table summarizes information concerning outstanding and exercisable stock options as of September 30, 2010**:**

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$0.47-$0.79	1,573,010	8.2	$ 0.53	664,466	$ 0.53
$0.88	2,007,677	7.8	$ 0.88	728,173	$ 0.88
$1.20-$1.74	1,700,810	9.0	$ 1.70	132,210	$ 1.29
$1.80-$3.30	777,081	9.2	$ 2.46	120,781	$ 2.41
$4.60-$19.38	305,687	4.8	$11.00	304,125	$11.02
	6,364,265	8.2	$ 1.69	1,949,755	$ 2.47

Restricted stock units ("RSU"). RSUs generally vest based on three years of continuous service and may not be sold or transferred until the awardee's termination of service. The following table summarizes the RSU activities for fiscal 2010:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested, October 1, 2009	1,812,986	$1.83
Granted	480,000	$2.00
Vested	(1,650,964)	$1.34
Forfeited	(120,819)	$2.08
Unvested, September 30, 2010	521,203	$3.46

The weighted average grant-date fair value of RSUs granted during fiscal 2010, 2009, and 2008 was $2.00, $0.44 and $1.48 per unit, respectively. The fair value of RSUs vested during fiscal 2010, 2009, and 2008 was approximately $2.2 million, $1.1 million and $763,000, respectively. As of September 30, 2010, the total unrecognized compensation cost related to unvested stock units was approximately $489,000, which is expected

to be recognized over a weighted-average period of 0.4 years, based on the vesting schedules and assuming no forfeitures.

At September 30, 2010, there were 1,158,138 shares of restricted stock with a weighted-average grant date fair value of $1.58 per share awarded to directors that have vested but are still restricted until the directors resign. In fiscal 2010, 2009, and 2008, 465,689, 519,062 and 173,387 shares of restricted stock, respectively, vested but remained restricted.

During fiscal 2010, the Company awarded an RSU representing the right to acquire a total of 120,000 shares of common stock to a non-employee. The grant date fair value of this award was $2.08 per share. The restricted stock units vest on the earlier of October 15, 2011 or the completion of a performance target, and are re-measured at each balance sheet date until vested.

During fiscal 2010, the Company awarded performance-based RSUs ("Performance RSUs") to purchase up to 120,000 shares of the Company's common stock. The grant date fair value of this award was $2.08 per share and it was exercisable at a price of $0.0001 per share. The RSU had a performance goal that determined when vesting began and the actual number of shares to be awarded up to 120,000 shares. For every quarter that the performance goal was not achieved through September 30, 2010, 20,000 RSU shares were forfeited. At September 30, 2010 the performance goal had not been achieved, and in accordance with the terms of the award, no shares are to be issued. Accordingly, no share-based compensation expense was recognized related to this award.

In November 2009, the Company's compensation committee approved a modification to the vesting schedule of RSUs originally granted on December 4, 2007 ("12/4/2007 Modified Awards"). The 12/4/2007 Modified Awards originally were to vest 50% upon the earlier of the completion of a Company milestone or December 4, 2010, and the remaining 50% on December 4, 2010. The awards' vesting was modified to vest equally over two specified dates, March 15, 2010 and December 4, 2010. The 12/4/2007 Modified Awards are for an aggregate of 480,785 RSUs held by eight employees, including officers. The modification did not change the probability of vesting and did not result in any incremental share-based compensation. At the date of modification, no RSUs were vested and the remaining unamortized share-based compensation expense will be amortized over the remaining vesting periods of the 12/4/2007 Modified Awards.

In June 2009, the Company's compensation committee approved a modification to the vesting schedule of RSUs originally granted on March 21, 2007 ("3/21/2007 Modified Awards"). The 3/21/2007 Modified Awards originally were to vest 50% upon the earlier of the completion of a Company milestone or March 21, 2010, and the remaining 50% on March 21, 2010. The awards' vesting was modified to vest equally over four specified dates through August 31, 2010. The 3/21/2007 Modified Awards were for an aggregate of 1,200,708 RSUs held by eight grantees, including officers and employees. The modification did not change the probability of vesting and did not result in any incremental share-based compensation. At the date of modification, no RSUs were vested and the remaining unamortized share-based compensation expense was amortized over the remaining vesting periods of the 3/21/2007 Modified Awards.

Restricted stock awards. Restricted stock awards ("RSAs") are grants that entitle the holder to acquire shares of restricted common stock at a fixed price, which is typically nominal. The shares of restricted stock cannot be sold, pledged, or otherwise disposed of until the award vests and any unvested shares may be reacquired by the Company for the original purchase price following the awardee's termination of service. The RSAs typically vest on the second or third anniversary of the grant date or on a graded vesting schedule over three years of employment.

The fair value of RSAs vested in fiscal 2008 was $253,000. There are no outstanding RSAs at September 30, 2010 and 2009.

12. Research, License, Supply and other Agreements

Center for Neurologic Study ("CNS") — The Company holds the exclusive worldwide marketing rights to NUEDEXTA for certain indications pursuant to an exclusive license agreement with CNS. The Company will be obligated to pay CNS up to $400,000 in the aggregate in milestones to continue to develop NUEDEXTA for both PBA and DPN pain, assuming they are both approved for marketing by the FDA. The Company is not currently developing, nor does the Company have an obligation to develop, any other indications under the CNS license agreement. In fiscal 2005, the Company paid $75,000 to CNS at the inception of the CNS license agreement, and in fiscal 2011, paid a $75,000 milestone upon FDA approval of NUEDEXTA for the treatment of PBA. In addition, the Company is obligated to pay CNS a royalty ranging from approximately 5% to 8% of net GAAP revenue generated by sales of NUEDEXTA with respect to each indication, if and when the drug is approved by the FDA for commercialization for such indications. Under certain circumstances, the Company may have the obligation to pay CNS a portion of net revenues received if the Company sublicenses NUEDEXTA to a third party. Under the agreement with CNS, the Company is required to make payments on achievement of up to a maximum of ten milestones, based upon five specific medical indications. Maximum payments for these milestone payments could total approximately $1.1 million if the Company pursued the development of NUEDEXTA for all of the licensed indications. Of the clinical indications that the Company currently expects that it may pursue, expected milestone payments could total approximately $400,000. In general, individual milestones range from approximately $75,000 to $125,000 for each accepted new drug application ("NDA") and a similar amount for each approved NDA in addition to the royalty discussed above net GAAP revenues. From inception through September 30, 2010, no milestone payments have been made under this agreement.

HBI Docosanol License Agreement — In July 2006, the Company entered into an exclusive license agreement with Healthcare Brands International, pursuant to which the Company granted to HBI the exclusive rights to develop and commercialize docosanol 10% in the following countries: Austria, Belgium, Czech Republic, Estonia, France, Germany, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Russia, Slovakia, Slovenia, Spain, Ukraine and the United Kingdom. The HBI License Agreement automatically expires on a country-by-country basis upon the later to occur of (a) the 15th anniversary of the first commercial sale in each respective country in the Licensed Territory or (b) the date the last claim of any patent licensed under the HBI License Agreement expires or is invalidated that covers sales of licensed products in each such country in the Licensed Territory. In fiscal 2008, the Company received payments of approximately $1.5 million due to HBI's attainment of European regulatory approvals and clearances to sell docosanol in two countries.

Kobayashi Docosanol License Agreement — In January 2006, the Company signed an exclusive license agreement with Kobayashi Pharmaceutical Co., Ltd. ("Kobayashi"), a Japanese corporation, to allow Kobayashi to market in Japan medical products that are curative of episodic outbreaks of herpes simplex or herpes labialis and that contain a therapeutic concentration of the Company's docosanol 10% cream.

In April 2009, the license agreement with Kobayashi was terminated and no termination fees were incurred. In the third quarter of fiscal 2009, the Company recognized approximately $170,000 in revenue which was previously deferred relating to the $860,000 data transfer fee received in March 2006 upon initiation of the agreement.

During fiscal 2009 and 2008, the Company recognized total revenues of approximately $284,000 and $228,000, respectively, related to the Kobayashi agreement.

GlaxoSmithKline Subsidiary, SB Pharmco Puerto Rico, Inc. ("GSK"). On March 31, 2000, the Company signed an exclusive license agreement with GSK for rights to manufacture and sell Abreva (docosanol 10% cream) as an over-the-counter product in the United States and Canada as a treatment for recurrent oral-facial herpes. Under the terms of the license agreement, GSK Consumer Healthcare is responsible for all sales and marketing activities and the manufacturing and distribution of Abreva in the U.S. and Canada. The terms of the license agreement provide for the Company to earn royalties on product sales. In October 2000 and August 2005, GSK launched Abreva in the United States and Canada, respectively. All milestones under the agreement were earned and paid

prior to fiscal 2003. During fiscal 2003, the Company sold an undivided interest in the GSK license agreement to Drug Royalty with a term until the later of December 13, 2013 or until the expiration of the patent for Abreva. (See Note 9, "Deferred Revenues/Sale of Licenses.")

P.N. Gerolymatos SA. ("Gerolymatos"). In May 2004, the Company signed an exclusive agreement with Gerolymatos giving them the rights to manufacture and sell docosanol 10% cream as a treatment for cold sores in Greece, Cyprus, Turkey and Romania. Under the terms of the agreement, Gerolymatos will be responsible for all sales and marketing activities, as well as manufacturing and distribution of the product. The terms of the agreement provide for the Company to receive a license fee, royalties on product sales and milestones related to product approvals in Greece, Cyprus, Turkey and Romania. This agreement will continue until the latest of the 12th anniversary of the first commercial sale in each of those respective countries, or the date that the patent expires, or the last date of the expiration of any period of data exclusivity in those countries. Gerolymatos is also responsible for regulatory submissions to obtain marketing approval of the product in the licensed territories. In fiscal 2010 and 2009, the Company recognized royalty revenue from product sales of approximately $1,800 and $6,000, respectively. No revenues were recognized from this agreement in fiscal 2008.

ACO HUD. In September 2004, the Company signed an exclusive agreement with ACO HUD giving them the rights to manufacture and sell docosanol 10% cream as a treatment for cold sores in Sweden, Norway, Denmark and Finland. Stockholm-based ACO HUD is the Scandinavian market leader in sales of cosmetic and medicinal skincare products. ACO HUD launched the product in fiscal 2005. Under the terms of the agreement, ACO HUD will be responsible for all sales and marketing activities, as well as manufacturing and distribution of the product. The terms of the agreement provide for the Company to receive a license fee, royalties on product sales and milestones related to product approvals in Norway, Denmark and Finland. This agreement will continue until either: 15 years from the anniversary of the first commercial sale in each of those respective countries, or, until the date that the patent expires, or, the last date of the expiration of any period of data exclusivity in those countries, whichever occurs last. ACO HUD is also responsible for regulatory submissions to obtain marketing approval of the product in the licensed territories. No revenue was recognized pursuant to this agreement in fiscal 2010 or 2009. Royalties in the amount of approximately $9,000 were recorded in fiscal 2008.

In November 2009, the license agreement between ACO HUD and the Company was terminated. The Company retains the right to license docosanol in Sweden, Norway, Denmark and Finland, and to other interested parties.

Emergent Biosolutions. In March 2008, the Company entered into an Asset Purchase and License Agreement with Emergent Biosolutions for the sale of the Company's anthrax antibodies and license to use the Company's proprietary Xenerex Technology platform which was used to generate fully human antibodies to target antigens. Under the terms of the Agreement, the Company completed the remaining work under an NIH/NIAID grant ("NIH grant") and transferred all materials to Emergent. Under the terms of the agreement, the Company is eligible to receive milestone payments and royalties on any product sales generated from this program. The Company earned $0, $250,000, and $500,000 in milestone payments in fiscal years 2010, 2009, and 2008, respectively.

Non-anthrax related antibodies. In September 2008, the Company entered into an Asset Purchase Agreement with a San Diego based biotechnology company for the sale of non-anthrax related antibodies as well as the remaining equipment and supplies associated with the Xenerex Technology platform. In connection with this sale, in fiscal 2008 the Company received an upfront payment of $210,000 and is eligible to receive future royalties on potential product sales, if any. No licensing revenue was recorded in fiscal 2010 and 2009 associated with this agreement.

Government research grants. Through June 2008, the Company was engaged in various research programs funded by government research grants. The government research grants were used for conducting research on various docosanol-based formulations for a potential genital herpes product and development of antibodies to

anthrax toxins. There was no remaining balance under the research grants as of September 30, 2008. In fiscal 2008 the Company recorded government research grant services revenue of approximately $1.0 million in the accompanying consolidated statement of operations.

13. Income Taxes

Components of the income tax provision are as follows for the fiscal years ended September 30, 2010, 2009 and 2008:

	2010	2009	2008
Current:			
State and foreign	$ 3,200	$ 3,200	$ 3,200
Deferred:			
Federal	(4,744,247)	(5,948,313)	(5,147,297)
State and foreign	(1,703,786)	(1,026,174)	(1,115,570)
	(6,448,033)	(6,974,487)	(6,262,867)
Increase in deferred income tax asset valuation allowance	6,448,033	6,974,487	6,262,867
Total income tax provision	$ 3,200	$ 3,200	$ 3,200

Deferred income taxes reflect the income tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's net deferred income tax balance were as follows:

	September 30,		
	2010	2009	2008
Net operating loss carryforwards	$ 97,127,486	$ 90,497,829	$ 83,265,183
Deferred revenue	3,336,963	3,920,337	4,943,699
Research credit carryforwards	11,283,223	11,295,872	10,964,507
Capitalized research and development costs	714,010	986,955	1,263,921
Capitalized license fees and patents	2,744,311	3,075,544	3,411,306
Share-based compensation and options	4,514,473	3,449,222	2,584,645
Foreign tax credits	595,912	595,912	595,912
Other	703,544	750,675	622,961
Deferred income tax assets	121,019,922	114,572,346	107,652,134
Deferred tax liabilities:			
Other	(2)	(459)	(54,734)
Deferred tax liabilities	(2)	(459)	(54,734)
Less valuation allowance for net deferred income tax assets	(121,019,920)	(114,571,887)	(107,597,400)
Net deferred tax assets/(liabilities)	$ —	$ —	$ —

The Company has provided a full valuation allowance against the net deferred income tax assets recorded as of September 30, 2010, 2009 and 2008 as the Company concluded that they are unlikely to be realized. As of September 30, 2010 the Company had federal and state net operating loss carryforwards of $254,400,000 and $193,400,000, respectively. As of September 30, 2010 the Company had federal and California research and

development credits of $7,000,000 and $6,400,000, respectively. The net operating loss and research credit carryforwards will expire on various dates through 2029, unless previously utilized. We also have foreign tax credit carryforwards of $600,000 which begin to expire in 2011, unless previously utilized. In the event of certain ownership changes, the Tax Reform Act of 1986 imposes certain restrictions on the amount of net operating loss and credit carryforwards that the Company may use in any year.

A reconciliation of the federal statutory income tax rate and the effective income tax rate is as follows for the fiscal years ended September 30:

	2010	2009	2008
Federal statutory rate	(34)%	(34)%	(34)%
Increase in deferred income tax asset valuation allowance	24	32	36
State income taxes, net of federal effect	(5)	(6)	(6)
Research and development credits	0	(1)	(4)
Expired net operating loss and other credits	15	8	7
Other	0	1	1
Effective income tax rate	0%	0%	0%

14. Employee Savings Plan

The Company has established an employee savings plan pursuant to Section 401(k) of the Internal Revenue Code. The plan allows participating employees to deposit into tax deferred investment accounts up to 50% of their salary, subject to annual limits. The Company is not required to make matching contributions under the plan. However, the Company voluntarily contributed approximately $58,000, $39,000 and $47,000 in fiscal 2010, 2009, and 2008, respectively, to the plan.

15. Segment Information

The Company operates the business on the basis of a single reportable segment, which is the business of discovery, development and commercialization of novel therapeutics for chronic diseases. The Company's chief operating decision-maker is the Chief Executive Officer, who evaluates the company as a single operating segment.

The Company categorizes revenues by geographic area based on selling location. All operations are currently located in the United States; therefore, total revenues for fiscal 2010, 2009, and 2008 are attributed to the United States. All long-lived assets at September 30, 2010 and 2009 are located in the United States.

Approximately 82%, 78%, and 50% of the Company's total revenues in fiscal 2010, 2009, and 2008, respectively, were derived from a license agreement with GSK and the sale of rights to royalties under that agreement. Royalties from Azur totaled approximately 18% of total revenue in fiscal 2010 and were less than 10% of total revenues in fiscal 2009 and 2008. Approximately 21% of the Company's total revenues in fiscal 2008 were derived from a license agreement with HBI and the sale of rights to royalties under that agreement. Revenues derived from the Company's government grant accounted for 14% of total revenues in fiscal 2008.

16. Subsequent Events

On October 29, 2010, the FDA approved NUEDEXTA for the treatment of PBA.

From October 1, 2010 through December 1, 2010, approximately 1.1 million shares of common stock were sold under the at-the-market facility with Cantor Fitzgerald at an average price of $4.76 per share, resulting in net proceeds of $4.7 million.

From October 1, 2010 through December 1, 2010, 177,857 shares were issued pursuant to the exercise of stock options and 56 shares were issued pursuant to the vesting of restricted stock units, resulting in proceeds of approximately $126,764 to the Company.

From October 1, 2010 through December 1, 2010, approximately 3.6 million shares were issued pursuant to the exercise of outstanding warrants, resulting in proceeds of $5.2 million to the Company.

In November 2010, the Company completed a common stock offering resulting in the issuance of 20.0 million shares. Gross proceeds from the offering totaled approximately $88.0 million (approximately $83.0 million in net proceeds after estimated discounts, expenses and commissions associated with the offering).

* * * * *

BOARD OF DIRECTORS

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ANNUAL MEETING

The Annual Meeting of Stockholders will be held on February 8, 2011 at 9:00 am at the Island Hotel in Newport Beach, CA. All stockholders are cordially invited to attend.

STOCKHOLDER INFORMATION

Stockholders of record needing to change their name or address, or to replace lost stock certificates, please write or call our transfer agent. Stockholders wishing to be added to the Company's e-mail list should sign up at www.avanir.com or contact Investor Relations at (949) 389-6700.

AVANIR COMMON STOCK

The Company's shares of Common Stock trade on the NASDAQ Global Market under the symbol AVNR.

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