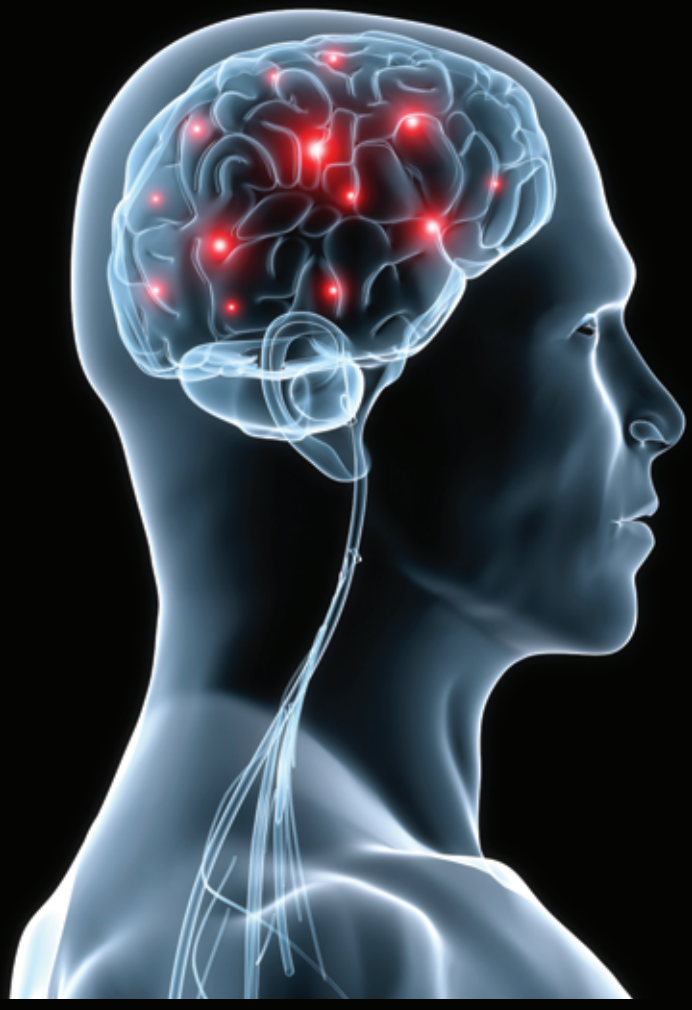

2009 Annual Report

AVANIR pharmaceuticals

AVANIR Pharmaceuticals, Inc.
2009 Letter to Stockholders

Dear Stockholders:

The past year was very successful for AVANIR and a critical turning point in our mission to become a leading specialty biopharmaceutical company focused on innovative therapies for disorders of the central nervous system. This year marked the point at which we began to transition our focus from clinical development to securing regulatory approval for our promising investigational drug Zenvia™. As we exit 2009, we find ourselves well positioned for success in 2010. The entire AVANIR team remains committed to our goals of making Zenvia available to the millions of patients in the U.S. currently suffering from the debilitating emotional outbursts of pseudobulbar affect (PBA) and creating significant value for our stockholders.

Clinical Success in 2009

We entered 2009 nearing the completion of enrollment in the Phase III confirmatory STAR trial for Zenvia in the treatment of PBA secondary to amyotrophic lateral sclerosis (ALS) or multiple sclerosis (MS). In March, we completed enrollment and were pleased that we had exceeded our targeted patient enrollment while simultaneously beating our original enrollment timeline.

In August, we were extremely pleased to announce positive top-line data that exceeded even our own expectations. The product profile that emerged from the STAR trial indicated that the new lower dose Zenvia formulations maintained statistically significant and clinically meaningful efficacy while providing improved safety and tolerability profiles relative to the previous higher dose formulation. Patients in both Zenvia dosing groups met the primary efficacy endpoint by substantially reducing PBA episode rates compared to placebo with approximately half of the Zenvia patients achieving complete remission of their PBA episodes by the end of the study. In October, we presented the detailed results of the double-blind trial at the prestigious American Neurological Association meeting as well as presented the results of the MS and ALS patient subsets at other leading medical conferences.

Also in October, we reported the results of the secondary endpoint of relief of MS-related pain from the STAR trial. In a post-hoc analysis, MS patients with moderate-to-severe pain at baseline that received Zenvia 30/10 mg reported a statistically significant improvement in their pain scores compared to placebo. This is the second study in which we have observed an efficacy signal in MS patients suffering from pain. As such, we are conducting a strategic assessment of our plans to develop Zenvia in pain. Relative to diabetic peripheral neuropathic pain, MS-related pain may offer several potential advantages to AVANIR, including lack of currently approved therapies, significant unmet medical need and good alignment with a sales and marketing organization built around the PBA indication.

In November, we announced the results from the 12-week open-label extension phase of the STAR trial, in which all continuing patients were treated with the new 30/10 mg formulation of Zenvia. The long-term data from the open-label study suggest that Zenvia 30/10 mg provides sustained efficacy by reducing the severity of PBA while demonstrating a favorable long-term safety and tolerability profile. Zenvia therapy was studied over a continuous six-month period over the course of the double-blind and open-label extension phases of the STAR trial. This was the first time that the efficacy of Zenvia has been studied beyond three-months and we were very pleased to see such a durable response over a six-month period.

Regulatory Planning and Corporate Progress

Now that we have all of the STAR data in hand, our team is now working to expeditiously assemble and submit our full response to the U.S. Food and Drug administration (FDA) approvable letter. In preparation for our submission, we had a productive dialogue with the FDA and reached alignment on the components of our submission package for the full response. Based on the feedback we received from the FDA, we intend to file with existing data as planned and submit our full response early in the second calendar quarter 2010.

In addition to our clinical success in 2009, we also made significant progress in the area of intellectual property protection. In October, we received a "Notice of Allowance" from the United States Patent and Trademark Office announcing that it intends to grant the Company a new patent that is expected to extend commercial exclusivity for

Zenvia in the United States well into 2025. The granting of this patent was an important part of our overall strategic plan and now lays the framework for our planned commercial launch and up to 14 years of revenue generation, if Zenvia is approved.

In August 2009, we enhanced our balance sheet by raising $10.8 million via the sale of common stock at favorable terms. Additionally, through the careful management of our expenses and negotiating favorable payment terms with our vendors, we were able to reduce our fiscal 2009 cash burn to $20.3 million from the initial estimated range of $24 to $27 million. As a result, we ended the fiscal year with $32 million in cash, which we believe will be sufficient to fund continuing operations beyond the anticipated FDA approval decision date in the second half of calendar year 2010.

Looking Forward

As we look toward 2010, we are extremely excited to transition our focus from clinical development to securing regulatory approval and preparing to launch Zenvia for the PBA indication.

We plan to submit our full response filing to the FDA early in the second calendar quarter of 2010 and expect an approval decision on Zenvia approximately six-months after filing. As a result, we are now taking measures to prepare for a U.S. launch in early 2011. On the commercial front, we are committed to making Zenvia a success and believe we have the core senior commercial leadership already in place to maximize the revenue potential of this promising drug candidate. Many members of our senior team have significant commercial experience at both large and small companies with numerous successful product launches in their past. We continue to believe we can successfully bring Zenvia to market ourselves, but are evaluating all strategic options in order to ensure that we do what is best for our stockholders.

2010 will be a pivotal year for AVANIR and one that brings us closer to realizing our mission of becoming a leading developer and marketer of innovative therapies for central nervous system disorders. More importantly, it is our hope that for the first time, patients suffering from PBA will have their first FDA-approved treatment option and that they will be able to focus on what is important to them without the concern of PBA interfering with their lives. I look forward to keeping you updated as we make progress toward fulfilling our mission.

Sincerely,

Keith Katkin
President and Chief Executive Officer

January 2010

Note: Please review the enclosed annual report on Form 10-K for the year ended September 30, 2009, including the information under the caption "Risk Factors," for important information regarding AVANIR and risks associated with forward-looking statements such as projected timelines and the approval of Zenvia.

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, 2009

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:

None

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, 2009 was approximately $32.0 million, based upon the closing price on the Nasdaq Stock 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.

83,169,838 shares of the registrant's Common Stock were issued and outstanding as of November 18, 2009.

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 2010 Annual Meeting of Stockholders, which will be held on February 18, 2010 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. You should review carefully the factors included 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.

Executive Overview

AVANIR is a pharmaceutical company focused on acquiring, developing and commercializing novel therapeutic products for the treatment of central nervous system disorders. Our lead product candidate, Zenvia™ (dextromethorphan hydrobromide/quinidine sulfate), has successfully completed three Phase III clinical trials for the treatment of pseudobulbar affect ("PBA") and has successfully completed a Phase III trial for the treatment of patients with diabetic peripheral neuropathic pain ("DPN pain"). 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 the Company. 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 U.S. Food and Drug Administration ("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. AVANIR was incorporated in California in August 1988 and was reincorporated in Delaware in March 2009.

Zenvia for the treatment of PBA

Zenvia has successfully completed three Phase III clinical trials in the treatment of patients with PBA, also known as emotional lability, and has successfully completed a Phase III trial for the treatment of patients with DPN pain.

In August 2009, we reported top line safety and efficacy data from the STAR trial. The STAR trial (Safety, Tolerability and Efficacy Results of AVP-923 in PBA) is a confirmatory Phase III trial of Zenvia in patients with PBA. The study results demonstrated that both doses of Zenvia met the primary efficacy endpoint in the treatment of PBA and were generally safe and well tolerated. Both doses of Zenvia provided a statistically significant reduction in episode rates over the course of the study when compared to placebo ($p<0.0001$). In an additional analysis of the primary endpoint, at week twelve (end of study), patients in the Zenvia 30/10 mg group reported a statistically significant mean reduction of 88% from baseline in PBA episode rates ($p=0.01$).

In November 2009, we reported safety, efficacy and tolerability data from the 12-week open-label extension phase of the STAR trial. The study results demonstrated that patients maintained on Zenvia 30/10 mg demonstrated statistically significant incremental improvement in their CNS-LS scores over the additional 12-week treatment period of the open-label study ($p<0.0001$). In addition, patients that were titrated from Zenvia 20/10 mg to Zenvia 30/10 mg demonstrated statistically significant improvement in their CNS-LS scores ($p<0.0001$) and patients originally on placebo that initiated Zenvia 30/10 mg demonstrated statistically significant improvement in their CNS-LS scores as well.

The STAR trial was conducted as a result of an approvable letter we received from the FDA for Zenvia in October of 2006. The approvable letter raised certain safety and efficacy concerns that have required additional clinical development to resolve. Based on discussions with the FDA, we were able to successfully resolve the outstanding efficacy concern relating to the original dose formulation that was tested in our earlier trials. However, to address the remaining safety concerns, we agreed to re-formulate Zenvia and conduct one additional

confirmatory Phase III clinical trial using lower quinidine dose formulations. The goal of this study was to demonstrate improved safety while maintaining significant efficacy at a lower quinidine exposure.

In October 2007, we reached agreement with the FDA under the Special Protocol Assessment ("SPA") process on the design of the STAR trial. We enrolled our first patient in the STAR trial in December 2007 and in March 2009, we completed enrollment with a total of 326 patients.

In addition to conducting the STAR trial, we have conducted various pre-clinical and clinical safety studies to enhance our complete response to the 2006 approvable letter and to assist with planned label discussions with the FDA. We expect that the FDA's approval decision for Zenvia will depend on the agency's overall assessment of benefits versus potential risks. (See additional information included in this report in Item 1A, "Risk Factors.")

After completion of the STAR trial and pre-clinical and clinical safety studies, we engaged in constructive written communication with the FDA. Based on the feedback we received, we will proceed with filing the full response with existing Zenvia data as planned, early in the second calendar quarter of 2010.

Zenvia for the treatment of neuropathic pain

In April 2007, we announced positive top-line data from our first Phase III clinical trial of Zenvia for DPN pain. Before discussing a second Phase III trial with the FDA, we made the decision to conduct 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, anticipating that some of the concerns with the quinidine component that were raised in the PBA approvable letter could affect the clinical development of this indication as well.

In May 2008, we reported a positive outcome of the formal PK study and announced that we identified alternative lower quinidine dose formulations of Zenvia 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 Zenvia in the treatment of patients with DPN pain to the FDA under the SPA process. In recent communications regarding the continued development of Zenvia for DPN pain, the FDA has expressed that the safety concerns and questions raised in the PBA approvable letter would be expected to necessitate the testing of a lower quinidine dose formulation in the DPN pain indication, as we had expected. Additionally, based on feedback we have received from the FDA on the proposed continued development of Zenvia for DPN pain, it is possible 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 current focus on gaining approval for the PBA indication, 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 Zenvia. Accordingly, we are evaluating our options to fund this program, including the potential for a development partner.

In September 2009, we reported on secondary efficacy endpoints from the double-blind phase of the Zenvia STAR trial in PBA, including an endpoint measuring reduction of pain in patients with underlying multiple sclerosis ("MS"). Zenvia 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 Zenvia to obtain a pain indication.

Drug Candidates and Marketed Products

Zenvia — Pseudobulbar Affect (PBA) Indication

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. PBA occurs secondary to progressive neurologic diseases such as amyotrophic lateral sclerosis ("ALS"), dementias including Alzheimer's disease, multiple sclerosis, and Parkinson's disease, as well as neurologic injuries such as stroke or traumatic brain injury. While the exact number of patients suffering from PBA

is unknown, based on our review of medical literature, independent surveys and our latest market research, we believe that there are an estimated two million patients in the U.S. suffering from the symptoms of moderate to severe PBA. In addition, our research also demonstrates that there are a significant number of patients who suffer from mild PBA and who would also be eligible for treatment. We believe that the availability of an FDA-approved treatment option for these patients may lead to the correct diagnosis of additional PBA patients. If the FDA approves Zenvia, it would be the first drug approved for the treatment of PBA. Zenvia is a patented, orally administered combination of two well-characterized compounds; the therapeutically active ingredient dextromethorphan ("DM") and the enzyme inhibitor quinidine ("Q"), which serves to increase the bioavailability of dextromethorphan in the human body.

We received an approvable letter from the FDA in October 2006 for our NDA submission for Zenvia for the treatment of patients with PBA. In October 2007, we reached agreement with the FDA under the SPA process on the design, conduct and analysis of the STAR trial. For this trial, we developed two new lower dose formulations of Zenvia; the first contains 30 mg of DM and 10 mg of Q (Zenvia 30/10) and the second contains 20 mg of DM and 10 mg of Q (Zenvia 20/10). The new lower quinidine dose formulations of Zenvia were expected to improve the safety and tolerability profile while maintaining statistically significant and clinically meaningful efficacy.

At the conclusion of enrollment, we had enrolled a total of 326 patients (197 with underlying ALS and 129 with underlying MS) who exhibited signs and symptoms of PBA across 52 sites in the U.S. and Latin America. The primary efficacy analysis was based on the changes in crying/laughing episode rates recorded in patient diaries over the course of the study. Secondary endpoints for this clinical trial included other CNS relevant measures such as: 1) Center for Neurologic Study-Lability Scale (CNS-LS) score; 2) Neuropsychiatric Inventory Questionnaire (NPI-Q); 3) SF-36 Health Survey; 4) Beck Depression Inventory (BDI-II); and 5) Pain Rating Scale score (MS patients only).

Top Line Safety and Efficacy Data from STAR Trial

In August 2009, we reported top line safety and efficacy data from the 12-week double-blind phase of the STAR trial. The study results demonstrated that Zenvia met the primary efficacy endpoint in the treatment of PBA and were generally safe and well tolerated. Zenvia 30/10 mg provided a 47.2% incremental reduction in episode rates compared to placebo over the course of the study ($p<0.0001$). In an additional analysis of the primary endpoint, at week twelve (end of study), patients in the Zenvia 30/10 mg group reported a statistically significant mean reduction of 88% from baseline in PBA episode rates compared to placebo ($p=0.01$). Finally, in a secondary analysis of the primary endpoint, Zenvia 20/10 mg also provided a statistically significant incremental reduction of episode rates compared to placebo ($p<0.0001$). In addition, Zenvia demonstrated statistically significant improvement versus placebo on a number of secondary endpoints including CNS-LS score, SF-36 Mental Health Summary and Beck Depression Inventory.

Overall, in the STAR trial, both doses of Zenvia were generally safe and well tolerated. In the STAR trial, 90.9%, 82.2% and 86.2% of patients completed the 12-week double blind phase of the study in the Zenvia 30/10 mg, Zenvia 20/10 mg and placebo groups, respectively. The most common reason for early withdrawals was due to adverse events (AEs). Early withdrawal due to AEs occurred in 3.7%, 7.8% and 1.9% for the Zenvia 30/10 mg, Zenvia 20/10 mg and placebo groups, respectively. Reported AEs were generally mild to moderate in nature. The most commonly reported adverse events that appeared to be more frequent than placebo were dizziness, nausea and diarrhea.

The proportion of patients reporting at least one serious adverse event (SAE) was 6.5% in the Zenvia 30/10 mg group, 8.8% in the Zenvia 20/10 mg group and 10.4% in the placebo group. A total of 38 SAEs occurred in 27 patients over the course of the study. Of the 38 SAEs reported in the study, only two were deemed by the investigators to be possibly or probably treatment-related; zero in the Zenvia 30/10 mg group, two in the Zenvia 20/10 mg group and zero in the placebo group. In addition, there was a numerical difference in respiratory SAEs with five patients (4.7%) in the Zenvia 30/10 mg group, three patients (2.9%) in the Zenvia 20/10 mg group and two patients (1.9%) in the placebo group experiencing respiratory SAEs.

Overall, there were seven deaths in the study, all related to patients with underlying ALS. In total, three deaths occurred in the Zenvia 30/10 mg arm, three in the 20/10 mg arm and one in the placebo arm. Of the seven deaths that

were reported, five of the deaths (four in the Zenvia treatments arms and one in the placebo arm) occurred at least five days after study drug had been discontinued. There was one reported death in the Zenvia 20/10 mg group that was considered possibly treatment-related, which occurred five days after study drug had been discontinued. The ALS mortality rate in the Zenvia treatment groups was in line with historical norms and the rate in the placebo group was below historical norms.

Open Label Safety and Efficacy Data from STAR Trial

In November 2009, we reported safety, efficacy and tolerability data from the 12-week open-label extension phase of the STAR trial. The study results demonstrated that patients maintained on Zenvia 30/10 mg demonstrated statistically significant incremental improvement in their CNS-LS scores over the additional 12-week treatment period of the open-label study ($p<0.0001$). In addition, patients that were titrated from Zenvia 20/10 mg to Zenvia 30/10 mg demonstrated statistically significant improvement in their CNS-LS scores ($p<0.0001$) and patients originally on placebo that initiated Zenvia 30/10 mg demonstrated statistically significant improvement in their CNS-LS scores as well.

Overall, Zenvia 30/10 mg was generally safe and well tolerated, with 92.9% of patients completing the 12-week treatment period of the open-label study. Reported adverse events were low overall, mild to moderate in nature and consistent with the reported adverse events in the double-blind phase. The overall mortality rate observed in patients with ALS was consistent with historic norms.

Based on the results from the STAR trial, we intend to submit our complete response to the approvable letter early in the second quarter of calendar 2010. The complete response will include the results from the STAR trial, data from the pre-clinical and clinical safety studies we have conducted, and the data from the open-label safety study.

Zenvia — Neuropathic Pain Indications

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 diabetic peripheral neuropathic 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 (i.e. the United States, Japan, France, Germany, Italy, Spain and the United Kingdom.)

In April 2007, we announced positive top-line data from our first Phase III clinical trial of Zenvia 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 Zenvia, 45/30 mg DMQ dosed twice daily ("Zenvia 45/30") and 30/30 mg DMQ dosed twice daily ("Zenvia 30/30"), were compared to placebo based on daily patient diary entries for the Pain Rating Scale. Both Zenvia treatment groups had lower pain ratings than placebo patients ($p<0.0001$ in both cases). In the Zenvia 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 Zenvia 30/30 patient group, average reductions were also significantly greater than placebo patients at Days 30 and 60 ($p<0.0001$) and Day 90 ($p=0.007$).

Zenvia 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 Zenvia 45/30 patient group ($p=0.0002$) and for the Zenvia 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

Zenvia 45/30 patients showed a greater improvement than placebo patients (p=0.05) and the Zenvia 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 Zenvia 45/30 and Zenvia 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 Zenvia 45/30, Zenvia 30/30 and placebo groups, respectively, and no deaths occurred during the study.

After receipt of these positive results, 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 an alternative lower quinidine dose formulation of Zenvia for DPN pain. The new dose is intended to deliver similar efficacy and improved safety/tolerability versus the formulations previously tested for this indication. In September 2008, we submitted our Phase III protocol and related questions for Zenvia for DPN pain to the FDA under a Special Protocol Assessment ("SPA"). We received the FDA's initial response to the SPA and are evaluating our options to fund this program, including the potential for a development partner.

In September 2009, we reported on secondary efficacy endpoints from the double-blind phase of the Zenvia STAR trial in PBA, including an endpoint measuring reduction of pain in patients with underlying multiple sclerosis ("MS"). Zenvia 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 Zenvia to obtain a pain indication.

Other Programs

Docosanol 10% Cream — Cold Sores

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 Canada, Denmark, Finland, Israel, Korea, Norway, Portugal, Spain, Poland, Germany, Greece and Sweden and is sold by our marketing partners in these territories. In 2000, we granted a subsidiary of GlaxoSmithKline, SB Pharmco Puerto Rico, Inc. ("GSK") the exclusive rights to market docosanol 10% cream in the U.S. and Canada. GSK markets the product under the name Abreva® in the United States and Canada. In fiscal 2003, we sold an undivided interest in our GSK license agreement for docosanol 10% cream to Drug Royalty USA, Inc. ("Drug Royalty USA") for $24.1 million. We 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. We also retained the rights to develop and license docosanol 10% cream outside the U.S. and Canada for the treatment of cold sores and other potential indications. We currently have several other collaborations for docosanol around the world. Two of these collaborations currently generate royalty revenue and the others may generate future royalty revenue for the Company depending on clinical and regulatory success outside of the United States.

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 sell the material to our licensees for commercialization. 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.

Zenvia for Pseudobulbar Affect. Although we anticipate that Zenvia, if approved, could be 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, Zenvia 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.

It is also possible that compounding pharmacies could produce Zenvia in an unauthorized fashion.

Zenvia for DPN pain. We anticipate that Zenvia 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 these identified below. Additionally, many other companies are developing drug candidates for this indication and we expect competition for Zenvia, 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 Zenvia 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 November 1, 2009, we owned or had the rights to 207 issued patents (59 U.S. and 148 foreign) and 213 pending applications (25 U.S. and 188 foreign). Patents and patent applications owned or licensed by the Company include Zenvia and other technologies, including but not limited to docosanol-related products and technologies, MIF inhibitor technologies, and TNF-alpha inhibitor technologies.

	United States			Foreign		
Description	**Issued**	**Expiration**	**Pending**	**Issued**	**Expiration**	**Pending**
Zenvia	7	Up to 2025	2	43	Up to 2023	17
Other	52	—	23	105	—	171
Total	**59**		**25**	**148**		**188**

In June 2008, the European Patent Office granted a new patent which extends the period of commercial exclusivity for Zenvia into 2023. The new European patent expands the available Zenvia dose ranges under prior patent protection and encompasses our current clinical development programs in PBA and DPN pain, as well as other neurologic conditions.

In October 2009, we received a "Notice of Allowance" from the United States Patent and Trademark Office ("USPTO") announcing that the office intends to grant the Company a new patent, extending the period of commercial exclusivity for Zenvia into 2025. Upon issuance, the patent will provide Avanir with patent protection for low-dose quinidine formulations of Zenvia used to treat PBA.

In addition to this newly allowed U.S. patent, the Company has exclusive rights under a royalty-bearing license 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 Zenvia.

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 expect that we would increase our product liability insurance coverage if Zenvia is approved and we commence marketing the drug.

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 November 18, 2009, we employed 20 persons, including 8 engaged in research and development activities, including clinical development, and regulatory affairs, and 12 in general and administrative functions such as human resources, finance, accounting, business development and investor relations.

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 16, "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.*

You are advised to read this 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. No portion of our website is incorporated by reference into this Annual Report on Form 10-K.

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

Risks Relating to Our Business

There can be no assurance that the FDA will approve Zenvia for PBA or any other indication.

In October 2006, we received an "approvable letter" from the FDA for our NDA submission for Zenvia in the treatment of patients with PBA. The approvable letter raised certain safety and efficacy concerns. Based on discussions with the FDA, we were able to successfully resolve the outstanding efficacy concern of the original dose formulation that was tested in earlier clinical trials. However, the safety concerns require additional clinical development to resolve. To address the safety concerns, we re-formulated Zenvia and conducted one additional confirmatory Phase III clinical trial using new lower quinidine dose formulations. Although we believe that the data from the confirmatory trial, combined with additional clinical and pre-clinical data, should be sufficient to address the issues outlined in the FDA approvable letter, it is possible that the FDA will continue to have safety concerns that could prevent or delay approval. Accordingly, there can be no assurance that the FDA will approve Zenvia for commercialization.

Additionally, although we have a Special Protocol Assessment ("SPA") from the FDA for our recently completed confirmatory Phase III trial for Zenvia in patients with PBA, there can be no assurance that the terms of the SPA will ultimately be binding on the FDA. An SPA is intended to serve as a binding agreement with the FDA on the adequacy of the planned design, conduct and analysis of a clinical trial. Even where an SPA has been granted, however, additional data may subsequently become available that causes the FDA to reconsider the previously agreed upon SPA and the FDA may have subsequent safety or efficacy concerns that override this agreement. As a result, even with positive data obtained under an SPA, we cannot be certain that the trial results will be found to be adequate to demonstrate a favorable risk-benefit profile required for product approval.

The FDA's safety concerns regarding Zenvia 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 Zenvia 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 Zenvia in the treatment of DPN pain. In communications regarding the continued development of Zenvia for this indication, the FDA has expressed that the safety concerns and questions raised in the PBA approvable letter necessitate the testing of a low-dose quinidine formulation in the DPN pain indication as well. Additionally, based on feedback we have received from the FDA on

the proposed continued development of Zenvia for this indication, it is possible that two large well-controlled Phase III trials would be needed to support an NDA filing for this indication. Due to our limited capital resources and current focus on gaining approval for the PBA indication, we do not expect that we will be able to conduct the trials needed for this indication without additional capital or a development partner for Zenvia. Moreover, although we achieved positive results in our initial Phase III trial, an alternative low-dose quinidine formulation may not yield the same levels of efficacy as seen in the earlier trials or as predicted based on our subsequent PK study. Any decrease in efficacy may be so great that the drug does not demonstrate a statistically significant improvement over placebo. Additionally, any alternative low-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 Zenvia for other indications or may need to undertake significant additional clinical trials, which would be costly and cause potentially substantial delays.

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

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

- regulatory authorities may require the addition of labeling statements, such as a "black box" warning, which is the strongest type of warning that the FDA can require for a drug and is generally reserved for warning prescribers about adverse drug reactions that can cause serious injury or death;
- regulatory authorities may withdraw approval of the product after its initial approval;
- product labeling may be amended to restrict use in certain populations;
- physicians may be required to conduct additional tests prior to dispensing product or monitor patients taking Zenvia;
- we may be required to conduct additional studies either post-marketing or before approval; and
- Zenvia may not be approved by the FDA for commercialization as the FDA may perceive that the benefit does not outweigh the potential risk.

Additionally, we experienced a total of seven deaths in the double-blind phase of the STAR trial, all among ALS patients. Although the overall mortality rate in the trial is consistent with published mortality rates, it is possible that these deaths may negatively affect the FDA decision on our PBA application. Any of these events could prevent us from achieving or maintaining market acceptance of our product, even if it receives marketing approval, or could substantially increase the cost of commercialization, which in turn could impair our ability to generate revenues from the product candidate.

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

We have experienced significant operating losses in funding the research, development and clinical testing of our drug candidates, accumulating losses totaling $278.0 million as of September 30, 2009, and we expect to continue to incur substantial operating losses for the foreseeable future. As of September 30, 2009, we had approximately $32.0 million in cash and cash equivalents and restricted investments in marketable securities. Additionally, we currently do not have any meaningful sources of recurring revenue or cash flow from operations.

In light of our current capital resources, lack of near-term revenue opportunities and substantial long-term capital needs, we will need to raise additional capital in the future to finance our long-term operations, including the planned launch of Zenvia, 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 filing, we estimate that we have

sufficient funds to sustain our operations at their current levels through calendar 2010, which includes the anticipated timing of the FDA approval decision for Zenvia in PBA in the second half of calendar year 2010. Although we expect to be able to raise additional capital, there can be no assurance that we will be able to do so or that the available terms of any financing would be acceptable to us. If we are unable to raise additional capital to fund future operations, then we may be unable to fully execute our development plans for Zenvia. This may result in significant delays in the development of Zenvia and may force us to further curtail our operations.

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

Although we believe that we will have adequate capital reserves to fund operations beyond the anticipated timing of the FDA approval decision for Zenvia in PBA, we expect that we will need to raise additional capital in the future. We may do so through various financing alternatives, including licensing or sales of our technologies, drugs and/or drug candidates, selling shares of common or preferred stock, 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.

In July 2009, we entered into a financing facility with Cantor Fitzgerald & Co., providing for the sale of up to 12.5 million shares of our common stock from time to time into the open market at prevailing prices. As of November 1, 2009, we had sold a total of 4.7 million shares under this facility. 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 Zenvia. If we actively sell shares under this facility, a significant number of shares of common stock could be issued in a short period of time, although we would attempt to structure the volume and price thresholds in a way that minimizes market impact. Notwithstanding these control efforts, these sales, or the perceived risk of dilution from potential sales of stock through this facility, may depress our stock price or cause holders of our common stock to sell their shares, or it may encourage short selling by market participants, which could contribute to a decline in our stock price. A decline in our stock price might impede our ability to raise capital through the issuance of additional shares of common stock or other equity securities, and may cause our stockholders to lose part or all of the value of their investment in our stock.

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

We have entered into agreements for the licensing out or sale of our non-core assets, including FazaClo, macrophage migration inhibitory factor ("MIF"), our anthrax antibody program, and other antibodies in our infectious disease program, as well as docosanol in major markets worldwide. From time to time, we have been and will continue to be engaged in discussions with potential licensing or development partners for Zenvia for PBA and/or other indications and we may choose to pursue a partnership or license involving Zenvia, 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 may result in disputes regarding representations and warranties, indemnities, earn-outs, and other provisions in the transaction agreements. If disputes are resolved unfavorably, our financial

condition and results of operations may be adversely affected and we may not realize the anticipated benefits from the transactions.

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

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

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

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

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

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.

Depending upon the timing, duration and specifics of FDA approval, if any, of Zenvia, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. If Zenvia is approved, the Hatch-Waxman Amendments may permit a patent restoration term of up to five years for one of our patents covering Zenvia as compensation for the patent term lost during product development and the regulatory review process. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. We intend to apply for patent term restoration. However, because Zenvia is not a new chemical entity, but is a combination of two previously approved products, it is uncertain whether Zenvia will be granted any patent term restoration under the U.S. Patent and Trademark Office guidelines. In addition, the patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years after the product's approval date.

Market exclusivity provisions under the Federal Food, Drug and Cosmetic Act, or the FDCA, also may delay the submission or the approval of certain applications for competing product candidates. The FDCA provides three

years of non-patent marketing exclusivity for an NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving abbreviated NDAs for drugs containing the original active agent.

Once the three-year FDCA exclusivity period has passed and after the patents (including the patent restoration term, if any) that cover Zenvia expire, generic drug companies would be able to introduce competing versions of the drug. If we are unsuccessful in defending our patents against generic competition, our long-term revenues from Zenvia sales may be less than expected and we may have greater difficulty finding a development partner or licensee for Zenvia.

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

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

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

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

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 Zenvia in DPN pain results in significantly different conclusions about the efficacy of the drug. Although we believe we have legitimate reasons to use the methods that we have adopted as outlined in our SPA with the FDA, the FDA may not agree with these reasons and may disagree with our conclusions regarding the results of these trials.

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

- delays in our ability to submit an NDA;
- the refusal by the FDA to accept for 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 Zenvia will face competition from antidepressants, atypical anti-psychotic agents and other agents in the treatment of PBA and from a variety of pain medications and narcotic agents for the treatment of DPN pain.

Our competitors may have specific expertise and development technologies that are better than ours and many of these companies, which include large pharmaceutical companies, either alone or together with their research partners, have substantially greater financial resources, larger research and development capabilities and substantially greater experience than we do. Accordingly, our competitors may successfully develop competing products.

We are also competing with other companies and their products with respect to manufacturing efficiencies and marketing capabilities, areas where we have limited or no direct experience.

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

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

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

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

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

The 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 affect materially and adversely our business and financial condition. Furthermore, various distributors of pharmaceutical products require minimum product liability insurance coverage before their purchase or acceptance of products for distribution. Failure to satisfy these insurance requirements could impede our ability to achieve broad distribution of our proposed products and the imposition of higher insurance requirements could impose additional costs on us. Additionally, we are potentially at risk if our insurance carriers become insolvent. Although we have historically obtained coverage through well rated and capitalized firms, the ongoing financial crisis may affect our ability to obtain coverage under existing policies or purchase insurance under new policies at reasonable rates.

Risks Related to Reliance on Third Parties

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

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

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

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

Under our 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 Zenvia to a third party or a development partner, it is likely that much of the long-term success of that drug will similarly depend on the efforts of the licensee.

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

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

Risks Relating to Our Stock

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

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

- 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;
- lack of volume of stock trading leading to low liquidity;
- market and economic conditions; and
- Announcements we may make regarding our compliance with continued listing standards on the NASDAQ Global Market.

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

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

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

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 11,319 square feet. The Aliso Viejo office lease expires in June 2011. 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. ***Submission of Matters to a Vote of Security Holders***

There were no matters submitted to a vote of our security holders during the fourth quarter of fiscal 2009.

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 closing sales 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 2009		Fiscal 2008	
	High	Low	High	Low
First Quarter	$0.70	$0.23	$2.84	$1.25
Second Quarter	$0.68	$0.25	$1.43	$0.94
Third Quarter	$2.62	$0.39	$1.35	$1.00
Fourth Quarter	$4.09	$1.75	$1.04	$0.40

On November 18, 2009, the closing sales price of our Common Stock was $1.84 per share.

As of November 13, 2009, we had approximately 23,023 stockholders, including 366 holders of record and an estimated 22,657 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.

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***

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

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.

In August 2007, we sold our FazaClo business and related support operations to Azur Pharma, Inc. We have reflected the financial results of this business as discontinued operations in the consolidated statements of

operations for the year ended September 30, 2008. Unless otherwise noted, this Management's Discussion and Analysis of Financial Condition and Results of Operations relates only to financial results from continuing operations.

Executive Overview

We are a pharmaceutical company focused on acquiring, developing and commercializing novel therapeutic products for the treatment of central nervous system disorders. Our lead product candidate, Zenvia™ (dextromethorphan hydrobromide/quinidine sulfate), has successfully completed three Phase III clinical trials for the treatment of pseudobulbar affect ("PBA") and has successfully completed a Phase III trial for the treatment of patients with diabetic peripheral neuropathic pain ("DPN pain"). 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 the Company. 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 U.S. Food and Drug Administration ("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. 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 2009 and subsequent to the end of fiscal 2009 through the date of this filing that have materially affected our operations, financial condition and prospects:

- In March 2009, we enrolled the last of 326 patients into the confirmatory Phase III STAR trial. The final number of patients exceeded the original target by approximately 20% allowing a larger safety database and increased statistical power for the study.
- In April 2009, we completed additional preclinical and clinical studies that were conducted to enhance the complete response to the approvable letter and to assist with planned label discussions with the FDA.
- In June 2009, we were added to the broad-market Russell 3000® Index, an investment tool comprised of 3,000 of the country's largest and most liquid stocks.
- In July 2009, we completed enrollment of the open label extension of the confirmatory Phase III STAR trial. In total, 282 of 326 patients (or 86.5%) completed the 12-week double-blind phase of the study and were eligible to enroll in the open label extension phase. A total of 253 (or 89.7%) of eligible patients chose to enroll in the 12-week open label safety extension.
- In August 2009, we announced the results of the double-blind phase of the confirmatory Phase III STAR trial which demonstrated that both doses of Zenvia met the primary efficacy endpoint in the treatment of patients with PBA and that Zenvia demonstrated an improved safety and tolerability profile relative to the original formulation.
- In August 2009, we raised gross proceeds of approximately $10.6 million through the sale of approximately 4.5 million shares of common stock. The shares were sold into the open market at prevailing prices through our financing facility with Cantor Fitzgerald & Co.
- In October 2009, we received a "Notice of Allowance" from the United States Patent and Trademark Office ("USPTO") thereby extending the period of commercial exclusivity for Zenvia into 2025. Upon issuance, the patent will provide Avanir with patent protection for low-dose quinidine formulations of Zenvia used to treat patients with PBA.
- In November 2009, we announced results of the 12-week open label phase of the confirmatory phase III STAR trial which demonstrated that the following patient groups displayed statistically significant improvement in their CNS-LS scores: 1) patients maintained on Zenvia 30/10 mg, 2) patients who titrated from Zenvia 20/10 mg to Zenvia 30/10 mg and 3) patients originally placed on placebo that initiated Zenvia 30/10 mg.

We have historically sought to maintain flexibility in our cost structure by actively managing several outsourced functions, such as clinical trials, legal counsel, documentation and testing of internal controls, pre-clinical development work, and manufacturing, warehousing and distribution services, rather than maintaining all of these functions in house. We believe that at this stage of our development the benefits of outsourcing, which include flexibility and rapid response to program delays or successes, far outweigh the higher costs often associated with outsourcing.

Our principal focus is currently on gaining regulatory approval for Zenvia for the PBA indication. We believe that cash and cash equivalents and restricted investments of approximately $32.0 million at September 30, 2009 will be sufficient to fund our operations for at least the next twelve months and through the date by which we expect that the FDA will render an approval decision with respect to Zenvia for PBA. 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 for Continuing Operations

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. The preparation of these 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 under the straight-line attribution method. As share-based compensation expense recognized in the consolidated statements of operations for fiscal 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. 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 $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 and 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 and 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 form 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. We have 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.

Research Services Arrangements. Revenue from research services is recognized during the period in which the services are performed and is based upon the number of full-time-equivalent personnel working on the specific project at the agreed-upon rate. Reimbursements from collaborative partners for agreed upon direct costs including direct materials and outsourced, or subcontracted, pre-clinical studies are classified as revenue and recognized in the period the reimbursable expenses are incurred. Payments received in advance are recorded as deferred revenue until the research and development services are performed or costs are incurred. These arrangements are often multiple element arrangements.

Government Research Grant Revenue. We recognize revenues from federal research grants during the period in which the related expenditures are incurred.

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.

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 two 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 2009 and 2008 are located in the United States.

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) margin	(73,135)	108,106	(181,241)	−168%
REVENUES AND COST OF RESEARCH SERVICES AND OTHER				
Revenues:				
Revenues 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 margin	$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.

Potential revenue-generating contracts that remained active as of September 30, 2009 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 13 “Research, License, Supply and other Agreements” and Note 16 “Segment Information” in Notes to Consolidated Financial Statements.

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.

	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 Zenvia. Following the completion of the STAR trial, we expect these expenses to decrease in fiscal 2010.

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 12, "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 approximately $1.9 million related to share-based compensation expense and other non-cash expenses, 2) increased spending in research and development 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, 2009	Increase (Decrease) During Period	September 30, 2008
Cash, cash equivalents and investments in securities	$31,954,487	$(10,286,040)	$42,240,527
Cash and cash equivalents	$31,486,012	$ (9,897,918)	$41,383,930
Net working capital	$26,685,567	$(10,486,069)	$37,171,636

	Year Ended September 30, 2009	Change Between Periods	Year Ended September 30, 2008
Net cash used in operating activities	$(20,290,160)	$ (3,611,951)	$(16,678,209)
Net cash provided by investing activities	357,362	(671,629)	1,028,991
Net cash provided by financing activities	10,034,880	(16,510,306)	26,545,186
Net increase (decrease) in cash and cash equivalents	$ (9,897,918)	$(20,793,886)	$ 10,895,968

Operating activities. Net cash used in operating activities was approximately $20.3 million in fiscal year 2009 compared to approximately $16.7 million in fiscal year 2008. The increase is 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 provided by investing activities was approximately $357,000 in fiscal year 2009, compared to approximately $1.0 million in fiscal year 2008. In fiscal year 2009, cash provided by investing activities arose primarily from sales and maturities of investments. 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 $10.0 million in fiscal year 2009 compared to approximately $26.5 million in fiscal year 2008. In fiscal 2009, we raised approximately $10.8 million in gross proceeds (approximately $10.2 million net of offering costs and commissions) from an open market offering. 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 $38.0 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 November 1, 2009, 4.7 million shares of common stock had been sold for total gross proceeds of $11.0 million through this facility under our 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 Zenvia.

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. No offerings have been made pursuant to this registration statement to date.

As of September 30, 2009, we have contractual obligations for long-term debt 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
Operating lease obligations(1)	$4,587,651	$1,530,249	$2,705,743	$351,659
Purchase obligations(2)	1,038,294	1,038,294	—	—
Total	$5,625,945	$2,568,543	$2,705,743	$351,659

(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, 2009 which approximates our contractual commitments for goods and services in the normal course of our business.

In connection with the Alamo acquisition, 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"). As previously discussed in this filing, we sold the FazaClo product line to Azur in August 2007. 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.

Zenvia License Milestone Payments. We hold the exclusive worldwide marketing rights to Zenvia 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 Zenvia 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. The Company will pay a $75,000 milestone if the FDA approves Zenvia for the treatment of PBA. In addition, the Company is obligated to pay CNS a royalty on commercial sales of Zenvia with respect to each indication, if the drug is approved by the FDA for commercialization. Under certain circumstances, the Company may have the obligation to pay CNS a portion of net revenues received if it sublicenses Zenvia 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 clinical indications. Maximum payments for these milestone payments could total approximately $2.1 million if the Company pursued the development of Zenvia for all of the licensed indications. Of the clinical indications that the Company currently plans to pursue, expected milestone payments could total $800,000. In general, individual milestones range from $150,000 to $250,000 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 revenues.

Management Outlook

We believe that cash, cash equivalents and restricted investments of approximately $32.0 million at September 30, 2009 will be sufficient to sustain our planned level of operations for at least the next twelve months and through the anticipated FDA approval decision for Zenvia for PBA. However, we cannot provide assurances that our plans will not change, or that changed circumstances or delays in clinical development 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 the Company.

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, 2009 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, 2009 and 2008, an increase of one percentage point in the interest rates would have resulted in increases in interest income of approximately $343,000 and $409,000, respectively.

As of September 30, 2009, $31.1 million of our cash and cash equivalents were maintained in six separate money market mutual funds, and approximately $379,000 of our cash and cash equivalents were maintained at two major financial institutions in the United States. At times, deposits held with the financial institution may exceed the amount of insurance provided on such deposits, and at September 30, 2009, such uninsured deposits totaled $31.1 million. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk. Effective October 3, 2008, the Emergency Economic Stabilization Act of 2008 raised the Federal Deposit Insurance Corporation deposit coverage limits to $250,000 per owner from $100,000 per owner. This program is currently available through December 31, 2009.

Financial instruments that potentially subject us to concentrations of credit risk consist principally of cash and cash. 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 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(T). *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, 2009. For the purpose of this review, disclosure controls and procedures means controls and procedures designed to ensure that information required to be disclosed by the Company 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 the Company 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, 2009.

This annual report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this annual report.

Changes in Internal Control over Financial Reporting

There has been no change in the Company's internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the Company's fourth fiscal quarter ended September 30, 2009, that has materially affected, or is reasonably likely to materially affect the Company's 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 2010 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 key employees and their ages as of November 1, 2009 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	**38**	**President and Chief Executive Officer**
Randall E. Kaye, M.D.	**47**	**Senior Vice President, Chief Medical Officer**
Christine G. Ocampo	**37**	**Vice President, Finance, Secretary**
Key Employees		
Eric S. Benevich	**44**	**Vice President, Communications**
Gregory J. Flesher	**39**	**Vice President, Business Development**

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, Amgen 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. 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 Pharmaceuticals, Inc. 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 and has completed several MBA courses at Villanova University.

Gregory J. Flesher. Mr. Flesher joined Avanir Pharmaceuticals, Inc. 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.

Code of Ethics

We have adopted a code of ethics for directors, officers (including our principal executive officer, principal financial officer, and principal accounting officer and controller), and employees. This code of ethics 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

Financial statements for the two years ended September 30, 2009 and 2008 are attached. The index to these financial statements appears 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. 333-161789), as Exhibit 4.3	September 8, 2009
4.3	Form of Subordinated Indenture	Registration Statement on Form S-3 (File No. 333-161789), as Exhibit 4.4	September 8, 2009

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
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
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	Research, Development and Commercialization Agreement, dated as of April 27, 2005, by and between Avanir Pharmaceuticals and Novartis International Pharmaceutical Ltd.*	Quarterly Report on Form 10-Q for the quarter ended June 30, 2005, as Exhibit 10.1	August 15, 2005
10.4	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
10.5	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
10.6	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
10.7	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
10.8	Sublease agreement, dated as of September 5, 2006, by and between Avanir Pharmaceuticals and Sirion Therapeutics, Inc.	Annual Report on Form 10-K for the fiscal year ended September 30, 2006, as Exhibit 10.9	December 18, 2006
10.9	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

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
10.10	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
10.11	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
10.12	Quality Agreement, dated as of January 4, 2006, by and between Avanir Pharmaceuticals and Patheon Inc.*	Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, as Exhibit 10.2	May 10, 2006
10.13	Docosanol License Agreement, dated as of January 5, 2006, by and between Kobayashi Pharmaceutical Co., Ltd. And Avanir Pharmaceuticals*	Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, as Exhibit 10.3	May 10, 2006
10.14	Docosanol Data Transfer and Patent License Agreement, dated as of July 6, 2006, by and between Avanir Pharmaceuticals and Healthcare Brands International Limited*	Annual Report on Form 10-K for the fiscal year ended September 30, 2006, as Exhibit 10.21	December 18, 2006
10.15	Development and License Agreement, dated as of August 7, 2006, by and between Eurand, Inc. and Avanir Pharmaceuticals*	Annual Report on Form 10-K for the fiscal year ended September 30, 2006, as Exhibit 10.22	December 18, 2006
10.16	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
10.17	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
10.18	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
10.19	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
10.20	2003 Equity Incentive Plan	Quarterly Report on Form 10-Q for the quarter ended March 31, 2003, as Exhibit 10.3	May 14, 2003
10.21	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
10.22	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
10.23	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

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
10.24	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
10.25	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
10.26	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
10.27	Form of Restricted Stock Unit Grant Agreement for use with 2005 Equity Incentive Plan and 2003 Equity Incentive Plan	Annual Report on Form 10-K for the fiscal year ended September 30, 2007, as Exhibit 10.36	December 21, 2007
10.28	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
10.29	Form of Change of Control Agreement	Current Report on Form 8-K, as Exhibit 10.2	December 10, 2007
10.30	Employment Agreement with Keith Katkin, dated as of June 13, 2005	Annual Report on Form 10-K for the fiscal year ended September 30, 2005, as Exhibit 10.25	December 14, 2005
10.31	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
10.32	Amended and Restated Change of Control Agreement, dated as of February 27, 2007, by and between Avanir Pharmaceuticals and Randall Kaye	Annual Report on Form 10-K for the fiscal year ended September 30, 2007, as Exhibit 10.43	December 21, 2007
10.33	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
10.34	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
10.35	Asset Purchase Agreement, dated as of July 2, 2007, by and among Avanir Pharmaceuticals, Alamo Pharmaceuticals, LLC and Azur Pharma Inc.*	Annual Report on Form 10-K for the fiscal year ended September 30, 2007, as Exhibit 10.49	December 21, 2007
10.36	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
10.37	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

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
10.38	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
10.39	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
10.40	Payoff Letter, dated as of June 2, 2008, by and between Neal R. Cutler and Avanir Pharmaceuticals	Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, as Exhibit 10.1	August 8, 2008
10.41	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
10.42	Controlled Equity Offering[SM] 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
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	
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	

* 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: November 25, 2009

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)	November 25, 2009
/s/ CHRISTINE G. OCAMPO Christine G. Ocampo	Vice President, Finance (Principal Financial Officer)	November 25, 2009
/s/ CRAIG A. WHEELER Craig A. Wheeler	Director, Chairman of the Board	November 25, 2009
/s/ STEPHEN G. AUSTIN, CPA Stephen G. Austin, CPA	Director	November 25, 2009
/s/ CHARLES A. MATHEWS Charles A. Mathews	Director	November 25, 2009
/s/ DAVID J. MAZZO, PH.D. David J. Mazzo, Ph.D.	Director	November 25, 2009
/s/ DENNIS G. PODLESAK Dennis G. Podlesak	Director	November 25, 2009
/s/ NICHOLAS SIMON Nicholas Simon	Director	November 25, 2009
/s/ SCOTT M. WHITCUP, M.D. Scott M. Whitcup, M.D.	Director	November 25, 2009

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, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity and comprehensive loss, and cash flows for the years then ended. 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. The Company has determined that it is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. 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, 2009 and 2008, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ KMJ CORBIN & COMPANY LLP

Costa Mesa, California
November 25, 2009

AVANIR Pharmaceuticals, Inc.

CONSOLIDATED BALANCE SHEETS

	September 30, 2009	September 30, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,486,012	$ 41,383,930
Inventories	114,098	17,000
Prepaid expenses	397,100	1,030,630
Other current assets	331,717	237,334
Current portion of restricted investments in marketable securities	200,775	388,122
Total current assets	32,529,702	43,057,016
Restricted investments in marketable securities, net of current portion	267,700	468,475
Property and equipment, net	310,677	806,909
Non-current inventories	710,531	1,316,277
Other assets	249,462	257,484
TOTAL ASSETS	$ 34,068,072	$ 45,906,161
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,214,117	$ 451,846
Accrued expenses and other liabilities	1,001,599	1,881,401
Accrued compensation and payroll taxes	1,345,859	1,192,457
Current portion of deferred revenues	2,282,560	2,333,932
Current portion of notes payable	—	25,744
Total current liabilities	5,844,135	5,885,380
Accrued expenses and other liabilities, net of current portion	652,395	868,517
Deferred revenues, net of current portion	7,629,807	10,152,100
Total liabilities	14,126,337	16,905,997
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, 2009 and 2008	—	—
Common stock — $0.0001 par value, 200,000,000 shares authorized; 83,084,182 and 78,213,986 shares issued and outstanding as of September 30, 2009 and 2008, respectively	8,308	7,821
Additional paid-in capital	297,923,915	284,986,815
Accumulated deficit	(277,990,488)	(255,994,472)
Total stockholders' equity	19,941,735	29,000,164
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 34,068,072	$ 45,906,161

See notes to consolidated financial statements.

AVANIR Pharmaceuticals, Inc.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended September 30,	
	2009	2008
REVENUES FROM PRODUCT SALES		
Net revenues	$ —	$ 129,820
Cost of revenues	73,135	21,714
Product gross (loss) margin	(73,135)	108,106
REVENUES AND COST OF RESEARCH SERVICES AND OTHER		
Revenues from royalties and royalty rights	3,642,675	3,616,102
Revenues from license agreements	533,834	2,205,724
Revenues from government research grant services	—	1,006,922
Revenues from research services and other	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 margin	4,166,285	5,639,337
Total gross margin	4,093,150	5,747,443
OPERATING EXPENSES		
Research and development	15,867,049	14,110,743
General and administrative	10,150,766	10,599,158
Total operating expenses	26,017,815	24,709,901
Operating loss	(21,924,665)	(18,962,458)
OTHER INCOME (EXPENSES)		
Interest income	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	(271,824)	1,222,481
Loss from continuing operations before provision for income taxes	(21,992,816)	(15,909,472)
Provision for income taxes	3,200	3,200
Loss from continuing operations	(21,996,016)	(15,912,672)
DISCONTINUED OPERATIONS		
Loss from discontinued operations	—	(231,848)
Loss from sale of discontinued operations	—	(1,351,219)
Loss from discontinued operations	—	(1,583,067)
Net loss	$(21,996,016)	$(17,495,739)
BASIC AND DILUTED NET LOSS PER SHARE:		
Loss from continuing operations	$ (0.28)	$ (0.27)
Loss from discontinued operations	—	(0.03)
Net loss	$ (0.28)	$ (0.30)
Basic and diluted weighted average number of common shares outstanding	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		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity	Comprehensive Loss
	Shares	Amount					
BALANCE, SEPTEMBER 30, 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)

See notes to consolidated financial statements.

AVANIR Pharmaceuticals, Inc.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended September 30,	
	2009	2008
OPERATING ACTIVITIES:		
Net loss	$(21,996,016)	$(17,495,739)
Loss from discontinued operations	—	1,583,067
Adjustments to reconcile loss from continuing operations to net cash used in operating activities:		
Depreciation and amortization	260,780	445,980
Share-based compensation expense	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	508,648	21,714
Prepaid expenses and other assets	547,169	1,220,915
Accounts payable	762,271	144,146
Accrued expenses and other liabilities	(1,095,924)	(471,342)
Accrued compensation and payroll taxes	153,402	780
Deferred revenues	(2,573,665)	(2,834,398)
Net cash used in operating activities of continuing operations	(20,290,160)	(16,460,266)
Net cash used in operating activities of discontinued operations	—	(217,943)
Net cash used in operating activities	(20,290,160)	(16,678,209)
INVESTING ACTIVITIES:		
Investments in securities	—	(527)
Proceeds from sales and maturities of investments in securities	388,122	2,300,111
Purchase of property and equipment	(33,010)	(134,374)
Proceeds from sale of Xenerex antibodies	—	210,000
Proceeds from disposal of assets	2,250	5,000
Net cash provided by investing activities	357,362	2,380,210
Net cash used in investing activities of discontinued operations	—	(1,351,219)
Net cash provided by investing activities	357,362	1,028,991
FINANCING ACTIVITIES:		
Proceeds from issuances of common stock and warrants, net of commissions and offering costs	10,246,880	37,838,842
Tax withholding payments reimbursed by surrender of restricted stock	(186,256)	(29,579)
Payments on notes and capital lease obligations	(25,744)	(11,264,077)
Net cash provided by financing activities	10,034,880	26,545,186
Net (decrease) increase in cash and cash equivalents	(9,897,918)	10,895,968
Cash and cash equivalents at beginning of year	41,383,930	30,487,962
Cash and cash equivalents at end of year	$ 31,486,012	$ 41,383,930
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Interest paid	$ 517	$ 447,508
Income taxes paid	$ 6,427	$ 51,108
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Common stock surrendered	$ 186,256	$ 29,850

See notes to consolidated financial statements.

1. Description of Business

AVANIR Pharmaceuticals, Inc. and subsidiaries ("AVANIR" or the "Company") is a pharmaceutical company focused on acquiring, developing and commercializing novel therapeutic products for the treatment of central nervous system disorders. The Company's lead product candidate, Zenvia™ (dextromethorphan hydrobromide/quinidine sulfate), has successfully completed three Phase III clinical trials for the treatment of pseudobulbar affect ("PBA") and has successfully completed a Phase III trial for the treatment of patients with diabetic peripheral neuropathic pain ("DPN pain"). In addition to the Company's focus on products for the central nervous system, the Company also has a number of partnered programs in other therapeutic areas which may generate future income. The Company's first commercialized product, docosanol 10% cream, (sold in the United States and Canada as Abreva® by their marketing partner GlaxoSmithKline Consumer Healthcare) is the only over-the-counter treatment for cold sores that has been approved by the U.S. Food and Drug Administration ("FDA"). In 2008, the Company licensed all monoclonal antibodies and remains 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 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, 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 will depend on license arrangements, the timing and success of reaching development milestones, and obtaining regulatory approvals and ultimately market acceptance of Zenvia for the treatment of PBA, assuming the FDA approves the Company's new drug application. The Company's operating expenses depend substantially on the level of expenditures for clinical development activities for Zenvia for the treatment of PBA and the rate of progress being made on such programs.

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. Certain amounts from prior years have been reclassified to conform to the current year presentation, as discussed below. The Company's fiscal year ends on September 30 of each year. The years ended September 30, 2009 and 2008 may be referred to as fiscal 2009 and fiscal 2008, respectively.

The Company has evaluated subsequent events through November 25, 2009, 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.

On August 3, 2007, the Company sold its rights to the FazaClo® product and the related assets and operations. The sale was made pursuant to an agreement entered into with Azur Pharma, Inc. ("Azur") in July 2007. In connection with the sale, the Company transferred certain assets and liabilities related to FazaClo to Azur. The accompanying consolidated financial statements of AVANIR include adjustments to reflect the classification of the Company's FazaClo business as discontinued operations. See Note 3 for information on discontinued operations.

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. Prior period amounts have been reclassified to conform to the current period presentation. 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 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, 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 lower of cost or market. The restricted amounts that apply to the terms of the leases, which expire in January 2013, were $468,475 and $856,597 for the years ended September 30, 2009 and 2008, respectively.

Concentrations

As of September 30, 2009, $31.1 million of the Company's cash and cash equivalents were maintained in six separate money market mutual funds, and approximately $379,000 of the Company's cash and cash equivalents were maintained at two major financial institutions in the United States. At times, deposits held with financial institutions may exceed the amount of insurance provided on such deposits, and at September 30, 2009, such uninsured deposits totaled $31.1 million. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk. Effective October 3, 2008, the Emergency Economic Stabilization Act of 2008 raised the Federal Deposit Insurance Corporation deposit coverage limits to $250,000 per owner from $100,000 per owner. This program is currently available through December 31, 2009.

Financial instruments that potentially subject us 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 goods on hand. The Company establishes reserves for excess and obsolete inventory 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 remaining lease term. Leased assets meeting certain capital lease criteria are capitalized and the present value of the related lease payments is recorded as a liability. Assets under capital lease arrangements are depreciated using the straight-line method over their estimated useful lives or their related 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 long-lived assets are not recoverable (i.e. the carrying amount is less than the future projected undiscounted cash flows), their carrying amount would be reduced to fair value. Factors we consider 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.

As a result of our impairment review conducted in fiscal 2008, the Company determined that approximately $41,000 of intangible assets were not recoverable. Accordingly, the Company recorded an impairment loss of approximately $41,000. This impairment loss was included in amortization expense in fiscal 2008. Based on its recent analysis, the Company's management believes that no impairment of the carrying value of its long-lived assets existed at September 30, 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, 2009 and 2008 was approximately $20,000 and $49,000, respectively, and is included in accrued expenses and other liabilities.

Fair value of financial instruments

At September 30, 2009 and 2008, the Company's financial instruments included cash and cash equivalents, restricted investments in marketable securities, accounts payable, accrued expenses and other liabilities, notes payable and accrued compensation and payroll taxes. The carrying amount of cash and cash equivalents, accounts payable, accrued expenses and other liabilities, notes payable 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 fair value based on quoted market prices. The fair value of the Company's notes payable at September 30, 2008 were estimated based on quoted market prices or

pricing models using current market rates. At September 30, 2008, the fair value of the Company's notes payable and capital lease obligations approximate their carrying 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 and 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 ("API Docosanol"). Revenue from sales of the Company's API 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 API Docosanol to various licensees upon receipt of a written order for the materials. Shipments generally occur fewer than five times a year. The Company's contracts for sales of the API 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 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 our 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, 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.

Research Services Arrangements. Revenues from research services are recognized during the period in which the services are performed and are based upon the number of full-time-equivalent personnel working on the specific project at the agreed-upon rate. Reimbursements from collaborative partners for agreed-upon direct costs including direct materials and outsourced services, or subcontracted, pre-clinical studies are classified as revenues and recognized in the period the reimbursable expenses are incurred. Payments received in advance are deferred until the research services are performed or costs are incurred. These arrangements are often multiple element arrangements.

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.

Government Research Grant Revenues. The Company recognizes revenues from federal research grants during the period in which the related expenditures are incurred.

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, including the Company's largest contract, representing a $7.1 million Phase III clinical trial contract that was entered into in the first quarter of fiscal 2008. A 3% variance in the Company's estimate of the work completed in the largest contract could increase or decrease quarterly operating expenses by approximately $213,000.

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 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. In the fourth quarter of fiscal 2009, the Company reviewed the estimated forfeiture rate considering recent actual data which resulted in a reduction to the estimated forfeiture rate from 30.0% to 12.6%. Additionally, the Company reduced the estimated forfeiture rate on certain restricted stock unit awards from 30.0% to zero percent, as the Company expects all these 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 basic and 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 2009 and 2008 was comprised of the following:

	Fiscal 2009	Fiscal 2008
From Continuing Operations:		
General and administrative expense	$2,213,242	$1,149,018
Research and development expense	663,721	490,738
Share-based compensation expense related to continuing operations	2,876,963	1,639,756
From discontinued operations:	—	13,905
Share-based compensation expense	$2,876,963	$1,653,661

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

Since the Company has a net operating loss carry-forward as of September 30, 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 2009 and 2008 that would have resulted in a reclassification from cash flows from operating activities to cash flows from financing activities.

Restructuring expense

We record 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, we 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 general and administrative expenses. Advertising costs were approximately $336,000 and $304,000 for fiscal 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 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.

Under Accounting Standards Codification 740-10-50 ("ASC 740-10-50"), Accounting for Uncertain Tax Positions, formerly Financial Accounting Standards Board Interpretation No. 48 ("FIN 48"), 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 Company adopted the authoritative guidance, ASC 740-10-50, on accounting for uncertain tax positions as of October 1, 2007. The total amount of unrecognized tax benefits as of the date of adoption was $3.0 million. The total unrecognized tax benefit resulting in a decrease in deferred tax assets and corresponding decrease in the valuation allowance at September 30, 2009 is $3.3 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, 2009 and 2008.

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.

Comprehensive income (loss)

Comprehensive income (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 foreign currency translation adjustments and unrealized gains and losses on marketable securities. The Company presents accumulated other comprehensive income (loss) in the 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 2009 and 2008.

For fiscal 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 2009	Fiscal 2008
Stock options	2,185,938	624,027
Performance stock options	2,031,218	2,048,200
Stock warrants	12,240,437	12,509,742
Restricted stock units(1)	2,505,434	2,432,416

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

Recent authoritative guidance

Multiple-Deliverable Revenue Arrangements. In September 2009, the FASB issued authoritative guidance regarding multiple-deliverable revenue arrangements. This guidance addresses how to separate deliverables and 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 after December 15, 2009 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 and results of operations.

Subsequent Events. In May 2009, the FASB issued authoritative guidance regarding subsequent events, which establishes the standards for accounting for and disclosure of events that occur after the balance sheet date, but before the financial statements are issued or are available to be issued. This guidance sets forth the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements. This guidance also identifies the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. This guidance was effective for interim and annual periods ending after June 15, 2009. The Company's adoption of this guidance in the third quarter ended June 30, 2009 did not have a material impact on its results of operations, consolidated financial position and cash flows.

Determining Fair Value when the Volume and Level of Activity for the Asset or Liability have Significantly Decreased and Identifying Transactions That Are Not Orderly. In April 2009, the FASB issued authoritative guidance regarding the determination of fair value when the volume and level of activity for the asset or liability have significantly decreased and the identification of transactions that are not orderly. This guidance was effective for the Company for the quarterly period beginning April 1, 2009. This guidance affirms that the objective of fair value when the market for an asset is not active is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date under current market conditions. The FASB provided guidance for estimating fair value when the volume and level of market activity for an asset or liability have significantly decreased and determining whether a transaction was orderly. This guidance

applies to all fair value measurements when appropriate. The Company's adoption of this guidance did not have a material impact on its results of operations, consolidated financial position and cash flows.

Recognition and Presentation of Other-Than-Temporary Impairments. In April 2009, the FASB issued authoritative guidance regarding the recognition and presentation of other-than-temporary impairments, which was effective for the Company for the quarterly period beginning April 1, 2009. The new guidance amends existing guidance for determining whether an other-than-temporary impairment of debt securities has occurred. Among other changes, the FASB replaced the existing requirement that an entity's management assert it has both the intent and ability to hold an impaired security until recovery with a requirement that management assert (a) it does not have the intent to sell the security, and (b) it is more likely than not it will not have to sell the security before recovery of its cost basis. The Company's adoption of this guidance did not have a material impact on its results of operations, consolidated financial position and cash flows.

Interim Disclosures about Fair Value of Financial Instruments. In April 2009, the FASB issued authoritative guidance on interim disclosures about fair value of financial instruments, which increases the frequency of fair value disclosures to a quarterly basis instead of an annual basis. The guidance relates to fair value disclosures for any financial instruments that are not currently reflected on the balance sheet at fair value and was effective for interim and annual periods ending after June 15, 2009. The Company's adoption of this guidance in the third quarter ended June 30, 2009 did not have a material impact on its results of operations, consolidated financial position 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. This guidance is effective for fiscal years beginning after December 15, 2008. Therefore, the Company will adopt this guidance in the fiscal year beginning October 1, 2009. The Company does not expect the adoption of this guidance to have a material impact on its results of operations, consolidated financial position 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. Therefore, the Company will adopt this guidance in the fiscal year beginning October 1, 2009. The Company does not expect the adoption of this guidance to have a material impact on its results of operations, consolidated financial position and cash flows.

The Fair Value Option for Financial Assets and Financial Liabilities. In February 2007, the FASB issued authoritative guidance that provided companies with an option to measure eligible financial assets and liabilities in their entirety at fair value. The fair value option may be applied instrument by instrument, and may be applied only to entire instruments. If a company elects the fair value option for an eligible item, changes in the item's fair value must be reported as unrealized gains and losses in earnings at each subsequent reporting period. The Company adopted this guidance on October 1, 2008. The adoption of this guidance did not have a material impact on its results of operations, consolidated financial position 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 (see Note 4, Fair Value of Financial Instruments). The Company is currently evaluating the effect that the adoption of the deferred provisions will have on its consolidated financial position and results of operations.

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 2009 and 2008, the Company recorded royalty revenues of approximately $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 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 $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 $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 $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

As of October 1, 2008, 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, 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, 2009 and 2008 consist of certificates of deposits, which are classified as held-to-maturity. At September 30, 2009 and 2008, the fair value of these investments approximated their cost basis. 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. Of these investments, $200,775 will mature in 2010 and $267,700 will mature throughout 2011 and 2013. Restricted investments of $388,122 matured in fiscal 2009. At September 30, 2008, restricted investments in marketable securities totaling $388,122 and $468,475 were recorded as current and non-current assets, respectively, in the consolidated balance sheet.

6. Inventories

Inventories are comprised of the active pharmaceutical ingredient ("API") docosanol and the active pharmaceutical ingredients of Zenvia, dextromethorphan ("DM") and quinidine ("Q").

The composition of inventories as of September 30, 2009 and 2008 is as follows:

	September 30, 2009	September 30, 2008
Raw materials	$ 824,629	$1,333,277
Less: current portion	(114,098)	(17,000)
Non-current portion	$ 710,531	$1,316,277

In fiscal 2009 the Company recorded a writedown of inventory of approximately $456,000 of which is primarily comprised of $383,000 which was established for DM and Q supplies that are scheduled to expire in fiscal 2011 and an additional inventory reserve of approximately $69,000 was recorded for Docosanol inventory.

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

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

	Balance at September 30, 2007	Additional Reserves	Balance at September 30, 2008
Reserve for excess and obsolete inventory			
Reserve for docosanol API	$50,000	$ —	$50,000
Reserve for DM and Q API	—	—	—
Total	$50,000	$ —	$50,000

7. Property and Equipment

Property and equipment as of September 30, 2009 and 2008 consist of the following:

	As of September 30, 2009			As of September 30, 2008		
	Gross Carrying Value	Accumulated Depreciation	Net	Gross Carrying Value	Accumulated Depreciation	Net
Computer equipment and related software	$1,330,223	$(1,211,096)	$119,127	$1,319,891	$(1,080,132)	$239,759
Leasehold improvements	37,790	(18,916)	18,874	37,790	(11,362)	26,428
Office equipment furniture and fixtures	756,672	(583,996)	172,676	763,260	(484,257)	279,003
Manufacturing equipment	—	—	—	261,719	—	261,719
Total property and equipment	$2,124,685	$(1,814,008)	$310,677	$2,382,660	$(1,575,751)	$806,909

Depreciation and amortization expense associated with property and equipment was approximately $261,000 and $415,000 for fiscal 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 Zenvia. The loss on disposal is included in other, net on the accompanying consolidated statements of operations.

In fiscal 2008, the Company retired approximately $850,000 of research and development equipment with a net book value of approximately $120,000 resulting in a decrease to accumulated depreciation of approximately $730,000. The related 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, 2009 and 2008 are as follows:

	September 30, 2009	September 30, 2008
Accrued research and development expenses	$ 372,494	$ 1,404,556
Accrued general and administrative expenses	270,401	160,759
Deferred rent	19,516	48,638
Lease restructuring liability(1)	991,583	1,135,965
Total accrued expenses and other liabilities	1,653,994	2,749,918
Less: current portion	(1,001,599)	(1,881,401)
Accrued expenses and other liabilities, non-current portion	$ 652,395	$ 868,517

(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 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
Total	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, 2009 and 2008 the net deferred revenue balances for the Company's sale of future Abreva® royalty rights to Drug Royalty USA and other agreements.

	Drug Royalty USA Agreement	Other Agreements	Total
Net deferred revenues as of October 1, 2008	$12,202,198	$ 283,834	$12,486,032
Changes during the period:			
Recognized as revenues during period	(2,289,831)	(283,834)	(2,573,665)
Net deferred revenues as of September 30, 2009	$ 9,912,367	$ —	$ 9,912,367
Classified and reported as:			
Current portion of deferred revenues	$ 2,282,560	$ —	$ 2,282,560
Deferred revenues, net of current portion	7,629,807	—	7,629,807
Total deferred revenues	$ 9,912,367	$ —	$ 9,912,367

	Drug Royalty USA Agreement	Other Agreements	Total
Net deferred revenues as of October 1, 2007	$14,738,509	$ 581,921	$15,320,430
Changes during the period:			
Additions	—	250,000	250,000
Recognized as revenues during period	(2,536,311)	(548,087)	(3,084,398)
Net deferred revenues as of September 30, 2008	$12,202,198	$ 283,834	$12,486,032
Classified and reported as:			
Current portion of deferred revenues	$ 2,106,740	$ 227,192	$ 2,333,932
Deferred revenues, net of current portion	10,095,458	56,642	10,152,100
Total deferred revenues	$12,202,198	$ 283,834	$12,486,032

Drug Royalty Agreement — In December 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 "GlaxoSmithKline 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 2009 and 2008, the Company recognized royalties in the amount of approximately $951,000 and $934,000, respectively, which is included in the consolidated statements of operations as revenues from royalties and royalty rights.

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 GlaxoSmithKline 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, to be recognized as revenue 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 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. 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 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.

10. Commitments and Contingencies

Operating lease commitments. The Company leases 11,319 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, 2009, the financial commitment for the remainder of the term of the lease is approximately $700,000.

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, 2009, the financial commitment for the remainder of the term of the lease is approximately $3.9 million (excluding the benefit of approximately $3.1 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 $468,000, to secure the Company's performance under the lease (see Note 5).

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

Year Ending September 30,	Minimum Payments	Less Payments to be Received from Subleases	Net Payments
2010	$1,530,249	$ 888,699	$ 641,550
2011	1,483,195	961,425	521,770
2012	1,222,548	997,422	225,126
2013	351,659	281,801	69,858
Total	$4,587,651	$3,129,347	$1,458,304

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 us 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 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.

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, 2009 and 2008.

Center for Neurologic Study ("CNS") — The Company holds the exclusive worldwide marketing rights to Zenvia 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 will need to pay a $75,000 milestone if the FDA approves Zenvia for the treatment of PBA. In addition, the Company is obligated to pay CNS a royalty on commercial sales of Zenvia with respect to each indication, if and when the drug is approved by the FDA for commercialization. Under certain circumstances, the Company may have the obligation to pay CNS a portion of net revenues received if it sublicenses Zenvia 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 $2.1 million if the Company pursued the development of Zenvia for all of the licensed indications. Of the clinical indications that the Company currently plans to pursue, expected milestone payments could total $800,000. In general, individual milestones range from $150,000 to $250,000 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 revenues.

11. Notes Payable

As of September 30, 2008, notes payable consisted of the following:

	September 30, 2008
10.43% equipment loan due February 2009	$ 16,275
10.17% equipment loan due January 2009	9,469
Total	25,744
Less: current portion	(25,744)
Total long-term notes payable	$ —

Senior Notes. In connection with the Alamo Acquisition, the Company issued promissory notes (the "Notes") totaling $29.1 million. In June 2008, the Company accelerated the repayment of the outstanding principal under the Notes. At the time of repayment, the Notes had an outstanding balance of $12.0 million, which was retired early in consideration for a single payment of $10.9 million in full satisfaction of the Notes. The Company recognized a gain on extinguishment of debt of $968,000 (net of unamortized origination discount of $140,000). The accelerated repayment of the Notes represented an estimated savings of approximately $1.2 million in principal and interest payments through the original maturity date, net of estimated lost earnings on cash balances that would have been held through the maturity date. Interest expense recorded in fiscal 2008 related primarily to the Notes.

Equipment Loans. In September 2004, the Company entered into a finance agreement with GE Healthcare Financial Services ("GE Capital") that provides for loans to purchase equipment, secured by the equipment purchased. The net book value of capital equipment financed and subject to lien at September 30, 2008 under the GE Capital finance agreement was approximately $26,000.

12. Stockholders' Equity

Preferred Stock

In March 2009, in connection with our change in domicile, our Board of Directors approved a stockholder rights plan (the "Plan") that provides for the issuance of Series A junior participating preferred stock to each of our stockholders of record under certain circumstances. None of the Series A junior participating preferred stock was outstanding on September 30, 2009 and 2008. The Plan provided for a dividend distribution of one preferred share purchase right (the "Right") on each outstanding share of our 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 our common stock or announces a tender offer for 20% or more of our common stock (a "Trigger Event").

If and when the Rights become exercisable, each Right will entitle shareholders, excluding the person or group causing the Trigger Event (an "Acquiring Person"), to buy a fraction of a share of our 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.

Our 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 expire on March 20, 2019, subject to a periodic review of the Plan by a committee of independent directors.

Common stock

Fiscal 2009. 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. As of September 30, 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 ($38 million after offering expenses) from a select group of institutional investors led by ProQuest Investments and joined by Clarus Ventures, Vivo Ventures, and OrbiMed Advisors. 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 Class A common stock for aggregate gross offering proceeds of $44,200 ($42,700 after offering expenses, including underwriting discounts and commissions). In April 2008, the Company notified Brinson Patrick Securities Corporation that it had terminated the outstanding financing facility with the Corporation.

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

Common Stock Issued and Warrants and Stock Options Exercised	Date	Common Stock Shares	Gross Amount Received(1)	Average Price per Share(2)
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 approximately 12,240,437 million 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, 2009, all these warrants are exercisable and remained outstanding.

In July 2003, warrants were issued to acquire up to approximately 269,305 shares of common stock at $8.92 per share. The warrants had a 5-year exercise term. No warrants were exercised prior to their expiration.

The following table summarizes all warrant activity for fiscal 2009 and 2008:

	Shares of Common Stock Purchasable Upon Exercise of Warrants	Weighted Average Exercise Price per Share	Range of Exercise Prices
Outstanding October 1, 2008	12,509,742	$1.59	$1.43-$8.92
Expired	(269,305)	$8.92	$ 8.92
Outstanding September 30, 2009	12,240,437	$1.43	$ 1.43

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 and the 1994 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 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, 2009, the Company had an aggregate of 11,821,730 shares of common stock reserved for issuance. Of those shares, 6,722,591 were subject to outstanding options and other awards and 5,099,140 shares were available for future grants of share-based awards. The Company also issued share-based awards outside of the Plans. As of September 30, 2009, 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, 2009.

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, 325,000 shares effective December 4, 2007, and an additional 325,000 shares effective November 6, 2008 to a total of 1,740,501 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 us to grant options, restricted stock awards and stock appreciation rights to directors, officers, employees and consultants. As of September 30, 2009, 440,632 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, and an additional 3,911,352 shares effective February 19, 2009 to a total of 10,080,974 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 us to grant options, restricted stock awards and stock appreciation rights to directors, officers, employees and consultants. As of September 30, 2009, 4,110,271 shares of common stock remained available for issuance under the 2003 Plan.

2000 Stock Option Plan. On March 23, 2000, the Company's stockholders approved the adoption of the 2000 Plan, pursuant to which an aggregate of 575,000 shares of common stock have been reserved for issuance. On March 14, 2002, the Company's stockholders approved an amendment to the 2000 Plan to increase the number of shares of common stock issuable under the Plan by 250,000 shares, for an aggregate of 825,000 shares. On March 13, 2003, the Company amended the 2000 Plan to allow for the issuance of restricted stock awards. As of September 30, 2009, 548,237 shares of common stock were available for grant under the 2000 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.

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 2009 and 2008 are presented below.

	Shares of Common Stock Purchasable Upon Exercise of Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value
Outstanding October 1, 2008	624,027	$ 6.61		
Granted	1,613,110	$ 0.53		
Forfeited	(49,039)	$ 4.74		
Expired	(2,160)	$ 5.22		
Outstanding September 30, 2009	2,185,938	$ 2.17	8.5	$2,606,644
Vested and expected to vest in the future, September 30, 2009	1,890,512	$ 2.40	8.5	$2,179,945
Exercisable, September 30, 2009	302,501	$10.73	5.8	$ 11,645

The weighted average grant-date fair values of options granted during fiscal 2009 and 2008 were $0.40 and $0.58 per share, respectively. There were no stock options exercised in fiscal 2009 or 2008. As of September 30, 2009, the total unrecognized compensation cost related to options was approximately $831,000, which is expected to be recognized over a weighted-average period of 2.9 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 2009 and 2008 were as follows:

	2009	2008
Expected volatility	100.8% — 101.3%	95.8%
Weighted-average volatility	100.8%	95.8%
Average expected term in years	5.0	5.0
Risk-free interest rate (zero coupon U.S. Treasury Note)	1.6% — 2.3%	2.9%
Expected dividend yield	0%	0%

The following table summarizes information concerning outstanding and exercisable stock options as of September 30, 2009**:**

	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-$ 0.53	1,428,010	9.2	$ 0.53	—	$ —
$ 0.54-$ 2.41	448,741	8.3	$ 1.29	13,000	$ 1.18
$ 4.60-$ 9.92	87,250	6.1	$ 6.66	72,251	$ 6.69
$10.24-$13.60	180,687	5.5	$11.93	180,687	$11.93
$15.84-$19.38	41,250	5.9	$16.16	36,563	$16.20
	2,185,938	8.5	$ 2.17	302,501	$10.73

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 performance stock options are not included in the above outstanding and exercisable stock options table. The contractual terms are ten years. The stock options have a performance goal related to the clinical development of Zenvia that determines when vesting begins and the actual number of shares to be 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. Vesting is over 3.75 years beginning on the date the performance goal is achieved ("Achievement Date"), with 6.25% vesting on the Achievement Date and 6.25% quarterly from the Achievement Date for the following fifteen quarters. During fiscal 2009, the performance goals related to 2,031,218 performance options were met and vesting began.

The fair value of each performance option was 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. The expected term of performance 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 performance options granted in fiscal 2008 were as follows:

	2008
Expected volatility	95.4% — 98.9%
Weighted-average volatility	97.8%
Average expected term in years	5.4 — 6.0
Risk-free interest rate (zero coupon U.S. Treasury Note)	3.4% — 3.5%
Expected dividend yield	0%

The following table summarizes information concerning outstanding and exercisable performance stock options as of September 30, 2009:

	Shares of Common Stock Purchasable Upon Exercise of Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value
Outstanding October 1, 2008	2,048,200	$0.88		
Forfeited	(16,982)	$0.88		
Outstanding September 30, 2009	2,031,218	$0.88	8.8	$2,437,462
Vested and expected to vest in the future, September 30, 2009	1,699,398	$0.88	8.8	$2,039,277
Exercisable, September 30, 2009	236,300	$0.88	8.8	$ 283,560

The weighted average grant-date fair value of performance stock options granted during fiscal 2008 was $0.70. The total unrecognized compensation cost related to performance stock options was approximately $1.0 million, which is expected to be recognized over a weighted-average period of 3.5 years at September 30, 2009, based on the vesting schedules.

Restricted stock units. 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 2009:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested, October 1, 2008	2,259,042	$1.85
Granted	420,000	$0.44
Vested	(865,356)	$1.22
Forfeited	(700)	$2.06
Unvested, September 30, 2009	1,812,986	$1.83

The weighted average grant-date fair value of RSUs granted during fiscal 2009 and 2008 was $0.44 and $1.48 per unit, respectively. The fair value of RSUs vested during fiscal 2009 and 2008 was approximately $1.1 million and $763,000, respectively. As of September 30, 2009, the total unrecognized compensation cost related to unvested stock units was approximately $1.1 million, which is expected to be recognized over a weighted-average period of 1.0 year, based on the vesting schedules and assuming no forfeitures.

At September 30, 2009, there were 692,448 shares of restricted stock with a weighted-average grant date fair value of $1.85 per share awarded to directors that have vested but are still restricted until the directors resign. In fiscal 2009, 519,062 shares of restricted stock vested but remain restricted.

In June 2009, the Company's compensation committee approved a modification to the vesting schedule of RSUs originally granted on March 21, 2007 ("Modified Awards"). The 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 Modified Awards are 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 will be amortized over the remaining vesting periods of the Modified Awards.

Restricted stock awards. Restricted stock awards 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 us for the original purchase price following the awardee's termination of service. The restricted stock awards 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 restricted stock awards vested in fiscal 2008 was approximately $253,000. There were no unvested restricted stock awards at September 30, 2008 and no activity during fiscal 2009.

13. Research, License, Supply and other Agreements

Center for Neurologic Study ("CNS") — The Company holds the exclusive worldwide marketing rights to Zenvia 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 Zenvia 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 under the CNS license agreement, and will need to pay a $75,000 milestone if the FDA approves Zenvia for the treatment of PBA. In addition, the Company is obligated to pay CNS a royalty on commercial sales of Zenvia with respect to each indication, if and when the drug is approved by the FDA for commercialization. Under certain circumstances, the Company may have the obligation to pay CNS a portion of net revenues received if the Company sublicenses Zenvia to a third party. Under the Company's 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 $2.1 million if the Company pursued the development of Zenvia for all of the licensed indications. Of the clinical indications that the Company currently plans to pursue, expected milestone payments could total $800,000. In general, individual milestones range from $150,000 to $250,000 for each accepted 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 revenues. From inception through September 20, 2009, 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. ("GlaxoSmithKline"). On March 31, 2000, the Company signed an exclusive license agreement with GlaxoSmithKline 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, GlaxoSmithKline 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 us to earn royalties on product sales. In October 2000 and August 2005, GlaxoSmithKline 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 GlaxoSmithKline 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 us 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 2009, the Company recognized royalty revenue from product sales of approximately $6,000. 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 us 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. Royalties in the amount of approximately $9,000 were recorded in fiscal 2008. No revenue was recognized pursuant to this agreement in fiscal 2009.

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. A gain of approximately $120,000 was recorded on the accompanying consolidated statements of operations as a result of this sale. 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 $250,000 and $500,000 in milestone payments in fiscal years 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 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 revenue of approximately $1.0 million.

14. Income Taxes

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

	2009	2008
Current:		
State and foreign	$ 3,200	$ 3,200
Deferred:		
Federal	(5,948,313)	(5,147,297)
State and foreign	(1,026,174)	(1,115,570)
	(6,974,487)	(6,262,867)
Increase in deferred income tax asset valuation allowance	6,974,487	6,262,867
Total income tax provision	$ 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,	
	2009	2008
Net operating loss carryforwards	$ 90,497,829	$ 83,265,183
Deferred revenue	3,920,337	4,943,699
Research credit carryforwards	11,295,872	10,964,507
Capitalized research and development costs	986,955	1,263,921
Capitalized license fees and patents	3,075,544	3,411,306
Share-based compensation and options	3,449,222	2,584,645
Foreign tax credits	595,912	595,912
Other	750,675	622,961
Deferred income tax assets	114,572,346	107,652,134
Deferred tax liabilities:		
Other	(459)	(54,734)
Deferred tax liabilities	(459)	(54,734)
Less valuation allowance for net deferred income tax assets	(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, 2009 and 2008 as the Company concluded that they are unlikely to be realized. As of September 30, 2009 the Company had federal and state net operating loss carryforwards of $240,000,000 and $163,000,000, respectively. As of September 30, 2009 the Company had federal and California research and development credits of $7,400,000 and $6,000,000, respectively. The net operating loss and research credit carryforwards will expire on various dates through 2028, 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:

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

15. 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 $39,000 in fiscal 2009 and $47,000 in fiscal 2008 to the plan.

16. 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 2009 and 2008 are attributed to the United States. All long-lived assets at September 30, 2009 and 2008 are located in the United States.

Approximately 78% and 50% of the Company's total revenues in fiscal 2009 and 2008, respectively, are derived from a license agreement with GlaxoSmithKline and the sale of rights to royalties under that agreement. Royalties from Azur totaled approximately 9% of total revenue in fiscal 2009 compared to 1% in fiscal 2008. Approximately 21% of the Company's total revenues in fiscal 2008 and are 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.

17. Subsequent Event

From October 1, 2009 through November 25, 2009, approximately 85,600 shares of common stock were sold under the financing facility with Cantor Fitzgerald and 56 shares were issued pursuant to the vesting of restricted stock units.

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BOARD OF DIRECTORS

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Partner, Swenson Advisors, LLP

Keith A. Katkin - Inside Director
President and Chief Executive Officer, AVANIR Pharmaceuticals, Inc.

Charles A. Mathews - Independent Director
Private Investor

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President and Chief Executive Officer, Regado Biosciences, Inc.

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Christine G. Ocampo
Vice President, Finance

LEGAL COUNSEL

Goodwin Procter
San Francisco, California

INDEPENDENT AUDITORS

KMJ Corbin & Company
Irvine, California

TRANSFER AGENT

American Stock Transfer & Trust Company
59 Maiden Lane
Plaza Level
New York, New York 10038
(718) 921-8200

ANNUAL MEETING

The Annual Meeting of Stockholders will be held on February 18, 2010 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.

CORPORATE OFFICE

101 Enterprise, Suite 300
Aliso Viejo, CA 92656
(949) 389-6700
www.avanir.com

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Aliso Viejo, CA 92656
(949) 389-6700
www.avanir.com