2008 ANNUAL REPORT

AVANIR Pharmaceuticals
2008 Letter to Shareholders

Dear Shareholders:

Over the past year, we have made significant progress in our clinical programs while enhancing our balance sheet. Together, these accomplishments have put us in a strong position to achieve our goals and realize our mission of becoming a leading developer and marketer of innovative therapies for central nervous system (CNS) disorders. These accomplishments are early steps in our long-term strategy to license, develop and market innovative therapies for CNS conditions with high unmet medical need, low-to-moderate competitive threshold and a neurology/psychiatry specialist prescriber base. We believe that this approach will yield significant long-term value creation for our stockholders.

2008: A Year of Significant Progress

We entered 2008 with the dual objectives of advancing the clinical development of our promising investigational drug Zenvia™ (dextromethorphan/quinidine) and increasing our financial resources. I am pleased to report that we successfully achieved both objectives and as a result have positioned ourselves well for 2009 and beyond.

During fiscal 2008 we made significant progress with both of our Zenvia clinical development programs. In our pseudobulbar affect (PBA) program, we initiated patient enrollment into our confirmatory Phase III STAR trial with outstanding enrollment results to date. By December 2008, we had already enrolled over 75% of the targeted number of PBA patients, a number that substantially exceeds our enrollment rate in previous trials. We anticipate enrolling the final patient into the STAR trial by March of 2009 and expect to have top-line data in hand no later than September. Based on those pivotal data, we plan to submit a full response to the U.S. Food and Drug Administration (FDA) approvable letter in the first half of 2010 and anticipate regulatory action in the second half of 2010.

We also made meaningful progress in 2008 with our Zenvia program in diabetic peripheral neuropathic (DPN) pain. In May, we completed a large, formal pharmacokinetic (PK) study that identified two new lower quinidine dose formulations of Zenvia that we expect will provide enhanced safety with similar efficacy as compared to the previously tested doses in DPN pain. In September, we submitted a Phase III study protocol to the FDA under the Special Protocol Assessment (SPA) process. We are pleased to have received an initial response from the FDA and are now engaged in a positive dialogue with the FDA regarding the design, conduct and analysis of the next Phase III study in DPN pain.

In April 2008, we strengthened our balance sheet by raising approximately $40 million in an equity offering to four leading biotech institutional investors. In addition, through careful management of operating expenses, we were able to reduce our fiscal 2008 cash burn to less than $20 million, as compared to the initial estimated budget expense of $25 to $27 million. As a result of these initiatives, we exited 2008 with over $42 million in cash, which we believe will be sufficient to fund our operations through the FDA approval decision on Zenvia anticipated in the second half of 2010.

In addition to clinical and financial momentum, we also made important advances from an intellectual property perspective. In July, we were granted a new patent by the European Patent Office that significantly extends the period of Zenvia commercial exclusivity in Europe into 2023.

Looking Forward

I expect that 2009 will be a pivotal year in the transformation of AVANIR into a CNS focused biopharmaceutical company with a number of important milestones throughout the year.

During the first calendar quarter we plan to enroll the final PBA patient into the confirmatory Phase III STAR trial and during the third calendar quarter we anticipate releasing the pivotal data that will serve as the basis for our full response to the FDA approvable letter. Having obtained a Special Protocol Assessment from the FDA for the STAR trial in PBA, we believe that if the data are positive we will have met the pre-specified requirements outlined by the FDA and we will be in a position to move forward with a full response to the approvable letter.

Also in 2009, we hope to gain full alignment with the FDA on the next steps for our neuropathic pain program by obtaining an SPA agreement with the FDA. The dialogue with the FDA, and ultimate agreement on a study protocol, will give AVANIR important clarity on the regulatory path forward in DPN pain and potentially, information on other possible neuropathic pain indications.

In my second year as CEO of AVANIR, I continue to be impressed by the accomplishments of the AVANIR team. We are dedicated to doing everything possible to maximize the likelihood of regulatory approval for Zenvia in PBA and to create long-term shareholder value. As the developers of Zenvia, we have been privileged to hear firsthand accounts from patients and investigators about their uplifting success stories from our previous clinical studies. These patients have shared with us the remarkable ability of Zenvia to help people suffering from the involuntary emotional episodes of PBA to "regain control" and resume a more normal life. It is our sincere hope that we will soon be able to allow many more PBA patients to regain control of their emotional expressions and improve their quality of life. I look forward to keeping you apprised of our progress as AVANIR continues on its mission to dramatically improve the lives of patients with CNS disorders.

Sincerely,

Keith Katkin
President and Chief Executive Officer

January 2009

Note: Please review the enclosed annual report on Form 10-K/A for the year ended September 30, 2008, including the information under the caption "Risk Factors," for important information regarding AVANIR and risks associated with forward-looking statements such as the expected timing and results for our clinical trials.

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K/A

(Amendment No. 1)

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

For the fiscal year ended September 30, 2008

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

(Exact name of registrant as specified in its charter)

California	**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
Class A Common Stock, no par value	**The NASDAQ Stock Market LLC**

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 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, 2008 was approximately $43.2 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.

78,213,986 shares of the registrant's Common Stock were issued and outstanding as of December 1, 2008.

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 2009 Annual Meeting of Shareholders, which will be held on February 19, 2009 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 *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 under the caption "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 Pharmaceuticals, a California corporation incorporated in August 1988, is a pharmaceutical company focused on developing, acquiring and commercializing novel therapeutic products for the treatment of chronic diseases. Our product candidates address therapeutic markets that include the central nervous system and inflammatory diseases. Our lead product candidate, Zenvia™ (dextromethorphan hydrobromide/quinidine sulfate), is currently in Phase III clinical development for the treatment of pseudobulbar affect ("PBA") and diabetic peripheral neuropathic pain ("DPN pain"). Our first commercialized product, docosanol 10% cream, (sold as Abreva® by our marketing partner GlaxoSmithKline Consumer Healthcare in North America) is the only over-the-counter treatment for cold sores that has been approved by the FDA. Our inflammatory disease program, which targets macrophage migration inhibitory factor ("MIF"), is currently partnered with Novartis. Our infectious disease program has historically been focused primarily on monoclonal antibodies. In 2008, we sold our rights to substantially all of these monoclonal antibodies to two biotechnology companies. As of June 30, 2008, we ceased all future research and development work related to our infectious disease program and remain eligible to receive additional milestone payments and royalties related to the program.

Zenvia Status

Zenvia is currently in Phase III clinical development for the treatment of two conditions: (1) PBA which is an involuntary emotional expression disorder and (2) DPN pain.

In October 2006, we received an "approvable" letter from the FDA for Zenvia in the treatment of patients with PBA. The approvable letter raised certain safety and efficacy concerns and the safety concerns will require additional clinical development to resolve. Based on discussions with the FDA, we were able to successfully resolve the outstanding efficacy concerns 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 the study is to demonstrate improved safety while maintaining significant efficacy at a lower quinidine dose.

In October 2007, we reached agreement with the FDA under the Special Protocol Assessment ("SPA") process, on the design of a single confirmatory Phase III clinical trial of Zenvia for the treatment of patients with PBA. We enrolled our first patient in this trial in December 2007 and as of December 2008, we are on target with our expected enrollment timeline with over 75% of the patients enrolled. We expect this study to be completed (as defined as top-line safety and efficacy data becomes available) during the third calendar quarter of 2009. In addition to the Phase III clinical trial for PBA, we are conducting other pre-clinical and clinical safety studies in order to enhance our complete response to the approvable letter received in October 2006 for PBA.

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 raised in the PBA approvable letter could affect the development of this indication as well. While we have received no formal direction from the FDA to lower

quinidine dose formulation for DPN pain, we believe it is the most prudent course of action given the current regulatory environment and the FDA's concerns raised over Zenvia in the PBA program.

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 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 for Zenvia for DPN pain to FDA under an SPA. We received the FDA's initial response to the SPA and we are currently engaged in discussions with the FDA regarding the design of the next Phase III study and overall program requirements.

Restructuring Activities

In May 2006, we acquired FazaClo® (clozapine, USP), a product marketed for the management of treatment-resistant schizophrenia and the reduction in the risk of recurrent suicidal behavior in schizophrenia or schizoaffective disorders. We had intended to leverage the FazaClo sales force to assist with the commercial launch of Zenvia for PBA, a launch that was planned for early 2007. However, due to the receipt of the approvable letter and the resulting delay in the planned launch of Zenvia, the strategic rationale for continued marketing of FazaClo by Avanir no longer existed. Therefore, we entered into an agreement in July 2007 to sell FazaClo to Azur Pharma, Inc. ("Azur"). The sale, which closed August 3, 2007, provided $43.9 million in an up-front cash payment. In addition, we are eligible to receive up to $2 million in royalties, based on 3% of annualized net product revenues in excess of $17 million. We are no longer eligible to receive the contingent payment that could have been earned in 2009 due to certain pre-defined regulatory conditions that were not met. Azur acquired the FazaClo sales force and support operations, representing approximately 80 employees in total. As a result of this sale, along with the restructuring and closing of our San Diego facilities, we became a substantially smaller organization.

As a result of these initiatives, we have undergone significant organizational changes since fiscal 2007. Our principal focus is currently on gaining regulatory approval for Zenvia, for the treatment of patients with PBA. We believe that the proceeds from the sale of FazaClo and the proceeds from the April 2008 common stock offering will be sufficient to fund our operations, including our planned confirmatory Phase III trial for Zenvia in patients with PBA, through the anticipated timing of the FDA approval decision in the second half of calendar year 2010 for Zenvia in PBA. For additional information about the risks and uncertainties that may affect our business and prospects, please see "Risk Factors."

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.* 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 Securities and Exchange Commission ("SEC"). No portion of our website is incorporated by reference into this Annual Report on Form 10-K. The public may read and copy the materials we file with the SEC at the SEC's Public Reference Room, located at 100 F Street, NE, Washington, D.C. 20549. The public may obtain information regarding the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The public may also read and copy the materials we file with the SEC by visiting the SEC's website at www.sec.gov.

Drug Candidates and Marketed Products

Zenvia — Pseudobulbar Affect (PBA) Indication

PBA is a complex neurological 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 and/or crying. PBA occurs secondary to neurological diseases such as amyotrophic lateral sclerosis ("ALS"), dementias including Alzheimer's disease ("AD"), multiple sclerosis ("MS"), and Parkinson's disease, as well as neurological 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 likely over one million patients in the U.S. suffering from the symptoms of PBA. In addition, 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 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 New Drug Application ("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 of a single confirmatory Phase III clinical trial of Zenvia for the treatment of patients with PBA. For this trial, we have developed two alternative dosage 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 formulation of Zenvia is expected to improve the safety and tolerability profile while maintaining comparable efficacy to the Zenvia 30/30 dose that was tested in prior Phase III trials. We enrolled our first patient in this trial in December 2007 and we currently expect that top-line data will be available in the third calendar quarter of 2009.

The NDA for Zenvia contains data from two randomized, controlled, multi-center Phase III clinical trials testing the Zenvia 30/30 dose in patients with 1) PBA secondary to ALS and 2) PBA secondary to MS. Zenvia 30/30 demonstrated positive results in both the primary and secondary efficacy endpoints in these two pivotal Phase III clinical trials in patients with PBA. The NDA also included data from an open-label clinical study evaluating the safety of long-term exposure to Zenvia 30/30 in patients with PBA associated with a variety of neurological disorders including ALS, MS, Alzheimer's disease, traumatic brain injury and Parkinson's disease.

The Phase III clinical study of Zenvia 30/30 in the treatment of 140 patients with PBA secondary to ALS was completed in June 2002 (Neurology, 2004; 63:1364-1370). This clinical trial had three treatment arms and compared Zenvia 30/30 to each of its two individual components; dextromethorphan 30 mg and quinidine 30 mg. Results from the Phase III trial in ALS patients with PBA demonstrated statistical significance for Zenvia 30/30 versus the comparators in terms of the change in CNS-LS score, the primary endpoint of the study. Zenvia 30/30 also demonstrated a significant reduction in episodes of laughing and/or crying versus the comparators. Nausea, dizziness and somnolence had a significantly higher incidence in the Zenvia 30/30 group as compared with the DM and Q groups.

The Phase III clinical study of Zenvia 30/30 in the treatment of patients with PBA secondary to MS, was completed in June 2004, (Ann Neurol 2006;59:780-787) and treated 150 patients at 22 clinical sites who were given either placebo or Zenvia 30/30 twice a day for 85 days. A validated scale that measures the severity of these involuntary episodes of inappropriate laughing or crying called "The Center for Neurological Study Lability Scale," or "CNS-LS"), was used to measure the effectiveness of Zenvia in this study. Results from the Phase III trial in MS patients with PBA demonstrated statistical significance for Zenvia 30/30 versus placebo in terms of the change in CNS-LS score, the primary endpoint of the study. Zenvia 30/30 also demonstrated a significant reduction in episodes of laughing and/or crying versus the comparators. The majority of reported adverse events were mild or moderate. Of the adverse events reported in 5% or more of the study participants, only dizziness was seen significantly more for Zenvia-treated patients than in the placebo-treated patients.

Zenvia — Diabetic Peripheral Neuropathic Pain ("DPN pain") Indication

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. 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-dose quinidine 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 we are currently engaged in discussions with the FDA regarding the design of the next Phase III study and overall program requirements.

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.

Macrophage Migration Inhibitory Factor ("MIF") — Inflammation

In April 2005, we entered into an exclusive Research Collaboration and License Agreement with Novartis International Pharmaceutical Ltd. ("Novartis") regarding the license of certain compounds that regulate macrophage migration inhibitory factor ("MIF") in the treatment of various inflammatory diseases. Under the terms of the license agreement, we are eligible to receive up to over $200 million in combined upfront and milestone payments upon achievement of development, regulatory, and sales objectives. We are also eligible to receive escalating royalties on any worldwide product sales generated from this program.

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 future 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®, Resperdal®, Abilify®, Geodon® and others; and
- Miscellaneous agents, including Symmetrel®, Lithium and others.

Zenvia for DPN pain. We anticipate that Zenvia for the treatment of painful diabetic neuropathy, 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 and carbamazepine, 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 December 1, 2008, 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 2019	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 pseudobulbar affect (PBA) and diabetic peripheral neuropathic (DPN) pain, as well as other neurologic conditions. We currently have the corresponding patent application pending within the U.S. Patent and Trademark Office.

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 under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Government Regulations

The FDA and comparable regulatory agencies in foreign countries regulate extensively 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 New Drug Application ("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.

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.

Human Resources

As of December 1, 2008, 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. Our staff includes 3 employees with Ph.D. or M.D. degrees.

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 17, "Segment Information" in the Notes to the Consolidated Financial Statements.

General Information

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 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 and 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. We make available free of charge on or through our Internet website located at www.avanir.com our SEC filings on Forms 10-K, 10-Q and 8-K and any amendments to those filings as soon as reasonably practicable after electronic filing with the SEC.

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

Risks Relating to Our Business

We must conduct additional clinical trials for Zenvia and there can be no assurance that the FDA will approve Zenvia.

In October 2006, we received an "approvable letter" from the FDA for NDA submission for Zenvia in the treatment of patients with PBA. The approvable letter raised certain safety and efficacy concerns and the safety concerns will require additional clinical development to resolve. Based on discussions with the FDA, we were able to successfully resolve the outstanding efficacy concerns of the original dose formulation that was tested in earlier trials. In order to address the safety concerns, however, we agreed to re-formulate Zenvia and conduct one additional confirmatory Phase III clinical trial using lower dose quinidine formulations. The goal of the study is to demonstrate improved safety while maintaining a significant degree of the efficacy seen in our earlier trials testing higher quinidine doses. The study is expected to be completed (with completion defined by top-line safety and efficacy data becoming available) during the third calendar quarter of 2009. It is possible that the efficacy will be so reduced at lower quinidine doses that we will not be able to satisfy the FDA's efficacy requirements, and there can be no assurance that the FDA will approve Zenvia for commercialization.

Even if the confirmatory trial is successful, the additional development work will be costly and time consuming. Because our patents covering Zenvia expire at various times from 2011 through 2019 (up to 2023 in Europe) (without accounting for potential extensions that might be available or new patents that may be issued), any substantial delays in regulatory approval would negatively affect the commercial potential for Zenvia for this indication.

Additionally, although we have a SPA from the FDA for our confirmatory Phase III trial for Zenvia for PBA, there can be no assurance that the terms of the SPA will ultimately be binding on the FDA. An SPA is intended to serve as a binding agreement from the FDA on the adequacy of the design of a planned clinical trial. Even where an SPA has been granted, however, additional data may subsequently become available that causes the FDA to reconsider the previously agreed upon scope of review and the FDA may have subsequent safety or efficacy concerns that override the SPA. For example, it is possible that we will not obtain enough data on cardiac risks in our ongoing Phase III trials to satisfy FDA safety concerns, which could necessitate further clinical trials. Additionally, because we expanded the planned number of patients to be enrolled in the ongoing PBA Phase III trial, the FDA may request other amendments to the trial design that could add to the trial's cost and/or time, as well as degree of

difficulty in reaching clinical endpoints. As a result, even with an SPA, we cannot be certain that the trial results will be found to be adequate to demonstrate the safety and efficacy to product approval.

The FDA's safety concerns regarding Zenvia for the treatment of PBA may extend to other clinical indications that we are pursuing, including DPN pain. Due to these concerns, we expect to develop Zenvia for other indications using alternative doses, which may negatively affect efficacy.

We are currently developing Zenvia for the treatment of DPN pain, for which we have completed a Phase III trial. Although the FDA has not expressly stated that the safety concerns and questions raised in the PBA approvable letter would apply to other indications such as DPN pain, we believe that it is possible that the FDA will raise similar concerns for this indication. Accordingly, we are planning to use a lower dose formulation of quinidine in the next Phase III trial for DPN pain. Although we achieved positive results in our initial Phase III trial, an alternative lower quinidine dose formulation may not yield the same levels of efficacy as seen in the earlier trials or as predicted based on our subsequent PK study. Any drop in efficacy may be so great that the drug does not demonstrate a statistically significant improvement over placebo. Additionally, any alternative lower quinidine dose formulation that we develop may not sufficiently satisfy the FDA's safety concerns. If this were to happen, we may not be able to pursue the development of Zenvia for other indications or may need to undertake significant additional clinical trials, which would be costly and cause potentially substantial delays. There is also a risk that due to the change in dosage levels, the FDA may require two additional Phase III trials for regulatory approval, which would be costly and delay the potential commercial launch of this drug.

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

Even if the FDA approves Zenvia for marketing in one or more indications, any side effects associated with this product candidate could cause the approval to be granted on terms less favorable than those we are seeking. This would in turn limit our ability to enter into licensing, partnering or collaboration arrangements with respect to Zenvia and to commercialize Zenvia and generate revenues from its sale. We are currently conducting additional pre-clinical and clinical safety studies designed to enhance our response to the FDA's approvable letter. We will continue to assess the side-effect profile of Zenvia in our ongoing clinical development program.

If the results of these additional studies show that Zenvia is associated with a significant risk of cardiac side effects, or we or others later identify undesirable side effects caused by the product, we could face one or more of the following:

- 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;
- we may be required to change the way the product is administered, monitor patients taking Zenvia, conduct additional clinical trials or change the labeling of the product; and
- Zenvia may not be approved for commercialization.

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 costs and expenses 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 $256 million as of September 30, 2008, and we expect to continue to incur substantial operating losses for the foreseeable future. As of September 30, 2008, we had approximately $42.2 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.

In light of our current capital resources, lack of near-term revenue opportunities and substantial long-term capital needs, we will need to raise additional capital in the future to finance our long-term operations until we

expect to be able to generate meaningful amounts of revenue from product sales. Based on our current loss rate and existing capital resources as of the date of this filing, we estimate that we have sufficient funds to sustain our operations at their current levels through the anticipated timing of the FDA approval decision for Zenvia in PBA in the second half of calendar year 2010, assuming that our trials are completed on our projected timelines. 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 shareholders and diminish certain commercial prospects.

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

We 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 drug development programs, including FazaClo, macrophage migration inhibitory factor ("MIF"), our anthrax antibody program, and other antibodies in our infectious disease program, as well as docosanol in major markets worldwide. We may also out-license or otherwise partner Zenvia for PBA and/or the DPN pain indications if we are able to find a licensee or partner on acceptable terms. 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 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. Such patents and patent

applications cover Zenvia, docosanol 10% cream and other potential drug candidates. 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 preserve our intellectual property rights, third parties, including other biotechnology or pharmaceutical companies, may allege that our technology infringes on their rights. Intellectual property litigation is costly, and even if we were to prevail in such a dispute, the cost of litigation could adversely affect our business, financial condition, and results of operations. Litigation is also time-consuming and would divert management's attention and resources away from our operations and other activities. If we were to lose any litigation, in addition to any damages we would have to pay, we could be required to stop the infringing activity or obtain a license. Any required license might not be available to us on acceptable terms, or at all. Some licenses might be non-exclusive, and our competitors could have access to the same technology licensed to us. If we were to fail to obtain a required license or were unable to design around a competitor's patent, we would be unable to sell or continue to develop some of our products, which would have a material adverse effect on our business, financial condition and results of operations.

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

Our PBA related patents for Zenvia in the U.S. expire at various times from 2011 through 2012 and our DPN pain patent for Zenvia expires in 2016 (we have longer patent protection for Zenvia in certain European markets). Depending upon the timing, duration and specifics of FDA approval, if any, of the use 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 approved products, it is uncertain whether Zenvia will be granted any patent term restoration under the U.S. Patent and Trademark Office guidelines. In addition, the patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years after the product's approval date.

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

Once the three-year FDCA exclusivity period has passed and after the patents (including the patent restoration term, if any) that cover Zenvia expire, generic drug companies would be able to introduce competing versions of the drug. Although we have filed additional new patents for Zenvia, there can be no assurance that these patents will issue or that any patents will have claims that are broad enough to prevent generic competition. If we are

unsuccessful in strengthening our patent portfolio on a timely basis to secure sufficient protection against generic competition, our long-term revenues from Zenvia sales may be less than expected.

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 has encountered significant difficulty in seeking approval of docosanol in that country and we may be 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, accounting and finance. Because we have a relatively small organization, the loss of any executive officers or other key employees could adversely affect our operations. For example, if we were to lose one or more of the senior members of our clinical and regulatory affairs team, the pace of clinical development for Zenvia could be slowed significantly. We have experienced employee turnover and the loss of key employees could adversely affect our business and cause significant disruption in our operations.

Risks Relating to Our Industry

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

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, such as the ongoing Phase III confirmatory trial for Zenvia for PBA, 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 statistically significant or 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; and
- the cost of our clinical trials may be greater than we currently anticipate.

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

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

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

- delays in our ability to submit an NDA;
- the refusal by the FDA to accept for file any NDA we may submit;
- requests for additional studies or data;
- delays of an approval;
- the rejection of an application; or
- the approval of the drug, but with adverse labeling claims that could adversely affect the commercial market.

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.

Clinical trials can be delayed for a variety of reasons. If we experience any such delays, we would be unable to commercialize our product candidates on a timely basis, which would materially harm our business.

Clinical trials may not begin on time or may need to be restructured after they have begun. Additionally, clinical trials can experience delays for a variety of other reasons, including delays related to:

- identifying and engaging a sufficient number of clinical trial sites;
- negotiating acceptable clinical trial agreement terms with prospective trial sites;
- obtaining institutional review board approval to conduct a clinical trial at a prospective site;
- recruiting eligible subjects to participate in clinical trials;
- competition in recruiting clinical investigators or patients, particularly if others are pursuing trials at the same time in the same patient population (whether or not for the same indication);
- shortage or lack of availability of supplies of drugs for clinical trials;
- the need to repeat clinical trials as a result of inconclusive results or poorly executed testing;
- the placement of a clinical hold on a study;
- the failure of third parties conducting and overseeing the operations of our clinical trials to perform their contractual or regulatory obligations in a timely fashion; and
- exposure of clinical trial subjects to unexpected and unacceptable health risks or noncompliance with regulatory requirements, which may result in suspension of the trial.

If we experience significant delays in or termination of clinical trials, our financial results and the commercial prospects for our product candidates or any other products that we may develop will be adversely impacted. In addition, our product development costs would increase and our ability to generate revenue could be impaired.

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

The pharmaceutical and biotechnology industries are highly competitive and subject to significant and rapid technological change. We compete with hundreds of companies that develop and market products and technologies in similar areas as our research. For example, 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.

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 staffs and substantially greater experience than we do. Accordingly, our competitors may successfully develop competing products. We are also competing with other companies and their products with respect to manufacturing efficiencies and marketing capabilities, areas where we have limited or no direct experience.

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

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

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

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

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

The testing, marketing and sale of pharmaceutical products involves the risk of product liability claims by consumers and other third parties. Although we maintain product liability insurance coverage, product liability claims can be high in the pharmaceutical industry and our insurance may not sufficiently cover our actual liabilities. If product liability claims were made against us, it is possible that our insurance carriers may deny, or attempt to deny, coverage in certain instances. If a lawsuit against us is successful, then the lack or insufficiency of insurance coverage could affect materially and adversely our business and financial condition. Furthermore, various distributors of pharmaceutical products require minimum product liability insurance coverage before their purchase or acceptance of products for distribution. Failure to satisfy these insurance requirements could impede our ability to achieve broad distribution of our proposed products and the imposition of higher insurance requirements could impose additional costs on us. Additionally, we are potentially at risk if our insurance carriers become insolvent. Although we have historically obtained coverage through well rated and capitalized firms, the ongoing financial crisis may affect our ability to obtain coverage under existing policies or purchase insurance under new policies at reasonable rates.

Risks Related to Reliance on Third Parties

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

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

We depend on third parties to manufacture, package and distribute compounds for our drugs and drug candidates. The failure of these third parties to perform successfully could harm our business.

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

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

Under our license arrangement for our MIF compound, we have no direct control over the development of this drug candidate and have only limited, if any, input on the direction of development efforts. These development efforts are ongoing by our licensing partner and if the results of their development efforts are negative or inconclusive, it is possible that our licensing partner could elect to defer or abandon further development of these programs, as was the case in early 2007 when AstraZeneca terminated our license and collaboration agreement. 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.

We expect to rely entirely on third parties for international 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 common stock could be delisted from The NASDAQ Global Market, which could negatively impact the price of our common stock and our ability to access the capital markets.

Our common stock is currently listed on The NASDAQ Global Market. The listing standards of The NASDAQ Global Market provide, among other things, that a company may be delisted if the bid price of its stock drops below $1.00 for a period of 30 consecutive business days. On August 13, 2008, we received a staff determination letter from NASDAQ indicating that we failed to comply with the $1.00 minimum bid price requirement for continued listing. We were given an initial cure period of 180 calendar days, or until February 9, 2009, to regain compliance by having the bid price of our common stock close at $1.00 per share or more for a minimum of 10 consecutive business days. In October 2008, the NASDAQ Stock Market suspended enforcement of the $1.00 minimum bid requirement due to the rapid deterioration of the capital markets through January 16, 2009. As a result, we believe we have until May 18, 2009 to regain the compliance with the minimum bid price requirement.

If we fail to comply with the listing standards, our common stock listing may be moved to the NASDAQ Capital Market, which is a lower tier market, or our common stock may be delisted and traded on the over-the-counter bulletin board network. Moving our listing to the NASDAQ Capital Market could adversely affect the liquidity of our common stock and the delisting of our common stock would significantly affect the ability of investors to trade our securities and could significantly negatively affect the value of our common stock. In addition, the delisting of our common stock could further depress our stock price and materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Delisting from NASDAQ could also have other negative results, including the potential loss of confidence by suppliers and employees, the loss of institutional investor interest and fewer business development opportunities.

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

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

- Announcements by us regarding our non-compliance with continued listing standards on the NASDAQ stock market;
- Comments made by securities analysts, including changes in their recommendations;
- Short selling activity by certain investors, including any failures to timely settle short sale transactions;
- Announcements by us of financing transactions and/or future sales of equity or debt securities;
- Sales of our common stock by our directors, officers, or significant shareholders;
- Announcements by our competitors of clinical trial results or product approvals; and
- Market and economic conditions.

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 our partnering arrangements for our MIF technology, which has been licensed to a third party that controls the continued progress and pace of development, meaning that the achievement of development milestones is outside of our control.

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

shareholder 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.

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 September 2009 and January 2013 for approximately 9,000 and 21,000 square feet of space respectively.

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 2008.

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.

	Class A Common Stock Price			
	Fiscal 2008		Fiscal 2007	
	High	Low	High	Low
First Quarter	$2.84	$1.25	$8.95	$2.27
Second Quarter	$1.43	$0.94	$2.52	$1.09
Third Quarter	$1.35	$1.00	$5.19	$1.19
Fourth Quarter	$1.04	$0.40	$2.70	$1.68

On December 1, 2008, the closing sales price of Common Stock was $0.28 per share. Our common stock is currently listed on The NASDAQ Global Market. The listing standards of The NASDAQ Global Market provide, among other things, that a company may be delisted if the bid price of its stock drops below $1.00 for a period of 30 consecutive business days. On August 13, 2008, we received a staff determination letter from NASDAQ indicating that we failed to comply with the $1.00 minimum bid price requirement for continued listing. We were given an initial cure period of 180 calendar days, or until February 9, 2009, to regain compliance by having the bid price of our common stock close at $1.00 per share or more for a minimum of 10 consecutive business days. In October 2008, the NASDAQ Stock Market suspended enforcement of the $1.00 minimum bid requirement due to the rapid deterioration of the capital markets through January 16, 2009. As a result, we believe we have until May 18, 2009 to regain the compliance with the minimum bid price requirement.

As of December 1, 2008, we had approximately 21,996 shareholders, including 927 holders of record and an estimated 21,069 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 Consolidated 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 under the caption, "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 years ended September 30, 2008 and 2007. 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 developing, acquiring and commercializing novel therapeutic products for the treatment of chronic diseases. Our product candidates address therapeutic markets that include the central nervous system and inflammatory diseases. Our lead product candidate, Zenvia™ (dextromethorphan hydrobromide/quinidine sulfate), is currently in Phase III clinical development for the treatment of pseudobulbar affect ("PBA") and diabetic peripheral neuropathic pain ("DPN pain"). Our first commercialized product, docosanol 10% cream, (sold as Abreva® by our marketing partner GSK Consumer Healthcare in North America) is the only over-the-counter treatment for cold sores that has been approved by the FDA. Our inflammatory disease program, which targets macrophage migration inhibitory factor ("MIF"), is currently partnered with Novartis. Our infectious disease program has historically been focused primarily on monoclonal antibodies. In 2008, we sold our rights to substantially all of these antibodies to two biotechnology companies. As of June 30, 2008, we ceased all future research and development work related to our infectious disease program and remain eligible to receive additional milestone payments and royalties related to the program.

The following is a summary of significant accomplishments in fiscal 2008 and subsequent to the end of fiscal 2008 through the date of this filing that have materially affected our operations, financial condition and prospects:

- In October 2007, we reached a definitive agreement with the FDA, under the SPA process, on the design of a single confirmatory Phase III clinical trial of Zenvia for PBA. Based on discussions with the FDA, we were able to successfully resolve the outstanding efficacy concern of the original dose formulation. However, in order to address 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 the study is to demonstrate improved safety while maintaining significant efficacy. This study is expected to be completed (as defined as top-line safety and efficacy data becomes available) during the third calendar quarter of calendar 2009.

- In December 2007, we enrolled the first PBA patient into our confirmatory Phase III clinical trial of Zenvia for PBA, only 8 weeks after receiving notification of the SPA approval from the FDA.
- In April 2008, we closed a registered securities offering raising approximately $40 million in gross proceeds from a select group of institutional investors led by ProQuest Investments and joined by Clarus Ventures, Vivo Ventures, and OrbiMed Advisors. The proceeds from this offering are expected to allow us to fund our operations through the date by which we expect to receive an approval decision from the FDA for Zenvia for the PBA indication.
- In May 2008, we reported that we were exceeding our early STAR Trial patient enrollment goals and that we would expand the trial size to increase the statistical power and size of the safety database without jeopardizing our initial timelines.
- In May 2008, we reported a positive outcome of our large, formal pharmacokinetic study that identified two new doses of Zenvia that we expect will provide enhanced safety with similar efficacy in the next Phase III DPN pain study compared to the previously tested doses.
- In June 2008, we obtained a new patent for Zenvia that significantly extends its period of commercial exclusivity in Europe into 2023.
- In June 2008, we reported that we successfully negotiated a 9.25% discount in exchange for prepaying our $12 million in notes payable 11 months early. This represented a savings of approximately $1.2 million to the two year operating plan and resulted in a third quarter gain on extinguishment of debt in the amount of $968,000.
- In August 2008, we achieved 50% enrollment of the targeted number of PBA patients in the STAR Trial.
- In September 2008, we submitted our Phase III protocol and related questions for Zenvia for DPN pain to the FDA under an SPA. We received the FDA's initial response to the SPA and we are currently engaged in discussions with the FDA regarding the design of the next Phase III study and overall program requirements.
- During 2008, we successfully negotiated two separate license agreements for assets derived from the Xenerex program resulting in incremental revenue to the Company.
- In December 2008, we achieved over 75% enrollment of the targeted number of PBA patients in the STAR Trial.

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, including being flexible and being able to rapidly respond to program delays or successes far outweigh the higher costs often associated with outsourcing.

We intend to continue to seek partnerships with pharmaceutical companies to help fund research and development programs and to commercialize any approved products in exchange for sharing in the rights to commercialize new drugs. Trends in revenues and various types of expenses are discussed further in the "Results of Operations."

Our principal focus is currently on gaining regulatory approval for Zenvia for PBA. We expect that the proceeds from our sale of FazaClo combined with the proceeds from the April 2008 common stock offering will be sufficient to fund our operations, including our planned confirmatory Phase III trial for Zenvia for PBA, 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 "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 and sales deductions for estimated chargebacks, rebates, sales incentives and allowances, certain royalties and returns and losses. Significant estimates and assumptions are also required in the appropriateness of capitalization and amortization periods for identifiable intangible assets, inventories, the potential impairment of goodwill and other intangible assets, income taxes, contingencies, estimate on net working capital adjustment and stock-based compensation. We base our estimates on historical experience and various other assumptions, available at that time, 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 expense

We grant options 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 subject to the provisions of revised Statement of Financial Accounting Standards ("FAS") No. 123, "*Share-Based Payment*" ("FAS 123R"), including the provisions of the SEC's Staff Accounting Bulletin ("SAB") No. 107 ("SAB 107"), that require the fair value method to account for share-based payments.

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%. FAS 123R 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 pre-vesting forfeitures based on our historical experience.

If factors change and we employ different assumptions in the application of FAS 123R in future periods, the compensation expense that we record under FAS 123R 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 under FAS 123R. 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 in accordance with FAS 123R and SAB 107 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 FAS 123R and SAB 107 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.

Revenue Recognition

General. We recognize revenue in accordance with the SEC's Staff Accounting Bulletin Topic 13 ("Topic 13"), "*Revenue Recognition*." Revenue is recognized 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 seller's price to the buyer is fixed and determinable; and (4) collectibility is reasonably assured.

Certain product sales are subject to rights of return. For these products, our revenue recognition policy is consistent with the requirements of Statement of FAS No. 48, "*Revenue Recognition When Right of Return Exists*" ("FAS 48"). FAS 48 states that revenue from sales transactions where the buyer has the right to return the product shall be recognized at the time of sale only if several criteria are met, including that the seller be able to reasonably estimate future returns.

Certain revenue transactions include multiple deliverables. We allocate revenue to separate elements in multiple element arrangements based on the guidance in Emerging Issues Task Force No. 00-21 ("EITF 00-21"), "*Accounting for Revenue Arrangements with Multiple Deliverables*." Revenue is allocated to a delivered product or service when all of the following criteria are met: (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. We use the relative fair values of the separate deliverables to allocate revenue.

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. In accordance with EITF 00-21, 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.

When a delivered product or service (or group of delivered products or services) meets the criteria for separation in EITF 00-21, 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.

Research and Development Services. Revenue from research and development 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 in accordance with EITF Issue No. 99-19, "*Reporting Revenue Gross as a Principal versus Net as an Agent,*" 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.

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 costs of unsaleable returns, managed care chargebacks, cash discounts, freight and 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.

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 in SAB Topic 13 are met. We sell the API Docosanol to various licensees upon receipt of a written order for the materials. Shipments generally occur fewer than five 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, and to provide research and development services. Amortization of acquired FazaClo product rights is classified within loss from discontinued operations.

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. A 3% variance in our estimate of the work completed in our largest contract could increase or decrease our 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 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.

Capitalization and Valuation of Long-Lived and Intangible Assets

In accordance with FAS No. 142, "*Goodwill and Other Intangible Assets*" ("FAS 142"), intangible assets determined to have an indefinite useful life are not amortized, but instead are tested for impairment on an annual basis or more frequently if certain indicators arise. Intangible assets are evaluated in the fourth quarter of each fiscal year.

Intangible assets with finite useful lives are amortized over their respective useful lives and reviewed for impairment in accordance with Statement of Financial Accounting Standards No. 144, "*Accounting for the Impairment or Disposal of Long-Lived Assets*" ("FAS 144".) The method of amortization shall reflect the pattern in which the economic benefits of the intangible asset are consumed or otherwise used up. If that pattern cannot be

reliably determined, a straight- line amortization method will be used. Intangible assets with finite useful lives include trade name and license agreements, which are being amortized over their estimated useful lives ranging from one to 15.5 years.

In accordance with FAS 144, intangible assets and other long-lived assets, except for goodwill, are evaluated for impairment whenever events or changes in circumstances indicate that their carrying value may not be recoverable. If the review indicates that intangible assets or 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.

Restructuring Expense

We record costs and liabilities associated with exit and disposal activities, as defined in FAS No. 146, "*Accounting for Costs Associated with Exit or Disposal Activities*" ("FAS 146"), 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 years 2008 and 2007, we recorded costs and liabilities for exit and disposal activities related to a relocation plan, including a decision to discontinue occupying certain leased office and laboratory facilities, in accordance with FAS 146. The liability is evaluated and adjusted as appropriate on at least a quarterly basis for changes in circumstances. Please refer to Note 4, "Relocation of Commercial and General and Administrative Operations" in the Notes to Consolidated Financial Statements for further information.

Critical Accounting Policies and Estimates for Discontinued Operations

Revenue Recognition

Product Sales — FazaClo. As discussed previously in this filing and also in Note 3, "Acquisition of Alamo Pharmaceuticals, Inc. / Sale of FazaClo" in the Notes to Consolidated Financial Statements, we acquired Alamo Pharmaceuticals LLC ("Alamo") on May 24, 2006, with one marketed product, FazaClo (clozapine, USP), that began shipping to wholesale customers in July 2004. In August 2007, we sold our product rights to FazaClo to Azur Pharma, Inc. As a result of our sale of FazaClo near the end of fiscal 2007, we have reflected all FazaClo-related revenue and expenses as discontinued operations for all periods presented.

During fiscal 2007, we sold FazaClo to pharmaceutical wholesalers, the three largest of which accounted for approximately 84% of our net wholesale shipments for the fiscal year ended 2007. They resold our product to outlets such as pharmacies, hospitals and other dispensing organizations. We had agreements with our wholesale customers, various states, hospitals, certain other medical institutions and third-party payers throughout the U.S. These agreements frequently contain commercial incentives, which may have included pricing allowances and discounts payable at the time the product was sold to the dispensing outlet or upon dispensing the product to patients. Consistent with pharmaceutical industry practice, wholesale customers can return purchased product during an 18-month period that begins six months prior to the product's expiration date and ends 12 months after the expiration date. Additionally, several of our dispensing outlets have the right to return expired product at any time. Once products have been dispensed to patients, the right of return expires.

Beginning in the first quarter of fiscal 2007, we obtained third-party information regarding certain wholesaler inventory levels, a sample of outlet inventory levels and third-party market research data regarding FazaClo sales. The third-party data includes, (i) IMS Health Audit — National Sales Perspective reports ("NSP"), which is a projection of near-census data of wholesaler shipments of product to all outlet types, including retail and non-retail and; (ii) IMS Health National Prescription Audit ("NPA") Syndicated data, which captures end-user consumption from retail-dispensed prescriptions based upon projected data from pharmacies estimated to represent

approximately 60% to 70% of the U.S. prescription universe. Further, we analyzed historical rebates and chargebacks earned by State Medicaid, Medicare Part D and managed care customers. Based upon this additional information and analysis obtained, we estimated the amount of product that was shipped that was no longer in the wholesale or outlet channels, and hence no longer subject to a right of return. Therefore, we began recognizing revenues, net of returns, chargebacks, rebates, and discounts, in the first quarter of fiscal 2007, for product that we estimated had been sold to patients and that was no longer subject to a right of return.

FazaClo product revenues were recorded net of provisions for estimated product pricing allowances including: State Medicaid base and supplemental rebates, Medicare Part D discounts, managed care contract discounts and prompt payment discounts were at an aggregate rate of approximately 25.8% of gross revenues for the fiscal year ended September 30, 2007. Provisions for these allowances are estimated based upon contractual terms and require management to make estimates regarding customer mix to reach. We considered our current contractual rates with States related to Medicaid base and supplemental rebates, with private organizations for Medicare Part D discounts and contracts with managed care organizations. We review these rates at least quarterly and make adjustments, if necessary.

Nature of Operating Expenses

In fiscal 2008, our operating expenses consisted mainly of our Phase III clinical trial expenses and general and administrative expenses such as finance, human resources and facilities. In fiscal 2007, our operating expenses consisted primarily of research costs that were funded by our partners, development costs for our infectious disease program, which was partially funded by a government grant, Zenvia clinical development expenses and general and administrative expenses. In fiscal 2008, our operating expenses consisted mainly of our Phase III clinical trial expenses and general and administrative expenses such as finance, human resources and facilities.

Our business is exposed to significant risks, as discussed in the section entitled “Risk Factors,” which may result in additional expenses, delays and lost opportunities that could have a material adverse effect on our results of operations and financial condition.

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) research and development, 2) government research grant, 3) licensing, 4) royalties and royalty rights and 5) product sales. All long-lived assets for fiscal 2008 and 2007 are located in the United States.

Comparision of Fiscal 2008 and 2007

Revenues and Cost of Revenues

	Year Ended September 30, 2008	2007	$ Change	% Change
PRODUCT SALES				
Net revenues	$ 129,820	$ 72,000	$ 57,820	80%
Cost of revenues	21,714	328,184	(306,470)	−93%
Product gross margin (deficit)	108,106	(256,184)	364,290	−142%
REVENUES AND COST OF RESEARCH SERVICES AND OTHER				
Revenues:				
Revenue from royalties and royalty rights	$3,616,102	$4,251,252	$ (635,150)	−15%
Revenues from license agreements	2,205,724	1,614,091	591,633	37%
Revenues from government research grant services	1,006,922	914,834	92,088	10%
Revenues from research and development services	—	2,372,384	(2,372,384)	−100%
Revenues from research services and other	6,828,748	9,152,561	(2,323,813)	−25%
Costs:				
Cost of research and development services	249,281	2,994,905	(2,745,624)	−92%
Cost of government research grant	940,130	1,324,427	(384,297)	−29%
Costs from research services and grants	1,189,411	4,319,332	(3,129,921)	−72%
Research services and other gross margin	5,639,337	4,833,229	806,108	17%
Total gross margin	$5,747,443	$4,577,045	$ 1,170,398	26%

Revenues

Net product revenues were $130,000 and $72,000 for the fiscal years ended September 30, 2008 and 2007, respectively. Product revenues are generated from the sale of the active pharmaceutical ingredient docosanol.

Revenues from licenses, research services and grants declined to $6.8 million for the fiscal year ended September 30, 2008 compared to $9.2 million for the fiscal year ended September 30, 2007. This decline was principally due to a decrease in research revenues of $2.4 million related to our research agreements with AstraZeneca and Novartis, both of which are no longer active. Revenue from license agreements increased by $592,000 primarily due to the sale of our anthrax antibody rights to Emergent Biosolutions. Revenue from royalties decreased by $635,000 primarily from the recognition of previously deferred revenue of $1.4 million from HBI for an upfront license fee in 2007. The decrease in fees from HBI was partially offset by an increase of $884,000 in royalties from GSK, resulting from the receipt of $934,000 related to U.S. and Canada Abreva sales in excess of $62 million, compared with $214,000 in fiscal 2007. See Note 14 “Research, License and Supply Agreements” and Note 17 “Segment Information” in Notes to Consolidated Financial Statements.

Cost of Revenues

Cost of product revenues was $22,000 and $328,000 for the fiscal years ended September 30, 2008 and 2007, respectively. The cost of product revenues in fiscal year ended September 30, 2007 includes a $260,000 write off of obsolete inventory in the second quarter of 2007.

Cost of licenses, research services and grants for fiscal year ended September 30, 2008 declined to $1.2 million or 17% of revenues compared with $4.3 million or 47% of revenues for the fiscal year ended September 30, 2007.

The decline is primarily attributed to the research portion of our license agreements with AstraZeneca and Novartis, both of which are no longer active. In addition, costs associated with the government funded anthrax antibody program decreased as compared to the prior fiscal year as the program was terminated following the sale of the anthrax antibody rights in June 2008. The cost of licenses, research services and grants includes primarily direct and indirect payroll costs and the costs of outside vendors.

	Year Ended September 30,			
	2008	2007	$ Change	% Change
OPERATING EXPENSES				
Research and development	$14,110,743	$13,115,712	$ 995,031	8%
General and administrative	10,599,158	20,830,188	(10,231,030)	−49%
Total Operating Expenses	$24,709,901	$33,945,900	$ (9,235,999)	−27%

Research and Development Expenses

Research and development expenses increased $995,000 or 8% for the fiscal year ended September 30, 2008 compared to the fiscal year ended September 30, 2007. The increase is primarily due to costs incurred for the Phase III trial for Zenvia for PBA which commenced in the first quarter of fiscal 2008. In fiscal 2009, we expect that our research and development costs will consist mainly of expenses related to this Phase III trial.

General and Administrative Expenses

General and administrative expenses decreased $10.2 million, or 49% for the fiscal year ended September 30, 2008, compared to the fiscal year ended September 30, 2007. The decrease resulted primarily from expenses incurred in the first quarter of fiscal 2007 in preparation for commercial readiness for the launch of Zenvia which were not repeated in fiscal 2008. In addition, the decrease is also attributed to a decrease in overall general and administrative expenses as a result of the restructuring and significant organizational changes that we made to our infrastructure in the last half of fiscal 2007.

Share-Based Compensation

Total compensation expense for our share-based payments in the fiscal year ended September 30, 2008 and 2007 was $1.6 million (excluding $14,000 included in discontinued operations) and $2.2 million (excluding $508,000 included in discontinued operations), respectively. General and administrative expense in the fiscal years ended September 30, 2008 and 2007 includes share-based compensation expense of $1.1 million and $1.9 million, respectively. Research and development expense in the fiscal year ended September 30, 2008 and 2007 includes share-based compensation expense of $491,000 and $365,000, respectively. As of September 30, 2008, $5.1 million of total unrecognized compensation costs related to unvested awards is expected to be recognized over a weighted average period of 2.6 years. See Note 2, “Summary of Significant Accounting Policies” in the Notes to Consolidated Financial Statements for further discussion.

Interest Expense and Interest Income

For the fiscal year ended September 30, 2008, interest expense decreased to $541,000, compared to $1.2 million for the prior fiscal year. The decrease in interest expense in 2008 is primarily due to a decrease in the balance on the Notes in fiscal 2008 as compared to the prior year principally due to the $11 million payment made in the fourth quarter of 2007. In June 2008, we accelerated payment on the outstanding principal of the Notes in exchange for a discount of approximately $968,000. In addition, the interest rate applied to the notes decreased by 1% in fiscal 2008 compared to fiscal 2007.

For the fiscal year ended September 30, 2008, interest income increased to $1.3 million, compared to $623,000 for the prior fiscal year. The increase is due to approximately a 103% increase in the average balance of cash, cash equivalents and investments in securities for fiscal 2008 compared to the prior year due to the receipt of net proceeds of $37.8 million from the issuance of common stock, primarily from our April 2008 registered offering.

Income/(Loss) from Discontinued Operations

For the fiscal year ended September 30, 2008, loss from discontinued operations was $1.6 million, compared to income of $7.4 million for the fiscal year ended September 30, 2007. The loss recognized in fiscal 2008 is attributed to the final net working capital adjustment of $1.4 million under our Fazaclo sale agreement with Azur, as well as additional trailing costs related to the operations of FazaClo.

For the fiscal year ended September 30, 2007, we sold our operations of the FazaClo business, recognizing a gain of $12.2 million upon sale, offset by operating losses of $4.8 million through the date of sale.

Net Loss

Net loss was $17.5 million, or $0.30 per share, for the fiscal year ended September 30, 2008, compared to a net loss of $20.9 million, or $0.53 per share for the fiscal year ended September 30, 2007. The decrease in net loss is primarily attributed to decreased operating expenses totaling $9.3 million, primarily due to decreased spending in general and administrative functions totaling $10.3 million. In addition, we recognized a gain on early extinguishment of debt and other income together totaling $2.2 million.

Liquidity and Capital Resources

We assess our liquidity by 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 accounts receivable, inventories, accounts payable and capital expenditures; the timing and extent of cash received from milestone payments under license agreements; funds required for acquisitions; funds required to repay notes payable and capital lease obligations as they become due; 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 investments, as well as, net cash provided by or used for operating, investing and financing activities, are summarized in the table below.

	September 30, 2008	Increase (Decrease) During Period	September 30, 2007
Cash, cash equivalents and investments in securities	$42,240,527	$ 8,599,129	$33,641,398
Cash and cash equivalents	$41,383,930	$10,895,968	$30,487,962
Net working capital	$37,171,636	$ 7,834,860	$29,336,776

	Year Ended September 30, 2008	Change Between Periods	Year Ended September 30, 2007
Net cash used in operating activities	$(16,678,209)	$ 29,966,225	$(46,644,434)
Net cash provided by investing activities	1,028,991	(58,540,319)	59,569,310
Net cash provided by financing activities	26,545,186	13,880,314	12,664,872
Net increase in cash and cash equivalents	$ 10,895,968	$(14,693,780)	$ 25,589,748

Operating activities. Net cash used in operating activities was $16.7 million in the fiscal year 2008 compared to $46.6 million in the fiscal year 2007. The decrease in cash used in operating activities resulted from our overall reduction in operating costs due to the restructuring and significant organizational changes implemented in fiscal 2007. These changes resulted in a significant decrease in spending in fiscal 2008 as demonstrated in the $3.4 million decrease in net loss coupled with a $13.5 million decrease in cash used for accounts payable and accrued expenses.

Investing activities. Net cash provided by investing activities was $1.0 million in the fiscal year 2008, compared to $59.6 million in the fiscal year 2007. The decrease in cash provided by investing activities is primarily related to the fiscal 2007 sale of FazaClo which provided $42.1 million in cash from investment activities in fiscal 2007. In addition, proceeds from the sale of investment securities provided $16.9 million in fiscal 2007 compared to $2.3 million in fiscal 2008.

Financing activities. Net cash provided by financing activities was $26.5 million in fiscal year 2008, consisting of $37.8 million in net proceeds from sales of our common stock offset by $11.3 million to reduce long-term debt. Net cash provided by financing activities amounted to $12.7 million in fiscal 2007, consisting of $30.9 million in net proceeds from sales of our common stock offset by $6.8 million to reduce long-term debt and $11.4 million net cash used in financing activities of discontinued operations in 2007. The increase in net cash provided by financing activities is primarily related to approximately $40.0 million of gross proceeds received from the sale of our common stock through a registered common stock offering in April 2008 (before commissions and offering costs) as compared to private placements totaling approximately $30.9 million in fiscal 2007. The increase is offset by an increase in debt payments of $4.5 million.

In April 2008, we closed a registered securities offering raising $40 million in gross proceeds (approximately $38 million net of offering costs and commissions) 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, we issued approximately 35 million shares of common stock at a price of $1.14 per share. We also issued warrants to purchase up to approximately 12.2 million shares of common stock at a price of $1.43 per share. These warrants have a 5 year term. The proceeds from this offering are expected to provide us with adequate capital to allow continuing operations through the date by which we expect to receive an approval decision from the FDA for Zenvia for the PBA indication.

As of September 30, 2008, 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	More than 5 Years
Long-term debt	$ 25,744	$ 25,744	$ —	$ —	$—
Operating lease obligations(1)	6,062,762	1,475,111	3,013,444	1,574,207	—
Purchase obligations(2)	1,280,216	1,280,216	—	—	—
Total	$7,368,722	$2,781,071	$3,013,444	$1,574,207	$—

(1) Operating lease obligations are exclusive of payments we expect to receive under subleases totaling $3.3 million, $1.0 million in less than 1 year, $1.4 million in 1-3 years and $0.9 million in 3-5 years.

(2) Purchase obligations consist of the total of trade accounts payable and trade related accrued expenses at September 30, 2008 which approximates our contractual commitments for goods and services in the normal course of our business.

As part of the purchase consideration of the Alamo acquisition, we initially issued three promissory notes in the principal amounts of $14,400,000, $6,675,000 and $4,000,000, (collectively, the "initial promissory Notes") . The initial promissory Notes were to mature on May 24, 2009. In connection with the equity offering we completed in fiscal year 2007, we used approximately $6.1 million to partially pay down the Notes. In connection with our sale of FazaClo in August 2007, we agreed to prepay $11 million of outstanding principal due under the Notes.

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"). Based on the results of the quarters ended March 31, 2007 and June 30, 2007, we issued the first and second of these revenue-based payments through the issuance of additional promissory notes in the principal amount of $2,000,000 per note (collectively, the "subsequent promissory Notes"). As previously discussed in this filing, we sold the FazaClo product line to Azur Pharma 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 Pharma, although we may remain liable for these payments if Azur defaults on these obligations.

In June 2008, the Company accelerated the repayment of the remaining outstanding principal under the initial and subsequent promissory Notes, which was then $12.0 million. In exchange for the early repayment of Notes, we negotiated for a repayment discount of $968,000 (net of unamortized origination discount of $140,000), which

resulted in the full repayment of the Notes for a total sum of approximately $10.9 million. 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.

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 both indications, 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. In fiscal 2005, we paid $75,000 to CNS under the CNS license agreement, and will need to pay a $75,000 milestone if the FDA approves our NDA for Zenvia for the treatment of PBA. In addition, we are 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, we may have the obligation to pay CNS a portion of net revenues received if we sublicense Zenvia to a third party.

Under our agreement with CNS, we are 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 we pursued the development of Zenvia for all of the licensed indications. Of the clinical indications that we currently plan 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, we are obligated to pay CNS a royalty ranging from approximately 5% to 8% of net revenues.

Management Outlook

Following the completion of our $40 million common stock offering, in April 2008, we believe that cash and investments in securities of approximately $42.2 million at September 30, 2008 will be sufficient to sustain our planned level of operations through the clinical development of Zenvia and 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 "Risk Factors."

Recent Accounting Pronouncements

See Note 2, "Summary of Significant Accounting Policies" in the Notes to Consolidated Financial Statements for a discussion of recent accounting pronouncements and their 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 fixed income instruments with an average duration of approximately 9-12 months as of September 30, 2008 (14 months as of September 30, 2007). The primary objective of our investments in debt securities is to preserve principal while achieving attractive yields, without

significantly increasing risk. We classify our restricted investments in securities as of September 30, 2008 as held-to-maturity. These held-to-maturity securities are subject to interest rate risk. In general, we would expect that the volatility of this portfolio would decrease as its duration decreases. Based on the average duration of our investments as of September 30, 2008 and 2007, an increase of one percentage point in the interest rates would have resulted in increases in comprehensive losses of approximately $409,000 and $280,000, respectively.

As of September 30, 2008, $36.6 million of our cash and cash equivalents were maintained in three separate money market mutual funds, and $4.8 million of our cash and cash equivalents were maintained at a major financial institution 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, 2008, such uninsured deposits totaled $22 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.

Effective September 19, 2008, the U.S. Treasury commenced its Temporary Guarantee Program for Money Market Mutual Funds. This program, which is offered to all money market mutual funds that are regulated under Rule 2A-7 of the Investment Company Act of 1940, guarantees the share price of any publicly offered eligible money market fund that applies for and pays a fee to participate in the program. As of September 30, 2008, two of the money market mutual funds which we had invested in, which had aggregate balances of approximately 51% of our cash and cash equivalents, were participating in the U.S. Treasury program. The current termination date for this program is April 30, 2009.

Financial instruments that potentially subject us to concentrations of credit risk consist principally of cash and cash equivalents and accounts receivable. 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. *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, 2008. 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). Based on our evaluation under this framework, our management concluded that our internal control over financial reporting was effective as of September 30, 2008.

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, 2008, 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 2009 Annual Meeting of Shareholders.

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 December 8, 2008 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	**37**	**President and Chief Executive Officer**
Randall E. Kaye, M.D.	**46**	**Senior Vice President, Chief Medical Officer**
Christine G. Ocampo	**36**	**Vice President, Finance, Secretary**

Key Employees

Eric S. Benevich	**43**	**Vice President, Communications**
Gregory J. Flesher	**38**	**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 he was promoted to President and Chief Executive Officer and as a director. Prior to joining Avanir, Mr. Katkin previously served as Vice President of Commercial Development for Peninsula Pharmaceuticals from May 2004 to July 2005, playing a key role in the sale of Peninsula to Johnson & Johnson. Prior to his tenure at Peninsula, Mr. Katkin was Vice President of Pulmonary and Infectious Disease Marketing at InterMune, Inc., a biopharmaceutical company, from May 2002 to April 2004. From 1996 to April 2002, Mr. Katkin held Sales and Marketing positions with Amgen Inc., a global biotechnology company. Earlier in his career, Mr. Katkin spent several years at Abbott Laboratories. Mr. Katkin received a Bachelor of Science 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 is also a Certified Public Accountant.

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 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 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 in July 2005 as Senior Director of Marketing. In August 2007, he was promoted to Vice President of Communications and is responsible for all external communications as well as commercial planning and market development activities for Avanir's portfolio products. During his tenure at Avanir, Mr. Benevich helped build the Avanir commercial infrastructure and successfully relaunched FazaClo®, more than doubling its sales in less than one year after Avanir acquired the product. 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. With over 16 years experience in the pharmaceutical industry, Mr. Benevich has been involved in marketing some of the most successful blockbuster prescription products including Prilosec®, EPOGEN® and Enbrel®. 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 in June 2006 as Senior Director of Commercial Strategy and in November 2006 assumed the additional responsibility for Business Development and Portfolio Planning. In these roles, Mr. Flesher was responsible for Zenvia lifecycle planning and new product development as well as the integration of Alamo Pharmaceuticals following their acquisition. In August 2007 he was promoted to Vice President of Business Development with responsibility for management of all ongoing and new partnerships, in/out-licensing activities, strategic planning, and Avanir's intellectual property portfolio. 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 has global marketing and clinical development experience from 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.

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 Accountant 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, 2008 and 2007 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	Amended and Restated Articles of Incorporation of the Registrant, as amended January 5, 2006	Annual Report on Form 10-K for the fiscal year ended September 30, 2007, as Exhibit 3.1	December 21, 2007
3.2	Amended and Restated Bylaws of the Registrant, dated September 25, 2005	Current Report on Form 8-K, as Exhibit 3.2	September 29, 2005
4.1	Form of Class A Common Stock Certificate	Registration Statement on Form S-1 (File No. 33-32742), declared effective by the Commission on May 8, 1990	May 8, 1990
4.2	Certificate of Determination with respect to Series C Junior Participating Preferred Stock of the Registrant	Current Report on Form 8-K, as Exhibit 4.1	March 11, 1999
4.3	Rights Agreement, dated as of March 5, 1999, with American Stock Transfer & Trust Company	Current Report on Form 8-K, as Exhibit 4.1	March 11, 1999
4.4	Form of Rights Certificate with respect to the Rights Agreement, dated as of March 5, 1999	Current Report on Form 8-K, as Exhibit 4.1	March 11, 1999
4.5	Amendment No. 1 to Rights Agreement, dated November 30, 1999, with American Stock Transfer & Trust Company	Current Report on Form 8-K, as Exhibit 4.5	December 3, 1999
4.6	Form of Class A Common Stock Warrant, issued in connection with the Securities Purchase Agreement dated July 21, 2003	Current Report on Form 8-K, as Exhibit 4.2	July 25, 2003
4.7	Form of Class A Common Stock Warrant, issued in connection with the Securities Purchase Agreement dated November 25, 2003	Current Report on Form 8-K, as Exhibit 4.2	December 11, 2003
4.8	Form of Class A Common Stock Warrant, issued in connection with the Securities Purchase Agreement dated November 2, 2006	Annual Report on Form 10-K for the fiscal year ended September 30, 2007, as Exhibit 4.8	December 21, 2007
4.9	Form of Class A 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

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
4.10	Amendment No. 2 to Rights Agreement, dated April 4, 2008, with American Stock Transfer & Trust Company.	Registration Statement on Form 8-A/A (File No. 001-15803), as Exhibit 4.2	April 10, 2008
4.11	Amendment No. 3 to Rights Agreement, dated November 11, 2008 with American Stock Transfer & Trust Company	Current Report on Form 8-K, as Exhibit 4.4	November 12, 2008
10.1	License Agreement, dated 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 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 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 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 ("Tenant") and Sorrento Plaza, a California limited partnership ("Landlord"), effective 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 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 August 1, 2000, by and between Avanir Pharmaceuticals ("Licensee") and IriSys Research & Development, LLC, a California limited liability company	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 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 April 2, 1997, by and between IriSys Research & Development, LLC and the Center for Neurologic Study	Quarterly Report on Form 10-Q for the quarter ended March 31, 2005, as Exhibit 10.1	May 13, 2005
10.10	Amendment to Exclusive Patent License Agreement, dated 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

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
10.11	Manufacturing Services Agreement, dated 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 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 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 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 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
10.24	Form of Indemnification Agreement with certain Directors and Executive Officers of the Registrant	Annual Report on Form 10-K for the fiscal year ended September 20, 2003, as Exhibit 10.4	December 23, 2003
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

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
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 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 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	Employment Agreement with Martin J. Sturgeon, dated February 12, 2007	Annual Report on Form 10-K for the fiscal year ended September 30, 2007, as Exhibit 10.42	December 21, 2007
10.33	Amended and Restated Change of Control Agreement, dated 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
10.34	Employment Agreement with Keith Katkin, dated March 13, 2007	Annual Report on Form 10-K for the fiscal year ended September 30, 2007, as Exhibit 10.44	December 21, 2007
10.35	Bonus Agreement, dated September 10, 2007, by and between Avanir Pharmaceuticals and Keith Katkin	Current Report on Form 8-K, as Exhibit 10.1	December 10, 2007
10.36	Separation and Consulting Agreement, dated June 25, 2007, by and between Avanir Pharmaceuticals and Jagadish Sircar	Annual Report on Form 10-K for the fiscal year ended September 30, 2007, as Exhibit 10.46	December 21, 2007
10.37	Sales Agreement, dated December 15, 2006, by and between Avanir Pharmaceuticals and Brinson Patrick Securities Corporation	Current Report on Form 8-K, as Exhibit 10.1	June 4, 2007
10.38	Amendment No. 1 to Sales Agreement, dated June 4, 2007, by and between Avanir Pharmaceuticals and Brinson Patrick Securities Corporation	Current Report on Form 8-K, as Exhibit 10.2	June 4, 2007
10.39	Asset Purchase Agreement, dated 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

Exhibit Number	Description	Incorporated by Reference Herein	
		Form	Date
10.40	Agreement, dated July 2, 2007, by and between Avanir Pharmaceuticals and Neal R. Cutler	Annual Report on Form 10-K for the fiscal year ended September 30, 2007, as Exhibit 10.50	December 21, 2007
10.41	Sublease Agreement, dated 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
10.42	Sublease Agreement, dated July 2, 2007, by and between Avanir Pharmaceuticals and Halozyme, Inc. (11404 Sorrento Valley Rd., San Diego, CA)	Annual Report on Form 10-K for the fiscal year ended September 30, 2007, as Exhibit 10.52	December 21, 2007
10.43	Third Amendment to Lease, dated 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
10.44	Asset Purchase and License Agreement, dated 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
10.45	Payoff Letter, dated 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
21.1	List of Subsidiaries	Annual Report on Form 10-K for the fiscal year ended September 30, 2006	December 18, 2006
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

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

Date: December 24, 2008

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

Signature	Title	Date
/s/ KEITH A. KATKIN Keith A. Katkin	President and Chief Executive Officer (Principal Executive Officer)	December 24, 2008
/s/ CHRISTINE G. OCAMPO Christine G. Ocampo	Vice President, Finance (Principal Financial Officer)	December 24, 2008
/s/ CRAIG A. WHEELER Craig A. Wheeler	Director, Chairman of the Board	December 24, 2008
/s/ STEPHEN G. AUSTIN, CPA Stephen G. Austin, CPA	Director	December 24, 2008
/s/ CHARLES A. MATHEWS Charles A. Mathews	Director	December 24, 2008
/s/ DAVID J. MAZZO, PH.D. David J. Mazzo, Ph.D.	Director	December 24, 2008
/s/ DENNIS G. PODLESAK Dennis G. Podlesak	Director	December 24, 2008
/s/ NICHOLAS SIMON Nicholas Simon	Director	December 24, 2008
/s/ SCOTT M. WHITCUP, M.D. Scott M. Whitcup, M.D.	Director	December 24, 2008

AVANIR Pharmaceuticals

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of
AVANIR Pharmaceuticals

We have audited the accompanying consolidated balance sheets of AVANIR Pharmaceuticals and subsidiaries (the "Company") as of September 30, 2008 and 2007, and the related consolidated statements of operations, shareholders' 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 and subsidiaries as of September 30, 2008 and 2007, 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

Irvine, California
December 12, 2008

AVANIR Pharmaceuticals

CONSOLIDATED BALANCE SHEETS

	September 30, 2008	September 30, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 41,383,930	$ 30,487,962
Short-term investments in marketable securities	—	1,747,761
Receivables	—	72,000
Inventories	17,000	17,000
Prepaid expenses	1,030,630	1,479,992
Other current assets	237,334	916,450
Current portion of restricted investments in marketable securities	388,122	688,122
Total current assets	43,057,016	35,409,287
Investments in marketable securities	—	249,078
Restricted investments in marketable securities, net of current portion	468,475	468,475
Property and equipment, net	806,909	1,215,666
Intangible assets, net	—	41,048
Non-current inventories	1,316,277	1,337,991
Other assets	257,484	374,348
TOTAL ASSETS	$ 45,906,161	$ 39,095,893
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 451,846	$ 307,700
Accrued expenses and other liabilities	1,881,401	2,050,864
Accrued compensation and payroll taxes	1,192,457	1,191,677
Current portion of deferred revenues	2,333,932	2,267,594
Current portion of notes payable	25,744	254,676
Total current liabilities	5,885,380	6,072,511
Accrued expenses and other liabilities, net of current portion	868,517	1,170,396
Deferred revenues, net of current portion	10,152,100	13,052,836
Notes payable, net of current portion	—	11,769,916
Total liabilities	16,905,997	32,065,659
Commitments and contingencies		
Shareholders' equity:		
Preferred stock — no par value, 10,000,000 shares authorized, no shares issued or outstanding as of September 30, 2008 and 2007	—	—
Class A Common stock — no par value, 200,000,000 shares authorized; 78,213,986 and 43,117,358 shares issued and outstanding as of September 30, 2008 and 2007, respectively	284,994,636	245,531,712
Accumulated deficit	(255,994,472)	(238,498,733)
Accumulated other comprehensive loss	—	(2,745)
Total shareholders' equity	29,000,164	7,030,234
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 45,906,161	$ 39,095,893

See notes to consolidated financial statements.

AVANIR Pharmaceuticals

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended September 30,	
	2008	2007
REVENUES FROM PRODUCT SALES		
Net revenues	$ 129,820	$ 72,000
Cost of revenues	(21,714)	(328,184)
Product gross margin (loss)	108,106	(256,184)
REVENUES AND COST OF RESEARCH SERVICES AND OTHER		
Revenue from royalties and royalty rights	3,616,102	4,251,252
Revenues from license agreements	2,205,724	1,614,091
Revenues from government research grant services	1,006,922	914,834
Revenues from research and development services	—	2,372,384
Revenues from research services and other	6,828,748	9,152,561
Cost of research and development services	(249,281)	(2,994,905)
Cost of government research grant	(940,130)	(1,324,427)
Research services and other gross margin	5,639,337	4,833,229
Total gross margin	5,747,443	4,577,045
OPERATING EXPENSES		
Research and development	14,110,743	13,115,712
General and administrative	10,599,158	20,830,188
Total operating expenses	24,709,901	33,945,900
Loss from continuing operations	(18,962,458)	(29,368,855)
OTHER INCOME (EXPENSES)		
Interest income	1,283,302	622,687
Interest expense	(540,618)	(1,247,875)
Gain on early extinguishment of debt	967,547	—
Gain on sale of Xenerex antibodies	120,274	—
Other, net	1,222,481	1,615,519
Loss from continuing operations before provision for income taxes	(15,909,472)	(28,378,524)
Provision for income taxes	3,200	3,200
Loss before discontinued operations	(15,912,672)	(28,381,724)
DISCONTINUED OPERATIONS		
Loss from discontinued operations	(231,848)	(4,760,056)
(Loss) gain on sale of discontinued operations	(1,351,219)	12,208,327
(Loss) income from discontinued operations	(1,583,067)	7,448,271
Net loss	$(17,495,739)	$(20,933,453)
BASIC AND DILUTED NET (LOSS) INCOME PER SHARE:		
Loss before discontinued operations	$ (0.27)	$ (0.72)
(Loss) income from discontinued operations	(0.03)	0.19
Net loss	$ (0.30)	$ (0.53)
Basic and diluted weighted average number of common shares outstanding	58,901,030	39,643,876

See notes to consolidated financial statements.

AVANIR Pharmaceuticals

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY AND COMPREHENSIVE LOSS

	Common Stock Class A		Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity (Deficit)	Comprehensive Loss
	Shares	Amount				
BALANCE, SEPTEMBER 30, 2006	31,708,461	$211,993,249	$(217,565,280)	$(102,504)	$ (5,674,535)	
Net loss	—	—	(20,933,453)	—	(20,933,453)	$(20,933,453)
Issuance of Class A common stock in connection with:						
Exercise of stock options	67,758	294,699	—	—	294,699	
Sale of stock and warrants, net of offering costs	11,388,790	30,547,713	—	—	30,547,713	
Issuance of restricted awards	44,250	—	—	—	—	
Vesting of restricted stock units	83,900	—	—	—	—	
Common stock surrendered	(18,135)	(41,209)	—	—	(41,209)	
Forfeiture of restricted awards	(157,666)	(500)	—	—	(500)	
Share-based compensation expense	—	2,737,760	—	—	2,737,760	
Unrealized gains on investments in marketable securities	—	—	—	99,759	99,759	99,759
BALANCE, SEPTEMBER 30, 2007	43,117,358	245,531,712	(238,498,733)	(2,745)	7,030,234	$(20,833,694)
Net loss	—	—	(17,495,739)	—	(17,495,739)	$(17,495,739)
Issuance of Class A common stock in connection with:						
Sale of stock, net of offering costs	35,007,246	37,838,842	—	—	37,838,842	
Vesting of restricted stock units and awards	113,361	271	—	—	271	
Common stock surrendered	(21,979)	(29,850)	—	—	(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	$284,994,636	$(255,994,472)	$ —	$ 29,000,164	$(17,492,994)

See notes to consolidated financial statements.

AVANIR Pharmaceuticals

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended September 30,	
	2008	2007
OPERATING ACTIVITIES:		
Net loss	$(17,495,739)	$(20,933,453)
Loss (income) from discontinued operations	1,583,067	(7,448,271)
Adjustments to reconcile loss before discontinued operations to net cash used in operating activities of continuing operations:		
Depreciation and amortization	445,980	2,843,814
Share-based compensation expense	1,639,756	2,230,122
Amortization of debt discount	232,776	413,822
Gain on extinguishment of debt	(967,547)	—
Gain on sale of Xenerex antibodies	(120,274)	—
Loss on impairment of assets	41,048	—
Loss (gain) on disposal of assets	26,852	(229,829)
Changes in operating assets and liabilities (net of effects of acquisition/disposition of business):		
Receivables	72,000	1,051,699
Inventories	21,714	(1,004,469)
Prepaid and other assets	1,220,915	(749,345)
Accounts payable	144,146	(10,537,357)
Accrued expenses and other liabilities	(471,342)	(3,327,404)
Accrued compensation and payroll taxes	780	(1,418,730)
Deferred revenue	(2,834,398)	(4,033,745)
Net cash used in operating activities of continuing operations	(16,460,266)	(43,143,146)
Net cash used in operating activities of discontinued operations	(217,943)	(3,501,288)
Net cash used in operating activities	(16,678,209)	(46,644,434)
INVESTING ACTIVITIES:		
Investments in securities	(527)	(101,818)
Proceeds from sales and maturities of investments in securities	2,300,111	16,900,000
Purchase of property and equipment	(134,374)	(58,699)
Proceeds from sale of Xenerex antibodies	210,000	—
Proceeds from disposal of assets	5,000	774,058
Net cash provided by investing activities of continuing operations	2,380,210	17,513,541
Net cash (used in) provided by investing activities of discontinued operations	(1,351,219)	42,055,769
Net cash provided by investing activities	1,028,991	59,569,310
FINANCING ACTIVITIES:		
Proceeds from issuances of common stock and warrants, net of commissions and offering costs	37,838,842	30,870,014
Tax withholding payments reimbursed by restricted stock payments on debt	(29,579)	(27,602)
Payments on notes and capital lease obligations	(11,264,077)	(6,785,208)
Net cash provided by financing activities of continuing operations	26,545,186	24,057,204
Net cash used in financing activities of discontinued operations	—	(11,392,332)
Net cash provided by financing activities	26,545,186	12,664,872
Net increase in cash and cash equivalents	10,895,968	25,589,748
Cash and cash equivalents at beginning of year	30,487,962	4,898,214
Cash and cash equivalents at ending of year	$ 41,383,930	$ 30,487,962
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Interest paid	$ 447,508	$ 1,435,982
Income taxes paid	$ 51,108	$ 22,368
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Purchase price adjustment of assumed liabilities	$ —	$ 3,980,229
Issuance of notes payable as additional consideration for the Alamo acquisition	$ —	$ 4,000,000
Common stock surrendered	$ 29,850	$ 13,607

See notes to consolidated financial statements.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Description of Business

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

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™ (formerly referred to as Neurodex™) for the treatment of PBA, assuming the FDA approves our 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 and its wholly-owned subsidiaries, Alamo Pharmaceuticals LLC ("Alamo") from the date of acquisition, Xenerex Biosciences, AVANIR Holding Company and AVANIR Acquisition Corp. All intercompany accounts and transactions have been eliminated. Certain amounts from prior years have been reclassified to conform to the current year presentation. Our fiscal year ends on September 30 of each year. The years ended September 30, 2008 and 2007 may be referred to as fiscal 2008 and fiscal 2007, respectively.

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 Pharmaceuticals include adjustments to reflect the classification of the Company's FazaClo business as discontinued operations. See Note 3 for information on discontinued operations.

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, provisions for uncollectible receivables, valuation of inventories and investments, recoverability of long-lived assets, purchase price allocations, share-based compensation expense, determination of expenses in outsourced contracts and realization of deferred tax assets.

Purchase Price Allocation

The allocation of purchase price for acquisitions requires extensive use of accounting estimates and judgments to allocate the purchase price to the identifiable tangible and intangible assets acquired, including in-process research and development, and liabilities assumed based on their respective fair values. In fiscal 2006, we completed the acquisition of Alamo Pharmaceuticals LLC. See Note 3, "Acquisition of Alamo Pharmaceuticals, Inc. / Sale of FazaClo" for detailed discussion.

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, consisting of certificates of deposit, represent amounts pledged to our bank as collateral for letters of credit issued in connection with certain of our lease agreements, 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 are as follows:

Lease Description	Restricted Amount as of September 30, 2008	Restricted Amount as of September 30, 2007	Lease Term Expires on
Facility lease — 11388 Sorrento Valley Road, San Diego	$388,122	$ 388,122	08/31/08(1)
Facility lease — 11404 and 11408 Sorrento Valley Road, San Diego	468,475	468,475	01/14/13
Equipment lease — GE Capital Fleet	—	300,000	10/23/07
Total	$856,597	$1,156,597	

(1) As of September 30, 2008, this letter of credit was pending release from landlord.

Investments in marketable securities

We account for and report our investments in marketable securities in accordance with the Financial Accounting Standards Board ("FASB") Statement of Financial Accounting Standards ("FAS") No. 115, "*Accounting for Certain Investments in Debt and Equity Securities*." Investments are comprised of marketable securities consisting primarily of certificates of deposit, and federal, state and municipal government obligations. All marketable securities are held in our name and primarily under the custodianship of two major financial institutions. Our policy is to protect the principal value of our investment portfolio and minimize principal risk. Except for restricted investments, our marketable securities are classified as "available-for-sale" and stated at fair value, with net unrealized gains or losses recorded as a component of accumulated other comprehensive loss. Short-term investments are marketable securities with maturities of less than one year from the balance sheet date. Marketable security investments are evaluated periodically for impairment. If it is determined that a decline of any investment is other than temporary, then the investment basis would be written down to fair value and the write-down would be included in earnings as a loss.

Concentrations

As of September 30, 2008, $36.6 million of our cash and cash equivalents were maintained in three separate money market mutual funds, and $6.6 million of our cash and cash equivalents were maintained at a major financial institution in the United States. At times, deposits held with financial institutions may exceed the amount of

insurance provided on such deposits. 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.

Effective September 19, 2008, the U.S. Treasury commenced its Temporary Guarantee Program for Money Market Mutual Funds. This program, which is offered to all money market mutual funds that are regulated under Rule 2A-7 of the Investment Company Act of 1940, guarantees the share price of any publicly offered eligible money market fund that applies for and pays a fee to participate in the program. As of September 30, 2008, two of the money market mutual funds which we had invested in, which had aggregate balances of approximately 51% of our cash and cash equivalents, were participating in the U.S. Treasury program. The current termination date for this program is April 30, 2009.

At September 30, 2008, our uninsured cash totaled approximately $22 million.

Financial instruments that potentially subject us to concentrations of credit risk consist principally of cash and cash equivalents and accounts receivable. Our cash and cash equivalents are placed in various money market mutual funds and at 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.

Allowance for doubtful accounts

We evaluate the collectibility of accounts receivable on a regular basis. The allowance is based upon various factors including the financial condition and payment history of major customers, an overall review of collections experience on other accounts and economic factors or events expected to affect our future collections experience. Based on management's evaluation, no allowance was recorded at September 30, 2008 or 2007.

Inventories

Inventories are stated at the lower of cost or market. Cost is determined on a first-in, first-out ("FIFO") basis. We evaluate the carrying value of inventories on a regular basis, taking into account such factors as historical and anticipated future sales compared to quantities on hand, the price we expect to obtain for products in their respective markets compared with historical cost and the remaining shelf life of goods on hand. Write-downs of inventories are considered to be permanent reductions in the cost basis of inventories.

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. Estimated useful lives of three to five years are used on computer equipment and related software. Office equipment, furniture and fixtures are depreciated over five years. Amortization of leasehold improvements is computed using 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

In accordance with FAS 144, 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, we determined that approximately $41,000 of intangible assets were not recoverable. Accordingly, we recorded an impairment loss of approximately $41,000.

Deferred rent

We account for rent expense in our operating leases (excluding leases related to exit activities) by accumulating total minimum rent payments on the leases over their respective periods and recognize 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, 2008 and 2007 was $49,000 and $34,000, respectively, and is included in accrued expenses and other liabilities.

Fair value of financial instruments

At September 30, 2008 and 2007, the Company's financial instruments included cash and cash equivalents, receivables, investments in marketable securities, accounts payable, accrued expenses, and accrued compensation and payroll taxes and long-term borrowings. The carrying amount of cash and cash equivalents, receivables, accounts payable, accrued expenses 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 investments in marketable securities are carried at fair value based on quoted market prices. The fair value of the Company's notes payable and capital lease obligations were estimated based on quoted market prices or pricing models using current market rates. At September 30, 2008 and 2007, the fair value of the Company's notes payable and capital lease obligations approximate the carrying value of the notes.

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 in accordance with the SEC's Staff Accounting Bulletin Topic 13 ("Topic 13"), "*Revenue Recognition*." Revenue is recognized 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 seller's price to the buyer is fixed and determinable; and (4) collectibility is reasonably assured. Certain product sales are subject to rights of return. In accordance with FAS No. 48, "*Revenue Recognition When Right of Return Exists*" ("FAS 48"), the Company recognizes such product revenues at the time of sale only if it has met all the criteria of FAS 48, including the ability to reasonably estimate future returns. FAS 48 states that revenue from sales transactions where the buyer has the right to return the product shall be recognized at the time of sale only if (1) the seller's price to the buyer is substantially fixed or determinable at the date of sale, (2) the buyer has paid the seller, 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 seller 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 seller 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 criteria of FAS 48, including that 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.

Certain sales transactions include multiple deliverables. The Company allocates amounts to separate elements in multiple element arrangements in accordance with the FASB's Emerging Issues Task Force ("EITF") Issue No. 00-21 ("EITF 00-21"), "*Accounting for Revenue Arrangements with Multiple Deliverables*." Revenues are allocated to a delivered product or service when all of the following criteria are met: (1) the delivered item has value to the customer on a standalone basis; (2) there is objective and reliable evidence of the fair value of the undelivered item; and (3) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in the Company's control. The Company uses the relative fair values of the separate deliverables to allocate revenue. For arrangements with multiple elements that are separated, the Company recognizes revenues in accordance with Topic 13.

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 in SAB Topic 13 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.

FazaClo. (Sales from Discontinued Operations). In August 2007, the Company sold FazaClo and all associated operations to Azur and as a result, all revenues, cost of revenues, and operating expenses related to FazaClo for fiscal 2007 have been classified as discontinued operations in the accompanying condensed consolidated financial statements (See Note 3 "Acquisition of Alamo Pharmaceuticals, Inc. / Sale of FazaClo").

As discussed in Note 3, "Acquisition of Alamo Pharmaceuticals, Inc. / Sale of FazaClo" , the Company acquired Alamo Pharmaceuticals LLC ("Alamo") on May 24, 2006, with one marketed product, FazaClo (clozapine, USP), that began shipping to wholesale customers in July 2004 in 48-pill boxes. At that time, FazaClo had a two-year shelf life. In June 2005, Alamo received FDA approval to extend the product expiration date to three years. In October 2005, Alamo began shipping 96-pill boxes and accepted returns of unsold or undispensed 48-pill boxes.

During fiscal 2007, the Company sold FazaClo to pharmaceutical wholesalers. They resold the Company's product to outlets such as pharmacies, hospitals and other dispensing organizations. The Company had agreements with its wholesale customers, various states, hospitals, certain other medical institutions and third-party payers throughout the U.S. These agreements frequently contained commercial incentives, which often included pricing allowances and discounts payable at the time the product was sold to the dispensing outlet or upon dispensing the product to patients. Consistent with pharmaceutical industry practice, the Company's wholesale customers could return purchased product during an 18-month period beginning six months prior to the product's expiration date and ending 12 months after the expiration date. Additionally, several of the Company's dispensing outlets had the right to return expired product at any time. Once products were dispensed to patients the right of return expired. Upon the sale of the FazaClo assets, Azur assumed all future liabilities for returns and allowances related to the FazaClo sales that were made by the Company. Therefore, as of the date of the sale of the FazaClo assets, the Company no longer had responsibility for returns and allowances related to its sales of FazaClo.

Beginning in the first quarter of fiscal 2007, the Company obtained third-party information regarding certain wholesaler inventory levels, a sample of outlet inventory levels and third-party market research data regarding FazaClo sales. The third-party data included, (i) IMS Health Audit — National Sales Perspective reports ("NSP"), which is a projection of near-census data of wholesaler shipments of product to all outlet types, including retail and non-retail and; (ii) IMS Health National Prescription Audit ("NPA") Syndicated data, which captures end-user consumption from retail dispensed prescriptions based upon projected data from pharmacies estimated to represent approximately 60% to 70% of the U.S. prescription universe. Further, the Company analyzed historical rebates and chargebacks earned by State Medicaid, Medicare Part D and managed care customers. Based upon this additional information and analysis obtained, the Company estimated the amount of product that was shipped that was no longer in the wholesale or outlet channels, and hence no longer subject to a right of return. Therefore, the Company began recognizing revenues, net of returns, chargebacks, rebates, and discounts, in the first quarter of fiscal 2007, for product that it estimated had been sold to patients and that was no longer subject to a right of return.

FazaClo product revenues were recorded net of provisions for estimated product pricing allowances including: State Medicaid base and supplemental rebates, Medicare Part D discounts, managed care contract discounts and prompt payment discounts were at an aggregate rate of approximately 25.8% of gross revenues for the fiscal year ended September 30, 2007. Provisions for these allowances were estimated based upon contractual terms and require management to make estimates regarding customer mix to reach. The Company considered its current contractual rates with States related to Medicaid base and supplemental rebates, with private organizations for Medicare Part D discounts and contracts with managed care organizations.

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. In accordance with EITF 00-21, 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.

When a delivered element meets the criteria for separation in accordance with EITF 00-21, 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 in accordance with EITF Issue No. 99-19, "*Reporting Revenue Gross as a Principal versus Net as an Agent*," 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. The Company recognizes royalty revenue in the period in which the threshold is 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, 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 quarter of fiscal 2008. A 3% variance in our estimate of the work completed in our largest contract could increase or decrease our 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 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.

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 subject to the provisions of revised FAS No. 123, "*Share-Based Payment*" ("FAS 123R"), including the provisions of the SEC's Staff Accounting Bulletin No. 107 ("SAB 107"), that require the fair value method to account for share-based payments.

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%.

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 2008 and 2007 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. FAS 123R 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.

Total compensation expense related to all of our share-based awards, recognized under FAS 123R, for fiscal 2008 and 2007 was comprised of the following:

	Fiscal 2008	Fiscal 2007
From Continuing Operations:		
General and administrative expense	$1,149,018	$1,864,689
Research and development expense	490,738	365,433
Share-based compensation expense related to continuing operations	1,639,756	2,230,122
From Discontinued Operations:	13,905	507,638
Share-based compensation expense	$1,653,661	$2,737,760

	Fiscal 2008	Fiscal 2007
Share-based compensation expense from:		
Stock options	$ 666,129	$1,304,944
Restricted stock units	848,535	725,368
Restricted stock awards	138,997	707,448
Total	$1,653,661	$2,737,760

Since we have a net operating loss carry-forward as of September 30, 2008 and 2007, 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 2008 and 2007 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, as defined in FAS No. 146, "*Accounting for Costs Associated with Exit or Disposal Activities*" ("FAS 146"), 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 2007 and 2006, we recorded costs and liabilities for exit and disposal activities related to a relocation plan, including a decision to discontinue occupying certain leased offices and laboratory facilities, in accordance with FAS 146. The liabilities are evaluated and adjusted as appropriate on at least a quarterly basis for changes in circumstances. Please refer to Note 4, "Relocation of Commercial and General and Administrative Operations" 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 $304,000 and $1.1 million for fiscal 2008 and 2007, respectively.

Income taxes

We account 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.

On July 13, 2006, the FASB issued Financial Interpretation ("FIN") No. 48, *Accounting for Uncertainty in Income Taxes — An Interpretation of FASB Statement No. 109.* FIN No. 48 clarifies the accounting for uncertainty in income taxes recognized in an entity's financial statements in accordance with FAS No. 109, *Accounting for Income Taxes,* and prescribes a recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken on a tax return. Under FIN No. 48, the impact of an uncertain income tax position on the income tax return must be recognized 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. Additionally, FIN No. 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

The Company adopted the provisions of FIN No. 48 on 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, 2008 is $3.2 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 condensed consolidated balance sheets at September 30, 2008 and 2007.

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 FIN No. 48 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. We present accumulated other comprehensive income (loss) in our consolidated statements of shareholders' 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 ("Basic EPS Method"). 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 ("Diluted EPS Method"). 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. For fiscal 2007, 22,500 restricted shares of Class A common stock with a right of repurchase have been excluded from the computation of basic net loss per share, because the right of repurchase for these restricted shares had not lapsed. There were no restricted shares with right of repurchase excluded from the computation of net loss per share in fiscal 2008.

For fiscal 2008 and 2007, 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 2008	Fiscal 2007
Stock options	624,027	1,040,581
Performance stock options	2,048,000	—
Stock warrants	12,509,742	1,322,305
Restricted stock units	2,259,042	1,914,988

Reclassifications

Certain prior year amounts have been reclassified to conform with the current presentation. At September 30, 2007, other receivables of $916,450 were previously included in receivables; however such amounts have been reclassified to other current assets. The other receivables primarily consist of receivables from sublease agreements and various other non-trade receivables.

Recent accounting pronouncements

Financial Accounting Standards No. 162 ("FAS 162"). In May 2008, the FASB issued FAS 162, "*The Hierarchy of Generally Accepted Accounting Principles*". FAS 162 is intended to improve financial reporting by identifying a consistent framework, or hierarchy, for selecting accounting principles to be used in preparing financial statements that are presented in conformity with GAAP for nongovernmental entities. FAS 162 is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *"The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles."* We do not expect the adoption of this statement to have a material impact on our results of operations, financial position or cash flows.

Financial Accounting Standards No. 163 ("FAS 163"). In May 2008, the FASB issued FAS No. 163, "*Accounting for Financial Guarantee Insurance Contracts — an interpretation of FASB Statement No. 60.*" FAS 163 requires that an insurance enterprise recognize a claim liability prior to an event of default (insured event) when there is evidence that credit deterioration has occurred in an insured financial obligation. This Statement also clarifies how Statement 60 applies to financial guarantee insurance contracts, including the recognition and measurement to be used to account for premium revenue and claim liabilities. Those clarifications will increase comparability in financial reporting of financial guarantee insurance contracts by insurance enterprises. This Statement requires expanded disclosures about financial guarantee insurance contracts. The accounting and disclosure requirements of the Statement will improve the quality of information provided to users of financial statements. SFAS 163 will be effective for financial statements issued for fiscal years beginning after December 15, 2008. The Company does not expect the adoption of FAS 163 will have a material impact on its financial condition or results of operation.

FASB Staff Position No. 142-3 ("FSP 142-3"). In April 2008, the FASB issued FSP No. 142-3, "*Determination of the Useful Life of Intangible Assets*". FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under Financial Accounting Standard No. 142, "*Goodwill and Other Intangible Assets*". FSP 142-3 is effective for fiscal years beginning after December 15, 2008. Therefore, we will be required to adopt FSP 142-3 for the fiscal year beginning October 1, 2009. We are currently evaluating the impact of FSP No. 142-3 on our consolidated financial position and results of operations.

Financial Accounting Standards No. 161 ("FAS 161"). In March 2008, the FASB issued FASB Statement No. 161, "*Disclosures about Derivative Instruments and Hedging Activities, an Amendment of FAS 133*". The new standard is intended to improve financial reporting about derivative instruments and hedging activities by

requiring enhanced disclosures to enable investors to better understand their effects on an entity's financial position, financial performance and cash flows. FAS 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. Therefore, we will be required to adopt FAS 161 for the fiscal year beginning October 1, 2009. We are currently evaluating the impact of FAS 161 on our consolidated financial position and results of operations.

Financial Accounting Standards No. 160 ("FAS 160"). In December 2007, the FASB issued FAS 160, "*Noncontrolling Interests in Consolidated Financials, an Amendment of ARB No. 51*", 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. FAS 160 is effective for fiscal years beginning on or after December 15, 2008. Therefore, we will be required to adopt FAS 160 for the fiscal year beginning October 1, 2009. We do not expect the adoption of FAS 160 to significantly affect our consolidated financial condition or results of operations.

Financial Accounting Standards No. 141(R) ("FAS 141R"). In December 2007, the FASB issued FAS 141R, "*Business Combinations: Applying the Acquisition Method*", which retains the fundamental requirements of FAS 141 but provides additional guidance on applying the acquisition method when accounting for similar economic events by establishing certain principles and requirements. FAS 141R is effective for fiscal years beginning on or after December 15, 2008. Therefore, we will be required to adopt FAS 141R for the fiscal year beginning October 1, 2009. We are evaluating the options provided under FAS 141R and their potential impact on our financial condition and results of operations when implemented. We do not expect the adoption of FAS 141R to significantly affect our consolidated financial condition or results of operations.

EITF Issue No. 07-1. In November 2007, the FASB's Emerging Issues Task Force issued EITF Issue No. 07-1, "*Accounting for Collaborative Arrangements,*" ("EITF 07-1") which defines collaborative arrangements and establishes reporting and disclosure requirements for such arrangements. EITF 07-1 is effective for fiscal years beginning after December 15, 2008. Therefore, we will be required to adopt EITF 07-1 for the fiscal year beginning October 1, 2009. We are continuing to evaluate the impact of adopting the provisions of EITF 07-1; however, we do not anticipate the adoption of EITF 07-1 will have a material effect on our consolidated financial condition or results of operations.

EITF Issue No. 07-3. In June 2007, the FASB's Emerging Issues Task Force reached a consensus on EITF Issue No. 07-3, "*Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities,*" ("EITF 07-3") that would require nonrefundable advance payments made by us for future R&D activities to be capitalized and recognized as an expense as the goods or services are received by us. EITF 07-3 is effective with respect to new arrangements entered into beginning January 1, 2008. The adoption of EITF 07-3 did not have a material impact on our consolidated financial condition or results of operations.

Financial Accounting Standards No. 159 ("FAS 159"). In February 2007, the FASB issued FAS 159, "*The Fair Value Option for Financial Assets and Financial Liabilities— Including an amendment of FASB Statement 115*," which provides 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 date. FAS 159 is effective for fiscal years beginning after November 15, 2007. Therefore, we will be required to adopt FAS 159 for the fiscal year beginning October 1, 2008. We are evaluating the options provided under FAS 159 and their potential impact on its financial condition and results of operations if implemented. We do not expect the adoption of FAS 159 to significantly affect our consolidated financial condition or results of operations.

Financial Accounting Standards No. 157 ("FAS 157"). In September 2006, the FASB issued FAS 157, "*Fair Value Measurements*." FAS 157 defines fair value, established a framework for measuring fair value in generally

accepted accounting principles (GAAP) and expands disclosures about fair value measurements. FAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. Therefore, we will be required to adopt FAS 157 for the fiscal year beginning October 1, 2008. In February 2008, the FASB released FSPFAS No. 157-2, "*Effective Date of FASB Statement No. 157*" which delayed the effective date of FAS 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually) until the fiscal year beginning October 1, 2009. The Company is currently evaluating the effect of FAS 157 on its consolidated financial condition and results of operations.

Financial Accounting Standards No. 157 ("FSP FAS 157-3"). In October 2008, the FASB issued FSP FAS No. 157-3, *"Determining the Fair Value of a Financial Asset When the Market for That Asset is Not Active*" ("FSP FAS 157-3"). FSP FAS No. 157-3 clarifies the application of SFAS 157 in a market that is not active, and provides an illustrative example intended to address certain key application issues. FSP FAS No. 157-3 is effective immediately, and applies to the Company's September 30, 2008 financial statements. The Company has concluded that the application of FSP FAS No. 157-3 did not have a material impact on its consolidated financial position and results of operations as of and for the periods ended September 30, 2008.

3. Acquisition of Alamo Pharmaceuticals, Inc. / Sale of Fazaclo

On May 24, 2006, pursuant to a Unit Purchase Agreement dated May 22, 2006 (the "Acquisition Agreement"), we acquired all of the outstanding equity interests in Alamo from the former members of Alamo (the "Selling Holders") for approximately $30.0 million in consideration, consisting of approximately $4.0 million in cash, $25.1 million in promissory notes and $912,000 in acquisition-related transaction costs. The purchase price exceeded the net assets acquired resulting in the recognition of $22.1 million of goodwill. The Company intended to leverage the FazaClo sales force to assist with the commercial launch of Zenvia, which was planned for early 2007; however, due to the receipt of the approvable letter and resulting delay in the planned launch of Zenvia, we entered into an agreement to sell FazaClo in July 2007.

In connection with the Alamo acquisition, we also agreed to pay the Selling Holders up to an additional $39,450,000 in revenue-based earn-out payments, based on future sales of FazaClo (clozapine USP), an orally disintegrating drug for the treatment of refractory schizophrenia. On May 15, 2007, we issued an additional $2,000,000 promissory note based on FazaClo sales rates through that quarter and on August 15, 2007, we issued a second promissory note, also in the principal amount of $2,000,000. The remaining earn-out payments of $35,450,000 are based on the achievement of certain target levels of FazaClo sales in the U.S. from the closing date of the acquisition through December 31, 2018. In connection with the FazaClo sale, Azur assumed these remaining contingent payment obligations; however, we are still contingently liable in the event of default by Azur.

We also previously agreed to pay the Selling Holders one-half of all net licensing revenues that we may receive through December 31, 2018 from licenses of FazaClo outside of the U.S., if any ("Non-US Licensing Revenues"). There were no Non-US Licensing Revenues through August 3, 2007, the date of sale of FazaClo, and these future obligations have been assumed by Azur as described below.

Sale of FazaClo and Presentation of Discontinued Operations

In August 2007, the Company sold FazaClo 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. 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.

In accordance with FAS 144 "*Accounting for the Impairment or Disposal of Long-Lived Assets*", the financial results relating to FazaClo have been classified as discontinued operations in the accompanying consolidated statements of operations for all periods presented.

Summarized statements of operations for the discontinued operations for fiscal 2008 and 2007 are as follows:

	Fiscal 2008	Fiscal 2007
REVENUES FROM PRODUCT SALES		
Net revenues	$ —	$17,132,171
Cost of revenues	—	4,599,105
Product gross margin	—	12,533,066
OPERATING EXPENSES		
Research and development	—	3,159,117
General and administrative	231,848	13,486,361
Loss from operations	(231,848)	(4,112,412)
OTHER INCOME (EXPENSES)		
Interest expense	—	(647,644)
(Loss) gain on sale of FazaClo	(1,351,219)	12,208,327
Other	—	—
(Loss) income before income taxes	(1,351,219)	7,448,271
Provision for income taxes	—	—
NET (LOSS) INCOME	$(1,583,067)	$ 7,448,271

The Asset Purchase Agreement (the "Agreement") with Azur provides 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 stipulates 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 $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 20, 2008. In accordance with FAS 154, "*Accounting for Changes and Error Corrections*", the Net Working Capital Adjustment is 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 an additional $218,000 of other costs related to the operations of the FazaClo business during the fiscal year ended September 30, 2008, which the Company initially estimated were assumed by Azur.

In fiscal 2007, in connection with the sale of the FazaClo assets, the Company recognized a gain of approximately $12.2 million. The following presents the calculation of the gain on sale and the carrying amounts of the major classes of the assets and liabilities related to FazaClo at the date of sale:

Consideration, net of transaction costs of $1,829,000	$42,055,000
Assets and liabilities related to FazaClo:	
Current assets	3,835,000
Property and equipment	612,000
Net intangible assets	8,653,000
Goodwill	22,130,000
Less: Current liabilities	(5,383,000)
Net assets	29,847,000
Gain on sale	$12,208,000

4. Relocation of Commercial and General and Administrative Operations

In fiscal 2006, we relocated all operations other than research and development from San Diego, California to Aliso Viejo, California and recorded restructuring and other related expenses of $515,000 which are included in general and administrative expenses, and consisting of $237,000 for employee severance and relocation benefits and $278,000 of lease restructuring liability. Further, in the quarter ended June 30, 2007, the Board of Directors approved a plan to exit the Company's facilities in San Diego. Pursuant to this plan, 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. The disposition of these facilities followed the Company's receipt of non-renewal and termination notices from Novartis and AstraZeneca in March 2007. In fiscal 2007, the Company recorded restructuring expenses of approximately $3.8 million which are included in general and administrative expenses. These restructuring expenses include severance of approximately $848,000, the acceleration of amortization of leasehold improvements of approximately $828,000 and the recognition of the estimated loss under the terms of the Company's leases of approximately $2.1 million. No further costs were incurred related to these restructuring events in fiscal 2008.

The following table presents the restructuring activities for fiscal 2008:

	Balance at September 30, 2007	Payments/ Reductions	Balance at September 30, 2008
Accrued Restructuring			
Employee severance and relocation benefits	$ 75,790	$ (75,790)	$ —
Lease restructuring liability	2,223,802	(1,087,837)	1,135,965
Total	2,299,592	$(1,163,627)	1,135,965
Less current portion	(1,163,627)		(316,086)
Total	$ 1,135,965		$ 819,879

The following table presents the restructuring activities for fiscal 2007:

	Balance at September 30, 2006	Charges/ Additions	Payments/ Reductions	Balance at September 30, 2007
Accrued Restructuring				
Employee severance and relocation benefits	$ 237,050	$ 847,642	$(1,008,902)	$ 75,790
Lease restructuring liability	273,998	2,101,771	(151,967)	2,223,802
Total	511,048	$2,949,413	$(1,160,869)	2,299,592
Less current portion	(280,598)			(1,163,627)
Total	$ 230,450			$ 1,135,965

The current portion of the lease restructuring liability of $316,000 and $1.2 million at September 30, 2008 and 2007, respectively, is included in "Accrued Expenses and Other Liabilities" and the non-current portion of lease restructuring liability of $820,000 and $1.1 million at September 30, 2008 and 2007, respectively, is included in "Accrued Expenses and Other Liabilities, Net of Current Portion" in the accompanying consolidated balance sheets.

5. Investments in Marketable Securities

Investments in marketable securities at September 30, 2008 consist of restricted investments in certificates of deposits, which are classified as held-to-maturity. At September 30, 2008, the fair value of these investments approximated their cost basis.

The following tables summarize our investments in securities as of September 30, 2008 and 2007, all of which are classified as available-for-sale except for restricted investments, which are classified as held-to-maturity.

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses(1)	Fair Value
As of September 30, 2008:				
Certificates of deposit	$856,597	—	—	$856,597
Government debt securities	—	—		—
Total	$856,597	—	$ —	$856,597
Reported as:				
Current investments in securities:				
Restricted investments				$388,122
Classified as available for sale				
Total current investments in securities				388,122
Non-current investments in securities:				
Restricted investments				468,475
Classified as available for sale				
Non-current investments in securities				468,475
Total investments in securities				$856,597

	Amortized Cost	Gross Unrealized Losses	Fair Value
As of September 30, 2007:			
Certificates of deposit	$1,156,597	$ —	$1,156,597
Government debt securities	1,999,584	(2,745)	1,996,839
Total	$3,156,181	$(2,745)	$3,153,436
Reported as:			
Current investments in securities:			
Restricted investments			$ 688,122
Classified as available for sale			1,747,761
Total current investments in securities:			2,435,883
Non-current investments in securities:			
Restricted investments			468,475
Classified as available for sale			249,078
Non-current investments in securities:			717,553
Total investments in securities			$3,153,436

6. Inventories

Inventories relate to the active pharmaceutical ingredient docosanol and the active pharmaceutical ingredients of Zenvia, dextromethorphan and quinidine.

The composition of inventories as of September 30, 2008 and 2007 is as follows:

	September 30, 2008	September 30, 2007
Raw materials	$1,333,277	$1,354,991
Less: current portion	(17,000)	(17,000)
Non-current portion	$1,316,277	$1,337,991

The amount classified as non-current inventories is comprised of docosanol and the raw material components for Zenvia, dextromethorphan and quinidine, which will be used in the manufacture of Zenvia capsules in the future.

7. Property and Equipment

Property and equipment as of September 30, 2008 and 2007 consist of the following:

	As of September 30, 2008			As of September 30, 2007		
	Gross Carrying Value	Accumulated Depreciation	Net	Gross Carrying Value	Accumulated Depreciation	Net
Research and development equipment	$ 9,421	$ (9,421)	$ —	$ 761,815	$ (588,325)	$ 173,490
Computer equipment and related software	1,319,891	(1,080,132)	239,759	1,285,454	(941,628)	343,826
Leasehold improvements	37,790	(11,362)	26,428	37,790	(3,787)	34,003
Office equipment furniture and fixtures	763,260	(484,257)	279,003	767,313	(364,685)	402,628
Manufacturing equipment	261,719	—	261,719	261,719	—	261,719
Total property and equipment	$2,392,081	$(1,585,172)	$806,909	$3,114,091	$(1,898,425)	$1,215,666

Depreciation expense associated with property and equipment was $415,000 for fiscal 2008. Depreciation expense associated with property and equipment was $3.6 million of which $768,000 was related to discontinued operations for fiscal 2007.

In fiscal 2008, the Company retired $850,000 of research and development equipment with a net book value of $120,000 resulting in a decrease to accumulated depreciation of $730,000.

8. Intangible Assets

During fiscal 2008, we wrote off our intangible assets consisting of licenses and trademarks of $41,048, as we deemed these costs not to be recoverable. The write-off of these assets are included in amortization expense for the period ended September 30, 2008.

Intangible assets, consisted of both intangible assets with finite and indefinite useful lives as of September 30, 2007, were as follows:

	September 30, 2007			
	Gross Carrying Value	Accumulated Amortization	Net	Weighted Average Amortization Period (in years)
Intangible assets with finite lives:				
Licenses	$42,461	$(22,418)	$20,043	15.5
Total intangible assets with finite lives	42,461	(22,418)	20,043	
Intangible assets with indefinite lives	21,005	—	21,005	
Total intangible assets	$63,466	$(22,418)	$41,048	

During fiscal 2007, the Company sold FazaClo, and therefore, its intangible assets pertaining to FazaClo product rights, customer relationships, trade name and non-compete agreements with a net book value of $10.1 million were eliminated in the transaction.

Amortization expense related to amortizable intangible assets was $41,000 and $22,000 for fiscal 2008 and 2007, respectively.

9. Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities at September 30, 2008 and 2007 are as follows:

	September 30, 2008	September 30, 2007
Accrued research and development expenses	$ 1,404,556	$ 419,989
Accrued general and administrative expenses	160,759	287,517
Deferred rent	48,638	34,432
Lease restructuring liability	1,135,965	2,223,802
Other	—	255,520
Total accrued expenses and other liabilities	2,749,918	3,221,260
Less: current	(1,881,401)	(2,050,864)
Non-current total accrued expenses and other liabilities	$ 868,517	$ 1,170,396

10. Deferred Revenues/Sale of Licenses

The following table sets forth as of September 30, 2008 and 2007 the net deferred revenue balances for our 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, 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 USA Agreement	Other Agreements	Total
Net deferred revenues as of October 1, 2006	$17,111,913	$ 2,242,262	$19,354,175
Changes during the period:			
Additions	—	278,910	278,910
Recognized as revenues during period	(2,373,404)	(1,939,251)	(4,312,655)
Net deferred revenues as of September 30, 2007	$14,738,509	$ 581,921	$15,320,430
Classified and reported as:			
Current portion of deferred revenues	$ 1,969,507	$ 298,087	$ 2,267,594
Deferred revenues, net of current portion	12,769,002	283,834	13,052,836
Total deferred revenues	$14,738,509	$ 581,921	$15,320,430

Drug Royalty Agreement — In December 2002, we sold to Drug Royalty USA an undivided interest in our 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. 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. In fiscal 2008 and 2007, we recognized royalties in the amount of $934,000 and $214,000, respectively, and is included as revenues from royalties.

In accordance with SAB Topic 13, revenues are recognized when earned, collection is reasonably assured and no additional performance of services is required. We classified the proceeds received from Drug Royalty USA as deferred revenue, to be recognized as revenue over the life of the license agreement consistent with SAB Topic 13 because of our 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 (Section 8) and events of default (Section 10) that require such performance on our part. Therefore, nonperformance on our 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 our rights to share in future Abreva royalties if wholesale sales by GlaxoSmithKline exceed $62 million a year. Because of our continuing involvement, we 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 our continuing involvement, we concluded that the sale proceeds did not meet any of the rebuttable presumptions in EITF 88-18 that would require classification of the proceeds as debt.

Kobayashi Docosanol License Agreement — In January 2006, we 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 our docosanol 10% cream either as the sole active ingredient or in combination with any other ingredient, substance or compound (the "Products") (the "Kobayashi License Agreement"). Pursuant to the terms of the Kobayashi License Agreement, we received a non-refundable know-how and data transfer fee ("License Fee") of $860,000 in March 2006.

Under the terms of the Kobayashi License Agreement, Kobayashi is responsible for obtaining all necessary approvals for marketing activities, and for the manufacturing and distribution of the Products. Because the know-how and expertise related to the docosanol 10% cream are proprietary to us, we agreed to provide assistance to Kobayashi, upon their request, in completing additional required clinical studies and in filing the new drug application ("NDA") submission for the licensed product in Japan. Pursuant to SAB Topic 13, revenue from the License Fee of $860,000 has been deferred and is being recognized on a straight-line basis over 3.75 years. Accordingly, we recognized $228,000 and $227,000 of the License Fee in fiscal 2008 and 2007, respectively, which is included in revenues from license agreements.

In October 2008, we received notice from Kobayashi that they have not been able to further advance the docosanol program due to the clinical and regulatory environment in Japan. Therefore, we expect to terminate the License Agreement in fiscal 2009.

HBI Docosanol License Agreement — In July 2006, we entered into an exclusive license agreement with Healthcare Brands International ("HBI"), pursuant to which we 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, we received an upfront data and know-how transfer fee of $1.4 million in July 2006 in exchange for providing certain data ("Data Transfer Requirements"). We received official notice from HBI in April 2007 that we met the initial data transfer obligations under the license agreement. As a result, we

recognized the $1.4 million as license revenue during fiscal 2007. We 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, we will receive an additional payment related to the future value of docosanol under the Agreement.

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. The $500,000 is included in revenues from licensing agreements.

11. Commitments and Contingencies

Operating lease commitments. We lease 11,319 square feet of office space in Aliso Viejo, CA. The lease has scheduled rent increases each year and expires in 2011. As of September 30, 2008, the financial commitment for the remainder of the term of the lease is $1.1 million.

We lease approximately 30,370 square feet of office and lab space in San Diego, CA. The lease has scheduled rent increases each year and expires in 2013. In September 2006, we subleased approximately 9,000 square feet of these buildings. The sublease has scheduled rent increases each year and a three-year term that expires in September 2009. In addition, the sublease provides the sublessee the option to renew the sublease through 2013. In July 2007, we subleased approximately 21,184 square feet. The sublease has scheduled rent increases each year and expires on January 14, 2013. As of September 30, 2008, the financial commitment for the remainder of the term of the lease is $5.0 million (excludes the benefit of $3.3 million of payments to be received from the subleases). We delivered an irrevocable standby letter of credit to the lessor in the amount of approximately $468,000, to secure our performance under the lease.

Rental payments, excluding common area charges and other executory costs, were $2.3 million in fiscal 2008 and $2.3 million in fiscal 2007. Sublease rental receipts totaled approximately $888,000 in fiscal 2008 and $292,000 in fiscal 2007. Future minimum rental payments under non-cancelable operating lease commitments as of September 30, 2008 are as follows:

Year Ending September 30,	Minimum Payments	Less Payments to be Received from Subleases	Net Payments
2009	$1,475,000	$ 904,000	$ 571,000
2010	1,530,000	680,000	850,000
2011	1,483,000	708,000	775,000
2012	1,223,000	736,000	487,000
2013	352,000	216,000	136,000
Total	$6,063,000	$3,244,000	$2,819,000

Legal contingencies. 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 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 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 and lawsuits will not likely have a material effect on our consolidated operations or financial position.

In September 2007, a court awarded the Company reimbursement of attorneys' fees incurred over a four-year period in connection with the enforcement of a settlement agreement entered into with a former employee. In April 2008, the Company received the proceeds from the settlement in the amount of $1.25 million. The proceeds were recorded as other income in the third fiscal quarter of 2008.

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

Guarantees and Indemnities. We indemnify our directors and officers to the maximum extent permitted under the laws of the State of California, 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. We have 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, 2008 and 2007.

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.

12. Notes Payable

As of September 30, 2008 and 2007, notes payable consist of the following:

	September 30, 2008	September 30, 2007
Senior notes with an interest rate of LIBOR + 1.33%; interest payable monthly; repaid June 2008; unamortized discount of $232,776 at September 30, 2007	$ —	$11,737,087
9.5% equipment loan repaid April 2008	—	174,224
10.43% equipment loan due February 2009	16,275	65,442
10.17% equipment loan due January 2009	9,469	47,839
Total	25,744	12,024,592
Less: current portion	(25,744)	(254,676)
Total long-term notes payable	$ —	$11,769,916

Senior Notes. In connection with the Alamo Acquisition, we issued promissory notes (the "Notes") totaling $29.1 million, including $4.0 million in notes issued in fiscal 2007 pursuant to an earn-out arrangement. The Notes bore interest at an average rate equal to the London Inter-Bank Offered Rate, or "LIBOR," plus 1.33%. The LIBOR rate at September 30, 2007 was 5.12%. The principal amount of the Notes was set to mature on May 24, 2009.

In fiscal 2007, we used approximately 20% of net proceeds from equity offerings, or $6.1 million, to pay down the Notes. In connection with our sale of FazaClo in August 2007, we agreed to prepay $11 million of outstanding principal due under the Notes.

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.

Equipment Loans. In September 2004, we 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 and 2007 under the GE Capital finance agreement is approximately $26,000 and $288,000, respectively. The balance of approximately $26,000 at September 30, 2008 is due in fiscal 2009.

13. Shareholders' Equity

Preferred Stock

In March 1999, our Board of Directors approved a shareholder rights plan (the "Plan") that provides for the issuance of Series C junior participating preferred stock to each of our shareholders of record under certain circumstances. None of the Series C junior participating preferred stock was outstanding on September 30, 2008 and 2007. 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 25, 1999 (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 15% or more of our common stock or announces a tender offer for 15% 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 C 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 $0.01 per Right at any time before a person has acquired 20% or more of the outstanding common stock. The Rights will expire on March 25, 2009.

Common stock

Fiscal 2008. In April 2008, we 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, we 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. The proceeds are expected to provide adequate capital to ensure continuing operations through the anticipated timing of the FDA approval decision for Zenvia for the PBA indication.

During fiscal 2008, we 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, we 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.

Fiscal 2007. In November 2006, we sold 5,263,158 shares of our common stock for aggregate gross offering proceeds of $15.0 million ($14.4 million after expenses). In connection with this offering, we issued warrants to purchase a total of 1,053,000 shares of our common stock at an exercise price of $3.30 per share. The warrants became exercisable beginning in May 2007 and all unexercised warrants expired in November 2007.

During fiscal 2007 we sold 6,125,632 shares of our common stock under our financing facility with Brinson Patrick Securities Corporation, raising net offering proceeds of $16.1 million. These offerings were made pursuant to our shelf registration statement on Form S-3 filed on July 22, 2005. Approximately $6.1 million of the net proceeds from these offerings were used to partially repay the outstanding principal balance of a note payable issued in the Alamo acquisition, with such repayment being made in accordance with the terms of the note. See Note 12 "Notes Payable".

Also during fiscal 2007, we issued to employees 29,250 shares of restricted stock related to awards granted in fiscal 2006 and 15,000 shares of restricted stock at a weighted average grant date fair value of $7.34 and with a purchase price of $0.01 per share. In fiscal 2007, we also awarded 2,321,043 of restricted stock units with a grant date fair value of $1.74 and no purchase price per share.

During fiscal 2007, our CEO and CFO exercised their option to pay for minimum required withholding taxes associated with certain vested shares of their restricted stock awards by surrendering 16,943 and 1,192 shares of common stock, respectively, at an average market price of $2.19 and $3.38, respectively.

A summary of common stock transactions during fiscal 2008 and 2007 are shown 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, 2008:				
Registered offering of common stock	April 2008	34,972,678	$40,000,000	$1.14
Private placement of common stock	January 2008	34,568	44,200	$1.28
Restricted stock awards and restricted stock units	Various	113,361	—	$ —
Total		35,120,607	$40,044,200	
Fiscal year ended September 30, 2007:				
Private placement of common stock	November 2006	5,263,158	$14,999,999	$2.85
Private placement of common stock	Various	6,125,632	16,827,007	$2.75
Restricted stock awards and restricted stock units	Various	128,150	—	$ —
Stock options	Various	67,758	294,699	$4.33
Total		11,584,698	$32,121,705	

(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 our registered securities offering, we issued warrants to acquire up to approximately 12,240,437 million shares of our 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, 2008, all these warrants are exercisable and remained outstanding.

In November 2006, 1,053,000 shares of our common stock were issued in connection with a private placement offering at an exercise price of $3.30 per share. The warrants became exercisable in May 2007 and all unexercised warrants expired in November 2007. None of the warrants were exercised.

The following table summarizes all warrant activity for fiscal 2008 and 2007:

	Shares of Common Stock Purchasable Upon Exercise of Warrants	Weighted Average Exercise Price per Share	Range of Exercise Prices
Outstanding at September 30, 2006	269,305	$8.92	$ 8.92
Issued	1,053,000	$3.30	$ 3.30
Outstanding at September 30, 2007	1,322,305	$4.45	$3.30-$8.92
Issued	12,240,437	$1.43	$ 1.43
Expired	(1,053,000)	$3.30	$ 3.30
Outstanding at September 30, 2008	12,509,742	$1.59	$1.43-$8.92

Employee Equity Incentive Plans

We currently have 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. All of the Plans were approved by the shareholders, 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 our Board of Directors. Our policy is to issue new common shares upon the exercise of stock options, conversion of share units or purchase of restricted stock.

During fiscal 2008 and 2007, we 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 our employees and consultants. Under the Plans, as of September 30, 2008, we had an aggregate of 8,050,287 shares of our common stock reserved for issuance. Of those shares, 5,104,643 were subject to outstanding options and other awards and 2,945,644 shares were available for future grants of share-based awards. We also issued share-based awards outside of the Plans. As of September 30, 2008, there were no options to purchase shares of our 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, 2008.

2005 Equity Incentive Plan. On March 17, 2005, our shareholders approved the adoption of the 2005 Plan that initially provided for the issuance of up to 500,000 shares of common stock, plus an annual increase beginning in fiscal 2006 equal to the lesser of (a) 1% of the shares of common stock outstanding on the last day of the immediately preceding fiscal year, (b) 325,000 shares of common stock, or (c) such lesser number of shares of common stock as the board of directors shall determine. Pursuant to the provisions of annual increases, the number of authorized shares of common stock for issuance under the 2005 Plan increased by 273,417 shares effective November 16, 2005, 317,084 shares effective November 30, 2006 and an additional 325,000 shares effective December 4, 2007 to a total of 1,415,501 shares. In February 2006, our shareholders 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 our directors, officers, employees and consultants. As of September 30, 2008, 555,540 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 and 2,158,220 shares effective February 21, 2008 to a total of 6,169,622 shares. The 2003 Plan allows us to grant options, restricted stock awards and stock appreciation rights to our directors, officers, employees and consultants. As of September 30, 2008, 1,751,212 shares of common stock remained available for issuance under the 2003 Plan.

2000 Stock Option Plan. On March 23, 2000, our shareholders approved the adoption of the 2000 Plan, pursuant to which an aggregate of 575,000 shares of our common stock have been reserved for issuance. On March 14, 2002, our shareholders 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, we amended the 2000 Plan to allow for the issuance of restricted stock awards. As of September 30, 2008, 540,737 shares of common stock were available for grant under the 2000 Plan.

1998 Stock Option Plan. On February 19, 1999, our shareholders approved the 1998 Plan. The 1998 Plan as amended in 2002 provides for the issuance of up to an aggregate of 468,750 shares of common stock. The 1998 Plan

allows us to grant options to our directors, officers, employees and consultants. As of September 30, 2008, options to purchase 98,155 shares of common stock were available for grant under the 1998 Plan.

Stock Options. Stock options are granted with an exercise price equal to the current market price of our 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; or

c. 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 2008 and 2007 are presented below.

	Shares of Common Stock Purchasable Upon Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value
Outstanding October 1, 2006	1,587,070	$10.07		
Granted	490,161	$ 4.47		
Exercised	(67,758)	$ 4.33		
Forfeited	(960,767)	$10.22		
Expired	(8,125)	$ 7.89		
Outstanding September 30, 2007	1,040,581	$ 7.69		
Granted	12,000	$ 0.79		
Forfeited	(419,720)	$ 9.13		
Expired	(8,834)	$ 5.20		
Outstanding September 30, 2008	624,027	$ 6.61	7.3	$—
Vested and expected to vest in the future, September 30, 2008	484,545	$ 7.76	7.0	$—
Exercisable, September 30, 2008	275,410	$10.50	5.9	$—
Exercisable, September 30, 2007	458,240	$ 9.85		

The weighted average grant-date fair values of options granted during fiscal 2008 and 2007 were $0.58 and $2.12 per share, respectively. There were no stock options exercised in fiscal 2008. The total intrinsic value of options exercised during fiscal 2007 was approximately $271,000 based on the differences in market prices on the dates of exercise and the option exercise prices. As of September 30, 2008, the total unrecognized compensation cost related to options was $797,000, net of forfeitures, which is expected to be recognized over a weighted-average period of 1.7 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 our 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 2008 and 2007 were as follows:

	2008	2007
Expected volatility	95.8%	75.0% — 113.4%
Weighted-average volatility	95.8%	93.7%
Average expected term in years	5.0	6.0
Risk-free interest rate (zero coupon U.S. Treasury Note)	2.9%	4.3% — 4.7%
Expected dividend yield	0%	0%

The following table summarizes information concerning outstanding and exercisable stock options as of September 30, 2008:

	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
$ 0.79-$ 1.20	32,000	9.0	$ 1.05	7,500	$ 1.20
$ 1.29	130,960	8.5	$ 1.29	—	$ —
$ 2.41	120,781	9.0	$ 2.41	—	$ —
$ 2.88-$ 6.92	91,849	5.8	$ 5.87	61,850	$ 5.59
$ 7.12-$11.68	63,187	6.0	$10.70	60,392	$10.65
$11.76	100,000	6.8	$11.76	75,000	$11.76
$12.12-$19.38	85,250	6.0	$14.57	70,668	$14.34
	624,027	7.3	$ 6.61	275,410	$10.50

Performance Stock Options. During fiscal 2008, we 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 our 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. 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. At September 30, 2008, there are 817,650 performance stock options expected to vest after consideration of expected forfeitures.

The fair value of each performance 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 our 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	96.4% — 99.3%
Weighted-average volatility	98.9%
Average expected term in years	5.3-6.3
Risk-free interest rate (zero coupon U.S. Treasury Note)	3.3% — 3.5%
Expected dividend yield	0%

All performance stock options granted in fiscal 2008 are unvested and outstanding at September 30, 2008. The weighted average grant-date fair values of performance stock options granted during fiscal 2008 was $0.70. The total unrecognized compensation cost related to performance stock options was $1.4 million, which is expected to be recognized over a weighted-average period of 4.5 years at September 30, 2008, based on the vesting schedules. Approximately $55,000 of share-based compensation expense was recognized in fiscal 2008.

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 2008:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested, October 1, 2007	1,914,988	$2.17
Granted	868,251	$1.48
Vested	(289,947)	$2.63
Forfeited	(234,250)	$1.75
Unvested, September 30, 2008	2,259,042	$1.85

The weighted average grant-date fair value of RSUs granted during fiscal 2008 and 2007 was $1.48 and $1.74 per unit, respectively. The fair value of RSUs vested during fiscal 2008 and 2007 was $763,000 and $232,000, respectively. As of September 30, 2008, the total unrecognized compensation cost related to unvested shares was $2.9 million, which is expected to be recognized over a weighted-average period of 1.8 years, based on the vesting schedules and assuming no forfeitures.

At September 30, 2008, there were 173,000 shares of restricted stock with a weighted-average grant date fair value of $4.22 per share awarded to directors that have vested but are still restricted until the directors resign.

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. A summary of our unvested restricted stock awards at September 30, 2008 and 2007 and changes during fiscal 2008 are presented below.

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested, October 1, 2007	22,500	$11.87
Vested	(20,500)	$12.35
Forfeited	(2,000)	$ 6.91
Unvested, September 30, 2008	—	$ —

There were no restricted stock awards granted in fiscal 2008. The weighted average grant-date fair value of restricted stock awards granted in fiscal 2007 was $7.34 per share. The fair value of restricted stock awards vested in fiscal 2008 and 2007 was $253,000 and $745,000. As of September 30, 2008, all outstanding restricted stock awards have been fully expensed and none are vested.

There were no exercises of stock options in fiscal 2008 and there were no cash received from the issuance of restricted stock awards in fiscal 2008. During fiscal 2007, we received a total of approximately $295,000 in cash from exercised options and restricted stock awards under all share-based payment arrangements. No tax benefit was realized for the tax deductions from option exercise of the share-based payment arrangements in fiscal 2007.

14. Research, License, Supply and other Agreements

Center for Neurologic Study ("CNS") — We hold the exclusive worldwide marketing rights to Zenvia for certain indications pursuant to an exclusive license agreement with 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. In fiscal 2005, we 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, we are 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, we may have the obligation to pay CNS a portion of net revenues received if we sublicense Zenvia to a third party. Under our agreement with CNS, we are 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 we pursued the development of Zenvia for all of the licensed indications. Of the clinical indications that we currently plan 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, we are obligated to pay CNS a royalty ranging from approximately 5% to 8% of net revenues. From inception through September 20, 2008, no milestone payments have been made under this agreement.

AstraZeneca UK Limited ("AstraZeneca"). In July 2005, we entered into an exclusive license and research collaboration agreement with AstraZeneca regarding the license of certain compounds for the potential treatment of cardiovascular disease. In March 2007, the Research Collaboration and License Agreement was mutually terminated. Pursuant to the agreement, AstraZeneca was required to pay the Company for certain research services for a period of up to three years. In fiscal 2007, we recorded research and development services and direct cost reimbursement revenues of approximately $1.2 million and other income resulting from a one-time termination fee in the amount of $1,250,000.

Novartis International Pharmaceutical Ltd. ("Novartis"). In April 2005, we entered into an exclusive Research Collaboration and License Agreement with Novartis regarding the license of certain compounds that regulate macrophage migration inhibitory factor ("MIF") in the treatment of various inflammatory diseases. For two years, we provided research support services to Novartis under this agreement and, in March 2007, Novartis made the decision to continue the MIF research program internally. As a result, the research collaboration portion of

this agreement was not renewed. Under the terms of the agreement, AVANIR is eligible to receive over $200 million in combined upfront and milestone payments upon achievement of development, regulatory, and sales objectives. AVANIR is also eligible to receive escalating royalties on any worldwide product sales generated from this program. In fiscal 2007, we recorded research and development services revenue of approximately $1.2 million. No revenues were earned in fiscal 2008 from this agreement.

HBI Docosanol License Agreement — In July 2006, we entered into an exclusive license agreement with Healthcare Brands International, pursuant to which we 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 April 2007, we recognized approximately $1.4 million of deferred revenue when we met the initial data transfer obligation under the license agreement. We received payments of approximately $1.5 million each in fiscal 2008 and fiscal 2007 due to HBI's attainment of European regulatory approvals and clearances to sell docosanol in two countries. In fiscal 2008 and 2007, $1.5 million and $2.9 million were earned from this agreement, respectively.

Kobayashi Docosanol License Agreement — In January 2006, we signed an exclusive license agreement with Kobayashi Pharmaceutical Co., Ltd., 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 our docosanol 10% cream either as the sole active ingredient or in combination with any other ingredient, substance or compound. The Kobayashi License Agreement automatically expires upon the latest to occur of (1) the tenth anniversary of the first commercial sale in Japan, (2) the last expiration date of any patent licensed under the Kobayashi License Agreement, or (3) the last date of expiration of the post marketing surveillance period in Japan. We recognized approximately $228,000 and $227,000 of deferred revenue in fiscal 2008 and 2007, respectively.

In October 2008, we received notice from Kobayashi that they have not been able to further advance the docosanol program due to the clinical and regulatory environment in Japan. Therefore, we expect to terminate the License Agreement in fiscal 2009.

Boryung Pharmaceuticals Company Ltd ("Boryung"). In March 1994, we entered into a 12-year exclusive license and supply agreement with Boryung, giving them the rights to manufacture and sell docosanol 10% cream in the Republic of Korea. Under the terms of the agreement, Boryung is responsible for manufacturing, marketing, sales and distribution of docosanol 10% cream, and paying a royalty to us on product sales. The agreement includes a supply provision under which Boryung purchases from us its entire requirement of active ingredient for use in the manufacture of topical docosanol 10% cream. Boryung launched the product, Herepair, in June 2002. No revenues were earned from this agreement in fiscal 2008 and 2007.

GlaxoSmithKline Subsidiary, SB Pharmco Puerto Rico, Inc. ("GlaxoSmithKline"). On March 31, 2000, we signed an exclusive license agreement with GlaxoSmithKline (NYSE: GSK) for rights to manufacture and sell Abreva (docosanol 10% cream) as an over-the-counter product in the United States and Canada as a treatment for recurrent oral-facial herpes. Under the terms of the license agreement, 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, we 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 10, "Deferred Revenues/Sale of Licenses.")

Bruno Farmaceutici ("Bruno"). In July 2002, we entered into an agreement with Bruno giving them the rights to manufacture and sell docosanol 10% cream in Italy, Europe's fourth largest market for the topical treatment of cold sores. The agreement requires that Bruno purchase its entire requirement of raw materials from us and pay us a royalty on product sales. Docosanol 10% cream is not yet approved for marketing in Italy. Bruno is responsible for obtaining regulatory approval in Italy. This agreement will continue until the fifteenth anniversary of the first shipment date. In September 2007, we recognized $75,000 of revenue that was deferred in fiscal 2004. No revenues were recognized from this agreement in fiscal 2008.

P.N. Gerolymatos SA. ("Gerolymatos"). In May 2004, we 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. No revenues were recognized from this agreement in fiscal 2008 or 2007.

ACO HUD. In September 2004, we 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 and $115,000 were recorded during the fiscal years ended September 30, 2008 and 2007, respectively.

In 2008, we received notice from ACO HUD that they plan to discontinue marketing of docosanol at year end. Avanir intends to terminate the license agreement and transfer rights to the countries covered in the agreement to a new partner in fiscal 2009.

Emergent Biosolutions. 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 future research and development work related to other infectious diseases on June 30, 2008. We earned $500,000 in licensing revenue in fiscal 2008.

Non-anthrax related antibodies. 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.

Government research grants. We are also engaged in various research programs funded by government research grants. The government research grants are to be used for conducting research on various docosanol-based

formulations for a potential genital herpes product and development of antibodies to anthrax toxins. In June 2006, we were notified that we had been awarded a $2.0 million research grant from the NIH for ongoing research and development related to our anthrax antibody. In May 2007, we were notified that we had been awarded a one-year extension of our $2.0 million research grant from the NIH/NIAID for ongoing research and development related to our anthrax antibody. Under the terms of the grant, the NIH will reimburse us for up to $2.0 million in certain expenses (including expenses incurred in the 90 days preceding the grant award date) related to the establishment of a cGMP manufacturing process and the testing of efficacy of the anthrax antibody. The balance remaining under the research grants as of September 30, 2008 and 2007 was approximately $0 and $1.1 million, respectively.

15. Income Taxes

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

	2008	2007
Current:		
State and foreign	$ 3,200	$ 3,200
Deferred:		
Federal	(5,147,297)	(7,011,828)
State and foreign	(1,115,570)	(714,424)
	(6,262,867)	(7,726,252)
Increase in deferred income tax asset valuation allowance	6,262,867	7,726,252
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 our net deferred income tax balance were as follows:

	September 30,	
	2008	2007
Net operating loss carryforwards	$ 83,265,183	$ 75,965,310
Deferred revenue	4,943,699	6,118,100
Research credit carryforwards	10,964,507	10,295,636
Capitalized research and development costs	1,263,921	1,379,468
Capitalized license fees and patents	3,411,306	3,724,831
Share-based compensation and options	2,584,645	1,946,490
Foreign tax credits	595,912	595,912
Other	622,961	1,387,534
Deferred income tax assets	107,652,134	101,413,281
Deferred tax liabilities:		
Other	(54,734)	(78,748)
Deferred tax liabilities	(54,734)	(78,748)
Less valuation allowance for net deferred income tax assets	(107,597,400)	(101,334,533)
Net deferred tax assets / (liabilities)	$ —	$ —

We have provided a full valuation allowance against the net deferred income tax assets recorded as of September 30, 2008 and 2007 as we concluded that they are unlikely to be realized. As of September 30, 2008 we had federal and state net operating loss carryforwards of $223,000,000 and $140,000,000, respectively. As of September 30, 2008 we had federal and California research and development credits of $7,000,000 and $6,900,000, respectively. The net operating loss and research credit carryforwards that will expire on various dates through 2028 begin to expire in 2011, unless previously utilized. In the event of certain ownership changes, the Tax Reform Act of 1986 imposes certain restrictions on the amount of net operating loss and credit carry forwards that we 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:

	2008	2007
Federal statutory rate	(34)%	(34)%
Increase in deferred income tax asset valuation allowance	36	36
State income taxes, net of federal effect	(6)	(6)
Research and development credits	(4)	(4)
Expired net operating loss and other credits	7	6
Other	1	2
Effective income tax rate	0%	0%

16. Employee Savings Plan

We have 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. We are not required to make matching contributions under the plan. However, we voluntarily contributed approximately $47,000 in fiscal 2008 and $206,000 in fiscal 2007 to the plan.

17. Segment Information

We operate our business on the basis of a single reportable segment, which is the business of discovery, development 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 geographic area based on selling location. All our operations are currently located in the United States; therefore, total revenues for fiscal 2008 and 2007 are attributed to the United States. All long-lived assets at September 30, 2008 and 2007 are located in the United States.

Approximately 50% and 28% of our total revenues in fiscal 2008 and 2007, respectively, are derived from our license agreement with GlaxoSmithKline and the sale of rights to royalties under that agreement. Approximately 21% and 31% of our total revenues in fiscal 2008 and 2007, respectively, are derived from our license agreement with HBI and the sale of rights to royalties under that agreement. Revenues derived from our license agreements with AstraZeneca and Novartis accounted for approximately 13% and 12%, respectively, of our total revenues in fiscal 2007. Revenues derived from our government grant account for 14% and 10% of total revenues in fiscal 2008 and 2007, respectively.

The Company had no accounts receivable at September 30, 2008. Net receivables from Bausch and Lomb accounted for 100% of our total accounts receivables at September 30, 2007.

18. Subsequent Events

On November 11, 2008, Avanir Pharmaceuticals (the "Company") and American Stock Transfer & Trust Company, as Rights Agent ("AST"), entered into Amendment No. 3 ("Amendment No. 3") to the Rights Agreement dated as of March 5, 1999 between the Company and AST, as amended on November 30, 1999 and April 4, 2008 (the "Rights Agreement"). Amendment No. 3 amended the definition of "Acquiring Person" by increasing the applicable beneficial ownership to 20% of the common stock of the Company then outstanding. Additionally, in light of the increase in the permitted level of beneficial ownership, the Company also deleted references to "Grandfathered Person," whereby one or more designated holders were previously allowed to hold a higher percentage of shares without becoming an "Acquiring Person."

In November 2008, we terminated our Development and License Agreement dated August 7, 2006 with Eurand, Inc. There were no fees resulting from this termination.

From October 1, 2008 through December 12, 2008, approximately 5,000 shares were issued pursuant to the vesting of restricted stock units.

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