AVANIR PHARMACEUTICALS
Form 10-K
December 21, 2007

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

Form 10-K

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

For the fiscal year ended September 30, 2007

OR

o 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:
Class A Common Stock, no par value

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 o NO þ

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 o NO þ

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 and Exchange Act of 1934 during the preceding 12 months (or for such shorter periods that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES þ NO o

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

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

Large Accelerated Filer o Accelerated Filer o Non-accelerated Filer þ

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of March 31, 2007 was approximately $46.9 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.

43,121,858 shares of the registrant s Common Stock were issued and outstanding as of December 7, 2007.

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 2008 Annual Meeting of Shareholders, which will be held on February 21, 2008 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 expe 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. Except as otherwise indicted herein, all dates referred to in this Report represent periods or dates fixed with reference to the calendar year, rather than our fiscal year ending September 30.

Executive Overview

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, inflammatory diseases and infectious 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 and our infectious disease program, which is focused primarily on anthrax antibodies, is currently being funded by grants from the National Institute of Health/National Institute of Allergy and Infectious Disease (NIH/NIAID).

Zenvia Status

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

In October 2006, we received an approvable letter from the FDA for Zenvia in the treatment of patients with PBA/IEED. 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 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 dose formulations. The goal of the study is to demonstrate improved safety while maintaining significant efficacy. 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 expect this study to be completed (as defined as top-line safety and efficacy data becomes available) during the second half of calendar 2009.

In April 2007, we announced top-line data results from our first Phase III clinical trial of Zenvia for DPN pain. After receipt of these positive results, we requested a meeting with the FDA to discuss the next steps for this program. The FDA informed Avanir it would not be necessary to meet and that Avanir should develop and then submit the protocol

for the next study as well as any questions related to the development program for Zenvia. We are proceeding forward under this guidance and are currently conducting 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 before interacting with the FDA. While we have received no formal direction 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 concerns raised over Zenvia for PBA.

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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, which 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 approximately $43.9 million in an up-front cash payment and may provide up to an additional $10 million in contingent payments to be paid in calendar year 2009, subject to certain regulatory conditions. In addition, the Company is eligible to receive up to $2 million in royalties, based on 3% of annualized net product revenues in excess of $17 million. Azur acquired the FazaClo sales force and support operations, representing approximately 80 employees in total. As a result, we became a substantially smaller organization following the sale of FazaClo and will be principally focused over the next two to three years on seeking regulatory approval of Zenvia for the treatment of patients with PBA and patients with DPN pain.

We also undertook other cost-cutting measures following receipt of the Zenvia approvable letter. We have ceased all pre-launch commercial readiness activities for Zenvia and have significantly reduced our administrative organization. We also cut back our drug discovery operations following (1) the non-renewal and termination of our Research Collaboration and License Agreement with AstraZeneca U.K. in March 2007 and (2) the completion of our two-year research collaboration with Novartis International Pharmaceutical Ltd. in March 2007. Our license agreement with Novartis currently remains in effect and Novartis is continuing clinical development of the licensed compounds. In late 2006 and early 2007, we consolidated operations to our headquarters in Orange County, California and, in July 2007, we subleased approximately 49,000 square feet of laboratory and office space, which represented all of our remaining excess facilities in San Diego, CA.

Based on our current capital resources and focus on obtaining approval for Zenvia, we have also structured the ongoing development of our anthrax human monoclonal antibody program so that direct development costs do not materially exceed funding levels from National Institutes of Health/National Institute of Allergy and Infectious Disease (NIH/NIAID) research grants or potential development partners. In May 2007, we received a one-year extension of our grant from the NIH/NIAID to fund further pre-clinical development of our anti-anthrax human monoclonal antibody and we are continuing development under this grant. We have suspended funding and development activity for our selective cytokine inhibitor program and will abandon the patents associated with this program if we are unable to find a licensing partner by the end of 2007.

As a result of these initiatives, we have undergone significant organizational changes in fiscal 2007. Our principal focus is currently on gaining regulatory approval for Zenvia, first for the treatment of patients with PBA and then for patients with DPN pain. We believe that the proceeds from the sale of FazaClo will be sufficient to fund our operations, including our planned confirmatory Phase III trial for Zenvia in patients with PBA, through the end of fiscal 2008. We are currently considering additional means of raising capital to fund ongoing Zenvia development and operations, including borrowing funds, selling common stock or other securities, and the monetization of remaining non-core assets. If we are unable to raise sufficient additional capital when needed in the future to fund our development programs, we may need to slow the development rate of some programs or sell additional rights to one or more drug candidates. 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, www.sec.gov.

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Avanir Product Pipeline 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 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 NDA submission for Zenvia for the treatment of patients with PBA/IEED. 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 low dose formulation of Zenvia is expected to improve the safety and tolerability profile while maintaining comparable efficacy to the Zenvia 30/30 dose tested in prior Phase III trials. We enrolled our first patient in this trial in the first quarter of fiscal 2008.

The NDA for Zenvia contained 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 in patients with 2) PBA secondary to MS. 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. Zenvia demonstrated positive results in both the primary and secondary efficacy endpoints in the prior two pivotal Phase III clinical trials in patients with PBA, as described below.

The Phase III clinical study of Zenvia 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.

The Phase III clinical study of Zenvia 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 at a significantly higher incidence in the Zenvia 30/30 group compared with the DM and Q groups.

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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. One of the most debilitating forms of DPN pain is caused by nerve damage that can result from diabetes. 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. In 2006, neuropathic pain therapies accounted for over $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 (DMQ 45) and 30/30 mg DMQ dosed twice daily (DMQ 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 DMQ 45 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 DMQ 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 DMQ 45 patient group ($p=0.0002$) and for the DMQ 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 Peripheral Neuropathy Quality of Life Scale Composite score and thus not achieving statistical significance, the DMQ 45 patients showed a greater improvement than placebo patients ($p=0.05$) and the DMQ 30 patients showed a 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 DMQ 45 and DMQ 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 DMQ 45, DMQ 30 and placebo groups, respectively, and no deaths occurred during the study.

After receipt of these positive results, we requested a meeting with the FDA to discuss the next steps for this program. The FDA informed Avanir it would not be necessary to meet and that Avanir should submit the protocol for the next study as well as any questions related to the development program for Zenvia. Before interacting further with the FDA we are proceeding forward under this guidance and are currently conducting 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. 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 concerns raised in the approvable letter for Zenvia for PBA.

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, 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. (GlaxoSmithKline) the exclusive rights to market docosanol 10% cream in North America. GlaxoSmithKline markets the product under the name Abreva® in the United States

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and Canada. In fiscal 2003, we sold an undivided interest in our GlaxoSmithKline 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 under the GlaxoSmithKline license agreement for annual net sales of Abreva in North America in excess of $62 million. We also retained the rights to develop and license docosanol 10% cream outside North America for the treatment of cold sores and other potential indications. We have six other collaborations for docosanol around the world. Two of these collaborations currently generate revenue and the other four may generate future 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 regarding the license of certain compounds that regulate macrophage migration inhibitory factor (MIF) in the treatment of various inflammatory diseases. 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 license agreement, we are eligible to receive 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

Our patented Xenerex antibody technology can be used to develop human monoclonal antibodies for use as prophylactic and therapeutic drugs, which may be used to prevent or treat anthrax and other infectious diseases. This proprietary technology provides a platform for accessing human monoclonal antibodies against disease antigens. The Xenerex technology is capable of generating fully human antibodies to target antigens and draws on the natural diversity of the human donor population. Using Xenerex technology, we have discovered a human monoclonal antibody, AVP-21D9, that provides immediate post-exposure neutralization and immediate immunity to animals exposed to a lethal dose of recombinant anthrax toxins.

Our anthrax antibody is in preclinical development and is currently being funded by grants from the NIH/NIAID. 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/NIAID will reimburse us for up to $2.0 million in certain expenses related to the establishment of a current Good Manufacturing Practices (cGMP) manufacturing process and the preclinical testing of the anthrax antibody. Subject to certain conditions, we, as the awardee organization, retain the principal worldwide patent rights to any invention developed with the U.S. government support. Our progress on this program will substantially depend on future grants, as well as our business priorities. Currently, we expect that we will continue with the development of this program only to the extent that its development is funded by research grants. Because all of our monoclonal antibody research is at an early preclinical stage of development and is unpredictable in terms of the outcome, we are unable to predict the cost and timing for development of this antibody.

Discontinued Programs

Reverse Cholesterol Transport (RCT) Technology Atherosclerosis

In July 2005, we entered into an exclusive Research Collaboration and License agreement with AstraZeneca regarding the license of certain compounds we discovered for the potential treatment of cardiovascular disease. In March 2007, the Research Collaboration and License agreement was mutually terminated. According to the terms of the agreement, AstraZeneca returned the lead molecule and will return or make available all related rights to

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Avanir. Following the mutual decision to terminate, we have elected to no longer prosecute any patents associated with this program and we do not expect to continue with any further development efforts for this program.

AVP-13358 Selective Cytokine Inhibitor

In November 2006, in an effort to reduce operating expenses we decided to suspend clinical activities associated with the selective cytokine inhibitor program and seek potential partners for the program. AVP-13358 is an internally discovered novel, orally active drug molecule that has anti-inflammatory and other pharmacological properties that could be useful against certain disease targets. Given our limited resources and the lack of partnership interest, we have made the decision to no longer prosecute any patents associated with this program and we do not expect to continue with any further development efforts for this program.

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 scientific 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 painful diabetic neuropathy. 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.

Antibody generation technology. Several companies, including Emergent BioSolutions, Medarex Inc., Elusys Therapeutics, PharmAthene, VaxGen and MedImmune have research programs focused on developing anthrax antibodies. These companies are generally large and have greater resources to dedicate to development work.

Docosanol 10% cream. Abreva faces intense competition in North America 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 GlaxoSmithKline, respectively, and

Famvir® famciclovir (oral) and Denavir® penciclovir (topical) prescription products marketed by Novartis.

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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.

We, and the manufacturers of our products and product candidates, rely on suppliers of raw materials used in the commercial manufacturing of our products. Some of these materials, including the active ingredients in docosanol 10% cream and Zenvia, are custom and available from only a limited number of sources. We currently attempt to mitigate the risk associated with such sole source raw materials and production by actively managing our inventories and supply and production arrangements. We attempt to remain apprised of the financial condition of our suppliers and their ability to continue to supply our raw materials and finished products in an uninterrupted and timely manner. We have not experienced any significant shortages in supplies of such raw materials or finished products. Unavailability of certain materials or the loss of current sources of production could cause an interruption in production and a reduced supply of finished product pending establishment of new sources, or in some cases, implementation of alternative processes. See Item 1A, Risk Factors, for additional discussion of the risks associated with our outsourcing of manufacturing functions.

Patents and Proprietary Rights

As of September 30, 2007, we owned or had the rights to 183 issued patents (42 U.S. and 141 foreign) and 271 pending applications (35 U.S. and 236 foreign). Patents and patent applications owned by the Company include Zenvia; docosanol-related products and technologies; Xenerex antibody technologies; selective cytokine inhibitor; MIF inhibitor technology and reverse cholesterol transport enhancer.

	United States			Foreign		
Description	**Issued**	**Expiration**	**Pending**	**Issued**	**Expiration**	**Pending**
Zenvia	7	2011 to 2019	3	13(1)	Various	21
Docosanol-related technologies	11	2008 to 2017	1	84	Various	37
Xenerex antibody technologies	2	2008 to 2015	0	13	Various	0
Selective cytokine inhibitor(2)	10	2019	6	22	Various	24
MIF inhibitor technology	12		14	5		96
Reverse cholesterol transport enhancer(2)	0		7	3		51
Other	0		4	1		7
Total	**42**		**35**	**141**		**236**

(1) Does not include November notification from European Patent office of intent to grant PBA and DPN pain patent.

We cannot assure you that the claims in our pending patent applications will be issued as patents, that any issued patents will provide us with significant competitive advantages, or that the validity or enforceability of any of our patents will not be challenged or, if instituted, that these challenges will not be successful. The cost of litigation to

uphold the validity and prevent infringement of our patents could be substantial. Furthermore, we cannot assure you that others will not independently develop similar technologies or duplicate our technologies or design around the patented aspects of our technologies. We can provide no assurance that our proposed technologies will not infringe patents or rights owned by others, the licenses to which might not be available to us.

In addition, the approval process for patent applications in foreign countries may differ significantly from the process in the U.S. The patent authorities in each country administer that country s laws and regulations relating to patents independently of the laws and regulations of any other country and the patents must be sought and obtained separately. Therefore, approval in one country does not necessarily indicate that approval can be obtained in other countries.

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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 new drug application 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. In addition, the handling, care and use of laboratory mice, including the hu-PBL-SCID mice and rats, used for Xenerex technology are subject to the Guidelines for the Humane

Use and Care of Laboratory Animals published by the National Institutes of Health.

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

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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 14, 2007, we employed 25 persons, including 9 engaged in research and development activities, including drug discovery, clinical development, and regulatory affairs, and 16 in general and administrative functions such as human resources, finance, accounting, business development and investor relations. Our staff includes 6 employees with Ph.D. or M.D. degrees. None of our employees are unionized and we believe that our relationship with our employees is good.

Financial Information about Segments

Refer to Note 19, Segment Information in the Notes to the Condensed Consolidated Financial Statements.

Research and Development

Our research and development expenses were $13.1 million in 2007, $27.0 million in 2006, and $26.1 million in 2005.

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 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 or that an approval, if granted, will be on terms we may seek.

In October 2006, we received an approvable letter from the FDA for our new drug application (NDA) submission for Zenvia in the treatment of patients with the PBA/IEED indication. 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 concern of the original dose formulation. However, in order to address the safety concerns, we agreed to re-formulate Zenvia and conduct one additional confirmatory Phase III clinical trial using lower dose formulations. The goal of the study is to demonstrate improved safety while maintaining significant efficacy. The study is expected to be completed (as

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defined as top-line safety and efficacy data becomes available) during the second half of calendar 2009. It is possible that the efficacy will be so reduced 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 (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, it is possible that Zenvia may not be approved with the labeling claims or for the patient population that we consider most desirable for the promotion of the product. Less desirable labeling claims could adversely affect the commercial potential for the product and could also affect our long-term prospects.

Additionally, although we have a Special Protocol Assessment (SPA) from the FDA for our recently completed Phase III trial for DPN pain and for our planned 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. However, even where an SPA has been granted, 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. As a result, even with an SPA, we cannot be certain that the trial results will be found to be adequate to support an efficacy claim and 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 investigating the potential use of alternative formulations with lower doses of quinidine and various DM levels in the next Phase III trial for Zenvia for this indication. Although we achieved positive results in our initial Phase III trial, an alternative lower dose may not yield the same levels of efficacy as seen in the earlier trials and any drop in efficacy may be so great that the drug does not demonstrate a statistically significant improvement over placebo. Additionally, any alternative dose 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.

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 operating losses totaling $238 million as of September 30, 2007, and we expect to continue to incur substantial operating losses for the foreseeable future. As of September 30, 2007, we had approximately $33.6 million in cash, cash equivalents, investments in marketable securities and restricted cash. Additionally, because we sold FazaClo in August 2007, 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 significant amounts of additional capital in the future to complete the development of

Zenvia and to finance our long-term operations. 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 next twelve months. Although we expect to be able to raise additional capital and/or curtail current levels of operations to be able to continue to fund our operations beyond that time, there can be no assurance that we will be able to do so. If we are unable to raise additional capital to fund future operations, then we

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may be unable to fully execute our development plans for Zenvia and DPN pain. This may result in significant delays in our planned clinical trial of Zenvia for PBA 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.

We will seek to raise additional capital and may do so at any time 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 and any such financing will dilute our existing shareholders. If we instead seek to raise capital through licensing transactions or sales of one or more of our technologies, drugs or drug candidates, as we have stated we are actively considering with certain investigational compounds, 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.

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 that could come from our technologies such as anti-inflammatory compounds and antibodies. 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; or
- 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.

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 for Zenvia, which could result in the introduction of generic competition within in a few years of product launch.

Our PBA related patents for Zenvia expire at various times from 2011 through 2012 and our DPN pain patents for Zenvia expire in 2016. These expirations do not account for any potential patent term restoration nor does this account for the issuance of any patents pending. If Zenvia is approved, we can apply for a five year extension to one patent covering Zenvia; however, as Zenvia is not a new chemical entity, it is unknown whether or not Zenvia will qualify for patent term restoration under the U.S. Patent and Trademark Office (USPTO) guidelines. Once the patents covering Zenvia expire or the three-year Hatch Waxman exclusivity period has passed, generic drug

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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, 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 process 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. 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 have recently experienced significant turnover in senior management.

Over the past 12 months, we have experienced significant turnover in our senior management team, including the departures of our President and Chief Executive Officer, Chief Financial Officer, Chief Accounting Officer, Vice President of Human Resources, Vice President of Drug Discovery, Vice President of Business Development, and Vice President of Clinical Affairs. As a result of these changes, we essentially have a new management team. It is not yet possible to assess how effective this management team will be and whether they will be able to work together to accomplish the Company s business objectives. Additionally, changes in management are disruptive to the organization and any further changes may slow the Company s progress toward its goals. Further, the Board of Directors may seek to reduce its size to streamline operations and to reflect the fact that the Company is significantly smaller than it was previously. Changes in Board composition may also be disruptive and the loss of the experience and capabilities of any of our Board members may reduce the effectiveness of the Board.

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, sales and marketing and 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 extensive employee turnover recently, as discussed above, and the loss of any additional 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 planned 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.

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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 recent 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 expect to be able to fully address these concerns, we may not be able to resolve these 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 a New Drug Application (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; or
- the rejection of an application.

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;
- shortage or lack of availability of supplies of drugs for clinical trials;

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- 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 compete against antidepressants, atypical anti-psychotic agents and other agents.

Our competitors may have specific expertise and development technologies that are better than ours and many of these 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, 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.

Developing and marketing pharmaceutical products for human use involves product liability risks, for which we currently have limited insurance coverage.

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

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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.

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. 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 API for docosanol 10% cream and supplies for 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. 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. Any delays or difficulties in obtaining APIs or in manufacturing, packaging or distributing our products and product candidates could delay Zenvia clinical trials for PBA and/or DPN pain. Additionally, the third parties we rely on for manufacturing and packaging are subject to regulatory review, and any regulatory compliance problems with these third parties could significantly delay or disrupt our commercialization activities.

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 for our reverse cholesterol transport (RCT) mechanism technology. 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

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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 revenue from international product sales will suffer.

Risks Relating to Our Stock

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

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

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

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

Announcements by us of financing transactions and/or future sales of equity or debt securities;

Sales of our Class A 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***

As of September 30, 2007, we lease and occupy an aggregate of 13,099 square feet of space used for research and development and administrative operations in three buildings in California. 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 also currently occupy 1,780 square feet of laboratory and office facilities in one building located in San Diego, California, and we sublease approximately 57,945 square feet in three buildings in San Diego. The terms of the leases for the San Diego facilities vary from August 2008 (representing 27,575 square feet) to January 2013 (representing 30,370 square feet).

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 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

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effect on our 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 operations or financial position. We have no significant legal proceedings ongoing at this time.

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 2007.

PART II

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

On April 11, 2006, our Class A common stock began trading on the NASDAQ Global Market under the stock symbol AVNR simultaneously with the discontinuation of trading of our stock on the American Stock Exchange. For approximately five years prior to April 11, 2006, our Class A common stock traded under the symbol AVN on The American Stock Exchange (the AMEX). The following table sets forth the high and low closing sales prices for our Class A common stock in each of the quarters over the past two fiscal years, as quoted on the NASDAQ and AMEX. This historical stock price information has been adjusted to reflect our one-for-four reverse stock split, which was effected on January 16, 2006.

	Class A Common Stock Price			
	Fiscal 2007		Fiscal 2006	
	High	Low	High	Low
First Quarter	$ 8.95	$ 2.27	$ 14.12	$ 10.00
Second Quarter	$ 2.52	$ 1.09	$ 17.90	$ 13.76
Third Quarter	$ 5.19	$ 1.19	$ 15.13	$ 5.88
Fourth Quarter	$ 2.70	$ 1.68	$ 8.76	$ 5.61

On December 7, 2007, the closing sales price of Class A Common Stock was $1.61 per share.

As of December 7, 2007, we had approximately 26,065 shareholders, including 927 holders of record and an estimated 25,138 beneficial owners. We have not paid any dividends on our Class A common stock since our inception and do not expect to pay dividends on our common stock in the foreseeable future.

The following graph compares the cumulative 5-year total return provided shareholders on AVANIR Pharmaceuticals common stock relative to the cumulative total returns of the Russell 2000 index and the NASDAQ Pharmaceutical index. An investment of $100 (with reinvestment of all dividends) is assumed to have been made in our common stock and in each of the indexes on 9/30/2002 and its relative performance is tracked through 9/30/2007.

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.

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Stock Performance Graph

***$100 Invested on 9/30/02 In stock or Index-Including reinvestment of dividends. Fiscal year ending September 30.**

	9/02	9/03	9/04	9/05	9/06	9/07
AVANIR Pharmaceuticals	**100.00**	**135.65**	**246.96**	**268.70**	**150.43**	**46.52**
Russell 2000	**100.00**	**136.50**	**162.12**	**191.23**	**210.20**	**236.14**
NASDAQ Pharmaceutical	**100.00**	**156.88**	**164.14**	**194.67**	**195.01**	**211.03**

The stock price performance included in this graph is not necessarily indicative of future stock price performance.

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

The selected consolidated financial data set forth below at September 30, 2007 and 2006, and for the fiscal years ended September 30, 2007, 2006 and 2005, are derived from our audited consolidated financial statements included elsewhere in this report. This information should be read in conjunction with those consolidated financial statements, the notes thereto, and with Management s Discussion and Analysis of Financial Condition and Results of Operations. The selected consolidated financial data set forth below at September 30, 2005, 2004 and 2003, and for the years ended September 30, 2004 and 2003, are derived from our audited consolidated financial statements that are contained in reports previously filed with the SEC, not included herein. The quarterly consolidated financial data are derived from unaudited financial statements included in our Quarterly Reports on Form 10-Q and have been modified to reflect the restatement of our quarterly results for the three months ended March 31, 2007. All share and per share information herein (including shares outstanding, earnings per share and warrant and stock option exercise prices) reflect the retrospective adjustment for a one-for-four reverse stock split implemented in January 2006.

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The following tables include selected consolidated financial data for each of our last five fiscal years and quarterly data for the last two fiscal years and include adjustments to reflect the classification of our FazaClo Business as discontinued operations. See Note 3 in the Notes to our Consolidated Financial Statements contained in Item 8 of this Annual Report on Form 10-K for information on discontinued operations.

Summary Financial Information

	Fiscal Years Ended September 30,				
Statement of operations data:	**2007**	**2006(1)(2)**	**2005**	**2004**	**2003**
Net revenues	$ 9,224,561	$ 15,185,852	$ 16,690,574	$ 3,589,317	$ 2,438,733
Loss before discontinued operations and cumulative effect of change in accounting principle	$ (28,381,724)	$ (50,234,040)	$ (30,606,564)	$ (28,154,853)	$ (23,236,348)
Income/(loss) from discontinued operations	$ 7,448,271	$ (8,702,716)	$	$	$
Cumulative effect of change in accounting principle	$	$ (3,616,058)	$	$	$
Net loss	$ (20,933,453)	$ (62,552,814)	$ (30,606,564)	$ (28,154,853)	$ (23,236,348)
Net loss attributable to common shareholders	$ (20,933,453)	$ (62,552,814)	$ (30,606,564)	$ (28,154,853)	$ (23,264,293)
Basic and diluted (loss)/income per share:					
Loss before cumulative effect of change in accounting principle and discontinued operations	$ (0.72)	$ (1.64)	$ (1.19)	$ (1.44)	$ (1.55)
Income/(loss) from discontinued operations	$ 0.19	$ (0.28)	$	$	$
Cumulative effect of change in accounting principle	$	$ (0.12)	$	$	$
Net loss	$ (0.53)	$ (2.04)	$ (1.19)	$ (1.44)	$ (1.55)
Net loss attributable to common shareholders	$ (0.53)	$ (2.04)	$ (1.19)	$ (1.44)	$ (1.55)
Basic and diluted weighted average number of shares of common stock outstanding	39,643,876	30,634,872	25,617,432	19,486,603	14,974,034
Cash dividends declared per share	$	$	$	$	$
Pro forma amounts assuming the method adopted in 2006 for patent-related costs was applied retroactively:					
Net loss	$	$ (58,936,756)	$ (31,255,373)	$ (29,056,101)	$ (23,786,583)
Net loss attributable to common shareholders	$	$ (58,936,756)	$ (31,255,373)	$ (29,056,101)	$ (23,814,528)
Basic and diluted loss per share	$	$ (1.92)	$ (1.22)	$ (1.49)	$ (1.59)

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Balance sheet data:	September 30, 2007	2006	2005	2004	2003
Cash and cash equivalents	$ 30,487,962	$ 4,898,214	$ 8,620,143	$ 13,494,083	$ 12,198,408
Investments in marketable securities	3,153,436	19,851,859	18,917,443	12,412,446	5,258,881
Total cash, cash equivalents and investments in marketable securities	$ 33,641,398	$ 24,750,073	$ 27,537,586	$ 25,906,529	$ 17,457,289
Working capital	$ 29,336,776	$ (6,969,777)	$ 11,969,450	$ 16,653,621	$ 10,619,216
Total assets	$ 39,095,893	$ 71,462,337	$ 41,401,990	$ 37,403,953	$ 29,645,257
Deferred revenues	$ 15,320,430	$ 19,354,175	$ 19,158,210	$ 21,009,115	$ 22,742,641
Notes payable and capital lease obligations	$ 12,024,592	$ 14,395,978	$ 990,594	$ 1,107,064	$
Total liabilities	$ 32,065,659	$ 77,136,872	$ 32,267,111	$ 27,206,694	$ 28,608,026
Shareholders equity (deficit)	$ 7,030,234	$ (5,674,535)	$ 9,134,879	$ 10,197,259	$ 1,037,231

atement of operations data for fiscal 2007 (Unaudited):	Fiscal Quarters Ended December 31, 2006	March 31, 2007 (as reported)	March 31, 2007 (as restated)	June 30, 2007	Se
	$ 2,136,897	$ 2,022,868	$ 2,022,868	$ 2,200,724	$
	$ 677,095	$ 585,791	$ 585,791	$ 620,070	$
e before discontinued operations	$ (13,771,294)	$ (4,577,583)	$ (6,920,435)	$ (8,010,403)	$
from discontinued operations	$ 153,767	$ (3,329,927)	$ (3,329,927)	$ (1,139,976)	$
ome	$ (13,617,527)	$ (7,907,510)	$ (10,250,362)	$ (9,150,379)	$
s) income per share	$ (0.39)	$ (0.20)	$ (0.26)	$ (0.23)	$
oss) income per share	$ (0.39)	$ (0.20)	$ (0.26)	$ (0.23)	$
ed average number of shares of common stock outstanding	34,626,117	39,047,597	39,047,597	40,580,326	
nted average number of shares of common stock outstanding	34,626,117	39,047,597	39,047,597	40,580,326	

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Quarterly statement of operations data for fiscal 2006 (Unaudited):	Fiscal Quarters Ended December 31, 2005	March 31, 2006	June 30, 2006(1)	September 30, 2006
Net revenues	$ 8,144,888	$ 2,469,028	$ 2,363,247	$ 2,208,689
Gross margin	$ 6,054,966	$ 576,428	$ 671,304	$ 389,544
Loss before discontinued operations and cumulative effect of change in accounting principle	$ (5,599,912)	$ (13,540,486)	$ (15,358,383)	$ (15,735,259)
Loss from discontinued operations	$	$	$ (2,260,835)	$ (6,441,881)
Cumulative effect of change in accounting principle	$ (3,616,058)	$	$	$
Net loss(2)	$ (9,215,970)	$ (13,540,486)	$ (17,619,218)	$ (22,177,140)
Basic and diluted net loss per share(2):				
Loss before cumulative effect of change in accounting principle	$ (0.20)	$ (0.44)	$ (0.56)	$ (0.70)
Cumulative effect of change in accounting principle	$ (0.13)	$	$	$
Net loss	$ (0.32)	$ (0.44)	$ (0.56)	$ (0.70)
Basic and diluted weighted average number of shares of common stock outstanding	28,579,357	31,086,874	31,419,394	31,472,217

(1) Includes a charge of $1.3 million in purchased IPR&D in connection with our acquisition of Alamo Pharmaceuticals, LLC in May 2006, based on purchase price allocation. See Note 3, Acquisition of Alamo Pharmaceuticals, Inc. / Sale of FazaClo, in Notes to the Consolidated Financial Statements.

(2) In the fourth quarter of fiscal 2006, we changed our method of accounting, effective October 1, 2005 for legal costs, all of which are external, associated with the application for patents. The $3.6 million cumulative effect of the change on prior years as of October 1, 2005 is included as a charge to net loss in fiscal 2006, retrospectively applied to the first quarter. The effect of the change was to increase the net loss by $3.5 million, or $0.12 per basic and diluted share, for the first quarter of fiscal 2006; $135,000, or $0.01 per basic and diluted share, for the second quarter of fiscal 2006; and $127,000, or $0.00 per basic and diluted share, for the third quarter for fiscal 2006.

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 sim 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, 2007 and 2006. The assets and liabilities of this business are reflected as assets and liabilities of discontinued operations in the consolidated balance sheet as of September 30, 2006. Unless otherwise noted, this Management s Discussion and Analysis of Financial Condition and Results of Operations relates only to financial results from continuing operations.

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Executive Overview

Avanir Pharmaceuticals 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, inflammatory diseases and infectious 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 and our infectious disease program, which is focused primarily on anthrax antibodies, is currently being funded by grants from the National Institute of Health/National Institute of Allergy and Infectious Disease (NIH/NIAID).

The following is a summary of significant developments in fiscal 2007 and subsequent to the end of fiscal 2007 through the date of this filing that have materially affected our operations, financial condition and prospects:

In December 2007, we initiated the enrollment of patients in the confirmatory Phase III trial of Zenvia.

On October 30, 2006, we received an approvable letter from the FDA for our NDA submission for Zenvia for the treatment of PBA/IEED. An approvable letter is an official notification from the FDA that certain additional conditions must be satisfied prior to obtaining U.S. marketing approval for a new drug. The approvable letter that we received from the FDA outlined concerns that the agency had regarding the efficacy and safety data contained in our NDA submission.

In April 2007, our preliminary top-line data was completed from our first Phase III clinical trial of Zenvia for DPN pain. In the trial, two doses of Zenvia, 45/30 mg DMQ dosed twice daily (DMQ 45) and 30/30 mg DMQ dosed twice daily (DMQ 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 DMQ 45 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 DMQ 30 patient group, average reductions were also significantly greater than placebo patients at Days 30 and 60 ($p < 0.0001$) and Day 90 ($p = 0.007$).

In August 2007, we sold FazaClo to Azur Pharma for $43.9 million in upfront consideration. The Company has the right to receive up to an additional $10 million in contingent payments in 2009, subject to the satisfaction of certain regulatory conditions. 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 Pharmaceuticals upon the achievement of certain milestones were assumed by Azur Pharma, however the Company is contingently liable in the event of default The Company transferred all FazaClo related business operations to Azur Pharma in August 2007. The gain resulting from the sale of FazaClo was $12.2 million.

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. 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 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 second half of calendar 2009. We enrolled the first patient in this

trial in December 2007.

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 the benefits of outsourcing, including being flexible and being able to

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rapidly respond to program delays or successes far outweigh the higher costs often associated with outsourcing at this stage of our development.

We intend to continue to seek partnerships with pharmaceutical companies to help fund research and development programs 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 and then for DPN pain. We expect that the proceeds from our sale of FazaClo will be sufficient to fund our operations, including our planned confirmatory Phase III trial for Zenvia for PBA, through the next twelve months. We are currently considering additional means of raising capital, including borrowing funds, selling common stock or other securities, and the monetization of additional assets. If we are unable to raise capital as needed to fund our operations, then we may need to slow the rate of development of some of our programs or sell additional rights to one or more of our drug candidates. 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. 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. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from our estimates if past experience or other assumptions do not turn out to be substantially accurate.

We believe that the application of our accounting policies for purchase price allocations in business combinations, share-based compensation expense, revenue recognition, expenses in outsourced contracts, research and development expenses and valuation of long-lived and intangible assets, all of which are important to our financial position and results of operations, require significant judgments and estimates on the part of management.

Purchase Price Allocation in Business Combinations

The allocation of purchase price for business combinations 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 in the Notes to Consolidated Financial Statements for a detailed discussion.

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 No. 123, *Share-Based Payment* (FAS 123R). Effective October 1, 2005, we adopted FAS 123R, including the provisions of the SEC s Staff Accounting Bulletin No. 107 (SAB 107), and use the fair value method to account for share-based payments with a modified prospective application that provides for

certain changes to the method for valuing share-based compensation. The valuation provisions of FAS 123R apply to new awards and to awards that are outstanding on the effective date and subsequently modified or cancelled. Under the modified prospective application, prior periods are not revised for comparative purposes.

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

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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. 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 guidance in FAS 123R and SAB 107 is relatively new, and best practices are not well established. The application of these principles 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. Additionally, the application of FAS 123R is very complex. In November 2007, we announced a restatement of our financial results for the three and six months ended March 31, 2007 and the three and nine months ended June 30, 2007 primarily due to computation errors in our software used to calculate FAS 123R expense.

Previous versions of the software system we use to calculate share-based compensation expense applied a weighted average forfeiture rate in the calculation of share-based compensation. The old version consistently applied the forfeiture rate throughout the vesting period and allowed for a true-up of share-based compensation expense once the award had vested in full. The true-up was necessary because the old method did not properly attribute the cost over the vesting period. Because of the use of this method, the old version failed to properly account for the full expense of

vested awards.

Under the new version of the software, forfeiture rates are applied in the calculation of share-based compensation expense up to the point each individual tranche is fully vested. As each tranche vests, the new version properly recognizes 100% of share-based compensation expense over the attribution period related to these vested tranches.

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In addition, our evaluation of share-based compensation expense uncovered a data input error when the forfeiture rate was adjusted to 30% in the second fiscal quarter of 2007. This data input error, combined with the software version issue discussed above, resulted in a material understatement of share-based compensation expense as of March 31, 2007.

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 Financial Accounting Standards 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

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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.

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 GlaxoSmithKline 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. Also, classified within cost of product sales is the amortization of the acquired FazaClo product rights.

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

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reporting periods, including our largest contract, representing a $7.1 million Phase III clinical trial contract that was entered into subsequent to September 30, 2007. 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 in-process research and development. In accordance with Statement of Financial Accounting Standards No. 141, *Business Combinations* (FAS 141), we immediately charge the costs associated with acquired in-process research and development (IPR&D) to research and development expense upon acquisition. These amounts represent an estimate of the fair value of acquired IPR&D for projects that, as of the acquisition date, had not yet reached technological feasibility, had no alternative future use, and had uncertainty in receiving future economic benefits from the acquired IPR&D. We determine the future economic benefits from the acquired IPR&D to be uncertain until such technology is approved by the FDA or when other significant risk factors are abated. We incurred significant IPR&D expense related to the Alamo acquisition. See also Note 3, Acquisition of Alamo Pharmaceuticals, Inc. / Sale of FazaClo In-Process Research and Development in the Notes to Consolidated Financial Statements.

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 141 and Statement of Financial Accounting Standards No. 142, *Goodwill and Other Intangible Assets* (FAS 142), goodwill and intangible assets acquired in a purchase business combination and 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. Goodwill represents the excess of purchase price of an acquired business over the fair value of the underlying net tangible and intangible assets. The Company operates in one segment and goodwill is evaluated at the company level as there is only one reporting unit. Goodwill is evaluated in the fourth fiscal quarter of each year. There was no impairment to goodwill for the fiscal years ended September 30, 2007 and

2006.

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

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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.

Prior to October 1, 2005, intangible assets with finite useful lives also include capitalized external legal costs incurred in connection with patents and patent applications pending. We amortized costs of approved patents and patent applications pending over their estimated useful lives. For patents pending, we amortized the costs over the shorter of a period of twenty years from the date of filing the application or, if licensed, the term of the license agreement. For patent and patent applications pending and trademarks that we abandon, we charge the remaining unamortized accumulated costs to expense.

Change in Method of Accounting for Patent-related Costs

In the fourth quarter of fiscal 2006, we changed our method of accounting, effective October 1, 2005 for legal costs, all of which were external, associated with the application for patents. Prior to the change, we expensed as incurred all internal costs associated with the application for patents and capitalized external legal costs associated with the application for patents. Costs of approved patents were amortized over their estimated useful lives or if licensed, the terms of the license agreement, whichever was shorter, while costs for patents pending were amortized over the shorter period of twenty years from the date of the filing application or if licensed, the term of the license agreement. Amortization expense for these capitalized costs was classified as research and development expenses in our consolidated statements of operations. Under the new method, external legal costs are expensed as incurred and classified as research and development expenses in our consolidated statements of operations. We believe that this change is preferable because it will result in a consistent treatment for all costs, that is, under our new method both internal and external costs associated with the application for patents are expensed as incurred. In addition, the change will provide a better comparison with our industry peers. The $3.6 million cumulative effect of the change on prior years as of October 1, 2005 is included as a charge to net loss in fiscal 2006, retrospectively applied to the first quarter. The effect of the change for the fiscal year ended September 30, 2006 was to increase the net loss by $3.7 million, $3.6 million of which represents the cumulative effect of the change on prior years, or $0.12 per basic and diluted share.

Pro forma amounts assuming the new method for patent-related costs was applied retroactively are as follows:

	Fiscal 2006	**Fiscal 2005**
Net loss	$ (58,936,756)	$ (31,255,373)

Basic and diluted loss per share	$ (1.92)	$ (1.22)

Restructuring Expense

We record costs and liabilities associated with exit and disposal activities, as defined in Statements of Financial Accounting Standards 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 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 office and laboratory facilities, in accordance with FAS 146. The liability is

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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 48-pill units. 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 units and accepted returns of unsold or undispensed 48-pill units. 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 2007, our operating expenses were influenced substantially by the amount of spending devoted to sales and marketing of FazaClo, program research funded by our partners and Zenvia clinical development expenses. During the past three years, we substantially expanded our drug development pipeline, which required that we allocate significant amounts of our resources to such programs, including increased spending on clinical

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trials as those programs advance in their development. We believe that future operating expenses over the next two years will be comprised 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 three years.

Results of Operations

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 2007, 2006 and 2005 are attributed to the United States. All long-lived assets for fiscal 2007 and 2006 are located in the United States.

Comparison of Fiscal 2007 and 2006

Revenues

Net product revenues were $72,000 and $18,000 for the fiscal years ended September 30, 2007 and 2006 respectively. See section Loss from Discontinued Operations for a detailed discussion of net revenues related to FazaClo.

Revenues from licenses, research services and grants declined to $9.2 million for the fiscal year ended September 30, 2007 compared to $15.2 million for the fiscal year ended September 30, 2006. This decline was principally due to a decrease in research revenues of $5.4 million due to a $5.0 million milestone earned under the AstraZeneca license agreement in the first quarter of fiscal year 2006 that was not repeated in the first quarter of fiscal year 2007. In addition, revenue from license arrangements declined $3.5 million. As a result of the termination of the contract research services that we were providing to AstraZeneca and Novartis, our revenues were lower than in 2006. These decreases were partially offset by an increase in revenue from royalties of $2.3 million primarily from the receipt of $1.5 million from HBI for their achievement of a regulatory milestone. However, we expect our related research and development expenses to be reduced by a corresponding amount in future periods. See Note 16 License and Research Collaboration Agreements and Note 19 Segment Information in Notes to Consolidated Financial Statements.

Cost of Revenues

Cost of product revenues was $328,000 and $3,000 for the fiscal years ended September 30, 2007 and 2006, respectively. The cost of product revenues in fiscal year ended September 30, 2007 is attributable to a $260,000 write off of obsolete inventory in the second quarter of 2007. See section Loss from Discontinued Operations for a detailed discussion of cost of product revenues related to FazaClo.

Cost of licenses, research services and grants declined to $4.3 million or 47% of revenues compared with $7.5 million or 49% of revenues for the fiscal year ended September 30, 2006. The cost of licenses, research services and grants includes primarily direct and indirect payroll costs and the costs of outside vendors.

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	Fiscal Year Ended			
	2007	2006	$ Change	% Change
OPERATING EXPENSES				
Research and development	$ 13,115,712	$ 26,994,335	$ (13,878,623)	–51%
Selling, general and administrative	20,830,188	32,375,366	(11,545,178)	–36%
Total Operating Expenses	$ 33,945,900	$ 59,369,701	$ (25,423,801)	–43%

Research and Development Expenses

Research and development expenses decreased $13.9 million or 51% for the fiscal year ended September 30, 2007 compared to the fiscal year ended September 30, 2006. The decrease is primarily due to decreased costs of $13.9 million incurred for Zenvia product research and development (PBA/IEED and DPN), which was spent in fiscal year ended September 30, 2006 in preparation for the planned product launch. In addition, decreased costs of $652,000 were incurred for the AVP-13358 Allergy study.

Over the next two years, we expect that our research and development costs will consist mainly of expenses related to the confirmatory Phase III trial for Zenvia for PBA.

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased $11.5 million, or 36% for the fiscal year ended September 30, 2007, compared to the fiscal year ended September 30, 2006. The decrease is primarily attributed to fiscal year 2006 expenditures that were not repeated in fiscal 2007 relating to external marketing costs in the amount of $7.7 million associated with the anticipated Zenvia product launch, for which commercialization was delayed in October 2006 following receipt of the approvable letter. In addition, $1.7 million for continuing medical education grants related to PBA/IEED in the prior fiscal year were not repeated in fiscal 2007 and fiscal 2007 compensation expense decreased by $1.4 million as compared to the prior year due to related decreases in overall headcount and compensation levels in general and administrative areas.

Additionally, in September 2007, a court awarded reimbursement of attorneys fees spent over a four-year period in connection with the enforcement of a settlement agreement entered into with a former employee. The total fees awarded were approximately $1.3 million. We cannot currently estimate the timing for collection or the probability of collecting the full amount, and therefore, no amounts have been recognized in income as of September 30, 2007.

Share-Based Compensation

Total compensation expense for our share-based payments in the fiscal year ended September 30, 2007 and 2006 was $2.2 million (excluding $508,000 included in discontinued operations) and $2.8 million (excluding $283,000 included in discontinued operations), respectively. Selling, general and administrative expense in the fiscal years ended September 30, 2007 and 2006 includes share-based compensation expense of $1.9 million and $2.4 million, respectively. Research and development expense in the fiscal year ended September 30, 2007 and 2006 includes share-based compensation expense of $365,000 and $465,000, respectively. As of September 30, 2007, $1.7 million of total unrecognized compensation costs related to unvested awards is expected to be recognized over a weighted average period of 2.1 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, 2007, interest expense increased to $1.2 million, compared to $406,000 for the prior fiscal year. The increase is primarily due to the Seller Notes with an original balance of $25.1 million issued in May 2006 in connection with the purchase of Alamo.

For the fiscal year ended September 30, 2007, interest income decreased to $623,000, compared to $1.8 million for the prior fiscal year. The decrease is due to approximately a 58% decrease in the average balance of cash, cash

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equivalents and investments in securities for fiscal year ended September 30, 2007, compared to the prior fiscal year.

Net Loss

Net loss was $20.9 million, or $0.53 per share, for the fiscal year ended September 30, 2007, compared to a net loss of $62.6 million, or $2.04 per share for the fiscal year ended September 30, 2006. The decrease in net loss is primarily attributed to decreased operating expenses totaling $24.9 million which is mainly due to decreased spending in the Zenvia product research and development area of $13.9 million, as well as, the decreased spending in marketing costs from the Zenvia product launch of $7.7 million, the gain on the sale of the FazaClo product line of $12.2 million, the decrease in the discontinued operations loss of $3.9 million and the $3.6 million cumulative effect of the change in accounting principle which occurred in 2006 only.

Income/(Loss) from Discontinued Operations

For the fiscal year ended September 30, 2007, income from discontinued operations was $7.5 million, compared to a loss of $8.7 million for the fiscal year ended September 30, 2006. This decrease in loss was mainly due to the recognition of net product revenues of FazaClo of $17.0 million in fiscal 2007, including revenue that was deferred as of September 30, 2006. No product revenues were recognized for FazaClo in the fiscal year ended September 30, 2006. Product margin on these net sales were $12.4 million for the year ended September 30, 2007. The product margin was offset with operating expenses incurred of $16.7 million in fiscal year ended September 30, 2007 compared to $7.9 million in fiscal year ended September 30, 2006. A majority of the operating expenses incurred in fiscal year 2007 pertain to the FazaClo product launch as well as the increase in headcount as a result of the Alamo acquisition. Also contributing to the decrease in net loss is the gain recorded in fiscal 2007 on the sale of FazaClo in the amount of $12.2 million.

Comparison of Fiscal 2006 and 2005

Revenues

Revenues decreased by $1.5 million, or 9%, to $15.2 million in fiscal 2006 from $16.7 million in fiscal 2005. The decrease is mainly due to a $7.6 million decrease in license revenues; partially offset by a $6.2 million increase in research and development service revenues. License revenues in fiscal 2006 consist mainly of our receipt of a $5.0 million payment relating to the achievement of a milestone under the AstraZeneca license agreement. License revenues in fiscal 2005 included $12.8 million of license fees from the AstraZeneca and Novartis license agreements. Research and development service revenues increased in fiscal 2006 as compared to the prior period due to the full year effect of research revenues generated from the AstraZeneca and Novartis license agreements in the current year, as opposed to our receipt of revenue for only a partial year in fiscal 2005.

Potential revenue-generating contracts that remained active as of September 30, 2006 included license agreements with AstraZeneca and Novartis, nine docosanol 10% cream license agreements and one Zenvia sublicense. AstraZeneca and Novartis were engaged in preclinical and/or clinical development efforts of our licensed RCT and MIF programs. See Note 16 License and Research Collaboration Agreements and Note 19 Segment Information in Notes to Consolidated Financial Statements.

Cost of Revenues

Cost of licenses, research services and grants increased to $7.5 million or 49% of revenues for the fiscal year ended September 30, 2006 compared with $2.8 million or 17% of revenues for the fiscal year ended September 30, 2005. The increase was due to a $4.9 million increase in cost of research services funded by partners.

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	Fiscal Year Ended			
	2006	2005	$ Change	% Change
OPERATING EXPENSES				
Research and development	$ 26,994,335	$ 26,140,504	$ 853,831	3%
Selling, general and administrative	32,375,366	18,796,188	13,579,178	72%
Total Operating Expenses	$ 59,369,701	$ 44,936,692	$ 14,433,009	32%

Research and Development Expenses

R&D expenses increased $854,000 or 3% for the fiscal year ended September 30, 2006 compared to the fiscal year ended September 30, 2005. R&D expenses increased to $27.0 million in fiscal 2006 from $26.1 million in fiscal 2005. R&D expenses in fiscal 2006 were related to continuation of the open label safety study of Zenvia in the treatment for IEED/PBA, a Phase III clinical trial of Zenvia for the treatment of diabetic neuropathic pain, and a Phase I clinical trial of our leading compound for the selective cytokine inhibitor program. R&D expenses also included pre-clinical research related to antibody development programs and compounds that regulate MIF and RCT Research. The MIF and RCT research programs were funded by our partners. The increase in R&D expenses was due to a $1.8 million increase in spending for the open label safety study of Zenvia for the treatment of IEED/PBA, a $7.6 million increase in spending for the Phase III clinical trial of Zenvia for the treatment of diabetic neuropathic pain and a $2.4 million increase in medical affairs. The increase was offset in part by a $3.7 million decrease in spending on the MIF and RCT research programs as they were fully funded by partners in fiscal 2006. In fiscal 2005, we incurred a one-time $7.2 million charge in connection with the acquisition of additional contractual rights to Zenvia.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased $13.6 million, or 72% for the fiscal year ended September 30, 2006, compared to the fiscal year ended September 30, 2005. Our selling, general and administrative expenses increased to $32.4 million in fiscal 2006, compared to $18.8 million in fiscal 2005. These increased expenses primarily related to a $6.2 million increase in expenses related to the expansion of our pre-launch activities and market research for Zenvia for the treatment of IEED/PBA, as well as the hiring of additional sales and marketing personnel; $2.5 million in share-based compensation expense; $1.7 million in expenses from continuing medical educational grants; a $1.4 million increase in expenses related to increases in headcount and compensation levels in general and administrative areas; and a $622,000 increase in legal fees.

Share-Based Compensation

Through fiscal year 2005, we accounted for our stock plans using the intrinsic value method. Effective at the beginning of fiscal year 2006, we adopted FAS 123R and elected to adopt the modified prospective application method. FAS 123R requires us to use a fair-valued based method to account for share-based compensation. Accordingly, share-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized as expense over the employees requisite service period. Total compensation cost for our share-based payments in fiscal 2006 was $2.8 million (excluding $283,000 included in discontinued operations), including $302,500 related to stock options granted in fiscal 1999 as discussed below. Selling, general and administrative expense and research and development expense in fiscal 2006 include: share-based compensation of $2.4 million and $465,000, respectively. As of September 30, 2006, $7.2 million of total unrecognized compensation costs related to

unvested awards is expected to be recognized over a weighted average period of 2.7 years. See Note 2, Significant Accounting Policies Change in Accounting Method for Share-Based Compensation in the Notes to Consolidated Financial Statements for further discussion.

On July 28, 2006, the Public Company Accounting Oversight Board (PCAOB) issued Staff Audit Practice Alert No. 1 entitled, *Matters Relating to Timing and Accounting for Options Grants.* Prompted by the PCAOB release, the Company and the independent audit committee of the Board of Directors authorized a review of the

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Company s historical stock option practices. The review was conducted with the assistance of an outside law firm and an outside consulting firm.

As a result of this review, one exception was found in which the measurement date for 50,000 fully vested common stock options should have been November 30, 1999 instead of October 30, 1999. Based on this, the Company should have recorded a non-cash charge of $302,500 and a corresponding increase in common stock in the first quarter of fiscal year 2000. The Company has concluded that this adjustment is not material to the Company s consolidated financial statements in any interim or annual period presented in this or any previously filed Form 10-K. Therefore, the charge was recognized in the quarter ended September 30, 2006.

Based upon this review, management and the independent audit committee of the Board of Directors were satisfied that no evidence was found that indicated that the Company otherwise intentionally manipulated stock option grant dates or was remiss in communicating grants to optionees in a timely manner. Further, the Company s documentation and practices followed the intent of the Board of Directors in granting such options and that the methods of approval and the Company s practices did not provide for management discretion in selecting or manipulating the option grant dates.

Interest Expense and Interest Income

For the fiscal year ended September 30, 2006, interest expense increased to $406,000, compared to $93,000 for the prior fiscal year. The increase was primarily due to the Seller Notes with an original balance of $25.1 million issued in May 2006 in connection with the purchase of Alamo.

For the fiscal year ended September 30, 2006, interest income increased to $1.8 million, compared to $620,000 for the prior fiscal year. The increase was primarily due to a 73% increase in average balance of cash, cash equivalents and investments in securities in fiscal 2006, compared to the prior year.

Cumulative Effect of Change in Accounting Principle

In the fourth quarter of fiscal 2006, we changed our method of accounting, effective October 1, 2006 for legal costs, all of which were external, associated with the application for patents. The $3.6 million cumulative effect of the change on prior years as of October 1, 2005 is included as a charge to net loss in fiscal 2006, retrospectively applied to the first quarter. The effect of the change for fiscal 2006 was to increase the net loss by $3.7 million, $3.6 million of which represents the cumulative effect of the change on prior years, or $0.12 per basic and diluted share.

Net Loss

Net loss was $62.6 million, or $2.04 per share, in fiscal 2006, compared to a net loss of $30.6 million, or $1.19 per share, in fiscal 2005. The increase in net loss was primarily attributed to the $3.6 million cumulative effect of the change of accounting method for legal costs, the $13.6 million increase in selling, general and administrative costs (that was mainly due to increased spending related to the expansion of the pre-launch activities and market research for Zenvia for the treatment of IEED/PBA), the increase in the discontinued operations loss of $8.7 million, and $4.7 million increase in cost of licenses, research services and grants mainly due to increased spending for research services funded by partners.

Loss from Discontinued Operations

For the fiscal year ended September 30, 2006, loss from discontinued operations was $8.7 million, compared to no loss for the fiscal year ended September 30, 2005. The loss from discontinued operations is a result of the operations

of FazaClo, which was acquired in May of 2006 as part of the Alamo acquisition.

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

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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 and 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, 2007	Increase (Decrease) During Period	September 30, 2006
Cash, cash equivalents and investment in securities	$ 33,641,398	$ 8,891,325	$ 24,750,073
Cash and cash equivalents	$ 30,487,962	$ 25,589,748	$ 4,898,214
Net working capital (deficit)	$ 29,336,776	$ 36,306,553	$ (6,969,777)

	Twelve Months Ended September 30, 2007	Change Between Periods	Twelve Months Ended September 30, 2006
Net cash used for operating activities	$ (46,644,434)	$ (5,834,918)	$ (40,809,516)
Net cash provided by (used for) investing activities	59,569,310	66,949,792	(7,380,482)
Net cash provided by financing activities	12,664,872	(31,803,197)	44,468,069
Net increase (decrease) in cash and cash equivalents	$ 25,589,748	$ 29,311,677	$ (3,721,929)

Operating activities. Net cash used for operating activities amounted to $46.6 million in the fiscal year 2007 compared to $40.8 million in the fiscal year 2006. The increase in cash used is primarily related to funding the operating loss for the period, recognition of deferred revenues, and reductions in accounts payable. Accounts payable and accrued expenses decreased by $13.9 million and was primarily due to payments of invoices in clinical, marketing and general and administrative activities.

Investing activities. Net cash provided by investing activities was $59.6 million in the fiscal year 2007, compared to net cash of $7.4 million used in the fiscal year 2006. This increase is mainly due to proceeds from investments in securities of $16.9 million compared to investments in securities of $65.8 million offset by proceeds from investments of $64.9 million in 2006. Net cash provided by investing activities of discontinued operations was $42.1 million compared to net cash used by investing activities of discontinued operations of $4.8 million in 2006. We invested $59,000 in property and equipment in fiscal 2007, compared to $1.7 million in fiscal 2006. In fiscal 2007, we generated $774,000 from disposals of property and equipment.

Financing activities. Net cash provided by financing activities was $12.7 million in fiscal year 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. Net cash provided by financing activities amounted to $44.5 million in fiscal 2006, consisting of $44.8 million received from the sale of our common stock through private placements and from exercises of warrants and stock options.

In June 2005, we filed a shelf registration statement on Form S-3 with the SEC to sell an aggregate of up to $100 million in Class A common stock and preferred stock, depositary shares, debt securities and warrants. This shelf registration statement was declared effective on August 3, 2005 and through September 30, 2007, we had sold a total of 14,406,755 shares of Class A common stock under this registration statement, raising gross offering proceeds of approximately $71.5 million and net offering proceeds of approximately $69.5 million. We have also issued under this registration statement common stock warrants to purchase a total of 1,053,000 shares of our

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Class A common stock at an exercise price of $3.30 per share. The warrants became exercisable in May 2007 and all unexercised warrants expired in November 2007. The warrants may be exercised on a net basis in certain circumstances but in no event would the company be required to settle the warrants in cash.

In December 2006 we entered into a financing facility with Brinson Patrick Securities Corporation. Under this facility, we have offered and sold an aggregate of 6,126,000 shares of Class A common stock, which resulted in net proceeds of $16.1 million. As of December 14, 2007, 5.6 million shares remained available for sale under this facility. Sales are made under our effective shelf registration statement.

As of September 30, 2007, we have contractual obligations for long-term debt, capital (finance) lease obligations 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 (principal and interest)	$ 13,339,769	$ 1,048,710	$ 12,291,059	$	$
Operating lease obligations	8,279,685	2,216,923	3,005,360	2,705,743	351,659
Purchase obligations(1)	2,763,172	2,763,172			
Total	$ 24,382,626	$ 6,028,805	$ 15,296,419	$ 2,705,743	$ 351,659

(1) Purchase obligations consist of the total of trade accounts payable and trade related accrued expenses at September 30, 2007, 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 (the First Note, Second Note and Third Note, respectively) (collectively, the Notes). The Notes bear interest at an average rate equal to the London Inter-Bank Offered Rate, or LIBOR, plus 1.33%. Interest accruing on the Notes is payable monthly and the principal amount of the Notes matures on May 24, 2009, provided that (i) the Selling Holders may demand early repayment of the First Note if the closing price of our common stock, as reported on the NASDAQ Global Market, equals or exceeds $15.00 per share for a total of 20 trading days in any 30 consecutive trading-day period (the Stock Contingency), and (ii) we must apply 20% of any future net offering proceeds from equity offerings and other financing transactions to repay the Notes (starting with the First Note), and must repay the Notes in full if we have raised in an offering more than $100,000,000 in future aggregate net proceeds. In connection with the equity offering we completed in the first nine months of fiscal year 2007, and in accordance with the terms of the Notes, we used approximately $6.1 million or 20% of the net proceeds received to pay down the First Note. In connection with our sale of FazaClo in August 2007, we agreed to prepay $11 million of outstanding principal due under the Notes, and the Note holder agreed to suspend the Company s obligation to use a portion of future equity offering proceeds to repay the Notes, up to $55 million in net offering proceeds. Twenty percent of any offering proceeds above this amount will need to be paid to the Note holders, as per the original agreement.

We have the right to prepay, in cash or in common stock, the amounts due under the Notes at any time, provided that we may only pay the Notes in common stock if the Stock Contingency has occurred prior to the maturity date and if

we have registered the shares on an effective registration statement filed with the SEC. If we elect to prepay the Notes with common stock, the shares will be valued at 95% of the average closing price of the common stock, as reported on the NASDAQ Global Market, for the five trading days prior to repayment, subject to a price floor.

Alamo Earn-Out Payments. 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. As previously discussed in this filing, we sold the FazaClo product line

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to Azur Pharma. 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.

Eurand Milestone and Royalty Payments. In August 2006, we entered into a development and license agreement (Eurand Agreement) with Eurand, Inc. (Eurand), under which Eurand will provide R&D services using Eurand s certain proprietary technology to develop a once-a-day controlled release capsule, a new formulation of Zenvia for the treatment of IEED/PBA (Controlled-Release Zenvia). Under the terms of the Eurand Agreement, we will pay Eurand for development services on a time and material basis. We will be required to make payments up to $7.6 million contingent upon achievement of certain development milestones and up to $14.0 million contingent upon achievement of certain sales targets. In addition, we will be required to make royalty payments based on sales of Controlled-Release Zenvia, if it is approved for commercialization. Development milestone events include program initiation, delivery of prototypes, delivery of clinical trial material for phase 1, achieving target PK Profile in the pilot clinical study, delivery of clinical trial material for phase 3, and filing of the first NDA for the Product with the FDA, completion of manufacturing validation and approval of the NDA with the FDA. Sales target milestones are $2.0 million upon achieving $100 million of U.S. net revenues, $4.0 million upon achieving $200 million of U.S. net revenues and $8.0 million upon achieving $400 million of U.S. net revenues. The agreement remains in effect on a country by country basis for the longer of 10 years after first commercial sale or the life of any Eurand patent, unless earlier terminated in accordance with the agreement. In November 2006, we notified Eurand to suspend activity on this project until further notice. The Company may terminate the agreement upon 30 days notice. Upon expiration of the agreement the Company shall own a fully-paid irrevocable license. Effective December 2006, we suspended further work under this agreement until resolution of further development plans for Zenvia resulting from our meeting with the FDA in late February 2007. All material remaining obligations would only be due in the event we reinstate the agreement in future.

Zenvia License Milestone Payments. We hold the exclusive worldwide marketing rights to Zenvia for certain indications pursuant to an exclusive 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/IEED. 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

The minimum amount of securities available for sale under our existing shelf registration was approximately $28.5 million as of September 30, 2007. We believe that cash equivalents and unrestricted investments in securities of approximately $33.6 million at September 30, 2007, which includes the net proceeds from the sale of FazaClo, will be sufficient to sustain our planned level of operations for the next twelve months. However, the Company cannot

provide assurances that our plans will not change, or that changed circumstances will not result in the depletion of capital resources more rapidly than anticipated. If we are unable to generate sufficient cash flows from licensed technologies or are unable to raise sufficient capital, management believes that expenditures could be curtailed in order to continue operations for the next 12 months.

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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 as 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 14 months as of September 30, 2007 (11 months as of September 30, 2006). The primary objective of our investments in debt securities is to preserve principal while achieving attractive yields, without significantly increasing risk. We classify our investments in securities as of September 30, 2007 as available-for-sale and our restricted investments in securities as held-to-maturity. These available-for-sale 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, 2007 and 2006, an increase of one percentage point in the interest rates would have resulted in increases in comprehensive losses of approximately $280,000 and $171,000, respectively.

At September 30, 2007, we had approximately $11.7 million of variable rate debt that was issued as part of the purchase price for the acquisition of Alamo. Based on the amount of outstanding variable rate debt at September 30, 2007, if the interest of our variable rate debt were to increase or decrease by 1%, interest expense would increase or decrease on an annual basis by approximately $117,000.

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 Interim Chief Financial Officer, 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.

As previously reported, in connection with that evaluation, our CEO and Interim CFO concluded that our disclosure controls and procedures were not effective as of March 31, 2007 due to a material weakness in internal controls over financial reporting. Subsequently, we determined that it was necessary to restate our condensed consolidated financial statements for the fiscal quarters ended March 31, 2007 and June 30, 2007 and that these financial statements should no longer be relied upon.

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These restatements had no impact on the Company s previously reported revenues, cash flows from operations or total cash and cash equivalents shown in the Company s condensed consolidated financial statements for the three and six months ended March 31, 2007 and the three and nine months ended June 30, 2007.

The Company did not have effective internal controls over financial reporting for the calculation of share-based compensation expense. Previous versions of a widely utilized software program used to calculate share-based compensation expense incorrectly applied a weighted average forfeiture rate in the calculation of share-based compensation. Previous versions consistently applied the forfeiture rate throughout the vesting period and allowed for a true-up of share-based compensation expense once the award had vested in full. The true-up was necessary because the old versions did not properly attribute the expense over the vesting period. Because of the use of this method, the old version failed to properly account for the full expense of vested awards during the interim periods prior to the award reaching its final vest date.

Under the new version of the software, forfeiture rates are applied in the calculation of share-based compensation expense up to the point each individual tranche is fully vested. As each tranche vests, the new version properly recognizes 100% of share-based compensation expense over the attribution period related to these vested tranches.

In addition, the Company s evaluation of share-based compensation expense uncovered a data input error when the forfeiture rate was adjusted to 30%. This data input error, combined with the software version issue discussed above, resulted in a material understatement of share-based compensation expense as of March 31, 2007.

The error had no impact on the Company s previously reported revenues, cash flows from operations or total cash and cash equivalents shown in the Company s condensed consolidated financial statements for the fiscal quarter ended March 31, 2007.

The Company s corporate monitoring controls failed to operate at a sufficient level of precision to detect the understatement of share-based compensation expense and the material misstatement of operating expenses and net loss.

The Company intends to review share-based compensation expense on a quarterly basis, supplemented by external consultants and independent computational reviews, to ensure that total share-based compensation expense is recognized for vested shares. The Company is in the process of evaluating remediation efforts to address the issues affecting the calculation of share-based compensation expense. The Company will perform these measures during the preparation of the 2008 first quarter financial reports. Additional measures may be forthcoming as the Company evaluates the effectiveness of these efforts.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. However, we have initiated or intend to initiate remediation measures to address the material weakness identified above. The remediation measures include or are expected to include the following:

The Company intends to review share-based compensation expense on a quarterly basis with the assistance of consultants and their computational review to ensure that total share-based compensation expense is recognized for vested shares.

The Company has hired a FAS 123R consultant who is also an experienced user of the software system utilized by the Company. This consultant will assist in the FAS 123R calculation and the Company s quarterly analysis

of total share-based compensation.

The Company has hired a consulting firm that offers FAS 123R calculation services for clients. This consulting firm will perform shadow calculations on certain awards to ensure that the software system is calculating share-based compensation expense accurately.

We may adopt additional remediation measures related to the identified control deficiencies as necessary as well as to continue to evaluate our internal controls on an ongoing basis and to upgrade and enhance them as needed.

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Our Audit Committee has taken an active role in reviewing and discussing the identified material weakness with our auditors and financial management. Our management and the Audit Committee will actively monitor the implementation and effectiveness of the remediation measures taken by the Company s financial management.

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

In November 2007, we entered into a task order (the Task Order) under the Company s Clinical Development Master Service Agreement (the Agreement) with Kendle International Inc. (Kendle). Pursuant to the Task Order, Kendle will provide clinical trial management and related clinical services to the Company relating to the Company s planned Phase III trial for Zenvia for the treatment of pseudobulbar affect (PBA) (An extension of services for Protocol No. 07-AVP-123, entitled: A Double-Blind, Randomized, Placebo Controlled, Multicenter Study to Assess the Safety and Efficacy and to Determine the Pharmacokinetics of Two Doses of AVP-923 (Dextromethorphan/Quinidine) in the treatment of Pseudobulbar Affect (PBA) in Patients with Amyotrophic Lateral Sclerosis and Multiple Sclerosis.)

This Task Order is effective as of November 1, 2007 and will terminate on September 9, 2009. Either party may terminate the Agreement or the Task Order upon material breach or insolvency or on 60 days prior written notice. In addition to the Double-Blind study, we also have a contract with Kendle to perform our Open Label study. .

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 2008 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 14, 2007 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.

Keith A. Katkin	**35**	**President and Chief Executive Officer**
Randall E. Kaye, M.D.	**45**	**Senior Vice President, Chief Medical Officer**
Martin J. Sturgeon	**49**	**Vice President, Finance, Interim Chief Financial Officer**
Eric S. Benevich	**42**	**Vice President, Communications**
Gregory J. Flesher	**37**	**Vice President, Business Development**

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.

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Randall E. Kaye, M.D. Dr. Kaye joined Avanir in January 2006 as Vice President of Medical Affairs and assumed the role of 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.

Martin J. Sturgeon. Mr. Sturgeon joined Avanir in February 2007 as Vice President and Chief Accounting Officer. In July 2007 Mr. Sturgeon assumed the role of Interim Chief Financial Officer. Previously, Mr. Sturgeon was a consultant with DLC, Inc., a consulting firm, serving in senior finance roles including Chief Accounting Officer and Chief Financial Officer for several publicly traded client companies. Mr. Sturgeon has over 25 years of experience in senior financial positions including eight years with Toshiba America Information Systems, Inc. as the Vice President, Group Controller. His career also includes experience in executive financial roles with companies such as Western Digital, Corinthian Colleges, and Novacare. Mr. Sturgeon holds a Bachelor s of Business Administration degree in Accounting from the University of San Diego and an M.B.A. in Finance from IESE, a European M.B.A. program sponsored by Harvard University.

Eric S. Benevich. Mr. Benevich joined Avanir in July 2005 as Senior Director of Marketing. In October 2006 he became the Executive Director of Marketing and in August 2007 he was promoted to Vice President of Communications. Previously, Mr. Benevich was the Senior Director of Marketing at Peninsula Pharmaceuticals leading all pre-launch activities to support the launch of two antibiotics into the hospital market. Mr. Benevich also has experience in other commercial areas such as sales, market research, and brand marketing at companies such as Astra Merck and Amgen Inc. Mr. Benevich completed his undergraduate studies in International Business at Washington State University and has completed several MBA courses at Villanova University.

Gregory J. Flesher. Mr. Flesher joined Avanir in 2006 as Senior Director of Commercial Strategy and was responsible for lifecycle and new product planning. While in this role, he also led the commercial integration of Alamo Pharmaceuticals following their acquisition. In November 2006 he became the Executive Director of Business Development and Portfolio Strategy and in August of 2007 he was promoted to Vice President of Business Development. Mr. Flesher has over 14 years of biotechnology and pharmaceutical industry experience and has held positions of increasing responsibility across R&D, Sales, Marketing, and Business Development. Prior to joining Avanir, he was a Sales Director at Intermune Pharmaceuticals with responsibility for trade relations, managed care, and patient support programs. Mr. Flesher also has brand management and commercial analytics experience from Amgen Inc. and Eli Lilly and Company. He began his career within the R&D organization of Eli Lilly and Company. Mr. Flesher completed his undergraduate studies in Biology at Purdue University and his doctorate studies 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.

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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 three years ended September 30, 2007, 2006 and 2005 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	Filed herewith	
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

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Exhibit Number	Description	Incorporated by Reference Herein Form	Date
4.6	Form of Class A Stock Purchase Warrant, issued in connection with the Securities Purchase Agreement dated July 21, 2003	Registration Statement on Form S-3 (File No. 333-107820), declared effective by the Commission on August 19, 2003	August 8, 2003
4.7	Form of Class A Stock Purchase 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 Stock Purchase Warrant, issued in connection with the Securities Purchase Agreement dated November 2, 2006	Filed herewith	
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	Research Collaboration and License Agreement, dated July 8, 2005, by and between Avanir Pharmaceuticals and AstraZeneca UK Limited*	Annual Report on Form 10-K for the fiscal year ended September 30, 2005, as Exhibit 10.4	December 14, 2005
10.5	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
10.6	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
10.7	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
10.8	License Agreement, dated August 1, 2000, by and between Avanir Pharmaceuticals (Licensee) and IriSys	Quarterly Report on Form 10-Q for the quarter ended June 30, 2000, as Exhibit 10.2	August 14, 2000

Research & Development, LLC, a
California limited liability company

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Exhibit Number	Description	Incorporated by Reference Herein Form	Date
10.9	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
10.10	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
10.11	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
10.12	Clinical Development Agreement, dated March 22, 2005, by and between Avanir Pharmaceuticals and SCIREX Corporation	Quarterly Report on Form 10-Q for the quarter ended March 31, 2005, as Exhibit 10.3	May 13, 2005
10.13	Unit Purchase Agreement, dated May 22, 2006, by and among Avanir Pharmaceuticals, the Sellers and Alamo Pharmaceuticals, LLC*	Quarterly Report on Form 10-Q for the quarter ended June 30, 2006, as Exhibit 10.1	August 9, 2006
10.14	Senior Note for $14.4 million payable to Neal R. Cutler, dated May 24, 2006	Quarterly Report on Form 10-Q for the quarter ended June 30, 2006, as Exhibit 10.2	August 9, 2006
10.15	Senior Note for $6,675,000 payable to Neal R. Cutler, dated May 24, 2006	Quarterly Report on Form 10-Q for the quarter ended June 30, 2006, as Exhibit 10.3	August 9, 2006
10.16	Senior Note for $4.0 million payable to Neal R. Cutler, dated May 24, 2006	Quarterly Report on Form 10-Q for the quarter ended June 30, 2006, as Exhibit 10.4	August 9, 2006
10.17	Registration Rights Agreement, dated May 24, 2006, by and between Avanir Pharmaceuticals and Neil Cutler	Quarterly Report on Form 10-Q for the quarter ended June 30, 2006, as Exhibit 10.7	August 9, 2006
10.18	Amended and Restated Development, License and Supply Agreement, dated August 22, 2005, by and between CIMA Labs Inc. and Alamo Pharmaceuticals, LLC*	Quarterly Report on Form 10-Q for the quarter ended June 30, 2006, as Exhibit 10.5	August 9, 2006
10.19	Amendment #1 to Amended and Restated Development, License and Supply Agreement, dated October 19, 2005, by and between CIMA Labs Inc. and Alamo Pharmaceuticals, LLC*	Quarterly Report on Form 10-Q for the quarter ended June 30, 2006, as Exhibit 10.6	August 9, 2006
10.20	Manufacturing Services Agreement, dated January 4, 2006, by and between	Quarterly Report on Form 10-Q for the quarter ended March 31, 2006, as	May 10, 2006

Patheon Inc. and Avanir Pharmaceuticals*	Exhibit 10.1

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Exhibit Number	Description	Incorporated by Reference Herein Form	Date
10.21	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
10.22	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
10.23	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
10.24	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
10.25	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
10.26	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
10.27	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
10.28	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
10.29	2003 Equity Incentive Plan	Quarterly Report on Form 10-Q for the quarter ended March 31, 2003, as Exhibit 10.3	May 14, 2003
10.30	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
10.31	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
10.32	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
10.33	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
10.34	2005 Equity Incentive Plan	Annual Report on Form 10-K for the fiscal year ended September 30, 2005,	December 14, 2005

		as Exhibit 10.21	
10.35	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

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Exhibit Number	Description	Incorporated by Reference Herein Form	Date
10.36	Form of Restricted Stock Unit Grant Agreement for use with 2005 Equity Incentive Plan and 2003 Equity Incentive Plan	Filed herewith	
10.37	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
10.38	Form of Change of Control Agreement	Current Report on Form 8-K, as Exhibit 10.2	December 10, 2007
10.39	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
10.40	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
10.41	Separation and Consulting Agreement, dated November 7, 2006, by and between Avanir Pharmaceuticals and James E. Berg	Filed herewith	
10.42	Employment Agreement with Martin J. Sturgeon, dated February 12, 2007	Filed herewith	
10.43	Amended and Restated Change of Control Agreement, dated February 27, 2007, by and between Avanir Pharmaceuticals and Randall Kaye	Filed herewith	
10.44	Employment Agreement with Keith Katkin, dated March 13, 2007	Filed herewith	
10.45	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
10.46	Separation and Consulting Agreement, dated June 25, 2007, by and between Avanir Pharmaceuticals and Jagadish Sircar	Filed herewith	
10.47	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
10.48	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
10.49	Asset Purchase Agreement, dated July 2, 2007, by and among Avanir Pharmaceuticals, Alamo	Filed herewith	

Pharmaceuticals, LLC and Azur Pharma Inc.*

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Exhibit Number	Description	Incorporated by Reference Herein Form	Date
10.50	Agreement, dated July 2, 2007, by and between Avanir Pharmaceuticals and Neal R. Cutler	Filed herewith	
10.51	Sublease Agreement, dated July 2, 2007, by and between Avanir Pharmaceuticals and Halozyme, Inc. (11388 Sorrento Valley Rd., San Diego, CA)	Filed herewith	
10.52	Sublease Agreement, dated July 2, 2007, by and between Avanir Pharmaceuticals and Halozyme, Inc. (11404 Sorrento Valley Rd., San Diego, CA)	Filed herewith	
10.53	Third Amendment to Lease, dated July 19, 2007, by and between Avanir Pharmaceuticals and RREEF America REIT II Corp. FFF	Filed herewith	
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	
23.2	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.

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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 20, 2007

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 20, 2007
/s/ Martin J. Sturgeon Martin J. Sturgeon	Vice President and Interim Chief Financial Officer (Principal Financial Officer)	December 20, 2007
/s/ Charles A. Mathews Charles A. Mathews	Director	December 20, 2007
/s/ Stephen G. Austin, CPA Stephen G. Austin, CPA	Director	December 20, 2007
/s/ David J. Mazzo, Ph.D. David J. Mazzo, Ph.D.	Director	December 20, 2007
/s/ Dennis G. Podlesak Dennis G. Podlesak	Director	December 20, 2007
/s/ Paul G. Thomas Paul G. Thomas	Director	December 20, 2007

/s/ Craig A. Wheeler	Director	December 20, 2007
Craig A. Wheeler		
/s/ Scott M. Whitcup, M.D.	Director	December 20, 2007
Scott M. Whitcup, M.D.		

Avanir Pharmaceuticals

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of
Avanir Pharmaceuticals

We have audited the accompanying consolidated balance sheet of AVANIR Pharmaceuticals and subsidiaries (the Company) as of September 30, 2007, and the related consolidated statements of operations, shareholders equity (deficit) and comprehensive loss, and cash flows for the year 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 audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether 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 audit 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. An audit also includes 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 audit provides a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of AVANIR Pharmaceuticals and subsidiaries as of September 30, 2007 and the results of their operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

We have also audited the retrospective adjustments to the Company s consolidated financial statements as of and for the year ended September 30, 2006 for the operations discontinued by the Company during 2007 discussed in Note 3 to the consolidated financial statements. Our audit procedures included auditing the reclassification of the discontinued operations in the 2006 consolidated financial statements and related disclosures. In our opinion, such retrospective adjustments to the consolidated financial statements and related disclosures for 2006 in Note 3 are appropriate and have been appropriately applied. However, we were not engaged to audit, review, or apply any procedures to the 2006 consolidated financial statements of the Company other than with respect to the retrospective adjustments and, accordingly, we do not express an opinion or any other form of assurance on the 2006 consolidated financial statements taken as a whole.

/s/ KMJ Corbin & Company LLP

Irvine, California
December 19, 2007

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of
Avanir Pharmaceuticals

We have audited, before the effects of the retrospective adjustments for the discontinued operations discussed in Note 3 to the consolidated financial statements, the accompanying consolidated balance sheet of Avanir Pharmaceuticals and subsidiaries (the Company) as of September 30, 2006, and the related consolidated statements of operations, shareholders (deficit) equity and comprehensive loss, and cash flows for each of the two years in the period ended September 30, 2006 (the 2006 and 2005 consolidated financial statements before the effects of the adjustments discussed in Note 3 to the consolidated financial statements are not presented herein). These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such 2006 and 2005 consolidated financial statements, before the effects of the retrospective adjustments for the discontinued operations discussed in Note 3 to the consolidated financial statements, present fairly, in all material respects, the financial position of Avanir Pharmaceuticals and subsidiaries as of September 30, 2006, and the results of their operations and their cash flows for each of the two years in the period ended September 30, 2006, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2 to the financial statements, the Company (1) adopted Statement of Financial Accounting Standards No. 123(R), *Share-based Payment*, and (2) changed its method of accounting for certain patent related costs, effective October 1, 2005.

We were not engaged to audit, review, or apply any procedures to the retrospective adjustments for the discontinued operations discussed in Note 3 to the consolidated financial statements and, accordingly, we do not express an opinion or any other form of assurance about whether such retrospective adjustments are appropriate and have been properly applied. Those retrospective adjustments were audited by other auditors.

/s/ Deloitte & Touche LLP

Costa Mesa, California
December 15, 2006

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Avanir Pharmaceuticals

CONSOLIDATED BALANCE SHEETS

	September 30, 2007	2006
ASSETS		
Current assets:		
Cash and cash equivalents	$ 30,487,962	$ 4,898,214
Short-term investments in marketable securities	1,747,761	16,778,267
Receivables, net	988,450	1,123,699
Inventories	17,000	3,098
Prepaid expenses	1,479,992	1,651,118
Current portion of restricted investments in marketable securities	688,122	
Current assets of discontinued operations		4,878,674
Total current assets	35,409,287	29,333,070
Investments in marketable securities	249,078	2,216,995
Restricted investments in marketable securities, net of current portion	468,475	856,597
Property and equipment, net	1,215,666	4,521,713
Intangible assets, net	41,048	43,305
Long-term inventories	1,337,991	347,424
Other assets	374,348	391,367
Non-current assets of discontinued operations		33,751,866
TOTAL ASSETS	$ 39,095,893	$ 71,462,337
LIABILITIES AND SHAREHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 307,700	$ 10,845,057
Accrued expenses and other liabilities	2,050,864	6,276,505
Accrued compensation and payroll taxes	1,191,677	2,610,407
Current portion of deferred revenues	2,267,594	3,637,413
Current portion of notes payable	254,676	670,737
Capital lease obligations		9,336
Current liabilities of discontinued operations		12,253,392
Total current liabilities	6,072,511	36,302,847
Accrued expenses and other liabilities, net of current portion	1,170,396	230,450
Deferred revenues, net of current portion	13,052,836	15,716,762
Notes payable, net of current portion	11,769,916	13,715,905
Non-current liabilities of discontinued operations		11,170,908
Total liabilities	32,065,659	77,136,872

Commitments and contingencies (Notes 3, 13, 16, and 18)		
Shareholders equity (deficit):		
Preferred stock no par value, 10,000,000 shares authorized, no shares issued or outstanding as of September 30, 2007 and 2006		
Common stock no par value, 200,000,000 shares authorized; 43,117,358 and 31,708,461 shares issued and outstanding as of September 30, 2007 and 2006, respectively	245,531,712	211,993,249
Accumulated deficit	(238,498,733)	(217,565,280)
Accumulated other comprehensive loss	(2,745)	(102,504)
Total shareholders equity (deficit)	7,030,234	(5,674,535)
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY (DEFICIT)	$ 39,095,893	$ 71,462,337

See notes to consolidated financial statements.

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Avanir Pharmaceuticals

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended September 30,		
	2007	**2006**	**2005**
REVENUES FROM PRODUCT SALES			
Net revenues	$ 72,000	$ 18,270	$ 17,400
Cost of revenues	(328,184)	(3,102)	(3,102)
Product gross (deficit) margin	(256,184)	15,168	14,298
REVENUES AND COST OF RESEARCH SERVICES AND OTHER			
Revenues from research and development services	2,372,384	7,837,788	1,617,525
Cost of research and development services	(2,994,905)	(7,198,397)	(2,346,044)
Revenues from government research grant services	914,834	236,882	503,328
Cost of government research grant services	(1,324,427)	(292,111)	(497,210)
Revenues from license agreements	1,614,091	5,154,709	12,800,000
Revenue from royalties and royalty rights	4,251,252	1,938,203	1,752,321
Research services and other gross margin	4,833,229	7,677,074	13,829,920
Total gross margin	4,577,045	7,692,242	13,844,218
OPERATING EXPENSES			
Research and development	13,115,712	26,994,335	26,140,504
Selling, general and administrative	20,830,188	32,375,366	18,796,188
Total operating expenses	33,945,900	59,369,701	44,936,692
Loss from continuing operations	(29,368,855)	(51,677,459)	(31,092,474)
OTHER INCOME (EXPENSES)			
Interest income	622,687	1,794,049	619,857
Interest expense	(1,247,875)	(405,752)	(92,533)
Other	1,615,519	57,552	(39,601)
Loss from continuing operations before provision for income taxes	(28,378,524)	(50,231,610)	(30,604,751)
Provision for income taxes	(3,200)	(2,430)	(1,813)
Loss before discontinued operations and cumulative effect of change in accounting principle	(28,381,724)	(50,234,040)	(30,606,564)
DISCONTINUED OPERATIONS			
Loss from discontinued operations	(4,760,056)	(8,702,716)	
Gain on sale of discontinued operations	12,208,327		

Income (loss) from discontinued operations	7,448,271	(8,702,716)	
Loss before cumulative effect of change in accounting principle	(20,933,453)	(58,936,756)	(30,606,564)
Cumulative effect of change in accounting principle		(3,616,058)	
Net Loss	$ (20,933,453)	$ (62,552,814)	$ (30,606,564)
BASIC AND DILUTED NET (LOSS) INCOME PER SHARE:			
Loss before discontinued operations and cumulative effect of change in accounting principle	$ (0.72)	$ (1.64)	$ (1.19)
Income (loss) from discontinued operations	0.19	(0.28)	
Cumulative effect of change in accounting principle		(0.12)	
Net Loss	$ (0.53)	$ (2.04)	$ (1.19)
Basic and diluted weighted average number of common shares outstanding	39,643,876	30,634,872	25,617,432

See notes to consolidated financial statements.

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Avanir Pharmaceuticals

CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY (DEFICIT) AND COMPREHENSIVE LOSS

	Common Stock Class A		Class B		Accumulated	Unearned	Accumulated Other Comprehensive Income	Total Shareholders Equity	Compreh
	Shares	Amount	Shares	Amount	Deficit	Compensation	(Loss)	(Deficit)	Los
NCE, BER 1,	23,826,439	$ 134,687,535		$	$ (124,405,902)	$	$ (84,374)	$ 10,197,259	
s					(30,606,564)			(30,606,564)	$ (30,60
e of n stock ection									
e of s	211,486	1,293,339						1,293,339	
e of ptions	27,974	125,491						125,491	
stock rrants	2,525,833	22,765,135						22,765,135	
tion of tual p	500,000	5,300,000						5,300,000	
e of ed	250,000	3,556,000				(3,555,000)		1,000	
zation rned sation ased sation e zed n ents in able es		10,803				77,856	(29,440)	77,856 10,803 (29,440)	(2
NCE, MBER	27,341,732	167,738,303			(155,012,466)	(3,477,144)	(113,814)	9,134,879	$ (30,63

5						
s e of			(62,552,814)		(62,552,814)	$ (62,55
n stock ection						
e of s	827,575	5,908,997			5,908,997	
e of ptions	524,807	3,264,953			3,264,953	
stock rrants	3,016,122	35,637,905			35,637,905	
e of ed	28,000					
n stock ered	(29,775)	(200,386)			(200,386)	
tion of d sation		(3,477,144)	3,477,144			
ased sation e		3,120,621			3,120,621	
zed n ents in able es				11,310	11,310	1
NCE, MBER 6	31,708,461	211,993,249	(217,565,280)	(102,504)	(5,674,535)	$ (62,54
s e of			(20,933,453)		(20,933,453)	$ (20,93
n stock ection						
e of ptions	67,758	294,699			294,699	
stock rrants, ffering	11,388,790	30,547,713			30,547,713	
e of ed	44,250 83,900					

of ed stock								
n stock ered	(18,135)	(41,209)					(41,209)	
re of ed	(157,666)	(500)					(500)	
ased sation e		2,737,760					2,737,760	
zed n ents in able es						99,759	99,759	9
NCE, MBER 7	43,117,358	$ 245,531,712	$	$ (238,498,733)	$	$ (2,745)	$ 7,030,234	$ (20,83

See notes to consolidated financial statements.

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Avanir Pharmaceuticals

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended September 30,		
	2007	2006	2005
OPERATING ACTIVITIES:			
Net loss	$ (20,933,453)	$ (62,552,814)	$ (30,606,564)
(Income) loss from discontinued operations	(7,448,271)	8,702,716	
Adjustments to reconcile loss before discontinued operations to net cash used in operating activities:			
Cumulative effect of change in accounting principle		3,616,058	
Depreciation and amortization	2,843,814	2,964,741	1,852,427
Share-based compensation expense	2,230,122	2,837,640	88,659
Amortization of debt discount	413,822	85,400	
Expense for issuance of common stock in connection with the acquisition of additional contractual rights to Zenvia			5,300,000
Loss on sale and impairment of investment			84,252
(Gain) loss on disposal of assets	(229,829)	36,985	16,400
Intangible assets impaired and abandoned		8,222	423,123
Changes in operating assets and liabilities (net of effects of acquisition/disposition of FazaClo):			
Receivables	135,249	45,955	(929,775)
Inventories	(1,004,469)	24,017	(365,237)
Prepaid and other assets	167,105	582,454	(848,219)
Accounts payable	(10,537,357)	4,200,733	4,615,629
Accrued expenses and other liabilities	(3,327,404)	2,472,798	1,604,136
Accrued compensation and payroll taxes	(1,418,730)	1,338,176	561,863
Deferred revenue	(4,033,745)	195,965	(1,850,905)
Net cash used in operating activities of continuing operations	(43,143,146)	(35,440,954)	(20,054,211)
Net cash used in operating activities of discontinued operations	(3,501,288)	(5,368,562)	
Net cash used in operating activities	(46,644,434)	(40,809,516)	(20,054,211)
INVESTING ACTIVITIES:			
Investments in securities	(101,818)	(65,823,381)	(23,448,802)
Proceeds from sales and maturities of investments in securities	16,900,000	64,900,275	16,830,113
Patent costs			(1,278,935)
Purchase of property and equipment	(58,699)	(1,663,347)	(990,601)
Proceeds from disposal of assets	774,058		
Net cash provided by (used in) investing activities of continuing operations	17,513,541	(2,586,453)	(8,888,225)
Net cash provided by (used in) investing activities of discontinued operations	42,055,769	(4,794,029)	

Net cash provided by (used in) investing activities	59,569,310	(7,380,482)	(8,888,225)
FINANCING ACTIVITIES:			
Proceeds from issuances of common stock and warrants, net of commissions and offering costs	30,870,014	44,811,855	24,184,966
Proceeds from issuances of notes payable		359,875	395,244
Tax withholding payments reimbursed by restricted stock payments on debt	(27,602)	(200,386)	
Payments on notes and capital lease obligations	(6,785,208)	(382,891)	(511,714)
Net cash provided by financing activities of continuing operations	24,057,204	44,588,453	24,068,496
Net cash used in financing activities of discontinued operations	(11,392,332)	(120,384)	
Net cash provided by financing activities	12,664,872	44,468,069	24,068,496
Net increase (decrease) in cash and cash equivalents	25,589,748	(3,721,929)	(4,873,940)
Cash and cash equivalents at beginning of year	4,898,214	8,620,143	13,494,083
Cash and cash equivalents at ending of year	$ 30,487,962	$ 4,898,214	$ 8,620,143
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:			
Interest paid	$ 1,435,982	$ 681,122	$ 92,533
Income taxes paid	$ 22,368	$ 2,430	$ 1,912
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	$	$
Issuance of promissory notes to sellers as consideration for the Alamo acquisition, net of discount (See Note 3 for other liabilities assumed and assets acquired in the acquisition)	$	$ 24,343,000	$
Elimination of unearned compensation	$	$ 3,477,144	$
Issuance of 250,000 shares of restricted Class A common stock for unearned compensation cost	$	$	$ 3,555,000
Accounts payable and accrued expenses for purchase of property plant and equipment	$	$ 74,617	$ 242,213
Restricted stock surrendered	$ 13,607	$ 18,135	$

See notes to consolidated financial statements.

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Avanir Pharmaceuticals

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Description of Business

Avanir Pharmaceuticals (AVANIR, we, or the Company,) 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, inflammatory diseases and infectious 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 and our infectious disease program, which is focused primarily on anthrax antibodies, is currently being funded by grants from the National Institute of Health/National Institute of Allergy and Infectious Disease (NIH/NIAID).

Our 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. Our ability to generate revenues in the future will depend on license arrangements, the timing and success of reaching development milestones, in obtaining regulatory approvals and ultimately market acceptance of Zenvia™ (formerly referred to as Neurodex™) for the treatment of PBA/IEED, assuming the FDA approves our new drug application. Our operating expenses depend substantially on the level of expenditures for clinical development activities for Zenvia for the treatment of PBA/IEED and diabetic neuropathic pain, and program funding authorized by our research partners 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, 2007, 2006 and 2005 may be referred to as fiscal 2007, fiscal 2006 and fiscal 2005, respectively.

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 and sales returns, valuation of inventories, 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.

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Avanir Pharmaceuticals

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

We have restricted investments in two securities totaling $1,156,597 and $856,597 as of September 30, 2007 and 2006, respectively. These restricted investments represent amounts pledged to our bank as collateral for letters of credit issued in connection with certain of our lease agreements, and 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, 2007	Restricted Amount as of September 30, 2006	Lease Term Expires on
Facility lease 11388 Sorrento Valley Road, San Diego	$ 388,122	$ 388,122	08/31/08
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	$ 1,156,597	$ 856,597	

Investments in Marketable Securities

We account for and report our investments in marketable securities in accordance with Statement of Financial Accounting Standards No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. Investments are comprised of marketable securities consisting primarily of certificates of deposit, federal, state and municipal government obligations and corporate bonds. 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

Substantially all of our cash and cash equivalents are maintained with two major financial institutions in the United States. Deposits held with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk.

Financial instruments that potentially subject us to concentrations of credit risk consist principally of cash and cash equivalents and marketable securities, interest rate instruments and accounts receivable. The counterparties to our investment securities and interest rate instruments are various major corporations 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. See Note 19 Segment Information in Notes to Condensed Consolidated Financial Statements .

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

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 and intangible assets

In accordance with Statement of Financial Accounting Standards No. 141, *Business Combinations* (FAS 141) and Statement of Financial Accounting Standards No. 142, *Goodwill and Other Intangible Assets* (FAS 142), goodwill and intangible assets acquired in a purchase business combination and 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. Goodwill represents the excess of purchase price of an acquired business over the fair value of the underlying net tangible and intangible assets. The Company operates in one segment and goodwill is evaluated at the Company level as there is only one reporting unit. Goodwill is evaluated in the fourth quarter of each fiscal year. The Company s goodwill and other intangible assets at September 30, 2006 related to the FazaClo assets acquired from Azur, have been classified with assets of discontinued operations (See Note 3 Acquisition of Alamo Pharmaceuticals, Inc. / Sale of FazaClo). The Company had no goodwill as of September 30, 2007 as a result of the sale of FazaClo. There was no impairment of goodwill for the fiscal years ended September 30, 2007 and 2006.

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 product rights, customer relationships, trade name, non-compete agreement and license agreement, and 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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

Prior to October 1, 2005, intangible assets with finite useful lives also included capitalized legal costs incurred in connection with approved patents and patent applications pending. We amortized costs of patents and patent applications pending over their estimated useful lives. For patents pending, we amortized the costs over the shorter of a period of twenty years from the date of filing the application or, if licensed, the term of the license agreement. For patent and patent applications pending and trademarks that we abandon, we charge the remaining unamortized accumulated costs to expense.

Change in Accounting for Patent-Related Costs

In the fourth quarter of fiscal 2006, we changed our method of accounting, effective October 1, 2005 for legal costs, all of which were external, associated with the application for patents. Prior to the change, we expensed as incurred all internal costs associated with the application for patents and capitalized external legal costs associated with the application for patents. Costs of approved patents were amortized over their estimated useful lives or if licensed, the terms of the license agreement, whichever was shorter, while costs for patents pending were amortized over the shorter period of twenty years from the date of the filing application or if licensed, the term of the license agreement. Amortization expense for these capitalized costs was classified as research and development expenses in our consolidated statements of operations. Under the new method, external legal costs are expensed as incurred and classified as research and development expenses in our consolidated statements of operations. We believe that this change is preferable because it will result in a consistent treatment for all costs, that is, under our new method both internal and external costs associated with the application for patents are expensed as incurred. In addition, the change will provide a better comparison with our industry peers. The $3.6 million cumulative effect of the change on prior years as of October 1, 2005 is included as a charge to net loss in fiscal 2006, retrospectively applied to the first quarter. The effect of the change for fiscal 2006 was to increase the net loss by $3.7 million, $3.6 million of which represents the cumulative effect of the change on prior years, or $0.12 per basic and diluted share.

Pro forma amounts assuming the new method for patent-related costs was applied retroactively are as follows:

	Fiscal 2006	Fiscal 2005
Net loss	$ (58,936,756)	$ (31,255,373)
Basic and diluted loss per share	$ (1.92)	$ (1.22)

Deferred rent

We account for rent expense by accumulating total minimum rent payments on non-abandoned leases over the lives of the lease agreements and recognize the rent as expense on a straight-line basis. The difference between the actual amount paid and the amount recorded as rent expense in each fiscal year has been recorded as an adjustment to deferred rent. The amount classified as deferred rent as of September 30, 2007 and 2006 was $34,000 and $681,000, respectively.

Fair value of financial instruments

At September 30, 2007 and 2006, our financial instruments included cash and cash equivalents, receivables, investments in marketable securities, accounts payable, accrued expenses, accrued compensation and payroll taxes and long-term borrowings. The carrying amount of cash and cash equivalents, receivables, accounts payable,

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accrued expenses and accrued compensation and payroll taxes approximates fair value due to the short-term maturities of these instruments. Our short- and long-term investments in marketable securities are carried at fair value based on quoted market prices. The fair value of our notes payable and capital lease obligations were estimated based on quoted market prices or pricing models using current market rates. At September 30, 2007 and 2006, the fair value of our notes payable approximate the carrying value of the notes.

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 Financial Accounting Standards 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, research reimbursement payments, 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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

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 GlaxoSmithKline 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.

Product Sales FazaClo (Sales from Discontinued Operations). In August 2007, we sold FazaClo to Azur and as a result, all revenues, cost of revenues, and operating expenses related to FazaClo for fiscal 2007 and 2006 have been classified as discontinued operations in the accompanying consolidated financial statements (See Note 3 Acquisition of Alamo Pharmaceuticals, Inc. / Sale of FazaClo).

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

As discussed in Note 3, Acquisition of Alamo Pharmaceuticals, Inc. / Sale of FazaClo 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 48-pill units. 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 units and accepted returns of unsold or undispensed 48-pill units.

During fiscal 2007 and 2006, we sold FazaClo to pharmaceutical wholesalers, the three largest of which accounted for approximately 83% and 86%, respectively, of our net wholesale shipments. 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 contained 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. However, upon the sale of the FazaClo assets, Azur assumed all 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, we no longer had responsibility for returns and allowances related to our sales of FazaClo.

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.

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 cost of product sales under discontinued operations.

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Shipping and Handling Costs

We do not charge customers for shipping and handling. We expense shipping and handling costs as incurred. Shipping and handling costs charged to selling, general and administration expense amounted to $72,000, $29,000 and $0 for fiscal 2007, 2006 and 2005, respectively.

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 effective August 13, 2007 (see Note 21, Subsequent Events). 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 in-process research and development. In accordance with FAS 141, we immediately charge the costs associated with acquired in-process research and development (IPR&D) to research and development expense upon acquisition. These amounts represent an estimate of the fair value of purchased IPR&D for projects that, as of the acquisition date, had not yet reached technological feasibility, had no alternative future use, and had uncertainty in receiving future economic benefits from the acquired IPR&D. We determine the future economic benefits from the acquired IPR&D to be uncertain until such technology is approved by the FDA or when other significant risk factors

are abated. We incurred significant IPR&D expense related to the Alamo acquisition. See also Note 3, Acquisition of Alamo Pharmaceuticals, Inc. / Sale of FazaClo.

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.

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Share-Based Compensation

We adopted the provisions of revised Statement of Financial Accounting Standards No. 123 (FAS 123R), *Share-Based Payment,* including the provisions of Staff Accounting Bulletin No. 107 (SAB 107) on October 1, 2005, the first day of our fiscal 2006, using the modified prospective transition method to account for our employee share-based awards. The valuation provisions of FAS 123R apply to new awards and to awards that are outstanding at the effective date and subsequently modified or cancelled. Estimated compensation expense for awards outstanding at the effective date are being recognized over the remaining service period using the compensation cost calculated for pro forma disclosure purposes under Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* (FAS 123). Our consolidated financial statements as of September 30, 2007 and 2006 and for the fiscal years ended September 30, 2007 and 2006 reflect the impact of FAS 123R. In accordance with the modified prospective transition method, our consolidated financial statements for prior periods were not restated to reflect, and do not include, the impact of FAS 123R.

On November 10, 2005, the FASB issued FASB Staff Position No. FAS 123R-3, *Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards* (FAS 123R-3). We have elected to adopt the alternative transition method provided in FAS 123R-3. The alternative transition method includes a simplified method to establish the beginning balance of the additional paid-in capital pool (APIC pool) related to the tax effects of employee share-based compensation, which is available to absorb tax deficiencies recognized subsequent to the adoption of FAS 123R.

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. Share-based compensation expense recognized in our consolidated statements of operations for fiscal 2007 and 2006 includes compensation expense for share-based payment awards granted prior to, but not yet vested as of September 30, 2005 based on the grant date fair value estimated in accordance with the pro forma provisions of FAS 123, adjusted for estimated forfeitures, and share-based payment awards granted subsequent to September 30, 2005 based on the grant date fair value estimated in accordance with FAS 123R. For share-based awards granted in fiscal 2007 and 2006, expenses are amortized under the straight-line attribution method. For share awards granted prior to fiscal 2006, expenses are amortized under the straight-line single option method prescribed by FAS 123. As share-based compensation expense recognized in the consolidated statements of operations for fiscal 2007 and 2006 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. In our pro forma information required under FAS 123 for the periods prior to fiscal 2006, we accounted for forfeitures as they occurred.

The Company considers many factors when estimating expected forfeitures, including types of awards, employee class and historical experience. The Company most recently updated its projected forfeiture rates in the second quarter of fiscal 2007 as it applies to share-based compensation, considering recent actual data following the implementation of various restructuring initiatives earlier that year. The pre-vesting forfeiture rate for fiscal 2007 was estimated to be 30% for officers, directors and other employees. The pre-vesting forfeiture rates for fiscal 2006 were estimated to be approximately 8% for both officers and directors and 13% for other employees in fiscal 2006. The pre-vesting forfeiture rates for fiscal 2006 for officers, directors and other employees were subsequently adjusted to 30% in fiscal 2007. Future estimates, may differ substantially from the Company s current estimates.

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Total compensation expense related to all of our share-based awards, recognized under FAS 123R, for fiscal 2007 and 2006 was comprised of the following:

	Fiscal 2007	Fiscal 2006
From Continuing Operations:		
Selling, general and administrative expense	$ 1,864,689	$ 2,372,356
Research and development expense	365,433	465,284
Share-based compensation expense related to continuing operations	2,230,122	2,837,640
From Discontinued Operations:	507,638	282,981
Share-based compensation expense	$ 2,737,760	$ 3,120,621

	Fiscal 2007	Fiscal 2006
Share-based compensation expense from:		
Stock options	$ 1,304,944	$ 1,795,610
Restricted stock awards	707,448	1,179,621
Restricted stock units	725,368	145,390
Total	$ 2,737,760	$ 3,120,621

Since we have a net operating loss carry-forward as of September 30, 2007 and 2006, no excess tax benefits for the tax deductions related to share-based awards were recognized in the consolidated statement of operations. Additionally, no incremental tax benefits were recognized from stock options exercised in fiscal 2007 and 2006 that would have resulted in a reclassification to reduce net cash provided by operating activities with an offsetting increase in net cash provided by financing activities. Compensation expense relating to employee share-based awards was not recognized in fiscal year ended September 30, 2005.

Prior to fiscal year 2006, we accounted for share-based awards to employees using the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* and related interpretations and provided the required pro forma disclosures of FAS 123.

The following table summarizes the pro forma effect on our net loss and per share data if we had applied the fair value recognition provisions of FAS 123 to share-based employee compensation for fiscal 2005.

	Fiscal 2005

Net loss, as reported		$ (30,606,564)
Add: Share-based employee compensation expense		77,856
Deduct: Total share-based employee compensation expense determined under fair value based method for all awards		(1,777,838)
Pro forma net loss		$ (32,306,546)
Net loss per share:		
Basic and diluted	as reported	$ (1.19)
Basic and diluted	pro forma	$ (1.26)

For employee stock options granted in fiscal 2005, we determined pro forma compensation expense under the provisions of FAS 123 using the Black-Scholes model and the following assumptions: (1) an expected volatility of 95%, (2) an expected term of 3.4 years, (3) a risk-free interest rate of 3.8% and (4) an expected dividend yield of 0%. The weighted average fair value of options granted in fiscal 2005 was $11.36 per share.

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We account for stock options granted to non-employees in accordance with Emerging Issues Task Force No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, (EITF 96-18). Under EITF 96-18, we determine the fair value of the stock options granted as either the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable.

Restructuring expense

We record costs and liabilities associated with exit and disposal activities, as defined in Statement of Financial Accounting Standards 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 2006 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 for further information.

Advertising expenses

Advertising costs are expensed as incurred, and these costs are included in selling, general and administrative expenses. Advertising costs were $1.1 million, $1.3 million and $61,000 for fiscal 2007, 2006 and 2005, 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.

Comprehensive loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources, including foreign currency translation adjustments and unrealized gains and losses on marketable securities. We present an accumulated other comprehensive loss in our consolidated statements of shareholders (deficit) 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, 2006 and 2005, 22,500, 194,665 and 250,000 restricted shares, respectively, 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 has not lapsed.

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For fiscal 2007, 2006, and 2005, 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 2007	Fiscal 2006	Fiscal 2005
Stock options	1,040,581	1,587,070	1,600,034
Stock warrants	1,322,305	269,305	1,122,047
Restricted stock awards		29,250	
Restricted stock units	1,914,988	51,480	

Recent accounting pronouncements

FASB Interpretation No. 48 (FIN 48). In July 2006, the FASB issued FIN 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB No. 109* which prescribes a recognition threshold and measurement process for recording in the financial statements uncertain tax positions taken or expected to be taken. Additionally, FIN 48 provides guidance on derecognition, classification, accounting in interim periods and disclosure requirements for uncertain tax positions. The accounting provisions of FIN 48 will be effective for us beginning October 1, 2007. We are in the process of determining the effect, if any, of the adoption of FIN 48 will have on our consolidated financial statements.

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. We do not expect the adoption of FAS 157 to significantly affect 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. The Company is 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.

Staff Accounting Bulletin No. 108 (SAB 108). In September 2006, the SEC released SAB 108 to address diversity in practice regarding consideration of the effects of prior year errors when quantifying misstatements in current year financial statements. The SEC staff concluded that registrants should quantify financial statement errors using both a balance sheet approach and an income statement approach and evaluate whether either approach results in quantifying a misstatement that, when all relevant quantitative and qualitative factors are considered, is material. SAB 108 states that if correcting an error in the current year materially affects the current year s income statement, the prior period

financial statements must be restated. SAB 108 is effective for fiscal years ending after November 15, 2006. The Company adopted SAB 108 in fiscal 2007. The adoption of SAB 108 did not materially affect the Company s consolidated financial statements.

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

exceeded the net assets acquired resulting in the recognition of $22.1 million of goodwill. The results of operations of Alamo have been included in our consolidated financial statements since the date of acquisition. 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. Details of the sale of FazaClo are described below.

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. We also agreed to apply 20% of any future net offering proceeds to repay the promissory notes and through June 30, 2007, we paid approximately $6.1 million of the principal amounts due under the notes. In August 2007, we paid an additional $11 million of outstanding principal and interest under these notes and amended our agreement with the Selling Holders to partially suspend the early payment obligations remaining under the promissory notes.

Purchase Price Allocation

In accordance with FAS 141, we allocated the total purchase price to the tangible and identifiable intangible assets acquired and liabilities assumed based on their estimated fair values as of the date of acquisition, using the purchase method of accounting. The components of the purchase price allocation are as follows:

Purchase price:	
Cash paid at closing	$ 4,040,000
Estimated fair value of notes payable issued	24,343,000
Transaction costs	911,536
	$ 29,294,536
Allocation:	
Net tangible assets acquired	$ 5,749,898
Identifiable intangible assets acquired	11,960,000
Goodwill	22,110,328
Total assets acquired	39,820,226

Accounts payable and accrued expenses	(3,611,653)
Liabilities assumed	(6,401,321)
Capital lease obligations	(512,716)
	$ 29,294,536

None of the goodwill for the acquisition of FazaClo is deductible for tax purposes.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The purchase price allocation shown above was adjusted during fiscal 2007 due to the following:

Issuance of additional notes payable totaling $4,000,000 issued in fiscal 2007 as the result of the contingency of certain revenue-based earn-out obligations being met.

The reduction of $3,980,229 of the liabilities related to the product returns and discounts from the original amounts.

A net increase of $19,771 to goodwill as a result of the two items described above.

The following table sets forth adjustments to goodwill during the fiscal year ending September 30, 2007:

Goodwill, as of the year ended September 30, 2006	$ 22,110,328
Contingent Consideration Issuance of additional notes payable	4,000,000
Reduction of assumed liabilities	(3,980,229)
Goodwill, balance prior to sale of FazaClo	$ 22,130,099

Pursuant to EITF 01-3, *Accounting in a Business Combination for Deferred Revenue of an Acquiree*, we did not assume Alamo s deferred revenue balance as of the acquisition date, and accordingly will not record revenue associated with product that was shipped prior to the acquisition date. However, in connection with the acquisition, we assumed an obligation for future product returns, chargebacks, rebates, discounts and royalties associated with pre-acquisition shipments of FazaClo. As such, we recorded preliminary estimated liabilities for such returns and other discounts of $6.4 million based on our estimate of the fair values of these liabilities at the acquisition date, which is included in current liabilities of discontinued operations in the accompanying consolidated balance sheet as of September 30, 2006. Since the acquisition in May 2006 through the date of the sale of the FazaClo assets, the Company received and analyzed historical data regarding FazaClo product returns and product pricing allowances (See Note 2 Summary of Significant Accounting Policies Revenue Recognition). Based on this analysis, the Company recorded net total adjustments of $4.0 million in fiscal 2007 to reduce the preliminary estimate of these assumed liabilities and to also reduce goodwill by the same amount. The remaining liabilities associated with Fazaclo have been eliminated as of September 30, 2007 in connection with our sale of FazaClo.

We acquired Alamo for the purpose of acquiring the sales force and a product that showed potentially greater sales opportunity with enhanced marketing and promotion. The value of the sales force is encompassed in goodwill. The lower allocation to intangible assets reflects a higher risk-adjusted discount rate for the identifiable intangible assets than other assets purchased in the transaction, which lowered the fair values of the intangible assets acquired and increased the residual being applied to goodwill.

We determined fair values of identifiable intangible assets acquired based on estimates and assumptions by management on projected sales and product returns, pricing allowances and discounts. Identifiable intangible assets acquired represent expected benefits of the FazaClo product rights, customer relationships, trade name and non-compete agreement. The fair values of the customer relationships, technology, trade name and covenants not to

compete were determined using an income approach and discounted cash flow (DCF) techniques. The fair value of the software registry and assembled workforce were determined using a cost approach. The remaining goodwill value of the Company was determined using a residual approach, by comparing the total fair market value of the assumed liabilities and equity consideration paid less the fair value of the tangible and identified intangible assets.

Identifiable Intangible Assets

We determined fair values of identifiable intangible assets acquired based on estimates and assumptions by management on projected sales and product returns, pricing allowances and discounts. Identifiable intangible assets acquired represent expected benefits of the FazaClo product rights, customer relationships, trade name and non-compete agreement. The fair values of the customer relationships, technology, trade name and covenants not to compete were determined using an income approach and discounted cash flow (DCF) techniques. The fair value

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

of the software registry and assembled workforce were determined using a cost approach. The remaining goodwill value of the Company was determined using a residual approach, by comparing the total fair market value of the assumed liabilities and equity consideration paid less the fair value of the tangible and identified intangible assets.

The identifiable intangible assets prior to the sale of the FazaClo assets were being amortized, with the annual amortization amount based on the rate of consumption of the expected benefits of the intangible or the straight-line method over the remaining estimated economic life ranging from one to 12 years, if the rate of consumption of the expected benefits could not be reasonably determined otherwise. Since the acquisition of Alamo, the Company has recorded amortization expense relating to the identifiable intangible assets of $2.0 million.

In-Process Research and Development

We evaluated research and development projects including new manufacturing technology for FazaClo under development by CIMA Labs. As the basis for identifying whether or not the development projects represented in-process research and development (IPR&D), we conducted an evaluation in the context of FASB Interpretation 4 (FIN 4: Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method). In accordance with these provisions, we examined the research and development projects to determine whether any alternative future uses existed. Such evaluation consisted of a specific review of the efforts, including the overall objectives of the project, progress toward the objectives, and the uniqueness of the developments of these objectives as well as our intended use of the developments. Further, we reviewed each development project to determine whether technological feasibility had been achieved. Based on our analysis, we determined that the DuraSolv technology, a certain technology being developed in collaboration with CIMA Labs for manufacturing FazaClo, was IPR&D.

In order to estimate the fair value of the DuraSolv technology, we used the relief from royalty valuation approach on incremental product revenues that could result from manufacturing with such technology. The fair value of the IPR&D was determined by measuring the present value of the after-tax cash flows from revenues from such technology based on an appropriate technology royalty rate. DuraSolv technology allows for the product to be packaged in a bottle, which is more convenient to open than the current blister packaging for FazaClo. We expected to use the DuraSolv manufacturing technology to replace the current OraSolv technology for manufacturing FazaClo, assuming the manufacturing process was approved by the FDA. We determined the future economic benefits from the purchased IPR&D to be uncertain because such technology has not been approved by the FDA. As DuraSolv was determined to be IPR&D, the estimated fair value of DuraSolv of $1.3 million was expensed in fiscal 2006, under guidelines in FAS 141.

Sale of FazaClo and Presentation of Discontinued Operations

In August 2007, the Company sold FazaClo to Azur. In connection with the sale, the Company received approximately $43.9 million in upfront consideration and has the right to receive up to an additional $10 million in contingent payments in 2009, subject to the satisfaction of certain regulatory conditions. 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. In addition, the asset and liabilities associated with FazaClo are separately presented on the accompanying consolidated balance sheet as of September 30, 2006 as assets of discontinued operations or liabilities of discontinued operations.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Summarized statements of operations for the discontinued operations for fiscal 2007 and 2006 is as follows:

	FIscal 2007	Fiscal 2006
REVENUES FROM PRODUCT SALES		
Net revenues	$ 17,132,171	$
Cost of revenues	4,599,105	411,943
Product gross margin (loss)	12,533,066	(411,943)
OPERATING EXPENSES		
Research and development	3,159,117	2,227,754
Selling, general and administrative	13,486,361	5,678,853
Loss from operations	(4,112,412)	(8,318,550)
OTHER INCOME (EXPENSES)		
Interest expense	(647,644)	(359,727)
Gain on sale of FazaClo	12,208,327	
Other		(24,439)
Income (loss) before income taxes	7,448,271	(8,702,716)
Provision for income taxes		
NET INCOME (LOSS)	$ 7,448,271	$ (8,702,716)

Summarized balance sheet information for the discontinued operations as of September 30, 2006 is set forth below:

	Fiscal 2006
Accounts receivable, net	$ 1,918,769
Inventories, net	2,832,105
Prepaid expenses and other current assets	127,800
Current assets of discontinued operations	4,878,674
Property, plant and equipment, net	1,526,016
Other assets	45,498
Intangible assets, net	10,070,024
Goodwill	22,110,328
Non-current assets of discontinued operations	33,751,866

Assets of discontinued operations	$ 38,630,540
Current portion of capital leases and long-term debt	$ 221,424
Deferred revenue	3,955,150
Assumed liabilities for returns and other discounts	3,980,229
Other accrued expenses	4,096,589
Current liabilities of discontinued operations	12,253,392
Capital leases and long-term debt, net of current portion	11,170,908
Liabilities of discontinued operations	$ 23,424,300

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In connection with the sale of the FazaClo assets, the Company recognized a gain of approximately $12.2 million in the fourth quarter of fiscal 2007. 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

Pro Forma Results of Operations

The following unaudited financial information presents the pro forma results of operations and gives effect to the Alamo acquisition as if the acquisition was consummated at the beginning of fiscal 2005. This information is presented for informational purposes only, and is not intended to be indicative of any expected results of operations for future periods, or the results of operations that actually would have been realized if the acquisition had in fact occurred as of the beginning of fiscal 2005.

	Fiscal 2006	Fiscal 2005
Pro forma net revenues(1)	$ 17,503,000	$ 18,522,000
Pro forma loss before cumulative effect of change in accounting principle(2)	$ (62,963,000)	$ (56,307,000)
Pro forma net loss(2)	$ (66,579,000)	$ (56,307,000)
Pro forma loss per basic and diluted share:		
Loss before cumulative effect of change in accounting principle	$ (2.06)	$ (2.20)
Net loss	$ (2.17)	$ (2.20)
Shares used for basic and diluted computation	30,634,872	25,617,432

(1) In accordance with the provisions of EITF 01-3 we did not assume Alamo s reported deferred revenue balance as of the acquisition date and accordingly did not record revenue associated with such deferred revenue, resulting in lower net revenues in the periods following the merger than Alamo would have achieved as a separate company.

(2) Pro forma net loss for the periods presented included the following pro forma adjustments:

Amortization of identifiable intangible assets,

Interest expense associated with the notes payable issued as part of purchase price,

Elimination of interest expense associated with Alamo s historical debt that was assumed by us in the acquisition,

Reduction of interest income by an amount determined by applying the average rate of return for the respective periods to the decrease in our cash balance of $4.0 million used to fund the acquisition,

Amortization of discount associated with the notes payable, and

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The charge of $1.3 million purchased IPR&D is not included in the pro forma results of operations. The purchased IPR&D is a one-time charge directly related to the acquisition and does not have a continuing impact on our future operations.

Assumed Liabilities for Returns and Other Discounts of Discontinued Operations

In connection with the Alamo Acquisition, we assumed outstanding obligations for future product returns, chargebacks, rebates, discounts and royalties associated with pre-acquisition shipments of FazaClo. As such, we recorded liabilities in the amount of $6.4 million for such returns and other discounts based on the estimated fair value at the acquisition date. The following table summarizes activity related to the assumed liabilities for returns and other discounts as of September 30, 2007 and 2006:

	2007	2006
Balance, at beginning of year	$ 3,980,229	$
Assumed liabilities for returns and other		6,401,321
Payments for returns and other discounts		(2,421,092)
Adjustment to goodwill	(3,980,229)	
Balance, at end of year	$	$ 3,980,229

The assumed liabilities for returns and other discounts are classified in current liabilities of discontinued operations as of September 30, 2006.

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 selling, 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 follows 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 selling, 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 are expected to be incurred related to these restructuring events in fiscal 2008.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table presents the restructuring activities for fiscal 2006:

	Balance at September 30, 2005	Charges/ Additions	Net Payments/ Reductions	Balance at September 30, 2006
Accrued Restructuring:				
Employee severance and relocation benefits	$	$ 237,050	$	$ 237,050
Lease restructuring liability		277,627	(3,629)	273,998
Total		514,677	(3,629)	511,048
Less current portion				(280,598)
Total	$			$ 230,450

The following table presents the restructuring activities for fiscal 2007:

	Balance at September 30, 2006	Charges/ Additions	Net 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 $1,088,000 is included in Accrued Expenses and Other Liabilities and the non-current portion of lease restructuring liability of $1,136,000 is included in Accrued Expenses and Other Liabilities, Net of Current Portion in the accompanying consolidated balance sheets.

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5. Investments in Marketable Securities

The following tables summarize our investments in securities, 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, 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(2)				$ 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(2)				468,475
Classified as available for sale				249,078
Non-current investments in securities:				717,553
Total investments in securites				$ 3,153,436

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses(1)	Fair Value
As of September 30, 2006:				
Certificates of deposit	$ 856,597			$ 856,597
Government debt securities	19,097,766		(102,504)	18,995,262
Total	$ 19,954,363		$ (102,504)	$ 19,851,859
Reported as:				

Current investments in securities:	
Classified as available for sale	$ 16,778,267
Total current investments in securities:	16,778,267
Non-current investments in securities:	
Classified as available for sale	2,216,995
Restricted investments(2)	856,597
Non-current investments in securities:	3,073,592
Total investments in securites	$ 19,851,859

(1) Unrealized loss is reported as accumulated other comprehensive loss on the consolidated balance sheets.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(2) Restricted investments represent amounts pledged to our bank as collateral for letters of credit issued in connection with our leases of office and laboratory space.

The gross realized loss for fiscal 2005 was $6,240. There were no realized gains or losses for fiscal 2007 and 2006.

6. Receivables, Net

Receivables as of September 30, 2007 and 2006 consist of the following:

	2007	2006
Accounts receivable(1)	$ 592,035	$ 49,300
Unbilled receivables		908,284
Other receivables	396,415	176,714
	988,450	1,134,298
Allowance for doubtful accounts		(10,599)
Receivables, net of allowances	$ 988,450	$ 1,123,699

(1) Fiscal 2007 amount includes non-trade related receivables from research partners of approximately $260,000.

7. Inventories

Inventories relate to the active pharmaceutical ingredients docosanol and Zenvia.

The composition of inventories as of September 30, 2007 and 2006 is as follows:

	2007	2006
Raw materials	$ 1,354,991	$ 350,522
Less: current portion	(17,000)	(3,098)
Long-term portion	$ 1,337,991	$ 347,424

The amount classified as long-term 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.

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8. Property and Equipment

Property and equipment as of September 30, 2007 and 2006 consist of the following:

	2007			2006		
	Gross Carrying Value	Accumulated Depreciation	Net	Gross Carrying Value	Accumulated Depreciation	Net
Research and development equipment	$ 761,815	$ (588,325)	$ 173,490	$ 4,210,214	$ (3,134,970)	$ 1,075,244
Computer equipment and related software	1,285,454	(941,628)	343,826	1,345,321	(751,391)	593,930
Leasehold improvements	37,790	(3,787)	34,003	5,671,209	(3,649,499)	2,021,710
Office equipment furniture and fixtures	767,313	(364,685)	402,628	990,654	(421,544)	569,110
Manufacturing equipment	261,719		261,719	261,719		261,719
Total property and equipment	$ 3,114,091	$ (1,898,425)	$ 1,215,666	$ 12,479,117	$ (7,957,404)	$ 4,521,713

Depreciation expense associated with property and equipment was $3.6 million of which $768,000 was related to discontinued operations, $3.3 million of which $300,000 was related to discontinued operations and $1.6 million for fiscal 2007, 2006 and 2005, respectively. In connection with the relocation plan discussed in Note 4, Relocation of Commercial and General and Administrative Operations , we revised the estimated remaining economic lives of the leasehold improvements in the buildings under the BC Sorrento lease and recorded additional depreciation expense of $1.3 million in fiscal 2006.

At September 30, 2007, scientific equipment acquired under capital leases totaled $601,000 with accumulated depreciation of $601,000. At September 30, 2006 scientific equipment acquired under capital leases totaled $601,000 with accumulated depreciation of $529,000. Depreciation expense associated with scientific equipment acquired under capital leases was $72,000 for fiscal 2007 due to the consolidation of operations to the Aliso Viejo office. Depreciation expense associated with scientific equipment acquired under capital leases was $102,000 and $106,000 for fiscal 2006 and 2005, respectively.

9. Intangible Assets

Intangible Assets. Intangible assets, consisting of both intangible assets with finite and indefinite useful lives as of September 30, 2007 and 2006, are as follows:

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	

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	2006			
	Gross Carrying Value	Accumulated Amortization	Net	Weighted Average Amortization Period (in years)
Intangible assets with finite lives:				
Licenses	$ 42,461	$ (20,161)	$ 22,300	15.5
Intangible assets with finite lives	42,461	(20,161)	22,300	
Intangible assets with indefinite lives	21,005		21,005	
Total intangible assets	$ 63,466	$ (20,161)	$ 43,305	

In the fourth quarter of fiscal 2006, we changed our method of accounting, effective October 1, 2005 for legal costs, all of which were external, associated with the application for patents. See Note 2, Summary of Significant Accounting Policies Change in Accounting for Patent-Related Costs for detailed discussion.

During fiscal 2006, FazaClo product rights (see Note 16, Research and Licensing Agreements CIMA Labs Inc. Royalty Agreement), customer relationships, a trade name and a non-compete agreement valued at a total of $10,660,000 were acquired in connection with the Alamo Acquisition.

During fiscal 2007, the Company sold FazaClo and therefore our 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 $1.4 million, $592,000 and $226,000 for fiscal 2007, 2006 and 2005, respectively. Charges for intangible assets abandoned and impaired for fiscal 2007, 2006 and 2005 were $0, $8,000 and $423,000 respectively. Charges for patents and patent applications pending abandoned and impaired in fiscal 2005 were included in research and development expense in our consolidated statements of operations. Charges for trademarks abandoned are included in selling, general and administrative expense in our consolidated statements of operations.

Estimated amortization expense of intangible assets for fiscal years ending September 30 is as follows:

	Amortization Expense
Fiscal year ending September 30:	
2008	$ 2,257
2009	2,257

2010		2,257
2011		2,257
2012		2,257
Thereafter		8,758
Total	$	20,043

In connection with the Alamo acquisition, we recognized $22.1 million of goodwill in fiscal 2006.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities at September 30, 2007 and 2006 are as follows:

	2007	2006
Accrued research and development expenses	$ 419,989	$ 3,947,191
Accrued sales and marketing expenses		1,146,222
Accrued general and admistrative expenses	287,517	299,190
Deferred rent	34,432	679,421
Lease restructuring liability	2,223,802	273,998
Other	255,520	160,933
Total accrued expenses and other liabilities	3,221,260	6,506,955
Less current	(2,050,864)	(6,276,505)
Non-current total accrued expenses and other liabilities	$ 1,170,396	$ 230,450

11. Deferred Revenues

The following table sets forth as of September 30, 2007 and 2006 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, 2005	$ 19,049,877	$ 108,333	$ 19,158,210
Changes during the period:			
License fees		2,288,638	2,288,638
Recognized as revenues during period	(1,937,964)	(154,709)	(2,092,673)
Net deferred revenues as of September 30, 2006	$ 17,111,913	$ 2,242,262	$ 19,354,175
Classified and reported as:			
Current portion of deferred revenues	$ 1,981,799	$ 1,655,614	$ 3,637,413
Deferred revenues, net of current portion	15,130,114	586,648	15,716,762
Total deferred revenues	$ 17,111,913	$ 2,242,262	$ 19,354,175

	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:			
Shipments, net		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

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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.

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 ratably 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 ratably 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. In addition, we will be eligible to receive milestone payments of up to 450 million Japanese Yen (or up to approximately U.S. $3.9 million based on the exchange rate as of September 30, 2007), subject to achievement of certain milestones relating to the regulatory approval and commercialization of docosanol in Japan and patent and know-how royalties for sales of Products in Japan, if commercial sales commence.

Under the terms of the Kobayashi License Agreement, Kobayashi will be responsible for obtaining all necessary approvals for marketing, all sales and marketing activities and the manufacturing and distribution of the Products. Because the know-how and expertise related to the docosanol 10% cream are proprietary to us, we will be providing 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. As of September 30, 2007, we estimated the period of time of our continuing involvement in advising and assisting Kobayashi with additional clinical studies and obtaining regulatory approval in Japan to be approximately three years. Pursuant to SAB Topic 13, revenue from the License Fee of $860,000 is deferred and being recognized on a straight-line basis over 3.75 years. Accordingly, we recognized $227,000 and $121,000 of the License Fee in fiscal 2007 and 2006, respectively, which is included in revenues from license agreements.

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.

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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 will also be eligible to receive £750,000 (or approximately U.S. $1.5 million based on the exchange rate as of September 30, 2007) for each of the first two regulatory approvals for marketing in any countries in the Licensed Territory. In July 2007, we received notice from HBI of HBI s achievement of regulatory approval in the European market. As a result, we received our first of two milestone payments in the amount of $1.5 million which was recorded as royalty revenue during the year ended September 30, 2007. 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.

12. Commitments and Contingencies

Operating lease commitments. We lease laboratory and office space and certain equipment under non-cancelable operating leases. In May 2006, we entered into a five-year lease agreement for a total of approximately 17,000 square feet of office space, commencing on July 10, 2006 with 6,245 square feet and increasing to the full amount in the second quarter of 2007. On July 1, 2007, we signed an amendment to the original lease to assume a total of only 11,319 square feet. As of September 30, 2007, we were in possession of 11,319 square feet of this office space. The lease has scheduled rent increases each year and expires on July 9, 2011. As of September 30, 2007, the financial commitment for the remainder of the term of the lease is $1.5 million.

In March 2000 (as amended in March 2006), we entered into an eight-year lease for 27,575 square feet of office and lab space in a building located at 11388 Sorrento Valley Road, Suite 200, San Diego, California, commencing on September 1, 2000. The lease has scheduled rent increases each year and expires on August 31, 2008. As of September 30, 2007, the financial commitment for the remainder of the term of the lease is approximately $793,000. We delivered an irrevocable standby letter of credit to the lessor in the amount of approximately $388,000, to secure our performance under the lease. In July 2007 we entered into a sublease agreement with Halozyme to sublease this building at 11388 Sorrento Valley Road. We anticipate receiving approximately $308,000 of sublease payments in fiscal 2008.

In May 2002, we signed a ten-year lease for approximately 26,770 square feet of office and lab space in buildings adjacent to our existing facilities, commencing on January 15, 2003. In April 2003, we signed an amendment to the lease for an additional 3,600 square feet of space in the building adjacent to our existing facilities. The lease has scheduled rent increases each year and expires on January 14, 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 January 14, 2013. In July 2007 we subleased approximately 21,184 rentable square feet to Halozyme Inc. The sublease has scheduled rent increases each year and expires on January 14, 2013. As of September 30, 2007, the financial commitment for the remainder of the term of the lease is $6.0 million (excluding $3.8 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.

In June 2007, we entered into a one-year lease for 1,594 square feet of office and lab space in a building located at 4050 Sorrento Valley Blvd, Suite J, San Diego, California, commencing on July 1, 2007. As of September 30, 2007, the financial commitment for the remainder of the term of the lease is $18,000.

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Rental expenses, excluding common area charges and other executory costs, were $2.3 million in fiscal 2007, $1.9 million in fiscal 2006 and $1.8 million in fiscal 2005. Sublease rental income was approximately $292,000 in fiscal 2007 and $18,000 in fiscal 2006. Future minimum rental payments under non-cancelable operating lease commitments as of September 30, 2007 are as follows:

Year Ending September 30,	Minimum Payments	Less Payments to be Received from Subleases	Net Payments
2008	$ 2,217,000	$ 888,000	$ 1,329,000
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
Thereafter	352,000	216,000	136,000
Total	$ 8,280,000	$ 4,132,000	$ 4,148,000

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 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 operations or financial position.

In September 2007, a court awarded reimbursement of attorneys fees spent over a four-year period in connection with the enforcement of a settlement agreement entered into with a former employee. The total fees awarded were approximately $1.3 million. We cannot currently estimate the timing for collection or the probability of collecting the full amount.

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 amounts 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, 2007 and 2006.

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13. Notes Payable

As of September 30, 2007 and 2006, notes payable consist of the following:

	September 30, 2007	2006
Senior notes with an interest rate of LIBOR + 1.33%; interest payable monthly; principal due May 2009, net of unamortized discount of $232,778 and $646,600, respectively	$ 11,737,087	$ 13,428,400
9.5% equipment loan due April 2008	174,224	451,405
7.9% business insurance financing repaid in June 2007		320,957
10.43% equipment loan due February 2009	65,442	106,170
10.17% equipment loan due January 2009	47,839	79,710
Total	12,024,592	14,386,642
Less: current portion	(254,676)	(670,737)
Total long-term notes payable	$ 11,769,916	$ 13,715,905

Senior Notes. In connection with the Alamo Acquisition, we issued three promissory notes in the respective principal amounts of $14,400,000, $6,675,000 and $4,000,000 (the First Note, Second Note and Third Note, respectively) (collectively, the Notes). The Notes bear 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 and 2006 was 5.12% and 5.33%, respectively. Interest accruing on the Notes is payable monthly and the principal amount of the Notes matures on May 24, 2009, provided that (i) the Selling Holders may demand early repayment of the First Note if the closing price of our common stock, as reported on the Nasdaq Global Market, equals or exceeds $15.00 per share for a total of 20 trading days in any 30 consecutive trading-day period (the Stock Contingency), and (ii) we must apply 20% of any future net offering proceeds from equity offerings to repay the Notes (starting with the First Note), and must repay the Notes in full if we have raised in an offering more than $100,000,000 in future aggregate net proceeds. In connection with the equity offering we completed in the fiscal year, and in accordance with the terms of the Notes, we used approximately $6.1 million or 20% of the net proceeds received to pay down the First Note. We classified the Notes as long term, because they are not reasonably expected to require any payments through fiscal 2008.

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. Based on the results in the fiscal year 2007, we issued the first of these revenue-based payments through the issuance of an additional promissory note in the principal amount of $2,000,000 on May 15, 2007. We issued a second promissory note in the principal amount of $2,000,000 on August 15, 2007.

In connection with our sale of FazaClo in August 2007, we agreed to prepay $11 million of outstanding principal due under the Notes. Therefore, $8.3 million was applied against the First Note, reducing the balance to $0, and the remaining $2.7 million was applied to the Second Note.

We have the right to prepay, in cash or in common stock, the amounts due under the Notes at any time, provided that we may only pay the Notes in common stock if the Stock Contingency has occurred prior to the maturity date and if we have registered the shares on an effective registration statement filed with the SEC. If we elect to prepay the Notes with common stock, the shares will be valued at 95% of the average closing price of the common stock, as reported on the NASDAQ Global Market, for the five trading days prior to repayment, subject to a price floor.

We have concluded that the First Note, Second Note and Third Note had fair values of $14.0 million, $6.4 million, and $3.9 million, respectively at date of issuance. These fair value amounts were determined by

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

discounting the expected payments on the notes to present value based on an estimated market rate of 10.75%. The timing and amount of expected payments were determined by 1) the note repayment terms, 2) mandatory prepayments as a result of future financings, and 3) lender prepayment rights in the event a trigger event occurs. Mandatory prepayments were developed based upon management s expectations regarding future financing activities. Trigger event likelihoods were determined based upon a Monte Carlo model using an expected annual volatility of 53%. The fair values are the amounts recognized for these notes as part of recording the business combination. We recorded the notes at their fair values at the acquisition date and are accreting the debt discount over the three-year periods of the notes as interest expense. Accretion of the debt discount for fiscal 2007 and 2006 was $414,000 and $85,000, respectively.

We also evaluated the three promissory notes for features that may be considered to be embedded derivatives under Statement of Financial Accounting Standards No. 133, Accounting for Derivative Instruments and Hedging Activities (FAS 133). We concluded that the embedded derivatives shall not be bifurcated from the host contracts and accounted for separately as derivative instruments because they fail the test of not being clearly and closely related. Our assessment is based on the fact that the notes were not issued at a substantial discount to the face value, which is the first test for bifurcation from the host debt instrument.

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 amount of capital equipment financed and subject to lien at September 30, 2007 and 2006 under the GE Capital finance agreement is approximately $288,000 and $637,000, respectively. The loans are for a term of 42 months at annual interest rates ranging from 9.5% to 10.4% per year with fixed monthly payments.

Aggregate annual maturities of notes payable as of September 30, 2007, are as follows:

Year Ending September 30,	Minimum Payments
2008	$ 1,040,250
2009	12,582,533
Total	13,622,783
Less amount representing interest	(1,365,413)
Present value of payments	12,257,370
Less unamortized discount	(232,778)
Less current portion	(254,676)
Long-term portion of obligation	$ 11,769,916

14. Shareholders Equity (Deficit)

The share and per share amounts and share prices have been adjusted for a one-for-four reverse stock split.

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, 2007 and 2006. 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).

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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 15% or more of the outstanding common stock. The Rights will expire on March 25, 2009.

Common stock

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 13 Notes Payable . As of December 14, 2007, 5.6 million shares remained available for sale under this facility. Sales are made under our effective shelf registration statement.

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.

Fiscal 2006. In October 2005, we issued and sold to certain institutional investors 1,523,585 shares of our common stock at a price of $10.60 per share, for aggregate net offering proceeds of approximately $16.2 million. In December 2005, we issued and sold to certain institutional investors 1,492,538 shares of our common stock at $13.40 per share, for aggregate offering proceeds of approximately $20.0 million and net offering proceeds of approximately $19.4 million, after deducting commissions and offering fees and expenses. These offerings were made pursuant to our shelf registration statement on Form S-3, filed with the SEC in June 2005.

In September 2006, our CEO exercised his option to pay for minimum required withholding taxes associated with certain vested shares of his restricted stock award by surrendering 29,775 shares of common stock at the market price of $6.73.

Also during fiscal 2006, we issued an aggregate of 1,352,382 shares of common stock in connection with the exercises of stock purchase warrants (827,575 shares at a weighted average price of $7.14 per share), employee stock options (524,807 shares at a weighted average price of $6.22 per share) and restricted stock awards (28,000 shares at a price of $0.00) for cash in the aggregate amount of approximately $9.2 million.

Fiscal 2005. In September 2005, we issued to our CEO a restricted stock award to purchase 250,000 shares of common stock at an exercise price of $0.004 per share (Restricted Stock). The Restricted Stock is subject to a right of repurchase by us at the original issue price of $0.004 per share that lapsed as to one-third of the shares in September 2006 and lapses as to an additional one-twelfth of the shares quarterly thereafter. In September 2005, the

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award was exercised to purchase all of the 250,000 shares of Restricted Stock for total cash of $1,000. The fair value of the award totaled $3.6 million based on the 5-day average closing sales price beginning two days before, the day of, and two days after the date of the agreement. The value of the Restricted Stock was recorded as unearned compensation in a separate component of shareholders equity to be amortized as compensation expense ratably over the repurchase period of three years. Pursuant to FAS 123R, unamortized unearned compensation of $3.5 million at October 1, 2005 was eliminated against common stock upon the adoption of FAS 123R. See Note 2, Significant Accounting Policies Share-based Compensation. During fiscal 2006 and 2005, $1.1 million and $78,000, respectively, was charged to compensation expense. As of September 30, 2006 and 2005, 83,335 and 0 shares, respectively, of the Restricted Stock were vested.

In April 2005, we issued and sold 1,942,500 shares of common stock in a registered direct offering at a price of $8.80 per share, for aggregate offering proceeds of approximately $17.1 million and net offering proceeds of approximately $15.9 million, after deducting commissions and offering fees and expenses. The offering was made pursuant to our shelf registration statement on Form S-3, filed with the SEC on April 9, 2004.

In March 2005, we issued 500,000 shares of common stock, with a fair value of $5.3 million, to IriSys, Inc. (IriSys) in connection with the acquisition of additional contractual rights to Zenvia, our late-stage drug candidate for the treatment of multiple central nervous system disorders. We valued these shares at $10.60 per share, based on the 5-day average closing price of our common stock, beginning two days before and ending two days after the close and announcement of the agreement on March 9, 2005. See Note 18, Related Party Transactions, for further discussions.

In December 2004, we issued and sold to an institutional investor, 583,333 shares of common stock at a price of $12.00 per share, for aggregate net offering proceeds of approximately $7 million. The offering was made pursuant to our shelf registration statement on Form S-3, filed with the SEC on April 9, 2004.

Also during fiscal 2005, we issued an aggregate of 239,459 shares of common stock in connection with the exercise of stock purchase warrants (211,486 shares at a weighted average price of $6.12 per share) and employee stock options (27,973 shares at a weighted average price of $4.48 per share) for cash in the aggregate amount of approximately $1.4 million.

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A summary of common stock transactions during fiscal 2007, 2006 and 2005 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, 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	
Fiscal year ended September 30, 2006:				
Private placement of common stock	October 2005	1,523,585	$ 16,150,001	$ 10.60
Private placement of common stock	December 2005	1,492,538	19,400,002	$ 13.00
Restricted stock award	Various	28,000	112	$
Stock options	Various	524,807	3,264,953	$ 6.22
Warrants(3)	Various	827,575	5,908,997	$ 7.14
Total		4,396,505	$ 44,724,065	
Fiscal year ended September 30, 2005:				
Private placement of common stock	December 2004	583,333	$ 6,999,999	$ 12.00
Private placement of common stock	April 2005	1,942,500	17,094,000	$ 8.80
Acquisition of certain contractual rights to Zenvia	March 2005	500,000	5,300,000	$ 10.60
Restricted stock award	September 2005	250,000	1,000	$
Stock options	Various	27,974	125,491	$ 4.49
Warrants(3)	Various	211,486	1,293,339	$ 6.12
Total		3,515,293	$ 30,813,829	

(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.

(3) Includes 4,780 shares issued on a cashless exercise basis at an average exercise price of $4.20 per share.

Warrants

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.

Between January 26, 2006 and February 7, 2006, we received proceeds of $4.7 million from the exercise of warrants to purchase 671,923 shares of common stock in connection with our call for redemption of a group of outstanding warrants. The warrants had been issued in connection with a financing transaction in December 2003 involving the sale of common stock and warrants (the Warrants). The exercise price of the Warrants was $7.00 per share. The Warrants had a five-year term, but included a provision that we could redeem the Warrants for $1.00 each if our stock price traded above twice the warrant exercise price for a certain period of time (the Redemption Right). On January 24, 2006, we sent the Warrant holders notice that the Redemption Right had been triggered

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and that the Warrants would expire, to the extent unexercised, on February 7, 2006. One of the warrants to purchase 25,167 shares of common stock expired unexercised.

Also during fiscal 2006, warrant holders exercised their rights to purchase an aggregate of 155,652 shares of common stock for total cash of $1.2 million. As of September 30, 2007, warrants to purchase 269,305 shares at $8.92 remained outstanding, in addition to the 1,053,000 warrants at $3.30 per share that expired in November 2007.

The following table summarizes all warrant activity for fiscal 2007, 2006 and 2005:

	Shares of Common Stock Purchasable Upon Exercise of Warrants	Weighted Average Exercise Price per Share	Range of Exercise Prices
Outstanding at September 30, 2004	1,333,539	$ 7.32	$ 5.52-$10.88
Exercised	(211,492)	$ 6.12	$ 5.80-$8.76
Outstanding at September 30, 2005	1,122,047	$ 7.56	$ 7.00-$8.92
Exercised	(827,575)	$ 7.14	$ 7.00-$8.92
Expired	(25,167)	$ 7.00	$ 7.00
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	$ 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 2007 and 2006, 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, 2007, we had an aggregate of 3,856,015 shares of our common stock reserved for issuance. Of those shares, 2,933,069 were subject to

outstanding options and other awards and 922,946 shares were available for future grants of share-based awards. We also issued share-based awards outside of the Plans. As of September 30, 2007, options to purchase 45,000 shares of our common stock that were issued outside of the Plans (inducement option grants) are outstanding. None of the share-based awards is classified as a liability as of September 30, 2007.

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 and increased an additional 317,084 shares to 1,090,501 shares effective November 30, 2006. In February 2006, our shareholders eliminated the limitation on the number of shares of common stock that may be

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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, 2007, 204,047 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 to 2,153,474 effective November 30, 2005. 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, 2007, 151,817 shares of common stock remained available for issuance under the 2003 Plan. On August 3, 2007, the number of shares of common stock available for issuance under the 2003 Plan increased by 1,857,928 shares to 4,011,402 shares in accordance with the provisions for increases set by the Board of Directors 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, 2007, 482,608 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, 2007, options to purchase 84,474 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 2007, 2006 and 2005 are presented below.

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	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value
Outstanding, September 30, 2004	1,313,398	$ 7.80		
Granted	379,875	$ 12.60		
Exercised	(27,974)	$ 4.48		
Forfeited	(56,641)	$ 14.18		
Expired	(8,624)	$ 13.75		
Outstanding, September 30, 2005	1,600,034	$ 8.76		
Granted	658,312	$ 10.83		
Exercised	(524,807)	$ 6.22		
Forfeited	(146,094)	$ 12.68		
Expired	(375)	$ 10.00		
Outstanding, September 30, 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	6.9	$ 130,000
Vested and expected to vest in the future, September 30, 2007	714,230	$ 8.68	5.8	$ 47,000
Exercisable, September 30, 2007	458,240	$ 9.85	4.0	$
Exercisable, September 30, 2006	765,411	$ 8.98		
Exercisable, September 30, 2005	1,257,896	$ 7.92		

The weighted average grant-date fair values of options granted during fiscal 2007, 2006 and 2005 were $2.12, $6.85 and $11.36 per share, respectively. The total intrinsic value of options exercised during fiscal 2007, 2006 and 2005 was approximately $271,000, $4.6 million and $228,000, respectively, based on the differences in market prices on the dates of exercise and the option exercise prices. As of September 30, 2007, the total unrecognized compensation

cost related to options was $1.7 million, which is expected to be recognized over a weighted-average period of 2.1 years, based on the vesting schedules.

The fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton option pricing model (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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 2007, 2006 and 2005 were as follows:

	2007	2006	2005
Expected volatility	75.0% 113.4%	77.4% 80.4%	76.6% 130.2%
Weighted-average volatility	93.7%	78.4%	95.5%
Average expected term in years	6.0	4.5	3.4
Risk-free interest rate (zero coupon U.S. Treasury Note)	4.3% 4.7%	4.5%	3.8%
Expected dividend yield	0%	0%	0%

The following table summarizes information concerning outstanding and exercisable stock options as of September 30, 2007**:**

	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
$ 1.20-$ 1.29	150,960	9.5	$ 1.28		$
$ 2.30-$ 2.88	154,685	9.1	$ 2.44	13,904	$ 2.88
$ 2.92-$ 6.80	154,429	5.3	$ 5.64	98,492	$ 5.63
$ 6.92-$ 9.92	175,169	5.4	$ 8.12	96,272	$ 8.37
$10.24-$11.76	243,354	5.7	$ 11.40	163,752	$ 11.26
$12.12-$16.60	148,709	7.7	$ 14.14	72,545	$ 13.92
$19.38	13,275	3.8	$ 19.38	13,275	$ 19.38
	1,040,581	6.9	$ 7.69	458,240	$ 9.85

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 2007:

	Number of Shares		Weighted Average Grant Date Fair Value
Unvested, October 1, 2006	51,480	$	15.54
Granted	2,321,043	$	1.74
Vested	(83,900)	$	2.76
Forfeited	(373,635)	$	1.19
Unvested, September 30, 2007	1,914,988	$	2.17

The weighted average grant-date fair value of RSUs granted during fiscal 2007 and 2006 was $1.74 and $15.54 per unit, respectively. There were no RSUs granted in fiscal 2005. The fair value of RSUs vested during fiscal 2007 was $232,000 and no shares vested in fiscal 2006. No RSUs were granted during fiscal 2005. As of September 30, 2007, 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 2.5 years, based on the vesting schedules.

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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, 2007 and 2006 and changes during fiscal 2007 are presented below.

	Number of Shares		Weighted Average Grant Date Fair Value
Unvested, October 1, 2006	223,915	$	13.48
Granted	15,000	$	7.34
Vested	(58,749)	$	12.68
Forfeited	(157,666)	$	13.42
Unvested, September 30, 2007	22,500	$	11.87

The weighted average grant-date fair value of restricted stock awards granted in fiscal 2007 and 2006 was $7.34 and $11.34, respectively. The fair value of restricted stock awards vested in fiscal 2007 and 2006 was $745,000 and $1.2 million, respectively. No restricted stock awards vested in fiscal 2005. As of September 30, 2007, the total unrecognized compensation cost related to unvested shares was $164,000, which is expected to be recognized over a weighted-average period of 0.5 years.

During fiscal 2007, 2006 and 2005, we received a total of approximately $295,000, $3.3 million and $126,000, respectively, 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, 2006 and 2005.

Review of Stock Options Practices and Related Accounting. On July 28, 2006, the Public Company Accounting Oversight Board (PCAOB) issued Staff Audit Practice Alert No. 1 entitled, *Matters Relating to Timing and Accounting for Options Grants.* Prompted by the PCAOB release, the Company and the independent audit committee of the Board of Directors authorized a review of the Company s historical stock option practices. The review was conducted with the assistance of an outside law firm and an outside consulting firm.

As a result of this review one exception was found in which the measurement date for 50,000 fully vested common stock options was determined to be later than the day that the Compensation Committee had initially met to approve the awards. Based on this, the Company should have recorded a non-cash charge of $302,500 and a corresponding increase in common stock in the first quarter of fiscal year 2000. The Company has concluded that this adjustment is not material to the Company s consolidated financial statements in any interim or annual period presented in this or any previously filed Form 10-K. Therefore, the charge was recognized in the quarter ended September 30, 2006.

Based upon this review, management and the independent audit committee of the Board of Directors were satisfied that no evidence was found that indicated that the Company otherwise intentionally manipulated stock option grant dates or was remiss in communicating grants to optionees in a timely manner. Further, the Company s documentation and practices followed the intent of the Board of Directors in granting such options and that the methods of approval and the Company s practices did not provide for management discretion in selecting or manipulating the option grant dates.

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15. Research and Licensing 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 IEED/PBA and diabetic peripheral neuropathic pain (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 IEED/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 new drug application (NDA) and a similar amount for each approved NDA. In addition, we are obligated to pay CNS a royalty ranging from approximately 5% to 7% of net revenues.

Eurand, Inc. In August 2006, we entered into a development and license agreement (Eurand Agreement) with Eurand, Inc. (Eurand), under which Eurand will provide research and development services (R&D) using Eurand s certain proprietary technology to develop a once-a-day controlled release capsule, a new formulation, of Zenvia for the treatment of IEED/PBA (Controlled-Release Zenvia). Under the terms of the Eurand Agreement, we will pay Eurand for development services on a time and material basis. We will be required to make payments up to $7.6 million contingent upon achievement of certain development milestones and up to $14.0 million contingent upon achievement of certain sales targets. In addition, we will be required to make royalty payments based on sales of Controlled-Release Zenvia. No such payments were made in fiscal 2007. We have recorded $283,000 in fees and services relating to the Eurand Agreement in fiscal 2006.

CIMA Labs Inc. Royalty Agreement. In connection with the Alamo Acquisition, we acquired a development, license and supply agreement with CIMA Labs Inc., which holds intellectual property rights related to certain aspects of the development and production of FazaClo (the FazaClo Supply Agreement). The FazaClo Supply Agreement was assigned to Azur in connection with the sale of FazaClo.

The FazaClo Supply Agreement granted, through our Alamo subsidiary, an exclusive license to us to market, distribute and sell FazaClo. The FazaClo Supply Agreement provided royalty rates of 5% to 6%, based on annual net revenue and minimum annual royalty targets set forth in the agreement. Minimum future annual royalty payments under the agreement were as follows:

Twelve-month period ending September 30:

2006	$ 250,000
2007	$ 300,000

2008 and each year thereafter	$ 400,000

Royalty expense was recognized in cost of product sales when revenue from FazaClo shipments was recognized. As of September 30, 2007, $665,000 in royalty costs were paid and are classified under loss from discontinued operations. As of September 30, 2006, $106,000 in royalty costs were paid but not recognized as expense and are included in current assets of discontinued operations in the accompanying consolidated balance sheet.

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16. License and Research Collaboration Agreements

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. Included in other income in fiscal 2007 is a one-time termination fee in the amount of $1,250,000.

Under the terms of the agreement, we were eligible to receive royalty payments, assuming the licensed product was successfully developed by AstraZeneca and approved for marketing by the FDA. We were also eligible to receive up to $330 million in milestone payments contingent upon AstraZeneca s performance and achievement of certain development and regulatory milestones, which could take several years of further development, including achievement of certain sales targets, if a licensed compound was approved for marketing by the FDA. Pursuant to the agreement with AstraZeneca, we could also perform certain research activities directed and funded by AstraZeneca.

Under this agreement, we received a license fee of $10 million in July 2005 that we recognized as revenue upon delivery of certain physical quantities of compounds, the designs of the compounds and structure-activity relationships, the conceptual framework and mechanism of action, and the rights to the patents or patents pending for such compounds. In determining whether the license had standalone value from the research activities, which was one of the necessary conditions for allocating revenue under a multiple deliverable arrangement, we concluded that AstraZeneca had the ability to continue development of the licensed compounds without our expertise and knowledge. AstraZeneca controls all aspects of development of the lead compound and other compounds that were provided by us under the agreement, and was solely responsible for ongoing development costs and efforts. We were not obligated to, and do not, take part in the ongoing development of any of the compounds, nor was our expertise and knowledge necessary for AstraZeneca s continued development.

Also under the agreement, AstraZeneca was paying us for certain research services of between $2.5 million and $4.0 million a year for a period of up to three years. Such research services that we provided to AstraZeneca were for specific projects and research activities assigned and directed by AstraZeneca that were primarily in connection with discovery of a screening assay, which was a unique method of testing or screening for additional compounds that could be used for the same therapeutic target. Such additional research and testing activities performed by us were not necessary for the successful development of the licensed compounds. Further, a reduction in, or termination of, the research services under the agreement did not affect other rights and obligations under the agreement, including the license grant to AstraZeneca, our right to keep the license fees already received from AstraZeneca, and the milestone and royalty payments that we would have been entitled to receive if the licensed compounds were successfully developed and commercialized by AstraZeneca. The rate being billed by us for the services represented fair value for such services, and was consistent with average rates charged by contract research organizations and other similar service providers in the biopharmaceutical industry.

In accordance with EITF 00-21, we determined that the license fee and research and development services were separate units of accounting, because the license had value to AstraZeneca on a standalone basis, there was objective and reliable evidence of the fair value of the undelivered research collaboration services and there was no right of return or refund relative to the license. We determined that the license fee had a standalone value because similar technology was sold separately by other vendors and AstraZeneca had the ability to sell or transfer the license.

Revenue from research and development services was recognized during the period in which the services were performed and was based upon the number of FTE personnel working on the project at the agreed-upon rates. Payments related to substantive, performance-based milestones were recognized as revenue upon the achievement of the milestones as specified in the agreement.

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As of September 30, 2005, we had delivered the license and therefore, we recognized the $10.0 million up-front payment as revenue in fiscal 2005. In fiscal 2006, we recognized $5.0 million revenue upon achievement of the first milestone. In addition, we have recorded research and development services and direct cost reimbursement revenues of approximately $1.2 million, $5.8 million and $825,000 in fiscal 2007, 2006 and 2005, respectively.

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 May 2005, under the terms of this agreement, we received a data transfer fee of $2.5 million that we recognized as revenue upon the transfer and delivery of certain physical quantities of compounds that regulate MIF, the designs of the compounds and structure-activity relationships, the conceptual framework and mechanism of action, and the rights to the patents or patents pending for such compounds. In determining whether the license had standalone value from the research activities, we concluded that Novartis had the ability to continue development of the licensed compounds without our expertise and knowledge. Novartis controlled all aspects of development of the licensed compounds that were provided by us under the agreement, and was solely responsible for ongoing development costs and efforts. We were not obligated to, and do not, take part in the ongoing development of any of the compounds, nor was our expertise and knowledge necessary for Novartis continued development.

Also under the agreement, Novartis was paying us for certain research services of between $1.5 million and $2.5 million a year for two years from the date of the agreement. Such research services that we provided to Novartis were for specific projects and research activities assigned and directed by Novartis. Such additional research and testing activities performed by us were not necessary for the successful development of the licensed compounds. Further, a reduction in, or termination of, the research services under the agreement did not affect other rights and obligations under the agreement, including the license grant to Novartis, our right to keep the data transfer fee already received from Novartis, and the milestone and royalty payments that we were entitled to receive if one or more of the licensed compounds were successfully developed and commercialized by Novartis. The rate being billed by us for the services represents fair value for such services, and was consistent with average rates charged by contract research organizations and other similar service providers in the biopharmaceutical industry.

In accordance with EITF 00-21, we determined that the license fee and research and development services were separate units of accounting, because the license had value to Novartis on a standalone basis, there was objective and reliable evidence of the fair value of the undelivered research collaboration services and there was no right of return or refund relative to the license. We determined that the license fee had a standalone value because similar technology was sold separately by other vendors and Novartis had the ability to sell or transfer the license. Revenue from research and development services was recognized during the period in which the services were performed and was based upon the number of FTE personnel working on the project at the agreed-upon rates. Payments related to substantive, performance-based milestones were recognized as revenue upon the achievement of the milestones as specified in the agreement.

As of September 30, 2005, we had delivered the license and therefore, we recognized the $2.5 million up-front payment as revenue in fiscal 2005. In addition, we have recorded research and development services revenue of approximately $1.2 million, $2.0 million and $682,000 in fiscal 2007, 2006 and 2005, respectively.

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

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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 a payment of approximately $1.5 million in August 2007 due the European regulatory approval and clearance to sell. No revenue was generated from this license agreement in 2006.

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 $227,000 and approximately $121,000 of deferred revenue in fiscal 2007 and 2006, respectively.

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.

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 North America. 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 11, Deferred Revenues.)

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 revenue was recognized in relation to this agreement in 2006 or 2005.

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,

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Cyprus, Turkey and Romania. This agreement will continue until the latest of the 12th anniversary of the first commercial sale in each of those respective countries, or the date that the patent expires, or the last date of the expiration of any period of data exclusivity in those countries. Gerolymatos is also responsible for regulatory submissions to obtain marketing approval of the product in the licensed territories. In September 2006, we recognized approximately $18,000 for the sale of docosanol. In January 2005, we received a milestone payment of $100,000. No revenues were recognized from this agreement in fiscal 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 $115,000 and $100,000 were recorded in September 2007 and May 2005, respectively. No royalties were recognized from this agreement in fiscal 2006.

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, 2007 and 2006 was approximately $1.1 million and $2.0 million, respectively.

17. Income Taxes

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

	2007	2006	2005
Current:			
State and foreign	$ (3,200)	$ (2,430)	$ (1,813)
Deferred:			
Federal	7,011,828	20,625,828	10,143,270
State and foreign	714,424	(540,800)	5,017,269

	7,726,252	20,085,028	15,160,539
Increase in deferred income tax asset valuation allowance	(7,726,252)	(20,085,028)	(15,160,539)
Total income tax provision	$ (3,200)	$ (2,430)	$ (1,813)

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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, 2007	2006
Net operating loss carryforwards	$ 75,965,310	$ 64,594,100
Deferred revenue	6,118,100	9,274,407
Research credit carryforwards	10,295,636	9,682,998
Capitalized research and development costs	1,379,468	1,800,079
Capitalized license fees and patents	3,724,831	4,037,033
Share-based compensation and options	1,946,490	1,136,117
Purchased intangible assets		450,751
Foreign tax credits	595,912	595,912
Other	1,387,534	2,036,885
Deferred income tax assets	101,413,281	93,608,282
Deferred tax liabilities:		
Other	(78,748)	
Deferred tax liabilities	(78,748)	
Less valuation allowance for net deferred income tax assets	(101,334,533)	(93,608,282)
Net deferred tax assets / (liabilities)	$	$

We have provided a full valuation allowance against the net deferred income tax assets recorded as of September 30, 2007 and 2006 as we concluded that they are unlikely to be realized. As of September 30, 2007 we had federal and state net operating loss carryforwards of $200,400,000 and $127,000,000, respectively. As of September 30, 2007 we had federal and California research and development credits of $6,600,000 and $5,600,000, respectively. The net operating loss and research credit carryforwards 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:

	2007	2006	2005

Federal statutory rate	(34)%	(34)%	(34)%
Increase in deferred income tax asset valuation allowance	36	32	50
State income taxes, net of federal effect	(6)	(5)	(6)
Research and development credits	(4)	(2)	(5)
Expired net operating loss and other credits	6	2	
Other	2	7	(5)
Effective income tax rate	0%	0%	0%

18. 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,

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

subject to annual limits. We are not required to make matching contributions under the plan. However, we voluntarily contributed $206,000 in fiscal 2007, $132,000 in fiscal 2006 and $96,000 in fiscal 2005 to the plan.

19. 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 2007, 2006 and 2005 are attributed to the United States. All long-lived assets at September 30, 2007 and 2006 are located in the United States. The evaluation for impairment of goodwill is done as the single operating segment.

Revenues derived from our license agreements with AstraZeneca and Novartis accounted for approximately 5% and 5%, respectively, of our total revenues in fiscal 2007 and 71% and 13%, respectively, of our total revenues in fiscal 2006 and 66% and 19%, respectively, of our total revenues in fiscal 2005. Approximately 11%, 13% and 10% of our total revenues in fiscal 2007, 2006 and 2005, respectively, are derived from our license agreement with GlaxoSmithKline and the sale of rights to royalties under that agreement. Net receivables from AstraZeneca and Novartis accounted for approximately 10% and 19%, respectively, of our net receivables at September 30, 2007 and 26% and 3%, respectively, of our total net receivables at September 30, 2006.

The wholesale value of FazaClo shipments, net of returns, to McKesson Corporation, AmeriSourceBergen Corporation and Cardinal Health were 37%, 20% and 26%, respectively, of our total net shipments totaling $19.2 million in fiscal 2007. Such amounts are disclosed in discontinued operations for fiscal 2007. The wholesale value of FazaClo shipments, net of returns, to McKesson Corporation, AmeriSourceBergen Corporation and Cardinal Health were 53%, 18% and 16%, respectively, of our total net shipments totaling $6.2 million in fiscal 2006. Such amounts are disclosed in discontinued operations for fiscal 2007. (See Note 3 Acquisition of Alamo Pharmaceuticals, Inc. / Sale of FazaClo .)

20. Related Party Transactions

IriSys Research and Development, LLC

License Agreement. On August 1, 2000, we entered into an agreement with IriSys Inc. (formerly IriSys Research and Development, LLC) to sublicense the exclusive worldwide rights to a patented drug formulation, Zenvia, to treat multiple central nervous system disorders (Sublicense Agreement). IriSys held exclusive rights to Zenvia under an Exclusive Patent License Agreement with the Center for Neurologic Study (CNS), dated April 2, 1997 (the License Agreement). Under the Sublicense Agreement, we were obligated to make certain payments upon achieving certain specified milestones, royalties on product sales and a specified percentage of any future royalties that we might have received from potential licensees. We had never made any payments nor were any payments due to IriSys under the Sublicense Agreement.

In March 2005, we entered into an Asset Purchase Agreement, pursuant to which our wholly owned subsidiary, Avanir Holding Company, acquired from IriSys certain additional contractual rights to Zenvia. As a result, through our wholly owned subsidiary we hold the exclusive worldwide marketing rights to Zenvia for certain indications as set forth under the License Agreement and have no further license arrangements with IriSys. We will be obligated to pay CNS milestone payments upon achievement of certain future events relating to the FDA s regulatory approval process for Zenvia and a royalty on commercial sales of Zenvia, if and when the drug is approved by the FDA for commercialization. Under certain circumstances, we may have the obligation to pay CNS a share of net revenues received if we sublicense Zenvia to a third party.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Pursuant to the Asset Purchase Agreement, we paid IriSys a purchase price of $7.2 million including $1.9 million in cash and 500,000 shares of our Class A common stock with a fair value of $5.3 million. The value of the acquired assets was determined based on various financial models for the commercialization of Zenvia for different indications, as well as the projected discounted cash flow and net present value under each such model. The fair value of the common stock issued in the transaction was calculated at $10.60 per share using the 5-day average closing price of our common stock, beginning two days before and ending two days after the close and announcement of the agreement on March 9, 2005. Because of the uncertainty of receiving future economic benefits from the acquired contractual rights, particularly given that Zenvia had not been approved by the FDA for commercialization at the time of this transaction, the purchase price was immediately charged to research and development expense in accordance with United States generally accepted accounting principles.

Dr. Yakatan, our former president and chief executive officer, was a founder and the majority shareholder of IriSys. As required by the Asset Purchase Agreement, Dr. Yakatan resigned as a director of IriSys effective April 9, 2005. In May 2005, Dr. Yakatan resigned as our president and chief executive officer and director. In connection with Dr. Yakatan s resignation, we agreed to pay him severance payments in the aggregate amount of approximately $496,000, which included health benefits for a period of 12 months. We also agreed to pay him a bonus of $88,000 for fiscal 2005 which was paid in full as of September 30, 2005. The severance payment obligations were expensed during fiscal 2005 and were paid in 26 installments over the period of one year from May 16, 2005.

Dr. Yakatan was retained by us as a consultant at an agreed-upon hourly rate until May 15, 2006 to advise us on FDA regulatory matters, if and as needed. Additionally, the vesting of options to purchase 227,580 shares of Class A common stock, held by Dr. Yakatan as of the resignation date, was accelerated to become immediately vested. No compensation charge had been recorded in the fiscal year ended September 30, 2005 for the accelerated vesting, because the acceleration did not result in any of the in-the-money options vesting that otherwise would have expired unvested at the conclusion of the consulting agreement.

21. Subsequent Events

Clinical Master Service Agreement

On November 9, 2007, we entered into a task order (the Task Order) under our Clinical Development Master Service Agreement (the Agreement) with Kendle International Inc. (Kendle). Pursuant to the Task Order, Kendle will provide clinical trial management and related clinical services to us relating to our planned Phase III trial for Zenvia for the treatment of pseudobulbar affect (PBA) (*A Double-Blind, Randomized, Placebo Controlled, Multicenter Study to Assess the Safety and Efficacy and to Determine the Pharmakinetics of Two Doses of AVP-923 (Dextromethorphan/Quinidine) in the Treatment of Pseudobulbar Affect (PBA) in Patients with Amyotrophic Lateral Sclerosis and Multiple Sclerosis*). In addition to the Double-Blind study, we also have a contract with Kendle to perform our Open Label study.

We expect to incur total costs of approximately $7 million over the next three fiscal years in connection with Kendle s performance of its services under the Task Order. The Task Order is effective as of August 13, 2007 and will terminate on August 19, 2009. A good faith payment totaling approximately $700,000 was paid and recorded in fiscal 2007 pursuant to a Letter of Intent that was signed in September 2007. Such amount is included in prepaid expenses in the accompanying consolidated balance sheet at September 30, 2007. Either party may terminate the Agreement or the

Task Order upon material breach or insolvency or on 60 days prior written notice.

Stock Issuance

In October 2007, 4,500 shares were issued pursuant to the vesting of restricted stock units.

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