AVANIR PHARMACEUTICALS
Form 10-K
December 18, 2006

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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, 2006

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. o

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 þ Non-accelerated Filer o

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, 2006 was approximately $271.1 million, based upon the closing price on the American Stock Exchange reported for such date. Shares of common stock held by each officer and director and by each person who is known to own 5% 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.

37,033,190 shares of the registrant s Common Stock were issued and outstanding as of December 5, 2006.

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 2007 annual meeting of shareholders, which will be held on February 1, 2007 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 expec similar expressions as they relate to Avanir are included to identify forward-looking statements. You should not rely on these forward-looking statements, because they are only predictions based on our current expectations and assumptions. 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 as set forth below and under the caption Risk Factors. We disclaim any intent to update any forward-looking statements to reflect subsequent 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.

The Company

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, cardiovascular disorders, inflammatory and infectious diseases.

We currently market FazaClo®, the only orally-disintegrating formulation of clozapine for the management of treatment resistant schizophrenia and reduction in the risk of recurrent suicidal behavior in schizophrenia or schizoaffective disorders. We acquired FazaClo in the acquisition of Alamo Pharmaceuticals, LLC (Alamo) in May 2006. See Note 4, Alamo Acquisition in the Notes to Consolidated Financial Statements for further discussion of the acquisition.

Our lead product candidate, Zenvia™ (formerly referred to as Neurodex™) for the treatment of involuntary emotional expression disorder (IEED), also known as pseudobulbar affect (PBA) or emotional lability, has completed two Phase III clinical trials. On October 30, 2006, we received an approvable letter from the FDA for our NDA submission for Zenvia for the treatment of IEED/PBA. 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 has regarding the efficacy and safety data contained in our NDA submission, which may require additional clinical trials and data in order to obtain marketing approval. The principal questions and/or concerns raised in the approvable letter related to the following: (i) the choice of statistical methods used to analyze a secondary endpoint in the amyotrophic lateral sclerosis (ALS) trial and whether the requirements of the combination drug policy have been met, and (ii) safety concerns relating to Zenvia s active ingredients, dextromethorphan and quinidine sulfate, particularly for the patient population that would be prescribed Zenvia.

Because the approvable letter did not specify the exact data and what additional clinical trials may be required, if any, we have scheduled a meeting with the FDA in the first quarter of 2007 to clarify what would be needed for marketing approval. Until we meet with the FDA, we will not know how extensive any required additional data and/or trials are likely to be. However, we believe that it is likely that the FDA s requirements for additional data may be substantial and that we may be required to undertake additional trials that would be costly and time consuming. Accordingly, we cannot be certain that, once we have met with the FDA, we will continue the development of Zenvia as previously planned.

We are also currently developing Zenvia for the treatment of chronic diabetic neuropathic pain and we are evaluating Zenvia for use for other clinical indications. We are currently engaged in a Phase III clinical trial of Zenvia in patients with painful diabetic neuropathy under a special protocol assessment (SPA). An SPA is an agreement between the FDA and the sponsor of a clinical trial documenting that if the study endpoints are met, the results should be acceptable to support a New Drug Application (NDA). Our future development plans for Zenvia for this indication may be affected by our upcoming meeting with the FDA.

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Our research and drug discovery programs have historically been focused primarily on small molecules that can be taken orally as therapeutic treatments. We have one Phase I development program, which is for the treatment of atherosclerosis and is partnered with AstraZeneca UK Limited (AstraZeneca). In November 2006, we announced that we had ended the development of our other Phase I program, AVP-13358, which was being developed as a potential treatment for lupus. We are currently evaluating strategic options as it relates to AVP-13358. Our pre-clinical research program targeting macrophage migration inhibitory factor (MIF) in the treatment of inflammatory diseases is partnered with Novartis International Pharmaceutical Ltd. (Novartis). We also have developed an anthrax antibody using our proprietary Xenerex™ technology, which is currently being funded by a $2.0 million grant from the National Institute of Allergy and Infectious Diseases at the National Institutes of Health (NIH).

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.

We were incorporated in California in 1988. 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.

Avanir Marketed Products and Product Pipeline

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

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FazaClo Resistant Schizophrenia/Reduction of Suicide

FazaClo is an orally disintegrating form of clozapine that was approved by the FDA in February 2004 and commercially launched in the United States in July 2004. FazaClo is indicated for treatment resistant schizophrenia and reduction in the risk of recurrent suicidal behavior in schizophrenia or schizoaffective disorders. Of the estimated two million Americans who suffer from schizophrenia, approximately 20% are termed treatment-refractory, because they derive little or no benefit from conventional antipsychotic medications. FazaClo is also indicated for reducing the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder who are judged to be at chronic risk for re-experiencing suicidal behavior, based on history and recent clinical state. FazaClo is not generally used as first line treatment because, like all clozapine products, it carries a significant black box warning concerning agranulocytosis, a potentially life threatening and unpredictable adverse event. FazaClo is an innovative dosage form that uses a proprietary technology to produce a tablet that rapidly disintegrates (in about 15 to 30 seconds) and is then swallowed reflexively in saliva. We believe that this orally disintegrating dosage form can be important in treating a disease such as schizophrenia in which rigorous patient compliance is an important component of therapy and any compliance barrier may significantly affect the patient s treatment.

Docosanol 10% Cream Cold Sores

Docosanol 10% cream is a topical treatment for cold sores. In 2000, we received FDA approval for marketing docosonal 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 and Sweden. Docosanol 10% is sold by our marketing partners in the United States, Canada, Korea, Israel, and Sweden. 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 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 wholesale sales of Abreva in North America in excess of $62 million. We estimate that wholesale sales reached $59.7 million in 2006. We also retained the rights to develop and license docosanol 10% cream outside North America for the treatment of cold sores and other indications.

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.

Zenvia Involuntary Emotional Expression Disorder (IEED)/Pseudobulbar Affect (PBA)

IEED/PBA is a complex neurological syndrome that is characterized by a lack of control of emotional expression, typically episodes of involuntary or exaggerated motor expression of emotion such as laughing and/or crying or weeping when the patient does not feel those emotions or in an exaggerated amount. IEED/PBA afflicts patients with neurological disorders such as amyotrophic lateral sclerosis (ALS), Alzheimer s disease (AD), multiple sclerosis (MS stroke, traumatic brain injury and Parkinson s disease. While the exact number 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 IEED/PBA. In addition, we believe that the availability of an FDA-approved treatment option for these patients may lead to the diagnosis of additional patients. If the FDA

approves Zenvia, it would be the first drug approved for the treatment of IEED/PBA. Zenvia is a patented, orally administered combination of two well-characterized compounds, the active ingredient dextromethorphan and the enzyme inhibitor quinidine, which serves to increase the bioavailablity of dextromethorphan in the human body.

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As discussed above, we received an approvable letter from the FDA in October 2006 for our NDA submission for Zenvia for the treatment of IEED/PBA. Because the approvable letter did not specify the exact data and what additional clinical trials may be required, if any, for approval of Zenvia, we will not know how extensive any required additional data and/or trials are likely to be until our planned meeting with the FDA in the first quarter of 2007. However, we believe that it is likely that the FDA s requirements for additional data may be substantial and that we may be required to undertake additional trials that would be costly and time consuming. Accordingly, we cannot be certain that, once we have met with the FDA, we will continue the development of Zenvia as previously planned.

We have been engaged in an open-label safety study for the treatment of IEED/PBA in a broad pool of patients who experience the symptoms of IEED/PBA associated with their underlying neurodegenerative disease or condition. We have ceased enrolling new patients in this study and, depending on the outcome of our meeting with the FDA, we may or may not continue with the open-label safety study.

The NDA for Zenvia contains data from two controlled, multicenter Phase III clinical trials one conducted in ALS patients and the other in MS patients. The NDA also includes data from an ongoing open-label clinical study evaluating the safety of long-term exposure to Zenvia in patients with IEED/PBA associated with a variety of neurological disorders. We believe that we have achieved positive results in both the primary and secondary efficacy endpoints of two pivotal Phase III clinical trials evaluating Zenvia in the treatment of IEED/PBA.

In a Phase III clinical study of Zenvia for the treatment of IEED/PBA in patients who have MS, completed in June 2004, 150 patients at 22 clinical sites were given either placebo or Zenvia twice a day for 85 days. A scale that helps describe how much these recurring episodes of inappropriate laughing or crying impacts their lives that is called The Center for Neurological Study Lability Scale, or CNS-LS Scale), was used to measure the effectiveness of Zenvia. Of those taking the drug, 84% reported improvement in the condition based on the CNS-LS Score, compared to 49% of those on placebo. The majority of reported side effects were mild or moderate. Of the side effects reported in 5% or more of the study participants, only dizziness was seen significantly more for Zenvia-treated patients than for placebo-treated patients.

The first Phase III clinical study of Zenvia for the treatment of IEED/PBA conducted in ALS patients was completed in June 2002 (*Neurology,* 2004; 63:1364-1370). This clinical trial had three treatment arms and compared Zenvia to each of its two individual components, dextromethorphan and quinidine. Results from the Phase III trial with ALS patients demonstrated a favorable clinical effect for the primary endpoint of the study.

In August 2006, we entered into a development and license 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.

Zenvia Painful Diabetic Neuropathy Indication

Painful diabetic neuropathy, which arises from nerve injury, can result in a chronic and debilitating form of pain that has historically been poorly diagnosed and treated. Conditions that can cause neuropathic pain include trauma (e.g. car accidents), cancer, viral infection (e.g. herpes zoster) and metabolic disease (e.g. diabetic neuropathy). According to the American Diabetes Association at least half of the 15.7 million Americans who have diabetes are estimated to suffer from nerve damage caused by the disease. The damaged nerves can alter the sensitivity of pain centers in the spinal cord and consequently intensify pain transmission within the central nervous system. Painful diabetic neuropathy currently is most commonly treated with tricyclic antidepressants, anticonvulsants, opioid analgesics and local anesthetics. Most of these treatments have limited effectiveness or undesirable side effects. It is estimated that the potential market size for drugs that treat painful diabetic neuropathy is at least $1 billion.

As of November 2006, we have enrolled the necessary number of patients needed to assess the efficacy endpoint in our ongoing Zenvia Phase III painful diabetic neuropathy trial. The protocol for the Phase III study was reviewed by the FDA through the SPA process. Assuming positive outcomes, we currently expect to use the data from this study as one of the pivotal Phase III clinical trials required before we would be able to submit an NDA for

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this indication. In the statistical plan, a total of 364 patients would be required to obtain 90% power with a 30% allowance for drop out. We have determined that it is unnecessary to enroll additional patients and now consider the trial fully enrolled with approximately 380 patients. The data from the trial is currently anticipated in mid-2007.

Reverse Cholesterol Transport Technology Atherosclerosis

In July 2005, we entered into an exclusive license and research collaboration agreement with AstraZeneca regarding the license of certain compounds we discovered for the potential treatment of cardiovascular disease. Under the terms of the agreement, we will be eligible to receive royalty payments, assuming the licensed product is successfully developed by AstraZeneca and approved for marketing by the FDA. We are 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 is approved for marketing by the FDA. Pursuant to the agreement with AstraZeneca, we will also perform certain research activities directed and funded by AstraZeneca. For more information regarding this license agreement, see Note 13, License and Research Collaboration Agreements in the Notes to Consolidated Financial Statements.

Macrophage Migration Inhibitory Factor (MIF) Inflammation

In April 2005, we entered into an exclusive license and research collaboration agreement with Novartis regarding the license of certain compounds that regulate macrophage migration inhibitory factor (MIF) in the treatment of various inflammatory diseases. Under the terms of the agreement, we will be eligible to receive royalty payments, assuming the licensed product is successfully developed by Novartis and approved for marketing by the FDA. We are also eligible to receive up to $198 million in milestone payments contingent upon Novartis performance and achievement of certain development and regulatory milestones, including approval for certain additional indications, and regulatory milestones, which could take several years of further development by Novartis, including achievement of certain sales targets, if a licensed compound is approved for marketing by the FDA. Pursuant to the agreement with Novartis, we will also perform certain research activities directed and funded by Novartis. For more information regarding this license agreement, see Note 13, License and Research Collaboration Agreements in the Notes to Consolidated Financial Statements.

Xenerex 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 to prevent and treat anthrax and other infectious diseases. The 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 National Institute of Allergy and Infectious Diseases at the National Institutes of Health (NIH). 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. Under the terms of the grant, the NIH will reimburse us for up to $2.0 million in certain expenses related to the establishment of a cGMP manufacturing process and the testing of efficacy 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 United States 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 a very 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.

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AVP-13358 Selective Cytokine Inhibitor

In November 2006, in an effort to reduce operating expenses we decided to place on hold activities associated with the selective cytokine inhibitor clinical development program. AVP-13358 is a novel, orally active drug molecule discovered by our scientists that has anti-inflammatory and other pharmacological properties that could be useful against certain disease targets. Experiments in animals have shown that it inhibits or prevents the production of one such target, immunoglobulin epsilon (IgE), a pro-inflammatory mediator, and certain cytokines associated with chronic inflammatory diseases. For example, the compound suppresses markers of disease in mouse models of asthma and Systemic Lupus Erythematosus (SLE), which could indicate that the compound has the potential to be effective in those diseases. We completed a multi-rising dose Phase Ib safety trial of AVP-13358 in November 2005, We have evaluated several therapeutic indications for this program and may elect to continue with its development in the future.

Competition

The pharmaceutical industry is characterized by rapidly evolving technology and intense competition. Many 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 and larger research and development and clinical and regulatory affairs staffs. 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.

FazaClo. The primary competition for FazaClo is:

Clozaril (Novartis)

Generic Clozapine (several manufacturers)

In addition, the broader potential market for FazaClo competes against so-called atypical antipsychotics, also known informally as second-generation antipsychotics. These include the following:

Abilify (aripiprazole, BMS)

Geodon (ziprasidone, Pfizer)

Risperdal (risperidone, Janssen)

Seroquel (quetiapine, AstraZeneca)

Zyprexa (olanszapine, Lilly)

Docosanol 10% cream. Abreva faces intense competition in North America from the following established products:

Over-the-counter monograph 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.

Zenvia for Involuntary Emotional Expression Disorder/Pseudobulbar Affect. Although we anticipate that Zenvia could be the first product to be marketed for the treatment of IEED/PBA, assuming we continue development and the FDA approves the drug, we are aware that physicians may utilize other products in an

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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 antipsychotics 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:

Cymbalta®;

Narcotic products; and

Off-label uses of non-narcotic products, such as the anticonvulsants phenytoin and carbamazepine, and the antidepressant amitriptyline.

Reverse Cholesterol Transport. Our reverse cholesterol transport program competes with a significant number of other compounds and approaches under development by other biotechnology and pharmaceutical companies. These companies include, but are not limited to, Merck & Co., Novartis Pharma AG and Bristol-Myers Squibb Company.

MIF Inhibitor Technology. The therapeutic area of inflammation represents a large market and many of the major pharmaceutical and biotechnology companies have research and development programs in this area. There are both direct and indirect competitors. Direct competitors include those with programs based on MIF as the molecular target. Indirect competitors are those developing agents based on other molecular targets relevant to the inflammation cascade and include Merck, Pfizer, GlaxoSmithKline, Amgen Inc. and Wyeth.

Antibody generation technology. Several companies, including Human Genome Sciences, Inc., Medarex Inc. and Abgenix, Inc., have research programs focused on developing anthrax antibodies.

AVP-13358 (selective cytokine inhibitor). If we continue the development of our AVP-13358 program, it would compete with several research approaches and numerous compounds under development by large pharmaceutical and biotechnology companies. One such example for asthma is the anti-IgE therapy using rhuMAB-E25 (Xolair®), a recombinant humanized monoclonal antibody developed in a collaboration between Genentech, Tanox and Novartis. The injectable antibody Xolair was approved for marketing by the FDA in 2003. The development of agents for lupus is less competitive but still includes large pharma companies such as Bristol-Myers Squibb Company and biotechnology companies such as Genentech Inc. and Medimmune Inc.

Marketing and Customers

We market and sell FazaClo only in the United States. We currently promote FazaClo to physicians, hospitals, pharmacies and wholesalers through our own sales force. FazaClo is typically distributed to pharmacies and hospitals through wholesalers. If we seek to commercialize FazaClo outside of the United States, we expect that we would do so through a marketing partner or license.

Manufacturing

We currently have no manufacturing or production facilities and, accordingly, rely on third parties for commercial and clinical production of our products and product candidates. FazaClo is manufactured by a single supplier, CIMA Labs, Inc., and 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 FazaClo, docosanol 10% cream and Zenvia, are custom and available from only a limited number of sources. We

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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 appraised 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 a discussion of the risks associated with our outsourcing of manufacturing functions.

Patents and Proprietary Rights

Patents. We presently own or have the rights to 144 issued patents (33 U.S. and 111 foreign) and 358 applications pending (37 U.S. and 321 foreign). Patents and patent applications owned by the Company include docosanol-related products and technologies, Xenerex technologies for developing monoclonal antibodies, Zenvia, selective cytokine inhibitor, MIF inhibitor technology and reverse cholesterol transport enhancer.

	Patents and Patent Applications					
	United States			Foreign		
Description:	**Issued**	**Expiration Dates**	**Pending**	**Issued**	**Expiration Dates**	**Pending**
Docosanol-related technologies	10	2008 to 2017	3	73	Various	48
FazaClo	0		2	1	April 2007	
Xenerex antibody technologies	6	2008 to 2015	12	0	Various	1
Selective cytokine inhibitor	8	2019	6	27	Various	130
Zenvia	7	2011 to 2019	1	5		24
MIF inhibitor technology	2		8	2		71
Reverse cholesterol transport enhancer	0		5	3		47
Total	33		37	111		321

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.

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 currently are 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

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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 produced and marketed for human use 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 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 an 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 as a result of recent announcements regarding safety problems with approved drugs. 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 (CDER) 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, 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 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.

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Executive Officers of the Registrant

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

Human Resources

As of December 5, 2006, we employed 150 persons, including 57 engaged in research and development activities, including drug discovery, medicinal chemistry, clinical development, and regulatory affairs, and 93 in selling, general and administrative functions such as sales, marketing, human resources, finance, accounting, purchasing and investor relations. Our staff includes 17 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.

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

Risks Relating to Our Business

The FDA will likely require additional data for the approval of Zenvia. The additional data requirements may necessitate new clinical trials, which are likely to be costly and cause a significant delay in any approval decision for Zenvia. Additionally, there can be no assurance that the FDA will approve Zenvia.

On October 30, 2006, we received an approvable letter from the FDA for our new drug application (NDA) submission for Zenvia for IEED/PBA. The approvable letter outlined concerns that the FDA has regarding certain efficacy and safety data contained in our NDA submission, which may require additional clinical data in order to obtain marketing approval. The FDA expressed concerns about safety in the use of dextromethorphan and quinidine sulfate, the active pharmaceutical ingredients in Zenvia. Quinidine sulfate presents well known cardiac risks for ventricular arrhythmias. The FDA has expressed concerns regarding these potential cardiac risks, as well as CYP2D6 and CYP3A4 inhibition, and dosing, particularly in the PBA/IEED patient population. Additionally, the FDA has expressed concerns regarding side effects associated with dextromethorphan, including respiratory depression, nausea and dizziness, in the PBA/IEED patient population, which may be particularly susceptible to these side effects. We will need to discuss with the FDA what additional safety data and/or labeling restrictions may be required to address these concerns.

The approvable letter did not specify the exact data and what additional clinical trials may be needed, if any, for marketing approval. Until we are able to meet with the FDA, we do not know how extensive any additional data requirements may be and what the resulting delays or costs would be. However, we believe that it is quite possible that the FDA s requirements for additional data may be substantial and that we may be required to undertake additional clinical trials that would 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), any substantial delays in regulatory approval would negatively affect the commercial potential for Zenvia. Depending on the extent of the additional trials required, we may elect to discontinue the development of Zenvia. Any such action could significantly diminish our long-term commercial prospects.

Additionally, even if Zenvia is approved for PBA/IEED, it 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.

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 $217.6 million as of September 30, 2006, and we expect to continue to incur substantial operating losses for the foreseeable future. As of September 30, 2006, we had approximately $23.9 million in cash and cash equivalents and unrestricted investments in securities and we do not expect to generate positive net cash flows from FazaClo sales unless we can significantly reduce marketing expenses and/or increase sales. Although we raised approximately $15 million in a financing completed in the first

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quarter of fiscal 2007, we will need to raise significant amounts of additional capital to finance our ongoing operations. Because we do not yet know the extent of the additional clinical development efforts that may be required by the FDA to allow us to resubmit our NDA for Zenvia, it is difficult to estimate our projected capital needs. If the FDA requires substantial additional clinical data, our capital requirements would be significant and we may have difficulty financing the continued development of Zenvia and/or our other product candidates.

We may seek to raise additional capital at any time and may do so through various financing alternatives, including licensing or sales of our technologies and drug candidates, selling shares of common or preferred stock, or through the issuance of one or more forms of senior or subordinated 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 or drug candidates, as we have with our RCT and MIF technologies, 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.

If we are unable to raise additional capital to fund future operations, then we may be unable to execute our commercialization plans for FazaClo or our development plans for Zenvia and may be required to reduce operations or defer or abandon one or more of our clinical or pre-clinical research programs.

The FDA s safety concerns regarding Zenvia for the treatment of PBA/IEED may extend to other clinical indications that we are pursuing, including diabetic neuropathic pain.

The FDA raised certain safety concerns and questions regarding Zenvia for the treatment of PBA/IEED. We are currently developing Zenvia for the treatment of other clinical indications, including neuropathic pain, for which we have an ongoing Phase III trial. Although the FDA has not stated that the safety concerns and questions raised in PBA/IEED indication would apply to our ongoing trials in neuropathic pain, it is possible that the FDA will raise similar concerns for this proposed indication. If the FDA does raise these concerns, we may be required to undertake additional non-clinical and/or clinical trials before we can submit an NDA for neuropathic pain. These additional trials may be costly and may delay our planned submission of an NDA for this indication.

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

Our success will partially depend on the success of our currently ongoing clinical trials and subsequent clinical trials that have not yet begun. It may take several years to complete the clinical trials of a product, and a failure of one or more of our clinical trials can occur at any stage of testing. We believe that the development of each of our product candidates involves significant risks at each stage of testing. If clinical trial difficulties and failures arise, our product candidates may never be approved for sale or become commercially viable.

There are a number of difficulties and risks associated with clinical trials. For instance, we may discover that a product candidate does not exhibit the expected therapeutic results in humans, may cause harmful side effects or have other unexpected characteristics that may delay or preclude regulatory approval or limit commercial use if approved.

In addition, the possibility exists that:

- the results from early clinical trials may not be statistically significant or predictive of results that will be obtained from expanded, advanced clinical 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.

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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, there are various statistical methods that can be used to analyze clinical trial data. In the FDA s approvable letter for Zenvia, the FDA expressed disagreement with one of the statistical methods we used to analyze certain efficacy data contained in our NDA submission. In addition, although we concluded that the safety data from our definitive QT safety study of quinidine sulfate suggested that cardiac risks were within an acceptable range, the FDA has expressed concern about these potential risks in the PBA/IEED patient population and has asked us to address these concerns.

Although we intend to respond to these concerns, we may not be able to resolve these disagreements favorably, if at all. Disputes that are not resolved favorably could result in one or more of the following:

- delays in our ability to submit an NDA;
- the refusal by the FDA to 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 grow revenues in future periods, which would result in significant harm to our financial position and adversely impact our stock price.

If our clinical trials for our product candidates are delayed, 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. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining an effective investigational new drug application, or IND, or regulatory approval to commence a clinical trial;
- 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 qualified subjects to participate in clinical trials;

competition in recruiting clinical investigators;

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

the need to repeat clinical trials as a result of inconclusive results or poorly executed testing;

the placement of a clinical hold on a study;

the failure of third parties conducting and overseeing the operations of our clinical trials to perform their contractual or regulatory obligations in a timely fashion; and

exposure of clinical trial subjects to unexpected and unacceptable health risks or noncompliance with regulatory requirements, which may result in suspension of the trial.

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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.

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

Our 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. With respect to our product candidates being developed, even if regulatory approval of a product is granted, 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 continual 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 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. Because many of our products contain ingredients that also are marketed in over-the-counter drug products, there is a risk that the FDA or an outside third party at some point would propose that our products be distributed over-the-counter rather than by prescription potentially affecting third-party and government reimbursement for our products.

Later discovery of previously unknown problems with our products, manufacturing processes or failure to comply with regulatory requirements, may result in any of the following:

- restrictions on our products or manufacturing processes;
- warning letters;
- withdrawal of the products from the market;
- voluntary or mandatory recall;
- fines;
- suspension or withdrawal of regulatory approvals;
- suspension or termination of any of our ongoing clinical trials;
- refusal to permit the import or export of our products;
- refusal to approve pending applications or supplements to approved applications that we submit;

product seizure; and

injunctions or the imposition of civil or criminal penalties.

We have only limited sales and marketing experience and capabilities.

Prior to our acquisition of Alamo Pharmaceuticals in May 2006, we had never directly marketed or sold any pharmaceutical products. In order to successfully market FazaClo, we will need to maintain an adequate and skilled sales force and sales and marketing management to effectively oversee this sales force. If FazaClo is not successfully relaunched, its longer-term commercial prospects could be significantly diminished.

We are dependent on a small number of physicians for a substantial percentage of FazaClo sales.

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Currently, one physician practice accounts for approximately 23% of the total patients receiving FazaClo. While we are focusing on broadening the base of prescribing physicians, we are currently dependent on this practice to maintain our historical levels of FazaClo sales. If any of these physicians in this practice curtail or stop writing prescriptions for FazaClo, our FazaClo shipments could be adversely affected.

It is difficult to integrate acquired companies, products, technologies and personnel into our operations and our inability to do so could greatly lessen the value of any such acquisitions.

In May 2006, we acquired Alamo Pharmaceuticals and we may make additional strategic acquisitions of companies, products or technologies in the future to complement our product pipeline or to implement our business strategy. If we are unable to successfully integrate businesses, products, technologies or personnel that we may acquire with our existing operations, we may not receive the intended benefits of such acquisitions. Additionally, disputes may arise following the consummation of acquisitions regarding representations and warranties, indemnities, earn-out rights and other provisions in the acquisition agreements. For these reasons, acquisitions may subject us to unanticipated liabilities or risks, disrupt our operations or divert management s attention from day-to-day operations.

Changes in board and management composition that are intended to strengthen the board and management team could adversely disrupt our operations.

We have recently made significant changes to our senior management team and board of directors to add to our pharmaceutical experience, significantly enhance our scientific and clinical expertise, and provide depth in managing profitable pharmaceutical businesses. For example, our Senior Vice President and Chief Financial Officer, Vice President of Clinical and Medical Affairs, Vice President of Sales and Vice President of Human Resources have all joined the Company in the last fiscal year. We also recently experienced turnover in other management areas. We have also made significant changes to the composition of our board of directors and we continue to recruit senior-level personnel to add to our management team. These changes could be disruptive, and we may experience difficulties in attracting and integrating new members of the management team and in transitioning our operating activities to a commercial focus.

Additionally, the receipt of the Zenvia approvable letter could impact our future personnel needs and require that we further restructure our organization. Any significant disruptions as a result of these changes could negatively impact our operations, including the success of our commercialization of FazaClo and the development of Zenvia.

We may face challenges attracting and retaining members of management and other key personnel, particularly following our receipt of the Zenvia approvable letter.

The industry in which we compete has a high level of employee mobility and aggressive recruiting of skilled personnel. This type of environment creates intense competition for qualified personnel, particularly in product research and development, sales and marketing and accounting and finance. Additionally, we have a relatively small organization and the loss of certain executive officers and other key employees could adversely affect our operations. For example, if we were to lose one or more of the senior members of our sales and marketing team, we could experience potentially significant disruptions in our FazaClo commercialization activities. Additionally, we recently moved our commercial and general and administrative operations from San Diego, California to Aliso Viejo, California. This move and having operations in multiple locations could cause us to lose affected personnel and any such losses could also harm our operations. Lastly, many members of the management team have recently joined after the initial filing of the NDA for Zenvia with the objective of launching Zenvia for IEED/PBA. Given the uncertainty around the commercialization opportunities for Zenvia following receipt of the FDA approvable letter, some of these employees may choose to pursue other opportunities. The loss of any of our key employees could adversely affect our business and cause significant disruption in our operations.

If we fail to obtain regulatory approval in foreign jurisdictions, we would not be able to market our products abroad, and the growth of our revenues, if any, would be limited.

We may seek to have our products 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

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

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

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

Under our license arrangements for our RCT and MIF compounds, we have no direct control over the development of these drug candidates and have only limited, if any, input on the direction of development efforts. These development efforts are ongoing by our licensing partners and if the results of their development efforts are negative or inconclusive, it is possible that our licensing partners could elect to defer or abandon further development of these programs. 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 our 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.

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 FazaClo, Zenvia, docosanol 10% cream and other potential drug candidates that could come from our technologies such as reverse cholesterol transport, selective cytokine inhibitors, 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

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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 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 FazaClo, Zenvia and the active pharmaceutical ingredient (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. Additionally, we have a sole supplier for the manufacture of FazaClo. We do not have any long-term agreements in place with our current docosanol supplier or Zenvia API supplier. Any delays or difficulties in obtaining APIs or in manufacturing, packaging or distributing our products and product candidates could disrupt commercial sales of FazaClo and could also delay Zenvia clinical trials for IEED/PBA and/or painful diabetic neuropathy. 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.

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.

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. Additionally, FazaClo is required by the FDA to carry the most severe type of warning (a black box warning) regarding adverse side effects, including the possibility of death, and other drugs of the same class are currently the subject of large class-action lawsuits relating to adverse effects. If product liability claims were made against us, it is possible that our insurance carriers may deny, or attempt to deny, coverage in certain instances. If a lawsuit against us is successful, then the lack or insufficiency of insurance coverage could affect materially and adversely our business and financial condition. Furthermore, various distributors of pharmaceutical products require minimum product liability insurance

coverage before their purchase or acceptance of products for distribution. Failure to satisfy these insurance requirements could impede our ability to achieve broad distribution of our proposed products and the imposition of higher insurance requirements could impose additional costs on us.

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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, particularly as we attempt to expand the marketing for FazaClo and begin to recognize revenue on sales. Our operating results and prospects may also vary depending on our partnering arrangements for our MIF and RCT technologies. These technologies have been licensed to third parties and the continued progress and pace of development will be dictated by our licensing partners, meaning that the achievement of development milestones is outside of our control.

Finally, our results of operations and stock price may vary due to acquisitions that we may make. Our acquisition of Alamo Pharmaceuticals in the third quarter of fiscal 2006 resulted in charges of approximately $8.4 million. We may acquire other companies or technologies, and if we do so, we will incur potentially significant charges in connection with such acquisitions and may have ongoing charges after the closing of any such transaction. Any such acquisitions could also be disruptive to our operations and may adversely affect our results of operations.

As a result of these factors, 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.

Risks Relating to Our Industry

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. Additionally, FazaClo competes with Clozaril (clozapine), which is marketed by Novartis, as well as other anti-psychotic agents, including several generic anti-psychotic drugs.

Our competitors may have specific expertise and 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.

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Item 1B. ***Unresolved Staff Comments***

None.

Item 2. ***Properties***

As of September 30, 2006, we lease and occupy an aggregate of 65,651 square feet of space used for research and development, commercial and administrative operations in four buildings in the United States. Our headquarters and commercial and administrative offices are located in Aliso Viejo, California, where we currently occupy 11,319 square feet of space, and are expected to grow to approximately 17,000 square feet by the second quarter of 2007. The Aliso Viejo office lease expires in June 2011. We also currently occupy 48,582 square feet of laboratory and office facilities in two buildings located in San Diego, California, and we sublease approximately 9,000 square feet in a third building in San Diego under a three-year term. The terms of the leases for the San Diego facilities vary from August 2008 (representing 27,212 square feet) to January 2013 (representing 30,370 square feet). We may seek to further reduce San Diego facilities depending on the outcome of our upcoming meeting with the FDA regarding Zenvia and depending on the progress of our development programs licensed to AstraZeneca and Novartis. We also are leasing through September 2009 5,750 square feet of office space located in Parsippany, New Jersey. We believe our current facilities in San Diego are in excess of our current needs and are seeking to sublease additional space.

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 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.

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 2006.

PART II

Item 5. ***Market for Registrant s Common Equity and Related Stockholder Matters***

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 2006		Fiscal 2005	
	High	Low	High	Low
First Quarter	$ 14.12	$ 10.00	$ 14.08	$ 11.20
Second Quarter	$ 17.90	$ 13.76	$ 14.92	$ 8.80
Third Quarter	$ 15.13	$ 5.88	$ 12.16	$ 8.92
Fourth Quarter	$ 8.76	$ 5.61	$ 14.76	$ 11.36

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On December 5, 2006, the closing sales price of Class A Common Stock was $2.89 per share.

As of December 5, 2006, we had approximately 28,355 shareholders, including 940 holders of record and an estimated 27,415 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.

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

The selected consolidated financial data set forth below at September 30, 2006 and 2005, and for the fiscal years ended September 30, 2006, 2005 and 2004, 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, 2004, 2003 and 2002, and for the years ended September 30, 2003 and 2002, 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. 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.

Summary Financial Information

	Fiscal Years Ended September 30,				
Statement of operations data:	**2006(1)(4)**	**2005**	**2004**	**2003**	**2002**
Total revenues	$ 15,185,852	$ 16,690,574	$ 3,589,317	$ 2,438,733	$ 8,853,742
Loss before cumulative effect of change in accounting principle	$ (58,936,756)	$ (30,606,564)	$ (28,154,853)	$ (23,236,348)	$ (10,249,512)
Cumulative effect of change in accounting principle	$ (3,616,058)	$	$	$	$
Net loss	$ (62,552,814)	$ (30,606,564)	$ (28,154,853)	$ (23,236,348)	$ (10,249,512)
Net loss attributable to common shareholders	$ (62,552,814)	$ (30,606,564)	$ (28,154,853)	$ (23,264,293)	$ (10,292,798)
Basic and diluted loss per share:					
Loss before cumulative effect of change in accounting principle	$ (1.92)	$ (1.19)	$ (1.44)	$ (1.55)	$ (0.70)
Cumulative effect of change in accounting principle	$ (0.12)	$	$	$	$
Net loss	$ (2.04)	$ (1.19)	$ (1.44)	$ (1.55)	$ (0.70)
Net loss attributable to common shareholders	$ (2.04)	$ (1.19)	$ (1.44)	$ (1.55)	$ (0.71)
Basic and diluted weighted average number of shares of common stock outstanding	30,634,872	25,617,432	19,486,603	14,974,034	14,551,742
Cash dividends declared per share	$	$	$	$	$
Pro forma amounts assuming the new method for patent-related costs was applied retroactively:					

Net loss	$ (58,936,756)	$ (31,255,373)	$ (29,056,101)	$ (23,786,583)	$ (10,724,214)
Net loss attributable to common shareholders	$ (58,936,756)	$ (31,255,373)	$ (29,056,101)	$ (23,814,528)	$ (10,767,500)
Basic and diluted loss per share	$ (1.92)	$ (1.22)	$ (1.49)	$ (1.59)	$ (0.74)

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Balance sheet data:	September 30, 2006	2005	2004	2003	2002
Cash and cash equivalents	$ 4,898,214	$ 8,620,143	$ 13,494,083	$ 12,198,408	$ 8,630,547
Investments in securities	19,851,859	18,917,443	12,412,446	5,258,881	4,538,460
Total cash, cash equivalents and investments in securities	$ 24,750,073	$ 27,537,586	$ 25,906,529	$ 17,457,289	$ 13,169,007
Working capital	$ (6,969,777)	$ 11,969,450	$ 16,653,621	$ 10,619,216	$ 5,918,083
Total assets	$ 71,462,337	$ 41,401,990	$ 37,403,953	$ 29,645,257	$ 20,332,929
Deferred revenues	$ 23,309,325	$ 19,158,210	$ 21,009,115	$ 22,742,641	$ 233,333
Notes payable and capital lease obligations	$ 25,788,310	$ 990,594	$ 1,107,064	$	$
Total liabilities	$ 77,136,872	$ 32,267,111	$ 27,206,694	$ 28,608,026	$ 5,752,259
Convertible preferred stock	$	$	$	$	$ 521,189
Shareholders (deficit) equity	$ (5,674,535)	$ 9,134,879	$ 10,197,259	$ 1,037,231	$ 14,059,481

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
Total revenues	$ 8,144,888	$ 2,469,028	$ 2,363,247	$ 2,208,689
Gross margin(2)	$ 472,921	$ 139,827	$ (1,003)	$ (424,358)
Loss before cumulative effect of change in accounting principle	$ (5,599,912)	$ (13,540,486)	$ (17,619,218)	$ (22,177,140)
Cumulative effect of change in accounting principle	$ (3,616,058)	$	$	$
Net loss(4)	$ (9,215,970)	$ (13,540,486)	$ (17,619,218)	$ (22,177,140)
Basic and diluted net loss per share(4):				
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

Quarterly statement of operations data for fiscal 2005 (Unaudited):	Fiscal Quarters Ended December 31, 2004	March 31, 2005(3)	June 30, 2005	September 30, 2005
Total revenues	$ 888,365	$ 644,733	$ 3,333,838	$ 11,823,638
Gross margin(2)	$ 13,771	$ (4,744)	$ (103,319)	$ (613,811)
Net loss	$ (7,088,589)	$ (14,050,947)	$ (8,207,544)	$ (1,259,484)
Basic and diluted net loss per share	$ (0.30)	$ (0.57)	$ (0.31)	$ (0.05)
	23,962,989	24,565,682	26,841,950	27,089,552

Basic and diluted weighted average number of shares of common stock outstanding				
Pro forma amounts assuming the new method for patent-related costs was applied retroactively:				
Net loss	$ (7,069,980)	$ (14,346,117)	$ (8,296,555)	$ (1,542,721)
Basic and diluted loss per share	$ (0.30)	$ (0.58)	$ (0.31)	$ (0.06)

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(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 4, Alamo Acquisition, in Notes to the Consolidated Financial Statements.

(2) Represents product sales, research and development services revenue and government research grant services, net of related costs and amortization of acquired FazaClo product rights.

(3) Includes a research and development expense of $7,225,000 related to the acquisition of contractual rights to Zenvia.

(4) 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 our company. When used in this report, the words intend, estimate, anticipate, believe, plan, goal, expect and similar expressions as they relate to Avanir are included to identify forward-looking statements. You should not rely on these forward-looking statements, because they are only predictions based on our current expectations and assumptions. 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 as set forth below and under the caption Risk Factors. We disclaim any intent to update any forward-looking statements to reflect subsequent 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.

Overview

Avanir Pharmaceuticals is focused on developing, acquiring and commercializing novel therapeutic products for the treatment of chronic diseases. Our products and product candidates address therapeutic markets that include the central nervous system, cardiovascular disorders, inflammatory and infectious diseases.

The following is a summary of developments in fiscal 2006 and subsequent to the end of fiscal 2006 through the date of this filing:

On October 30, 2006, we received an approvable letter from the FDA for our NDA submission for Zenvia for the treatment of IEED/PBA. 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 has regarding the efficacy and safety data contained in our NDA submission, which may require additional clinical trials and data in order to obtain marketing approval. The principal questions and/or concerns raised in the approvable letter related to the following: (i) the choice of statistical methods used to analyze a secondary endpoint in the ALS trial and whether the requirements of the combination drug policy have been met and (ii) safety concerns relating to Zenvia s active ingredients, dextromethorphan and quinidine sulfate, particularly for the patient population that

would be prescribed Zenvia.

Because the approvable letter did not specify the exact data and what additional clinical trials may be required, if any, we have scheduled a meeting with the FDA in the first quarter of 2007 to clarify what would be needed for marketing approval. Until we meet with the FDA, we will not know how extensive any required additional data and/or trials are likely to be. However, we believe that it is likely that the FDA s requirements for additional data may be substantial and that we may be required to undertake additional

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trials that would be costly and time consuming. Accordingly, we cannot be certain that, once we have met with the FDA, we will continue the development of Zenvia as previously planned.

Following receipt of the approvable letter from the FDA for Zenvia, we took several steps intended to significantly reduce on-going operating expenses. In November 2006, we suspended all commercial initiatives focused on Zenvia for the treatment of IEED and have reduced research and development expenses including placing on hold activities associated with AVP-13358, our program targeting selective cytokine inhibitor.

In May 2006, we acquired Alamo Pharmaceuticals, LLC (Alamo) as a wholly-owned subsidiary. As part of the acquisition, we acquired FazaClo, the only orally-disintegrating formulation of clozapine for the management of treatment resistant schizophrenia and reduction in the risk of recurrent suicidal behavior in schizophrenia or schizoaffective disorders. Because the acquisition occurred in the third quarter of fiscal 2006, the full year impact on operating expenses and interest expense associated with the acquisition will not be reflected until fiscal 2007. See Note 4, Alamo Acquisition, in the Notes to Consolidated Financial Statements for further discussion.

In July 2006, we entered into an exclusive agreement with Healthcare Brands International (HBI) to develop and market our docosanol 10% cream as a treatment for cold sores in the European Union, (with the exception of Denmark, Finland, Greece, Italy, and Sweden, all of which are covered by previous license grants from us) Russia and Ukraine. In connection with the agreement we received an upfront fee of £750,000 (U.S. $1.4 million) in July 2006, plus we will be eligible to receive aggregate payments of up to £1,500,000 (approximately $2.8 million, based on the exchange rate on September 30, 2006) if 10% docosanol cream receives certain regulatory approvals in the licensed territory. Additionally, if there is any subsequent divestiture or sublicense of 10% docosanol cream by HBI (including through a sale of HBI), or any initial public offering of HBI s securities, we will receive a payment calculated based on a percentage of the assigned value of 10% docosanol cream to the overall value of the transaction. HBI will be responsible for all expenses related to the regulatory approval and commercialization of 10% docosanol cream in the territory.

In June 2006, we were notified that we had been awarded a $2.0 million research grant from the National Institutes of Health/National Institute of Allergy and Infectious Disease (NIH) for ongoing research and development related to our fully human monoclonal antibody for the treatment of post-exposure anthrax infection (the 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 in non-human primate animal models.

In May 2006, our Board of Directors authorized a space restructuring plan and the relocation of our commercial and general and administrative operations. We currently occupy three laboratory buildings in San Diego, California. We are in the process of relocating all operations other than research and development to Orange County, California. We have subleased one of the San Diego buildings in September 2006 under a three-year sublease and plan to sublease the other San Diego building after our relocation is complete. Also in May 2006, we entered into a five-year lease for the new Orange County offices, and currently occupy approximately 11,319 square feet of office space, which we expect will increase to 17,000 square feet in the second quarter of 2007. The aggregate minimum payments over the initial term of the lease are expected to be approximately $2.8 million.

On April 3, 2006, The NASDAQ Stock Market approved our application for listing our common stock for trading on the NASDAQ Global Market (formerly the NASDAQ National Market System). On April 11, 2006, our stock began trading on the NASDAQ under the stock symbol AVNR simultaneously with the

discontinuation of trading on the American Stock Exchange. On January 17, 2006, we implemented a one-for-four reverse stock split of our common stock. Authorization to implement the reverse stock split had been previously approved on March 17, 2005 by our shareholders at our annual meeting of shareholders. Our common stock began trading on the American Stock Exchange on a split-adjusted basis on January 18, 2006.

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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 the reverse stock split.

In January 2006, we signed an exclusive license agreement with Kobayashi Pharmaceutical Co., Ltd. (Kobayashi) giving Kobayashi the rights to manufacture and sell docosanol 10% cream as a treatment for cold sores in Japan.

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 rapidly respond to program delays or successes far outweigh the higher costs often associated with outsourcing at this stage of our development. Assuming successful growth of FazaClo sales and if Zenvia is successfully developed or other products are acquired, we expect more of these functions may be brought in-house.

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. Additionally, we may acquire other drugs to leverage the current infrastructure and sales organization being used for the marketing and sales of FazaClo. We are unable to determine if and when we might be able to reach profitability until we know the outcome of future discussions with the FDA regarding Zenvia. Trends in revenues and various types of expenses are discussed further in the Results of Operations.

We will need to raise additional capital and we will need to raise a significant amount of additional capital if we continue to develop Zenvia for IEED/PBA and for painful diabetic neuropathy. We may seek to raise this additional capital at any time through various financing alternatives, including licensing or sales of our technologies and drug candidates, selling shares of common or preferred stock, or through the issuance of one or more forms of senior or subordinated debt. Our future capital needs will also depend substantially on our ability to reach predetermined milestones under our existing collaboration agreements, as well as the economic terms and the timing of any new partnerships or collaborative arrangements with pharmaceutical companies under which we would expect our partners to fund the costs of such activities. If we are unable to raise capital as needed to fund our operations, or if we are unable to reach these milestones or enter into any such collaborative arrangements, then we may need to slow the rate of development of some of our programs or sell the rights to one or more of our drug candidates.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements prepared in accordance with generally accepted accounting principles 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

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completed the acquisition of Alamo Pharmaceuticals LLC. See Note 4 in the Notes to Consolidated Financial Statements, Alamo Acquisition, 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 which 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. Total compensation cost for our share-based payments recognized in fiscal 2006 was $3.1 million, including $2.5 million related to selling, general and administrative expense and $606,000 related to research and development.

The fair value of each option award is estimated on the date of grant using a Black-Scholes-Merton option pricing model (Black-Scholes model) that uses assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, our expected stock price volatility, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends. Expected volatilities are based on historical volatility of our common stock and other factors. The expected terms of options granted are based on analyses of historical employee termination rates and option exercises. The risk-free interest rates are based on the U.S. Treasury yield in effect at the time of the grant. Since we do not expect to pay dividends on our common stock in the foreseeable future, we estimated the dividend yield to be 0%. FAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We estimate pre-vesting forfeitures based on our historical experience.

If factors change and we employ different assumptions in the application of FAS 123R in future periods, the compensation expense that we record under FAS 123R may differ significantly from what we have recorded in the current period. There is a high degree of subjectivity involved when using option pricing models to estimate share-based compensation under FAS 123R. Because changes in the subjective input assumptions can materially affect our estimates of fair values of our share-based compensation, in our opinion, existing valuation models, including the Black-Scholes and lattice binomial models, may not provide reliable measures of the fair values of our share-based compensation. Consequently, there is a risk that our estimates of the fair values of our share-based compensation awards on the grant dates may bear little resemblance to the actual values realized upon the exercise, early termination or forfeiture of those share-based payments in the future. Certain share-based payments, such as employee stock options, may expire worthless or otherwise result in zero intrinsic value as compared to the fair values originally estimated on the grant date and reported in our financial statements. 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

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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.

For purpose of estimating the fair value of stock options granted during fiscal 2006 using the Black-Scholes model, we have made an estimate regarding our stock price volatility (weighted average of 78.4%). If our stock price volatility assumption were increased to 88.7%, the weighted average estimated fair value per share of stock options granted during fiscal 2006 would increase by $0.74, or 11%. The volatility percentage assumed in fiscal 2006 was based on the historical prices of our common stock.

The expected term of options granted is based on our analyses of historical employee terminations and option exercises (weighted average of 4.5 years for fiscal 2006) which, if increased to 5.5 years, would increase the weighted average estimated fair value per share of stock options granted during fiscal 2006 by $0.73 or 11%.

The risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of grant (weighted average of 4.5% for fiscal 2006) which, if increased to 5.4%, would increase the weighted average estimated fair value per share of stock options granted during fiscal 2006 by $0.26, or 4%.

The pre-vesting forfeiture rate is estimated using historical option cancellation information (weighted average of 8.0% for both officers and directors and 13.0% for employees for fiscal 2006) which, if decreased to 3.0% for officers and directors and 8.0% for employees, would increase the share-based compensation expense for fiscal 2006 by $207,000, or 7%. See Note 3, Significant Accounting Policies Change in Accounting Method for Share-Based Compensation, in the Notes to Consolidated Financial Statements for a detailed discussion.

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

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inception of the arrangement and as each product or service is delivered. If a product or service is not separable, the combined deliverables will be accounted for as a single unit of accounting.

When a delivered product or service (or group of delivered products or services) meets the criteria for separation in EITF 00-21, we allocate revenue based upon the relative fair values of each element. We determine the fair value of a separate deliverable using the price we charge other customers when we sell that product or service separately; however if we do not sell the product or service separately, we use third-party evidence of fair value. We consider licensed rights or technology to have standalone value to our customers if we or others have sold such rights or technology separately or our customers can sell such rights or technology separately without the need for our continuing involvement.

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

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

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

Research and Development Services. Revenue from research and development services is recognized during the period in which the services are performed and is based upon the number of full-time-equivalent personnel working on the specific project at the agreed-upon rate. Reimbursements from collaborative partners for agreed upon direct costs including direct materials and outsourced, or subcontracted, pre-clinical studies are classified as revenue in accordance with EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent,* and recognized in the period the reimbursable expenses are incurred. Payments received in advance are recorded as deferred revenue until the research and development services are performed or costs are incurred.

Royalty Revenues. We recognize royalty revenues from licensed products when earned in accordance with the terms of the license agreements. Net sales figures used for calculating royalties include deductions for costs of unsaleable returns, managed care chargebacks, cash discounts, freight and warehousing, and miscellaneous write-offs.

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.

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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. As discussed in Note 4, Alamo Acquisition, in the Notes to Consolidated Financial Statements, we acquired Alamo Pharmaceuticals LLC (Alamo) on May 24, 2006. Alamo has one product, FazaClo (clozapine, USP), that Alamo began shipping 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 to ship 96-pill units and accepted returns of unsold or undispensed 48-pill units.

FazaClo is sold primarily to third-party wholesalers that in turn sell this product to retail pharmacies, hospitals, and other dispensing organizations. Alamo has entered into agreements with its wholesale customers, various states, hospitals, certain other medical institutions and third-party payers throughout the United States. These agreements frequently contain commercial incentives, which may include favorable product pricing and discounts and rebates payable upon dispensing the product to patients. Additionally, these agreements customarily provide the customer with rights to return the product, subject to the terms of each contract. Consistent with 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, some dispensing organizations, such as pharmacies and hospitals, have the right to return expired product at any time.

At the present time, we are unable to reasonably estimate future returns due to the lack of sufficient historical returns data for FazaClo. Accordingly, we currently defer recognition of revenue on shipments of FazaClo until the right of return no longer exists, i.e. when we receive evidence that the products have been dispensed to patients. We determine when products are dispensed to patients from rebate requests that have been submitted to us by various state agencies and others. We are not able to estimate how much has been dispensed until we receive the rebate requests. Rebate requests are generally received in 30 to 90 days from the last day of the quarter in which the product was dispensed to patients. Since the date of the Alamo acquisition (May 24, 2006), we have recorded all rebate requests as a reduction of the assumed liabilities for returns and discounts which was recorded as part of the acquisition, because we believe this method reasonably estimates the matching of the initial shipments to the related rebate. Accordingly, no FazaClo revenue was recognized in fiscal year 2006.

For our FazaClo shipments, we invoice the wholesaler, record deferred revenue at gross invoice sales price less estimated cash discounts and classify the inventory shipped as inventory subject to return. We estimate rebates and other discounts based on our historical experience. Net deferred revenues represent the sum of all FazaClo shipments subsequent to the acquisition, net of estimated rebates, sales returns and chargebacks, for which revenue recognition criteria have not been met. Deferred rebates, sales returns and chargebacks are included in accrued expenses. Sales incentives are also deferred until the related product shipments are recognized as revenue. Sales incentives are classified as deductions from revenue in accordance with EITF Issue No. 01-09, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor s Products).* The cost of product relative to deferred revenue has also been deferred and is included in inventories, categorized as inventories subject to return.

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.

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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 $10.7 million Phase III clinical trial contract as of September 30, 2006. A 3% variance in our estimate of the work completed in our largest contract could increase or decrease our quarterly operating expenses by approximately $320,000.

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 4, Alamo Acquisition 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

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the fourth quarter of each fiscal year. There was no impairment of goodwill for the fiscal year ended September 30, 2006. The Company had no goodwill as of September 30, 2005.

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, 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	Fiscal 2004
Net loss	$ (58,936,756)	$ (31,255,373)	$ (29,056,101)
Basic and diluted loss per share	$ (1.92)	$ (1.22)	$ (1.49)

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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 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 evaluated and adjusted as appropriate on at least a quarterly basis for changes in circumstances. Please refer to Note 5, Relocation of Commercial and General and Administrative Operations in the Notes to Consolidated Financial Statements for further information.

Nature of Operating Expenses

Our operating expenses are 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 trials as those programs advance in their development. Building rent, excluding common area maintenance and other executory costs, amounted to approximately $1.9 million in fiscal 2006 and has scheduled rent increases averaging approximately 4% a year for at least the next three years.

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 sales 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 2006, 2005 and 2004 are attributed to the United States. All long-lived assets for fiscal 2006 and 2005 are located in the United States.

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 include license agreements with AstraZeneca and Novartis, nine docosanol 10% cream license agreements and one Zenvia sublicense. AstraZeneca and Novartis are currently engaged in preclinical and/or clinical development efforts of our

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licensed RCT and MIF programs. To the extent that these development efforts produce negative or inconclusive results, our partners may terminate the development services we are providing, which would negatively affect revenues in future periods and would limit the potential financial returns from these licensing arrangements. Partnering, licensing and research collaborations have been, and will continue to be, an important part of our business development strategy. We may continue to seek partnerships with pharmaceutical companies that can help fund our remaining research programs in exchange for sharing in the rights to commercialize new drugs resulting from this research.

Operating Expenses

Total operating expenses increased by $27.4 million, or 57%, to $75.2 million in fiscal 2006, compared to $47.8 million in fiscal 2005. The 57% increase in operating expenses was due to a $5.1 million or 178% increase in cost of revenues, a $3.1 million or 12% increase in research and development expenses and a $19.3 million or 102% increase in selling, general and administrative expenses. Explanations of operating expenses in both fiscal 2006 and fiscal 2005 are described more fully in the paragraphs that follow.

	Operating Expenses Fiscal Years Ended September 30,		
	2006	**2005**	**2004**
Operating expenses:			
Research and development	39%	55%	67%
Selling, general and administrative	50%	39%	29%
Costs of revenues	11%	6%	4%
Total operating expenses	100%	100%	100%

Research and development (R&D) expenses. R&D expenses increased to $29.2 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 are funded by our partners. The increase in R&D expenses is due to a $1.3 million charge for in-process R&D acquired in connection with the Alamo acquisition, 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 is offset in part by a $3.7 million decrease spending on the MIF and RCT research programs as they are 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.

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The following table sets forth the status of, and costs attributable to, our proprietary research and clinical development programs.

Research and Development Projects and Expenses

	Fiscal Years Ended September 30,			Inception Through September 30,	Estimated Costs to Complete
	2006(1)	2005(1)	2004(1)	2006(1)(2)	Projects(1)(3)
Company-funded Projects:					
Development programs for Zenvia (two), Atherosclerosis, MIF inhibitor, selective cytokine inhibitor and other programs projected through fiscal 2007	$ 27,922,089	$ 26,140,505	$ 21,502,499	$ 116,556,869	Unknown at this time
Partner-funded Projects:					
Atherosclerosis and MIF inhibitor research programs	7,198,397	2,346,043		16,742,837	Funded by Partners
Government-funded Projects:					
Preclinical research on various projects. Estimated timing to complete the current anthrax research project is less than 12 months	292,111	497,210	979,182	2,830,655	$2.0M
Purchased in-process research and development(4)	1,300,000			1,300,000	$0.5M
Total	$ 36,712,597	$ 28,983,758	$ 22,481,681	$ 137,430,361	

(1) Each project includes an allocation of laboratory occupancy costs. M refers to millions. Estimated costs and timing to complete the projects are subject to the availability of funds and FDA requirements. For each of the projects set forth in the table, other than Zenvia for IEED/PBA (which we intend to market ourselves if fully developed), the reverse cholesterol transport and the MIF inhibitor programs (both of which we have partnered), we may seek development partners or licensees to defray part or all of the ongoing development costs.

(2) Inception dates are on or after October 1, 1998, at which time we began identifying and tracking program costs.

(3) We currently cannot estimate the extent of additional spending on Zenvia. We plan to meet with the FDA to discuss the approvable letter and may, at that time, be able to reasonably estimate additional development costs. Further development of the selective cytokine inhibitor is on hold.

(4) See Note 4, Alamo Acquisition in the Notes to Consolidated Financial Statements.

We expect that R&D spending for painful diabetic neuropathy and the selective cytokine inhibitor will decline significantly in fiscal 2007. Any future R&D spending on compounds that regulate MIF and reverse cholesterol

transport enhancing compounds is expected to be fully reimbursed by our collaborative partners. We expect that spending on our antibody to anthrax will depend on government grants.

Status of R&D Programs and Plans Company-funded Projects

Zenvia for the treatment of Involuntary Emotional Expression Disorder/Pseudobulbar Affect. As described above in Item 1, we received an approvable letter in October 2006 from the FDA for our new drug application (NDA) submission for Zenvia for the treatment of IEED/PBA.

Because the approvable letter did not specify the exact data and what additional clinical trials may be required, if any, for approval of Zenvia, we will not know how extensive any required additional data and/or trials are likely to be until our planned meeting with the FDA in the first quarter of 2007. However, we believe that it is likely that the

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FDA s requirements for additional data may be substantial and that we may be required to undertake additional trials that would be costly and time consuming. Accordingly, we cannot be certain that, once we have met with the FDA, we will continue the development of Zenvia as previously planned.

We have been engaged in an open-label safety study for the treatment of IEED/PBA in a broad pool of patients who experience the symptoms of IEED/PBA associated with their underlying neurodegenerative disease or condition. We have ceased enrolling new patients in this trial and, depending on the outcome of our meeting with the FDA, we may or may not continue with the open-label safety study.

Zenvia for the treatment of painful diabetic neuropathy. As of November 2006, we reached the targeted number of patients needed to assess the efficacy endpoint in the ongoing Zenvia Phase III painful diabetic neuropathy trail. The protocol for the Phase III study was reviewed by the FDA through a SPA. Assuming positive outcomes, we currently expect to use the data from this study as one of the pivotal Phase III clinical trials required before we would be able to submit an NDA for this indication. In the statistical plan, a total of 364 patients would be required to obtain 90% power with a 30% allowance for drop out. We have determined that it is unnecessary to enroll additional patients and now consider the trial fully enrolled with approximately 380 patients. The data from the trial is currently anticipated in mid-2007.

Development program for selective cytokine inhibitor. In an effort to reduce operating expenses, we decided to place on hold activities associated with the selective cytokine inhibitor clinical development activities. We completed a multi-rising dose Phase Ib safety trial of AVP-13358 in November 2005. In 2004, we completed the first Phase Ia clinical trial of AVP-13358 in 54 healthy volunteers. The placebo-controlled study was intended to assess safety, tolerability and pharmacokinetics following single rising oral doses. Results of the Phase Ia study suggest AVP-13358 was well tolerated at all single rising doses up through 15 milligrams. The study also demonstrated AVP-13358 was detectable in the bloodstream at all doses administered and remains in circulation long enough to allow potentially once or twice daily dosing.

Status of R&D Programs and Plans Partner-funded Projects

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. Under the terms of the agreement, we will be eligible to receive royalty payments, assuming the licensed product is successfully developed by AstraZeneca and approved for marketing by the FDA. We are 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 is approved for marketing by the FDA. Pursuant to the agreement with AstraZeneca, we will also perform certain research activities directed and funded by AstraZeneca. If the results of this development program turn out to be negative, then it is possible that AstraZeneca could cease funding the program research.

Novartis International Pharmaceutical Ltd. (Novartis). In April 2005, we entered into an exclusive license and research collaboration agreement with Novartis regarding the license of certain compounds that regulate macrophage migration inhibitory factor (MIF) in the treatment of various inflammatory diseases. Under the terms of the agreement, we will be eligible to receive royalty payments, assuming the licensed product is successfully developed by Novartis and approved for marketing by the FDA. We are also eligible to receive up to $198 million in milestone payments contingent upon Novartis performance and achievement of certain development and regulatory milestones, including approval for certain additional indications, and regulatory milestones, which could take several years of further development by Novartis, including achievement of certain sales targets, if a licensed compound is approved for marketing by the FDA. Pursuant to the agreement with Novartis, we will also perform certain research activities

directed and funded by Novartis.

Status of R&D Programs and Plans Government-Funded Projects

Government research grants have helped us fund research programs, including the development of antibodies to anthrax toxins and docosanol-based formulations for the treatment of genital herpes. Subject to certain

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conditions, we, as the awardee organization, retain the principal worldwide patent rights to any invention developed with the United States government support.

Our anthrax antibody was in preclinical development for use as a prophylactic and therapeutic drug to treat anthrax infections and was funded by a two-year $750,000 federal (SBIR) research grant. The grant was completed in the quarter ended March 31, 2006. On June 29, 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. 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.

Much of the work related to anthrax had been funded by government research grants, and our progress in this area will substantially depend on future grants. Because all of our monoclonal antibody research is at a very 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 any antibody or drug.

Our genital herpes project came to a formal end during the third quarter of fiscal 2005 and we do not anticipate that we will perform any further work on that project. We have no grant requests pending nor do we anticipate submitting in the future any grant requests for further research related to genital herpes.

Selling, general and administrative expenses. Our selling, general and administrative expenses increased to $38.1 million in fiscal 2006, compared to $18.8 million in fiscal 2005. These increased expenses primarily relate 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; $5.7 million in expenses from operations of Alamo acquired in May 2006; $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.

Cost of revenues. Cost of revenues increased to $7.9 million in fiscal 2006, compared to $2.8 million in fiscal 2005. The increase is due to $4.9 million increase in cost of research services funded by partners. In addition, cost of revenues in fiscal 2006 included amortization of the acquired FazaClo product rights.

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 $3.1 million, 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 $2.5 million and $606,000, respectively. As of September 30, 2006, $7.2 million of total unrecognized compensation costs related to nonvested awards is expected to be recognized over a weighted average period of 2.7 years. See Note 3, 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 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

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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 Income

Interest income increased to $1.8 million in fiscal 2006, compared to $620,000 in fiscal 2005. The increase is 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.

We expect to continue to operate at a loss at least through fiscal 2007, although the amount of this loss will depend significantly upon the outcome of our planned meeting with the FDA to discuss the future development requirements for Zenvia, as well as the rate of growth in FazaClo sales.

Comparison of Fiscal 2005 and 2004

Revenues

Revenues increased by $13.1 million, or 365%, to $16.7 million in fiscal 2005 from $3.6 million in fiscal 2004. The increase is primarily due to increases in license and research and development service revenues, partially offset by a decrease in product sales. License revenues increased by $12.5 million in fiscal 2005 compared to fiscal 2004 primarily due to license fees from the AstraZeneca and Novartis license agreements. Research and development service revenues in fiscal 2005 were also generated from the AstraZeneca and Novartis license agreements. Sales of docosanol decreased by $770,000, which was mainly due to an unusually large sale of API Docosanol to GlaxoSmithKline in fiscal 2004.

Operating Expenses

Total operating expenses increased to $47.8 million in fiscal 2005, compared to $32.0 million in fiscal 2004. The 49% increase in operating expenses was due to a $1.7 million or 139% increase in cost of revenues, a $4.6 million or 22%

increase in research and development expenses and a $9.5 million or 101% increase in selling, general and administrative expenses. Explanations of operating expenses in both fiscal 2005 and fiscal 2004 are described more fully in the paragraphs that follow

Research and development (R&D) expenses. R&D expenses increased to $26.1 million in fiscal 2005 from $21.5 million in fiscal 2004. R&D spending in fiscal 2005 was related to the open label safety study of Zenvia in the treatment for IEED/PBA, preparation for and initiation of a Phase III clinical trial of Zenvia for the treatment of

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neuropathic pain, and Phase I clinical trials of our leading compound for the selective cytokine inhibitor program. R&D expenses also included pre-clinical research related to the MIF inhibitor, reverse cholesterol transport and antibobody development programs. The increase in R&D expenses is primarily due to $7.2 million in expenses related to the acquisition of additional contractual rights to Zenvia (see Note 19, Related Party Transactions, in Notes to Consolidated Financial Statements), a $1.8 million increase in spending for pre-clinical development of our reverse cholesterol transport program and a $1.5 million increase in spending related to initiation of a Phase III trial of Zenvia for the treatment of neuropathic pain. The increase is partially offset by a $937,000 decrease in spending on our selective cytokine inhibitor program. R&D expenses in fiscal 2004 included the issuance of $2.7 million in common stock in connection with the MIF technology (see Note 3, Summary of Significant Accounting Policies Research and Development Expenses, in the accompanying Notes to Consolidated Financial Statements).

Selling, general and administrative expenses. Our selling, general and administrative expenses increased by $9.5 million, or 101%, to $18.8 million in fiscal 2005 from $9.3 million in fiscal 2004. These increased expenses primarily relate to a $6.4 million increase in expenses related to the continued expansion of our medical education and awareness programs for IEED/PBA, market research, and pre-launch planning activities for Zenvia and hiring of additional sales and marketing personnel; a $1.0 million increase in professional services mainly associated with corporate governance and SEC reporting, internal controls documentation and testing under the Sarbanes-Oxley Act of 2002; a $945,000 increase in expenses related to increases in headcount and salaries in general and administrative areas; a $669,000 aggregate amount of severance expenses, including a $584,000 severance expense related to the resignation of our former CEO; and a $471,000 increase in recruiting and temporary labor expenses.

Cost of Revenues. Cost of revenues increased to $2.8 million in fiscal 2005 from $1.2 million in fiscal 2004. The increase is mainly due to an increase in cost of research services being funded by partners.

Interest Income

Interest income increased by $330,000, or 114%, to $620,000 in fiscal 2005 from $290,000 in fiscal 2004. The increase is primarily due to a 73% increase in average balance of investments in fiscal 2005, compared to fiscal 2004.

Net Loss

Net loss was $30.6 million, or $1.19 per share, in fiscal 2005 compared to a net loss of $28.2 million, or $1.44 per share, in fiscal 2004. A higher weighted average number of shares was outstanding in fiscal 2005, which accounts for the lower loss per share.

Liquidity and Capital Resources

As of September 30, 2006, we had cash, cash equivalents, investments in securities and restricted investments totaling $24.8 million, including cash and cash equivalents of $4.9 million, short- and long-term investments of $19.0 million and restricted investments in securities of approximately $857,000. We had a negative net working capital balance of $7.0 million as of September 30, 2006. As of September 30, 2005, we had cash, cash equivalents, investments in securities and restricted investments totaling $27.5 million, including cash and cash equivalents of $8.6 million, short- and long-term investments of $18.1 million, and restricted investments of approximately $857,000. Our net working capital balance as of September 30, 2005 was $12.0 million. Explanations of net cash provided by or used for operating, investing and financing activities are provided in the table below.

	September 30,	Increase (Decrease)	September 30,

	2006	During Period	2005
Cash, cash equivalents and investment in securities	$ 24,750,073	$ (2,787,513)	$ 27,537,586
Cash and cash equivalents	$ 4,898,214	$ (3,721,929)	$ 8,620,143
Net working capital	$ (6,969,777)	$ (18,939,227)	$ 11,969,450

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	Year Ended September 30, 2006	Change Between Periods	Year Ended September 30, 2005
Net cash used for operating activities	$ (41,009,903)	$ (20,955,692)	$ (20,054,211)
Net cash used for investing activities	(7,380,482)	1,507,743	(8,888,225)
Net cash provided by financing activities	44,668,456	20,599,960	24,068,496
Net increase (decrease) in cash and cash equivalents	$ (3,721,929)	$ 1,152,011	$ (4,873,940)

Operating activities. Net cash used for operating activities amounted to $41.0 million in fiscal 2006, $21.0 million higher than the net cash used for operating activities in fiscal 2005. The increase in cash used for operating activities was due to spending on an open-label study and consulting fees relating to Zenvia[tm] in the treatment of IEED/PBA and a Phase III clinical study for Zenvia in the treatment of painful diabetic neuropathy. The increase in cash used was also due to the continued expansion of our medical education and awareness programs for IEED/PBA, market research, and pre-launch activities for Zenvia, in anticipation of the drug being approved by the FDA.

Net cash used for operating activities was $20.1 million in fiscal 2005, compared to $24.7 million in fiscal 2004. The decrease in cash used for operating activities is mainly due to increases in accounts payable and accrued expenses and other liabilities, partially offset by an increase in net loss and an increase in receivables. Increases in accounts payable and accrued expenses and other liabilities reflect the expansion of our medical education and awareness programs for PBA, market research, and pre-launch activities for Zenvia, assuming the drug is approved by the FDA for marketing, and formulation and pre-formulation work and clinical advisory services related to our potential products. Selling, general and administrative expenses increased by $9.5 million in fiscal 2005, compared to fiscal 2004, of which $4.6 million represented an increase in the fourth quarter of fiscal 2005, resulting in a corresponding increase in accounts payables and accrued expenses. The increase in receivables is mainly due to a $1.0 million increase in receivables from research and development services performed under the collaborative research agreements.

Increase in balance sheet accounts at September 30, 2006 as compared to September 30, 2005 was primarily due to the Alamo acquisition.

Investing activities. Net cash used for investing activities was $7.4 million in fiscal 2006, compared to $8.9 million provided by investing activities in fiscal 2005. Our investments in securities increased by $923,000 in fiscal 2006 and increased by $6.6 million in fiscal 2005, net of proceeds from sales and maturities of investments in securities. We paid $4.8 million in cash as consideration for the Alamo acquisition and acquisition transaction costs, net of cash acquired. We invested $1.7 million in property and equipment in fiscal 2006, compared to $991,000 in fiscal 2005. The increased spending was related primarily to additional computer equipment, and in making improvements in office space utilization to accommodate additional personnel within existing leased space. We expect that capital expenditures for property and equipment will likely remain level, but will depend greatly on if we will need to make accommodations for additional sales and marketing personnel that will be necessary to support commercialization of Zenvia, assuming the drug is approved by the FDA. (See Management s Discussion and Analysis of Financial Condition and Results of Operations, Selling, General and Administrative Expenses.)

Net cash used for investing activities was $8.9 million in fiscal 2005, compared to $9.2 million in fiscal 2004 and $6.7 million in fiscal 2003. Our investments in securities were $6.6 million in fiscal 2005 and $7.2 million in fiscal 2004, net of proceeds from sales and maturities of investments in securities. Capital expenditures related to patent costs were $1.3 million in fiscal 2005, compared to $1.2 million in fiscal 2004. We invested $991,000 in leasehold

improvements and equipment during fiscal 2005, compared to $794,000 during fiscal 2004.

Financing activities. Net cash provided by financing activities was $44.7 million in fiscal 2006, consisting of $35.6 million in net proceeds from sales of our common stock through private placements and $9.2 million from exercises of warrants and stock options to purchase our common stock. Net cash provided by financing activities was $24.1 million in fiscal 2005, consisting primarily of $22.8 million in net proceeds from sales of our Class A common stock through private placements and $1.3 million from exercises of warrants to purchase our Class A common stock. Net cash provided by financing activities amounted to $35.2 million in fiscal 2004, consisting

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primarily of $34.0 million received from the sale of our Class A common stock and from issuance of notes payable totaling $1.1 million.

In October 2005, we sold 1,523,585 shares of Class A common stock under an effective shelf registration statement to certain institutional investors at $10.60 per share for aggregate net offering proceeds of $16.15 million. In December 2005, we sold 1,492,538 shares of our Class A common stock under an effective shelf registration statement to certain institutional investors 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.

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

Subsequent to September 30, 2006, we sold 5,265,000 shares of Class A common stock at a price of $2.85 per share to certain accredited investors. As part of the offering of the common stock, the purchasers also received warrants to purchase a total of 1,053,000 shares under an effective shelf registration statement of Class A common stock at an exercise price of $3.30 per share. The warrants become exercisable six months after the closing and then remain exercisable for a period of six months. The gross proceeds of the offering were approximately $15.0 million, before offering expenses and commissions, and the net offering proceeds were approximately $14.4 million. Pursuant to the terms of certain outstanding promissory notes, we were required to use 20% of the net proceeds from this offering to pay down a portion of our debt obligations.

As of September 30, 2006, we have contractual obligations for long-term debt, capital (finance) lease obligations and operating lease obligations, as summarized in the table that follows. We anticipate being able to satisfy the obligations described below out of cash, cash equivalents and investments in securities held by us as of September 30, 2006 and from proceeds from additional sales of financings under our effective shelf registration statement, which currently has approximately $48.8 million of securities available for offering and sale by us. (See Financing Activities above and Note 23, Subsequent Event, in the accompanying Notes to Consolidated Financial Statements). We do not have any 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 obligations(1)	$ 30,689,599	$ 2,394,674	$ 28,294,925	$	$
Capital (finance) lease obligations	424,571	252,479	172,092		
Operating lease obligations	11,597,443	2,380,226	4,319,167	3,323,843	1,574,207
Purchase obligations	19,759,591	17,991,010	1,768,581		
Total	$ 62,471,204	$ 23,018,389	$ 34,554,765	$ 3,323,843	$ 1,574,207

(1) Includes interest.

Purchase obligations presented above represent contractual commitments entered into for goods and services in the normal of course of our business. The amount includes all known contracts and open purchase orders that exceed $25,000 in the aggregate from any single vendor. The purchase obligations do not include potential severance payment obligations to our executive officers in the event of a not-for-cause termination or change of control under their existing employment contracts. For information regarding these severance and change in control benefits, refer to Executive Compensation.

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As part of the purchase consideration of the Alamo acquisition, we issued three promissory notes in the initial 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%. 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 subsequent to fiscal 2006 and in accordance with the terms of the Notes, we used $2.9 million or 20% of the net proceeds to pay down the First Note. The principal balance of the First Note is $11.5 million as of December 5, 2006.

If the Selling Holders demand repayment of the First Note following satisfaction of the Stock Contingency, we must repay the First Note within 180 days from the demand in our choice of cash or shares of common stock. If we elect to repay the First Note in shares of 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 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.

The following contingent payments are excluded from the contractual obligations presented above:

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 United States from the closing date of the acquisition through December 31, 2018 (the Contingent Payment Period) and are payable to the Selling Holders as follows:

A promissory note that would have been issuable in the principal amount of $4,000,000 if FazaClo sales, as reported by IMS Health Incorporated, for each of the months of April and May 2006 exceeded $1,266,539. Since the closing of the acquisition, we have determined that FazaClo sales for the months April and May 2006 did not satisfy this condition and thus this promissory note was not issued pursuant to this contingency.

If the preceding condition is not satisfied, then (A) a promissory note, in the principal amount of $2,000,000, payable one time if monthly FazaClo net product sales, as reported by us, exceed $1,000,000 for each of the three months in a given fiscal quarter during the Contingent Payment Period, and (B) an additional promissory note in the principal amount of $2,000,000, payable one time if monthly FazaClo net product sales, as reported by us, exceed $1,500,000 for each of the three months in a given fiscal quarter during the Contingent Payment Period. None of these conditions were satisfied as of September 30, 2006.

A one-time cash payment of $10,450,000 if FazaClo net product sales, as reported by us, exceed $40.0 million over four consecutive fiscal quarters during the Contingent Payment Period.

A one-time cash payment of $25,000,000 if FazaClo net product sales, as reported by us, exceed $50.0 million over four consecutive fiscal quarters during the Contingent Payment Period.

We have also agreed to pay the Selling Holders one-half of all net licensing revenues that we received during the Contingent Payment Period from licenses of FazaClo outside of the United States (Non-US Licensing Revenues). Any amounts paid to the Selling Holders on Non-US Licensing Revenues will be recognized in the consolidated statement of operations in the period such amounts are paid.

CIMA Royalty payments. In connection with the Alamo acquisition, we acquired a development, license and supply agreement with CIMA Labs Inc. (CIMA), which holds intellectual property rights related to certain

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aspects of the development and production of FazaClo (the FazaClo Supply Agreement). The FazaClo Supply Agreement grants, through our Alamo subsidiary, an exclusive license to us to market, distribute and sell FazaClo. The FazaClo Supply Agreement provides royalty rates of 5% to 6%, based on annual net sales and minimum annual royalty targets set forth in the agreement. Minimum future annual royalty payments under the agreement are as follows:

Twelve-month period ending December 31:	
2006	$ 250,000
2007	$ 300,000
2008 and each year thereafter	$ 400,000

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 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. We have recorded $283,000 fees relating to the Eurand Agreement in fiscal 2006.

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 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.

In March 2005, we entered into an asset purchase agreement, pursuant to which our wholly owned subsidiary, Avanir Holding Company, acquired from IriSys, LLC certain additional contractual rights to Zenvia for $1,925,000 and 500,000 shares of Class A common stock. The fair 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, or $5,300,000 in aggregate, 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. (See Note 19, Related Party Transactions, in the Notes to Consolidated Financial Statements.) As a result of this transaction, we acquired the exclusive worldwide marketing rights to Zenvia for certain indications as set forth in the aforementioned license agreement with CNS.

Management Outlook

In order to maintain sufficient cash and investments to fund future operations, including sales of FazaClo, and to prepare for the additional clinical work that may be required for the commercialization of Zenvia, we will need to raise additional capital in the near term. We may seek to raise this additional capital at any time and may do so

through various financing alternatives, including licensing or sales of our technologies and drug candidates, selling shares of common or preferred stock, or through the issuance of one or more forms of senior or subordinated debt. The balance of securities available for sale under our existing shelf registration was approximately $48.8 million as of December 5, 2006. We believe that these anticipated offering proceeds plus our cash, cash equivalents and unrestricted investments in securities of approximately $23.9 million at September 30, 2006 as well as anticipated future cash flows generated from licensed technologies and sales from the shipments of FazaClo should be sufficient to sustain our planned level of operations for at least the next 12 months. If we are unable to raise

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sufficient additional capital to fund future operations, we would defer or abandon one or more of our clinical or pre-clinical research programs and may be required to undertake additional cost-cutting measurements.

During fiscal 2007, we expect to earn sufficient revenues from R&D services, under license agreements with AstraZeneca and Novartis, to fully offset the expenses that we incur in connection with providing those services. If either AstraZeneca or Novartis were to reduce or terminate development efforts and funding, then we would expect to reduce or terminate our own research and development spending associated with these programs, although we may incur unreimbursed charges associated with the reduction or termination of these programs. In general, potential milestone payments to be received under existing license agreements are outside of our control and the timing of potential payment cannot be predicted. Revenues from new sources in fiscal 2007, such as license fees and milestone payments, will depend substantially on whether or not we enter into additional license arrangements and whether or not we achieve milestones under existing arrangements. Such arrangements may be in the form of licensing or partnering agreements for Zenvia or for our other product development programs including development of a selective cytokine inhibitor. Many of our product development programs could take years of additional development before they reach the stage of being licensable to other pharmaceutical companies.

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 3, Summary of Significant Accounting Policies Recent Accounting Pronouncements, 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 eleven months as of September 30, 2006 (1.2 years as of September 30, 2005). 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, 2006 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, 2006 and 2005, an increase of one percentage point in the interest rates would have resulted in increases in comprehensive losses of approximately $171,000 and $222,000, respectively.

At September 30, 2006, we had approximately $25.1 million of variable rate debt that was issued as part of the purchase price for the acquisition of Alamo. If the interest of our variable rate debt were to increase or decrease by

1%, interest expense would increase or decrease on annual basis by approximately $251,000 based on the amount of outstanding variable rate debt at September 30, 2006.

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

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

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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

Our chief executive officer and chief financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in the Securities Exchange Act of 1934, Rules 13a-15(e) and 15d-15(e), as of the end of the period covered by this report, have concluded that, based on such evaluation, as of September 30, 2006 our disclosure controls and procedures were effective and designed to provide reasonable assurance that the information required to be disclosed is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms. For the purpose of this review, disclosure controls and procedures means controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that we file or submit is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms. These disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that we file or submit it is accumulated and communicated to management, including our principal executive officer, principal financial officer and principal accounting officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Controls over Financial Reporting

There has been no change in the Company s internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the Company s fourth fiscal quarter ended September 30, 2006, that has materially affected, or is reasonably likely to materially affect the Company s internal control over financial reporting. However, since the acquisition of Alamo in May 2006, we are in the process of integrating Alamo s operations and controls into our internal controls and expect that this process may result in additions or changes to our internal control over financial reporting.

Management s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f).

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on our evaluation under the framework in *Internal Control Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of September 30, 2006.

Based on our assessment using those criteria, we believe that, as of September 30, 2006, our internal control over financial reporting is effective. In making this assessment, management has excluded the operations of Alamo Pharmaceuticals LLC (Alamo), which was acquired on May 24, 2006 and whose financial statements constitute (467) percent and 54 percent of net and total assets, respectively, 0 percent of revenues, and 13 percent of net loss of the consolidated financial statement amounts as of and for the year ended September 30, 2006, as we did not have sufficient time to make an assessment of Alamo s internal controls using the COSO criteria in accordance with Section 404 of the Sarbanes-Oxley Act of 2002. In excluding Alamo from our assessment, we have considered the Frequently Asked Questions as set forth by the Office of the Chief Accountant of the Division of Corporate Finance on June 24, 2004 which acknowledges that it may not be possible to conduct an assessment of an acquired business s internal controls over financial reporting in the period between the consummation date and the date of

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management s assessment and contemplates that such business would be excluded from management s assessment in the year of acquisition.

Our assessment of the effectiveness of our internal control over financial reporting as of September 30, 2006 has been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report, which is set forth below in this Item 9A.

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
Avanir Pharmaceuticals

We have audited management s assessment, included in the accompanying Management s Report on Internal Control Over Financial Reporting, that AVANIR Pharmaceuticals and subsidiaries (the Company) maintained effective internal control over financial reporting as of September 30, 2006 based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. As described in Management s Report on Internal Control over Financial Reporting, management excluded from its assessment the internal control over financial reporting at Alamo Pharmaceuticals, LLC, which was acquired on May 24, 2006 and whose financial statements constitute (467) percent and 54 percent of net and total assets, respectively, 0 percent of revenues, and 13 percent of net loss of the consolidated financial statement amounts as of and for the year ended September 30, 2006. Accordingly, our audit did not include the internal control over financial reporting at Alamo Pharmaceuticals, LLC. The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management s assessment and an opinion on the effectiveness of the Company s internal control over financial reporting based on our audit.

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

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

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management s assessment that the Company maintained effective internal control over financial reporting as of September 30, 2006, is fairly stated, in all material respects, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway

Commission. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of September 30, 2006, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements as of and for the year ended September 30, 2006 of the Company and our report dated December 15, 2006 expressed an unqualified opinion on those financial statements and, included an explanatory paragraph relating to the adoption of Statement of Financial Accounting Standards No. 123(R), *Share-based Payment,* and the change in method of accounting for certain patent-related costs, effective October 1, 2005.

/s/ Deloitte & Touche LLP

San Diego, California
December 15, 2006

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

None.

PART III

Item 10. ***Directors and Executive Officers***

The information relating to our directors that are required by this item is incorporated by reference from the information under the caption Election of Directors contained in our definitive proxy statement (the Proxy Statement), which will be filed with the Securities and Exchange Commission in connection with our 2007 Annual Meeting of Shareholders.

Executive Officers of the Registrant

The names of our executive officers and their ages as of December 5, 2006 are set forth below. The 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.

Name	Age	Position
Eric K. Brandt	44	President and Chief Executive Officer
Keith A. Katkin	35	Senior Vice President, Sales and Marketing
Michael J. Puntoriero	53	Senior Vice President of Finance and Chief Financial Officer
Gregory P. Hanson, CMA	60	Vice President, Chief Accounting Officer and Secretary
Theresa Hope-Reese	49	Vice President, Human Resources
Randall E. Kaye, M.D.	44	Vice President, Clinical and Medical Affairs
Jagadish C. Sircar, Ph.D.	71	Vice President, Drug Discovery

Eric K. Brandt. Mr. Brandt joined AVANIR in September 2005 as President and Chief Executive Officer and as a director. Previously, Mr. Brandt was Executive Vice President, Finance and Technical Operations, Chief Financial Officer of Allergan, Inc. He had increasing influence at Allergan, having previously served in the various roles of Executive Vice President, Finance, Strategy and Corporate Development; Chief Financial Officer; President of the Global Consumer Eye Care Business; and Corporate Vice President and Chief Financial Officer. Prior to joining Allergan in 1999, Mr. Brandt spent ten years with the Boston Consulting Group, Boston, Massachusetts, serving as Vice President/Partner. Mr. Brandt has a Bachelor of Science degree in Chemical Engineering from MIT and an M.B.A. degree from the Harvard Business School. Mr. Brandt serves on the Board of Vertex Pharmaceuticals, Inc., where he is Chair of the Audit Committee and on the Board of Dentsply International Inc.

Keith Katkin. Mr. Katkin joined AVANIR in July of 2005 as Senior Vice President of Sales and Marketing. Mr. Katkin previously served as Vice President, 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 where he gained product launch and brand management experience on products such as Neupogen, Neulasta, and Biaxin. 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.

Michael J. Puntoriero. Mr. Puntoriero joined AVANIR in May 2006 as Senior Vice President of Finance and Chief Financial Officer. His responsibilities include the areas of finance, treasury, business planning, investor relations and information technology. Prior to joining AVANIR, Mr. Puntoriero spent over 20 years with Arthur

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Andersen LLP, including positions as audit partner, head of the Orange County, California audit practice and ultimately as Managing Partner of the Orange County, California office. Most recently, Mr. Puntoriero held senior executive positions from July 2004 to March 2006 with Fleetwood Enterprise, Inc., and as Executive Vice President and Chief Financial Officer of First Consulting Group, Inc. from January 2003 to September 2003. In addition, Mr. Puntoriero serves as a director of Oakley, Inc., chair of the audit committee and member of the nominating and corporate governance committee. Mr. Puntoriero earned a Bachelor of Science degree in Accounting from California State University, Northridge and an M.B.A degree from the University of Southern California. Mr. Puntoriero is a licensed Certified Public Accountant.

Gregory P. Hanson, CMA. Mr. Hanson has served as the Vice President and Chief Accounting Officer since May 2006, Corporate Compliance Officer since 2002, and Corporate Secretary since July 1998. He also has served as Vice President, Finance and Chief Financial Officer (CFO) from July 1998 to May 2006. From September 1995 to July 1998, he was the Chief Financial Officer of XXsys Technologies Inc., a composite materials technology company; and from May 1993 to September 1995, he held a number of financial positions within The Titan Corporation, a diversified telecommunications and information technology company, including acting CFO and acting Controller for its subsidiary, Titan Information Systems. Earlier in his career, Mr. Hanson held various management positions at Ford Motor Company over a 14-year span and at Solar Turbines Incorporated, a subsidiary of Caterpillar Inc., over a three-year span. Mr. Hanson has a B.S. degree in Mechanical Engineering from Kansas State University and an M.B.A. degree with honors from the University of Michigan. He is a Certified Management Accountant and has passed the examination for Certified Public Accountants. Mr. Hanson has been a member of the Financial Accounting Standards Board s Small Business Advisory Committee (SBAC) since April 2004 and serves on the SBAC s Agenda Committee.

Theresa Hope-Reese. Ms. Hope-Reese joined AVANIR in August 2006 as Vice President of Human Resources. Ms. Hope-Reese is responsible for overseeing all human resource practices and policies for AVANIR. Prior to joining AVANIR, Ms. Hope-Reese spent over six years with Water Pik Technologies, Inc. as Corporate Vice President of Human Resources where she was responsible for all global human resource functions for over 1,200 employees. Prior to joining Water Pik, she worked for Varco International, Inc., where she was Vice President of Human Resources. Ms. Hope-Reese earned her Bachelor of Science degree in Management from California State University, San Diego and her M.B.A. degree from the University of North Texas. Additionally, she has earned an Executive Certificate in Management after completing a post graduate program at the Peter F. Drucker and Masatoshi Ito Graduate School of Management in Claremont, California.

Randall E. Kaye, M.D. Dr. Kaye joined AVANIR in January 2006 in the newly created role of Vice President of Medical Affairs and assumed the role of Vice President Clinical and Medical Affairs starting in November 2006. Immediately prior to joining AVANIR, Dr. Kaye was the Vice President of Medical Affairs for Scios Inc., a division of Johnson & Johnson from 2004 to 2006. 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.

Jagadish Sircar, Ph.D. Dr. Sircar joined AVANIR in November 1995 as Director of Chemistry, and was responsible for creating AVANIR s medicinal chemistry drug discovery program. From April 2000 to November 2002, he held the position of Executive Director, Drug Discovery at AVANIR and has served as our Vice President of Drug Discovery since November 2002. Before joining AVANIR, Dr. Sircar held the position of Senior Vice President, Research and Discovery for Biofor, Inc. from January 1992 to November 1995. Previously, from 1969 to 1991, Dr. Sircar worked with Warner-Lambert/Parke-Davis in its Research Division (currently Pfizer), where he attained the position of Associate Research Fellow and Chairman of the Immunoinflammatory Project Team. During his tenure at

Warner-Lambert/Parke-Davis, he was responsible for the discovery and pre-clinical development of six compounds. Dr. Sircar holds a Ph.D. degree in Organic Chemistry, an M.S. degree in Pure Chemistry and a B.S. degree (Honors) in Chemistry, all from the University of Calcutta, Calcutta, India. Dr. Sircar is the author of 170 patents and scientific publications.

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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 or 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 caption Executive Compensation contained in the Proxy Statement.

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

The information required by this item is incorporated by reference to the information under the caption 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***

The information required by this item is incorporated by reference to the information under the caption Certain Relationships and Related Transactions 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, Financial Statements and Schedules***

(a) Financial Statements and Schedules

(1) Index to consolidated financial statements appears on page F-1.

(b) Exhibits

3.1 Restated Articles of Incorporation of the Registrant, dated April 1, 2004(13)

3.2 Amended and Restated Bylaws of the Registrant, dated September 25, 2005(14)

4.1 Form of Class A Common Stock Certificate(1)

4.2 Certificate of Determination with respect to Series C Junior Participating Preferred Stock of the Registrant(2)

4.3 Rights Agreement, dated as of March 5, 1999, with American Stock Transfer & Trust Company(2)

4.4 Form of Rights Certificate with respect to the Rights Agreement, dated as of March 5, 1999(2)

4.5 Amendment No. 1 to Rights Agreement, dated November 30, 1999, with American Stock Transfer & Trust Company(4)

4.6 Form of Class A Stock Purchase Warrant, issued in connection with the Securities Purchase Agreement dated July 21, 2003(10)

4.7 Form of Class A Stock Purchase Warrant, issued in connection with the Securities Purchase Agreement dated November 25, 2003(11)

10.1 License Agreement, dated March 31, 2000, by and between Avanir Pharmaceuticals and SB Pharmco Puerto Rico, a Puerto Rico Corporation(5)

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10.2	License Agreement, dated November 22, 2002, by and between Avanir Pharmaceuticals and Drug Royalty USA, Inc.(17)
10.3	Research, Development and Commercialization Agreement, dated April 27, 2005, by and between Avanir Pharmaceuticals and Novartis International Pharmaceutical Ltd.*(18)
10.4	Research Collaboration and License Agreement, dated July 8, 2005, by and between Avanir Pharmaceuticals and AstraZeneca UK Limited* (23)
10.5	Standard Industrial Net Lease by and between Avanir Pharmaceuticals and BC Sorrento, LLC, effective September 1, 2000(6)
10.6	Standard Industrial Net Lease by and between Avanir Pharmaceuticals (Tenant) and Sorrento Plaza, a California limited partnership (Landlord), effective May 20, 2002(8)
10.7	Office lease agreement by and between RREEF AMERICA REIT II CORP. FFF and Avanir Pharmaceuticals, dated April 28, 2006
10.8	License Agreement, dated August 1, 2000, by and between Avanir Pharmaceuticals (Licensee) and Irisys Research and Development, LLC, a California limited liability company(6)
10.9	Sublease agreement between Avanir Pharmaceuticals and Sirion Therapeutics, Inc., dated September 5, 2006
10.10	License Agreement, dated April 2, 1997, by and between Irisys Research & Development, LLC and the Center for Neurologic Study(16)
10.11	Amendment to License Agreement, dated April 11, 2000, by and between IriSys Research & Development, LLC and the Center for Neurologic Study(16)
10.12	Clinical Development Agreement, dated March 22, 2005, by and between Avanir Pharmaceuticals and SCIREX Corporation(16)
10.13	Unit Purchase Agreement by and among AVANIR Pharmaceuticals, the Sellers and Alamo Pharmaceuticals, LLC, dated May 22, 2006 *(24)

10.14 Senior Note for $14.4 million payable to Neal R. Cutler, dated May 24, 2006 (24)

10.15 Senior Note for $6,675,000 payable to Neal R. Cutler, dated May 24, 2006 (24)

10.16 Senior Note for $4.0 million payable to Neal R. Cutler, dated May 24. 2006 (24)

10.17 Registration Rights Agreement between Avanir Pharmaceuticals and Neil Cutler, dated May 24, 2006 (24)

10.18 Amended and Restated Development, License and Supply Agreement by and between CIMA Labs Inc. and Alamo Pharmaceuticals, LLC, dated August 22, 2005* (24)

10.19 Amendment #1 to Amended and Restated Development, License and Supply Agreement by and between CIMA Labs Inc. and Alamo Pharmaceuticals, LLC, dated October 19, 2005* (24)

10.20 Docosanol License Agreement between Kobayashi Pharmaceutical Co., Ltd. and AVANIR Pharmaceuticals, dated January 5, 2006* (28)

10.21 Docosanol Data Transfer and Patent License Agreement between AVANIR Pharmaceuticals and Healthcare Brands International Limited, dated July 6, 2006*

10.22 Development and License Agreement between Eurand, Inc. and AVANIR Pharmaceuticals, dated August 7, 2006*

10.23 Amended and Restated 1998 Stock Option Plan(7)

10.24 Amended and Restated 1994 Stock Option Plan(7)

10.25 Amended and Restated 2000 Stock Option Plan(9)

10.26 Form of Restricted Stock Grant Notice for use with Amended and Restated 2000 Stock Option Plan(9)

10.27 2003 Equity Incentive Plan(9)

10.28 Form of Non-qualified Stock Option Award Notice for use with 2003 Equity Incentive Plan(9)

10.29 Form of Restricted Stock Grant for use with 2003 Equity Incentive Plan(9)

10.30 Form of Restricted Stock Grant Notice (cash consideration) for use with 2003 Equity Incentive Plan(9)

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10.31	Form of Indemnification Agreement with certain Directors and Executive Officers of the Registrant(12)
10.32	2005 Equity Incentive Plan (23)
10.33	Form of Stock Option Agreement for use with 2005 Equity Incentive Plan (20)
10.34	Form of Restricted Stock Unit Agreement for use with 2005 Equity Incentive Plan and 2003 Equity Incentive Plan
10.35	Form of Restricted Stock Agreement for use with 2005 Equity Incentive Plan
10.36	Form of Change of Control Agreement (26)
10.37	Employment Agreement with Eric Brandt, dated August 15, 2005* (23)
10.38	Employment Agreement with Keith Katkin, dated June 13, 2005 (23)
10.39	Employment Agreement with Michael J. Puntoriero, dated May 4, 2006
10.40	Employment Agreement with Randall Kaye, dated December 23, 2005 (25)
10.41	Employment Agreement with Theresa Hope-Reese, dated August 7, 2006 (27)
18.1	Letter regarding change in accounting principle
21.1	List of Subsidiaries
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002

31.3 Certification of Chief Accounting Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002

32.1 Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

32.2 Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

32.3 Certification of Chief Accounting Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

* Certain confidential portions of this exhibit have been retracted. A complete copy of this exhibit has been filed with the Secretary of the Securities and Exchange Commission pursuant to an application requesting confidential treatment under Rule 246-2 of the Securities Exchange Act of 1934.

(1) Incorporated by reference to the similarly described exhibit included with the Registrant s Registration Statement on Form S-1, File No. 33-32742, declared effective by the Commission on May 8, 1990.

(2) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K, filed March 11, 1999.

(3) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K, filed April 1, 1999.

(4) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K, filed December 3, 1999.

(5) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K, filed May 4, 2000.

(6) Incorporated by reference to the similarly described exhibit included with the Registrant s Quarterly Report on Form 10-Q, filed August 14, 2000.

(7) Incorporated by reference to the similarly described exhibit included with the Registrant s Annual Report on Form 10-K, filed December 21, 2001.

(8) Incorporated by reference to the similarly described exhibit included with the Registrant s Quarterly Report on Form 10-Q, filed August 13, 2002.

(9) Incorporated by reference to the similarly described exhibit included with the Registrant s Quarterly Report on Form 10-Q, filed May 13, 2003.

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(10) Incorporated by reference to the similarly described exhibit included with the Registrant s Registration on From S-3, File No. 333-107820, declared effective by the Commission on August 19, 2003.

(11) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K, filed December 11, 2003.

(12) Incorporated by reference to the similarly described exhibit included with the Registrant s Annual Report on Form 10-K, filed December 23, 2003.

(13) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K, filed on April 6, 2004.

(14) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K, filed September 28, 2005.

(15) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K, filed September 21, 2004.

(16) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 10-Q, filed May 13, 2005.

(17) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K, filed January 7, 2003.

(18) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 10-Q, filed August 12, 2005.

(19) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K, filed March 23, 2005.

(20) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K, filed October 24, 2005.

(21) Incorporated by reference to the similarly described exhibit included with the Registrant s Annual Report on Form 10-K, filed December 14, 2005.

(22) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 10-Q, filed August 9, 2006.

(23) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 10-Q, filed February 9, 2006.

(24) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K, filed June 26, 2006.

(25) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K, filed August 10, 2006.

(26)

Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 10-Q, filed May 10, 2006.

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SIGNATURES

Pursuant to the requirements 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/ Eric K. Brandt
Eric K. Brandt
President and Chief Executive Officer

Date: December 15, 2006

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/ Eric K. Brandt Eric K. Brandt	President and Chief Executive Officer (Principal Executive Officer)	December 15, 2006
/s/ Michael J. Puntoriero, CPA Michael J. Puntoriero, CPA	Senior Vice President of Finance and Chief Financial Officer (Principal Financial Officer)	December 15, 2006
/s/ Gregory P. Hanson, CMA Gregory P. Hanson, CMA	Vice President and Chief Accounting Officer (Principal Accounting Officer)	December 15, 2006
/s/ Charles A. Mathews Charles A. Mathews	Director	December 15, 2006
/s/ Stephen G. Austin, CPA Stephen G. Austin, CPA	Director	December 15, 2006
/s/ David J. Mazzo, Ph.D. David J. Mazzo, Ph.D.	Director	December 15, 2006
/s/ Dennis G. Podlesak Dennis G. Podlesak	Director	December 15, 2006

/s/ Jonathan T. Silverstein, J.D.	Director	December 15, 2006
Jonathan T. Silverstein, J.D.		
/s/ Paul G. Thomas	Director	December 15, 2006
Paul G. Thomas		
/s/ Craig A. Wheeler	Director	December 15, 2006
Craig A. Wheeler		
/s/ Scott M. Whitcup, M.D.	Director	December 15, 2006
Scott M. Whitcup, M.D.		

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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 sheets of Avanir Pharmaceuticals and subsidiaries (the Company) as of September 30, 2006 and 2005, and the related consolidated statements of operations, shareholders (deficit) equity and comprehensive loss, and cash flows for each of the three years in the period ended September 30, 2006. 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 consolidated financial statements present fairly, in all material respects, the financial position of Avanir Pharmaceuticals and subsidiaries as of September 30, 2006 and 2005, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2006, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company s internal control over financial reporting as of September 30, 2006, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated December 15, 2006 expressed an unqualified opinion on management s assessment of the effectiveness of the Company s internal control over financial reporting and an unqualified opinion on the effectiveness of the Company s internal control over financial reporting.

As discussed in Note 3 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.

/s/ Deloitte & Touche LLP

San Diego, California
December 15, 2006

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Avanir Pharmaceuticals

CONSOLIDATED BALANCE SHEETS

	September 30, 2006	2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,898,214	$ 8,620,143
Short-term investments in securities	16,778,267	14,215,005
Receivables, net	3,042,468	1,169,654
Inventories	2,835,203	27,115
Prepaid expenses	1,778,918	2,370,801
Total current assets	29,333,070	26,402,718
Investments in securities	2,216,995	3,845,566
Restricted investments in securities	856,597	856,872
Property and equipment, net	6,047,729	6,004,527
Intangible assets, net	10,113,329	3,665,086
Goodwill	22,110,328	
Long-term inventories	347,424	347,424
Other assets	436,865	279,797
TOTAL ASSETS	$ 71,462,337	$ 41,401,990
LIABILITIES AND SHAREHOLDERS (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	$ 10,845,057	$ 6,751,781
Accrued expenses and other liabilities	9,857,639	4,094,295
Assumed liabilities for returns and other discounts	3,980,229	
Accrued compensation and payroll taxes	3,125,862	1,272,231
Deferred revenues, net	7,592,563	1,970,989
Notes payable	670,737	317,667
Capital lease obligations	230,760	26,305
Total current liabilities	36,302,847	14,433,268
Other liabilities	230,450	
Deferred revenues, net of current portion	15,716,762	17,187,221
Notes payable, net of current portion	24,715,905	637,285
Capital lease obligations, net of current portion	170,908	9,337
Total liabilities	77,136,872	32,267,111
Commitments and contingencies (Notes 4, 14, 17 and 19)		
Shareholders (deficit) equity:		

Preferred stock no par value, 10,000,000 shares authorized, no shares issued or outstanding as of September 30, 2006 and 2005, respectively:		
Common stock no par value, 200,000,000 shares authorized; 31,708,461 and 27,341,732 shares issued and outstanding as of September 30, 2006 and 2005, respectively	211,993,249	167,738,303
Unearned compensation		(3,477,144)
Accumulated deficit	(217,565,280)	(155,012,466)
Accumulated other comprehensive loss	(102,504)	(113,814)
Total shareholders (deficit) equity	(5,674,535)	9,134,879
TOTAL LIABILITIES AND SHAREHOLDERS (DEFICIT) EQUITY	$ 71,462,337	$ 41,401,990

See notes to consolidated financial statements.

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Avanir Pharmaceuticals

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended September 30,		
	2006	**2005**	**2004**
REVENUES:			
Research and development services	$ 7,837,788	$ 1,617,525	$
Licenses	5,154,709	12,800,000	328,000
Royalties and sale of royalty rights	1,938,203	1,752,321	1,715,152
Government research grants	236,882	503,328	758,827
Product sales	18,270	17,400	787,338
Total revenues	15,185,852	16,690,574	3,589,317
OPERATING EXPENSES:			
Cost of research and development services	7,198,397	2,346,044	979,182
Cost of government research grant services	292,111	497,210	
Research and development	29,222,089	26,140,504	21,502,499
Selling, general and administrative	38,054,219	18,796,188	9,340,260
Cost of product sales	415,045	3,102	213,192
Total operating expenses	75,181,861	47,783,048	32,035,133
Loss from operations	(59,996,009)	(31,092,474)	(28,445,816)
Interest income	1,794,049	619,857	290,067
Interest expense	(765,871)	(92,533)	(34,508)
Other income (expense)	33,505	(39,601)	38,068
Loss before income taxes	(58,934,326)	(30,604,751)	(28,152,189)
Provision for income taxes	(2,430)	(1,813)	(2,664)
Loss before cumulative effect of change in accounting principle	(58,936,756)	(30,606,564)	(28,154,853)
Cumulative effect of change in accounting principle (Note 3)	(3,616,058)		
Net loss	$ (62,552,814)	$ (30,606,564)	$ (28,154,853)
Basic and diluted net loss per share (Note 2):			
Loss before cumulative effect of change in accounting principle	$ (1.92)	$ (1.19)	$ (1.44)
Cumulative effect of change in accounting principle	(0.12)		
Net loss	$ (2.04)	$ (1.19)	$ (1.44)
	30,634,872	25,617,432	19,486,603

Basic and diluted weighted average number of common shares outstanding (Note 2)

See notes to consolidated financial statements.

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Avanir Pharmaceuticals

CONSOLIDATED STATEMENTS OF SHAREHOLDERS (DEFICIT) EQUITY AND COMPREHENSIVE LOSS

Common Stock								
Class A		Class B		Accumulated	Unearned	Accumulated Other Comprehensive Income	Total Shareholders (Deficit)	C
Shares (Note 2)	Amount	Shares	Amount	Deficit	Compensation	(Loss)	Equity	
16,454,109	$ 97,286,433	3,375	$ 8,395	$ (96,251,049)	$	$ (6,548)	$ 1,037,231	
				(28,154,853)			(28,154,853)	$
73,724	448,671						448,671	
31,002	160,823						160,823	
7,005,027	34,015,320						34,015,320	
259,202	2,733,023						2,733,023	
3,375	8,395	(3,375)	(8,395)					
	34,870						34,870	
						(77,826)	(77,826)	
23,826,439	134,687,535			(124,405,902)		(84,374)	10,197,259	
				(30,606,564)			(30,606,564)	$

	211,486	1,293,339				1,293,339	
	27,974	125,491				125,491	
	2,525,833	22,765,135				22,765,135	
	500,000	5,300,000				5,300,000	
	250,000	3,556,000		(3,555,000)		1,000	
				77,856		77,856	
		10,803				10,803	
					(29,440)	(29,440)	
	27,341,732	167,738,303	(155,012,466)	(3,477,144)	(113,814)	9,134,879	$
			(62,552,814)			(62,552,814)	$
	827,575	5,908,997				5,908,997	
	524,807	3,264,953				3,264,953	
	3,016,122	35,637,905				35,637,905	
	28,000						
	(29,775)	(200,386)				(200,386)	
		(3,477,144)		3,477,144			

on		3,120,621						3,120,621
						11,310		11,310
30,	31,708,461	$ 211,993,249	$	$ (217,565,280)	$	$ (102,504)	$ (5,674,535)	$

See notes to consolidated financial statements.

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Avanir Pharmaceuticals

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended September 30,		
	2006	**2005**	**2004**
OPERATING ACTIVITIES:			
Net loss	$ (62,552,814)	$ (30,606,564)	$ (28,154,853)
Adjustments to reconcile net loss to net cash provided by (used for) operating activities:			
Cumulative effect of change in accounting principle	3,616,058		
Depreciation and amortization	3,871,278	1,852,427	1,826,372
Share-based compensation expense	2,920,234	88,659	34,870
Amortization of debt discount	85,400		
Purchased in-process research and development	1,300,000		
Expense for issuance of common stock in connection with the acquisition of additional contractual rights to Zenvia		5,300,000	
Research milestone obligation paid with common stock			2,733,023
Loss on sale and impairment of investment		84,252	
Loss on disposal of assets	36,985	16,400	162
Intangible assets impaired and abandoned	8,222	423,123	
Changes in operating assets and liabilities:			
Receivables	(846,075)	(929,775)	31,802
Inventory	(510,971)	(365,237)	201,552
Prepaid expenses and other assets	835,112	(848,219)	(9,912)
Accounts payable	3,188,980	4,615,629	(300,210)
Accrued expenses and other liabilities	3,973,998	1,604,136	612,151
Assumed liabilities for returns and other discounts	(2,421,092)		
Accrued compensation and payroll taxes	1,333,667	561,863	84,214
Deferred revenue	4,151,115	(1,850,905)	(1,733,526)
Net cash used for operating activities	(41,009,903)	(20,054,211)	(24,674,355)
INVESTING ACTIVITIES:			
Investments in securities	(65,823,381)	(23,448,802)	(9,381,391)
Proceeds from sales and maturities of investments in securities	64,900,275	16,830,113	2,150,000
Acquisition of businesses, net of cash acquired	(4,794,029)		
Patent costs		(1,278,935)	(1,156,975)
Purchases of property and equipment	(1,663,347)	(990,601)	(793,913)
Net cash used for investing activities	(7,380,482)	(8,888,225)	(9,182,279)
FINANCING ACTIVITIES:			
Proceeds from issuances of common stock and warrants, net of commissions and offering costs	44,811,855	24,184,966	34,624,814
Proceeds from issuances of notes payable	359,875	395,244	1,074,570
Payments on notes and capital lease obligations	(503,274)	(511,714)	(547,075)

Net cash provided by financing activities	44,668,456	24,068,496	35,152,309
Net increase (decrease) in cash and cash equivalents	(3,721,929)	(4,873,940)	1,295,675
Cash and cash equivalents at beginning of year	8,620,143	13,494,083	12,198,408
Cash and cash equivalents at end of year	$ 4,898,214	$ 8,620,143	$ 13,494,083
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:			
Interest paid	$ 681,122	$ 92,533	$ 34,508
Income taxes paid	$ 2,430	$ 1,912	$ 2,664
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:			
Issuance of promissory notes to sellers as consideration for the Alamo acquisition, net of discount (See Note 4 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 purchases of property and equipment	$ 74,617	$ 242,213	$ 3,951

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 for chronic human diseases. Our product candidates address therapeutic markets that include the central nervous system, cardiovascular disorders, inflammatory diseases and infectious diseases.

We currently market FazaClo, (clozapine, USP), the only orally-disintegrating formulation of clozapine for the management of treatment resistant schizophrenia and reduction in the risk of recurrent suicidal behavior in schizophrenia or schizoaffective disorders. We acquired FazaClo in the acquisition of Alamo Pharmaceuticals, LLC (Alamo) in May 2006. Alamo was a privately owned specialty pharmaceutical company that developed and marketed pharmaceutical products with a sales force of approximately 41 representatives currently marketing FazaClo. In addition to the sales force, Alamo employs a FazaClo Patient Registry team that is composed of dedicated healthcare, registry, call center, administrative support, data management and professional management. See Note 4, Alamo Acquisition for further discussion.

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 substantially on sales of our marketed product, FazaClo®, 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 IEED/PBA, assuming the FDA approves our new drug application. Our operating expenses depend substantially on the level of expenditures for marketing and sales of FazaClo, clinical development activities for Zenvia for the treatment of IEED/PBA and diabetic neuropathic pain, and program funding authorized by our research partners and the rate of progress being made on such programs.

Since our inception through September 30, 2006, the Company has reported accumulated net losses of approximately $218 million, and recurring negative cash flows from operations. In order to maintain sufficient cash and investments to fund future operations we will seek to raise additional capital in fiscal year 2007 through various financing alternatives. The balance of securities available for sale under our existing shelf registration was approximately $48.8 million as of December 5, 2006. We believe that these anticipated offering proceeds plus our cash, cash equivalents and unrestricted investments in securities of approximately $23.9 million at September 30, 2006 as well as anticipated future cash flows generated from licensed technologies and sales from the shipments of FazaClo, will be sufficient to sustain our planned level of operations for at least the next 12 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 sales from the shipments of FazaClo and unable to raise sufficient capital management believes that planned expenditures could be curtailed in order to continue operations for the next 12 months.

2. Reverse Stock Split

On January 17, 2006, we implemented a one-for-four reverse stock split of our common stock. 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 this reverse stock split.

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Avanir Pharmaceuticals

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. 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 LLP (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, 2006, 2005, and 2004 may be referred to as fiscal 2006, fiscal 2005 and fiscal 2004, 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.

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 4, Alamo Acquisition, for detailed discussion.

Cash and cash equivalents

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

Restricted investments in securities

We have restricted investments in two securities totaling $856,597 and $856,872 as of September 30, 2006 and 2005, respectively. These restricted investments represent amounts pledged to our bank as collateral for letters of credit issued in connection with our real estate lease agreements, and are classified as held-to-maturity and are stated at lower of cost or market. The restricted amounts that apply to the terms of the leases are as follows:

Property Location	Restricted Amount as of September 30, 2006	Lease Term Expires on
11388 Sorrento Valley Road, San Diego	$ 388,122	08/31/08
11404 and 11408 Sorrento Valley Road, San Diego	468,475	08/31/12

Total	$	856,597

Investments

We account for and report our investments 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

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Avanir Pharmaceuticals

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 three 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 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.

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.

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 shorter of the remaining lease term or eight years. 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 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

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Avanir Pharmaceuticals

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

quarter of each fiscal year. There was no impairment of goodwill for the fiscal year ended September 30, 2006. The Company had no goodwill as of September 30, 2005.

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, 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 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**	**Fiscal 2004**
Net loss	$ (58,936,756)	$ (31,255,373)	$ (29,056,101)
Basic and diluted loss per share	$ (1.92)	$ (1.22)	$ (1.49)

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Avanir Pharmaceuticals

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Deferred rent

We account for rent expense by accumulating total minimum rent payments 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, 2006 and 2005 was $681,000 and $598,000, respectively.

Fair value of financial instruments

At September 30, 2006 and 2005, our financial instruments included cash and cash equivalents, receivables, investments in 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, 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 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, 2006 and 2005, the fair value of our notes payable were approximately $25.3 million and $825,000, respectively.

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

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Avanir Pharmaceuticals

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 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

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Avanir Pharmaceuticals

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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. As discussed in Note 4, Alamo Acquisition, in the Notes to Consolidated Financial Statements, we acquired Alamo Pharmaceuticals LLC (Alamo) on May 24, 2006. Alamo has one product, FazaClo (clozapine, USP), that Alamo began shipping 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 to ship 96-pill units and accepted returns of unsold or undispensed 48-pill units.

FazaClo is sold primarily to third-party wholesalers that in turn sell this product to retail pharmacies, hospitals, and other dispensing organizations. Alamo has entered into agreements with its wholesale customers, various states, hospitals, certain other medical institutions and third-party payers throughout the United States. These agreements frequently contain commercial incentives, which may include favorable product pricing and discounts and rebates payable upon dispensing the product to patients. Additionally, these agreements customarily provide the customer with rights to return the product, subject to the terms of each contract. 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, some dispensing organizations, such as pharmacies and hospitals, have the right to return expired product at any time.

At the present time, we are unable to reasonably estimate future returns due to the lack of sufficient historical returns data for FazaClo. Accordingly, we currently defer recognition of revenue on shipments of FazaClo until the right of return no longer exists, i.e. when we receive evidence that the products have been dispensed to patients. We determine when products are dispensed to patients from rebate requests that have been submitted to us by various state agencies and others. We are not able to estimate how much has been dispensed until we receive the rebate requests. Rebate requests are generally received in 30 to 90 days from the last day of the quarter in which the product was dispensed to patients. Since the date of the Alamo acquisition (May 24, 2006), we have recorded all rebate requests as a reduction of the assumed liabilities for returns and discounts which was recorded as part of the acquisition, because we believe this method reasonably estimates the matching of the initial shipments to the related rebate. Accordingly, no FazaClo revenue was recognized in fiscal 2006.

For our FazaClo shipments, we invoice the wholesaler, record deferred revenue at gross invoice sales price less estimated cash discounts and classify the inventory shipped as inventories subject to return. We estimate rebates and other discounts based on our historical experience. Net deferred revenues represent the sum of all FazaClo shipments subsequent to the acquisition, net of estimated rebates, sales returns and chargebacks, for which revenue recognition criteria have not been met. Deferred rebates, sales returns and chargebacks are included in accrued expenses. Sales incentives are also deferred until the related product shipments are recognized as revenue. Sales incentives are classified as deductions from revenue in accordance with EITF Issue No. 01-09, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor s Products).* The cost of product relative to deferred revenue has also been deferred and is included in inventories, categorized as inventories subject to return.

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.

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Avanir Pharmaceuticals

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 $29,000, $0 and $0 for fiscal 2006, 2005 and 2004, 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 $10.7 million Phase III clinical trial contract as of September 30, 2006. A 3% variance in our estimate of the work completed in our largest contract could increase or decrease our quarterly operating expenses by approximately $320,000.

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 4, Alamo Acquisition In-Process Research and Development.

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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Avanir Pharmaceuticals

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Change in Accounting Method for 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, 2006 and for the fiscal year ended September 30, 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 during the period. Share-based compensation expense recognized in our consolidated statement of operations for fiscal 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 awards granted in fiscal 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 statement of operations for fiscal 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. Pre-vesting forfeitures were estimated to be approximately 8% for both officers and directors and 13% for other employees in fiscal 2006 based on our historical experience. In our pro forma information required under FAS 123 for the periods prior to fiscal 2006, we accounted for forfeitures as they occurred.

The adoption of FAS 123R resulted in incremental share-based compensation expense of 1.5 million in fiscal year ended September 30, 2006. The incremental share-based compensation caused our loss from continuing operations before income taxes, loss from operations and net loss to increase by the same amount and the basic and diluted loss per share to increase by $0.05 per share. Total compensation expense related to all of our share-based awards, recognized under FAS 123R, for fiscal 2006 was comprised of the following:

Fiscal 2006

Selling, general and administrative expense	$ 2,514,427
Research and development expense	606,194
Share-based compensation expense before taxes	3,120,621
Related income tax benefits	
Share-based compensation expense	$ 3,120,621
Net share-based compensation expense per common share basic and diluted	$ (0.10)

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Avanir Pharmaceuticals

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	Fiscal 2006
Share-based compensation expense from:	
Stock options	$ 1,795,610
Restricted stock awards	1,179,621
Restricted stock units	145,390
Total	$ 3,120,621

Since we have a net operating loss carry-forward as of September 30, 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 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 and 2004.

	Fiscal 2005	Fiscal 2004
Net loss, as reported	$ (30,606,564)	$ (28,154,853)
Add: Share-based employee compensation expense	77,856	24,069
Deduct: Total share-based employee compensation expense determined under fair value based method for all awards	(1,777,838)	(1,026,844)
Pro forma net loss	$ (32,306,546)	$ (29,157,628)
Net loss per share:		
Basic and diluted as reported	$ (1.19)	$ (1.44)
Basic and diluted pro forma	$ (1.26)	$ (1.50)

For employee stock options granted in fiscal 2005 and 2004, 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% and 133%, respectively, (2) an expected term of 3.4 years, (3) a risk-free interest rate of 3.8% and 2.4%, respectively, and (4) an expected dividend yield of 0%. The weighted average fair value of options granted in fiscal 2005 and 2004 was $11.36 and $7.24 per share, respectively.

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 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

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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 evaluated and adjusted as appropriate on at least a quarterly basis for changes in circumstances. Please refer to Note 5, 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 $1.3 million, $61,000 and $0 for fiscal 2006, 2005 and 2004, 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 2006, 2005 and 2004, 194,665, 250,000 and 0 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.

For fiscal 2006, 2005, and 2004, 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 antidilutive:

	Fiscal 2006	Fiscal 2005	Fiscal 2004
Stock options	1,587,070	1,600,034	1,313,398
Stock warrants	269,305	1,122,047	1,333,539

Restricted stock awards	29,250
Restricted stock units	51,480

Recent accounting pronouncements

Financial Accounting Standards No. 154 (FAS 154). In May 2005, the FASB issued FAS 154, *Accounting Changes and Error Corrections.* FAS 154 establishes retrospective application as the required method for reporting a change in accounting principle in the absence of explicit transition requirements specific to the newly adopted accounting principle. FAS 154 also provides guidance for determining whether retrospective application of a change in accounting principle is impracticable and for reporting a change when retrospective application is

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impracticable. FAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. We do not expect the adoption of FAS 154 to significantly affect our financial condition or results of operations.

Financial Accounting Standards No. 155 (FAS 155). In February 2006, the FASB issued FAS 155, *Accounting for Certain Hybrid Financial Instruments,* an amendment of Financial Accounting Standards No. 133, *Accounting for Derivative Instruments and Hedging Activities* (FAS 133) and Financial Accounting Standards No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities* (FAS 140). With respect to FAS 133, FAS 155 simplifies accounting for certain hybrid financial instruments by permitting fair value remeasurement for any hybrid financial instrument that contains an embedded derivative that otherwise would require bifurcation and eliminates the interim guidance in Statement 133 Implementation Issue No. D1, *Application of Statement 133 to Beneficial Interests in Securitized Financial Assets,* which provided that beneficial interests in securitized financial assets are not subject to the provision of FAS 133. With respect to FAS 140, FAS 155 eliminates a restriction on the passive derivative instruments that a qualifying special-purpose entity may hold. FAS 155 is effective for all financial instruments acquired or issued after the beginning of an entity s first fiscal year that begins after September 15, 2006. We do not expect the adoption of FAS 155 to significantly affect our financial condition or results of operations.

FASB Interpretation No. 48 (FIN 48). In July 2006, the FASB issued FIN 48, *Accounting for Uncertainty in Income Taxes* which prescribes a recognition threshold and measurement process for recording in the financial statements uncertain tax positions taken or expected to be taken in a tax return. 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, the adoption of FIN 48 will have on our 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 financial condition or results of operations.

Financial Accounting Standards No. 158 (FAS 158). In September 2006, the FASB issued FAS 158, *Employers Accounting for Defined Benefit Pension and Other Postretirement Plans-an Amendment of FASB Statements No. 87, 88, 106 and 132(R).* FAS 158 requires an employer to recognize the overfunded or underfunded status of a defined benefit postretirement plan (other than a multiemployer plan) as an asset or liability in its statement of financial position and to recognize the changes in that funded status in the year in which the changes occur through comprehensive income of a business entity or changes in unrestricted net assets of a not-for-profit organization. FAS 158 is effective for us as of the end of the fiscal year ending after December 15, 2006. We do not expect the adoption of FAS 158 to significantly affect our financial condition or results of operations.

Staff Accounting Bulleting 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. We do not expect the adoption of SAB 108 to significantly affect our financial condition or results of operations.

FASB Staff Position No. FAS 123R-5 (FAS 123R-5). In October 2006, the FASB issued FAS 123R-5, *Amendment of FASB Staff Position FAS 123R-1,* to address whether a modification of an instrument in connection

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with an equity restructuring should be considered a modification for purposes of applying FAS 123R-1, *Classification and Measurement of Freestanding Financial Instruments Originally Issued in Exchange for Employee Services under FASB Statement No. FAS 123(R).* The provisions in FAS 123R-5 are effective for us in the quarter beginning January 1, 2007. We do not expect the adoption of FAS 123R-5 to significantly affect our financial condition or results of operations.

4. Alamo Acquisition

On May 24, 2006, pursuant to a Unit Purchase Agreement dated May 22, 2006 (the Acquisition Agreement), we acquired all of the outstanding equity interests in Alamo from the former members of Alamo (the Selling Holders) for approximately $30.0 million in consideration, consisting of approximately $4.0 million in cash, $25.1 million in promissory notes and $912,000 in acquisition related transaction costs. The purchase price exceeded the net assets acquired resulting in the recognition of $22.1 million goodwill. The results of operations of Alamo have been included in our consolidated financial statements since the date of acquisition.

We also agreed to pay up to an additional $39,450,000 in revenue-based earn-out payments, based on future sales of FazaClo (clozapine USP), Alamo s orally disintegrating drug for the treatment of refractory schizophrenia. These earn-out payments are based on FazaClo sales in the United States from the closing date of the acquisition through December 31, 2018 (the Contingent Payment Period) and are payable to the Selling Holders as follows:

A promissory note that would have been issuable in the principal amount of $4,000,000 if FazaClo sales, as reported by IMS Health Incorporated, for each of the months of April and May 2006 exceeded $1,266,539. Since the closing of the acquisition, we have determined that FazaClo sales for the months April and May 2006 did not satisfy this condition and thus this promissory note will not be issued pursuant to this contingency.

If the preceding condition is not satisfied, then (A) a promissory note, in the principal amount of $2,000,000, payable one time if monthly FazaClo net product sales, as reported by us, exceed $1,000,000 for each of the three months in a given fiscal quarter during the Contingent Payment Period, and (B) an additional promissory note in the principal amount of $2,000,000, payable one time if monthly FazaClo net product sales, as reported by us, exceed $1,500,000 for each of the three months in a given fiscal quarter during the Contingent Payment Period. As discussed in Note 3, *Summary of Significant Accounting Policies Revenue Recognition Product Sales FazaClo,* all revenue from FazaClo shipments since acquisition date are deferred; therefore, monthly FazaClo net product sales in the quarter ended September 30, 2006 did not meet these conditions at September 30, 2006.

A one-time cash payment of $10,450,000 if FazaClo net product sales, as reported by us, exceed $40.0 million over four consecutive fiscal quarters during the Contingent Payment Period.

A one-time cash payment of $25,000,000 if FazaClo net product sales, as reported by us, exceed $50.0 million over four consecutive fiscal quarters during the Contingent Payment Period.

Any of these additional revenue-based earn-out payments that are ultimately paid upon satisfying the contingent conditions above will be treated as additional consideration and recorded as goodwill.

We have also agreed to pay the Selling Holders one-half of all net licensing revenues that we received during the Contingent Payment Period from licenses of FazaClo outside of the United States (Non-US Licensing Revenues). Any amounts paid to the Selling Holders on Non-US Licensing Revenues will be recognized in the consolidated statement of operations in the period such amounts are paid.

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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:	
Cash	$ 157,507
Accounts receivable	1,026,740
Inventories	2,297,117
Property and equipment	1,845,077
Other assets	423,457
Identifiable intangible assets acquired:	
Product rights	7,200,000
In-process research and development	1,300,000
Customer relationships	2,900,000
Trade name	400,000
Non-compete agreement	160,000
Goodwill	22,110,328
Total assets acquired	39,820,226
Liabilities assumed:	
Accounts payable and accrued expenses	(3,611,653)
Assumed liabilities for returns and other discounts	(6,401,321)
Capital lease obligations	(512,716)
Total liabilities assumed	(10,525,690)
	$ 29,294,536

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The following are the estimated amortization percentages by year for amortizable intangible assets:

Year:	Product Rights	Customer Relationships	Trade Name	Non-Compete Agreements
1	14%	15%	8%	100%
2	15%	22%	9%	
3	15%	18%	8%	
4	14%	13%	9%	
5	14%	9%	8%	
6	14%	8%	9%	
7	14%	8%	8%	
8		7%	9%	
9			8%	
10			9%	
11			8%	
12			8%	

None of the goodwill will be deductible for tax purposes.

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 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 based on our estimate of the fair values of the liabilities at the acquisition date, which is classified as Assumed Liabilities for Returns and Other Discounts in the accompanying consolidated balance sheets.

The purchase price allocation shown above differs from the initial preliminary purchase price recorded in the third quarter ended June 30, 2006 primarily due to an increase of goodwill of $22.1 million and a corresponding reduction in value of identifiable intangible assets acquired. 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.

The fair values of the assets acquired and liabilities assumed were determined in accordance with FAS 141 and are substantially finalized. We may adjust certain elements of the purchase price which are still considered to be a preliminary allocation. This will be done after obtaining additional information about the amount and type of FazaClo product in the distribution channel as of the purchase date in order to appropriately determine the reserve for product returns and the resulting effect on goodwill. We are working with our key wholesalers to obtain this information. We expect this will occur by the second quarter of fiscal 2007, at which time we will finalize the purchase price

allocation. Liabilities assumed in connection with the acquisition and subject to change and that could impact the purchase price allocation include product returns due to expired or changed product formulation, manufacturing technology and packaging, chargebacks from wholesalers, and rebates. These amounts comprise the balance of assumed liabilities for returns and other discounts in the accompanying consolidated balance sheet as of September 30, 2006.

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, rebates, chargebacks and discounts. Identifiable intangible

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assets acquired represent expected benefits of the FazaClo product rights (see Note 17, Research and Licensing Agreements CIMA Labs Inc. Royalty Agreement), 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.

The identifiable intangible assets are being amortized, with the annual amortization amount based on the rate of consumption of the expected benefits of the intangible, if identifiable, 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 cannot be reasonably determined otherwise.

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. We expect to begin generating material positive cash flows from the technology in the second half of 2007, assuming the FDA approves the use of the technology for manufacturing FazaClo.

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 is determined by measuring the present value of the after-tax cash flows from revenues from such technology based on an appropriate technology royalty rate applied over 12 years commencing after FDA approval (if approved), discounted of a risk-adjusted rate of 29%. 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 expect to use the DuraSolv manufacturing technology to replace the current OraSolv technology for manufacturing FazaClo, assuming the manufacturing process is 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. No material change in pricing or manufacturing cost is anticipated. 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.

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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 will 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 not 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

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

5. Relocation of Commercial and General and Administrative Operations

On May 4, 2006, our Board of Directors authorized the relocation of our commercial and general and administrative operations (the Relocation Plan). During fiscal 2006, we expanded our sales and marketing operations and began relocating all operations other than research and development from San Diego, California to Aliso Viejo, California. The Relocation Plan included decisions to enter into a lease for new office facilities in Aliso Viejo, to discontinue occupying approximately 30,000 square feet of office and laboratory buildings in San Diego under an operating lease to us (BC Sorrento Lease) and relocate certain commercial and general and administrative positions.

In May 2006, we entered into a lease for the Aliso Viejo facilities and are in possession of approximately 9,245 square feet under the lease agreement as of September 30, 2006. See Note 14, Commitments and Contingencies Operating Lease Commitments for further discussion. In connection with the Relocation Plan, we anticipate that we will incur estimated total restructuring charges of $420,000 relating to one-time termination

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and relocation benefits and $984,000 relating to a lease restructuring liability. In fiscal 2006, we recorded restructuring and other related expenses of $515,000, consisting of $237,000 for employee severance and relocation benefits and $278,000 of the lease restructuring liability.

The following table presents the cumulative restructuring activities through September 30, 2006:

	Charge for Twelve Months Ended September 30, 2006	Payments in Fiscal 2006	Accruals As of September 30, 2006
Employee severance and relocation benefits	$ 237,050	$	$ 237,050
Lease restructuring liability	277,627	(3,629)	273,998
Balance, September 30, 2006	$ 514,677	$ (3,629)	$ 511,048

6. Investments in 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, 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:				
Short-term investments:				
Classified as available-for-sale				$ 16,778,267
Long-term investments:				
Classified as available-for-sale				2,216,995
Restricted investments(2)				856,597
Long-term investments				3,073,592

Total	$ 19,851,859

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	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses(1)	Fair Value
As of September 30, 2005:				
Certificates of deposit	$ 956,872	$ 48	$	$ 956,920
Government debt securities	18,074,385		(113,862)	17,960,523
Total	$ 19,031,257	$ 48	$ (113,862)	$ 18,917,443
Reported as:				
Short-term investments:				
Classified as available-for-sale				$ 14,215,005
Long-term investments:				
Classified as available-for-sale				3,845,566
Restricted investments(2)				856,872
Long-term investments				4,702,438
Total				$ 18,917,443

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

(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.

Gross realized loss for fiscal 2005 was $6,240. There were no realized gains or losses for fiscal 2006 and 2004.

7. Receivables, Net

Receivables as of September 30, 2006 and 2005 consist of the following:

	2006	2005
Accounts receivable	$ 1,966,164	$ 60,391
Unbilled receivables	908,284	1,010,902
Other receivables	178,619	126,460
	3,053,067	1,197,753
Allowance for doubtful accounts	(10,599)	(28,099)

Receivables, net of allowances	$ 3,042,468	$ 1,169,654

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8. Inventories

Inventories include FazaClo product and active pharmaceutical ingredients docosanol as of September 30, 2006 and docosanol only as of September 30, 2005, with the following carrying amounts as of those dates:

	2006	2005
Finished goods	$ 1,642,208	$
Raw materials	923,822	374,539
Work in progress	80,580	
Inventories subject to return	536,017	
Total inventories	3,182,627	374,539
Less: current portion	(2,835,203)	(27,115)
Long-term portion	$ 347,424	$ 347,424

Inventories subject to return represent the costs of FazaClo product shipped to customers that have not been recognized as cost of product sales based on our revenue recognition policies. See Note 3, Significant Accounting Policies Revenue Recognition Product Sales, FazaClo, for further discussion.

9. Property and Equipment

Property and equipment as of September 30, 2006 and 2005 consist of the following:

	2006			2005		
	Gross Carrying Value	Accumulated Depreciation	Net	Gross Carrying Value	Accumulated Depreciation	Net
Research and development equipment	$ 4,210,214	$ (3,134,970)	$ 1,075,244	$ 3,903,735	$ (2,567,843)	$ 1,335,892
Computer equipment and related software	2,207,370	(872,592)	1,334,778	1,038,390	(565,137)	473,253
Leasehold improvements	5,826,441	(3,665,799)	2,160,642	5,583,177	(1,641,485)	3,941,692
Office equipment, furniture and fixtures	1,293,775	(453,547)	840,228	558,911	(305,221)	253,690
Automobiles	499,275	(124,157)	375,118			
Manufacturing equipment	261,719		261,719			
	$ 14,298,794	$ (8,251,065)	$ 6,047,729	$ 11,084,213	$ (5,079,686)	$ 6,004,527

Total property and equipment	

Depreciation expense associated with property and equipment was $3.3 million, $1.6 million and $1.6 million for fiscal 2006, 2005 and 2004, respectively. In connection with the Relocation Plan as discussed in Note 5, 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 an additional depreciation expense of $1.3 million in fiscal 2006.

At September 30, 2006 and 2005, scientific equipment acquired under capital leases totaled $601,000 and $601,000, respectively, with accumulated depreciation of $529,000 and $427,000, respectively. Depreciation expense associated with scientific equipment acquired under capital leases was $102,000, $106,000 and $106,000

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for fiscal 2006, 2005 and 2004, respectively. In connection with the Alamo acquisition in May 2006, we acquired automobiles under capital leases totaled $499,000 with accumulated depreciation of $124,000 at September 30, 2006. Depreciation expense associated with automobiles acquired under capital leases was $124,000.

10. Intangible Assets and Goodwill

Intangible Assets. Intangible assets, consisting of both intangible assets with finite and indefinite useful lives as of September 30, 2006 and 2005, are as follows:

	2006			
	Gross Carrying Value	Accumulated Amortization	Net	Weighted Average Amortization Period (in Years)
Intangible assets with finite lives:				
FazaClo product rights	$ 7,200,000	$ (365,144)	$ 6,834,856	7
Customer relationships	2,900,000	(156,200)	2,743,800	8
Trade name	400,000	(11,833)	388,167	12
Non-compete agreement	160,000	(56,800)	103,200	1
Licenses	42,461	(20,160)	22,301	15.5
Total intangible assets with finite lives	10,702,461	(610,137)	10,092,324	7.4
Intangible assets with indefinite useful lives	21,005		21,005	
Total intangible assets	$ 10,723,466	$ (610,137)	$ 10,113,329	

	2005			
	Gross Carrying Value	Accumulated Amortization	Net	Weighted Average Amortization Period (in Years)
Intangible assets with finite lives:				
Patent applications pending	$ 3,029,127	$ (336,457)	$ 2,692,670	20.0
Patents	1,429,532	(506,144)	923,388	15.4
Licenses	42,461	(17,904)	24,557	15.5

Total intangible assets with finite lives	4,501,120	(860,505)	3,640,615	18.5
Intangible assets with indefinite useful lives	24,471		24,471	
Total intangible assets	$ 4,525,591	$ (860,505)	$ 3,665,086	

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

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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. See Note 3, Summary of Significant Accounting Policies Change in Accounting for Patent-Related Costs for detailed discussion.

During fiscal 2006, FazaClo product rights (see Note 17, Research and Licensing Agreements CIMA Labs Inc. Royalty Agreement), customer relationships, a trade name and a non-compete agreement were acquired in connection with the Alamo Acquisition. During fiscal 2005, there were additions of $1.3 million in capitalized patent and patent pending costs.

Amortization expense related to amortizable intangible assets was $592,000, $226,000 and $253,000 for fiscal 2006, 2005, and 2004, respectively. Charges for intangible assets abandoned and impaired for fiscal 2006, 2005 and 2004 were $8,000, $423,000 and $0, respectively. Charges for patents and patent applications pending abandoned and impaired in fiscal 2005 and 2004 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 are as follows:

Amortization Expense

Fiscal year ending September 30:	
2007	$ 1,681,000
2008	1,665,000
2009	1,525,000
2010	1,386,000
2011	1,304,000
Thereafter	2,531,000
Total	$ 10,092,000

Goodwill. In connection with the Alamo acquisition, we recognized $22.1 million goodwill in fiscal 2006 (see Note 4, Alamo Acquisition).

11. Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities at September 30, 2006 and 2005 are as follows:

	2006	2005
Accrued returns, rebates and other discounts	$ 2,371,703	$

Accrued research and development expenses	3,947,191	1,909,229
Accrued sales and marketing expenses	2,354,344	1,065,229
Deferred rent	680,730	597,551
Other	503,671	522,286
Total	$ 9,857,639	$ 4,094,295

12. Assumed Liabilities for Returns and Other Discounts

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 estimated fair value

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at the acquisition date. The following table sets forth the assumed liabilities for returns and other discounts as of September 30, 2006:

Balance, at acquisition date	$ 6,401,321
Payments for returns and other discounts	(2,421,092)
Balance, at September 30, 2006	$ 3,980,229

13. Net Deferred Revenues

The following table sets forth as of September 30, 2006 the net deferred revenue balances for our sale of future abreva® royalty rights to Drug Royalty USA, FazaClo product shipments and other agreements.

	Drug Royalty USA Agreement	FazaClo Product Shipments, Net	Other Agreements	Total
Net deferred revenues as of October 1, 2005	$ 19,049,877	$	$ 108,333	$ 19,158,210
Changes during the period:				
Shipments, net		3,955,150		3,955,150
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	$ 3,955,150	$ 2,242,262	$ 23,309,325
Classified and reported as:				
Current portion of deferred revenues,	$ 1,981,799	$ 3,955,150	$ 1,655,614	$ 7,592,563
Deferred revenues, net of current portion	15,130,114		586,648	15,716,762
Total deferred revenues	$ 17,111,913	$ 3,955,150	$ 2,242,262	$ 23,309,325

FazaClo Product The amount of deferred revenues from FazaClo product shipments is shown net of estimated rebates, returns and chargebacks. The amount that ultimately will be recognized as net revenues in our consolidated financial statements may be different. See Note 3, Significant Accounting Policies Revenue Recognition Product Sales, FazaClo, for further discussion.

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

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(Section 10) that require such performance 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. $3.8 million based on the exchange rate as of September 30, 2006), 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, 2006, 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 four 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 four years. Accordingly, we recognized $121,000 of the License Fee in fiscal 2006.

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 the United Kingdom (the Licensed Territory) (the HBI License Agreement).

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 will also be eligible to receive £750,000 (or approximately U.S. $1.4 million based on the exchange rate as of September 30, 2006) for each of the first two regulatory approvals for marketing in any countries in the Licensed Territory. If there is any subsequent divestiture or sublicense of docosanol by HBI (including through a sale of HBI), or any initial public offering of HBI s securities, we will receive an additional payment related to the future value of docosanol under the Agreement.

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

September 30, 2006, we have not completed the Data Transfer Requirements; therefore, the upfront transfer fee of $1.4 million is deferred and will be recognized as revenue upon completion of Data Transfer Requirements.

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14. 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. As of September 30, 2006, we were in possession of 9,245 square feet of this office space. The lease has scheduled rent increases each year and expires on June 14, 2011. As of September 30, 2006, the financial commitment for the remainder of the term of the lease is $2.5 million.

In connection with the Alamo acquisition, we acquired a lease for 5,750 square feet of sales and marketing offices, located in New Jersey. The lease has scheduled rent increases every year and expires in September 2009. As of September 30, 2006 the financial commitment for the remainder of the term of this lease is $383,000.

In March 2000 (as amended in February 2001), we entered into an eight-year lease for 27,212 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, 2006, the financial commitment for the remainder of the term of the lease is $1.6 million. We delivered an irrevocable standby letter of credit to the lessor in the amount of $388,122, to secure our performance under the lease.

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. As of September 30, 2006, the financial commitment for the remainder of the term of the lease is $7.0 million (excluding $766,000 rental income to be received from the sublease). We delivered an irrevocable standby letter of credit to the lessor in the amount of $468,475, to secure our performance under the lease.

Rental expenses, excluding common area charges and other executory costs, were $1.9 million in fiscal 2006, $1.8 million in fiscal 2005 and $1.8 million in fiscal 2004. Sublease rental income was $18,000 in fiscal 2006. Future minimum rental payments under non-cancelable operating lease commitments as of September 30, 2006 are as follows:

Year Ending September 30,	Minimum Payments(1)
2007	$ 2,380,000
2008	2,537,000
2009	1,782,000
2010	1,721,000
2011	1,603,000
Thereafter	1,574,000

Total	$ 11,597,000

(1) Minimum payments have not been reduced by minimum sublease rentals of $766,000. Due in the future under noncancelable subleases.

Capital lease commitments. In September 2001, January 2002 and May 2002, we acquired several pieces of equipment under three-year, four-year and five-year capital lease obligations, respectively. Each of these capital leases provides us with the option at the expiration of the lease term to purchase all the equipment leased for a price

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of one dollar ($1.00). In connection with the Alamo acquisition in May 2006, we acquired certain automobiles under 36-month capital lease obligations. Each of these capital leases provides us with the option at the expiration of the lease term to purchase the automobile leased for a price of $250 plus over mileage charge at 4 cents per mile.

Future minimum payments under the capital leases as of September 30, 2006 are as follows:

Year Ending September 30,	Minimum Payments
2007	$ 252,479
2008	172,092
Total	424,571
Less amount representing interest	(22,903)
Present value of net lease payments	401,668
Less current portion	(230,760)
Long-term portion of obligation	$ 170,908

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.

Employment and Severance Agreements. We have an employment agreement with our Chief Executive Officer, which provides for minimum salaries, as adjusted, incentive bonuses and share-based award and severance provisions in the event of termination under specified conditions, including change of control. We also have employment agreements and change of control severance agreements with our Chief Financial Officer and certain other executive officers (Employees). The employment agreements provide for severance payments in the event of termination without cause. The employment agreements provide for severance payments in the event of termination without cause or resignation with good reason (as such terms are defined). If these conditions are met for a particular Employee, that Employee will receive severance payments equal to certain number of months of base salary (ranges from six to twelve months), plus an amount equal to the greater of (a) certain percentage of the Employee s base salary or (b) certain percentage of the last bonus payment received by such Employee in the Company s preceding fiscal year. The change in control severance agreements provide for severance payments in the event that employment is involuntarily terminated in connection with a change in control of the Company. These severance benefits will be paid

only if (i) the termination of employment occurs within 12 months following the change of control and (ii) the termination was without cause or was a resignation for good reason (as such terms are defined). If these conditions are met for a particular Employee, the Employee will receive severance payments equal to either 12 or 24 months of base salary, plus an amount equal to the greater of (A) the aggregate bonus payment(s) received by such Employee in the Company s preceding fiscal year or (B) the Employee s then-current target bonus amount. Additionally, the vesting of outstanding equity awards will accelerate and the Employee will be entitled to up to 12 months of post-termination Company-paid benefits continuation under COBRA.

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15. Notes Payable

As of September 30, 2006 and 2005, notes payable consist of the following:

	September 30, 2006	2005
Senior notes with an interest rate of LIBOR + 1.33%; interest payable monthly; principal due May 2009, net of $646,600 unamortized discount	$ 24,428,400	$
9.5% equipment loan due April 2008	451,405	703,560
7.9% business insurance financing due June 2007	320,957	
10.43% equipment loan due February 2009	106,170	142,881
10.17% equipment loan due January 2009	79,710	108,511
Total	25,386,642	954,952
Less: current portion	(670,737)	(317,667)
Total long-term notes payable	$ 24,715,905	$ 637,285

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%. LIBOR rate at September 30, 2006 was 5.33%. 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 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. Subsequent to September 30, 2006, we completed an equity offering and received net offering proceeds of approximately $14.4 million. See Note 23, Subsequent Events, for further discussion. As a result, we repaid $2.9 million against the First Note in November 2006. We classified the Notes as long term, because they are not reasonably expected to require the use of existing resources.

If the Selling Holders demand repayment of the First Note following satisfaction of the Stock Contingency, we must repay the First Note within 180 days from the demand in our choice of cash or shares of common stock. At our sole option, if we elect to repay the First Note in shares of 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 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 have fair values of $14.0 million, $6.4 million, and $3.9 million, respectively. These fair value amounts were determined by discounting the expected payments on the notes to present value based on a 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

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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.

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, 2006 and 2005 under the GE Capital finance agreement is approximately $637,000 and $955,000, 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.

Insurance Financing. In fiscal 2006, we obtained $360,000 from a third party to facilitate annual payments on certain insurance premiums. The financing is for a term of nine months at an annual interest rate of 7.9% with a monthly payment of approximately $41,000. The balance of this note is $321,000 at September 30, 2006.

Aggregate annual maturities of notes payable as of September 30, 2006, are as follows:

Year Ending September 30,	Minimum Payments
2007	$ 2,394,674
2008	1,935,682
2009	26,359,243
Total	30,689,599
Less amount representing interest	(5,302,957)
Present value of payments	25,386,642
Less current portion	(670,737)
Long-term portion of obligation	$ 24,715,905

16. Shareholders (Deficit) Equity

The share and per share amounts and share prices have been adjusted for a one-for-four reverse stock split. See Note 2, Reverse Stock Split.

On April 1, 2004, we amended and restated our Articles of Incorporation, pursuant to the authority granted us by our shareholders at our 2004 Annual Meeting of Shareholders. Upon the filing of our Amended and Restated Articles of Incorporation, we eliminated all classes and series of stock that were no longer outstanding and increased our authorized Class A common stock to 200 million shares. As of September 30, 2006 and 2005, we have authorized 200 million shares of Class A common stock and 10 million shares of preferred stock, of which 1 million shares have been designated Class C Junior Participating Preferred.

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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, 2006 and 2005. The Plan provided for a dividend distribution of one preferred share purchase right (the Right) on each outstanding share of our Class A common stock, payable on shares outstanding as of March 25, 1999 (the Record Date). All shares of Class A common stock issued by the Company after the Record Date have been issued with such Rights attached. Subject to limited exceptions, the Rights would become exercisable if a person or group acquires 15% or more of our common stock or announces a tender offer for 15% or more of our common stock (a Trigger Event).

If and when the Rights become exercisable, each Right will entitle shareholders, excluding the person or group causing the Trigger Event (an Acquiring Person), to buy a fraction of a share of our Series C junior participating preferred stock at a fixed price. In certain circumstances following a Trigger Event, each Right will entitle its owner, who is not an Acquiring Person, to purchase at the Right s then current exercise price, a number of shares of Class A 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

Class A common stock.

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 Class A common stock at the market price of $6.73.

Also during fiscal 2006, we issued an aggregate of 1,352,382 shares of Class A 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 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 Class A 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

award was exercised to purchase all of 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 2 days before, the day of, and 2 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 3, Significant Accounting Policies Change in Accounting Method for Share-based Compensation.

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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 was vested.

In April 2005, we issued and sold 1,942,500 shares of Class A 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 Class A 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 19, Related Party Transactions, for further discussions.

In December 2004, we issued and sold to an institutional investor 583,333 shares of Class A 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 Class A 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.

Fiscal 2004. In August 2004, we issued to the Ciblex Corporation 259,202 shares of Class A common stock in connection with an amendment to that certain Technology Acquisition Agreement with Ciblex dated August 2001.

In June 2004, we completed an underwritten public offering of 4,921,260 shares of Class A common stock at $5.08 per share ($4.72 per share after underwriter s discount). The financing transaction was made pursuant to the terms of an underwriting agreement. On June 10, 2004, the underwriter exercised its option to purchase from us an additional 738,189 shares of Class A common stock at the public offering price of $5.08 per share ($4.72 per share after underwriter s discount) to cover over-allotments. This offering generated net proceeds of approximately $26.5 million after the underwriter s discount of $2.0 million and issuance costs of approximately $267,000.

In December 2003, we sold and issued 1,345,579 shares of Class A common stock and warrants to purchase an additional 807,347 shares of Class A common stock to several accredited investors and received approximately $8.0 million in gross proceeds. The warrant exercise price is $7.00 per share. The financing transaction was made pursuant to the terms of a securities purchase agreement that provided each investor with a warrant to purchase six-tenths of a share of Class A common stock for every share of Class A common stock purchased under the agreement. The effect of the financing transaction was an increase in cash and shareholders equity in the amount of approximately $7.5 million after taking into effect the costs of the transaction. In connection with this transaction and its costs, the placement agent was paid $415,000 in fees and expenses, and issued a warrant to purchase 40,367 shares of our Class A common stock at $7.00 per share.

Also during fiscal 2004, we issued an aggregate of 104,726 shares of Class A common stock in connection with the exercise of stock purchase warrants (73,724 shares at a weighted average price of $6.36 per share) and employee stock

options (31,002 shares at a weighted average price of $5.20 per share) for cash in the aggregate amount of approximately $609,000, representing a weighted average price per share of $5.80.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

A summary of common stock transactions during fiscal 2006, 2005 and 2004 are shown below.

Common Stock Issued and Warrants and Stock Options Exercised	Date	Class A Common Stock	Gross Amount Received(1)	Average Price Per Share(2)
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	$ 0.00
Stock options	Various	524,807	3,264,953	$ 6.22
Warrants(4)	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	$ 0.00
Stock options	Various	27,974	125,491	$ 4.49
Warrants(4)	Various	211,486	1,293,339	$ 6.12
Total		3,515,293	$ 30,813,829	
Fiscal year ended September 30, 2004:				
Underwritten public offering(3)	June 2005	5,659,449	$ 26,737,500	$ 4.72
Private placement of common stock and warrants	December 2004	1,345,579	8,019,652	$ 5.96
Issuance of common stock to Ciblex	August 2005	259,202	2,733,023	$ 10.54
Conversions of Class B common stock	Various	3,375	8,395	$ 2.49
Stock options	Various	31,002	160,823	$ 5.19
Warrants(4)	Various	73,724	448,671	$ 6.09
Total		7,372,331	$ 38,108,064	

(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) Price per share of $4.72 in the underwritten public offering is after underwriter s discount of $2.0 million, representing approximately $0.36 per share.

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

Class B common stock conversions. As of September 30, 2004, there were no shares of Class B common stock issued or outstanding. During fiscal 2004, 3,375 shares of Class B common stock were converted to 3,375 shares of Class A common stock. In March 2004, our shareholders voted on, and approved an amendment to our articles of incorporation that eliminated our Class B common stock.

Warrants

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 Class A common stock in connection with our call for redemption of a group

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of outstanding warrants. The warrants had been issued in connection with a financing transaction in December 2003 involving the sale of Class A 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 and that the Warrants would expire, to the extent unexercised, on February 7, 2006. One of the warrants to purchase 25,167 shares of Class A common stock expired unexercised.

Also during fiscal 2006, Class A warrant holders exercised their rights to purchase an aggregate of 155,652 shares of Class A common stock for total cash of $1.2 million. As of September 30, 2006, Class A warrants to purchase 269,305 shares at $8.92 remained outstanding.

The following table summarizes all warrant activity for fiscal 2006, 2005 and 2004:

	Shares of Class A Common Stock Purchasable Upon Exercise of Warrants	Weighted Average Exercise Price per Share	Range of Exercise Prices
Outstanding at October 1, 2003	572,475	$ 7.64	$ 3.64 - $10.88
Issued	850,727	$ 7.00	$ 7.00
Tendered(1)	(7,720)	$ 4.20	$ 4.20
Exercised	(73,724)	$ 6.36	$ 4.20 - $ 7.00
Expired	(8,219)	$ 9.76	$ 9.76
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

(1) Warrant shares tendered represent 7,720 in the amount of warrant shares given up, in lieu of cash, for warrants exercised (cashless exercise).

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. Stock-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 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, 2006, we had an aggregate of 2,207,305 shares of our common stock reserved for issuance. Of those shares, 1,527,800 were subject to outstanding options and other awards and 679,505 shares were available for future grants of share-based awards. We also issued share-based awards outside of the Plans. As of September 30, 2006, options to purchase

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140,000 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, 2006.

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 Class A common stock, plus an annual increase beginning in fiscal 2006 equal to the lesser of (a) 1% of the shares of Class A common stock outstanding on the last day of the immediately preceding fiscal year, (b) 325,000 shares of Class A common stock, or (c) such lesser number of shares of Class A common stock as the board of directors shall determine. Pursuant to the provisions of annual increases, the number of authorized shares of Class A common stock for issuance under the 2005 Plan increased by 273,417 shares to 773,417 shares effective November 16, 2005. In February 2006, our shareholders eliminated the limitation on number of shares of Class A common stock that may be issued 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, 2006 and 2005, 249,687 and 321,250 shares of Class A common stock, respectively, remained available for issuance under the 2005 Plan. On November 30, 2006, the number of shares of Class A common stock available for issuance under the 2005 Plan increased by 317,084 shares in accordance with the provisions for annual increases 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 Class A common stock, plus an annual increase beginning January 2004 equal to the lesser of (a) 5% of the number of shares of Class A common stock outstanding on the immediately preceding December 31, or (b) a number of shares of Class A common stock set by the board of directors. 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, 2006 and 2005, 343,813 and 582,500 shares of Class A common stock, respectively, remained available for issuance under the 2003 Plan. On November 30, 2006, the number of shares of Class A common stock available for issuance under the 2003 Plan increased by 1,528,474 shares in accordance with the provisions for annual increases 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 Class A 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 Class A 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, 2006 and 2005, 75,721 and 2,442 shares of Class A common stock, respectively, 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 Class A common stock. The 1998 Plan allows us to grant options to our directors, officers, employees and consultants. As of September 30, 2006 and 2005, options to purchase 10,284 and 1,826 shares of Class A common stock, respectively, 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.

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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 2006 are presented below.

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value
Outstanding, October 1, 2003	1,327,151	$ 7.84		
Granted	60,750	$ 7.24		
Exercised	(31,002)	$ 5.20		
Forfeited	(18,616)	$ 11.06		
Expired	(24,885)	$ 10.16		
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	7.2	$ 817,000
Vested and expected to vest in the future, September 30, 2006	1,472,726	$ 10.05	7.2	$ 799,000
Exercisable, September 30, 2006	765,411	$ 8.98	5.0	$ 732,000
Exercisable, September 30, 2005	1,257,896	$ 7.92		
Exercisable, September 30, 2004	1,164,103	$ 7.96		

The weighted average grant-date fair values of options granted during fiscal 2006, 2005 and 2004 were $6.85, $11.36 and $7.24 per share, respectively. The total intrinsic value of options exercised during fiscal 2006, 2005 and 2004 was $4.6 million, $228,000 and $72,000, respectively, based on the differences in market prices on the dates of exercise and the option exercise prices.

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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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 2006, 2005 and 2004 were as follows:

	2006	2005	2004
Expected volatility	77.4% - 80.4%	76.6% - 130.2%	132.9 - 133.3%
Weighted-average volatility	78.4%	95.5%	133.1%
Average expected term in years	4.5	3.4	3.4
Risk-fee interest rate (zero coupon U.S. Treasury Note)	4.5%	3.8%	2.4%
Expected dividend yield	0%	0%	0%

The following table summarizes information concerning outstanding and exercisable Class A stock options as of September 30, 2006**:**

	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 $ 4.64	214,271	4.2	$ 3.98	214,271	$ 3.98
$ 5.12 $ 6.92	234,725	6.3	$ 6.13	124,225	$ 6.10
$ 7.12 $ 9.92	196,921	6.6	$ 8.66	132,128	$ 8.99
$10.10 $10.70	181,750	9.6	$ 10.64	3,126	$ 10.24
$11.08 $11.76	327,892	8.7	$ 11.69	45,914	$ 11.70
$12.12 $13.84	262,061	7.2	$ 13.26	183,797	$ 13.33
$14.28 $19.38	169,450	7.6	$ 16.19	61,950	$ 17.10
	1,587,070	7.2	$ 10.07	765,411	$ 8.98

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 2006:

	Weighted Average

	Number of Shares		Grant Date Fair Value
Unvested, October 1, 2005		$	
Granted	51,480	$	15.54
Vested		$	
Forfeited		$	
Unvested, September 30, 2006	51,480	$	15.54

The grant-date fair value of RSUs granted during fiscal 2006 was $800,000. No RSUs were granted during fiscal 2005 and 2004. As of September 30, 2006, the total unrecognized compensation cost related to unvested shares was $550,000, which is expected to be recognized over a weighted-average period of 2.4 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 as September 30, 2006 and changes during the fiscal year then ended are presented below.

	Number of Shares		Weighted Average Grant Date Fair Value
Unvested, October 1, 2005	250,000	$	14.22
Granted	57,250	$	11.34
Vested	(83,335)	$	14.22
Forfeited		$	
Unvested, September 30, 2006	223,915	$	13.48

The grant-date fair value of restricted stock awards granted fiscal 2006 was $649,000. No restricted stock awards were granted in fiscal 2005 and 2004. As of September 30, 2006, the total unrecognized compensation cost related to unvested shares was $2.4 million, which is expected to be recognized over a weighted-average period of 1.7 years.

During fiscal 2006, 2005 and 2004, we received a total of $3.3 million, $126,000 and $161,000, 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-base payment arrangements in fiscal 2006, 2005 and 2004.

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 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.

17. Research and Licensing Agreements

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

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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. 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 grants, through our Alamo subsidiary, an exclusive license to us to market, distribute and sell FazaClo. The FazaClo Supply Agreement provides 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 are as follows:

Twelve-month period ending December 31:	
2006	$ 250,000
2007	$ 300,000
2008 and each year thereafter	$ 400,000

Royalty expense is recognized in cost of product sales when revenue from FazaClo shipments is recognized. As of September 30, 2006, $106,000 in royalty costs were paid but not recognized as expense and are included in prepaid expenses and other current assets in the accompanying consolidated balance sheets.

18. 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. Under the terms of the agreement, we will be eligible to receive royalty payments, assuming the licensed product is successfully developed by AstraZeneca and approved for marketing by the FDA. We are 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 is approved for marketing by the FDA. Pursuant to the agreement with AstraZeneca, we will 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 has standalone value from the research activities, which is 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 is solely responsible for ongoing development costs and efforts. We are not obligated to, and

do not, take part in the ongoing development of any of the compounds, nor is our expertise and knowledge necessary for AstraZeneca s continued development.

Also under the agreement, AstraZeneca is 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 provide to AstraZeneca are for specific projects and research activities assigned and directed by AstraZeneca that are primarily in connection with discovery of a screening assay, which is a unique method of testing or screening for additional compounds that

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could be used for the same therapeutic target. Such additional research and testing activities performed by us are not necessary for the successful development of the licensed compounds. Further, a reduction in, or termination of, the research services under the agreement would 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 be entitled to receive if the licensed compounds are successfully developed and commercialized by AstraZeneca. The rate being billed by us for the services represents fair value for such services, and is 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 are separate units of accounting, because the license has value to AstraZeneca on a standalone basis, there is objective and reliable evidence of the fair value of the undelivered research collaboration services and there is no right of return or refund relative to the license. We determined that the license fee has a standalone value because similar technology is sold separately by other vendors and AstraZeneca has the ability to sell or transfer the license. Revenue from research and development services is recognized during the period in which the services are performed and is based upon the number of FTE personnel working on the project at the agreed-upon rates. Payments related to substantive, performance-based milestones are 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 $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 $5.8 million and $825,000 in fiscal 2006 and 2005, respectively.

Novartis International Pharmaceutical Ltd. (Novartis). In April 2005, we entered into an exclusive license and research collaboration agreement with Novartis regarding the license of certain compounds that regulate macrophage migration inhibitory factor (MIF) in the treatment of various inflammatory diseases. Under the terms of the agreement, we will be eligible to receive royalty payments, assuming the licensed product is successfully developed by Novartis and approved for marketing by the FDA. We are also eligible to receive up to $198 million in milestone payments contingent upon Novartis performance and achievement of certain development and regulatory milestones, including approval for certain additional indications, and regulatory milestones, which could take several years of further development by Novartis, including achievement of certain sales targets, if a licensed compound is approved for marketing by the FDA. Pursuant to the agreement with Novartis, we will also perform certain research activities directed and funded by Novartis.

Under this agreement, we received a data transfer fee of $2.5 million that we recognized as revenue in May 2005 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 has 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 controls all aspects of development of the licensed compounds that were provided by us under the agreement, and is solely responsible for ongoing development costs and efforts. We are not obligated to, and do not, take part in the ongoing development of any of the compounds, nor is our expertise and knowledge necessary for Novartis continued development.

Also under the agreement, Novartis is 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 provide to Novartis are for specific projects and research activities assigned and directed by Novartis. Such additional research and testing activities performed by us are not necessary for the successful development of the licensed compounds. Further, a reduction in, or termination of, the research services under the agreement would 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 would be entitled to receive if one

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or more of the licensed compounds are successfully developed and commercialized by Novartis. The rate being billed by us for the services represents fair value for such services, and is 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 are separate units of accounting, because the license has value to Novartis on a standalone basis, there is objective and reliable evidence of the fair value of the undelivered research collaboration services and there is no right of return or refund relative to the license. We determined that the license fee has a standalone value because similar technology is sold separately by other vendors and Novartis has the ability to sell or transfer the license. Revenue from research and development services is recognized during the period in which the services are performed and is based upon the number of FTE personnel working on the project at the agreed- upon rates. Payments related to substantive, performance-based milestones are 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 $2.0 million and $682,000 in fiscal 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 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.

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.

CTS Chemical Industries, Ltd. (CTS). In July 1993, we entered into a license agreement with CTS giving them the rights to manufacture and sell docosanol 10% cream as a topical cold sore treatment in Israel. The five-year period of the license began in June 2002, the date of approval of the product by regulatory agencies in Israel. Under the terms of the agreement, CTS is responsible for manufacturing, marketing, sales and distribution of docosanol 10% cream in Israel, and paying a royalty to us on product sales. The agreement includes a supply provision under which CTS purchases its entire requirement of active ingredient from us for use in the manufacture of topical docosanol 10% cream. CTS launched the product, Abrax, in January 2003.

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.

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Avanir Pharmaceuticals

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 13, Deferred Revenue.)

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.

P.N. Gerolymatos SA. (Gerolymatos). In May 2004, we signed an exclusive agreement with Gerolymatos giving them the rights to manufacture and sell docosanol 10% cream as a treatment for cold sores in Greece, Cyprus, Turkey and Romania. Under the terms of the agreement, Gerolymatos will be responsible for all sales and marketing activities, as well as manufacturing and distribution of the product. The terms of the agreement provide for us to receive a license fee, royalties on product sales and milestones related to product approvals in Greece, Cyprus, Turkey and Romania. This agreement will continue until the latest of the 12th anniversary of the first commercial sale in each of those respective countries, or the date that the patent expires, or the last date of the expiration of any period of data exclusivity in those countries. Gerolymatos is also responsible for regulatory submissions to obtain marketing approval of the product in the licensed territories.

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.

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. 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, 2006 and 2005 was approximately $2.0 million and $161,000, respectively.

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Avanir Pharmaceuticals

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

19. 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.

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. The balance of accrued but unpaid severance payment obligations for Dr. Yakatan is approximately $0 and $319,000 as of September 30, 2006 and 2005, respectively.

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.

Fair Value Analysis. Standard & Poor s Corporate Value Consulting group (S&P) served as the financial advisor to the Corporate Governance Committee, which negotiated the contract on behalf of the Board and the Company. S&P reviewed the terms of the Asset Purchase Agreement and provided the Committee with a favorable

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Avanir Pharmaceuticals

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

opinion regarding the fairness, from a financial point of view, of the agreement to Avanir and its shareholders. In assessing the value of the assets acquired pursuant to the agreement, S&P considered 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.

Research and development. In June 2003, we engaged IriSys to continue Zenvia stability studies previously being carried out for us by another company that was no longer in the business of providing such services. The service arrangement was transferred to IriSys following termination with the other company because IriSys was already familiar with the stability protocol. During fiscal 2006, 2005 and 2004, we paid IriSys $0, $0 and $4,200, respectively, related to continuation of the stability testing.

20. Income Taxes

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

	2006	2005	2004
Current:			
State and foreign	$ (2,430)	$ (1,813)	$ (2,664)
Deferred:			
Federal	20,625,828	10,143,270	10,900,106
State	(540,800)	5,017,269	246,528
	20,085,028	15,160,539	11,146,634
Increase in deferred income tax asset valuation allowance	(20,085,028)	(15,160,539)	(11,146,634)
Total income tax provision	$ (2,430)	$ (1,813)	$ (2,664)

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:

	2006	2005	2004
Federal statutory rate	(34)%	(34)%	(34)%
Increase in deferred income tax asset valuation allowance	32	50	40
State income taxes, net of federal effect	(5)	(6)	(6)
Research and development credits	(2)	(5)	(4)
Expired net operating loss and other tax credits	2		1
Other	7	(5)	3

Effective income tax rate	0%	0%	0%

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Avanir Pharmaceuticals

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 2006	September 30, 2005
Net operating loss carryforwards	$ 64,594,100	$ 46,522,001
Deferred revenue	9,274,407	7,631,558
Research credit carryforwards	9,682,998	8,799,375
Capitalized research and development costs	1,800,079	2,216,029
Capitalized license fees and patents	4,037,033	2,959,707
Share-based compensation and options	1,136,117	
Purchased intangible assets	450,751	
Foreign tax credits	595,912	595,912
Other	2,036,885	779,763
Deferred income tax assets	93,608,282	69,504,345
Less valuation allowance for net deferred income tax assets	(93,608,282)	(69,504,345)
	$	$

We have provided a full valuation allowance against the net deferred income tax assets recorded as of September 30, 2006 and 2005 as we concluded that they are unlikely to be realized. The net operating loss and research credit carryforwards expire on various dates through 2026. We also have foreign tax credit carryforwards of $596,000, which begin to expire in 2011, unless previously utilized. In the event of certain ownership changes, the Tax Reform Act of 1986 imposes certain restrictions on the amount of net operating loss carry forwards that we may use in any year. As of September 30, 2006, we had $175.7 million and $91.5 million of Federal and State net operating loss carryforwards, respectively. As of September 30, 2006, we had $5.9 million and $5.3 million of Federal and California research and development credit carryforwards, respectively.

21. Employee Savings Plan

We have established an employee savings plan pursuant to Section 401(k) of the Internal Revenue Code. The plan allows participating employees to deposit into tax deferred investment accounts up to 50% of their salary, subject to annual limits. We are not required to make matching contributions under the plan. However, we voluntarily contributed $132,000 in fiscal 2006, $96,000 in fiscal 2005 and $56,000 in fiscal 2004 to the plan.

22. 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 2006, 2005 and 2004 are attributed to the United States. All long-lived assets at September 30, 2006 and 2005 are located in the United States.

Revenues derived from our license agreements with AstraZeneca and Novartis accounted for approximately 71% and 13%, respectively, of our total revenues in fiscal 2006 and 66% and 19%, respectively, of our total revenues in fiscal 2005. Approximately 13%, 10% and 48% of our total revenues in fiscal 2006, 2005 and 2004, 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 26% and 3%,

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Avanir Pharmaceuticals

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

respectively, of our net receivables at September 30, 2006 and 81% and 5%, respectively, of our total net receivables at September 30, 2005.

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. Net receivables from McKesson Corporation, AmeriSourceBergen Corporation and Cardinal Health accounted for 27%, 11% and 14%, respectively, of our total net receivables at September 30, 2006.

23. Subsequent Events

Approvable Letter On October 30, 2006, we received an approvable letter from the FDA for our NDA submission for Zenvia for the treatment of IEED/PBA. 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 has regarding the efficacy and safety data contained in our NDA submission, which may require additional clinical trials and data in order to obtain marketing approval. The principal questions and/or concerns raised in the approvable letter related to the following: (i) the choice of statistical methods used to analyze a secondary endpoint in the ALS trial and whether the requirements of the combination drug policy have been met and (ii) safety concerns relating to Zenvia s active ingredients, dextromethorphan and quinidine sulfate, particularly for the patient population that would be prescribed Zenvia.

Because the approvable letter did not specify the exact data and what additional clinical trials may be required, if any, we have requested a meeting with the FDA in the first quarter of 2007 to clarify what would be needed for marketing approval. Until we meet with the FDA, we will not know how extensive any required additional data and/or trials are likely to be. However, we believe that it is likely that the FDA s requirements for additional data may be substantial and that we may be required to undertake additional trials that would be costly and time consuming. Accordingly, we cannot be certain that, once we have met with the FDA, we will continue the development of Zenvia as previously planned. We submitted the NDA for Zenvia in January 2006, seeking to market Zenvia for the treatment of IEED/PBA in patients with neurologic diseases and brain injuries.

Following receipt of the approvable letter from the FDA for Zenvia, we have taken several steps intended to significantly reduce on-going operating expenses. Effective November 9, 2006, we have suspended all commercial initiatives focused on Zenvia for the treatment of IEED and have reduced research and development expenses including placing on hold activities associated with the selective cytokine inhibitor clinical development program.

Sale of Common Stock and Warrants On November 3, 2006, we entered into a securities purchase agreement with certain investors pursuant to which we issued and sold 5,265,000 shares of Class A common stock at a price of $2.85 per share (the Offering). As part of the Offering, the purchasers also received warrants to purchase a total of 1,053,000 shares of Class A common stock at an exercise price of $3.30 per share. The warrants become exercisable six months after the closing on November 7, 2006 and then remain exercisable for a period of six months. The gross proceeds of the offering were approximately $15.0 million, before offering expenses and commissions, and the net offering proceeds were approximately $14.4 million. The offering was made pursuant to our shelf registration statement on Form S-3 filed on July 22, 2005. Pursuant to the terms of the Notes, $2.9 million of the funds raised were used to repay the first note.

* * * * *

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Exhibit Index

3.1	Restated Articles of Incorporation of the Registrant, dated April 1, 2004(13)
3.2	Amended and Restated Bylaws of the Registrant, dated September 25, 2005(14)
4.1	Form of Class A Common Stock Certificate(1)
4.2	Certificate of Determination with respect to Series C Junior Participating Preferred Stock of the Registrant(2)
4.3	Rights Agreement, dated as of March 5, 1999, with American Stock Transfer & Trust Company(2)
4.4	Form of Rights Certificate with respect to the Rights Agreement, dated as of March 5, 1999(2)
4.5	Amendment No. 1 to Rights Agreement, dated November 30, 1999, with American Stock Transfer & Trust Company(4)
4.6	Form of Class A Stock Purchase Warrant, issued in connection with the Securities Purchase Agreement dated July 21, 2003(10)
4.7	Form of Class A Stock Purchase Warrant, issued in connection with the Securities Purchase Agreement dated November 25, 2003(11)
10.1	License Agreement, dated March 31, 2000, by and between Avanir Pharmaceuticals and SB Pharmco Puerto Rico, a Puerto Rico Corporation(5)
10.2	License Agreement, dated November 22, 2002, by and between Avanir Pharmaceuticals and Drug Royalty USA, Inc.(17)
10.3	Research, Development and Commercialization Agreement, dated April 27, 2005, by and between Avanir Pharmaceuticals and Novartis International Pharmaceutical Ltd.*(18)
10.4	Research Collaboration and License Agreement, dated July 8, 2005, by and between Avanir Pharmaceuticals and AstraZeneca UK Limited*(23)
10.5	Standard Industrial Net Lease by and between Avanir Pharmaceuticals and BC Sorrento, LLC, effective September 1, 2000(6)
10.6	Standard Industrial Net Lease by and between Avanir Pharmaceuticals (Tenant) and Sorrento Plaza, a California limited partnership (Landlord), effective May 20, 2002(8)
10.7	Office lease agreement by and between RREEF AMERICA REIT II CORP. FFF and Avanir Pharmaceuticals, dated April 28, 2006
10.8	License Agreement, dated August 1, 2000, by and between Avanir Pharmaceuticals (Licensee) and Irisys Research and Development, LLC, a California limited liability company(6)
10.9	Sublease agreement between Avanir Pharmaceuticals and Sirion Therapeutics, Inc., dated September 5, 2006
10.10	License Agreement, dated April 2, 1997, by and between Irisys Research & Development, LLC and the Center for Neurologic Study(16)
10.11	Amendment to License Agreement, dated April 11, 2000, by and between IriSys Research & Development, LLC and the Center for Neurologic Study(16)
10.12	Clinical Development Agreement, dated March 22, 2005, by and between Avanir Pharmaceuticals and SCIREX Corporation(16)
10.13	Unit Purchase Agreement by and among AVANIR Pharmaceuticals, the Sellers and Alamo Pharmaceuticals, LLC, dated May 22, 2006*(24)
10.14	Senior Note for $14.4 million payable to Neal R. Cutler, dated May 24, 2006(24)
10.15	Senior Note for $6,675,000 payable to Neal R. Cutler, dated May 24, 2006(24)
10.16	Senior Note for $4.0 million payable to Neal R. Cutler, dated May 24. 2006(24)
10.17	Registration Rights Agreement between Avanir Pharmaceuticals and Neil Cutler, dated May 24, 2006(24)
10.18	Amended and Restated Development, License and Supply Agreement by and between CIMA Labs Inc. and Alamo Pharmaceuticals, LLC, dated August 22, 2005*(24)
10.19	

	Amendment #1 to Amended and Restated Development, License and Supply Agreement by and between CIMA Labs Inc. and Alamo Pharmaceuticals, LLC, dated October 19, 2005*(24)
10.20	Docosanol License Agreement between Kobayashi Pharmaceutical Co., Ltd. and AVANIR Pharmaceuticals, dated January 5, 2006*(28)

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10.21	Docosanol Data Transfer and Patent License Agreement between AVANIR Pharmaceuticals and Healthcare Brands International Limited, dated July 6, 2006*
10.22	Development and License Agreement between Eurand, Inc. and AVANIR Pharmaceuticals, dated August 7, 2006*
10.23	Amended and Restated 1998 Stock Option Plan(7)
10.24	Amended and Restated 1994 Stock Option Plan(7)
10.25	Amended and Restated 2000 Stock Option Plan(9)
10.26	Form of Restricted Stock Grant Notice for use with Amended and Restated 2000 Stock Option Plan(9)
10.27	2003 Equity Incentive Plan(9)
10.28	Form of Non-qualified Stock Option Award Notice for use with 2003 Equity Incentive Plan(9)
10.29	Form of Restricted Stock Grant for use with 2003 Equity Incentive Plan(9)
10.30	Form of Restricted Stock Grant Notice (cash consideration) for use with 2003 Equity Incentive Plan(9)
10.31	Form of Indemnification Agreement with certain Directors and Executive Officers of the Registrant(12)
10.32	2005 Equity Incentive Plan(23)
10.33	Form of Stock Option Agreement for use with 2005 Equity Incentive Plan(20)
10.34	Form of Restricted Stock Unit Agreement for use with 2005 Equity Incentive Plan and 2003 Equity Incentive Plan
10.35	Form of Restricted Stock Agreement for use with 2005 Equity Incentive Plan
10.36	Form of Change of Control Agreement(26)
10.37	Employment Agreement with Eric Brandt, dated August 15, 2005*(23)
10.38	Employment Agreement with Keith Katkin, dated June 13, 2005(23)
10.39	Employment Agreement with Michael J. Puntoriero, dated May 4, 2006
10.40	Employment Agreement with Randall Kaye, dated December 23, 2005(25)
10.41	Employment Agreement with Theresa Hope-Reese, dated August 7, 2006(27)
18.1	Letter regarding change in accounting principle
21.1	List of Subsidiaries
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.3	Certification of Chief Accounting Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.3	Certification of Chief Accounting Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

* Certain confidential portions of this exhibit have been retracted. A complete copy of this exhibit has been filed with the Secretary of the Securities and Exchange Commission pursuant to an application requesting confidential treatment under Rule 246-2 of the Securities Exchange Act of 1934.

(1) Incorporated by reference to the similarly described exhibit included with the Registrant s Registration Statement on Form S-1, File No. 33-32742, declared effective by the Commission on May 8, 1990.

(2) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K, filed March 11, 1999.

(3) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K, filed April 1, 1999.

(4) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K, filed December 3, 1999.

(5) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K, filed May 4, 2000.

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(6) Incorporated by reference to the similarly described exhibit included with the Registrant s Quarterly Report on Form 10-Q, filed August 14, 2000.

(7) Incorporated by reference to the similarly described exhibit included with the Registrant s Annual Report on Form 10-K, filed December 21, 2001.

(8) Incorporated by reference to the similarly described exhibit included with the Registrant s Quarterly Report on Form 10-Q, filed August 13, 2002.

(9) Incorporated by reference to the similarly described exhibit included with the Registrant s Quarterly Report on Form 10-Q, filed May 13, 2003.

(10) Incorporated by reference to the similarly described exhibit included with the Registrant s Registration on From S-3, File No. 333-107820, declared effective by the Commission on August 19, 2003.

(11) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K, filed December 11, 2003.

(12) Incorporated by reference to the similarly described exhibit included with the Registrant s Annual Report on Form 10-K, filed December 23, 2003.

(13) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K, filed on April 6, 2004.

(14) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K, filed September 28, 2005.

(15) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K, filed September 21, 2004.

(16) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 10-Q, filed May 13, 2005.

(17) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K, filed January 7, 2003.

(18) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 10-Q, filed August 12, 2005.

(19) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K, filed March 23, 2005.

(20) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K, filed October 24, 2005.

(21) Incorporated by reference to the similarly described exhibit included with the Registrant s Annual Report on Form 10-K, filed December 14, 2005.

(22)

Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 10-Q, filed August 9, 2006.

(23) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 10-Q, filed February 9, 2006.

(24) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K, filed June 26, 2006.

(25) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 8-K, filed August 10, 2006.

(26) Incorporated by reference to the similarly described exhibit included with the Registrant s Current Report on Form 10-Q, filed May 10, 2006.