AVANIR PHARMACEUTICALS
Form 10-K
December 14, 2005

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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, 2005

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.)*
11388 Sorrento Valley Road, San Diego, California	**92121**
(Address of principal executive offices)	*(Zip Code)*

(858) 622-5200
(Registrant s telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:
None
Securities registered pursuant to Section 12(g) of the Act:
Class A Common Stock, no par value

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 an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes þ No o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2of 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, 2005 was approximately $197,000,000, 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.

116,049,821 shares of the registrant s Common Stock were issued and outstanding as of December 12, 2005.

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, which will be filed with the Securities and Exchange Commission in connection with the registrant s Annual Meeting of Shareholders to be held on February 6, 2006.

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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 and expect and 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 obligation to update or announce revisions to any forward-looking statements to reflect actual events or developments. Except as otherwise indicted herein, all dates referred to in this Report represent periods or dates fixed with reference to the calendar year, rather than our fiscal year ending September 30.

The Company

Avanir Pharmaceuticals is a pharmaceutical company focused on developing and commercializing novel therapeutic products for the treatment of chronic diseases. Our product candidates address therapeutic markets that include the central nervous system, atherosclerosis, inflammatory diseases and infectious diseases. We are currently developing Neurodex[tm] for the treatment of pseudobulbar affect (PBA), also known as emotional lability, and for the treatment of chronic diabetic neuropathic pain. We are in the process of finalizing the submission to the U.S. Food and Drug Administration (FDA) of our new drug application (NDA) for Neurodex for the treatment of PBA. Additionally, in June 2005 we initiated a Phase III clinical trial of Neurodex in patients with diabetic neuropathic pain.

Our research and drug discovery programs are focused primarily on small molecules that can be taken orally as therapeutic treatments. In fiscal 2005, we formed new collaborative partnerships with two of the world s largest pharmaceutical companies to continue development of two of our pre-clinical programs. One development program for the treatment of atherosclerosis through the use of reverse cholesterol transport is partnered with AstraZeneca UK Limited (AstraZeneca). Another research program targeting macrophage migration inhibitory factor (MIF) in the treatment of inflammatory diseases is partnered with Novartis International Pharmaceutical Ltd. (Novartis). Using our proprietary Xenerex[tm] technology, we are also conducting research to develop injectable human monoclonal antibody products for anthrax and other infectious diseases. 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 11388 Sorrento Valley Road, San Diego, California 92121. Our telephone number is (858) 622-5200 and our e-mail address is *info@avanir.com.* Additional information about Avanir can be found on our website, at *www.avanir.com*, and in our periodic and current reports filed with the Securities and Exchange Commission (SEC). Copies of our current and periodic reports filed with the SEC are available at the SEC Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549, and online at *www.sec.gov* and our website at *www.avanir.com.* No portion of our website is incorporated by reference into this report.

Neurodex Pseudobulbar Affect (PBA)/ Emotional Lability Indication

Pseudobulbar affect (PBA)/emotional lability 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 at the wrong time or in an exaggerated amount. PBA afflicts patients with neurological disorders such as amyotrophic lateral sclerosis (ALS), Alzheimer s disease, multiple sclerosis (MS), stroke, traumatic brain injury and Parkinson s disease. While the exact number is unknown, the medical literature indicates that there are approximately 800,000 to 1,000,000 patients who have PBA in North America. If the FDA approves our leading drug candidate, Neurodex, we

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expect it would be the first drug approved for the treatment of PBA. Neurodex is a patented, orally administered combination of dextromethorphan and an enzyme inhibitor, quinidine, that sustains elevated levels of dextromethorphan in the human body.

In December 2004, we began submission to the FDA of our rolling NDA for Neurodex for the treatment of PBA. A rolling submission allows us to submit the NDA in separate reviewable modules. We recently submitted the final reviewable unit of our NDA. However, the FDA has requested that we expand certain summary analyses and re-format the materials in our application to better support the filing. We expect that the FDA will set the receipt date of the NDA filing to coincide with our submission of this information, which we expect will occur in January 2006. Please refer to Management s Discussion and Analysis of Financial Condition and Results of Operations for additional information regarding this submission. If the FDA approves Neurodex for marketing in the treatment of PBA, we intend to market the drug directly through a sales force that we are currently in the process of building.

The NDA for Neurodex 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 Neurodex in patients with PBA associated with a variety of neurological disorders. We have achieved positive results in both the primary and secondary endpoints of two pivotal Phase III clinical trials evaluating the safety and effectiveness of Neurodex in the treatment of PBA.

In a Phase III clinical study of Neurodex for the treatment of PBA/emotional lability in patients who have MS, completed in June 2004, 150 patients at 22 clinical sites were given either placebo or Neurodex 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 Neurodex. Of those taking the drug, 84% reported improvement in the condition based on the CNS-LS Score, compared to 49% of those on placebo ($p<0.0001$). Overall, Neurodex was well tolerated in the patient population for this clinical trial. 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 Neurodex-treated patients than for placebo-treated patients.

The first Phase III clinical study of Neurodex for the treatment of PBA/emotional lability conducted in ALS patients was completed in June 2002 (*Neurology*, 2004; 63:1364-1370). This clinical trial had three treatment arms and compared Neurodex to each of its two individual components, dextromethorphan and quinidine. Results from the Phase III trial with ALS patients demonstrated a substantial favorable clinical effect with a p value of <0.0013 for the primary endpoint of the study.

Neurodex Neuropathic Pain Indication

Neuropathic pain, which arises from nerve injury, can result in a chronic and debilitating form of pain that has been poorly diagnosed and treated. Conditions that cause neuropathic pain include trauma (e.g. car accidents), cancer, viral infection (e.g. herpes zoster) and metabolic disease (e.g. diabetic neuropathy). For example, 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. Diabetic neuropathic pain 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 neuropathic pain is at least $1 billion.

Commencing in June 2005, we began a double-blind, placebo-controlled, multicenter, phase III clinical trial of Neurodex that is designed to evaluate its use in the treatment of diabetic neuropathic pain. The randomized, placebo-controlled study will assess efficacy, overall safety and tolerability of our investigational drug targeting central nervous system receptors to treat diabetic neuropathic pain. The study will assess the efficacy of Neurodex in relieving pain over a three-month study period in adult patients with distal

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symmetrical diabetic neuropathy with daily pain in the lower extremities. The clinical trial will be conducted in 450 subjects and will include both assessment scales that are completed in the clinic and patient diary records to assess pain. The enrollment is targeted for completion at the end of 2006. Patients will be randomized to receive placebo or one of two dose levels of Neurodex. The clinical trial protocol was reviewed by the FDA through a special protocol assessment (SPA) process. An SPA is a binding agreement between the FDA and the sponsor of a clinical trial that documents if the study endpoints are met, the results should be sufficient to support approval of an NDA. We expect that this will be the first of two Phase III clinical trials needed to submit an NDA for Neurodex for this indication. Please refer to Management s Discussion and Analysis of Financial Condition and Results of Operations for more information.

In June 2003, we completed a four-week open label dose escalation study of Neurodex in 36 patients with diabetic neuropathic pain. Results from the study indicated that Neurodex was well tolerated up to the highest target dose in the non-placebo controlled study. Patients in the study reported decreased pain intensity that was significantly different from baseline. Additionally, 91% and 97% of the patients reported pain relief by Day 8 and Day 15, respectively, compared to baseline. Pain relief reported by patients during the study improved with the duration of the open label study. Commonly reported adverse events (reported by three or more individuals) included nausea, constipation, diarrhea, dry mouth, fatigue, dizziness, insomnia, headache, upper respiratory tract infection and somnolence. Most adverse events were either mild or moderate in intensity, and 92% of the participants completed the study. There was minimal need for alternative (rescue) pain medication.

AVP-13358 Selective Cytokine Inhibitor

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.

In November 2005, we completed a multi-rising dose Phase Ib safety study of AVP-13358 and are currently in the process of evaluating the results of the study. In fiscal 2004, we completed a Phase I study in 54 healthy volunteers that was intended to assess safety, tolerability and pharmacokinetics following a single oral administration. Results from the Phase I study suggest AVP-13358 was well tolerated at all doses. The study also demonstrated AVP-13358 was detectable in the bloodstream at concentrations at or near to those which are biologically active in experimental models.

Reverse Cholesterol Transport Technology Atherosclerosis

We have been developing the next generation of lipid lowering drugs. Unlike currently available drugs that focus on lowering plasma levels of LDL cholesterol, our compounds are designed to promote a natural process known as reverse cholesterol transport, whereby cholesterol is effluxed from the fatty-plaques in blood vessel walls and transported to the liver for elimination from the body. Preliminary studies in animal models suggest our compounds may reduce fatty plaques and increase fecal cholesterol excretion.

In July 2005, we entered into an exclusive licensing and research collaboration agreement with AstraZeneca to discover, develop and commercialize reverse cholesterol transport enhancing compounds for the treatment of cardiovascular disease. Under the terms of the agreement, we will be eligible to receive royalty payments, assuming the product is successfully developed and approved for marketing by the FDA. We are also eligible to receive up to $330 million in milestone payments contingent upon achievement of certain development and regulatory milestones, which could take several years of further development, including achievement of certain sales targets, when and if a licensed compound is approved for marketing by the FDA. Under the terms of the agreement, we received an up-front payment of $10 million in July 2005 and will also receive research funding of between $2.5 million and $4.0 million per year for providing research and

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development services to AstraZeneca for up to three years. We have identified a lead compound, designated as AVP-26452, and expect to begin a Phase I study in fiscal 2006 following allowance of an investigational new drug application (IND) by the FDA. AstraZeneca has the responsibility for overall development and for the development costs, with both parties contributing scientific expertise in the research collaboration.

Macrophage Migration Inhibitory Factor (MIF) Inflammation

In April 2005, we entered into a research, development and commercialization agreement with Novartis for orally active small molecule therapeutics utilizing our novel MIF technology as a potential treatment for inflammatory diseases. Under the terms of the agreement, we will be eligible to receive royalty payments, assuming the product is successfully developed and approved for marketing by the FDA. We are also eligible to receive up to $169 million in milestone payments contingent upon achievement of certain development and regulatory milestones, which could take several years of further development, including achievement of certain sales targets, when and if a MIF compound is approved for marketing by the FDA. Additionally, we received an up-front payment of $2.5 million in May 2005 and will also receive research funding of between $1.5 million and $2.5 million per year for providing research and development services to Novartis for two years from the date of the agreement, or longer upon mutual agreement of the parties. While both parties to the agreement will contribute expertise and intellectual property to the research and development collaboration, Novartis is responsible for all development expenses.

Xenerex Antibody Technology Anthrax/ Other Infectious Diseases

We have used our patented Xenerex antibody technology to develop antibodies for use as prophylactic and therapeutic drugs to prevent and treat anthrax and other infectious diseases. These programs have been partially funded by government grants. Two of our lead antibodies, AVP-21D9 and AVP-22G12, inhibit anthrax toxin complex assembly in the picomolar range. Further, preclinical research suggests protection may be possible by a single dose of AVP-21D9.

From early fiscal 2004 through mid fiscal 2005, the National Institute of Allergy and Infectious Diseases at the National Institutes of Health helped fund our research in the development of antibodies for the treatment of anthrax through an aggregate of $850,000 in grants. We could seek additional government grants to complete the development process required prior to submitting an IND to the FDA. However, there can be no assurance that these research programs will receive additional government grants.

Docosanol 10% Cream Cold Sores

Docosanol 10% cream, a topical treatment for cold sores, inhibits the fusion in the body between the plasma membrane and the herpes simplex virus envelope, thereby preventing viral entry into cells and subsequent viral replication. Normally, cold sores progress when the cold sore infection spreads from infected cells to healthy ones. In 2000, we received FDA approval for marketing docosonal 10% cream as an over-the-counter product in the United States. Since that time, docosanol 10% cream, has been approved by regulatory agencies in Canada, Denmark, Finland, Israel, Korea, Norway, Portugal, Spain and Sweden. Sales of docosanol 10% have commenced 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 sales of Abreva in North America in excess of $62 million, a level that could be achieved by 2007, assuming current growth rates. We also retained the rights to develop and license docosanol 10% cream outside North America for the treatment of cold sores and to develop and license docosanol 10% cream in all jurisdictions for all other indications other than cold sore treatment.

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Under the terms of our various 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 continue to pursue licensing opportunities for docosanol 10% cream in other countries in Europe and in Japan. However, we can provide no assurance that any of our licensees will be able to obtain regulatory approval, either as an over-the-counter product or as a prescription product or that the market will support additional licensees.

We purchase the active pharmaceutical ingredient (API), docosanol, from a large supplier in Western Europe. This manufacturing source was inspected by the FDA in 1998 and found to be in compliance with the FDA s current good manufacturing practice regulations. Both we and GlaxoSmithKline have relied on this supplier for purchases of the API. We believe GlaxoSmithKline maintains reserves of the API as a precautionary measure in the event of a delay or problem in the manufacture of docosanol. We also maintain a limited quantity of the API for sale to our foreign licensees. We currently store our API in the United States. Any material disruption in manufacturing could cause a delay in shipments and possible loss of sales.

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.

Neurodex for Pseudobulbar Affect/ Emotional Lability. Although we anticipate that Neurodex will be the first product to be marketed for the treatment of PBA, assuming the FDA approves the drug, we are aware that physicians may utilize other products in an off-label manner for the treatment of this disorder. For example, Neurodex may face worldwide 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.

Neurodex for neuropathic pain. We anticipate that Neurodex for the treatment of neuropathic pain, if fully developed by the Company and approved by the FDA for marketing, will 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., Pfizer Inc., Novartis Pharma AG and Bristol-Myers Squibb Company. One of the most advanced programs is under development by Pfizer Inc. and is based on the inhibition of a key enzyme in the cholesterol metabolism pathway known as CETP. The Pfizer program is currently in phase III clinical development and as such is substantially ahead of our program.

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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.

AVP-13358 (IgE down-regulation program). Our AVP-13358 program competes 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.

Antibody generation technology. Several companies, including Abgenix, Inc., Medarex, Inc., Cambridge Antibody Technology Group, plc. and Human Genome Sciences, Inc. have human antibody generation technologies and have been in business longer and have substantially greater financial resources and personnel than we have.

Docosanol 10% cream. Abreva faces, and will continue to face, in North America intense competition 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.

Patents and Proprietary Rights

Patents. We presently own or have the rights to 142 issued patents (29 U.S. and 113 foreign) and 392 applications pending (32 U.S. and 360 foreign). Patents and patent applications owned by the Company include docosanol-related products and technologies, Xenerex technologies for developing monoclonal antibodies, Neurodex, compounds capable of down-regulating the target IgE in controlling symptoms of allergy and asthma, compounds capable of down-regulating the target MIF in the treatment of several inflammatory diseases, and compounds for the treatment of atherosclerosis.

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
Xenerex proprietary antibody generation technologies	5	2008 to 2015	5	14	Various	2
IgE down-regulation technology	7	2019	8	23	Various	140
Neurodex	7	2011 to 2019	1	2		26
MIF inhibitor technology	0		8	1		73
Atherosclerosis	0		7	0		71

Total	29	32	113	360

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.

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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 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. (See Risk Factors.)

The FDA s Center for Drug Evaluation and Research (CDER) must approve a new drug application or biologics license application for a drug before the drug 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 be subject to rigorous regulation, including compliance with current good

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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 approval to market docosanol 10% cream and other proposed products 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.

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, 2005, we employed 76 persons, including 40 engaged in research and development activities, including drug discovery, medicinal chemistry, clinical development, and regulatory affairs, and 36 in selling, general and administrative functions such as sales, marketing, human resources, finance, accounting, purchasing and investor relations. Our staff includes 22 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.

RISK FACTORS

Risks Relating to Our Business

We have a history of losses and we may never achieve or maintain profitability.

To date, we have experienced significant operating losses in funding the research, development and clinical testing of our drug candidates and we expect to continue to incur substantial operating losses through at least fiscal 2007. As of September 30, 2005, our accumulated deficit was approximately $155.0 million. To achieve profitability, we would need to generate significant additional revenue with positive gross margins to offset our other operating expenses, which we expect will increase as we increase our pre-launch activities and sales and marketing efforts over the next several quarters while awaiting the FDA s decision regarding the approval of Neurodex for the treatment of PBA.

We may also increase spending on our clinical and pre-clinical programs to the extent our progress in development is favorable. Although we have recently entered into research collaborations with major pharmaceutical companies for two of our research programs, we continue to seek and to negotiate revenue-generating licenses for docosanol 10% cream, and for our other research programs for a selective cytokine inhibitor and our antibody technology. However, we may not find additional attractive arrangements, if at all, and any such arrangements may not provide adequate revenues to cover future operating expenses. Increases in expenditures may not be offset by new or adequate sources of revenues, and as a result, we may not achieve profitability.

We have experienced delays in obtaining the FDA s acceptance for filing of our new drug application for Neurodex due to requests by the Agency for additional discussions about the data. Any further delays or any

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adverse decisions in the regulatory review or approval process may harm our prospects and could harm our stock price.

In late August 2005, the FDA informed us that the Agency had restarted the review date for the Neurodex NDA to August 10, 2005 (from June 29, 2005) because of a submission that we had made at the request of the Agency containing supplemental data with certain pre-clinical information. The Agency has the discretion to determine whether responses to the Agency are sufficient to reset the start date for the review. At the time that we submitted the additional data, we did not know our submission would reset the review timeline for the Neurodex NDA. On September 21, 2005, the FDA informed us that there were formatting and summarization issues with our NDA, which we clarified in detail at a meeting with the Agency in October 2005.

Based on commentary that we received from the FDA, we are further strengthening and enhancing our NDA before re-submitting the data, as the submission will contain data from additional patients who had completed treatment for more than 6 months in our open-label study, bringing the total number above the relevant requirements for chronic exposure. The current plan is to re-submit the expanded data, refined narratives, and re-formatted materials in January 2006. Thereafter, the Agency will have 60 days to determine whether the file is complete and assign a review timeline, namely whether it will be a standard or priority review. These filing and acceptance delays, and any subsequent delays, might extend our operating losses, which would likely increase our cash requirements over the long run.

We also cannot be certain that Neurodex will ultimately be approved by the FDA for marketing or that we will be able to obtain the labeling claims desirable for the promotion of the product. Recent public announcements regarding safety problems with certain approved drugs may also affect the FDA s policies regarding safety data for all new drug applications and may result in the FDA requiring additional safety data before approving Neurodex, and FDA may require closer surveillance after commercialization if the drug is approved.

We have yet to market or sell Neurodex or any of our other potential products.

We have never before marketed or sold any pharmaceutical products. In order to market Neurodex, assuming it is approved by the FDA, or market any other drug candidates, we will need to hire additional personnel with relevant pharmaceutical experience to staff our sales management and marketing group to help ensure the potential success in marketing our products. If we cannot develop the required marketing and sales expertise internally, our ability to generate revenue from product sales will likely suffer.

In international markets, we may rely on collaborative partners to obtain regulatory approvals, and to market and sell our products in those markets. We have not yet entered into any collaborative arrangement with respect to marketing or selling Neurodex, with the exception of one such agreement relating to Israel. We cannot guarantee that we will be able to enter into any other arrangements on terms favorable to us, or at all. If we are able to enter into sales and marketing arrangements with collaborative partners, we cannot assure you that such collaborators will apply adequate resources and skills to their responsibilities, or that their marketing efforts will be successful. If we are unable to enter into favorable collaborative arrangements with respect to marketing or selling Neurodex or docosanol 10% cream or our collaborators efforts are not successful, our ability to generate revenue from product sales will suffer.

We expect that over the next 12 to 24 months we will need to raise additional capital to fund ongoing operations. If we are unable to raise additional capital, we may be forced to curtail operations. If we succeed in raising additional capital through a licensing or financing transaction, it may affect our stock price and future revenues.

In order to maintain sufficient cash and investments to fund future operations and to prepare for the commercialization of Neurodex, we will need to raise additional capital over the next 12 to 24 months through various alternatives, including licensing or sales of our technologies and drug candidates, selling shares of our Class A common stock 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 an existing shelf registration is

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approximately $84.0 million. See Management Outlook in Management s Discussion and Analysis of Financial Condition and Results of Operations.

If we raise capital by issuing additional shares of Class A common stock at a price per share less than the then-current market price per share, the per-share value of our Class A common stock may be reduced. Further, even if we sell shares of common stock at prices equal to or higher than the then-current market price, the issuance of additional shares may depress the market price of our Class A common stock and will dilute voting rights of our other shareholders. If we raise capital through licensing 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 drug candidates licensed or sold to third parties will no longer be in our control. Because license arrangements typically provide us with revenue only as the drug candidate is successfully developed and marketed, and because the development of any out-licensed drug candidates will typically be outside of our control, we may not realize a significant portion of the potential value of any such license arrangements.

If we are unable to raise additional capital to fund future operations, then we may not be able to execute our commercialization plans for Neurodex and may be required to reduce operations or defer or abandon one or more of our clinical or pre-clinical research programs.

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. Our President and Chief Executive Officer joined the Company in September 2005 and our Senior Vice President of Sales and Marketing joined the Company in July 2005. Since September 2004, seven new directors have joined our board and we continue to recruit senior-level sales and marketing and regulatory personnel to add to our management team. Accordingly, we anticipate that we could experience other changes in management and infrastructure as we expand our organization, prepare for the commercialization of Neurodex and effect our transition from a research and development company to a pharmaceutical company. These changes could be disruptive, and we may experience difficulties in retaining new directors, attracting and integrating new members of the management team and in transitioning our operating activities.

Our inability to attract and retain key management and scientific personnel could negatively affect our business.

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. The loss of certain executive officers and other key employees could adversely affect our operations.

Additionally, in order to expand the Company as planned and to effect our transition to a pharmaceutical company, we will need to hire, train, retain and motivate high quality personnel, including sales and marketing personnel for the commercialization of Neurodex. Any inability to hire qualified sales and marketing personnel would harm our commercialization plans. If we were to lose one or more of our key scientists, then we would likely lose some portion of our institutional knowledge and technical know-how, which could potentially cause a substantial delay in one or more of our development programs until adequate replacement personnel could be hired and trained.

Our patents may be challenged and our pending patents 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 patents pending cover Neurodex, docosanol 10% cream and other potential drug candidates that could come from our technologies such as reverse cholesterol transport, selective cytokine inhibitors, anti-

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

We depend on third parties to manufacture 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 docosanol 10% cream, Neurodex and active pharmaceutical ingredients and supplies for our other drug candidates. We have no experience in manufacturing and do not have any manufacturing facilities. Currently, we have sole suppliers for the active pharmaceutical ingredients (API) for docosanol and Neurodex, and a sole manufacturer of Neurodex. Further, we do not have any long-term agreements in place with either of these suppliers. Any delays or difficulties in obtaining API or in manufacturing Neurodex could delay our clinical trials for neuropathic pain and delay the commercialization of Neurodex for PBA. Additionally, although we and GlaxoSmithKline maintain a strategic reserve of docosanol to mitigate against a short-term supply disruption, any sustained disruption of our docosanol supply could harm our operations.

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 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 activities in an adequate or timely manner, the development and commercialization of our drug candidates could have to be abandoned or delayed.

Developing new 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. We maintain product liability insurance coverage for our clinical trials in

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the amount of $5 million per incident and $5 million in the aggregate. We expect to increase this coverage if we receive a favorable marketing approval of Neurodex by the FDA. However, product liability claims can be high in the pharmaceutical industry and our insurance may not sufficiently cover our actual liabilities. Additionally, our insurance carriers may deny, or attempt to deny, coverage in certain instances. If a suit against our business or proposed products is successful, then the lack of 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.

Risks Relating to Our Stock

Our stock price has historically been volatile and we expect that this volatility may 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, including the following:

Unfavorable announcements by us regarding our Neurodex NDA submission, clinical trial results or results of operations;

Announcements of developments regarding our agreements with Novartis and AstraZeneca, including delays in meeting goals or performance milestones by us or our partners;

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

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

Announcements by us of significant acquisitions, strategic partnerships, joint ventures, or capital commitments;

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 periodic variations in our operating results. We expect our operating results to continue to vary from quarter-to-quarter and these variations may be significant. Variations may result from the following factors:

Performance under partnering arrangements The recognition of the revenue under our partnering arrangements, including our license agreements for our MIF and RCT programs, will partially depend on the efforts and performance of our licensees in reaching milestones that are outside of our control, such as regulatory approval, product launch, or reaching a sales threshold.

Timing of FDA regulatory decisions We are in the process of building a sales force for the planned commercialization of Neurodex. The timing and extent of these development expenditures will vary depending on the status and timing of the FDA s review and decision on approval of our NDA for Neurodex. As a result, our expenses could vary significantly from quarter-to-quarter while we await regulatory decisions and complete this building process.

Acquisitions/alliances Our acquisition of certain rights relating to Neurodex in fiscal 2005 resulted in charges of approximately $7.2 million. In the future, if we acquire complementary technologies, products, or businesses, 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 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.

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Our future financial results will be affected by changes in the accounting rules governing the recognition of stock-based compensation expense.

Through fiscal 2005, we measured compensation expense for our employee stock compensation plans under the intrinsic value method of accounting prescribed by Accounting Principles Board Opinion No. 25 (APB No. 25), Accounting for Stock Issued to Employees. Commencing in our 2006 fiscal year, we and other companies will be required to measure equity compensation expense using the fair value method, which will adversely affect our results of operations by reducing our income or increasing our losses and which may adversely affect our stock price. Had we accounted for our compensation expense under the fair value method of accounting prescribed by FAS 123, our equity compensation expenses would have been significantly higher, increasing by approximately $1.7 million, $1.0 million and $1.6 million, net of reported amounts prescribed under APB No. 25, during fiscal 2005, 2004 and 2003, respectively.

The board of directors currently has the authority to effect a reverse stock split within a stated range until March 16, 2006. If implemented, the reverse stock split could negatively affect the price and liquidity of our Class A common stock.

At our 2005 Annual Meeting of Shareholders, the shareholders granted to the board of directors the authority to implement, within its discretion and until March 16, 2006, a reverse split of our Class A common stock within a range of 1:2 to 1:5. The board of directors is seeking a similar grant of authority at the 2006 Annual Meeting of Shareholders, with the authority to extend until March 31, 2007.

Under this grant of authority, the board of directors may implement a reverse stock split within this range at any time. However, if the board of directors were to effect a reverse stock split, the bid price of the Class A common stock may not continue at a level in proportion to the reduction in the number of outstanding shares resulting from the reverse stock split. For example, if the board of directors decided to implement a reverse stock split at a ratio of 1-for-5, the post-split market price of our Class A common stock might not continue at a level at least five times greater than the pre-split price. Accordingly, the total market capitalization of our Class A common stock after a reverse stock split, if implemented, could be lower than the total market capitalization before the reverse stock split. Additionally, the liquidity of our Class A common stock could be affected adversely by the reduced number of shares outstanding after the reverse stock split.

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 Neurodex, if approved by the FDA for marketing as a treatment of PBA, will compete against antidepressants, atypical anti-psychotic agents and other agents for the treatment of this condition.

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. If we commence commercial sales for Neurodex for PBA, we may potentially be competing with other companies and their products with respect to manufacturing efficiencies and marketing capabilities, areas where we have limited or no direct experience.

Our industry is highly regulated and our failure or inability to comply with government regulations regarding the development, production, testing, manufacturing and marketing of our products may adversely affect our operations.

Government authorities in the U.S., including the FDA, and other countries highly regulate the development, production, testing, manufacturing and marketing of pharmaceutical products. The clinical testing and regulatory approval process can take many years and requires the expenditure of substantial

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resources. Failure to obtain, or delays in obtaining, these approvals will adversely affect our business operations, including our ability to commence marketing of any of the proposed products. We may find it necessary to use a significant portion of our financial resources for research and development and the clinical trials necessary to obtain these approvals for our proposed products. We will continue to incur costs of development without any assurance that we will ever obtain regulatory approvals for any of our products under development. Additionally, we cannot predict the extent to which adverse government regulations might arise from future U.S. or foreign legislative or administrative actions. Moreover, we cannot predict with accuracy the effects of any future changes in the regulatory approval process and in the domestic health care system for which we develop our products, or the costs of on-going compliance regulations after marketing approval has been obtained. Future changes could affect adversely the time frame required for regulatory review, our financial resources, and the sales prices of our proposed products, if approved for sale.

Item 2. ***Properties***

We currently lease 57,582 square feet of laboratory and office space in three buildings located at 11388, 11404, and 11408 Sorrento Valley Road, San Diego, California for combined base rental payments of approximately $147,000 per month in fiscal 2006. Our lease agreements provide for scheduled rent increases each year. The agreement for the building at 11388 Sorrento Valley Road expires on August 31, 2008. The lease agreement for buildings at 11404 and 11408 Sorrento Valley Road expires on January 14, 2013. See Note 8, Commitments and Contingencies, in the accompanying Notes to Consolidated Financial Statements and Exhibits 10.5 and 10.12. We maintain irrevocable standby letters of credit to the lessors or their creditors totaling $857,000 to secure our performance under the leases.

Item 3. ***Legal Proceedings***

In the ordinary course of business, we face various claims brought by third parties, including 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 results of operations and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business.

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 2005.

PART II

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

Our Class A common stock trades 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 AMEX.

	Class A Common Stock Price			
	Fiscal 2005		Fiscal 2004	
	High	Low	High	Low
First Quarter	$ 3.52	$ 2.80	$ 1.71	$ 1.42
Second Quarter	$ 3.73	$ 2.20	$ 2.24	$ 1.53
Third Quarter	$ 3.04	$ 2.23	$ 1.91	$ 1.33
Fourth Quarter	$ 3.69	$ 2.84	$ 3.15	$ 1.56

On December 5, 2005, the closing sales price of Class A Common Stock was $3.11 per share.

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As of December 5, 2005, we had approximately 25,642 shareholders, including 1,014 holders of record and an estimated 24,628 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, 2005 and 2004, and for the fiscal years ended September 30, 2005, 2004 and 2003, 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 the report of independent registered public accounting firm thereon, 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, 2003, 2002 and 2001, and for the years ended September 30, 2002 and 2001, are derived from our audited consolidated financial statements that are contained in reports previously filed with the SEC. The quarterly consolidated financial data are derived from unaudited financial statements included in our Quarterly Reports on Form 10-Q.

Summary Financial Information

	Fiscal Years Ended September 30,				
Statement of operations data:	**2005(1)**	**2004**	**2003**	**2002**	**2001**
Total revenues	$ 16,690,574	$ 3,589,317	$ 2,438,733	$ 8,853,742	$ 12,678,602
Net income (loss)	$ (30,606,564)	$ (28,154,853)	$ (23,236,348)	$ (10,249,512)	$ 233,122
Net income (loss) attributable to common shareholders	$ (30,606,564)	$ (28,154,853)	$ (23,264,293)	$ (10,292,798)	$ 189,888
Basic net income (loss) per share	$ (0.30)	$ (0.36)	$ (0.39)	$ (0.18)	$ 0.00
Diluted net income (loss) per share	$ (0.30)	$ (0.36)	$ (0.39)	$ (0.18)	$ 0.00
Weighted average number of shares of common stock outstanding:					
Basic	102,469,726	77,946,413	59,896,135	58,206,969	57,475,748
Diluted	102,469,726	77,946,413	59,896,135	58,206,969	61,130,415
Cash dividends declared per share	$	$	$	$	$

	September 30,				
Balance sheet data:	**2005**	**2004**	**2003**	**2002**	**2001**
Cash and cash equivalents	$ 8,620,143	$ 13,494,083	$ 12,198,408	$ 8,630,547	$ 16,542,545
Investments in securities	18,917,443	12,412,446	5,258,881	4,538,460	5,308,691

Total cash, cash equivalents and investments in securities	$ 27,537,586	$ 25,906,529	$ 17,457,289	$ 13,169,007	$ 21,851,236
Working capital	$ 11,969,450	$ 16,653,621	$ 10,619,216	$ 5,918,083	$ 16,027,577
Total assets	$ 41,401,990	$ 37,403,953	$ 29,645,257	$ 20,332,929	$ 27,053,953
Deferred revenues	$ 19,158,210	$ 21,009,115	$ 22,742,641	$ 233,333	$ 125,000
Long-term obligations	$ 990,594	$ 1,107,064	$	$	$
Total liabilities	$ 32,267,111	$ 27,206,694	$ 28,608,026	$ 5,752,259	$ 2,592,490
Convertible preferred stock	$	$	$	$ 521,189	$ 502,903
Shareholders equity	$ 9,134,879	$ 10,197,259	$ 1,037,231	$ 14,059,481	$ 23,958,560

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Quarterly statement of operations data for fiscal 2005:	Fiscal Quarters Ended December 31, 2004	March 31, 2005(1)	June 30, 2005	September 30, 2005
Total revenues	$ 888,365	$ 644,733	$ 3,333,838	$ 11,823,638
Gross margin on product sales(2)	$ 14,298	$	$	$
Net loss	$ (7,088,589)	$ (14,050,947)	$ (8,207,544)	$ (1,259,484)
Basic and diluted net loss per share	$ (0.07)	$ (0.14)	$ (0.08)	$ (0.01)
Basic and diluted weighted average number of shares of common stock outstanding	95,851,957	98,262,726	107,367,798	108,358,209

Quarterly statement of operations data for fiscal 2004:	Fiscal Quarters Ended December 31, 2003	March 31, 2004	June 30, 2004	September 30, 2004
Total revenues	$ 1,509,645	$ 855,837	$ 591,354	$ 632,481
Gross margin on product sales(2)	$ 549,258	$ 10,590	$ 14,298	$
Net loss	$ (6,280,212)	$ (6,690,555)	$ (6,617,493)	$ (8,566,593)
Basic and diluted net loss per share	$ (0.09)	$ (0.09)	$ (0.08)	$ (0.09)
Basic and diluted weighted average number of shares of common stock outstanding	67,804,604	71,285,690	78,256,417	94,369,912

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

(2) Represents product sales, net of cost of product sales.

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 and expect an 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 obligation to update or announce revisions to any forward-looking statements to reflect actual events or developments. Except as otherwise indicted herein, all dates referred to in this Report represent periods or dates fixed with reference to the calendar year, rather than our fiscal year ending September 30.

Overview

Avanir Pharmaceuticals is a pharmaceutical company focused on developing and commercializing novel therapeutic products for the treatment of chronic diseases. Our product candidates address therapeutic markets that include the central nervous system, atherosclerosis, inflammatory diseases and infectious diseases. We are currently developing Neurodex for the treatment of pseudobulbar affect (PBA), also known as emotional lability, and for the treatment of chronic diabetic neuropathic pain. We are in the process of finalizing the submission to the FDA of our NDA for Neurodex[tm] for the treatment of PBA. Additionally, in June 2005 we initiated a Phase III clinical trial of

Neurodex in patients with diabetic neuropathic pain.

Our research and drug discovery programs are focused primarily on small molecules that can be taken orally as therapeutic treatments. In fiscal 2005, we formed new collaborative partnerships with two of the world s largest pharmaceutical companies to continue development of two of our pre-clinical programs. One development program for the treatment of atherosclerosis through the use of reverse cholesterol transport is partnered with AstraZeneca UK Limited. Another research program targeting macrophage migration inhibitory factor (MIF) in the treatment of inflammatory diseases is partnered with Novartis International

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Pharmaceutical Ltd. Using our proprietary Xenerex technology, we are also conducting research to develop injectable human monoclonal antibody products for anthrax and other infectious diseases. 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.

The following chart illustrates the approximate status of research activities for our products, product candidates and licensed technologies that are under development as of December 5, 2005.

We strive to maintain a lean organizational structure while working on a diverse product development pipeline. We also strive to maintain flexibility in our cost structure by actively managing outsourced functions such as clinical trials, legal counsel, documentation and testing of internal controls, pre-clinical development work, manufacturing, warehousing and distribution, rather than maintaining all of these functions in house. We believe the benefits of outsourcing, being flexible and being able to rapidly respond to program delays or successes far outweigh the higher costs often associated with outsourcing.

If the Neurodex NDA is approved by the FDA in 2006, we intend to begin marketing and selling the product within several months of the FDA s decision. We are in the process of transforming from a research and development organization into a commercially viable pharmaceutical company. In order to facilitate that transformation, we are starting to build the necessary infrastructure to support the planned commercial launch of Neurodex if it is approved by the FDA. In preparation for the commercial launch of Neurodex, we are in the process of developing our sales and marketing strategy and are recruiting sales and marketing personnel for key positions within the organization.

In March 2005, we entered into an asset purchase agreement, pursuant to which our wholly owned subsidiary, Avanir Holding Company, acquired from IriSys, Inc. certain additional contractual rights to Neurodex. As a result, through our subsidiary we hold the exclusive worldwide marketing rights to Neurodex

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for five indications under a royalty-bearing license with the owner of the underlying technology, The Center for Neurologic Study (CNS). Going forward, we will be obligated, if we achieve certain contingent events, to pay CNS milestone payments, a patent royalty on product sales, and a share of revenues received if we sublicense Neurodex to a third party. We have no future financial obligations to IriSys. In the transaction, IriSys was paid $1,925,000 in cash and received 2,000,000 shares of our Class A common stock. (See Note 12, Related Party Transactions, in our Notes to Consolidated Financial Statements.)

In fiscal 2005, we entered into collaborative license agreements with Novartis and AstraZeneca which, in the aggregate, represent the rights to receive up-front payments totaling $12.5 million and approximately $500 million in potential milestone payments contingent upon achievement of certain development, regulatory and sales milestones. These milestones are expected to take several years of further development, including achievement of certain sales targets, when and if a licensed compound is approved for marketing by the FDA. In addition, we will be eligible to receive royalty payments, assuming the licensed compounds are successfully developed and approved for marketing by the FDA, and we expect to receive research funding for providing research and development services under these collaborations.

Novartis Collaboration. In April 2005, we entered into the research, development and commercialization agreement with Novartis for orally active small molecule therapeutics utilizing our novel MIF technology as a potential treatment for inflammatory diseases. Under the terms of the agreement, we will be eligible to receive an ongoing royalty and up to $169 million in milestone payments, contingent on program progress. Additionally, we received an up-front payment of $2.5 million in May 2005 and we expect to receive research funding of between $1.5 million and $2.5 million per year for providing research and development services to Novartis for two years from the date of the agreement, or longer upon mutual agreement of the parties.

AstraZeneca Collaboration. In July 2005, we entered into the licensing and research collaboration agreement with AstraZeneca to discover, develop and commercialize reverse cholesterol transport enhancing compounds for the treatment of cardiovascular disease. Under the terms of the agreement, we will be eligible to receive an ongoing royalty and up to $330 million in milestone payments, contingent on program progress. Under the terms of the agreement, we received an up-front payment of $10 million in July 2005 and we expect to receive research funding of between $2.5 million and $4.0 million per year for providing research and development services to AstraZeneca for up to three years.

We intend to continue to seek partnerships with pharmaceutical companies to help fund other research and development programs in exchange for sharing in the rights to commercialize new drugs. In addition to the development of the MIF and reverse cholesterol transport programs, we have licensed certain rights to docosanol 10% cream. We may also seek to develop other drug candidates through research collaborations with larger pharmaceutical companies, allowing us to share the risks and the opportunities that come from such development efforts.

We expect that our selling, marketing, development and other operational costs will continue to exceed revenues from existing sources through at least fiscal 2007. Trends in revenues and various types of expenses are discussed further in the Results of Operations. We expect that we will have to raise additional capital to prepare for and execute a product launch of Neurodex for PBA, if approved by the FDA for marketing, and to fund our ongoing clinical trials for Neurodex for neuropathic pain, as well as selected research and other operating activities. Our future capital needs will 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 they will share 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, and our commercialization plans for Neurodex may be adversely affected. For additional information about the risks and uncertainties that may affect our business and prospects, please see Risk Factors.

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Critical Accounting Policies and Estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the United States requires that management make a number of assumptions and estimates that affect the reported amounts of assets, liabilities, revenues and expenses in our consolidated financial statements and accompanying notes. Management bases its estimates on historical information and assumptions believed to be reasonable. Although these estimates are based on management s best knowledge of current events and circumstances that may impact us in the future, actual results may differ from these estimates.

Our critical accounting policies are those that affect our financial statements materially and involve a significant level of judgment by management. Our critical accounting policies regarding revenue recognition are in the following areas: license and research contracts, royalty revenues, sale of rights to future royalties, grant revenues and product sales. Our critical accounting policies also include recognition of expenses in research contracts and research and development expenses and the valuation of long-lived and intangible assets.

Revenue Recognition

We recognize revenue in accordance with SEC Staff Accounting Bulletin Topic 13 (SAB Topic 13), Revenue Recognition and Emerging Issues Task Force No. 00-21 (EITF 00-21), Accounting for Revenue Arrangements with Multiple Deliverables. Revenue is recognized when the four basic criteria of revenue recognition are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) the fee is fixed or determinable; and (4) collectibility is reasonably assured.

License and Research and Development Service Revenues. Our license and research and development service revenues are generated through collaborative arrangements with strategic partners and license agreements. Collaborative arrangements typically consist of non-refundable and/or exclusive technology access or data transfer fees, reimbursements for costs of specific research and development, and various milestone and future product royalty payments. In accordance with EITF 00-21, we analyze our multiple element arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting. The evaluation is performed before entering into the agreement and at the inception of the arrangement. The delivered item(s) is considered a separate unit of accounting if all of the following criteria are met: (a) the delivered item(s) has value to the customer on a standalone basis; (b) there is objective and reliable evidence of the fair value of the undelivered item(s); and (c) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in our control.

If the delivered item does not have standalone value or if we do not have objective or reliable evidence of the fair value of the undelivered component, the amount of revenue allocable to the delivered item is deferred. Nonrefundable, up-front license or technology access fees with standalone value that are not dependent on any future performance by us under the arrangements are recognized as revenue upon the earlier of when payments are received or collection is assured, but are deferred if we have continuing performance obligations. If we have continuing involvement through research and development collaborations or other contractual obligations, such up-front fees are deferred and recognized over the collaboration period or the period for which we continue to have a performance obligation, unless all of the following criteria exist: (1) the delivered item(s) have standalone value to the customer, (2) there is objective and reliable evidence of the fair value of the undelivered item(s), and (3) there is no general right to return the delivered item(s).

Payments related to substantive, performance-based milestones are recognized as revenue upon the achievement of the milestones as specified in the underlying agreements, which represent the culmination of the earnings process. Revenue from research services is recognized during the period in which the services are performed and is based upon the number of FTE personnel working on the specific project at the agreed-upon rate. Payments received in advance are recorded as deferred revenue until the research is performed, costs are incurred, or milestone is reached.

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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, which may vary over the course of the license agreement.

Revenues from Sale of Royalty Rights. In agreements where we have sold our rights to future royalties under license agreements and we maintain continuing involvement in earning such royalties, we defer revenues and recognize them over the life of the license agreement. For example, in the sale of an undivided interest of our Abreva license agreement to Drug Royalty USA, revenue recognition is being determined 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 (i) 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 (ii) 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. Revenue from product sales, which consist of sales of our active pharmaceutical ingredient docosanol, is recorded when the revenue recognition criteria as described under SAB Topic 13 are met, generally when title and risk of loss have passed to the buyer upon delivery. We sell the active pharmaceutical ingredient docosanol to various licensees and ship only on written order for the materials. Total shipments generally occur fewer than five times a year. Our contracts for sales of the active pharmaceutical ingredient docosanol include buyer acceptance provisions that give our buyers the right of replacement if the delivered materials do not meet specified criteria, by giving notice within 30 days after receipt of such defective materials, and we have the option to refund or replace 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. Therefore, we recognize revenue from sales of the active pharmaceutical ingredient docosanol without providing for such contingency upon shipment.

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, an evaluation by the project manager of the work that has been completed during the period, measurement of progress prepared internally and/or provided by the third-party service provider, analysis of data that justifies the progress, and finally, management s judgment. Several of our contracts extend across multiple reporting periods, including our largest contract, representing an $8.5 million Phase III clinical trial contract as of September 30, 2005. A 3% variance in our estimate of the work completed in our largest contract could increase or decrease our operating expenses by $255,000.

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.

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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 of the technology or product being successful;

There will be difficulty in completing the remaining development; and

There is substantial cost to complete the work.

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

Capitalization and Valuation of Long-Lived and Intangible Assets

Intangible assets with finite useful lives consist of capitalized legal costs incurred in connection with patents, patent applications pending and license agreements. We amortize costs of approved patents, patent applications pending and license agreements over their estimated useful lives, or terms of the agreements, whichever are shorter. For patents pending, we amortize 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. We re-assess the useful lives of patents when they are issued, or whenever events or changes in circumstances indicate the useful lives may have changed. For patents, patent applications pending and trademarks that we abandon, we charge the remaining unamortized accumulated costs to expense.

Intangible assets and long-lived assets are evaluated for impairment whenever events or changes in circumstances indicate that their carrying value may not be recoverable. If the review indicates that 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.

When we determine that the carrying value of intangible assets or long-lived assets are not recoverable based upon the existence of one or more of the above indicators of impairment, we may be required to record impairment charges for these assets.

As of September 30, 2005, our largest group of intangible assets with finite lives was patents and patents pending for our selective cytokine inhibitor, consisting of intangible assets with a net carrying value of approximately $1.2 million.

Nature of Operating Expenses

Our operating expenses are influenced substantially by the amount of spending devoted to research and development. During the past three years, we have substantially expanded our drug development pipeline, which requires that we allocate significant amounts of our resources to such programs, including increased spending on clinical trials as those programs advance in their development. We expect research and development expenses will represent approximately 50% to 55% of our operating expenses for fiscal 2006, compared to an average of 61% for fiscal 2005. We expect that selling, general and administrative expenses for fiscal 2006 will represent 45% to 50% of our operating expenses, compared to an average of 39% for fiscal

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2005. We attribute the expected increase in selling, general and administrative expenses as a share of overall operating expenses in fiscal 2006 to be attributable to higher spending for medical education and marketing programs for Neurodex and increased staffing, as we build our infrastructure for pharmaceutical operations, assuming the FDA approves the new drug application for Neurodex. Occupancy costs, including building rent, utilities, maintenance, operation of our laboratory and office facilities, insurance and depreciation, are allocated to the various departments based on headcount. Building rent amounted to approximately $1.8 million in fiscal 2005 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 discovery, development and commercialization of novel therapeutics for chronic diseases. Our chief operating decision-maker reviews our operating results on an aggregate basis and manages our operations as a single operating segment. We have developed one commercial product, docosanol 10% cream, also known as Abreva in North America, and we have several other product candidates in various stages of development. We have licensed docosanol 10% cream to other companies in the world that market the product and provide us royalties on product sales. We also have exclusively licensed our reverse cholesterol transport and MIF programs to AstraZeneca and Novartis, respectively, which provide us with license fee and research funding revenues. These license agreements accounted for substantially all of our revenues during the past three years. The license agreements also provide future milestone payments upon achievement of certain development and regulatory milestones, which could take several years of further development, including achievement of certain sales targets as well as royalties on sales, when and if the products are approved for marketing by the FDA.

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 years ended September 30, 2005, 2004 and 2003 are attributed to the United States. All long-lived assets for fiscal years ended September 30, 2005 and 2004 are located in the United States.

Comparison of Fiscal 2005 and 2004

Revenues 2005 vs. 2004

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 is mainly due to an unusually large sale of docosanol to GlaxoSmithKline in fiscal 2004.

Revenue-generating contracts. Revenue-generating contracts that remained active as of September 30, 2005 include license agreements with Novartis and AstraZeneca, seven docosanol 10% cream license agreements and one Neurodex sublicense. Partnering, licensing and research collaborations have been, and will continue to be, an important part of our business development strategy. We intend to partner with pharmaceutical companies that can help fund our research in exchange for sharing in the rights to commercialize new drugs resulting from this research. We have licensed and continue to seek licensees in

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other countries for docosanol 10% cream and other potential products in our development pipeline. Research collaborations also represent an important way to achieve our development goals, while sharing in the risks and the opportunities that come from such development efforts.

Operating Expenses 2005 vs. 2004

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 $6.5 million or 29% 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.

	Operating Expenses Fiscal Years Ended September 30,		
	2005	**2004**	**2003**
Operating expenses:			
Research and development	61%	70%	72%
Selling, general and administrative	39%	29%	28%
Costs of product sales	0%	1%	0%
Total operating expenses	100%	100%	100%

Research and development (R&D) expenses. R&D expenses increased to $29.0 million in fiscal 2005 from $22.5 million in fiscal 2004. R&D spending in fiscal 2005 was related to the open label safety study of Neurodex for the treatment of PBA, preparation for and initiation of a Phase III clinical trial of Neurodex for the treatment of 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 Neurodex (see Note 12, Related Party Transactions, in Notes to Consolidated Financial Statements), a $3.4 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 Neurodex for the treatment of neuropathic pain. The increase is partially offset by decreases in pre-clinical development, including a $1.1 million decrease in our MIF program and 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 2, Summary of Significant Accounting Policies Research and Development Expenses, in the accompanying Notes to Consolidated Financial Statements).

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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
	2005(1)	2004(1)	2003(1)	2005(1)(2)	Projects(1)(3)
Company-funded Projects:					
Development programs for Neurodex, selective cytokine inhibitor and other programs projected through fiscal 2007	$ 22,481,481	$ 15,057,628	$ 14,690,717	$ 78,752,783	$ 40M to $50M
Partner-funded Projects:					
Preclinical atherosclerosis and MIF inhibitor research programs	6,005,067	6,444,871	3,085,453	19,426,437	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	497,210	979,182	781,847	2,538,544	$ 0.2M
Total	$ 28,983,758	$ 22,481,681	$ 18,558,017	$ 100,717,764	

(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. For each of the projects set forth in the table, other than Neurodex for PBA (which we intend to market ourselves) and the reverse cholesterol transport and the MIF inhibitor programs (which we have partnered), we may seek development partners or licensees to help 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) Assumes completion of development of Neurodex in the treatment of PBA and for one Phase III clinical trial in the treatment of neuropathic pain, and continuation of studies of our selective cytokine inhibitor program. Projected spending thereafter will be subject to progress made in research that is currently underway.

We expect that increases in R&D spending for neuropathic pain will offset the expected decline in spending related to PBA in the coming years as we continue Phase III clinical trials of Neurodex in the treatment of neuropathic pain. R&D spending on MIF and reverse cholesterol transport programs are expected to be fully reimbursed by our collaborative partners. We expect that spending on our selective cytokine inhibitor program and on development of monoclonal antibodies will depend in part on our strategy for partnering these programs, or in obtaining additional government grants, so that we are able to defray part or all of these ongoing development costs.

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

Neurodex for the treatment of Pseudobulbar Affect/ Emotional Lability. We plan to complete the submission of the Neurodex NDA to the FDA in January 2006. Assuming the drug is accepted by the FDA for review, we expect the FDA will take either six months or ten months from the submission date to complete its review of the NDA, depending on whether it is a priority review or standard review, respectively. We have

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been engaged in an open-label safety study for the treatment of PBA in a broad pool of patients who have PBA associated with their underlying neurodegenerative disease or condition. We expect to continue this open-label study until we have a decision from the FDA on approval of the drug for marketing, plus any additional time until launch, if approved. In June 2004, we successfully completed the treatment phase of a Phase III clinical trial of Neurodex for the treatment of PBA in 150 patients with MS. Prior to engaging in these recent and current ongoing studies, we successfully completed the initial Phase III clinical trial of PBA in patients with ALS in May 2002.

Neurodex for the treatment of neuropathic pain. In June 2005, we initiated our first Phase III clinical trial of Neurodex in patients who have diabetic neuropathic pain and we are currently evaluating the balance of our development plan. Simultaneously, we are evaluating commercial development alternatives for this indication, including continuing development on our own (including conducting a second Phase III clinical trial) or co-promotion/licensing opportunities in which a partner would fund the second trial. Estimated timing to complete the first Phase III clinical trial and potentially partner this indication is up to two years. There can be no assurances that we will choose or be able to negotiate a licensing and/or co-promotion arrangement for Neurodex in the treatment of diabetic neuropathic pain on attractive terms, if at all.

Development program for selective cytokine inhibitor. In November 2005, we completed a multi-rising dose Phase Ib safety trial of AVP-13358 and are currently in the process of evaluating the results of the study. Assuming the results of the multi-rising dose study are favorable, we intend to proceed with proof of concept studies for the clinical indications to be explored. In 2004 we completed the first Phase I 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 I study suggest AVP-13358 was well tolerated at all single rising doses up through 16 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

Anti-inflammatory research program (MIF inhibitor). In April 2005, we entered into a research, development and commercialization agreement with Novartis International Pharmaceutical Ltd. for orally active small molecule therapeutics utilizing our novel MIF technology as a potential treatment for inflammatory diseases. Under the terms of the agreement, we will be eligible to receive royalty payments, assuming the product is successfully developed and approved for marketing by the FDA. We are also eligible to receive up to $169 million in milestone payments contingent upon achievement of certain development and regulatory milestones, which could take several years of further development, including achievement of certain sales targets, when and if a MIF compound is approved for marketing by the FDA. Additionally, we received an up-front payment of $2.5 million in May 2005 and will also receive research funding of between $1.5 million and $2.5 million per year for providing research and development services to Novartis for two years from the date of the agreement, or longer upon mutual agreement of the parties. While both parties to the agreement will contribute expertise and intellectual property to the research and development collaboration, Novartis assumes responsibility for all development expenses.

In August 2004, we entered into an amendment to the Ciblex Technology Acquisition Agreement initially signed in August 2001 for the MIF inhibitor technology (the Ciblex Amendment). In connection with entering into the Ciblex Amendment, we issued Ciblex 1,036,807 shares of Class A common stock in lieu of potential future milestones that would have likely been due in the future under the technology acquisition agreement, assuming continued successful development. The shares were valued at $2,733,023 and charged to R&D expense in the fourth quarter of fiscal 2004 (see Note 10, Shareholders Equity Common Stock, in the accompanying Notes to Consolidated Financial Statements). Pursuant to the Ciblex Amendment, we will no longer be obligated to make up to $9.0 million in milestone payments to Ciblex upon the occurrence of certain events relating to the clinical development and/or commercialization of the MIF inhibitor technology in the United States, nor will we be obligated to share milestone payments we receive from outside the United States. We will be required to pay a royalty to Ciblex if and when there are commercial sales of products utilizing the MIF inhibitor technology.

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Development program for atherosclerosis. Consistent with our strategy of licensing our large research and development programs, in July 2005 we entered into an exclusive licensing and research collaboration agreement with AstraZeneca to discover, develop and commercialize reverse cholesterol transport enhancing compounds for the treatment of cardiovascular disease. Under the terms of the agreement, we are eligible to receive royalty payments, assuming the product is successfully developed and approved for marketing by the FDA. We are also eligible to receive up to $330 million in milestone payments contingent upon achievement of certain development and regulatory milestones, which could take several years of further development, including achievement of certain sales targets, when and if a licensed compound is approved for marketing by the FDA. Under the terms of the agreement, we received an up-front payment of $10.0 million in July 2005 and will also receive research funding of between $2.5 million and $4.0 million per year for providing research and development services to AstraZeneca for up to three years. AstraZeneca has the responsibility for overall development and for the development costs, with both parties contributing scientific expertise to the research collaboration.

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 conditions, we, as the awardee organization, retain the principal worldwide patent rights to any invention developed with the United States government support. Approximately $161,000 in aggregate funds remains to be spent in the remainder of 2005 and in 2006 under the government research grant related to development of antibodies to anthrax toxins. Our genital herpes project came to a formal end during the third quarter ended 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.

Monoclonal antibodies anthrax toxin. Two of our most potent anthrax antibodies, AVP-21D9 and AVP-22G12, appear unique both in mechanism of action and in terms of the binding site on an anthrax toxin. AVP-21D9 is currently in preclinical development for use as a prophylactic and therapeutic drug to treat anthrax infections and is being funded by a two-year $750,000 federal (SBIR) research grant. Much of the work related to anthrax has 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.

Other government-funded research. During fiscal 2004, we completed the development of a blood donor program intended to find high-affinity antibodies to infectious diseases.

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 PBA, market research, and pre-launch planning activities for Neurodex and hiring of additional sales and marketing personnel, including a new Senior Vice President, Sales and Marketing, and a new Senior Director, Marketing.

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.

We expect that costs related to professional services mainly associated with compliance with the Sarbanes-Oxley Act of 2002 will continue at the present level in the next fiscal year. Based on our current

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commercial development plans for Neurodex for the treatment of PBA, we expect sales and marketing expenses in fiscal 2006 will continue to increase.

Interest Income 2005 vs. 2004

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 2005 vs. 2004

Net loss was $30.6 million, or $0.30 per share, in fiscal 2005 compared to a net loss of $28.2 million, or $0.36 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.

We expect to continue to pursue our drug development strategy focused on the development of Neurodex, followed by other programs in earlier stages of development that are in large therapeutic areas and that have significant partnering and licensing potential. Effective April 2005, Novartis assumed all responsibility for product development expenses for our MIF technology. Effective July 2005, AstraZeneca assumed all responsibility for product development expenses for our reverse cholesterol transport program. To help fund and develop our products, we may elect to license our other technologies and drug candidates to help offset the costs of development. These potential license arrangements could materially change our outlook for future revenues and costs. However, the timing of such potential arrangements is unpredictable.

Comparison of Fiscal 2004 and 2003

Revenues 2004 vs. 2003

Revenues in fiscal 2004 amounted to $3.6 million, including $1.7 million from the recognition of deferred revenue relating to the sale of an undivided interest in our Abreva license agreement to Drug Royalty USA (See Note 7, Deferred Revenue, in the accompanying Notes to Consolidated Financial Statements), $787,000 in sales of the active ingredient docosanol to licensees, $759,000 from government research grants, and $328,000 from milestones and fees earned in license agreements. Revenues from government research grants included preclinical development of docosanol as a potential treatment for genital herpes ($373,000) and preclinical research on a potential antibody to anthrax ($265,000). Revenues for fiscal 2003 amounted to $2.4 million, including $1.8 million from the recognition of deferred revenue relating to the sale of an undivided interest in our Abreva license agreement, $587,000 from government research grants and $17,000 in docosanol product sales.

Operating Expenses 2004 vs. 2003

Total operating expenses amounted to $32.0 million in fiscal 2004, compared to $25.9 million in fiscal 2003. The $6.1 million, or 24%, increase in operating expenses was primarily caused by a $3.9 million, or 21%, increase in spending on research and development programs including a $2.7 million charge in fiscal 2004 related to the issuance of common stock to the Ciblex Corporation, in lieu of potential future milestone payments related to our MIF technology. Clinical development of Neurodex for the treatment of PBA remained the leading research and development program for fiscal 2004, accounting for $7.4 million or approximately 33% of all research program spending. We also incurred a $2.0 million, or 27% increase in selling, general and administrative expenses. Research and development programs accounted for 70% and 72% of total operating expenses for fiscal 2004 and 2003, respectively. The increase in selling, general and administrative expenses, which accounted for 29% and 28% of total operating expenses for fiscal 2004 and 2003, respectively, was primarily attributable to increases in legal, consulting, other costs associated with corporate governance and compliance with the Sarbanes Oxley Act of 2002 and medical education and marketing activities related to Neurodex.

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Research and development expenses. R&D expenses totaled $22.5 million in fiscal 2004, including the issuance of $2.7 million in common stock in connection with the MIF technology, compared to $18.6 million in fiscal 2003. (See Note 2, Summary of Significant Accounting Policies Research and Development Expenses, in the accompanying Notes to Consolidated Financial Statements.) Higher R&D spending for fiscal 2004, other than for the MIF technology, was primarily related to clinical development of Neurodex for the treatment of PBA. The Neurodex program had a higher number of patients enrolled in both the Phase III clinical trial and the open label safety study in the treatment of PBA in fiscal 2004, which resulted in a $2.4 million or 47% increase over fiscal 2003 program spending. Costs associated primarily with Phase I clinical trials of our selective cytokine inhibitor program accounted for 16% of total R&D spending in fiscal 2004. The balance of R&D spending was for other programs, including pre-clinical research related to the development of compounds for the treatment of inflammation and atherosclerosis and antibody research programs.

In fiscal 2003, the clinical trials of Neurodex for the treatment of PBA in patients with MS accounted for 27% of all R&D spending. Costs associated with completion of toxicology, submitting an IND, and initiating Phase I clinical trials of our selective cytokine inhibitor program accounted for 25% of total R&D spending. The balance of R&D spending was for other programs, including clinical research of Neurodex for the treatment of neuropathic pain, pre-clinical research related to the development of compounds for the treatment of inflammation and atherosclerosis, and antibody research programs.

Selling, general and administrative expenses. Our selling, general and administrative expenses increased to $9.3 million in fiscal 2004, compared to $7.4 million in fiscal 2003. These increased expenses primarily related to:

- a $851,000 increase in expenses related to the continued expansion of our medical education and awareness programs for PBA, market research, and pre-launch planning activities for Neurodex.
- a $472,000 increase related to human resources, employee training, and other Company-wide employee programs;
- a $436,000 increase related to legal and other professional services associated with corporate governance and compliance with the Sarbanes-Oxley Act of 2002; and
- a $248,000 increase in building occupancy costs, primarily resulting from the utilization of additional office space in fiscal 2004.

These increases were partially offset by a $183,000 reduction in outside services for investor relations.

Liquidity and Capital Resources

Historically, we have funded our operations primarily through sales of our equity securities, payments received under our collaboration agreements, government grants and interest income. As of September 30, 2005, we had cash, cash equivalents and investments in securities 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 in securities of approximately $857,000. Our net working capital balance as of September 30, 2005 was $12.0 million. As of September 30, 2004, we had cash, cash equivalents and investments in securities totaling $25.9 million, including cash and cash equivalents of $13.5 million, short- and long-term investments of $11.6 million, and restricted investments of approximately $857,000. Our net working capital balance as of September 30, 2004 was $16.7 million. Explanations of net cash provided by or used for operating, investing and financing activities are provided below.

	September 30, 2005	Increase (Decrease) During Period	September 30, 2004
Cash, cash equivalents and investment in securities	$ 27,537,586	$ 1,631,057	$ 25,906,529

Cash and cash equivalents	$ 8,620,143	$ (4,873,940)	$ 13,494,083
Net working capital	$ 11,969,450	$ (4,684,171)	$ 16,653,621

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	Year Ended September 30, 2005	Change Between Periods	Year Ended September 30, 2004
Net cash used for operating activities	$ (20,054,211)	$ 4,620,144	$ (24,674,355)
Net cash used for investing activities	(8,888,225)	294,054	(9,182,279)
Net cash provided by financing activities	24,068,496	(11,083,813)	35,152,309
Net increase (decrease) in cash and cash equivalents	$ (4,873,940)	$ (6,169,615)	$ 1,295,675

Operating activities. 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 Neurodex, 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. Based on our current commercial development plans for Neurodex for the treatment of PBA, we expect sales and marketing expenses in fiscal 2006 will continue to increase. We also expect to continue clinical development of Neurodex in the treatment of diabetic neuropathic pain. Additionally, we expect to increase spending on preclinical research related to the development of compounds for the MIF and reverse cholesterol transport programs in fiscal 2006. However, expenses for the MIF and reverse cholesterol transport programs will be reimbursed by our collaborative partners.

Net cash used for operating activities in fiscal 2004 was $24.7 million, compared to net cash provided by operating activities of $1.0 million in fiscal 2003. The net loss of $28.2 million in fiscal 2004, which reflects high levels of spending on our R&D programs, combined with low revenues from existing sources, primarily accounted for the cash used for operating activities in that year. Depreciation and amortization of $1.8 million in fiscal 2004 was $815,000 higher than in fiscal 2003. The additional depreciation in fiscal 2004 represents the full-year effect of depreciation on $4.1 million in tenant improvements on approximately 30,400 square feet of additional office and laboratory space that was completed in May 2003. In addition, the net cash provided by operating activities in fiscal 2003 included $24.1 million in cash, net of transaction costs, received from Drug Royalty USA from the sale of an undivided interest in our Abreva license agreement with GlaxoSmithKline. The sale of rights to future Abreva royalties was initially recorded as deferred revenue on the date of sale (see Note 7, Deferred Revenue).

Investing activities. 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. We expect that capital expenditures for property and equipment will likely increase as we make modifications to improve office space utilization and to make accommodations in our existing facilities for additional sales and marketing personnel that will be necessary to support commercialization of Neurodex, 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.)

Financing activities. 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 the fiscal 2004, consisting primarily of

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

In April 2004, we filed a shelf registration statement on Form S-3 with the SEC to sell an aggregate of up to $50 million in Class A common stock. In June 2004, we sold 22,637,796 shares of Class A common stock at a price of $1.27 per share for aggregate offering proceeds of $28.8 million ($26.5 million net of underwriting discount and costs of the financing transaction). In December 2004, we sold an additional 2,333,333 shares of Class A common stock to an institutional investor at $3.00 per share for aggregate offering proceeds of $7.0 million. In April 2005, we amended this registration statement to increase the dollar amount of securities registered under the registration statement to $52.9 million. In April 2005, we sold to certain investors 7,770,000 shares of Class A common stock at a price of $2.20 per share, for aggregate offering proceeds of $17.1 million ($15.9 million net of offering expenses and commissions).

In June 2005, we filed shelf registration statement on Form S-3 with the SEC to sell an aggregate of up to $100 million in Class A common stock and preferred stock, depositary shares, debt securities and warrants. This shelf registration statement was declared effective on August 3, 2005.

Subsequent to the year ended September 30, 2005, we sold 6,094,339 shares of Class A common stock to certain institutional investors at $2.65 per share for aggregate net offering proceeds of $16.15 million. (See Note 16, Subsequent Event, in the accompanying Notes to the Consolidated Financial Statements.)

As of September 30, 2005, 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 the Company as of September 30, 2005 and proceeds from additional sales of Class A Common Stock under our June 2005 shelf registration statement (see Financing Activities above and Note 16, 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	$ 1,095,046	$ 396,612	$ 698,434	$	$
Capital (finance) lease obligations	38,322	28,742	9,580		
Operating lease obligations	10,462,636	1,801,259	3,683,185	2,224,547	2,753,645
Purchase obligations	15,741,408	14,403,794	1,337,614		
Total	$ 27,337,412	$ 16,630,407	$ 5,728,813	$ 2,224,547	$ 2,753,645

In September 2004, we entered into an equipment line of credit with GE Healthcare Financial Services for financing of up to $1.4 million. As of September 30, 2005, the outstanding balance due under the line of credit was approximately $955,000. Long-term debt obligations represent monthly principal and interest payment obligations on the line of credit.

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.

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 Neurodex for $1,925,000 and 2,000,000 shares of Class A common stock. The fair value of the acquired assets was determined based on various financial models for the commercialization of Neurodex for different indications, as well as the projected discounted cash flow and net present value under each such model. The fair value of

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the common stock issued in the transaction was calculated at $2.65 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 12, Related Party Transactions, in the Notes to Consolidated Financial Statements.) Following this transaction, we hold, through our wholly-owned subsidiary, the exclusive worldwide marketing rights to Neurodex for certain indications as set forth under a license agreement with the Center for Neurologic Study (CNS). We will be obligated to pay CNS milestone payments upon achievement of certain future events relating to the FDA s regulatory approval process for Neurodex and a royalty on commercial sales of Neurodex, 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 Neurodex to a third party. We expect to pay CNS a $75,000 milestone in 2006 if the FDA approves our NDA.

Management Outlook

We believe that cash, cash equivalents, and investments in securities of approximately $36.0 million at December 5, 2005, plus anticipated future cash from licensed technologies, should be sufficient to sustain our planned level of operations for at least the next 12 months. During fiscal 2006, we expect to earn $1.5 million to $2.5 million a quarter in revenues from R&D services that we are obligated to provide under collaborative agreements that will fully offset the expenses in connection with those services. Potential milestone payments to be received under existing license agreements are outside of our control and far less predictable. Fiscal 2006 revenues from new sources, such as license fees and milestone payments, will depend substantially on whether or not we elect to enter into additional license arrangements and whether or not we achieve milestones under those arrangements. Such arrangements could be in the form of licensing or partnering agreements for docosanol 10% cream, Neurodex, 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.

In anticipation of a product launch of Neurodex within several months of approval of the drug, if approved by FDA for marketing, we expect to raise additional capital to support the potential launch and marketing of the drug. Potential alternatives that we could pursue for raising capital include, but are not limited to, partnering arrangements where partners share development costs, issuance of debt or equity securities under our June 2005 shelf registration statement, and licensing or sales of one or more of our platform technologies or new drug candidates. The balance of securities available for sale under the existing shelf registration is approximately $84.0 million. If we are unable to raise capital as needed to fund our operations, or if we are unable to reach milestones in our license agreements or enter into any new 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. For information regarding the risks associated with our need to raise capital to fund our ongoing and planned operations, please see Risk Factors.

Recent Accounting Pronouncements

See Note 2, Summary of Significant Accounting Policies 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 risk related to changes in interest rates. Because substantially all our revenues, 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 exposures as the needs and risks should arise.

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Interest Rate Sensitivity

Our investment portfolio consists primarily of fixed income instruments with an average duration of 1.2 years as of September 30, 2005 (1.2 years as of September 30, 2004). 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, 2005 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, 2005 and 2004, an increase of one percentage point in the interest rates would have resulted in increases in comprehensive losses of approximately $222,000 and $137,000, respectively.

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

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

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

None.

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

Disclosure Controls and Procedures

With the supervision and with the participation of our management, including the principal executive officer and principal financial officer, we have evaluated the effectiveness of our disclosure controls and procedures (as defined in the Securities Exchange Act of 1934, Rules 13a-15(e) and 15(d)-15(e)), as of the end of the period covered by this report. Based on that evaluation, the principal executive officer and principal financial officer have concluded that these disclosure controls and procedures were effective as of the end of the period covered by this report. Additionally, there were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that occurred during the fiscal quarter ended September 30, 2005 that have materially affected, or are reasonably likely to materially affect, the Registrant s 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. 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, 2005.

Our assessment of the effectiveness of our internal control over financial reporting as of September 30, 2005 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, 2005 based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. 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, 2005, 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, 2005, based on the criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet and related consolidated statements of operations, shareholders equity and comprehensive loss and cash flows as of and for the year ended September 30, 2005 of the Company and our report dated December 14, 2005 expressed an unqualified opinion on those financial statements.

/s/ Deloitte & Touche LLP
San Diego, California
December 14, 2005

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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 our Annual Meeting of Shareholders to be held in 2006.

Executive Officers of the Registrant

The names of our executive officers and their ages as of December 5, 2005 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	43	President and Chief Executive Officer
Keith A. Katkin	34	Senior Vice President, Sales and Marketing
James E. Berg	54	Vice President, Clinical and Regulatory Affairs
R. Martin Emanuele, Ph.D.	51	Vice President, Business Development and Licensing
Gregory P. Hanson, CMA	59	Vice President, Finance; Chief Financial Officer and Secretary
Jagadish C. Sircar, Ph.D.	70	Vice President, Drug Discovery

Eric K. Brandt. Mr. Brandt has served as our President and Chief Executive Officer and as a director since September 2005. Prior to joining Avanir, Mr. Brandt was Executive Vice President, Finance and Technical Operations, Chief Financial Officer of Allergan, Inc., where he exercised broad corporate and operational responsibility. He also served at Allergan in the 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, lastly in the roles of a Vice President/ Partner and as a senior member of the firm s health care practice, having worked with several of the largest global pharmaceutical companies on issues such as commercial strategy, mergers and acquisitions, post-merger integration, manufacturing strategy and streamlining research and development processes. Mr. Brandt has a B.S. 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. Keith Katkin has served as Senior Vice President of Sales and Marketing since July 2005. Mr. Katkin brings strong biotech and pharmaceutical industry experience to this newly created position at Avanir. Prior to joining Avanir, Mr. Katkin served as Vice President, Commercial Development for Peninsula Pharmaceuticals, playing a key role in the sale of Peninsula to Johnson & Johnson. Prior to his joining Peninsula in May 2004, 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 a variety of sales and marketing positions of increasing responsibility at Amgen Inc., a global biotechnology company. Earlier in his career, Mr. Katkin spent several years at Abbott Laboratories. Mr. Katkin s product launch and brand management experience on products such as Neupogen, Neulasta, and Biaxin will be especially valuable to Avanir during its planned transformation into a fully

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integrated pharmaceutical company. 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.

James E. Berg. Mr. Berg has served as Vice President, Clinical and Regulatory Affairs, since March 1997. Mr. Berg led the team responsible for the clinical trials program for docosanol 10% cream and had the responsibility for working with the FDA and other regulatory agencies that led to the approvals of the product in the U.S., Canada and Sweden and other countries. Mr. Berg is also responsible for managing the clinical trials of Neurodex for the treatment of PBA and neuropathic pain and for the Company s selective cytokine inhibitor program. From August 1992 to March 1997, Mr. Berg was Director of Clinical Affairs and Product Development at the Company. Earlier in his career, Mr. Berg held various sales and management positions at QUIDEL Corporation, San Diego, California, and at Krupp Bilstein Corporation of America, Inc., San Diego, California. Mr. Berg received his B.A. degree from the University of Wisconsin in 1973.

R. Martin Emanuele, Ph.D. Dr. Emanuele has served as Vice President, Business Development and Licensing, since August 2002. Dr. Emanuel is responsible for our partnering, licensing and related business development activities. From May 1988 to July 2002, Dr. Emanuele was employed by CytRx Corporation, where he held a number of R&D and business development positions and attained the position of Vice President of Research and Business Development. Prior to CytRx, Dr. Emanuele was a clinical research scientist with Dupont Critical Care. Dr. Emanuele holds a B.S. degree from Colorado State University, an M.S. degree from Northern Illinois University, and a Ph.D. degree in Pharmacology & Experimental Therapeutics from Loyola University of Chicago.

Gregory P. Hanson, CMA. Mr. Hanson has served as Vice President, Finance and Chief Financial Officer (CFO) and Corporate Secretary since July 1998. Mr. Hanson also serves as the Corporate Compliance Officer. 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.

Jagadish Sircar, Ph.D. Dr. Sircar has served as our Vice President, Drug Discovery since November 2002. From November 1995 to March 2000, he held the position of Director of Chemistry at Avanir and from April 2000 to November 2002 he was Executive Director, Drug Discovery of the Company. Before joining the Company, Dr. Sircar held the position of Senior Vice President, Research and Discovery for Biofor, Inc. from January 1992 to November 1995. From 1969 to 1991, Dr. Sircar was employed by 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 preclinical 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 has a total of 162 patents, presentations and publications that are credited to him.

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.

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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)
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*

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10.5	Standard Industrial Net Lease by and between Avanir Pharmaceuticals and BC Sorrento, LLC, effective September 1, 2000(6)
10.6	License Agreement, dated August 1, 2000, by and between Avanir Pharmaceuticals (Licensee) and Irisys Research and Development, LLC, a California limited liability company(6)
10.7	Asset Purchase Agreement, dated March 8, 2005, by and among Avanir Pharmaceuticals, Avanir Holding Company, IriSys, Inc., Gerald J. Yakatan, Ph.D. and Gina M. Stack(19)
10.8	License Agreement, dated April 2, 1997, by and between Irisys Research & Development, LLC and the Center for Neurologic Study(16)
10.9	Amendment to License Agreement, dated April 11, 2000, by and between IriSys Research & Development, LLC and the Center for Neurologic Study(16)
10.10	Amended and Restated 1998 Stock Option Plan(7)
10.11	Amended and Restated 1994 Stock Option Plan(7)
10.12	Standard Industrial Net Lease by and between Avanir Pharmaceuticals (Tenant) and Sorrento Plaza, a California limited partnership (Landlord), effective May 20, 2002(8)
10.13	Amended and Restated 2000 Stock Option Plan(9)
10.14	Form of Restricted Stock Grant Notice for use with Amended and Restated 2000 Stock Option Plan(9)
10.15	2003 Equity Incentive Plan(9)
10.16	Form of Non-qualified Stock Option Award Notice for use with 2003 Equity Incentive Plan(9)
10.17	Form of Restricted Stock Grant for use with 2003 Equity Incentive Plan(9)
10.18	Form of Restricted Stock Grant Notice (cash consideration) for use with 2003 Equity Incentive Plan(9)
10.19	Form of Indemnification Agreement with certain Directors and Executive Officers of the Registrant (12)
10.20	Clinical Development Agreement, dated March 22, 2005, by and between Avanir Pharmaceuticals and SCIREX Corporation(16)
10.21	2005 Equity Incentive Plan
10.22	Form of Stock Option Agreement for use with 2005 Equity Incentive Plan (20)
10.23	Employment Agreement with Eric Brandt, dated August 15, 2005*
10.24	Stock Purchase Agreement, dated October 18, 2005 (21)

10.25	Employment Agreement with Keith Katkin, dated June 13, 2005
21.1	List of Subsidiaries
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (contained on signature page)
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
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

* Confidential treatment requested.

(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.

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(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.

(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 11, 2005.

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

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

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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 14, 2005

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 14, 2005
/s/ Gregory P. Hanson, CMA Gregory P. Hanson, CMA	Vice President, Finance, Chief Financial Officer (Principal Financial and Accounting Officer)	December 14, 2005
/s/ Charles A. Mathews Charles A. Mathews	Chairman of the Board	December 14, 2005
/s/ Stephen G. Austin, CPA Stephen G. Austin, CPA	Director	December 14, 2005
/s/ David J. Mazzo, Ph.D. David J. Mazzo, Ph.D.	Director	December 14, 2005
/s/ Dennis G. Podlesak Dennis G. Podlesak	Director	December 14, 2005
/s/ Jonathan T. Silverstein, J.D. Jonathan T. Silverstein, J.D.	Director	December 14, 2005
/s/ Paul G. Thomas Paul G. Thomas	Director	December 14, 2005
/s/ Craig A. Wheeler	Director	December 14, 2005

Craig A. Wheeler		
/s/ Scott M. Whitcup, M.D.	Director	December 14, 2005
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, 2005 and 2004, and the related consolidated statements of operations, shareholders equity and comprehensive loss, and cash flows for each of the three years in the period ended September 30, 2005. 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 the Avanir Pharmaceuticals and subsidiaries of September 30, 2005 and 2004, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2005, 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, 2005, 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 14, 2005 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.

/s/ Deloitte & Touche LLP
San Diego, California
December 14, 2005

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Avanir Pharmaceuticals
CONSOLIDATED BALANCE SHEETS

	September 30, 2005	2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,620,143	$ 13,494,083
Short-term investments in securities	14,215,005	8,803,982
Receivables, net	1,169,654	239,879
Inventory	27,115	9,302
Prepaid expenses	2,370,801	1,526,282
Total current assets	26,402,718	24,073,528
Investments in securities	3,845,566	2,751,867
Restricted investments in securities	856,872	856,597
Property and equipment, net	6,004,527	6,390,964
Intangible assets, net	3,665,086	3,035,024
Long-term inventory	347,424	
Other assets	279,797	295,973
TOTAL ASSETS	$ 41,401,990	$ 37,403,953
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 6,751,781	$ 1,961,938
Accrued expenses and other liabilities	4,094,295	2,418,209
Accrued compensation and payroll taxes	1,272,231	710,368
Current portion of deferred revenue	1,970,989	1,961,530
Current portion of notes payable	317,667	211,092
Current portion of capital lease obligations	26,305	156,770
Total current liabilities	14,433,268	7,419,907
Deferred revenue, net of current portion	17,187,221	19,047,585
Notes payable, net of current portion	637,285	703,560
Capital lease obligations, net of current portion	9,337	35,642
Total liabilities	32,267,111	27,206,694
COMMITMENTS AND CONTINGENCIES (Notes 4, 8 and 12)		
SHAREHOLDERS EQUITY:		
Preferred stock no par value, 10,000,000 shares authorized, no shares issued or outstanding as of September 30, 2005 and 2004, respectively:		
	167,738,303	134,687,535

Common stock no par value, 200,000,000 shares authorized; 109,366,926 and 95,305,757 shares issued and outstanding as of September 30, 2005 and 2004, respectively		
Unearned compensation	(3,477,144)	
Accumulated deficit	(155,012,466)	(124,405,902)
Accumulated other comprehensive loss	(113,814)	(84,374)
Total shareholders equity	9,134,879	10,197,259
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	$ 41,401,990	$ 37,403,953

See notes to consolidated financial statements.

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Avanir Pharmaceuticals
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended September 30,		
	2005	**2004**	**2003**
REVENUES:			
Licenses	$ 12,800,000	$ 328,000	$ 53,000
Royalties and sale of royalty rights	1,752,321	1,715,152	1,780,893
Research and development services	1,617,525		
Government research grants	503,328	758,827	587,440
Product sales	17,400	787,338	17,400
Total revenues	16,690,574	3,589,317	2,438,733
OPERATING EXPENSES:			
Research and development	28,983,758	22,481,681	18,558,017
Selling, general and administrative	18,796,188	9,340,260	7,358,111
Cost of product sales	3,102	213,192	3,102
Total operating expenses	47,783,048	32,035,133	25,919,230
LOSS FROM OPERATIONS	(31,092,474)	(28,445,816)	(23,480,497)
Interest income	619,857	290,067	265,874
Other income (expense)	(39,601)	38,068	26,801
Interest expense	(92,533)	(34,508)	(44,927)
LOSS BEFORE INCOME TAXES	(30,604,751)	(28,152,189)	(23,232,749)
Provision for income taxes	(1,813)	(2,664)	(3,599)
NET LOSS	$ (30,606,564)	$ (28,154,853)	$ (23,236,348)
NET LOSS ATTRIBUTABLE TO COMMON SHAREHOLDERS:			
Net loss	$ (30,606,564)	$ (28,154,853)	$ (23,236,348)
Dividends on redeemable convertible preferred stock			(16,122)
Accretion of discount related to redeemable convertible preferred stock			(11,823)
NET LOSS ATTRIBUTABLE TO COMMON SHAREHOLDERS	$ (30,606,564)	$ (28,154,853)	$ (23,264,293)
NET LOSS PER SHARE:			
BASIC AND DILUTED	$ (0.30)	$ (0.36)	$ (0.39)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:			

BASIC AND DILUTED	102,469,726	77,946,413	59,896,135

See notes to consolidated financial statements.

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Avanir Pharmaceuticals
CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY AND COMPREHENSIVE LOSS

	Common Stock								
	Class A		Class B				Accumulated Other Comprehensive	Total	
	Shares	Amount	Shares	Amount	Accumulated Deficit	Unearned Compensation	Income (Loss)	Shareholders Equity	Comprehens Loss
LANCE, TOBER 1, 02	58,270,533	$ 87,053,257	13,500	$ 8,395	$ (73,002,878)	$	$ 707	$ 14,059,481	
t loss					(23,236,348)			(23,236,348)	$ (23,236,34
uance of ss A mmon ck in nection h:									
xercise of arrants	53,200	59,850						59,850	
xercise of ock options	24,000	25,500						25,500	
estricted ock anted to rectors	80,000	92,800						92,800	
le of stock d warrants	6,728,396	9,381,317						9,381,317	
onversions Series D edeemable nvertible eferred ock	660,305	536,630						536,630	
vidends on ferred ck		(16,120)						(16,120)	
cretion of count ated to ries D eemable nvertible ferred ck.					(11,823)			(11,823)	
mpensation pense		153,199						153,199	

ated to uation of ck options nted to ployees l n-employees services dered								
realized ses on estments ecurities						(7,255)	(7,255)	(7,2
LANCE, PTEMBER 30, 03	65,816,434	97,286,433	13,500	8,395	(96,251,049)	(6,548)	1,037,231	$ (23,243,6
t loss					(28,154,853)		(28,154,853)	$ (28,154,8
uance of ss A mmon ck in nnection h:								
xercise of arrants	294,895	448,671					448,671	
xercise of ock options	124,009	160,823					160,823	
le of stock d warrants	28,020,112	34,015,320					34,015,320	
esearch lestone ligation of IF chnology	1,036,807	2,733,023					2,733,023	
onversions Class B mmon ock	13,500	8,395	(13,500)	(8,395)				
mpensation pense ated to uation of ck options nted to ployees l n-employees services dered		34,870					34,870	

realized ses on estments ecurities					(77,826)	(77,826)	(77,8
LANCE, PTEMBER 30, 04	95,305,757	134,687,535		(124,405,902)	(84,374)	10,197,259	$ (28,232,6
t loss				(30,606,564)		(30,606,564)	$ (30,606,5
uance of ass A mmon ck in nnection h:							
xercise of arrants	845,942	1,293,339				1,293,339	
xercise of ock options	111,894	125,491				125,491	
le of stock d warrants	10,103,333	22,765,135				22,765,135	
cquisition certain ntractual ghts to eurodex	2,000,000	5,300,000				5,300,000	
uance of tricted ass A mmon ck	1,000,000	3,556,000		(3,555,000)		1,000	
nortization unearned mpensation				77,856		77,856	
mpensation pense ated to uation of ck options nted to n-employees services dered		10,803				10,803	
realized ses on estments ecurities					(29,440)	(29,440)	(29,4
LANCE, PTEMBER 30,	109,366,926	$ 167,738,303	$	$ (155,012,466)	$ (3,477,144)	$ (113,814)	$ 9,134,879	$ (30,636,0

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See notes to consolidated financial statements.

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Avanir Pharmaceuticals
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended September 30,		
	2005	**2004**	**2003**
OPERATING ACTIVITIES:			
Net loss	$ (30,606,564)	$ (28,154,853)	$ (23,236,348)
Adjustments to reconcile net loss to net cash provided by (used for) operating activities:			
Depreciation and amortization	1,852,427	1,826,372	1,011,802
Compensation paid with common stock, stock options and warrants	88,659	34,870	245,999
Expense for issuance of common stock in connection with the acquisition of additional contractual rights to Neurodex (Note 12)	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	16,400	162	7,193
Intangible assets impaired and abandoned	423,123		74,432
Changes in assets and liabilities:			
Receivables	(929,775)	31,802	827,273
Inventory	(365,237)	201,552	27,272
Prepaid expenses and other assets	(848,219)	(9,912)	(845,761)
Accounts payable	4,615,629	(300,210)	(1,578)
Accrued expenses and other liabilities	1,604,136	612,151	207,431
Accrued compensation and payroll taxes	561,863	84,214	164,036
Deferred revenue	(1,850,905)	(1,733,526)	22,509,308
Net cash provided by (used for) operating activities	(20,054,211)	(24,674,355)	991,059
INVESTING ACTIVITIES:			
Investments in securities	(23,448,802)	(9,381,391)	(3,727,676)
Proceeds from sales and maturities of investments in securities	16,830,113	2,150,000	3,000,000
Patent costs	(1,278,935)	(1,156,975)	(615,627)
Purchases of property and equipment	(990,601)	(793,913)	(5,361,054)
Net cash used for investing activities	(8,888,225)	(9,182,279)	(6,704,357)
FINANCING ACTIVITIES:			
Proceeds from issuances of common stock and warrants, net of commissions and offering costs	24,184,966	34,624,814	9,466,667
Dividends paid on preferred stock			(12,500)
Proceeds from issuances of notes payable	395,244	1,074,570	244,805

Payments on notes and capital lease obligations	(511,714)	(547,075)	(417,813)
Net cash provided by financing activities	24,068,496	35,152,309	9,281,159
Net increase (decrease) in cash and cash equivalents	(4,873,940)	1,295,675	3,567,861
Cash and cash equivalents at beginning of year	13,494,083	12,198,408	8,630,547
Cash and cash equivalents at end of year	$ 8,620,143	$ 13,494,083	$ 12,198,408
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:			
Interest paid	$ 92,533	$ 34,508	$ 44,927
Income taxes paid	$ 1,912	$ 2,664	$ 3,599
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES:			
Issuance of 1.0 million shares of restricted Class A common stock for unearned compensation cost	$ 3,555,000	$	$
Purchases of property and equipment which are included in ending balances of accounts payable and accrued expense	$ 242,213	$ 3,951	$ 595,407
Conversions of Series D redeemable convertible preferred stock to Class A common stock	$	$	$ 536,630

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 focused on the discovery and development of therapeutic products for the treatment for chronic diseases. Our product candidates address therapeutic markets that include the central nervous system, atherosclerosis, inflammatory diseases and infectious disease.

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 license arrangements, the timing and success of reaching development milestones, in obtaining regulatory approvals and market acceptance of Neurodex, assuming the FDA approves our new drug application. Our operating expenses depend substantially on the level of expenditures for research and development programs and the rate of progress being made on such programs.

2. Summary of Significant Accounting Policies

Basis of presentation

The consolidated financial statements include the accounts of Avanir Pharmaceuticals and its wholly-owned subsidiaries, Xenerex Biosciences and Avanir Holding Company. 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, 2005, 2004, and 2003 may be referred to as fiscal 2005, fiscal 2004, and fiscal 2003, 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.

Cash and cash equivalents

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

Restricted investments in securities

We have restricted investments in two securities totaling $856,872 and $856,597 as of September 30, 2005 and 2004, 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, 2005	Lease Term Expires on
11388 Sorrento Valley Road, San Diego	$	388,122	08/31/08
11404 and 11408 Sorrento Valley Road, San Diego		468,750	08/31/12
Total	$	856,872	

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Avanir Pharmaceuticals
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 accumulated other comprehensive loss. Short-term investments are marketable securities with maturities of less than one year from the balance sheet date. Marketable security investments are evaluated periodically for impairment. If it is determined that a decline of any investment is other than temporary, then the investment basis would be written down to fair value and the write-down would be included in earnings as a loss.

Concentrations

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

Financial instruments that potentially subject us to concentrations of credit risk consist principally of marketable securities and interest rate instruments. 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.

Inventory

Inventory is stated at the lower of cost (first-in, first-out) or market. Inventory consists primarily of the raw material docosanol, which is the active pharmaceutical ingredient in docosanol 10% cream. Docosanol in its present form as stored by us has a substantial shelf life, a relatively stable value and long-term use, and carries a low risk of becoming excess inventory or obsolete. We do not own or store any docosanol 10% cream in its finished product form. We and one of our licensees receive docosanol from a single supplier. We also supply several of our licensees with docosanol from the same supplier. Inventory is $374,539 and $9,302 as of September 30, 2005 and 2004, respectively, of which $347,424 and $0, respectively, is in excess of management s estimated 12-month usage and, accordingly, being classified as long-term.

Impairment of long-lived assets

All long-lived assets are reviewed for potential impairment in value whenever events or changes in circumstances indicate a carrying value of an asset may not be recoverable under Statement of Financial Accounting Standards No. 144, Accounting for Impairment or Disposal of Long-lived Assets. Impairment is determined by comparing future projected undiscounted cash flows to be generated by the asset to its carrying value. If impairment is identified, a loss would be recognized and reflected in current earnings, to the extent the carrying amount of an asset exceeds its estimated fair value determined by the use of appraisals, discounted cash flow analyses or comparable fair values of similar assets.

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 or

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Avanir Pharmaceuticals
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

the life of the project, whichever is less, if the equipment has been purchased for a particular use. 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.

Intangible assets

We account for intangible assets in accordance with Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets , (FAS 142). In accordance with FAS 142, goodwill and other intangible assets that have indefinite useful lives are not amortized; however, these assets must be reviewed at least annually for impairment. Intangible assets with finite lives are to be amortized over their useful lives.

Intangible assets with indefinite useful lives consist of costs of trademarks for Avanir^{tm} and Xenerex and similar names.

Intangible assets with finite useful lives consist of capitalized legal costs incurred in connection with patents, patent applications pending and license agreements. We amortize costs of approved patents and license agreements over their estimated useful lives, or terms of the agreements, whichever are shorter. For patents pending, we amortize the costs over the shorter of their estimated useful lives or, if licensed, the term of the license agreement. For patents and trademarks that we abandon, we charge the remaining unamortized accumulated costs to research and development expense.

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 in actual amount paid and amount recorded as rent expense in the fiscal year has been credited to deferred rent. The amount classified as deferred rent as of September 30, 2005 and 2004 is $597,551 and $557,481, respectively.

Fair value of financial instruments

At September 30, 2005 and 2004, 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, 2005 and 2004, the fair value of our notes payable were approximately $825,000 and $775,000, respectively, and the fair value of our capital lease obligations were approximately $34,000 and $181,000, respectively.

Revenue recognition

We recognize revenue in accordance with SEC Staff Accounting Bulletin Topic 13, Revenue Recognition and Emerging Issues Task Force No. 00-21 (EITF 00-21), Accounting for Revenue Arrangements with Multiple Deliverables. Revenue is recognized when the four basic criteria of revenue recognition are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) the fee is fixed or determinable; and (4) collectibility is reasonably assured.

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Avanir Pharmaceuticals
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Licenses and Research and Development Service Revenues. Collaborative arrangements typically consist of non-refundable and/or exclusive technology access fees, reimbursements for specific costs of research and development, and various milestone and product royalty payments. In accordance with EITF 00-21, we analyze our multiple element arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting. The evaluation is performed before entering into the agreement and at the inception of the arrangement. The delivered item(s) is considered a separate unit of accounting if all of the following criteria are met: (a) the delivered item(s) has value to the customer on a standalone basis; (b) there is objective and reliable evidence of the fair value of the undelivered item(s); and (c) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in our control.

If the delivered item does not have standalone value or if we do not have objective or reliable evidence of the fair value of the undelivered component, the amount of revenue allocable to the delivered item is deferred. Nonrefundable, up-front license or technology access fees with standalone value that are not dependent on any future performance by us under the arrangements are recognized as revenue upon the earlier of when payments are received or collection is assured, but are deferred if we have continuing performance obligations. If we have continuing involvement through research and development collaborations or other contractual obligations, such up-front fees are deferred and recognized over the collaboration period or the period for which we continue to have a performance obligation, unless all of the following criteria exist: (1) the delivered item(s) have standalone value to the customer, (2) there is objective and reliable evidence of the fair value of the undelivered item(s), and (3) there is no general right to return the delivered item(s).

Payments related to substantive, performance-based milestones are recognized as revenue upon the achievement of the milestones as specified in the underlying agreements, which represent the culmination of the earnings process. Revenue from research services is recognized during the period in which the services are performed and is based upon the number of full time equivalent (FTE) personnel working on the specific project at the agreed-upon rate. Payments received in advance are recorded as deferred revenue until the technology is transferred, services are performed, costs are incurred, or the milestone is reached.

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, which may vary over the course of the license agreement.

Revenues from Sale of Royalty Rights. In agreements where we have sold our rights to future royalties under license agreements and we maintain continuing involvement in earning such royalties, we defer revenues and recognize them over the life of the license agreement. For example, in the sale of an undivided interest of our Abreva license agreement to Drug Royalty USA, revenue recognition is being determined 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 (i) 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 (ii) 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. Revenue from product sales, which consist of sales of our active pharmaceutical ingredient docosanol, is recorded when the revenue recognition criteria as described under SAB Topic 13 are met, generally when title and risk of loss have passed to the buyer upon delivery. We sell the active pharmaceutical ingredient docosanol to various licensees and ship only on written order for the materials. Total shipments generally occur fewer than five times a year. Our contracts for sales of the active pharmaceutical ingredient docosanol include buyer acceptance provisions that give our

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Avanir Pharmaceuticals
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

buyers the right of replacement if the delivered materials do not meet specified criteria, by giving notice within 30 days after receipt of such defective materials, and we have the option to refund or replace 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. Therefore, we recognize revenue from sales of the active pharmaceutical ingredient docosanol without providing for such contingency upon shipment.

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, an evaluation by the project manager of the work that has been completed during the period, measurement of progress prepared internally and/or provided by the third-party service provider, analysis of data that justifies the progress, and finally, management s judgment. Several of our contracts extend across multiple reporting periods, including our largest contract, representing an $8.5 million Phase III clinical trial contract as of September 30, 2005. A 3% variance in our estimate of the work completed in our largest contract could increase or decrease our operating expenses by $255,000.

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 of the technology or product being successful;

There will be difficulty in completing the remaining development; and

There is substantial cost to complete the work.

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.

Expenses for contract rights to Neurodex. In March 2005, our wholly-owned subsidiary, Avanir Holding Company, acquired certain contract rights to Neurodex from IriSys, Inc. for total consideration of $7,225,000 (see Note 12, Related Party Transactions, for further discussion). Because of the uncertainty of receiving future economic benefits from the acquired contractual rights, particularly given that Neurodex 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 fiscal year 2005 in accordance with United States generally accepted accounting principles.

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Expenses related to the MIF inhibitor technology. In August 2004, we entered into an amendment to a Technology Acquisition Agreement with the Ciblex Corporation dated August 8, 2001 (the Amendment). Under the Amendment, we will no longer be obligated to make up to $9 million in milestone payments to Ciblex upon the occurrence of certain events relating to the clinical development and/or commercialization of the MIF inhibitor technology in the United States and will no longer have to share any other milestone payments received from potential licenses outside the United States. In exchange for the elimination of obligations to pay milestones or share in the receipt of milestones, we issued Ciblex 1,036,807 shares of Class A common stock. For the purpose of determining the fair market price for the common stock for the financial statements, we used the 5-day average closing sales price of our common stock, beginning two days before and ending two days after the date of the Amendment, or $2.636 per share, establishing a value of the common stock of $2,733,023. We recorded the value of the common stock as research and development expense.

The MIF inhibitor technology includes certain compounds, any and all patents and patent applications, any divisions, continuations, reexaminations or reissues thereof and any foreign counterparts which may be issued or issuing on any of the foregoing regarding the use of those compounds in the treatment of auto immune and inflammatory diseases, and all preclinical data related to those compounds, and all technology and know-how relating to the foregoing, including laboratory data and previous experimental results.

In accounting for the cost of the Amendment, we used a number of factors to determine the allocation of costs between research and development expense and other intangible assets, which might have a useful life or indefinite life. Such determining factors included the stage of completion of the technology, the complexity of the work completed to date, the projected difficulty of completing the remaining development, and the expected cost to complete the project. Because of the early stage of development of the MIF inhibitor technology, uncertainty of successfully completing toxicology studies and clinical trials that are necessary to show evidence of safety and efficacy of the compounds among other requirements, and no alternative future uses without further development, we allocated 100% of the cost of the transaction as research and development expense.

Accounting for stock-based compensation

In December 2004, the Financial Accounting Standards Board (FASB) revised Statement of Financial Accounting Standards No. 123 (FAS 123R), Share-Based Payment. FAS 123R will require us to measure the cost of all employee stock-based compensation awards based on the grant date fair value of those awards and to record that cost as compensation expense over the period during which the employee is required to perform service in exchange for the award (generally over the vesting period of the award). Excess tax benefits, as defined by FAS 123R, will be recognized as an addition to common stock. On April 14, 2005, the U.S. Securities and Exchange Commission (SEC) adopted a new rule amending the compliance dates for FAS 123R. In accordance with the new rule, the accounting provisions of FAS 123R will be effective for us in the fiscal year starting October 1, 2005. The SEC also issued Staff Accounting Bulletin No. 107 (SAB 107), which provides interpretive guidance to assist issuers in their initial implementation of FAS 123R.

We have not yet completed the process of determining how the guidance regarding valuing share-based compensation as prescribed in FAS 123R will be applied to valuing share-based awards granted after the effective date and the impact that the recognition of compensation expense related to such awards will have on our financial condition and results of operations.

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Until FAS 123R became effective on October 1, 2005, we chose to continue to account for stock-based compensation using the intrinsic value method prescribed in APB Opinion No. 25 and related interpretations for all periods presented. Accordingly, compensation costs for stock options granted to employees are measured as the excess, if any, of the fair value of our common stock at the date of the grant over the amount the employee must pay to acquire the stock. For the purpose of determining compensation expense for stock options granted to non-employees, all of our directors are considered to be employees. The following table summarizes the pro forma effect on our net loss if compensation costs had been determined based upon the fair value at the grant date for awards under the stock option plans consistent with the methodology prescribed under FAS 123.

	Year Ended September 30,		
	2005	2004	2003
Net loss attributable to common shareholders, as reported	$ (30,606,564)	$ (28,154,853)	$ (23,264,293)
Add: Stock-based employee compensation included in reported net loss attributable to common shareholders	77,856	24,069	234,638
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(1,777,838)	(1,026,844)	(1,788,674)
Pro forma net loss attributable to common shareholders	$ (32,306,546)	$ (29,157,628)	$ (24,818,329)
Net loss per share:			
Basic and diluted as reported	$ (0.30)	$ (0.36)	$ (0.39)
Basic and diluted pro forma	$ (0.32)	$ (0.37)	$ (0.41)

We estimate the weighted average fair values per share of the options granted during fiscal 2005, 2004 and 2003 to be $2.84, $1.81, and $0.96, respectively, using the Black-Scholes option-pricing model and the following assumptions:

	Years Ended September 30,		
	2005	2004	2003
Risk free interest rate	3.8%	2.4%	2.7%
Expected life (years)	3.4	3.4	4.6
Expected volatility	95%	133%	125%
Expected dividends	None	None	None

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.

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.

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Comprehensive income (loss)

Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources, including foreign currency translation adjustments and unrealized gains and losses on marketable securities. We present comprehensive loss in our consolidated statements of shareholders equity and comprehensive loss.

Computation of net loss per common share

Basic net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period (Basic EPS Method). Diluted net loss per common share is computed by dividing net loss by the weighted-average number of common and dilutive common equivalent shares outstanding during the period (Diluted EPS Method). In the loss periods, the shares of common stock issuable upon exercise of stock options and warrants are excluded from the computation of diluted net loss per share, as their effect is anti-dilutive. For fiscal 2005, one million restricted shares of Class A common stock with a right of repurchase have been excluded from the computation of basic net loss per share, because the right of repurchase for these restricted shares has not lapsed. (See Note 10, Shareholders Equity, for further discussions.)

For fiscal 2005, 2004, and 2003, the following options and warrants to purchase shares of common stock were excluded from the computation of diluted net loss per share, as the inclusion of such shares would be antidilutive:

	Years Ended September 30,		
	2005	**2004**	**2003**
Stock options	6,400,131	5,253,593	5,308,604
Stock warrants	4,488,211	5,322,106	2,289,900

Recent accounting pronouncements

Financial Accounting Standards No. 151 (FAS 151). In November 2004, the FASB issued FAS 151, Inventory Costs , which requires abnormal amounts of idle facility expense, freight, handling costs and wasted material (spoilage), as well as unallocated overhead, to be recognized as current period charges. FAS 151 will be effective for inventory costs incurred during the fiscal years beginning after June 15, 2005. We do not expect FAS 151 to significantly affect our financial condition or results of operations.

Financial Accounting Standards No. 153 (FAS 153). In December 2004, the FASB issued FAS 153, Exchanges of Nonmonetary Assets , which eliminates the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. FAS 153 will be effective for nonmonetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. Adoption of FAS 153 did not significantly affect our financial condition or results of operations.

FASB Interpretation No. 47 (FIN 47). In March 2005, the FASB issued FIN 47, Accounting for Conditional Asset Retirement Obligations. FIN 47 clarifies that an entity must record a liability for a conditional asset retirement obligation if the fair value of the obligation can be reasonably estimated. The provision is effective no later than the end of fiscal years ending after December 15, 2005. We do not expect FIN 47 to significantly affect our financial condition or results of operations.

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

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retrospective application of a change in accounting principle is impracticable and for reporting a change when retrospective application is 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.

Emerging Issues Task Force No. 05-6 (EITF 05-6). In June 2005, the FASB ratified the consensus reached by the Task Force in EITF 05-6. The Task Force reached a consensus that leasehold improvements that are placed in service significantly after and not contemplated at or near the beginning of the lease term should be amortized over the shorter of the useful life of the assets or a term that includes required lease periods and renewals that are deemed to be reasonably assured at the date of the leasehold improvements are purchased. In addition, leasehold improvements acquired in a business combination should be amortized over the shorter of the useful lives of the assets or a term that includes required lease periods and renewals that are deemed to be reasonably assured at the date of acquisition. EITF 05-6 is effective for leasehold improvements (within the scope of this issue) that are purchased or acquired in the reporting period beginning after June 29, 2005. Adoption of EITF 05-6 did not significantly affect our financial condition or results of operations.

3. 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(1)	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

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	Amortized Cost	Gross Unrealized Gains(4)	Gross Unrealized Losses(4)	Fair Value
As of September 30, 2004:				
Certificates of deposit	$ 1,356,597	$ 3,558	$	$ 1,360,155
Adjustable rate mutual fund(3)	3,014,365		(68,650)	2,945,715
Government debt securities	8,125,858	6,186	(25,468)	8,106,576
Total	$ 12,496,820	$ 9,744	$ (94,118)	$ 12,412,446
Reported as:				
Short-term investments:				
Classified as available-for-sale				$ 8,803,982
Long-term investments:				
Classified as available-for-sale				2,751,867
Restricted investments(2)				856,597
Long-term investments				3,608,464
Total				$ 12,412,446

(1) Gross unrealized gains of $48 and gross unrealized losses of $113,862 on government securities and certificates of deposit represent an accumulated net unrealized loss of $113,814, which is reported as accumulated other comprehensive loss on the consolidated balance sheet as of September 30, 2005.

(2) Restricted investments amounting to $856,872 and $856,597 as of September 30, 2005 and 2004, respectively, represent amounts pledged to our bank as collateral for letters of credit issued in connection with our leases of office and laboratory space.

(3) Represents an investment in a mutual fund that invested primarily in adjustable rate mortgage-backed securities. This investment was sold in February 2005.

(4) Gross unrealized gains of $9,744 and gross unrealized losses of $94,118 on government securities, the adjustable rate mutual fund, and certificates of deposit represent an accumulated net unrealized loss of $84,374, which is reported as accumulated other comprehensive loss on the consolidated balance sheet as of September 30, 2004.

Gross realized loss and gains for fiscal year ended September 30, 2005 were $6,240 and $0, respectively. There were no realized gains or losses for fiscal years ended September 30, 2004 and 2003.

4. Receivables, Net

Receivables as of September 30, 2005 and 2004 consist of the following:

Years Ended September 30,

	2005	2004
Unbilled receivables	$ 1,010,902	$
Other receivables	186,851	257,379
	1,197,753	257,379
Allowance for doubtful accounts	(28,099)	(17,500)
Receivables, net	$ 1,169,654	$ 239,879

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5. Property and Equipment

Property and equipment as of September 30, 2005 and 2004 consist of the following:

	September 30, 2005			September 30, 2004		
	Gross Carrying Value	Accumulated Depreciation	Net	Gross Carrying Value	Accumulated Depreciation	Net
Research and development equipment	$ 3,903,735	$ (2,567,843)	$ 1,335,892	$ 3,701,461	$ (2,021,193)	$ 1,680,268
Computer equipment and related software	1,038,390	(565,137)	473,253	999,073	(545,953)	453,120
Leasehold improvements	5,583,177	(1,641,485)	3,941,692	5,032,605	(1,048,184)	3,984,421
Office equipment, furniture, and fixtures	558,911	(305,221)	253,690	558,970	(285,815)	273,155
Total property and equipment	$ 11,084,213	$ (5,079,686)	$ 6,004,527	$ 10,292,109	$ (3,901,145)	$ 6,390,964

Depreciation expense associated with property and equipment was $1,606,801, $1,553,337 and $942,397 for fiscal 2005, 2004 and 2003, respectively. At September 30, 2005 and 2004, assets acquired under capital leases totaled $600,624 with accumulated depreciation of $427,267 and $321,467, respectively. Depreciation of assets acquired under capital leases was $105,800, $106,090 and $105,800 for fiscal 2005, 2004 and 2003, respectively.

6. Intangible Assets

Intangible assets, consisting of both intangible assets with finite and indefinite useful lives as of September 30, 2005 and 2004, are as follows:

	September 30, 2005			
	Gross Carrying Value	Accumulated Amortization	Net	Weighted Average Amortization Period (in Years)
Intangible assets with finite lives:				
Patent applications pending(1)	$ 3,029,127	$ (336,457)	$ 2,692,670	20.0
Patents(2)	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
Intangible assets with indefinite useful lives(3)	24,471		24,471
Total intangible assets	$ 4,525,591	$ (860,505)	$ 3,665,086

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September 30, 2004

	Gross Carrying Value	Accumulated Amortization	Net	Weighted Average Amortization Period (in Years)
Intangible assets with finite lives:				
Patent applications pending	$ 2,462,704	$ (166,000)	$ 2,296,704	20.0
Patents	1,010,097	(339,552)	670,545	17.0
Licenses	42,461	(15,647)	26,814	15.5
Total intangible assets with finite lives	3,515,262	(521,199)	2,994,063	
Intangible assets with indefinite useful lives	40,961		40,961	
Total intangible assets	$ 3,556,223	$ (521,199)	$ 3,035,024	

(1) Patent applications pending are net of impairments of $111,497 in fiscal 2005 based on management s determination that certain patent applications pending had no future value. Patent applications pending are also net of abandonments totaling $220,324 (net of accumulated amortization of $34,621) in fiscal 2005. We abandoned certain therapeutic use patent applications pending in selected countries, because we were able to obtain superior claims in composition-of-matter patents.

(2) Patents are net of impairments of $64,889 and an abandonment of $2,944 (net of accumulated amortization of $68) in fiscal 2005 for the same reasons as described above.

(3) Intangible assets with indefinite useful lives are net of $23,469 in trademarks abandoned in fiscal 2005.

Amortization expense related to amortizable intangible assets was $225,750, $253,159 and $69,405 for fiscal years 2005, 2004, and 2003, respectively. During fiscal 2005 and 2004, there were additions of $1,278,935 and $1,156,975, respectively, in intangible assets. Based solely on the amortizable intangible assets as of September 30, 2005, the estimated annual amortization expense of intangible assets for the fiscal years ending September 30 is as shown in the following table. Actual amortization expense to be reported in future periods could differ from these estimates as a result of acquisitions, divestitures, asset impairments or abandonments, and other relevant factors.

Amortization Expense

Fiscal year ending September 30:	
2006	$ 249,834
2007	249,834
2008	249,491

2009	241,812
2010	219,600
Thereafter	2,430,044
Total	$ 3,640,615

7. Deferred Revenue

We have license and other types of agreements with additional or continuing obligations to perform under the agreements. In such arrangements, certain revenues have been deferred until the performance obligations have been met or ratably achieved. 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 GlaxoSmithKline License Agreement , respectively).

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Under the Drug Royalty Agreement, Drug Royalty has the right to receive royalties from GlaxoSmithKline on sales of Abreva until December 2013.

The terms of the Drug Royalty Agreement contain certain covenants under which we must perform in order to satisfy the continuing terms and conditions of the arrangement. In certain circumstances, nonperformance on our part could result in default of the arrangement, and could trigger a separate security agreement with Drug Royalty, which could result in loss of our rights to share in future Abreva royalties if wholesale sales by GlaxoSmithKline exceed $62 million a year. The nature of these terms and covenants results in our continuing involvement and, accordingly, we recorded the net proceeds of the transaction as deferred revenue, to be recognized as revenue ratably over the expected life of the license agreement.

The following table sets forth as of September 30, 2005 the deferred revenue balances for the Drug Royalty Agreement and other agreements. The portion of deferred revenue classified as a current liability represents the amount we expect to realize as revenue within the next 12 months.

	Drug Royalty USA Agreement	Other Agreements	Total
Deferred revenue as of September 30, 2004	$ 20,800,782	$ 208,333	$ 21,009,115
Changes during the year:			
Recognized as revenue during the year	(1,750,905)	(100,000)	(1,850,905)
Deferred revenue as of September 30, 2005	$ 19,049,877	$ 108,333	$ 19,158,210
Classified as:			
Current portion of deferred revenue	$ 1,937,656	$ 33,333	$ 1,970,989
Deferred revenue, net of current portion	17,112,221	75,000	17,187,221
Total deferred revenue	$ 19,049,877	$ 108,333	$ 19,158,210

8. Commitments and Contingencies

Operating lease commitments. We lease laboratory and office space and certain equipment under non-cancelable operating leases. In March 2000, we signed an eight-year lease for 27,047 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. In February 2001, we signed an amendment to the lease for an additional 165 square feet of office and lab space. The lease has scheduled rent increases each year and expires on August 31, 2008. As of September 30, 2005, the financial commitment for the remainder of the term of the lease is $2,406,571. 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. As of September 30, 2005, the financial commitment for the remainder of the term of the lease is $8,004,337. We delivered an irrevocable standby letter of credit to the lessor in the amount of $468,475, to secure our performance under the lease.

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Rental expenses were $1,834,193 in fiscal 2005, $1,797,324 in fiscal 2004 and $1,724,403 in fiscal 2003. Future minimum rental payments under non-cancelable operating lease commitments as of September 30, 2005 are as follows:

Year Ending September 30,	Minimum Payments
2006	$ 1,801,259
2007	1,850,930
2008	1,832,255
2009	1,090,463
2010	1,134,084
Thereafter	2,753,645
Total	$ 10,462,636

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 of one dollar ($1.00).

Future minimum payments under the capital leases as of September 30, 2005 are as follows:

Year Ending September 30,	Minimum Payments
2006	$ 28,742
2007	9,581
Total	38,323
Less amount representing interest	(2,681)
Present value of net lease payments	35,642
Less current portion	(26,305)
Long-term portion of obligation	$ 9,337

Legal contingencies. In the ordinary course of business, we may face various claims brought by third parties, including 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 and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business. Management believes the outcome of currently identified claims and lawsuits will not have a material adverse effect on our results of operations or financial position.

9. Notes Payable

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, 2005 and 2004 under the GE Capital finance agreement is approximately $955,000 and $915,000, respectively. The loans are for a term of 42 months at

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annual interest rates ranging from 9.5% to 10.4% per year with fixed monthly payments. Future minimum payments under the GE Capital finance agreement as of September 30, 2005, are as follows:

Year Ending September 30,	Minimum Payments
2006	$ 396,612
2007	396,612
2008	268,194
2009	33,628
Total	1,095,046
Less amount representing interest	(140,094)
Present value of payments	954,952
Less current portion	(317,667)
Long-term portion of obligation	$ 637,285

Other Notes Payable. We obtained approximately $160,000 from a third party in fiscal 2004 to facilitate annual payments on certain insurance premiums. The financing was for a term of nine months at an interest rate of approximately 3.1% per year with a monthly payment of approximately $18,000. The note was repaid in full as of September 30, 2004.

10. Shareholders Equity

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, 2005 and 2004, 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.

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, 2005 and 2004. 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 one one-hundredth of a share of our Series C junior participating preferred stock at an exercise price of $10.00 per share. 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.

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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 2005. In September 2005, we issued to our CEO a restricted stock award to purchase 1,000,000 shares of Class A common stock at an exercise price of $0.001 per share (Restricted Stock). The Restricted Stock is subject to a right of repurchase by us at the original issue price of $0.001 per share that will lapse as to one-third of the shares in September 2006 and as to an additional one-twelfth of the shares quarterly thereafter. 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. This unearned compensation is amortized as compensation expense ratably over the repurchase period of three years. In September 2005, the award was exercised to purchase all of 1,000,000 shares of Restricted Stock for total cash of $1,000. During fiscal 2005, $78,000 was charged to compensation expense. As of September 30, 2005, the balance of unearned compensation was $3,477,144. As of September 30, 2005, none of the Restricted Stock was vested.

In April 2005, we issued and sold 7,770,000 shares of Class A common stock in a registered direct offering at a price of $2.20 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 2,000,000 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 Neurodex, our late-stage drug candidate for the treatment of multiple central nervous system disorders. We valued these shares at $2.65 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 12, Related Party Transactions, for further discussions.

In December 2004, we issued and sold to an institutional investor 2,333,333 shares of Class A common stock at a price of $3.00 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 957,836 shares of Class A common stock in connection with the exercise of stock purchase warrants (845,942 shares at a weighted average price of $1.53 per share) and employee stock options (111,894 shares at a weighted average price of $1.12 per share) for cash in the aggregate amount of approximately $1.4 million.

Fiscal 2004. In August 2004, we issued the Ciblex Corporation 1,036,807 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 19,685,040 shares of Class A common stock at $1.27 per share ($1.18 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 2,952,756 shares of Class A common stock at the public offering price of $1.27 per share ($1.18 per share after underwriter s discount) to cover over-allotments. This offering

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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 5,382,316 shares of Class A common stock and warrants to purchase an additional 3,229,389 shares of Class A common stock to several accredited investors and received approximately $8,020,000 in gross proceeds. The warrant exercise price is $1.75 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 161,470 shares of our Class A common stock at $1.75 per share.

Also during fiscal 2004, we issued an aggregate of 418,904 shares of Class A common stock in connection with the exercise of stock purchase warrants (294,895 shares at a weighted average price of $1.59 per share) and employee stock options (124,009 shares at a weighted average price of $1.30 per share) for cash in the aggregate amount of approximately $609,000, representing a weighted average price per share of $1.45.

Fiscal 2003. In May 2003, the holders of Series D redeemable convertible preferred stock (Series D Shares) exercised their rights to convert all of the remaining 50 Series D Shares, representing $500,000 in redeemable convertible preferred stock and $36,630 in accrued and unpaid dividends, into 660,305 shares of Class A common stock, for an average price of $0.81 per share. The Series D Shares were issued in connection with a securities purchase agreement made with certain investors on March 22, 1999.

In July 2003, we sold and issued 6,728,396 shares of Class A common stock and warrants to purchase an additional 1,345,673 shares of Class A common stock to several accredited investors and received $10.0 million in gross proceeds. The warrant exercise price is $2.23 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 one share of Class A common stock for every five shares 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 $9.4 million after taking into effect the cost of the transaction.

Also during fiscal 2003, we issued an aggregate of 77,200 shares of Class A common stock in connection with the exercise of stock purchase warrants (53,200 shares at a weighted average price of $1.13) and employee stock options (24,000 shares at a weighted average price of $1.06) for cash in the aggregate amount of $85,350, representing a weighted average price per share of $1.11.

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Details of common stock transactions during fiscal 2005, 2004 and 2003 are shown in the tables that follow.

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, 2005:				
Private placement of common stock	December 2004	2,333,333	$ 6,999,999	$ 3.00
Private placement of common stock	April 2005	7,770,000	17,094,000	$ 2.20
Acquisition of certain contractual rights to Neurodex	March 2005	2,000,000	5,300,000	$ 2.65
Restricted stock award	September 2005	1,000,000	1,000	$ 0.00
Stock options	Various	111,894	125,491	$ 1.12
Warrants(4)	Various	845,942	1,293,339	$ 1.53
Total		14,061,169	$ 30,813,829	
Fiscal year ended September 30, 2004:				
Underwritten public offering(3)	June 2004	22,637,796	$ 26,737,500	$ 1.18
Private placement of common stock and warrants	December 2003	5,382,316	8,019,652	$ 1.49
Issuance of common stock to Ciblex	August 2004	1,036,807	2,733,023	$ 2.64
Conversions of Class B common stock	Various	13,500	8,395	$ 0.62
Stock options	Various	124,009	160,823	$ 1.30
Warrants(4)	Various	294,895	448,671	$ 1.59
Total		29,489,323	$ 38,108,064	
Fiscal year ended September 30, 2003:				
Private placement of common stock and warrants	July 2003	6,728,396	$ 10,025,320	$ 1.49
Conversions of Series D redeemable convertible preferred stock	May 2003	660,305	536,630	$ 0.81
Restricted stock grants to directors	March 2003	80,000	92,800	$ 1.16
Stock options	Various	24,000	25,500	$ 1.06

Warrants(4)	Various	53,200	59,850	$ 1.13
Total		7,545,901	$ 10,740,100	

(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 $1.18 in the underwritten public offering is after underwriter s discount of $2.0 million, representing approximately $0.09 per share.

(4) Includes 19,119 shares issued on a cashless exercise basis at an average exercise price of $1.05 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, 13,500 shares of Class B common stock were converted to 13,500 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.

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Warrants

Class A warrants. During fiscal 2005, Class A warrant holders exercised their rights to purchase an aggregate of 26,845 shares of Class A common stock for total cash of $59,864. As of September 30, 2005, Class A warrants to purchase 1,318,828 and 3,169,383 shares at $2.23 and $1.75, respectively, remained outstanding.

Class G warrants. During fiscal 2005, the Class G warrant holder exercised its right to purchase 757,050 shares of Class A common stock for total cash of $1.1 million. The Class G warrant was issued in connection with the conversion of a 1997 convertible note payable. As of September 30, 2005, none of the Class G warrants remained outstanding.

Class J warrants. During fiscal 2005, Class J warrant holders exercised their rights to purchase an aggregate of 62,047 shares of Class A common stock for the total cash of $135,753. During fiscal 2004, Class J warrant holders were issued the rights to purchase an additional 12,047 shares of Class A common stock in accordance with antidilution provisions in the warrant agreement. The Class J warrants were issued in connection with Series D redeemable convertible preferred stock that was issued in fiscal 2000 and 1999. As of September 30, 2005, none of the Class J warrants remained outstanding.

The following table summarizes all warrant activity for fiscal 2005, 2004 and 2003:

	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, 2002	1,084,550	$ 1.42	$ 0.91 $2.72
Issued	1,345,673	$ 2.23	$ 2.23
Expired	(87,123)	$ 1.28	$ 1.28
Exercised	(53,200)	$ 1.13	$ 1.13
Outstanding at September 30, 2003	2,289,900	$ 1.91	$ 0.91 $2.72
Issued	3,402,906	$ 1.75	$ 1.75
Tendered(1)	(30,881)	$ 1.05	$ 1.05
Expired	(32,877)	$ 2.44	$ 2.44
Exercised	(294,895)	$ 1.59	$ 1.05-$1.75
Outstanding at September 30, 2004	5,334,153	$ 1.83	$ 1.38 $2.72
Exercised	(845,942)	$ 1.53	$ 1.45-$2.19
Outstanding at September 30, 2005	4,488,211	$ 1.89	$ 1.75-$2.23

(1) Warrant shares tendered represent 30,881 in the amount of warrant shares given up, in lieu of cash, for warrants exercised (cashless exercise).

Stock options

Stock options to employees. During fiscal 2005, we issued incentive stock options under our stock option plans to our officers and non officer employees for the purchase of an aggregate of 630,000 and 335,000 shares, respectively,

of Class A common stock at exercise prices of $2.56 to $3.46 per share. The exercise price for each of these options equals the closing market price for the common stock on the dates of the grants.

Stock options to non-employee directors. During fiscal 2005, we issued to our non-employee directors stock options to purchase an aggregate of 165,000 shares of Class A common stock at exercise prices of $2.48

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to $3.29 per share. The exercise price of each option equals the closing market price for the common stock on the dates of grant.

2005 Equity Incentive Plan. On March 17, 2005, our shareholders approved the adoption of a 2005 equity incentive plan (the 2005 Plan) that provides for the issuance of up to 2,000,000 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) 1,300,000 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. Additionally, the maximum number of shares of Class A common stock that may be issued under the 2005 Plan shall not exceed 15% of the aggregate shares of Class A common stock reserved for issuance under this 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, 2005, 1,285,000 shares of Class A common stock remained available for issuance under the 2005 Plan. On November 16, 2005, the number of shares of Class A common stock available for issuance under the 2005 Plan increased by 1,093,669 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 a 2003 equity incentive plan (the 2003 Plan) that provides for the issuance of up to 2,500,000 shares of Class A common stock. 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, 2005 and 2004, 2,330,000 and 2,500,000 shares of Class A common stock, respectively, remained available for issuance under the 2003 Plan.

2000 Stock Option Plan. On March 23, 2000, our shareholders approved the adoption of the 2000 Stock Option Plan (the 2000 Plan), pursuant to which an aggregate of 2,300,000 shares of our Class A common stock have been reserved for issuance. On March 14, 2002, our shareholders approved an amendment to the Plan to increase the number of shares of Class A common stock issuable under the Plan by 1,000,000 shares, for an aggregate of 3,300,000 shares. On March 13, 2003, we amended the 2000 Plan to allow for the issuance of restricted stock awards. As of September 30, 2005 and 2004, 9,769 and 517,701 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 Stock Option Plan (the 1998 Plan). The 1998 Plan as amended in 2002 provides for the issuance of up to an aggregate of 1,875,000 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, 2005 and 2004, options to purchase 7,303 shares of Class A common stock, respectively, were available for grant under the 1998 Plan.

Canceled stock options. During fiscal 2005, options to purchase an aggregate of 134,500 shares of Class A common stock at prices ranging from $2.94 to $6.44 per share were canceled following their expiration dates. Also, options to purchase 126,568 shares at prices ranging from $1.00 to $4.85 per share were canceled due to voluntary and involuntary terminations. The weighted average price per share for all canceled options was $3.53.

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The following table summarizes all common stock option activity for fiscal 2004, 2003 and 2002:

	Number of Shares Underlying Class A Stock Options	Weighted Average Option Price Per Share
Outstanding at October 1, 2002	5,739,306	$ 2.25
Granted	737,500	$ 1.15
Exercised	(24,000)	$ 1.06
Canceled	(1,144,202)	$ 2.93
Outstanding at September 30, 2003	5,308,604	$ 1.96
Granted	243,000	$ 1.81
Exercised	(124,009)	$ 1.30
Canceled	(174,002)	$ 2.64
Outstanding at September 30, 2004	5,253,593	$ 1.95
Granted	1,519,500	$ 3.15
Exercised	(111,894)	$ 1.12
Canceled	(261,068)	$ 3.53
Outstanding at September 30, 2005	6,400,131	$ 2.19
Exercisable at September 30, 2005	5,031,583	$ 1.98
Exercisable at September 30, 2004	4,656,411	$ 1.99
Exercisable at September 30, 2003	4,303,092	$ 1.99

The following table summarizes information concerning outstanding and exercisable Class A stock options as of September 30, 2005**:**

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$0.30 $0.72	882,974	3.44	$ 0.69	882,974	$ 0.69
$0.78	15,000	3.79	$ 0.78	15,000	$ 0.78
$1.00 $1.16	838,305	6.36	$ 1.13	768,689	$ 1.12

$1.28	$2.31	1,638,466	4.28	$ 1.66	1,544,200	$ 1.66
$2.47	$2.94	1,131,631	6.83	$ 2.70	614,965	$ 2.57
$3.00	$3.57	1,705,000	7.73	$ 3.37	1,017,000	$ 3.39
$4.00	$6.44	188,755	5.72	$ 4.70	188,755	$ 4.70
		6,400,131	5.85	$ 2.18	5,031,583	$ 1.98

11. License and Other Agreements

Novartis International Pharmaceutical Ltd. (Novartis). In April 2005, we entered into a research, development and commercialization agreement with Novartis for orally active small molecule therapeutics utilizing our novel macrophage migration inhibitory factor (MIF) technology as a potential treatment for inflammatory diseases. Under the terms of the agreement, we will be eligible to receive royalty payments,

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assuming the product is successfully developed and approved for marketing by the FDA. We are also eligible to receive up to $169 million in milestone payments contingent upon achievement of certain development and regulatory milestones, which could take several years of further development, including achievement of certain sales targets, when and if a MIF compound is approved for marketing by the FDA. Additionally, we received an up-front payment of $2.5 million in May 2005 for the license fee and transfer of data and know-how of the MIF technology to Novartis. We will also receive research funding of between $1.5 million and $2.5 million per year for providing research and development services to Novartis for two years from the date of the agreement, or longer upon mutual agreement of the parties. While both parties to the agreement will contribute expertise and intellectual property to the research and development collaboration, Novartis assumes responsibility for all development expenses.

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 have delivered the license and therefore, we recognized the $2.5 million up-front payment as revenue in the fiscal year ended September 30, 2005. In addition, we have recorded research and development services revenue of approximately $682,000 based on the number of full time equivalent employees that worked directly on the project at the agreed upon compensation rates in the fiscal year ended September 30, 2005.

AstraZeneca UK Limited (AstraZeneca). In July 2005, we entered into an exclusive licensing and research collaboration agreement with AstraZeneca to discover, develop and commercialize reverse cholesterol transport enhancing compounds for the treatment of cardiovascular disease. Under the terms of the agreement, we will be eligible to receive royalty payments, assuming the product is successfully developed and approved for marketing by the FDA. We are also eligible to receive up to $330 million in milestone payments contingent upon achievement of certain development and regulatory milestones, which could take several years of further development, including achievement of certain sales targets, when and if a licensed compound is approved for marketing by the FDA. Under this agreement, we received an up-front payment of $10 million in July 2005 and will also receive research funding of between $2.5 million to $4.0 million per year for providing research and development services to AstraZeneca for up to three years. AstraZeneca will assume responsibility for overall development and for the development costs, with both parties contributing scientific expertise in the research collaboration.

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 have delivered the license and therefore, we recognized the $10.0 million up-front payment as revenue in the fiscal year ended September 30, 2005. In addition, we have recorded

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research and development services revenue of approximately $825,000 based on the number of full time equivalent employees that worked directly on the project at the agreed upon compensation rates in the fiscal year ended September 30, 2005.

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.

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 7, 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,

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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 balance remaining under the research grants as of September 30, 2005 and 2004 was approximately $161,000 and $724,000, respectively. 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.

12. 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, Neurodex, to treat multiple central nervous system disorders (Sublicense Agreement). IriSys held exclusive rights to Neurodex 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 Neurodex. As a result, through our wholly owned subsidiary we hold the exclusive worldwide marketing rights to Neurodex 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 Neurodex and a royalty on commercial sales of Neurodex, 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 Neurodex to a third party.

Pursuant to the Asset Purchase Agreement, we paid IriSys a purchase price of $7,225,000 including $1,925,000 in cash and 2,000,000 shares of our Class A common stock with a fair value of $5,300,000. The value of the acquired assets was determined based on various financial models for the commercialization of Neurodex 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 $2.65 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 Neurodex 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.

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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 the fiscal year ended September 30, 2005 and are being 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 $319,000 as of September 30, 2005.

Dr. Yakatan has been 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 has 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 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 Neurodex 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 Neurodex 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 2005, 2004 and 2003, we paid IriSys $0, $4,200 and $18,840, respectively, related to continuation of the stability testing.

13. Income Taxes

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

	2005	2004	2003
Current:			
State and foreign	$ (1,813)	$ (2,664)	$ (3,599)
Deferred:			
Federal	10,143,270	10,900,106	8,676,371
State	5,017,269	246,528	3,892,419
	15,160,539	11,146,634	12,568,790
Increase in deferred income tax asset valuation allowance	(15,160,539)	(11,146,634)	(12,568,790)
Total income tax provision	$ (1,813)	$ (2,664)	$ (3,599)

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Avanir Pharmaceuticals
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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:

	2005	2004	2003
Federal statutory rate	(34)%	(34)%	(34)%
Increase in deferred income tax asset valuation allowance	50	40	54
State income taxes, net of federal effect	(6)	(6)	(6)
Research and development credits	(5)	(4)	(5)
Foreign tax credit			
State net operating loss limitations		1	(1)
Other	(5)	3	(8)
Effective income tax rate	0%	0%	0%

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,	
	2005	2004
Net operating loss carryforwards	$ 45,035,045	$ 36,718,417
Deferred revenue	7,631,558	8,368,855
Research credit carryforwards	10,468,702	8,720,996
Capitalized research and development costs	3,903,561	2,449,685
Capitalized license fees	5,193,944	626,822
Foreign tax credits	595,912	590,342
Other	694,531	887,461
Net deferred income tax assets	73,523,253	58,362,578
Less valuation allowance for net deferred income tax assets	(73,523,253)	(58,362,578)
	$	$

We have provided a full valuation allowance against the net deferred income tax assets recorded as of September 30, 2005 and 2004 as we concluded that they are unlikely to be realized. The net operating loss and research credit carryforwards expire on various dates through 2025. 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, 2005, we had $43,614,623 and $1,420,422 of Federal and California net operating loss carryforwards, respectively. As of September 30, 2005, we had $5,908,239 and $4,560,463 of Federal and California research and development credit carryforwards, respectively.

14. 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 $96,353 in fiscal 2005, $56,480 in fiscal 2004 and $70,753 in fiscal 2003 to the plan.

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Avanir Pharmaceuticals
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15. 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 reviews our operating results on an aggregate basis and manages our operations as a single operating segment. We have developed one commercial product, docosanol 10% cream, known as Abreva in North America, and we have several other product candidates in various stages of development. We have licensed docosanol 10% cream to other companies in the world that market the product and provide us royalties on product sales. We also have exclusively licensed our reverse cholesterol transport and MIF programs to AstraZeneca and Novartis, respectively, which provide us with license fee and research funding revenues. These collaborative agreements will also provide milestone payments upon achievement of certain development and regulatory milestones, which could take several years of further development, and on achievement of certain sales targets, if and when the products are approved for marketing by the FDA and royalties on sales, if and when the products are approved for marketing by the FDA.

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 years ended September 30, 2005, 2004 and 2003 are attributed to the United States. All long-lived assets for fiscal years ended September 30, 2005 and 2004 are located in the United States.

In fiscal 2005, revenues derived from our license agreements with AstraZeneca and Novartis accounted for approximately 66% and 19%, respectively, of our total revenues. Approximately 10%, 48% and 73% of our total revenues in fiscal 2005, 2004 and 2003, respectively, are derived from our license agreement with GlaxoSmithKline and the sale of rights to royalties under that agreement. As of September 30, 2005, net receivables from AstraZeneca accounted for approximately 81% of our total net receivables.

16. Subsequent Event

On October 18, 2005, we entered into a stock purchase agreement with certain institutional investors pursuant to which we issued and sold 6,094,339 shares of Class A common stock at a price of $2.65 per share (the Offering), for aggregate net offering proceeds of approximately $16.15 million. The Offering was made pursuant to our shelf registration statement on Form S-3 filed on July 22, 2005.

* * * * *

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Exhibit Index

Number	Exhibit Title
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*
10.5	Standard Industrial Net Lease by and between Avanir Pharmaceuticals and BC Sorrento, LLC, effective September 1, 2000(6)
10.6	License Agreement, dated August 1, 2000, by and between Avanir Pharmaceuticals (Licensee) and Irisys Research and Development, LLC, a California limited liability company(6)
10.7	Asset Purchase Agreement, dated March 8, 2005, by and among Avanir Pharmaceuticals, Avanir Holding Company, IriSys, Inc., Gerald J. Yakatan, Ph.D. and Gina M. Stack(19)

10.8	License Agreement, dated April 2, 1997, by and between Irisys Research & Development, LLC and the Center for Neurologic Study(16)
10.9	Amendment to License Agreement, dated April 11, 2000, by and between IriSys Research & Development, LLC and the Center for Neurologic Study(16)
10.10	Amended and Restated 1998 Stock Option Plan(7)
10.11	Amended and Restated 1994 Stock Option Plan(7)
10.12	Standard Industrial Net Lease by and between Avanir Pharmaceuticals (Tenant) and Sorrento Plaza, a California limited partnership (Landlord), effective May 20, 2002(8)
10.13	Amended and Restated 2000 Stock Option Plan(9)
10.14	Form of Restricted Stock Grant Notice for use with Amended and Restated 2000 Stock Option Plan(9)
10.15	2003 Equity Incentive Plan(9)
10.16	Form of Non-qualified Stock Option Award Notice for use with 2003 Equity Incentive Plan(9)
10.17	Form of Restricted Stock Grant for use with 2003 Equity Incentive Plan(9)
10.18	Form of Restricted Stock Grant Notice (cash consideration) for use with 2003 Equity Incentive Plan(9)
10.19	Form of Indemnification Agreement with certain Directors and Executive Officers of the Registrant (12)
10.20	Clinical Development Agreement, dated March 22, 2005, by and between Avanir Pharmaceuticals and SCIREX Corporation(16)
10.21	2005 Equity Incentive Plan

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Number	Exhibit Title
10.22	Form of Stock Option Agreement for use with 2005 Equity Incentive Plan (20)
10.23	Employment Agreement with Eric Brandt, dated August 15, 2005*
10.24	Stock Purchase Agreement, dated October 18, 2005 (21)
10.25	Employment Agreement with Keith Katkin, dated June 13, 2005
21.1	List of Subsidiaries
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (contained on signature page)
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
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

* Confidential treatment requested.

(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.

(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.

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(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 11, 2005.

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

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