ADVENTRX PHARMACEUTICALS INC
Form 10KSB
March 31, 2005
10KSB

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-KSB

(Mark one)

[X] **Annual report under Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the Fiscal Year December 31, 2004, or

[ ] **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Commission file number: 001-32157

ADVENTRX PHARMACEUTICALS, INC.
(Name of Small Business Issuer in its charter)

Delaware	**84-1318182**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

6725 Mesa Ridge Road, Suite 100, San Diego, California 92121
(Address of principal executive offices)

(858) 552-0866
(Issuer's telephone number, including area code)

Securities registered under Section 12(b) of the Exchange Act: **None**

Securities registered under Section 12(g) of the Exchange Act:

Common Stock, par value $0.001 per share

Indicate by check mark whether the issuer (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the issuer was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-B is not contained herein, and will not be contained, to the best of issuer's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. [ ]

State issuer's revenues for its most recent fiscal year: $103,042

The aggregate market value of the Common Stock held by non-affiliates of the issuer, as of March 28, 2004 was approximately $53,056,708 based upon the closing price of the issuer's Common Stock reported for such date on the American Stock Exchange. For purposes of this disclosure, shares of Common Stock held by persons who the issuer believes beneficially own more than 5% of the outstanding shares of Common Stock and shares held by officers and directors of the issuer have been excluded because such persons may be deemed to be affiliates of the issuer. This determination is not necessarily conclusive.

As of March 28, 2004, 53,811,072 shares of the issuer's Common Stock were outstanding.

Portions of the definitive Proxy Statement to be delivered to stockholders in connection with the 2005 Annual Meeting of Stockholders to be held May 24, 2005 are incorporated by reference into Part III.

Certain exhibits filed with the registrant's prior forms 10-K and forms 10-Q are incorporated herein by reference into Part IV of this Report.

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PART I

This Annual Report on Form 10-KSB contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which include, without limitation, statements about the market for our technology, our strategy, competition, expected financial performance and other aspects of our business identified in this Annual Report, as well as other reports that we file from time to time with the Securities and Exchange Commission. Any statements about our business, financial results, financial condition and operations contained in this Annual Report that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words "believes," "anticipates," "expects," "intends," "projects," or similar expressions are intended to identify forward-looking statements. Our actual results could differ materially from those expressed or implied by these forward-looking statements as a result of various factors, including the risk factors described in Part II., Item 6, "Plan of Operation—Risk Factors," and elsewhere in this report. We undertake no obligation to update publicly any forward-looking statements for any reason, except as required by law, even as new information becomes available or other events occur in the future

CoFactor™, SeloneÔ, ThiovirÔ, EradicAideÔ, BlockAide/CR™ and BlockAide/VP™ are our trademarks. Product names, trade names and trademarks of other entities are also referred to in this report.

Item 1. Description of Business.

In this report, the terms "ADVENTRX," "Company," "we," "us" and "our" refer to ADVENTRX Pharmaceuticals, Inc. T term "Common Stock" refers to our Common Stock, par value $0.001 per share.

Business Development

We organized as a corporation under the Delaware General Corporation Law in December 1995.

On May 30, 2003, we merged our wholly owned subsidiary, Biokeys, Inc., into itself and changed our name from Biokeys Pharmaceuticals, Inc. to ADVENTRX Pharmaceuticals, Inc. The merger had no effect on our financial statements.

In July 2004, we formed a wholly owned subsidiary, ADVENTRX (Europe) Ltd., in the United Kingdom for the purpose of conducting clinical trials in the European Union.

Business of Issuer

We are a biopharmaceutical research and development company focused on introducing new technologies for anticancer and antiviral treatments that improve the performance of existing drugs and address significant problems such as drug metabolism, bioavailability and resistance. Our business is in the development stage; we have not generated any significant revenues and we have not yet marketed any products.

Principal Products

General information regarding each of the products currently in our pipeline is listed below.

Product/Description	Development Stage	Indication	Intellectual Property
CoFactor™ 5-FU Biomodulator	Phase I/II trials completed in Europe	Metastatic GI and Breast cancers	Exclusive license to use patents and other intellectual property from the University of Southern California ("USC").
	Phase II first-line U.S. trial began in Q1 2004. Patient enrollment complete Q1 2005	Metastatic Colorectal Cancer	
	Filed in U.S. for Phase III first- line randomized controlled trial in Q1 2005	Metastatic Colorectal Cancer	
	Filed in the UK for Phase IIb first-line randomized controlled trial in Q1 2005	Metastatic Colorectal Cancer	
	Plan to file in EU for Phase III trial in 1H 2005	Metastatic Pancreatic Cancer	
Selone™ Alkylating Agent	Preclinical	Drug Resistant Cancers	Exclusive license to use patents and other intellectual property from USC.
Thiovir™ Pyrophosphate Analogue	Preclinical	HIV/AIDS	Exclusive license to use patents and other intellectual property from USC.
EradicAide™ Therapeutic Vaccine	Preclinical	HIV/AIDS	Exclusive license to use patents and other intellectual property from MD Anderson.
BlockAide/CR™ Viral Entry Inhibitor	Preclinical	HIV/AIDS	Exclusive license to use patents and other intellectual property from the University of Texas MD Anderson Cancer Center ("MD Anderson") and the National Institutes of Health

("NIH").

BlockAide/VP™ Viral Entry Inhibitor	Preclinical	HIV/AIDS	Exclusive license to use patents and other intellectual property from MD Anderson and NIH.

CoFactor

CoFactor™ is a folate-based biomodulator drug developed to enhance the activity of the widely used cancer chemotherapeutic, 5-fluorouracil (5-FU). CoFactor enhances 5-FU activity to block cancer cell growth by creating more stable binding of the target enzyme, thymidylate synthase (TS), compared to leucovorin, which is the currently approved folate on the market. CoFactor bypasses the chemical pathway required by leucovorin to deliver the active form of folate to allow 5-FU to work more effectively. This improves 5-FU performance and lowers toxicity. Data from previous clinical trials in Europe demonstrated clinical benefit and improved overall median survival in patients with advanced cancer tumors, including colorectal, pancreatic, stomach and breast cancer. We have an exclusive license from the University of Southern California to develop and commercialize CoFactor.

In Q1 2004, we launched a Phase II Simon two-stage clinical trial using CoFactor with 5-FU in metastatic colorectal cancer patients in the US and in Q2 2004, we expanded the trial by including clinical sites in Europe under the same Investigational New Drug ("IND") application we filed in the United States. In Q4 2004, the FDA granted allowance to begin recruiting patients for the second stage of our Phase II trial of CoFactor to treat metastatic colorectal cancer patients. In Q1 2005, we completed patient enrollment and met the primary endpoint for response rate in this trial.

In Q4 2004, we announced that CoFactor received orphan drug status in the EU and US for pancreatic cancer. In the US, orphan drug status is available for products to treat diseases that affect fewer than 200,000 people in the US and provides for tax incentives for clinical development of CoFactor trials conducted in the US and seven years of market exclusivity following drug approval. In the EU, orphan medicines are defined as those drugs for treating life threatening medical conditions that affect fewer than 5 out of every 10,000 people in the EU. EU orphan status provides incentives, such as reduced fees for protocol assistance and scientific advice and ten years of marketing exclusivity following drug approval.

We announced results of CoFactor preclinical studies at three oncology conferences in 2004. At the American Society of Clinical Oncology 40th Annual Meeting in June, we presented encouraging data from a xenograft mouse model for colorectal cancer comparing combination treatments of CoFactor/5-FU and an antibody against VEGF (vascular endothelial growth factor) with CoFactor/5-FU, leucovorin/5-FU and 5-FU alone. The results were the first to suggest that treatment with CoFactor/antiVEGF/5-FU might have utility as a colorectal tumor therapy with greater antitumor activity than standard 5-FU therapies. In June at the American Association for Cancer Research (AACR) Pancreatic Advances and Challenges Conference in San Francisco, we presented a poster showing significant tumor inhibition in mice treated with CoFactor/5-FU but not leucovorin/5-FU. Combining anti-VEGF with CoFactor/5-FU resulted in the greatest tumor inhibition compared to all other treatment groups, including those with or without anti-VEGF. Likewise, CoFactor/anti-VEGF/5-FU treated mice had significantly greater survival compared to other treatment groups including mice treated with combination leucovorin/anti-VEGF/5-FU. In September, at the 16th EORTC/NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics in Geneva, Switzerland, we presented a poster showing data from a preclinical study in which CoFactor/5-FU showed significantly lowered toxicity than the leucovorin/5-FU or 5-FU alone treated groups, without concomitant loss of antitumor activity.

In Q1 2005 we filed for clearance with the U.S. Food and Drug Administration (FDA) to launch a Phase III randomized controlled trial in metastatic colorectal cancer. Additionally, we filed Clinical Trial Applications in the European Union (EU), including the United Kingdom and Germany, and in countries outside the EU for clearance to evaluate CoFactor in a Phase IIb, international, multi-center, randomized, controlled trial for metastatic colorectal cancer. We plan to submit a Clinical Trial Application in Europe to conduct a Phase III study using CoFactor in patients with advanced pancreatic cancer in 1H 2005 based on a final advice letter from the EMEA.

Selone

Selone™ is a compound in a class of drugs known as organoselenones, consisting of carbon, oxygen and selenium. Selone and its analogues are effective, at even relatively low concentrations, against human ovarian, breast, lung and head/neck cancers, and against leukemias and lymphomas, based upon current in vitro screening methods. Their potency is high for their rate of alkylating activity, suggesting an increased specificity of action. Preclinical efforts have demonstrated effectiveness of Selone in treatment of leukemia in mice at doses predicted to easily achieve effective blood concentrations, as well as in a variety of human tumor cell lines in laboratory testing. We intend to undertake further preclinical testing of Selone during 2005 in order to determine the potential for this drug to be moved into human testing in the future. We have an exclusive license from the University of Southern California to develop and commercialize Selone.

Thiovir

Thiovir™, and other Thiovir-analogues under development, are parts of a class of compounds known as thiophosphonoformates, which have demonstrated powerful antiviral properties. Thiovir was designed as an oral replacement for the IV-administered antiviral drug, foscarnet, which is FDA-approved for treatment of cytomegalovirus (CMV) infection in HIV patients. We have an exclusive license from the University of Southern California to develop and commercialize Thiovir.

Although foscarnet is an effective, broad-spectrum antiviral, it has limitations from a commercial perspective. Foscarnet is a small molecule with a parent structure that restricts modification which could lead to improved oral bioavailability or effectiveness. We believe that Thiovir can serve as an effective oral replacement for foscarnet as part of HAART therapy where foscarnet is not currently used since it is difficult to administer. Thiovir is a NNRTI (non nucleoside reverse transcriptase inhibitor), which we believe can be used with NRTIs (nucleoside reverse transcriptase inhibitors) and protease inhibitors. Thiovir has a different mode of action toward HIV, which is complimentary to NRTIs and protease inhibitors, with the added benefit of effectiveness against CMV and HSV-6-8, associated with Kaposi's sarcoma. Preclinical studies on human cells have demonstrated that Thiovir is equivalent to foscarnet as a reverse transcriptase inhibitor and has a dosage profile similar to foscarnet to direct HIV inhibition, with lower toxicity toward human DNA.

EradicAide

EradicAide™ vaccine technology is based upon a cell-mediated immunity approach to controlling HIV, by stimulating disease-fighting cells, called killer-T cells (cytotoxic T cells) whose function it is to clear HIV infected cells. We have an exclusive license from MD Anderson to develop and commercialize EradicAide.

EradicAide is a therapeutic vaccine designed to not stimulate the production of antibodies, which have been shown to enhance HIV infection in studies designed to observe how HIV spreads. We are the exclusive licensee of this compound. EradicAide is being studied in preclinical assay systems for its ability to inhibit the spread of HIV. At this time, we are testing different adjuvants for optimization of the EradicAide vaccine.

BlockAide/CR

BlockAide/CR&#-3884; is a peptide-based drug that is intended to work by blocking viral entry and infection of human immune system cells. We have an exclusive license from MD Anderson and the NIH to develop and commercialize BlockAide/CR. BlockAide/CR is being studied in preclinical assays for its ability to inhibit HIV entry into immune system cells. We have decided to postpone the initiation of a Phase I clinical trial, for which BlockAide/CR was cleared in Q2 2004, in order to assess the market feasibility of an oral or IV formulation of this drug.

BlockAide/VP

BlockAide/VP™ is an HIV viral entry inhibitor that mimics a section of the CD4 receptor on human immune system cells. When BlockAide/VP comes into contact with the gp120 protein present on the surface of HIV, it appears to cause a change in the protein-folding configuration of gp120, rendering the gp120 unable to initiate the infection process that requires it to bind to the CD4 receptor. Early *in vitro* tests indicate that HIV virus exposed to human immune system cells, with the BlockAide/VP compound present, are unable to bind to and infect such cells. BlockAide/VP remains in preclinical development. We have an exclusive license from MD Anderson and the NIH to develop and commercialize BlockAide/VP.

Markets for our Products

Cancer Chemotherapy Market

On a worldwide basis, cancer killed over 6 million people in 2003, according to statistics published by the World Health Organization. After cardiovascular disease, cancer is the second most frequent cause of death in developing countries, accounting for 21% of all deaths. In the U.S., cancer is responsible for approximately 23% of all deaths according to recent statistics. The American Cancer Society estimates that more than 1.3 million new cases of cancer were diagnosed in the U.S. and over 563,000 people died due to cancer in 2004.

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Treatment choices for the cancer patient depend on the stage of the cancerous tumor, and whether and/or how far the cancer has spread. Treatment options include surgery, radiation, chemotherapy, hormone therapy and immunotherapy. Treatment of cancer with chemicals is referred to as chemotherapy, which represents a current market in the U.S. of approximately $9 billion ($15 billion worldwide) per year, according to Frost & Sullivan Market Research and IMS Market Research.

Chemotherapy is highly individualized, depending on the type of disease and its progression, the action of the agents used, and the side effects in the patient, and may be used alone or in combination with other cancer therapies, such as surgery or radiation. Most chemotherapy drugs are chemical agents that are extremely toxic, are generally not curative, and historically achieve poor results in extending patient survival. The antimetabolite, 5-FU (5-fluorouracil) is a widely used chemotherapeutic. Primary use of 5-FU includes treatment of colorectal, breast, gastric and hepatic cancers. 5-FU is sometimes used to treat other cancers, such as ovarian, pancreatic, prostate, bladder, cervical and head and neck cancers.

Chemotherapy regimens for diseases such as metastatic colorectal cancer now include the addition of toxic agents, such as Camptosar™ (CPT-11, irinotecan) and Eloxatin® (oxaliplatin), to 5-FU and the drug Leucovorin. Newer, less toxic drugs, such as Erbitux™ (cetuximab) and Avastin™ (bevacizumab) are also added to 5-FU and Leucovorin.

In order for 5-FU to work more effectively, the folate-based compound Leucovorin, is often administered to the cancer patient. However, Leucovorin is inactive directly and must undergo several metabolic steps. Leucovorin has been shown to be only modestly effective when used with 5-FU in improving clinical outcomes in cancer patients.

Our drug, CoFactor, bypasses the chemical pathway required for Leucovorin metabolism. This biochemical strategy delivers the correct form of folate that allows 5-FU to kill cancer cells more effectively. We believe that our understanding of the biochemistry of folate metabolism and 5-FU-based therapies will overcome the limitations of Leucovorin and lead to developments that will increase patient survival, while reducing side effects and improving the quality of life of patients on chemotherapy.

We believe that the market potential for CoFactor is related to the broad use of Leucovorin in 5-FU-based cancer therapies. According to the NDTI database from IMS Health, in 2003 in the U.S. there were 490,000 patient visits for leucovorian therapy for colorectal cancer in the U.S. This prescription level is significantly larger than that of most other anticancer drugs used to treat colorectal cancer. We believe that if CoFactor shows improved clinical benefit and patient survival, it may be widely used as a replacement for Leucovorin in 5-FU based cancer therapies.

Selone, which functions in part as an alkylating agent against cancer cell lines that exhibit drug resistance to currently available alkylating and platinating agents, may serve as a useful new anticancer drug. Alkylating agents as a class are the most broadly used anticancer agents in the world, collectively surpassing the use of 5-FU as single agent. In recent years, they have been used increasingly in dose intensification strategies, such as bone marrow transplant, and have exhibited further promise when used with the thiophosphate protection agents. Approximately one-half of all cancers can become resistant to treatment with current chemotherapy products. Accordingly, we believe there is great potential for new products, such as Selone, that address drug resistance in cancer therapy.

HIV Drug Therapy Market

The World Health Organization and the Centers for Disease Control report that there are 1.5 million HIV positive individuals in the U.S. and Europe where the vast majority of HIV drugs are used. According to a report by the United Nations Program on HIV/AIDS (UNAIDS), more than 42 million adults and children in the world are living with HIV and there are thousands of new infections each day.

Significant advancements have been made in the treatment of asymptomatic HIV positive patients with HAART treatment (highly active antiretroviral therapy) consisting of a three or four drug "cocktail" that can reduce HIV viral load to below "detectable levels." However, studies have shown that poor patient treatment compliance, due to toxic side effects, number of pills and cost, will continue to cause problems of viral resistance, rendering many drugs ineffective. HIV has the ability to mutate into forms that are resistant to drug treatments. No one combination of drugs is effective for all patients and therapies are continually modified based upon patient progress.

According to Datamonitor, the global commercial market for HIV treatments is worth about $6 billion and is expected to grow to almost $12 billion by 2012. The current HIV market consists of 5 different classes of drugs: nucleoside reverse transcriptase inhibitors (NRTI), non-nucleoside reverse transcriptase inhibitors (NNRTI), nucleotide reverse transcriptase inhibitors (NtRTIs) and protease inhibitors (PI), which are dosed orally in various forms, as well as one entry inhibitor, which was approved in March 2003 and is dosed by injection.

We believe that new options are needed in the fight against HIV/AIDS, including therapies that would be complementary to current and future approved drugs. We are exploring Thiovir, EradicAide, BlockAide/CR and BlockAide/VP to address this need.

Marketing, Distribution and Sales

We have not received the necessary regulatory approval from the FDA or any other similar government agency to commercially market, distribute or sell any of our products. We presently have a Vice President of Business Development and a Director of Marketing with experience and background in biotechnical business development and marketing functions. If we approach the point at which we anticipate receiving regulatory approval to commercially market, distribute or sell any of our products, we will likely arrange with third parties, such as pharmaceutical companies, to market, distribute and sell our products. While we have held preliminary discussions on a number of occasions with potential commercialization and marketing partners, we have not yet entered into any binding agreements regarding the commercialization or marketing of any of our products.

Manufacturing

We do not have our own manufacturing facilities, and do not currently intend to establish them. We contract with outside manufacturers in order to produce our clinical trial materials. Merck Eprova AG, of Schaffhausen, Switzerland, currently produces CoFactor for our clinical trial requirements on a purchase order basis. Additional manufacturers have been contacted and may serve as secondary manufacturing sites for CoFactor. Manufacturing of the other drugs in our portfolio is similarly outsourced.

Raw Materials

Raw materials and supplies required for the production of our products for clinical trials are generally available from various suppliers in quantities adequate to meet our needs. However, we will need to be selective with our choice of suppliers of raw materials for our products and use only suppliers who have expertise in production of either chemical or biological formulations in accordance with current Good Manufacturing Practices ("cGMP").

Patents, Licensing and Research Agreements

Patents

Listed below are patents that have issued to USC, M.D. Anderson, and the NIH which have been exclusively licensed to us. Our rights under these patents are more fully described below.

Licensor: USC

Patent Number	Patent Title	Expiration Date
U.S. 5,376,658	5,10-Methylene-Tetrahydrofolate as a Modulator of a Chemotherapeutic Agent	12-23-13
U.S. 5,534,519	5,10-Methylene-Tetrahydrofolate as a Modulator of a Chemotherapeutic Agent	10-20-14
CA 2,082,811	5,10-Methylene-Tetrahydrofolate as a Modulator of a Chemotherapeutic Agent	05-13-11
U.S. 5,072,032	Preparation and use of Thiophosphonates and Thio-analogues of Phosphonoformic Acid	06-21-09
U.S. 5,183,812	Preparation and use of Thiophosphonates and Thio-analogues of Phosphonoformic Acid	09-30-11
U.S. 6,147,244	Preparations of Thiophosphites and Thiophosphates	05-03-19
U.S. 6,284,909	Preparations of Thiophosphites and Thiophosphates	11-01-20
U.S. 6,441,214	Derivatives and Analogs	07-13-19
U.S. 6,444,837	Synthesis and Antiviral Activity of a Series of Pyrophosphate Analogs	03-23-20
U.S. 6,147,245	Preparation and use of Alpha-Keto Bisphosphonates	07-13-19
U.S. 5,614,562	Method of Treating Drug Resistant Tumor Cells using Organoselenones	03-25-14

Licensor: M.D. Anderson

Patent Number	Patent Title	Expiration Date
U.S. 5,128,319	Prophylaxis and Therapy of Acquired Immunodeficiency Syndrome	09-20-09
U.S. 6,265,539	Prophylaxis and Therapy of Acquired Immunodeficiency Syndrome	07-24-18
U.S. 5,603,933	CD-4 Peptides for Binding to Viral Envelope Proteins	02-18-14
U.S. 6,210,873	Methods and Compositions for the Priming of Specific Cytotoxic T-lymphocyte Response	04-03-18
U.S. 6,645,471	HIV Specific T-Cell Induction	11-16-19
EP 0671947	Compositions for Eliciting Cytotoxic T-Lymphocyte Responses Against Viruses	02-12-12

Licensor: NIH

Patent Number	Patent Title	Expiration Date
U.S. 5,562,905	Human Immunodeficiency Virus (HIV) ENV-coded Peptide Capable of Eliciting HIV Inhibiting Antibodies in Mammals	10-08-13
EP 0400076	A Synthetic Antigen Evoking Anti-HIV Response	01-17-09
AU 621097	A Synthetic Antigen Evoking Anti-HIV Response	01-17-09
CA 1,340,907	A Synthetic Antigen Evoking Anti-HIV Response	01-17-09
IL 89012	Peptides Eliciting T-Cell Cytotoxicity Against HIV	01-17-09
JP 2569185	Peptides Eliciting T-Cell Cytotoxicity Against HIV	01-17-09

In addition to the licensed patents noted above, we have filed three provisional patent applications in the United States covering technology developed pursuant to our research and development activities.

There can be no assurance that others will not independently develop similar or competing technology or design around any patents that may be issued to us, or that we will be able to enforce our patents against infringement. The actual protection afforded by any patent we may be issued or obtain license rights under depends upon the type of patent, the scope of its coverage, the country issuing such patent and the availability of legal remedies to enforce rights under such patent.

We consider our patent applications and licenses under patents owned by the third parties listed above of material importance to our business. Our copyrights, trademarks, trade secrets and similar intellectual property are also critical to our success. We rely on a combination of patent, trademark, copyright and trade secret laws to protect our proprietary rights. We cannot, however, assure that the patents and other intellectual property rights we acquire or hold will afford us significant commercial protection.

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The biotechnology industry is characterized by frequent litigation regarding patent and other intellectual property rights. While we have not received formal notice of any infringement of the rights of any third party, questions of infringement in the biotechnology industry involve highly technical and subjective analyses. Litigation may be necessary in the future to enforce any patents we may be issued and other intellectual property rights, to protect our trade secrets, to determine the validity and scope of the proprietary rights of others or to defend against claims of infringement or invalidity, and there can be no assurance that we would prevail in any future litigation. Any such litigation, whether or not determined in our favor or settled by us, would be costly and would divert the efforts and attention of our management and technical personnel from normal business operations, which would likely have a material adverse effect on our business, financial condition and results of operations. Adverse determinations in litigation could result in the loss of our proprietary rights, subject us to significant liabilities, require us to seek licenses from third parties or prevent us from licensing our technology, any of which could have a material adverse effect on our business, financial condition and results of operations. Moreover, the laws of certain foreign countries in which our technology is or may in the future be licensed may not protect our intellectual property rights to the same extent as the laws of the U. S., thus increasing the possibility of infringement of our intellectual property.

License Agreements

USC Agreements

Under the Option and License Agreement with USC dated January 23, 1998 (as amended August 16, 2000) ("1998 USC License"), we hold exclusive rights under a number of patents that have issued to USC in the United States and Canada covering products (CoFactor and Selone) and methods intended for use in connection with cancer chemotherapy. Under the Option and License Agreement with USC dated August 17, 2000 (as amended April 21, 2003) (the "2000 USC License"), we hold exclusive rights under a number of additional patents that have issued in the United States relating to the antiviral product Thiovir and drugs useful for the treatment of HPV (human papillomavirus) infections, HIV infections, HIV/HPV coinfections and other human therapeutic uses. Additional patent applications relating to Thiovir are pending in Europe, Canada and Australia and would be covered by the 2000 USC License upon issuance.

Pursuant to the 1998 USC License we must pay USC a 3% royalty on net sales of products made or sold in a country in which a patent has issued or is pending. Pursuant to the 2000 USC License we must pay USC a 1% royalty on net sales of products made or sold in a country in which a patent has issued or is pending. Both the 1998 USC License and the 2000 USC License require that we pay USC these royalties as well as the cost of filing, prosecuting and maintaining the licensed patents. We must also make certain milestone payments to USC pursuant to the 2000 USC License upon entry into human trials and receiving regulatory approval for each drug candidate developed ($75,000 at Phase I, $100,000 at Phase II, $125,000 at Phase III and $250,000 at market approval). We have not yet paid any royalties to USC pursuant to either the 1998 USC License or the 2000 USC License.

M.D. Anderson Agreement

Pursuant to the Patent and Technology License Agreement, dated June 14, 1996, as amended June 15, 2000, with MD Anderson, M.D. Anderson granted to us exclusive, worldwide rights to develop, manufacture and market technologies in the field of HIV therapy. To date, a number of patents have issued in the United States and Europe covering these technologies, and several additional patent applications are pending in the United States, Canada and Europe. Pursuant to this license agreement we must pay MD Anderson a 1.5% royalty on net sales of products covered by the licensed patents as well as 15% of any sub-licensing revenues we receive. We are also required to reimburse MD Anderson for the cost of preparing, filing, prosecuting and maintaining the licensed patents. In addition, we must issue to MD Anderson shares of our Common Stock with a value of $1,000,000 upon the enrollment of the first patient in the first Phase I human trial of any product that utilizes licensed subject matter. We do not currently have an estimate of when we expect to be required to issue these shares of Common Stock. We have not yet paid any royalties or

sublicensing revenues to MD Anderson pursuant to this license agreement.

Also, we currently plan to renegotiate the terms of our license agreement with MD Anderson. We have no guarantee that we will be able to negotiate terms, including the royalty and milestone payment terms, which would be mutually acceptable to both MD Anderson and the Company.

NIH Agreement

In August 2002, we entered into a Patent License Agreement with NIH pursuant to which NIH granted us exclusive, worldwide rights to patents covering a peptide product (BlockAide) for the treatment and prevention of HIV. The agreement was amended in February 2003. Under the terms of the agreement, we agreed to pay an annual royalty of 1.5% on net sales of less than $2 million and 2% on net sales above $2 million, with a minimum annual royalty of $25,000. In addition, we agreed to pay NIH "benchmark royalties" as follows: $25,000 upon initiation of a Phase I trial; $75,000 upon initiation of a Phase II trial; $150,000 upon initiation of a Phase III trial; $750,000 upon first approval in the US of a Product License Application for an HIV therapeutic or vaccine; and $750,000 upon first approval of a product license in Europe.

Sponsored Research Agreements

We periodically enter into sponsored research agreements pursuant to which an institution will provide research service to us on a fee for services basis. We currently have no obligation to make payments under any such sponsored research agreements.

Competition

If we receive regulatory approval to market, distribute and sell any of our products, we will face significant competition and believe significant long-term competition can be expected from pharmaceutical companies, pharmaceutical divisions of chemical companies and biotechnology companies. This competition can be expected to become more intense as commercial applications for biotechnology products increase. Most competitors, particularly large pharmaceutical companies, have greater clinical, regulatory and marketing resources and experience than we have. Many of these companies have commercial arrangements with other companies in the biotechnology industry to supplement their own research capabilities.

The introduction of new products or the development of new processes by competitors or new information about our existing products may impact potential pricing of our products or cause us to discontinue the development of one or more of our products, even for products protected by patents. However, we believe our competitive position is enhanced by our commitment to research leading to the discovery and development of new products.

Over the longer term, our and our collaborators' abilities to successfully market, distribute and sell current products, expand their usage and bring new products to the marketplace will depend on many factors, including, but not limited to, the effectiveness and safety of the products, FDA and foreign regulatory agencies' approvals of new products and indications, the degree of patent protection afforded to particular products and the effect of managed care as an important purchaser of pharmaceutical products.

CoFactor

We intend to target replacement of Leucovorin with CoFactor in 5-FU/Leucovorin-based therapies for various cancers. With an ongoing need for significant improvement in the clinical response of tens of thousands of cancer patients, especially those with metastatic colorectal cancer where 5-FU/Leucovorin performs poorly and other regimens that are highly toxic, we currently believe CoFactor could successfully compete against or be used in conjunction with other therapies.

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There are approximately 40 different companies marketing generic 5-FU-related drugs. In addition, Roche markets the branded prodrug (drug that activates *in vivo*), Xeloda™, which is an oral formulation that converts to 5-FU. Since CoFactor is formulated for IV delivery, generic forms of oral Leucovorin represent competition for CoFactor. We are currently working on the development of an oral form for CoFactor. Leucovorin is also marketed by more than a dozen companies as a generic drug for IV dosing in conjunction with 5-FU. As an IV drug, Leucovorin represents competition to CoFactor based upon generic pricing.

Thiovir

We currently intend to develop Thiovir as a component of HAART therapy for treatment of HIV/AIDS. Thiovir would compete in a large market of HAART drugs, and would be only one potential component of a three to four drug cocktail, but classified as a non-nucleoside reverse transcriptase inhibitor. There are currently three drugs approved in that specific sector with additional drugs under development.

Government Regulation and Clinical Testing for New Drugs

The manufacture, distribution, marketing and sale of therapeutic drugs are subject to government regulation in the U.S. and in various foreign countries including Japan and the member countries of the European Union. In the U.S., we must follow rules and regulations established by the FDA requiring the presentation of data indicating that our products are safe and efficacious and are manufactured in accordance with cGMP regulations. Japan, the member countries of the European Union and various other countries have similar rules and regulation with which we must comply.

The steps required to be taken before a new prescription drug may be marketed in the U.S. include (i) preclinical laboratory and animal tests, (ii) the submission to the FDA of an IND application, which must be evaluated and found acceptable by the FDA before human clinical trials may commence, (iii) adequate and well-controlled human clinical trials to establish the safety and effectiveness of the drug, (iv) the submission of a New Drug Application ("NDA") to the FDA and (v) FDA approval of the NDA. Prior to obtaining FDA approval of an NDA, the facilities that will be used to manufacture the drug must undergo a preapproval inspection to ensure compliance with the FDA's cGMP regulations.

Preclinical tests include laboratory evaluation of product chemistry or biology and animal studies to assess the safety and effectiveness of the product and its formulation. The results of the preclinical tests are submitted to the FDA as part of an IND application, and unless the FDA objects, the IND application will become effective 30 days following its receipt by the FDA, after which clinical trials can begin. If the FDA has concerns about the proposed clinical trial, it may delay the trial and require modifications to the trial protocol prior to permitting the trial to begin.

Clinical trials involve the administration of the pharmaceutical product to healthy volunteers or to patients identified as having the condition for which the product is being tested. The pharmaceutical product is administered under the supervision of a qualified principal investigator. Clinical trials are conducted in accordance with protocols previously submitted to the FDA as part of the IND application that detail the objectives of the trial, the parameters used to monitor safety and the efficacy criteria that are being evaluated. Each clinical trial is conducted under the auspices of an institutional review board ("IRB") at the institution at which the trial is conducted. The IRB considers, among other things, ethical factors, the safety of the human subjects and the possible liability risk for the institution.

Clinical trials are typically conducted in three sequential phases that may overlap. In Phase I, the initial introduction of the pharmaceutical into healthy human volunteers, the emphasis is on testing for safety (adverse effects), dosage tolerance, metabolism, distribution, excretion and clinical pharmacology. Phase II involves trials in a limited patient population to determine the effectiveness of the pharmaceutical for specific targeted indications, to determine dosage tolerance and optimal dosage and to identify possible adverse side effects and safety risks.

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In serious diseases such as HIV/AIDS, patients suffering from the disease rather than healthy volunteers are used in Phase I trials. In addition, Phase I trials may be divided between Phase Ia, in which single doses of the drug are given, and Phase Ib, in which multiple doses are given. In the latter instance, some efficacy data may be obtained if the subjects are patients suffering from the disease rather than healthy volunteers, and these trials are referred to as "Phase Ib/IIa."

After a compound has been shown in Phase II trials to have an acceptable safety profile and probable effectiveness, Phase III trials are undertaken to evaluate clinical effectiveness further and to further test for safety within an expanded patient population at multiple clinical study sites. The FDA reviews both the clinical trial plans and the results of the trials at each phase, and may discontinue the trials at any time if there are significant safety issues.

The results of the preclinical tests and clinical trials are submitted to the FDA in the form of an NDA for marketing approval. The testing and approval process requires substantial time and effort, and FDA approval may not be granted on a timely basis or at all. The approval process is affected by a number of factors, including the severity of the disease, the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. Additional animal studies or clinical trials may be requested during the FDA review process and may delay marketing approval.

Upon approval, a drug may be marketed only for the FDA approved indications in the approved dosage forms. Further clinical trials are necessary to gain approval for the use of the product for any additional indications or dosage forms. The FDA may also require post-market reporting and may require surveillance programs to monitor the side effects of the drug, which may result in withdrawal of approval after marketing begins.

The FDA has developed several regulatory procedures to accelerate the clinical testing and approval of drugs intended to treat serious or life-threatening illnesses under certain circumstances. We believe that several of our drugs may be candidates for accelerated development or approval under these procedures.

Once the sale of a product is approved, the FDA regulates the manufacturing and marketing of the product. The FDA periodically inspects both domestic and foreign drug manufacturing facilities to ensure compliance with applicable cGMP regulations and other requirements. In addition, manufacturers in the U.S. must register with the FDA and submit a list of every drug in commercial distribution. Foreign manufacturers are subject only to the drug listing requirement. Post-marketing reports are also required to monitor the product's usage and effects. Product approvals may be withdrawn, or sanctions imposed, if compliance with regulatory requirements is not maintained.

Many foreign countries also regulate the clinical testing, manufacturing, marketing and use of pharmaceutical products. The requirements relating to the conduct of clinical trials, product approval, manufacturing, marketing, pricing and reimbursement vary widely from country to country. In addition to the import requirements of foreign countries, a company must also comply with U.S. laws governing the export of FDA regulated products.

Health Care Reform Measures and Third Party Reimbursement

Pharmaceutical companies are affected by the efforts of governments and third party payors to contain or reduce the cost of health care through various means. A number of legislative and regulatory proposals aimed at changing the health care system have been proposed in recent years. In addition, an increasing emphasis on managed care in the U.S. has and will continue to increase pressures on pharmaceutical pricing. While we cannot predict whether legislative or regulatory proposals will be adopted or the effect such proposals or managed care efforts may have on our business, the announcement or adoption of such proposals or efforts could have a material adverse effect on us. In the U.S. and elsewhere, sales of prescription pharmaceuticals are dependent in large part on the availability of reimbursement to the consumer from third party payors, such as government and private insurance plans that mandate predetermined discounts from list prices.

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Research and Development Outlays

During fiscal year 2004 and 2003, we expended $2,744,328 and $748,997, respectively, on research and development activities.

Environment

We seek to comply with all applicable statutory and administrative requirements concerning environmental quality. We have made, and will continue to make, expenditures for environmental compliance and protection. Expenditures for compliance with environmental laws have not had, and are not expected to have, a material effect on our capital expenditures, results of operation, financial position or competitive position.

Employees

At December 31, 2004, we had twelve employees all of whom were employed on a full-time basis.

Item 2. Description of Property.

Our principal office is located at 6725 Mesa Ridge Road, Suite 100, San Diego, California 92121. Our principal office consists of 8,865 square feet of office and lab space, which we use pursuant to a lease that will expire on August 31, 2009. The base rent for this space is currently $177,282 annually, with incremental operating cost adjustments.

We believe our facilities are in good operating condition and that the real property leased by us is adequate for all present and near term uses. We believe any additional facilities we may need in the foreseeable future can be obtained with our capital resources.

We do not have any investments in and do not plan to make any investments in any real estate, real estate mortgages or securities of or interests in persons primarily engaged in real estate activities. We do not own or have an interest in any real property the book value of which amounts to 10% or more of our total assets.

Item 3. Legal Proceedings.

From time to time we may be subject to legal proceedings and claims in the ordinary course of business. These claims, even if not meritorious, could result in the expenditure of significant financial and managerial resources.

On March 28, 2005, the Company received a letter from counsel to a former executive in which the former executive claims that the Company constructively terminated him, discriminated against him on the basis of age and committed various torts against him. No settlement demand was specifically made by the former executive in this letter and the letter otherwise did not state any specific monetary damages that this former executive has purportedly sustained. The Company believes that these claims lack merit and intends to vigorously defend against them.

Item 4. Submission of Matters to a Vote of Security Holders.

No matters were submitted to a vote of the holders of the Company's securities, through solicitation of proxies or otherwise, during 2004.

Part II

Item 5. Market For Common Equity and Related Stockholder Matters.

Market Information.

Our Common Stock is quoted on the American Stock Exchange under the symbol ANX.

The following table lists the high and low closing price information for our Common Stock for each quarter for the fiscal years 2003 and 2004. All prices listed herein reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions.

Quarter Ending	High	Low
March 31, 2003	$ 0.62	$ 0.25
June 30, 2003	$ 1.45	$ 0.39
September 30, 2003	$ 1.75	$ 0.90
December 31, 2003	$ 1.61	$ 0.86
March 31, 2004	$ 2.40	$ 0.87
June 30, 2004	$ 2.30	$ 1.55
September 30, 2004	$ 1.74	$ 0.99
December 31, 2004	$ 1.19	$ 0.82

Holders.

As of December 31, 2004, there were 270 holders of record of our Common Stock.

Dividends.

We have never paid cash dividends on any of our securities and do not currently expect to pay any cash dividends on our securities in the foreseeable future. There are no restrictions that limit our ability to pay dividends on our Common Stock or that are likely to do so in the future other than restrictions under the Delaware General Corporation Law and other applicable law.

Securities Authorized for Issuance Under Equity Compensation Plans.

As of March 28, 2005, other than the individual compensation arrangements set forth in the table below, we did not have any compensation plans under which our equity securities are authorized for issuance.

	Number of shares of Common Stock to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans

Equity compensation plans approved by security holders	0	$	0.00	0
Equity compensation plans not approved by security holders	1,625,000	$	0.75	0
Total	1,625,000	$	0.75	0

The equity compensation plans not approved by our security holders disclosed in the table above consist of individual option agreements with seven of our employees and eight of our non-employee advisors and directors. The number of shares subject to each of these option agreements ranges from 25,000 to 500,000. The option agreements have exercise prices that range from $0.20 to $1.50 and expire on December 30, 2008. The right to exercise shares subject to these option agreements generally vests over one to five years for employee option grants and non-employee advisor and director grants. Each of the option agreements permits the optionee to exercise on a cashless basis. None of the shares issuable upon exercise of these options is covered by a Form S-8 or other registration statement.

Recent Sales of Unregistered Securities.

In October 2004, we issued a warrant to purchase 300,000 shares of Common Stock at $2.50 per share to an individual in settlement of a claim. No commission or other remuneration was paid or given, directly or indirectly, in connection with this warrant issuance. The person to whom we issued the warrant represented to us, and we reasonably believe that, that he is an "accredited investor." The issuance of this warrant was deemed to be exempt from registration under the Securities Act of 1933, as amended (the "Securities Act"), in reliance on Section 4(2) of the Securities Act, as a transaction by an issuer not involving a public offering.

Item 6. Plan of Operations.

This Plan of Operations should be read in conjunction with the accompanying consolidated financial statements and notes included in this report.

General

As a development-stage biomedical research company, we have not yet generated any operating revenues from the sale of our products or otherwise. We have had no operating earnings since inception, and have an accumulated deficit of $(35,182,194) as of December 31, 2004. Our expenses have related mainly to costs incurred in research activities for the development of our drug candidates and from administrative expenses required to support these efforts. We expect losses to continue for the near future, and such losses will likely increase as human clinical trials are undertaken in the U.S. and Europe for our cancer drugs. Future profitability will be dependent upon our ability to complete the development of our pharmaceutical products, obtain necessary regulatory approvals and effectively market such products. Also, future profitability will require that we establish agreements with other parties for the clinical testing, manufacturing, commercialization and sale of our products.

Since inception, we have generally funded our operations through short-term loans and the sale of equity securities. We will need to obtain additional financing in order to sustain our efforts, as discussed below under "Liquidity and Capital Resources."

Plan of Operations

We have used the proceeds from recent private placements of our capital stock primarily to expand our preclinical and clinical efforts for CoFactor, as well as for general working capital. At this time we are committing significantly fewer resources to the development of our other programs.

We began a trial for metastatic colorectal cancer patients with 5-FU in a combination therapy with our drug CoFactor in QI 2004, based upon an IND application filed in the U.S. to treat metastatic colorectal cancer patients. In Q1 2005 we filed for clearance with the FDA to launch a Phase III randomized controlled trial in metastatic colorectal cancer. Additionally, we filed Clinical Trial Applications in the European Union (EU), including the United Kingdom and Germany, and in countries outside the EU for clearance to evaluate CoFactor in a Phase IIb, international, multi-center, randomized, controlled trial for metastatic colorectal cancer. In Q1 2005 we received of a final advice letter from the European Medicines Agency (EMEA) for our proposed CoFactor™ trial protocol in pancreatic cancer. Based on this information, the Company currently plans to file a Clinical Trial Application for a pivotal Phase III multinational study in patients with advanced pancreatic cancer in the second quarter of 2005 and will initiate the trial following regulatory clearance.

We previously reported that we intended to file an IND application in QI 2005 to initiate a clinical trial using Thiovir in HIV patients. Because of continued unexpected manufacturing delays we do not currently anticipate having the issue resolved until Q4 2005.

Additional detail regarding the human trials and INDs that we plan to file are discussed in Part I, Item 1, Description of Business, of this annual report. We currently expect to expend the estimated amounts set forth below over the next 12 months:

Expenditure		Estimated Cost
CoFactor trials	$	5,453,000
Other research and development costs		2,875,000
Total estimated research and development		8,328,000
Estimated selling, general and administrative		3,058,000
Total estimated costs	$	11,386,000

Our current cash position of $13,032,263 is sufficient to meet our currently expected expenditures over the next 12 months as set forth above. However, we continue to evaluate our need to raise additional capital to execute our research and development plans and believe that we will need to raise additional capital prior to receiving regulatory approval to sell any of our products.

Our facility is under lease through August 2009. We do not currently believe we will need any additional space for the remainder of 2005.

In conjunction with the additional research and development activities we expect to conduct, we anticipate adding six development and administrative personnel in the next 12 months.

Liquidity and Capital Resources

We have incurred negative cash flows since inception, and have funded our activities primarily through short-term loans and sales of equity securities. As of December 31, 2004 and 2003, we had cash and cash equivalents of $13,032,263 and $4,226,397. We expect our cash flow to continue to be negative in the foreseeable future and until such time as one of our drug candidates is approved for commercial production.

We do not have any bank or any other commercial financing arrangements. Our operations over the last 12 months have been funded by the proceeds from private equity placements.

Our dependence on raising additional capital will continue at least until we are able to commercially market one or more of our products at significant sales level. Depending on profit margins and other factors, we may still need additional funding to continue research and development efforts. Our future capital requirements and the adequacy of our financing depend upon numerous factors, including: the successful commercialization of our drug candidates; progress in our product development efforts; progress with preclinical studies and clinical trials; the cost and timing of production arrangements; the development of effective sales and marketing activities; the cost of filing, prosecuting, defending and enforcing intellectual property rights; competing technological and market developments; and the development of strategic alliances for the marketing of our products.

We will be required to obtain such funding through equity or debt financing, strategic alliances with corporate partners and others, or through other sources not yet identified. We do not believe that debt financing from financial institutions will be available until at least the time that one of our products is approved for commercial production. We do not have any committed sources of additional financing, and cannot guarantee that additional funding will be available on acceptable terms, if at all. If adequate funds are not available, we will be required to delay, scale-back or eliminate certain aspects of our operations or attempt to obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies, product candidates, products or potential markets.

Quantitative and Qualitative Information About Market Risk

We do not engage in trading market-risk sensitive instruments and do not purchase hedging instruments or "other than trading" instruments that are likely to expose us to market risk, whether interest rate, foreign currency exchange, commodity price or equity price risk. We have no outstanding debt instruments, have not entered into any forward or future contracts, and have purchased no options and entered into no swaps. We have no credit lines or other borrowing facilities, and do not view ourselves as subject to interest rate fluctuation risk at the present time.

Critical Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the U. S. requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Management believes that the estimates utilized in preparing our financial statements are reasonable and prudent. Actual results could differ from those estimates.

The most significant accounting estimates relate to valuing equity transactions as described below. The value assigned to stock warrants granted to non-employees are accounted for in accordance with SFAS No. 123 and Emerging Issues Task Force (EITF) 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, which require that such costs be measured at the end of each reporting period to account for changes in the fair value of our Common Stock until the options are vested. We value warrants using the Black-Scholes pricing model. Common Stock is valued using the market price of Common Stock on the measurement date as defined in EITF 96-18.

Accounting for Stock-Based Compensation

We apply Statement of Financial Accounting Standards No. 123 and related interpretations in accounting for employee stock-based compensation and include the required footnote disclosures thereon.

We account for nonemployee stock-based compensation in accordance with Emerging Issues Task Force (EITF) 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. Amounts are based on the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable.

The value assigned to stock warrants granted to non-employees are accounted for in accordance with SFAS No. 123 and EITF 96-18, which require that such costs be measured at the end of each reporting period to account for changes in the fair value of our Common Stock until the options are vested. We value warrants using the Black-Scholes pricing model. Common Stock is valued using the market price of Common Stock on the measurement date as defined in EITF 96-18.

Revenue Recognition

We recognize revenue at the time service is performed on commercial contracts and when ability to collect is assured. Revenue from government grants is a reimbursement for expenditures associated with the research. We submit bills to the grant agency and revenue is recognized at the time the reimbursement request is submitted.

New Accounting Pronouncements

In December 2004, the FASB issued Statement of Financial Accounting standards No. 123 (revised 2004), Share-Based Payment (SFAS 123R). We currently recognize our option grants and associated expenses in accordance with SFAS 123R guidance, and therefore SFAS 123R is not expected to have a material effect on our consolidated financial position or results of operations.

In December 2004, the FASB issued SFAS No. 153, Exchanges of Nonmonetary Assets, an amendment of APB Opinion No. 29. The guidance in APB Opinion No 29, Accounting for Nonmonetary Transactions, is based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of assets exchanged. The guidance in that Opinion, however, included certain exceptions to that principle. This Statement amends Opinion 29 to eliminate the exception for nonmonetary exchanges of similar productive assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. SFAS No. 153 is effective for nonmonetary exchanges occurring in fiscal periods beginning after June 15, 2005. The adoption of SFAS No. 153 is not expected to have a material impact on our financial position and results of operations.

In November 2004, the FASB issued SFAS No. 151, Inventory Costs, an amendment of ARB No. 43, Chapter 4. This statement amends the guidance in ARB No. 43, Chapter 4, Inventory Pricing, to clarify the accounting for abnormal amounts idle facility expense, freight, handling costs, and wasted material (spoilage). We currently have no inventory, sales or cost of goods, and therefore it is not expected to have a material impact on our financial position and results of operations.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity." SFAS No. 150 changes the accounting for certain financial instruments with characteristics of both liabilities and equity that, under previous pronouncements, issuers could account for as equity. The new accounting guidance contained in SFAS No. 150 requires that those instruments be classified as liabilities in the balance sheet. The adoption of this new accounting pronouncement is not expected to have a material impact on the Company's financial statements.

In January 2003, the FASB issued FASB Interpretation No. 46 (revised December 2003), *Consolidation of Variable Interest Entities* (FIN 46R) which addressed consolidation by business enterprises of variable interest entities that meet certain criteria. FIN 46R was effective upon issuance, but did not have an impact on the Company's financial

position or results of operations.

Risk Factors

If any of the following risks actually occur, our business, results of operations and financial condition could suffer significantly.

We have a substantial accumulated deficit and limited working capital.

We had an accumulated deficit of $35,182,194 as of December 31, 2004. Since we presently have no source of revenues and are committed to continuing our product research and development program, significant expenditures and losses will continue until development of new products is completed and such products have been clinically tested, approved by the FDA or other regulatory agencies and successfully marketed. In addition, we fund our operations primarily through the sale of securities, and have had limited working capital for our product development and other activities. We do not believe that debt financing from financial institutions will be available until at least the time that one of our products is approved for commercial production.

We have no current product sales revenues or profits.

We have devoted our resources to developing a new generation of therapeutic drug products, but such products cannot be marketed until clinical testing is completed and governmental approvals have been obtained. Accordingly, there is no current source of revenues, much less profits, to sustain our present activities, and no revenues will likely be available until, and unless, the new products are clinically tested, approved by the FDA or other regulatory agencies and successfully marketed, either by us or a marketing partner, an outcome which we are not able to guarantee.

It is uncertain that we will have access to future capital or government grants.

It is not expected that we will generate positive cash flow from operations for at least the next several years. As a result, substantial additional equity or debt financing or the receipt of one or more government grants for research and development or clinical development will be required to fund our activities. We cannot be certain that we will be able to consummate any such financing on favorable terms, if at all, or receive any such government grants or that such financing or government grants will be adequate to meet our capital requirements. Any additional equity financing could result in substantial dilution to stockholders, and debt financing, if available, will most likely involve restrictive covenants that preclude us from making distributions to stockholders and taking other actions beneficial to stockholders. If adequate funds are not available, we may be required to delay or reduce the scope of our drug development program or attempt to continue development by entering into arrangements with collaborative partners or others that may require us to relinquish some or all of our rights to proprietary drugs. The inability to fund our capital requirements would have a material adverse effect on us.

We are not certain that we will be successful in the development of our drug candidates.

The successful development of any new drug is highly uncertain and is subject to a number of significant risks. Our drug candidates, all of which are in a development stage, require significant, time-consuming and costly development, testing and regulatory clearance. This process typically takes several years and can require substantially more time. Risks include, among others, the possibility that a drug candidate will (i) be found to be ineffective or unacceptably toxic, (ii) have unacceptable side effects, (iii) fail to receive necessary regulatory clearances, (iv) not achieve broad market acceptance, (v) be subject to competition from third parties who may market equivalent or superior products, or (vi) be affected by third parties holding proprietary rights that will preclude us from marketing a drug product. There can be no assurance that the development of our drug candidates will demonstrate the efficacy and safety of our drug candidates as therapeutic drugs, or, even if demonstrated, that there will be sufficient advantages to their use over other drugs or treatments so as to render the drug product commercially viable. In the event that we are not successful in developing and commercializing one or more drug candidates, investors are likely to realize a loss of their entire

investment.

Positive results in preclinical and early clinical trials do not ensure that future clinical trials will be successful or that drug candidates will receive any necessary regulatory approvals for the marketing, distribution or sale of such drug candidates.

Success in preclinical and early clinical trials does not ensure that large-scale clinical trials will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. The length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly and may be difficult to predict.

We will face intense competition from other companies in the pharmaceutical industry.

We are engaged in a segment of the pharmaceutical industry that is highly competitive and rapidly changing. If successfully developed and approved, any of our drug candidates will likely compete with several existing therapies. In addition, other companies are pursuing the development of pharmaceuticals that target the same diseases as are targeted by the drugs being developed by us. We anticipate that we will face intense and increasing competition in the future as new products enter the market and advanced technologies become available. We cannot assure that existing products or new products developed by competitors will not be more effective, or more effectively marketed and sold than those we may market and sell. Competitive products may render our drugs obsolete or noncompetitive prior to our recovery of development and commercialization expenses.

Many of our competitors will also have significantly greater financial, technical and human resources and will likely be better equipped to develop, manufacture and market products. In addition, many of these competitors have extensive experience in preclinical testing and clinical trials, obtaining FDA and other regulatory approvals and manufacturing and marketing pharmaceutical products. A number of these competitors also have products that have been approved or are in late-stage development and operate large, well-funded research and development programs. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and biotechnology companies. Furthermore, academic institutions, government agencies and other public and private research organizations are becoming increasingly aware of the commercial value of their inventions and are actively seeking to commercialize the technology they have developed. Accordingly, competitors may succeed in commercializing products more rapidly or effectively than us, which would have a material adverse effect on us.

There is no assurance that our products will have market acceptance.

Our success will depend in substantial part on the extent to which a drug product, once approved, achieves market acceptance. The degree of market acceptance will depend upon a number of factors, including (i) the receipt and scope of regulatory approvals, (ii) the establishment and demonstration in the medical community of the safety and efficacy of a drug product, (iii) the product's potential advantages over existing treatment methods and (iv) reimbursement policies of government and third party payors. We cannot predict or guarantee that physicians, patients, healthcare insurers or maintenance organizations, or the medical community in general, will accept or utilize any of our drug products.

The unavailability of health care reimbursement for any of our products will likely adversely impact our ability to effectively market such products and whether health care reimbursement will be available for any of our products is uncertain.

Our ability to commercialize our technology successfully will depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, private health insurers and other third-party payors. Significant uncertainty exists as to the reimbursement status of newly approved medical products. We cannot guarantee that adequate third-party insurance coverage will be available

for us to establish and maintain price levels sufficient for realization of an appropriate return on our investments in developing new therapies. Government, private health insurers, and other third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new therapeutic products approved for marketing by the FDA. Accordingly, even if coverage and reimbursement are provided by government, private health insurers, and third-party payors for use of our products, the market acceptance of these products would be adversely affected if the amount of reimbursement available for the use of our therapies proved to be unprofitable for health care providers.

Uncertainties related to health care reform measures may affect our success.

There have been a number of federal and state proposals during the last few years to subject the pricing of health care goods and services, including prescription drugs, to government control and to make other changes to U.S. health care system. It is uncertain which legislative proposals will be adopted or what actions federal, state, or private payors for health care treatment and services may take in response to any health care reform proposals or legislation. We cannot predict the effect health care reforms may have on our business, and there is no guarantee that any such reforms will not have a material adverse effect on us.

Further testing of our drug candidates will be required and there is no assurance of FDA approval.

The FDA and comparable agencies in foreign countries impose substantial requirements upon the introduction of medical products, through lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures. Satisfaction of these requirements typically takes several years or more and varies substantially based upon the type, complexity, and novelty of the product.

The effect of government regulation and the need for FDA approval will delay marketing of new products for a considerable period of time, impose costly procedures upon our activities, and provide an advantage to larger companies that compete with us. There can be no assurance that the FDA or other regulatory approval for any products developed by us will be granted on a timely basis or at all. Any such delay in obtaining or failure to obtain, such approvals would materially and adversely affect the marketing of any contemplated products and the ability to earn product revenue. Further, regulation of manufacturing facilities by state, local, and other authorities is subject to change. Any additional regulation could result in limitations or restrictions on our ability to utilize any of our technologies, thereby adversely affecting our operations.

Human pharmaceutical products are subject to rigorous preclinical testing and clinical trials and other approval procedures mandated by the FDA and foreign regulatory authorities. Various federal and foreign statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of pharmaceutical products. The process of obtaining these approvals and the subsequent compliance with appropriate U.S. and foreign statutes and regulations are time-consuming and require the expenditure of substantial resources. In addition, these requirements and processes vary widely from country to country.

Among the uncertainties and risks of the FDA approval process are the following: (i) the possibility that studies and clinical trials will fail to prove the safety and efficacy of the drug, or that any demonstrated efficacy will be so limited as to significantly reduce or altogether eliminate the acceptability of the drug in the marketplace, (ii) the possibility that the costs of development, which can far exceed the best of estimates, may render commercialization of the drug marginally profitable or altogether unprofitable, and (iii) the possibility that the amount of time required for FDA approval of a drug may extend for years beyond that which is originally estimated. In addition, the FDA or similar foreign regulatory authorities may require additional clinical trials, which could result in increased costs and significant development delays. Delays or rejections may also be encountered based upon changes in FDA policy and the establishment of additional regulations during the period of product development and FDA review. Similar delays or rejections may be encountered in other countries.

Our success will depend on licenses and proprietary rights we receive from other parties, and on any patents we may obtain.

Our success will depend in large part on our ability and our licensors' ability to (i) maintain license and patent protection with respect to their drug products, (ii) defend patents and licenses once obtained, (iii) maintain trade secrets, (iv) operate without infringing upon the patents and proprietary rights of others and (iv) obtain appropriate licenses to patents or proprietary rights held by third parties if infringement would otherwise occur, both in the U.S. and in foreign countries. We have obtained licenses to patents and other proprietary rights from M.D. Anderson, University of Southern California and the National Institutes of Health.

The patent positions of pharmaceutical companies, including ours, are uncertain and involve complex legal and factual questions. There is no guarantee that we or our licensors have or will develop or obtain the rights to products or processes that are patentable, that patents will issue from any of the pending applications or that claims allowed will be sufficient to protect the technology licensed to us. In addition, we cannot be certain that any patents issued to or licensed by us will not be challenged, invalidated, infringed or circumvented, or that the rights granted thereunder will provide competitive disadvantages to us.

Litigation, which could result in substantial cost, may also be necessary to enforce any patents to which we have rights, or to determine the scope, validity and unenforceability of other parties' proprietary rights, which may affect our rights. U.S. patents carry a presumption of validity and generally can be invalidated only through clear and convincing evidence. There can be no assurance that our licensed patents would be held valid by a court or administrative body or that an alleged infringer would be found to be infringing. The mere uncertainty resulting from the institution and continuation of any technology-related litigation or interference proceeding could have a material adverse effect on us pending resolution of the disputed matters.

We may also rely on unpatented trade secrets and know-how to maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with employees, consultants and others. There can be no assurance that these agreements will not be breached or terminated, that we will have adequate remedies for any breach, or that trade secrets will not otherwise become known or be independently discovered by competitors.

Our license agreements can be terminated in the event of a breach.

The license agreements pursuant to which we license our core technologies for our potential drug products permit the licensors, respectively M.D. Anderson, National Institutes of Health and University of Southern California, to terminate the agreement under certain circumstances, such as the failure by us to use our reasonable best efforts to commercialize the subject drug or the occurrence of any other uncured material breach by us. The license agreements also provide that the licensor is primarily responsible for obtaining patent protection for the technology licensed, and we are required to reimburse the licensor for the costs it incurs in performing these activities. The license agreements also require the payment of specified royalties. Any inability or failure to observe these terms or pay these costs or royalties could result in the termination of the applicable license agreement in certain cases. The termination of any license agreement would have a material adverse effect on us.

Protecting our proprietary rights is difficult and costly.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. Accordingly, we cannot predict the breadth of claims allowed in these companies' patents or whether we may infringe or be infringing these claims. Patent disputes are common and could preclude the commercialization of our products. Patent litigation is costly in its own right and could subject us to significant liabilities to third parties. In addition, an adverse decision could force us to either obtain third-party licenses at a material cost or cease using the technology or product in dispute.

Our success is dependent on our key personnel.

We depend on a small management and scientific/clinical group and on independent researchers, some of whom are inventors of the patents licensed to us for core technologies and drugs developed at M.D. Anderson and University of Southern California. Scientific personnel may from time to time serve as consultants to us and may devote a portion of their time to our business, as well as continue to devote substantial time to the furtherance of our sponsored research at M.D. Anderson, University of Southern California and other affiliated institutions as may be agreed to in the future, but such personnel are not our employees and are not bound under written employment agreements. The services of such persons are important to us, and the loss of any of these services may adversely affect us.

We may be unable to retain skilled personnel and maintain key relationships.

The success of our business depends, in large part, on our ability to attract and retain highly qualified management, scientific and other personnel, and on our ability to develop and maintain important relationships with leading research institutions and consultants and advisors. Competition for these types of personnel and relationships is intense from numerous pharmaceutical and biotechnology companies, universities and other research institutions. There can be no assurance that we will be able to attract and retain such individuals on commercially acceptable terms or at all, and the failure to do so would have a material adverse effect on us.

We currently have no sales capability, and limited marketing capability.

We currently do not have sales personnel. We have limited marketing and business development personnel. We will have to develop a sales force, or rely on marketing partners or other arrangements with third parties for the marketing, distribution and sale of any drug product which is ready for distribution. There is no guarantee that we will be able to establish marketing, distribution or sales capabilities or make arrangements with third parties to perform those activities on terms satisfactory to us, or that any internal capabilities or third party arrangements will be cost-effective.

In addition, any third parties with which we may establish marketing, distribution or sales arrangements may have significant control over important aspects of the commercialization of a drug product, including market identification, marketing methods, pricing, composition of sales force and promotional activities. There can be no assurance that we will be able to control the amount and timing of resources that any third party may devote to our products or prevent any third party from pursuing alternative technologies or products that could result in the development of products that compete with, or the withdrawal of support for, our products.

We do not have manufacturing capabilities and may not be able to efficiently develop manufacturing capabilities or contract for such services from third parties on commercially acceptable terms.

We do not have any manufacturing capacity. When required, we will seek to establish relationships with third-party manufacturers for the manufacture of clinical trial material and the commercial production of drug products as we have with our current manufacturing partners. There can be no assurance that we will be able to establish relationships with third-party manufacturers on commercially acceptable terms or that third-party manufacturers will be able to

manufacture a drug product on a cost-effective basis in commercial quantities under good manufacturing practices mandated by the FDA.

The dependence upon third parties for the manufacture of products may adversely affect future costs and the ability to develop and commercialize a drug product on a timely and competitive basis. Further, there can be no assurance that manufacturing or quality control problems will not arise in connection with the manufacture of our drug products or that third party manufacturers will be able to maintain the necessary governmental licenses and approvals to continue manufacturing such products. Any failure to establish relationships with third parties for our manufacturing requirements on commercially acceptable terms would have a material adverse effect on us.

We are dependent in part on third parties for drug development and research facilities.

We do not possess research and development facilities necessary to conduct all of our drug development activities. We engage consultants and independent contract research organizations to design and conduct clinical trials in connection with the development of our drugs. As a result, these important aspects of a drug's development will be outside our direct control. In addition, there can be no assurance that such third parties will perform all of their obligations under arrangements with us or will perform those obligations satisfactorily.

In the future, we anticipate that we will need to obtain additional or increased product liability insurance coverage and it is uncertain that such increased or additional insurance coverage can be obtained on commercially reasonable terms.

Our business will expose us to potential product liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical products. There can be no assurance that product liability claims will not be asserted against us. We intend to obtain additional limited product liability insurance for our clinical trials, directly or through our marketing development partners or contract research organization (CRO) partners, when they begin in the U.S. and to expand our insurance coverage if and when we begin marketing commercial products. However, there can be no assurance that we will be able to obtain product liability insurance on commercially acceptable terms or that we will be able to maintain such insurance at a reasonable cost or in sufficient amounts to protect against potential losses. A successful product liability claim or series of claims brought against us could have a material adverse effect on us.

Insurance coverage is increasingly more difficult to obtain or maintain.

Obtaining insurance for our business, property and products is increasingly more costly and narrower in scope, and we may be required to assume more risk in the future. If we are subject to third-party claims or suffer a loss or damage in excess of our insurance coverage, we may be required to pay claims in excess of our insurance coverage on our own. Furthermore, any first- or third-party claims made on any of our insurance policies may impact our ability to obtain or maintain insurance coverage at reasonable costs or at all in the future.

The market price of our shares, like that of many biotechnology companies, is highly volatile.

Market prices for the our Common Stock and the securities of other medical and biomedical technology companies have been highly volatile and may continue to be highly volatile in the future. Factors such as announcements of technological innovations or new products by us or our competitors, government regulatory action, litigation, patent or proprietary rights developments, and market conditions for medical and high technology stocks in general can have a significant impact on any future market for the Common Stock.

We are not paying dividends on our Common Stock.

We have never paid cash dividends on our Common Stock, and do not intend to do so in the foreseeable future.

The issuance of shares of our Preferred Stock may adversely affect our Common Stock.

Our Board of Directors is authorized to designate one or more series of Preferred Stock and to fix the rights, preferences, privileges and restrictions thereof, without any action by the stockholders. The designation and issuance of such shares of our Preferred Stock may adversely affect the Common Stock, if the rights, preferences and privileges of such Preferred Stock (i) restrict the declaration or payment of dividends on Common Stock, (ii) dilute the voting power of Common Stock, (iii) impair the liquidation rights of the Common Stock or (iv) delay or prevent a change in control for us from occurring, among other possibilities.

Under provisions of our certificate of incorporation, bylaws and Delaware law, our management may be able to block or impede a change in control.

Our certificate of incorporation authorizes our Board of Directors to designate shares of Preferred Stock without stockholder approval on such terms as our Board of Directors may determine. The rights of the holders of Common Stock may be subject to or adversely affected by, the rights of the holders of any such Preferred Stock that may be issued in the future. The issuance of Preferred Stock may make it more difficult for a third party to acquire, or may discourage a third party from acquiring, a majority of the voting stock. These and other provisions of our certificate of incorporation and our by-laws, as well as certain provisions of Delaware law, could delay or impede the removal of incumbent directors and could make more difficult a merger, tender offer or proxy contest involving a change of control of the company, even if such events could be beneficial to the interest of the stockholders as a whole. Such provisions could limit the price that certain investors might be willing to pay in the future for our Common Stock.

Officers' and directors' liabilities are limited under Delaware law.

Pursuant to our certificate of incorporation and by-laws, as authorized under applicable Delaware law, directors are not liable for monetary damages for breach of fiduciary duty, except in connection with a breach of the duty of loyalty, for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, for dividend payments or stock repurchases illegal under Delaware law or for any transaction in which a director has derived an improper personal benefit. Our certificate of incorporation and by-laws provide that we must indemnify our officers and directors to the fullest extent permitted by Delaware law for all expenses incurred in the settlement of any actions against such persons in connection with their having served as officers or directors.

Item 7. Financial Statements.

See the Financial Statements and Reports of J.H. Cohn LLP set forth in Item 13, which are incorporated herein by reference. You should read the following selected financial data in conjunction with our financial statements and related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this annual report.

Item 8. Change in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 8A. Controls and Procedures.

Evaluation of disclosure controls and procedures

Disclosure controls and procedures are controls and other procedures that are designed to ensure that the information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports that a company files or submits under the Exchange Act is accumulated and communicated to the company's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Under the supervision of our Chief Executive Officer and our Chief Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2004. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that as of December 31, 2004, our disclosure controls and procedures were not effective to ensure that management is alerted to material information required to be disclosed by us in the reports we file with the SEC and that such material information is recorded and reported within the time periods specified in the SEC's rules and forms. However, since the date of that evaluation, management has begun to implement changes to improve certain aspects of our disclosures controls and procedures.

In connection with J.H. Cohn LLP’s audit of our financial statements for the fiscal year ended December 31, 2004, J.H. Cohn, our independent registered public accounting firm, advised our Audit Committee that it had identified material weaknesses in our accounting function that we need to re-evaluate and strengthen. J.H. Cohn informed the Audit Committee that our accounting system software has many limitations that may not allow us to ensure prior period financial information is not changed. This software allows users to make changes to historical data and is limited in its ability to provide us with accurate costing information. We are unaware of any instances in which any users of such software made any changes to historical data. J.H. Cohn also noted that we lacked a formal process to review and document journal entries. In addition, J.H. Cohn stated that we may need to enhance our internal accounting capability by hiring a controller or entering into an agreement with a third party consultant with the appropriate level of technical expertise. In addition to identifying the foregoing material weaknesses, J.H. Cohn also made certain other suggestions to improve our financial information and internal control procedures.

Changes in internal controls

Since the end of the fiscal year ended December 31, 2004, we have undertaken a number of remediation actions to improve our internal controls over financial reporting, including the following:

- Replacing our legacy computer accounting system with one that supports project tracking, audit trails, and allows for greater internal audit oversight. Our auditors have endorsed our efforts to migrate to a new accounting system that would better meet our needs;

- Supplementing our accounting department with additional expertise for preparation or approval of transactions; and

- Engaging a third-party consultant to aid us in designing, implementing and testing new procedures to bring our controls and procedures into compliance with Section 404 of the Sarbanes-Oxley Act of 2002 within the time frame required under the Securities Exchange Act of 1934.

The remediation actions described above are in varying stages of completion. We currently expect to complete these actions by the end of 2005.

Part III

Item 9. Director, Executive Officers, Promoters and Control Persons; Compliance with Section 16(a) of the Exchange Act.

Directors, Executive Officers and Significant Employees.

The names of our directors and executive officers, including those persons nominated or chosen to become such, significant employees, and certain information about each of them are set forth below:

Name	Age	Position(s) with the Company
Evan Levine	39	Chief Executive Officer, President, Chief Operating Officer, Secretary and Vice Chairman of the Board
M. Ross Johnson, Ph.D.	60	Chairman of the Board
Carrie E. Carlander	34	Chief Financial Officer, Vice President, Finance, and Treasurer
Joan M. Robbins	44	Chief Technical Officer
Brian Culley	33	Vice President, Business Development
Cellia Habita	37	Senior Vice President, Clinical and Medical Affairs
Michael M. Goldberg, M.D. (1)(2)	46	Director (3)
Mark J. Pykett, V.M.D., Ph.D (1)(2)	40	Director (3)
Mark Bagnall, CPA (1)(2)	48	Director (4)

(1) Member of the Audit Committee of the Board of Directors.
(2) Member of the Compensation Committee of the Board of Directors.
(3) Appointed in January 2004.
(4) Appointed in February 2004.

M. Ross Johnson, Ph.D. Dr. Johnson has served as our Chairman of the Board since October 2002. From October 2000 until May 2003, Dr. Johnson also served as a Director for Biokeys, Inc., a wholly owned subsidiary of the Company that was merged with and into the Company in May 2003. Dr. Johnson is also currently Chief Executive Officer, Director and Co-Founder of Parion Sciences, Inc. He has served on numerous boards and currently holds additional board positions with Cortex Pharmaceuticals, Inc. (COR), ChemCodes, Inc., the Board of Governors of Research Triangle Institute and the University of North Carolina Education Advancement Board. He also currently serves on the Advisory Board of the Chemistry Department at the University of California at Berkley and the University of North Carolina at Chapel Hill. From 1995 to 1999, he was President, Chief Executive Officer and Chief Scientific Officer of Trimeris, Inc. (TRMS), a company he took public in 1997. From 1987 to 1994, he was Vice President of Chemistry at Glaxo Inc. (GSK) where he was part of the original scientific founding team for Glaxo's research entry in the U. S. From 1971 to 1987, Dr. Johnson served in key scientific and research management positions with Pfizer Central Research (PFE). He has also served as a Special Advisor to Nobex Corporation, Ceretec, AtheroGenics, Inc. (AGIX) and Albany Molecular Research, Inc. (AMRI). Dr. Johnson received his B.S. in Chemistry from the University of California at Berkeley in 1967 and a Ph.D. in organic chemistry from the University of California at Santa Barbara in 1970.

Evan M. Levine. Mr. Levine has served as our Chief Executive Officer and President since September 2004, as our Vice Chairman of the Board since January 2004 and as our Chief Operating Officer and Secretary and a Director since October 2002. Currently, Mr. Levine also acts as the Managing Member of Mark Capital LLC, a venture capital and consulting firm specializing in technology and biotechnology investments. From March 2002 to June 2002, Mr. Levine served as the Interim Chief Executive Officer of Digital Courier Technologies, Inc., a provider of advanced e-payment services for businesses, merchants and financial institutions. From 1997 to 2001, Mr. Levine served as a Managing Principal and Portfolio Manager of Brown Simpson Asset Management, specializing in structured finance for public companies. From 1996 to 1997, Mr. Levine served as Senior Vice President of Convertible Sales and Trading at Dillon Read & Company, a financial services company. From 1993 to 1996, Mr. Levine served as Vice President of Convertible Sales and Trading at Hambrecht & Quist, a financial services company. From 1992 to 1993, Mr. Levine served as a Global Arbitrage Trader at Spectrum Trading Partners, financial derivatives trading company. Mr. Levine received his B.A. in Economics and Finance from Rutgers University and has completed graduate coursework for an MBA at New York University's Stern School of Business.

Carrie E. Carlander. Ms. Carlander has served as our Chief Financial Officer, Vice President, Finance and Treasurer since December 2004. From August 2004 to December 2004, Ms. Carlander served in a consulting capacity as Chief Financial Officer of Singlefin, Inc., an email/internet security software company. From December 2003 to December 2004, Ms. Carlander served in a consulting capacity as Chief Financial Officer of SofLinx, Inc., a wireless sensor network and software company. From December 2002 to June 2004, Ms. Carlander served as Vice President of Finance of V-Enable, Inc., a software company specializing in multimodal software for wireless devices. From December 1996 to May 2000, Ms. Carlander served first as Director of Finance and Human Resources, and then as Vice President, Finance and Administration, of Websense Inc., a publicly traded company that provides software products that analyze, report and manage computing resource use by employees. Ms. Carlander received her B.A. in Political Science from University of California, San Diego, her MBA from San Diego State University and a Certified Management Accountant designation from the IMA.

Joan M. Robbins, Ph.D. Dr. Robbins is our Chief Technical Officer and has served in this role since March 2003. From 1996-2003, Dr. Robbins was employed by Immusol, Inc., a biopharmaceutical company specializing in anticancer and antiviral therapeutics in addition to certain dermatologic and ophthalmic disorders. At Immusol, she held several positions, including Vice President, Product Development, Senior Director, Product Development, and Director, Therapeutics. Dr. Robbins has directed drug discovery and development resulting in the advancement of drug candidates into Phase I, II and III human trials, including the development of clinical protocols with the FDA. She has also led programs for formulation, manufacturing, toxicology and pharmacology development. From 1994 to 1995, she was Research Scientist and Project Leader for Cancer Research at Chiron where she developed gamma-IFN recombinant retroviral immuno-gene therapy for cancer, and tk-recombinant retroviral gene therapy for brain tumors. From 1992 to 1993, Dr. Robbins was a Post Graduate Researcher at University of California, San Diego, where she developed a novel DNA-based immunotherapeutic for treatment of Her2/neu expressing tumors. From 1990 to 1991, she was a Research Fellow at the Garvin Institute for Medical Research, Centre for Immunology in Sydney, Australia, and from 1981 to 1989, Dr. Robbins was a Microbiologist at the Laboratory of Tumor Immunology and Biology at the National Cancer Institute in Bethesda, Maryland. Dr. Robbins' background in drug discovery and development has resulted in over 20 scientific publications and 5 patents. Dr. Robbins received her B.S. degree in genetics from the University of California, Davis, and a Ph.D. degree in genetics from George Washington University, Washington D.C.

Cellia Habita, M.D., Ph.D. Dr. Habita is our Senior Vice President of Medical and Clinical Affairs and has served in this role since January 2005. Previously, Dr. Habita was Vice President of Medical and Clinical Affairs since joining us in March 2004. From 2001 to 2004, Dr. Habita was employed by Immusol, Inc., a biopharmaceutical company involved in development of therapies for cancer, viral diseases and certain dermatologic and ophthalmic disorders, where her most recent title was Director of Product Development and Preclinical. At Immusol, Dr. Habita directed product formulation, toxicology and pharmacology testing and oversaw offsite manufacturing. Dr. Habita was responsible for regulatory submissions in addition to assisting with clinical protocols and trial design. Under her leadership, two drug candidates were successfully launched into clinical trials. Previous to Immusol, Dr. Habita was Assistant Project Scientist at the Center for Molecular Genetics at the University of California, San Diego (UCSD). While at UCSD, Dr. Habita developed an in vivo gene transfer model in fetal tissue and neonates for the study of metabolic disorders and therapies to treat such disorders. Dr. Habita earned a Ph.D. in Human Genetics, completed her graduate research at Oxford University in the UK at The Wellcome Trust for Human Genetics where she identified chromosomal regions involved in Type I Diabetes. Dr. Habita received an MS in Biology and Genetics of Aging from The University of Paris VII in France and an M.D. in General Medicine from the National Institute of Medical Sciences in Algiers, Algeria. Her clinical training covered Pediatric and Adult Endocrinology, Obstetrics/Gynecology and Orthopedic Surgery at The Saint Louis and Robert Debré Hospitals in Paris, and she has conducted Genetic studies for Diabetes and Aging and Epidemiological studies in public health.

Brian M. Culley, MS, MBA. Mr. Culley is Vice President, Business Development and has served in this role since joining us in December 2004. From 2002 until 2004, Mr. Culley managed all strategic collaborations and licensing agreements for Immusol, Inc. in San Diego, where his most recent title was Director of Business Development and Marketing. From 1999 until 2000, he was a licensing and marketing associate at the University of California, San Diego Department of Technology Transfer & Intellectual Property Services and from 1996 to 1999, he was a research associate for Neurocrine Biosciences, Inc., where he performed drug discovery research. Mr. Culley has over 12 years of experience in the biotechnology industry, including deal structure and negotiation, licensing, due diligence, market and competitive research, and venture funding. He received a MS in Biochemistry from the University of California Santa Barbara and an MBA from The Johnson School of Business at Cornell University with an emphasis on private equity and entrepreneurship.

Michael M. Goldberg, M.D. Dr. Goldberg has served as a Director since January 2004. Since August 1990, Dr. Goldberg has been with Emisphere Technologies, Inc. where he is now Chairman and Chief Executive Officer. Emisphere is a biopharmaceutical company specializing in the oral delivery of therapeutic macromolecules and other compounds that are not currently deliverable by oral means. Dr. Goldberg was previously a Vice President for The First Boston Corporation, where he was a founding member of the Healthcare Banking Group. He received a B.S. from Rensselaer Polytechnic Institute, an M.D. from Albany Medical College of Union University and an M.B.A. from Columbia University Graduate School of Business.

Mark J. Pykett, V.M.D., Ph.D Dr. Pykett has served as a Director since January 2004. Since November 2004, Dr. Pykett has been with Boston Life Sciences, Inc. where he is now President and Chief Operating Officer. In 1996, Dr. Pykett co-founded Cytomatrix, LLC, a private biotechnology company focused on the research, development and commercialization of novel cell-based therapies. Dr. Pykett served as Cytomatrix' President and Chief Executive Officer and a Director until April 2003, when Cytomatrix merged with Cordlife, Pte. Ltd., a subsidiary of CyGenics, Ltd., a public biotechnology company. From April 2003 to February 2004, Dr. Pykett served as President of Cordlife, Pte. Ltd. and then as President and Director of CyGenics from February 2004 until November 2004. Cytomatrix is. Dr. Pykett graduated Phi Beta Kappa, Summa Cum Laude from Amherst College, holds a veterinary degree, Phi Zeta, Summa Cum Laude, and doctorate in molecular biology from the University of Pennsylvania, and received an M.B.A. degree Beta Gamma Sigma from Northeastern University. He completed post-doctoral fellowships at the University of Pennsylvania and Harvard University. In his research in academia, Dr. Pykett focused on understanding the molecular basis of cancer. Dr. Pykett also held an adjunct faculty position at the Harvard School of Public Health from 1997 to 2003.

Mark Bagnall, CPA . Mr. Bagnall has served as a Director since February 2004. Since June 2000, Mr. Bagnall has been at Metabolex, Inc. where he now serves as Senior Vice President and Chief Business Officer. Metabolex is a privately held pharmaceutical company focused on the development of drugs to treat diabetes and related metabolic disorders. Mr. Bagnall has been in the biotechnology industry for over 15 years. In the 12 years prior to joining Metabolex, Mr. Bagnall held the top financial position at four life science companies: Metrika, Inc., a privately held diagnostics company, and three public biotechnology companies, Progenitor, Inc., Somatix Therapy Corporation, and Hana Biologics, Inc. During his career in biotechnology, he has managed several private and public financings, merger and acquisition transactions and corporate licensing agreements. Mr. Bagnall received his Bachelor of Science degree in Business Administration from the U.C. Berkeley Business School and is a Certified Public Accountant.

Compliance with Section 16(a) of the Exchange Act

Section 16(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), requires our directors and officers, and persons who own more than 10% of a registered class of our equity securities ("Section 16 Persons"), to file with the Securities and Exchange Commission (the "SEC") initial reports of ownership and reports of changes in ownership of our Common Stock and derivative securities to acquire our Common Stock. Section 16 Persons are required by SEC regulation to furnish us with copies of all Section 16(a) reports they file. Based on our review of the forms we have received, on other reports filed by Section 16 Persons with the SEC and on our records, we believe that during 2004 Cellia Habita and Mark Bagnall did not timely file a Form 3 to report their beneficial ownership of our Common Stock.

Audit Committee

As of the date of this report, Messrs. Goldberg, Pykett and Bagnall serve on the Audit Committee of the Company's board of directors. The Company believes that each of Messrs. Goldberg, Pykett and Bagnall is independent within the meaning of Section 121(a) of the AMEX's listing standards and is an "audit committee financial expert" within the meaning of Item 401(e)(2) of Regulation S-B under the Securities Act of 1933, as amended.

Code of Ethics

The Company has adopted a Code of Business Conduct and Ethics (the "Code") that applies to all of the Company's employees (including our executive officers) and directors. The Company shall provide to any person without charge, upon request, a copy of the Code. Any such request must be made in writing to the Company, c/o Investor Relations, 6725 Mesa Ridge Road, Suite 100, San Diego, California 92121.

Item 10. Executive Compensation.

The information required by Item 10 of Form 10-KSB is incorporated by reference from the information contained in the section captioned *"Executive Compensation and Other Information"* in our Proxy Statement related to the Annual Meeting of Stockholders to be held on May 24, 2005.

Item 11. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by Item 11 of Form 10-KSB concerning security ownership of certain beneficial owners and management is incorporated by reference from the information contained in the section captioned *"Ownership of Securities"* in our Proxy Statement related to the Annual Meeting of Stockholders to be held on May 24, 2005.

Item 12. Certain Relationships and Related Transactions.

The information required by Item 12 of Form 10-KSB is incorporated by reference from the information contained in the section captioned *"Certain Relationships and Related Transactions"* in our Proxy Statement related to the Annual Meeting of Stockholders to be held on May 24, 2005.

Item 13. Exhibits.

Financial Statements Incorporated by Reference

The Financial Statements and Reports of J.H. Cohn LLP which are set forth in the index to Consolidated Financial Statements beginning on page F-1 of this report are filed as part of this report. You should read the

following selected financial data in conjunction with our financial statements and related notes and “Plan of Operations” appearing elsewhere in this annual report.

Exhibits.

Exhibit Index

Exhibit	Description
3.1 (1)	Certificate of Incorporation of Victoria Enterprises, Inc.
3.2 (1)	Certificate of Amendment of Certificate of Incorporation of Victoria Enterprises, Inc.
3.3 (1)	Certificate of Amendment of Certificate of Incorporation of BioQuest, Inc.
3.4 (1)	Certificate of Amendment of Certificate of Incorporation of BioQuest, Inc.
3.5 (1)	Certificate of Ownership and Merger Merging Biokeys, Inc. with and into Biokeys Pharmaceuticals, Inc.
3.6 (2)	Amended and Restated Bylaws of Biokeys Pharmaceuticals, Inc.
3.7 (1)	Certificate of Amendment to the Certificate of Incorporation of ADVENTRX Pharmaceuticals, Inc.
3.8 (3)	Certificate of Designation of BioQuest, Inc.
3.9 (4)	Certificate of Designation of Series B Convertible Preferred Stock and Series C Convertible Preferred Stock of Biokeys Pharmaceuticals, Inc.
4.1 (5)	Common Stock and Warrant Purchase Agreement, dated as of April 5, 2004, among the Company and the Investors named therein
4.2 (5)	A-1 Warrant to Purchase Common Stock issued to Investors pursuant to the Common Stock and Warrant Purchase Agreement with the Investors
4.3 (5)	A-2 Warrant to Purchase Common Stock issued to Investors pursuant to the Common Stock and Warrant Purchase Agreement with the Investors
4.4 (6)	Common Stock and Warrant Purchase Agreement, dated April 8, 2004, between the Company and CD Investment Partners, Ltd.
4.5 (6)	A-1 Warrant to Purchase Common Stock issued to CD Investment Partners, Ltd.
4.6 (6)	A-2 Warrant to Purchase Common Stock issued to CD Investment Partners, Ltd.
4.7 (6)	Warrant to Purchase Common Stock issued on April 8, 2004 to Burnham Hill Partners
4.8 (6)	

	Warrant to Purchase Common Stock issued on April 8, 2004 to Ernest Pernet
4.9 (6)	Warrant to Purchase Common Stock issued on April 8, 2004 to W.R. Hambrecht + Co., LLC
4.10 (5)	Registration Rights Agreement, dated as of April 5, 2004, among the Company and the Investors named therein
4.11 (6)	Registration Rights Agreement, dated as of April 8, 2004, between the Company and CD Investment Partners, Ltd.
4.12	Not used
4.13	Not used

4.14	(7)	Common Stock and Warrant Purchase Agreement, dated April 19, 2004, between the Company and Franklin Berger
4.15	(7)	A-1 Warrant to Purchase Common Stock issued to Franklin Berger
4.16	(7)	A-2 Warrant to Purchase Common Stock issued to Franklin Berger
4.17	(7)	Registration Rights Agreement, dated as of April 19, 2004, between the Company and Franklin Berger
4.18	(5)	Registration Rights Agreement, dated _____, 2001, between the Company and certain stockholders
4.19	(5)	Warrant to Purchase Common Stock issued by the Company
4.20	(5)	Stock Subscription Agreement
4.21	(5)	Warrant to Purchase Common Stock issued by the Company
4.22	(5)	Warrant for the Purchase of Shares of Common Stock No. WA-2A issued June 14, 2001 to Robert J. Neborsky and Sandra S. Neborsky, JTWROS
10.1	(8)	Patent and Technology License Agreement, dated June 14, 1996, among the Company, the Board of Regents of the University of Texas System and the University of Texas M. D. Anderson Cancer Center (Request for confidential treatment of certain data)
10.2	(8)	Amendment No. 1 to Patent and Technology License Agreement, dated June 15, 2000, between the Company and the University of Texas M. D. Anderson Cancer Center(Request for confidential treatment of certain data)
10.3	(8)	Option and License Agreement, dated January 23, 1998, between the Company and the University of Southern California (Request for confidential treatment of certain data)
10.4	(2)	First Amendment to License Agreement, dated August 16, 2000, between the Company and the University of Southern California (Request for confidential treatment of certain data)
10.5	(8)	Option and License Agreement, dated August 17, 2000, between the Company and the University of Southern California (Request for confidential treatment of certain data)
10.6	(9)	Standard Multi-Tenant Office Lease - Gross, dated June 3, 2004, between the Company and George V. Casey & Ellen M. Casey, Trustees of the Casey Family Trust dated June 22, 1998
10.7	(10)	Patent License Agreement, effective August 1, 2002, between the Company and the National Institutes of Health

10.9	(11)	Offer Letter, dated March 5, 2003, from the Company to Joan M. Robbins, Ph.D.
10.10	(12)	Amendment to Option and License Agreement, dated April 21, 2003, the Company and the University of Southern California

10.11	Offer Letter, dated March 1, 2004, from the Company to Cellia Habita, Ph.D.
10.12	Offer Letter, dated November 15, 2004, from the Company to Brian Culley
10.13	Offer Letter, dated November 17, 2004, from the Company to Carrie Carlander
21.1	Subsidiaries of ADVENTRX Pharmaceuticals, Inc.
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Powers of Attorney (included on signature page)
31.1	Rule 13a-14(a)/15d-14(a) Certification
31.2	Rule 13a-14(a)/15d-14(a) Certification
32.1	Section 1350 Certifications
32.2	Section 1350 Certifications

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(1) Incorporated by reference to the same-numbered exhibit to the Company's Form 8-A, filed April 27, 2004

(2) Incorporated by reference to the same-numbered exhibit to the Company's Registration Statement on Form 10-SB, filed October 2, 2001.

(3) Incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form 10-SB, filed October 2, 2001.

(4) Incorporated by reference to Exhibit 4.2 to the Company's Quarterly Report on Form 10-QSB, filed November 26, 2002 (exhibit included in the body of the Form 10-QSB and not filed as a separate exhibit file).

(5) Incorporated by reference to the same-numbered exhibit to the Company's Registration Statement on Form S-3, filed June 30, 2004.

(6) Incorporated by reference to the same-numbered exhibit to the Company's Current Report on Form 8-K, filed April 13, 2004.

(7) Incorporated by reference to the same-numbered exhibit to the Company's Quarterly Report on Form 10-QSB, filed May 12, 2004.

(8) Incorporated by reference to the same-numbered exhibit to the Company's Registration Statement on Form 10-SB/A, filed January 14, 2002.

(9) Incorporated by reference to the same-numbered exhibit to the Company's Quarterly Report on Form 10-QSB, filed August 10, 2004.

(10) Incorporated by reference to the same-numbered exhibit to the Company's Quarterly Report on Form 10-QSB, filed November 26, 2002.

(11) Incorporated by reference to the same-numbered exhibit to the Company's Annual Report on Form 10-KSB, filed April 16, 2003.

(12) Incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-QSB, filed August 14, 2003.

Item 14. Principal Accountant Fees and Services.

2003				2004			
Audit Fee	Audit Related Fee	Tax Fee	All Other Fees	Audit Fee	Audit Related Fee	Tax Fee	All Other Fees
$ 36,534	--	$ 4,244	--	$ 61,780	$ 6,340	-	--

Audit Fees.

During the fiscal years ended December 31, 2004 and 2003, the fees billed for professional services rendered by J.H. Cohn LLP for the audit of our annual financial statements and review of financial statements included in our Forms 10-QSB for fiscal years 2004 and 2003 were $61,780 and $36,534, respectively.

Audit-Related Fees.

During the fiscal years ended December 31, 2004 and 2003, audit-related fees billed for professional services rendered by J.H. Cohn LLP were $6,340 and $0, respectively. These were professional services requested by the Audit Committee in connection with the review and/or filing of our Forms S-3 and 8K in 2004.

Tax Fees.

During the fiscal years ended December 31, 2004 and 2003, tax fees billed by J.H. Cohn LLP for tax compliance, tax advice or tax planning services were $0 and $4,244, respectively.

All Other Fees.

During the fiscal years ended December 31, 2004 and 2003, no fees were billed by J.H. Cohn LLP, other than the fees set forth above.

Pre-Approval Policies and Procedures of the Audit Committee.

The Audit Committee has the sole authority to appoint, terminate and replace our independent auditor. The Audit Committee may not delegate these responsibilities. The Audit Committee has the sole authority to approve the scope, fees and terms of all audit engagements, as well as all permissible non-audit engagements of our independent auditor.

SIGNATURES

Pursuant to the requirements of the Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on the 31st day of March 2004.

ADVENTRX PHARMACEUTICALS, INC

By: ***/s/ Evan Levine***

Evan Levine
Chief Executive Officer, President and Secretary

By: ***/s/ Carrie Carlander***

Carrie Carlander
Chief Financial Officer

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Evan Levine and Carrie Carlander, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to his Report on Form 10-KSB, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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 dates indicated.

Signature	**Title**	**Date**
/s/ M. Ross Johnson		
M. Ross Johnson, Ph.D.	Chairman of the Board	March 31, 2005
/s/ Evan Levine		
Evan Levine	Chief Executive Officer, Director, President and Secretary	March 31, 2005
/s/ Carrie Carlander		
Carrie Carlander	Chief Financial Officer, Vice President Finance and Treasurer	March 31, 2005

/s/ Michael M. Goldberg		
Michael M. Goldberg, M.D.	Director	March 31, 2005
/s/ Mark J. Pykett		
Mark J. Pykett, V.M.D., Ph.D.	Director	March 31, 2005
/s/ Mark Bagnall		
Mark Bagnall, CPA	Director	March 31, 2005

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders
ADVENTRX Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of ADVENTRX Pharmaceuticals, Inc. and Subsidiary (a development stage enterprise) as of December 31, 2004 and 2003, and the related consolidated statements of operations, shareholders' equity and cash flows for the years then ended and for the period from June 12, 1996 (date of inception) to December 31, 2004. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. The consolidated financial statements for the period from June 12, 1996 (date of inception) to December 31, 2001 were audited by other auditors whose report, dated April 10, 2003, expressed an unqualified opinion and included an explanatory paragraph concerning the Company's ability to continue as a going concern. Our opinion on the consolidated statements of operations, shareholders' equity and cash flows for the period from June 12, 1996 (date of inception) to December 31, 2004, insofar as it relates to amounts for the period for June 12, 1996 (date of inception) to December 31, 2001, is based solely on the report of the other auditors.

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, based on our audits and the report of the other auditors, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of ADVENTRX Pharmaceuticals, Inc. and Subsidiary (a development stage enterprise) as of December 31, 2004 and 2003, and their results of operations and cash flows for the years then ended and for the period from June 12, 1996 (date of inception) to December 31, 2004, in conformity with accounting principles generally accepted in the United States of America.

/s/ J.H. Cohn LLP

San Diego, California
February 3, 2005 except for Note 9, as to which the date is March 28, 2005

ADVENTRX PHARMACEUTICALS, INC.
(Formerly Biokeys Pharmaceuticals, Inc.)
(A Development Stage Enterprise)
Consolidated Balance Sheets

	December 31, 2004	December 31, 2003
Assets		
Current assets:		
Cash and cash equivalents	$ 13,032,263	$ 4,226,397
Accrued interest income	10,808	—
Prepaid expenses	115,144	28,376
Assets available for sale	108,000	—
Total current assets	13,266,215	4,254,773
Property and equipment, net	285,304	20,840
Other assets	57,268	7,743
Total assets	$ 13,608,787	$ 4,283,356
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 532,327	$ 90,243
Accrued liabilities	628,754	—
Accrued salaries and related taxes	57,315	—
Accrued dividends payable	—	72,800
Total liabilities	1,218,396	163,043
Commitments and contingencies		
Shareholders' equity:		
Series A cumulative convertible Preferred Stock, $0.01 par value; Authorized 8,000 shares; issued and outstanding, 473 shares in 2003(aggregate involuntary liquidation preference $473,000 at December 31, 2003)	—	4
Series B convertible Preferred Stock, $0.01 par value; Authorized 200,000 shares in 2003; issued and outstanding, 200,000 shares (no liquidation preference)	—	2,000
Common Stock, $0.001 par value; Authorized 100,000,000 shares; issued 53,834,237 in 2004 and issued and outstanding 42,491,708 shares in 2003	53,835	42,492
Additional paid-in capital	47,553,497	32,556,963
Deficit accumulated during the development stage	(35,182,194)	(28,481,146)
Treasury stock, at cost, 23,165 shares	(34,747)	—
Total shareholders' equity	12,390,391	4,120,313

Total liabilities and shareholders' equity	$ 13,608,787	$ 4,283,356

See accompanying notes to consolidated financial statements.

ADVENTRX PHARMACEUTICALS, INC.
(Formerly Biokeys Pharmaceuticals, Inc.)
(A Development Stage Enterprise)
Statements of Operations

	Year Ended December 31,		Inception (June 12, 1996) through December 31,
	2004	2003	**2004**
Net sales	$ —	$ —	$ 174,830
Cost of goods sold	—	—	51,094
Gross margin	—	—	123,736
Grant revenue	—	3,603	129,733
Interest income	103,042	9,269	202,278
Total income	103,042	12,872	455,747
Operating expenses:			
Research and development	2,744,328	748,997	7,474,254
General and administrative	4,018,453	1,585,596	12,433,297
Depreciation and amortization	41,309	8,970	10,140,016
Impairment loss - write off of goodwill	—	—	5,702,130
Interest expense	—	1,386	179,090
Equity in loss of investee	—	—	178,936
Total operating expenses	6,804,090	2,344,949	36,107,723
Loss before cumulative effect of change in accounting principle	(6,701,048)	(2,332,077)	(35,651,976)
Cumulative effect of change in accounting principle	—	—	(25,821)
Net loss	(6,701,048)	(2,332,077)	(35,677,797)
Preferred Stock dividends	—	(37,840)	(621,240)
Net loss applicable to Common Stock	$ (6,701,048)	$ (2,369,917)	$ (36,299,037)
Loss per Common Share - basic and diluted	$ (0.13)	$ (0.07)	

See accompanying notes to consolidated financial statements.

ADVENTRX PHARMACEUTICALS, INC. AND SUBSIDIARY
(A Development Stage Enterprise)
Consolidated Statements of Shareholders' Equity
Inception (June 12, 1996) through December 31, 2004

	Cumulative convertible Preferred Stock, series A		Cumulative convertible Preferred Stock, series B		Cumulative convertible Preferred Stock, series C	
	Shares	Amount	Shares	Amount	Shares	Amount
Balances at June 12, 1996 (date of incorporation)	—	$ —	—	$ —	—	$ —
Sale of Common Stock without par value	—	—	—	—	—	—
Change in par value of Common Stock	—	—	—	—	—	—
Issuance of Common Stock and net liabilities assumed in acquisition	—	—	—	—	—	—
Issuance of Common Stock	—	—	—	—	—	—
Net loss	—	—	—	—	—	—
Balances at December 31, 1996	—	—	—	—	—	—
Sale of Common Stock, net of offering costs of $9,976	—	—	—	—	—	—
Issuance of Common Stock in acquisition	—	—	—	—	—	—
Minority interest deficiency at acquisition charged to the Company	—	—	—	—	—	—
Net loss	—	—	—	—	—	—
Balances at December 31, 1997	—	—	—	—	—	—
Rescission of acquisition	—	—	—	—	—	—
Issuance of Common Stock at conversion of notes payable	—	—	—	—	—	—
Expense related to stock warrants issued	—	—	—	—	—	—
Net loss	—	—	—	—	—	—
Balances at December 31, 1998	—	—	—	—	—	—
Sale of Common Stock	—	—	—	—	—	—
Expense related to stock warrants issued	—	—	—	—	—	—
Net loss	—	—	—	—	—	—
Balances at December 31, 1999	—	—	—	—	—	—
Sale of Preferred Stock, net of offering costs of $76,500	3,200	32	—	—	—	—

Issuance of Common Stock at conversion of notes and interest payable	—	—	—	—	—	—
Issuance of Common Stock at conversion of notes payable	—	—	—	—	—	—
Issuance of Common Stock to settle obligations	—	—	—	—	—	—
Issuance of Common Stock for acquisition	—	—	—	—	—	—
Issuance of warrants for acquisition	—	—	—	—	—	—
Stock issued for acquisition costs	—	—	—	—	—	—
Expense related to stock warrants issued	—	—	—	—	—	—
Dividends payable on Preferred Stock	—	—	—	—	—	—
Cashless exercise of warrants	—	—	—	—	—	—
Net loss	—	—	—	—	—	—
Balances at December 31, 2000	3,200	32	—	—	—	—
Dividends payable on Preferred Stock	—	—	—	—	—	—
Repurchase of warrants	—	—	—	—	—	—
Sale of warrants	—	—	—	—	—	—
Cashless exercise of warrants	—	—	—	—	—	—
Issuance of Common Stock to pay preferred dividend	—	—	—	—	—	—

	Cumulative convertible Preferred Stock, series A		Cumulative convertible Preferred Stock, series B		Cumulative convertible Preferred Stock, series C	
	Shares	Amount	Shares	Amount	Shares	Amount
Detachable warrants issued with notes payable	—	—	—	—	—	—
Issuance of warrants to pay operating expenses	—	—	—	—	—	—
Issuance of Common Stock to pay operating expenses	—	—	—	—	—	—
Issuance of Preferred Stock to pay operating expense	137	1	—	—	—	—
Net loss	—	—	—	—	—	—
Balances at December 31, 2001	3,337	33	—	—	—	—
Dividends payable on Preferred Stock	—	—	—	—	—	—
Repurchase of warrants (note 6)	—	—	—	—	—	—
Sale of warrants (note 6)	—	—	—	—	—	—
Cashless exercise of warrants (note 6)	—	—	—	—	—	—
Exercise of warrants	—	—	—	—	—	—
Sale of Preferred Stock at $1.50 per share	—	—	200,000	2,000	—	—
Sale of Preferred Stock at $10.00 per share	—	—	—	—	70,109	701
Conversion of Preferred Stock into Common Stock	(3,000)	(30)	—	—	—	—
Preferred Stock dividends forgiven	—	—	—	—	—	—
Issuance of warrants to pay operating expenses (note 6)	—	—	—	—	—	—
Issuance of Common Stock to pay operating expenses (note 6)	—	—	—	—	—	—
Issuance of Preferred Stock to pay operating expenses (note 6)	136	1	—	—	—	—
Issuance of stock options to employees (note 6)	—	—	—	—	—	—
Net loss	—	—	—	—	—	—
Balances at December 31, 2002	473	4	200,000	2,000	70,109	701
Dividends payable on Preferred Stock	—	—	—	—	—	—
Conversion of Series C Preferred Stock into Common Stock	—	—	—	—	(70,109)	(701)
Issuance of Common Stock to pay interest on Bridge Notes	—	—	—	—	—	—
Sale of Common Stock at $0.40 per share, net of issuance costs	—	—	—	—	—	—

Sale of Common Stock at $1.00 per share, net of issuance costs	—	—	—	—	—	—
Exchange of warrants	—	—	—	—	—	—
Issuance of Common Stock to pay operating expenses (note 6)	—	—	—	—	—	—
Issuance of warrants to pay operating expenses (note 6)	—	—	—	—	—	—
Issuance of stock options to employees (note 6)	—	—	—	—	—	—
Net loss	—	—	—	—	—	—
Balances at December 31, 2003	473	4	200,000	2,000	—	
Extinguishment of dividends payable on Preferred Stock	—	—	—	—	—	—
Conversion of Series A cumulative Preferred Stock into Common Stock	(473)	(4)	—	—	—	—
Conversion of Series B Preferred Stock into Common Stock	—	—	(200,000)	(2,000)	—	—
Exercise of warrants	—	—	—	—	—	—
Sale of Common Stock at $1.50 per share	—	—	—	—	—	—
Payment of financing and offering costs	—	—	—	—	—	—
Issuance of stock options to employees	—	—	—	—	—	—
Acquisition of treasury stock	—	—	—	—	—	—
Net Loss	—	—	—	—	—	—
Balances at December 31, 2004	–$	—	–$	—	–$	—

See accompanying notes to consolidated financial statements.

ADVENTRX PHARMACEUTICALS, INC. AND SUBSIDIARY
(A Development Stage Enterprise)
Consolidated Statements of Shareholders' Equity
Inception (June 12, 1996) through December 31, 2004
CONTINUED FROM PREVIOUS PAGE

	Common Stock		Additional paid-in capital	Deficit accumulated during the development stage	Treasury Stock	Total stockholders' equity (deficit)
	Shares	Amount	Capital	**stage**	**At Cost**	**(deficit)**
Balances at June 12, 1996 (date of incorporation)	—	$ —	$ —	$ —	$ —	—
Sale of Common Stock without par value	503	5	5	—	—	10
Change in par value of Common Stock	—	(4)	4	—	—	—
Issuance of Common Stock and net liabilities assumed in acquisition	1,716,132	1,716	3,224	(18,094)	—	(13,154)
Issuance of Common Stock	2,010,111	2,010	456	(2,466)	—	—
Net loss	—	—	—	(259,476)	—	(259,476)
Balances at December 31, 1996	3,726,746	3,727	3,689	(280,036)	—	(272,620)
Sale of Common Stock, net of offering costs of $9,976	1,004,554	1,004	1,789,975	—	—	1,790,979
Issuance of Common Stock in acquisition	375,891	376	887,874	—	—	888,250
Minority interest deficiency at acquisition charged to the Company	—	—	—	(45,003)	—	(45,003)
Net loss	—	—	—	(1,979,400)	—	(1,979,400)
Balances at December 31, 1997	5,107,191	5,107	2,681,538	(2,304,439)	—	382,206
Rescission of acquisition	(375,891)	(376)	(887,874)	561,166	—	(327,084)
Issuance of Common Stock at conversion of notes payable	450,264	451	363,549	—	—	364,000
Expense related to stock warrants issued	—	—	260,000	—	—	260,000
Net loss	—	—	—	(1,204,380)	—	(1,204,380)
Balances at December 31, 1998	5,181,564	5,182	2,417,213	(2,947,653)	—	(525,258)
Sale of Common Stock	678,412	678	134,322	—	—	135,000

Expense related to stock warrants issued	—	—	212,000	—	—	212,000
Net loss	—	—	—	(1,055,485)	—	(1,055,485)
Balances at December 31, 1999	5,859,976	5,860	2,763,535	(4,003,138)		(1,233,743)
Sale of Preferred Stock, net of offering costs of $76,500	—	—	3,123,468	—	—	3,123,500
Issuance of Common Stock at conversion of notes and interest payable	412,487	412	492,085	—	—	492,497
Issuance of Common Stock at conversion of notes payable	70,354	70	83,930	—	—	84,000
Issuance of Common Stock to settle obligations	495,111	496	1,201,664	—	—	1,202,160
Issuance of Common Stock for acquisition	6,999,990	7,000	9,325,769	—	—	9,332,769
Issuance of warrants for acquisition	—	—	4,767,664	—	—	4,767,664
Stock issued for acquisition costs	150,000	150	487,350	—	—	487,500
Expense related to stock warrants issued	—	—	140,000	—	—	140,000
Dividends payable on Preferred Stock	—	—	(85,000)	—	—	(85,000)
Cashless exercise of warrants	599,066	599	(599)	—	—	—
Net loss	—	—	—	(3,701,084)	—	(3,701,084)
Balances at December 31, 2000	14,586,984	14,587	22,299,866	(7,704,222)	—	14,610,263
Dividends payable on Preferred Stock	—	—	(256,000)	—	—	(256,000)
Repurchase of warrants	—	—	(55,279)	—	—	(55,279)
Sale of warrants	—	—	47,741	—	—	47,741
Cashless exercise of warrants	218,493	219	(219)	—	—	—

	Common Stock		Additional paid-in capital	Deficit accumulated during the development stage	Treasury Stock	Total stockholders' equity (deficit)
	Shares	Amount	Capital	**stage**	**At Cost**	**(deficit)**
Issuance of Common Stock to pay preferred dividend	93,421	93	212,907	—	—	213,000
Detachable warrants issued with notes payable	—	—	450,000	—	—	450,000
Issuance of warrants to pay operating expenses	—	—	167,138	—	—	167,138
Issuance of Common Stock to pay operating expenses	106,293	106	387,165	—	—	387,271
Issuance of Preferred Stock to pay operating expense	—	—	136,499	—	—	136,500
Net loss	—	—	—	(16,339,120)	—	(16,339,120)
Balances at December 31, 2001	15,005,191	15,005	23,389,818	(24,043,342)	—	(638,486)
Dividends payable on Preferred Stock	—	—	(242,400)	—	—	(242,400)
Repurchase of warrants (note 6)	—	—	—	—	—	—
Sale of warrants (note 6)	240,000	240	117,613	—	—	117,853
Cashless exercise of warrants (note 6)	100,201	100	(100)	—	—	—
Exercise of warrants	344,573	345	168,477	—	—	168,822
Sale of Preferred Stock at $1.50 per share	—	—	298,000	—	—	300,000
Sale of Preferred Stock at $10.00 per share	—	—	700,392	—	—	701,093
Conversion of Preferred Stock into Common Stock	1,800,000	1,800	(1,770)	—	—	—
Preferred Stock dividends forgiven	—	—	335,440	—	—	335,440
Issuance of warrants to pay operating expenses (note 6)	—	—	163,109	—	—	163,109
Issuance of Common Stock to pay operating expenses (note 6)	6,292	6	12,263	—	—	12,269
Issuance of Preferred Stock to pay operating expenses (note 6)	—	—	6,000	—	—	6,001
Issuance of stock options to employees (note 6)	—	—	329,296	—	—	329,296
Net loss	—	—	—	(2,105,727)	—	(2,105,727)
Balances at December 31, 2002	17,496,257	17,496	25,276,138	(26,149,069)	—	(852,730)
Dividends payable on Preferred Stock	—	—	(37,840)	—	—	(37,840)
Conversion of Series C Preferred Stock into Common Stock	14,021,860	14,022	(13,321)	—	—	—
	165,830	165	53,326	—	—	53,491

Issuance of Common Stock to pay interest on Bridge Notes						
Sale of Common Stock at $0.40 per share, net of issuance costs	6,640,737	6,676	2,590,656	—	—	2,597,332
Sale of Common Stock at $1.00 per share, net of issuance costs	3,701,733	3,668	3,989,181	—	—	3,992,849
Exchange of warrants	235,291	235	49,486	—	—	49,721
Issuance of Common Stock to pay operating expenses (note 6)	230,000	230	206,569	—	—	206,799
Issuance of warrants to pay operating expenses (note 6)	—	—	156,735	—	—	156,735
Issuance of stock options to employees (note 6)	—	—	286,033	—	—	286,033
Net loss	—	—	—	(2,332,077)	—	(2,332,077)
Balances at December 31, 2003	42,491,708	42,492	32,556,963	(28,481,146)	—	4,120,313
Extinguishment of dividends payable on Preferred Stock	—	—	72,800	—	—	72,800
Conversion of Series A cumulative Preferred Stock	236,500	236	(232)	—	—	—
Conversion of Series B Preferred Stock	200,000	200	1,800	—	—	—
Cashless exercise of warrants	464,573	465	(465)	—	—	—
Exercise of warrants	23,832	23	27,330	—	—	27,353
Issuance of warrants in settlement of a claim	—	—	86,375	—	—	86,375
Sale of Common Stock at $1.50 per share	10,417,624	10,419	15,616,031	—	—	15,626,450
Payment of financing and offering costs	—	—	(1,366,774)	—	—	(1,366,774)
Issuance of stock options to employees	—	—	524,922	—	—	524,922
Acquisition of treasury stock	—	—	34,747	—	(34,747)	—
Net Loss	—	—	—	(6,701,048)	—	(6,701,048)
Balances at December 31, 2004	53,834,237	$ 53,835	$ 47,553,497	$ (35,182,194)	$ (34,747)	$ 12,390,391

ADVENTRX PHARMACEUTICALS, INC.
(Formerly Biokeys Pharmaceuticals, Inc.)
(A Development Stage Enterprise)
Consolidated Statements of Cash Flow

	Year ended December 31,		Inception (June 12, 1996) through December 31,
	2004	**2003**	**2004**
Cash flows from operating activities:			
Net loss	$ (6,701,048)	$ (2,332,077)	$ (35,677,797)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization			41,309
			8,970
			9,690,016
Amortization of debt discount			—
			—
			450,000
Forgiveness of employee advance			—
			—
			30,036
Impairment loss - write off of goodwill			—
			—
			5,702,130

Expenses paid by warrants									
									86,375
									156,735
									573,357
Expenses paid by Preferred Stock									
									—
									—
									142,501
Expenses related to stock warrants issued									
									—
									—
									612,000
Expenses related to employee stock options issued									
									524,922
									286,033
									1,140,251
Expenses paid by issuance of Common Stock									
									—
									206,799
									817,548
Equity in loss of investee									
									—
									—
									178,936
Write-off of license agreement									

			—
			—
			152,866
Cumulative effect of change in accounting principle			
			—
			—
			25,821
Changes in assets and liabilities, net of effect of acquisitions:			
Increase in prepaid and other assets			
			(255,101)
			(23,136)
			(430,588)
Increase (decrease) in accounts payable and accrued liabilities	1,128,153	(550,433)	697,125
Increase in sponsored research payable and license obligation	—	—	924,318
Net cash used in operating activities	(5,175,390)	(2,247,109)	(14,971,480)
Cash flows from investing activities:			
Purchase of certificate of deposit	—	—	(1,016,330)
Maturity of certificate of deposit	—	—	1,016,330
Purchases of property and equipment	(305,773)	(16,376)	(428,242)
Payment on obligation under license agreement	—	—	(106,250)
Cash acquired in acquisition of subsidiary	—	—	64,233
Issuance of note receivable - related party	—	—	(35,000)
Payments on note receivable	—	—	405,993
Advance to investee	—	—	(90,475)
Cash transferred in rescission of acquisition	—	—	(19,475)
Cash received in rescission of acquisition	—	—	230,000
Net cash provided by (used in) investing activities	(305,773)	(16,376)	20,784
Cash flows from financing activities:			
Proceeds from sale of Preferred Stock	—	—	4,200,993
Proceeds from sale of Common Stock	15,626,450	6,590,181	24,152,596
Proceeds from sale or exercise of warrants	27,353	—	411,590
Repurchase of warrants	—	49,721	(55,279)
Payment of financing and offering costs	(1,366,774)	—	(1,465,750)
Payments of notes payable and long-term debt	—	(253,948)	(605,909)

Proceeds from issuance of notes payable and detachable warrants	—	—	1,344,718
Net cash provided by financing activities	14,287,029	6,385,954	27,982,959
Net increase in cash and cash equivalents	8,805,866	4,122,469	13,032,263
Cash and cash equivalents at beginning of period	4,226,397	103,928	-
Cash and cash equivalents at end of period	$ 13,032,263	$ 4,226,397	$ 13,032,263

See accompanying notes to consolidated financial statements.

(1) Description of the Company

ADVENTRX Pharmaceuticals, Inc., a Delaware corporation, (the Company), is a biopharmaceutical research and development company focused on introducing new technologies for anticancer and antiviral treatments that improve the performance of existing drugs and address significant problems such as drug metabolism, bioavailability and resistance. The Company currently does not manufacture, market, sell or distribute any product. Through our license agreements with University of Texas M.D. Anderson Cancer Center (M.D. Anderson), University of Southern California (USC), and the National Institutes of Health (NIH), the Company has rights to drug candidates in varying early stages of development.

On May 30, 2003, the Company merged our wholly owned subsidiary, Biokeys, Inc., into itself and changed the name of the Company from Biokeys Pharmaceuticals, Inc. to ADVENTRX Pharmaceuticals, Inc. The merger had no effect on the financial statements of the Company.

In July 2004, the Company formed a wholly owned subsidiary, ADVENTRX (Europe) Ltd., in the United Kingdom for the purpose of conducting drug trials in the European Union.

(2) Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the U. S. requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

The most significant accounting estimates relate to valuing equity transactions as described below. The value assigned to stock warrants granted to non-employees is accounted for in accordance with SFAS No. 123 and Emerging Issues Task Force (EITF) Issue 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). The Company values warrants using the Black-Scholes option pricing model. Common Stock is valued using the market price of Common Stock on the measurement date as defined in EITF 96-18.

Accounting for Stock-Based Compensation

The Company applies Statement of Financial Accounting Standards No. 123 and related interpretations in accounting for employee stock-based compensation, and includes the required footnote disclosures thereon.

Cash Equivalents

Highly liquid investments with original maturities of three months or less when purchased are considered to be cash equivalents.

Financial Instruments

The carrying amounts of cash and cash equivalents and accounts payable are a reasonable estimate of their fair values at the balance sheet dates due to the short-term nature of these instruments.

The Company maintains cash and cash equivalents with banks, which from time to time may exceed federally insured limits. The Company periodically assesses the financial condition of the institutions and believes that the risk of any loss is minimal. At December 31, 2004, cash and cash equivalents with banks exceeded federally insured limits by approximately $12,960,000.

Property and Equipment

Property and equipment are stated at cost. Depreciation and amortization are calculated using the straight-line method over the estimated useful lives of the assets. The costs of improvements that extend the lives of the assets are capitalized. Repairs and maintenance are expensed as incurred.

Revenue Recognition

The Company recognizes revenue at the time service is performed on commercial contracts and ability to collect is reasonably assured. Revenue from government grants is a reimbursement for expenditures associated with the research. The Company submits bills to the grant agency and revenue is recognized at the time reimbursement is requested.

Research and Development Costs

All research and development costs are expensed as incurred, including Company-sponsored research and development and cost of patent rights and technology rights under license agreements that have no alternative future use when incurred.

Impairment of Long-lived Assets

In the event that facts and circumstances indicate that property and equipment and intangible or other long-lived assets with finite lives may be impaired, an evaluation of the recoverability of currently recorded costs will be made. If an evaluation is required, the estimated value of undiscounted future net cash flows associated with the asset is compared to the asset's carrying value to determine if impairment exists. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets.

Advertising Expenses

Advertising costs are expensed as incurred. Advertising costs charged to operations for the years ended December 31, 2004 and 2003 totaled $67,782 and $88,221 respectively.

Income Taxes

Income taxes are accounted for using the asset and liability method under which deferred tax assets and liabilities are recognized for estimated future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on

deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Deferred tax expense or benefit is recognized as a result of the change in the asset or liability during the period.

Supplementary Cash Flow Information

Interest of $0 and $1,386 was paid during the years ended December 31, 2004 and 2003, respectively. No income taxes were paid during 2004 or 2003.

Noncash investing and financing transactions excluded from the consolidated statements of cash flows for the years ended December 31, 2004 and 2003 and for the period from Inception (June 12, 1996) to December 31, 2004 are as follows:

	2004	2003	Inception (June 12, 1996) through December 31, 2004
Issuance of warrants, Common Stock and Preferred Stock for:			
Conversion of notes payable and accrued interest	$ —	$ 53,491	$ 1,213,988
Payment of operating expenses	—	—	1,224,281
Conversion of Preferred Stock	2,004	701	2,705
Acquisitions	—	—	14,617,603
Payment of dividends	—	—	213,000
Financial advisor services in conjunction with private placement	1,137,456	—	1,137,456
Settlement of claim	86,375	—	86,375
Acquisition of treasury stock in settlement of a claim	34,747	—	34,747
Assumptions of liabilities in acquisitions	—	—	1,009,567
Acquisition of license agreement for long-term debt	—	—	161,180
Cashless exercise of warrants	465	2,360	3,742
Dividends accrued	—	37,840	621,040
Trade asset converted to available for sale asset	108,000	—	108,000
Dividends extinguished	72,800	—	408,240
Trade payable converted to note payable		—	83,948
Issuance of warrants for return of Common Stock	—	50,852	50,852
Detachable warrants issued with notes payable	—	—	450,000

New Accounting Pronouncements

In December 2004, the FASB issued Statement of Financial Accounting standards No. 123 (revised 2004), Share-Based Payment (SFAS 123R). We currently recognize our option grants and associated expenses in accordance with SFAS 123R guidance, and therefore SFAS 123R is not expected to have a material effect on our consolidated financial position or results of operations.

In December 2004, the FASB issued SFAS No. 153, Exchanges of Nonmonetary Assets, an amendment of APB Opinion No. 29. The guidance in APB Opinion No 29, Accounting for Nonmonetary Transactions, is based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of assets exchanged. The guidance in that Opinion, however, included certain exceptions to that principle. This Statement amends Opinion 29 to eliminate the exception for nonmonetary exchanges of similar productive assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. SFAS No. 153 is effective for nonmonetary exchanges occurring in fiscal periods beginning after June 15, 2005. The adoption of SFAS No. 153 is not expected to have a material impact on our financial position and results of operations.

In November 2004, the FASB issued SFAS No. 151, Inventory Costs, an amendment of ARB No. 43, Chapter 4. This statement amends the guidance in ARB No. 43, Chapter 4, Inventory Pricing, to clarify the accounting for abnormal amounts idle facility expense, freight, handling costs, and wasted material (spoilage). We currently have no inventory, sales or cost of goods, and therefore it is not expected to have a material impact on our financial position and results of operations.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity." SFAS No. 150 changes the accounting for certain financial instruments with characteristics of both liabilities and equity that, under previous pronouncements, issuers could account for as equity. The new accounting guidance contained in SFAS No. 150 requires that those instruments be classified as liabilities in the balance sheet. The adoption of this new accounting pronouncement is not expected to have a material impact on the Company's financial statements.

In January 2003, the FASB issued FASB Interpretation No. 46 (revised December 2003), *Consolidation of Variable Interest Entities* (FIN 46R) which addressed consolidation by business enterprises of variable interest entities that meet certain criteria. FIN 46R was effective upon issuance, but did not have an impact on the Company's financial position or results of operations.

(3) Property and Equipment

Property and equipment at December 31, 2004 and December 31, 2003 were as follows:

	Useful lives	2004	2003
Office furniture, computer and lab equipment	3 - 5 years	$ 333,286	$ 48,259
Computer software	3 years	11,845	11,845
		345,131	60,104
Less accumulated depreciation and amortization		(59,827)	(39,264)
		$ 285,304	$ 20,840

(4) Income Taxes

A reconciliation of the expected income tax benefit at the U.S. Federal income tax rate to the income tax benefit actually recognized for the years ended December 31, 2004 and 2003 is set forth below:

	2004	2003
Expected income tax benefit	$ 2,278,000	$ 793,000
State income benefit, net of federal tax	371,000	135,000
Increase in valuation allowance	(2,518,000)	(931,000)
Other	(19,000)	3,000
Stock options previously expensed, forfeited	(112,000)	—
Income tax benefit	$ —	$ —

The tax effects of temporary differences that give rise to deferred tax assets at December 31, 2004 and December 31, 2003 are as follows:

	2004	2003
Net operating loss carryforwards	$ 6,864,000	$ 4,654,000
Change in temporary deferred assets:		
Other	25,000	3,000
Stock options expense under FAS 123	292,000	215,000
Accrued settlements	209,000	—
Total deferred tax assets	7,390,000	4,872,000
Less valuation allowance	(7,390,000)	(4,872,000)
Net deferred tax assets	$ —	—

At December 31, 2004, the Company had unused net operating loss carryforwards of approximately $17,271,000 and $15,586,000, which expire from 2010 through 2023, for state and federal purposes, respectively.

(5) Equity Transactions

In January 2003, the Company paid accrued interest on notes payable through the issuance of 119,454 shares of Common Stock, having a fair market value on the date of issuance of $26,646.

In January 2003, the Company completed a private placement of 1,589,856 shares of Common Stock and warrants to purchase an additional 476,962 shares of Common Stock at $0.40 per share to investors for gross proceeds of $635,949 in cash.

In March 2003, the holders of 70,109.3 shares of Series C convertible Preferred Stock elected to convert their shares of Series C Preferred Stock into 14,021,860 shares of Common Stock.

In March 2003, the Company paid two consulting firms for services rendered with 125,000 shares of Common Stock with a fair market value on the date of issuance of $68,750, and two warrants to purchase 37,500 shares of Common Stock at an exercise price of $0.50 per share. Each warrant will expire on March 25, 2006. The fair market value of

the warrants on the date of issuance was $33,777.

In March 2003, the Company issued three warrants to three individuals in consideration of certain investment banking advice. The three warrants represent the right to purchase 50,000, 50,000 and 10,000 shares of Common Stock at an exercise price of $0.50 per share. Each warrant will expire on March 25, 2006. The fair market value of the warrants on the date of issuance was $52,886.

In March 2003, the Company issued a warrant to a former executive in consideration of certain covenants related to his separation from the Company. The warrant represents the right to purchase 150,000 shares of Common Stock at an exercise price of $1.25 per share. The warrant will expire on December 12, 2005. The Company recognized compensation expense of $50,852 in connection with the issuance of this warrant.

During the three months ended March 31, 2003, $10,955 was recognized in conjunction with the vesting of warrants previously issued for consulting services.

In April 2003, the Company paid accrued interest on notes payable through the issuance of 46,376 shares of Common Stock, having a fair market value on the date of issuance of $26,845.

In June 2003, the Company completed a private placement of 5,027,328 shares of Common Stock and warrants to purchase an additional 1,508,199 shares of Common Stock at $0.60 per share to private investors for gross proceeds of $2,010,931 in cash.

The Company paid cash commissions of $49,400 in connection with the private placement.

In June 2003 the Company issued 59,535 shares of Common Stock as commissions on the private placement. The value of the commission was $56,099.

In June 2003 the Company issued warrants to purchase 43,422 shares of Common Stock at $0.60 per share and warrants to purchase 86,844 shares of Common Stock at $0.01 per share as commissions on the private placement. The value of these warrants was $129,521.

In June 2003, the Company paid a consulting firm for services rendered with 75,000 shares of Common Stock with a fair market value on the date of issuance of $91,500.

Between August 2003 and October 2003, the Company completed a private placement of 2,691,990 shares of Common Stock and warrants to purchase an additional 834,600 shares of Common Stock at $1.25 per share to private investors for gross proceeds of $2,691,990 in cash.

The Company paid cash commissions of $124,500 in connection with the private placement.

In September 2003 the Company issued 124,200 shares of Common Stock as commissions on the private placement. The value of the commission was $188,596.

In September 2003, a warrant to purchase a total of 150,000 shares of Common Stock at $1.25 per share was exercised in a cashless exchange for 23,165 shares of Common Stock.

In November 2003, the Company paid a consulting firm for services rendered with 30,000 shares of Common Stock with a fair market value on the date of issuance of $46,549.

In December 2003, the Company completed a private placement of 849,561 shares of Common Stock, 649,797 shares of treasury stock, and warrants to purchase an additional 435,000 shares of Common Stock at $1.25 per share to private investors for gross proceeds of $1,488,961.

In December 2003, the Company paid $63,750 and issued warrants to purchase 63,750 shares of Common Stock as commissions on the private placement. The value of the commission was $56,478.

In December 2003, warrants to purchase a total of 244,526 shares of Common Stock at between $0.01 and $0.60 per share were exercised. Warrants representing 175,100 shares of Common Stock were issued for proceeds of $49,721. The remaining warrants representing 69,426 shares of Common Stock were exchanged for a total of 37,026 shares in a cashless exchange.

In March 2004, a warrant to purchase 3,750 shares of Common Stock at $0.60 per share was exercised for proceeds of $2,250 and the Company issued 38,372 shares of Common Stock upon the cashless exercise of a warrant to purchase 50,000 shares of Common Stock at $0.50 per share.

In March 2004, 473 shares of Series A cumulative convertible Preferred Stock, representing all of the Series A cumulative convertible Preferred Stock then outstanding, was converted into 236,500 shares of Common Stock. In conjunction with the conversion, dividends payable of $72,800 at December 31, 2003, were extinguished.

In March 2004, 200,000 shares of Series B convertible Preferred Stock, representing all of the Series B convertible Preferred Stock then outstanding, were converted into 200,000 shares of Common Stock.

In April 2004, the Company sold 10,417,624 shares of Common Stock at $1.50 per share and issued warrants to purchase 3,125,272 shares of Common Stock at $2.00 and warrants to purchase 2,083,518 shares of Common Stock at $2.50 per share to accredited investors in a private placement for aggregate gross proceeds of $15,626,450 in cash. In connection with the private placement, the Company paid cash commissions of $900,452 and other related expenses of $466,322 and issued warrants to purchase 632,547 shares of Common Stock at $2.00 per share to two placement agents, having a fair market value of $890,963 on the date of issuance.

In April 2004, the Company engaged W.R. Hambrecht + Co., LLC for financial advisory and investment banking services related to the private placement, and in connection with that engagement, issued to it a warrant to purchase 175,000 shares of Common Stock at $2.00 per share, having a fair market value of $246,493 on the date of issuance.

In May 2004, a warrant to purchase 20,082 shares of Common Stock at $1.25 per share was exercised for gross proceeds of $25,103.

In May 2004, the Company issued 46,784 shares of Common Stock upon the cashless exercise of two warrants to purchase a total of 60,000 shares of Common Stock at $0.50 per share.

In June 2004, the Company issued 379,417 shares of Common Stock upon the cashless exercise of a warrant to purchase 502,528 shares of Common Stock at $0.49 per share.

In October 2004, the Company issued a warrant to purchase 300,000 shares of Common Stock at an exercise price of $2.50 in settlement of a claim. The warrant, which expires in October 2007, had a value of $86,375 on the date of issuance.

Nonemployee stock-based compensation that is not valued at the fair value of consideration received is valued, as of the grant date, using the Black-Scholes pricing model with the following assumptions for grants in 2004 and 2003: no dividend yield for either year; expected volatility of 81% to 199%; risk-free interest rates 2.78% to 4.74%; and expected lives of three and seven years, respectively.

At December 31, 2004, there were outstanding warrants to purchase a total of 11,154,964 shares of Common Stock as follows:

Warrants	Exercise price	Expiration date
118,094	$ 0.49	Sep-05
440,000	0.50	Oct-05
100,000	3.00	Apr-06
2,090,537	0.60	May-06
502,528	0.49	Jun-06
914,175	1.25	Oct-06
150,000	0.50	Dec-06
523,293	1.25	Dec-06
300,000	2.50	Oct-07
3,932,819	2.00	Apr-09
2,083,518	2.50	Apr-09
Total 11,154,964		

(6) Stock Compensation Plans

In October 2002, the Company granted two non-statutory stock options to purchase an aggregate of 1,500,000 shares and one non-statutory stock option to purchase 165,000 shares of Common Stock at $0.20 and $0.50 per share, respectively. The value of the options on the date of the grant was $329,296. In July 2004, stock options to purchase an aggregate of 1,665,000 shares of Common Stock were forfeited.

In March 2003, the Company granted four non-statutory stock options to purchase an aggregate of 1,900,000 shares of the Company's Common Stock at $0.50 per share. The options were valued using the Black-Scholes pricing model. The value of the options on the date of the grant was $948,846. In April and June 2003, the Company and four of our option holders agreed to revise the vesting schedules of the non-statutory stock options held by such optionholders. No other terms were changed. In addition, in June 2003 one non-statutory stock option was modified such that any portion of the option that was not vested as of July 1, 2003 was cancelled in exchange for cash compensation.

On July 1, 2003, the Company formed a Scientific Advisory Board (the SAB). Each of the three SAB members was granted an option to purchase 30,000 shares of Common Stock at a purchase price of $1.25 per share. The value of the options on the date of grant, July 1, 2003, was $97,086.

In November 2003, the Company granted a non-statutory stock option to purchase 50,000 shares of the Company’s Common Stock at $1.25 per share. The value of the option on the date of grant was $68,088.

In January and February 2004, three individuals became members of the Company’s board of directors. Each new director was granted an option to purchase 50,000 shares of Common Stock at a purchase price of $1.50 per share. The options begin vesting 90 days from the date of grant and vest in equal installments over the next four quarters. The options expire on December 30, 2008. The value of the options on the dates of grant was $223,826.

In February 2004, an individual became a member of the Company’s Scientific Advisory Board. The new member was granted an option to purchase 30,000 shares of Common Stock at a purchase price of $1.50 per share. The option will vest in equal installments over eight quarters, starting March 1, 2004. The option will expire on December 30, 2008. The value of the option on the date of grant was $45,350.

In March 2004, the Company granted an option to purchase 100,000 shares of Common Stock at a purchase price of $1.50 per share to the Company's Vice President of Clinical and Medical Affairs. The option will vest in three installments over three years starting March 2004. The value of the option on the date of grant was $88,627.

In April 2004, the Company granted an option to purchase 30,000 shares of Common Stock at a purchase price of $1.50 per share to the Senior Scientist, Antiviral Research. The option will vest in three installments over three years starting April 2004. The value of the option on the date of grant was $37,600.

In the period May 2004 through August 2004, the Company granted options to purchase an aggregate of 66,000 shares of Common Stock at purchase prices of $1.20 to $1.80 per share to employees. AMEX listing requirements prohibit granting equity without a shareholder vote or an approved stock option plan; therefore, the options were rescinded in February 2005. Accordingly, the financial statement effect of the options granted has been reversed in 2004.

The Company recognized compensation expense of $524,922 in the year ended December 31, 2004, related to the portion of the options that vested in that period.

	December 31, 2004		December 31, 2003	
Non-statutory Stock Options	**Shares (000)**	**Weighted-Average Exercise Price**	**Shares (000)**	**Weighted Average Exercise Price**
Outstanding at beginning of period	2,980	$ 0.38	1,690	$ 0.23
Granted	310	$ 1.50	2,040	$ 0.58
Forfeited	(1,665)	$ 0.23	(750)	$ 0.50
Outstanding at end of period	1,625	$ 0.75	2,980	$ 0.38
Options exercisable at year end	1,073		1,808	
Weighted-average fair value of options granted during the year	$ 1.28		$ 0.54	

	Options Outstanding			Options Exercisable	
Range of Exercise Price	**Number Outstanding at 12/31/04**	**Weighted Average Remaining Contractual Life**	**Weighted-Average Exercise Price**	**Number Exercisable at 12/31/04**	**Weighted-Average Exercise Price**
$0.20 to $1.50	1,625,000	4.03 years	$ .75	1,072,502	$ .71

None of the foregoing options were issued pursuant to a stock option plan. The options expire on December 30, 2008 and vest as follows:

Options	Exercise price	Vesting date
12,500	0.20	October 2002
100,000	0.50	March 2003
137,500	0.50	April 2003
179,167	0.50	July 2003
11,250	1.25	July 2003
54,167	0.50	October 2003
11,250	1.25	October 2003
12,500	0.20	December 2003
54,167	0.50	January 2004
11,250	1.25	January 2004
33,750	1.50	March 2004
154,167	0.50	April 2004
11,250	1.25	April 2004
47,500	1.50	April 2004
3,750	1.50	June 2004
54,167	0.50	July 2004
11,250	1.25	July 2004
37,500	1.50	July 2004
3,750	1.50	September 2004
54,167	0.50	October 2004
11,250	1.25	October 2004
37,500	1.50	October 2004
25,000	1.25	November 2004
3,750	1.50	December 2004
54,167	0.50	January 2005
11,250	1.25	January 2005
37,500	1.50	January 2005
33,750	1.50	March 2005
141,667	0.50	April 2005
11,250	1.25	April 2005
10,000	1.50	April 2005
3,750	1.50	June 2005
41,667	0.50	July 2005
3,750	1.50	

		September 2005
41,667	0.50	October 2005
25,000	1.25	November 2005
3,750	1.50	December 2005
41,667	0.50	January 2006
40,000	1.50	March 2005
41,663	0.50	April 2006
10,000	1.50	April 2006
Total 1,625,000		

(7) Net Loss per Common Share

The computation of basic and diluted net loss per share for the years ended December 31, 2004 and 2003 is as follows:

	2004	2003
Numerator:		
Net loss	$ (6,701,048)	$ (2,332,077)
Preferred Stock dividends	—	(37,840)
Numerator for basic and diluted loss per common share	$ (6,701,048)	$ (2,369,917)
Denominator for basic and diluted loss per share - weighted average common shares outstanding	50,720,180	31,797,986
Loss per common share-basic and diluted	$ (0.13)	$ (0.07)

Net loss per common share is calculated according to Statement of Financial Accounting No. 128, *Earnings per Share*, using the weighted average number of shares of Common Stock outstanding during the period. The following potentially dilutive shares were not included in the computation of net loss per common share - diluted, as their effect would have been antidilutive due to the Company's net losses in 2004 and 2003:

	December 31, 2004	2003
Preferred Stock	—	318,250
Warrants	11,154,964	5,474,987
Options	1,625,000	2,980,000
Total	12,779,964	8,773,237

(8) License Agreements

M.D. Anderson

Pursuant to a patent and technology license agreement dated June 14, 1996 between M.D. Anderson and the Company (the M.D. Anderson License Agreement), the Company acquired a license to seven patents and patent applications related to technology for HIV/AIDS therapy and prevention. Under the M.D. Anderson License Agreement, the Company is obligated to pay M.D. Anderson for all out-of-pocket expenses incurred in filing, prosecuting, enforcing, and maintaining the licensed patent rights and all future patent-related expenses paid by M.D. Anderson as long as the M.D. Anderson License Agreement remains in effect.

The M.D. Anderson License Agreement was amended effective June 15, 2000 (the Amendment). The Amendment incorporated additional licensed subject matter, revised certain royalty rates due to M.D. Anderson upon commercialization, and settled past due patent and research and development amounts from the Company to M.D. Anderson. The Company gave consideration valued at approximately $172,000 through the issuance of 71,555 shares of Common Stock to reimburse M.D. Anderson for patent costs incurred through June 15, 2000. The Company also issued 414,829 shares of Common Stock to M.D. Anderson valued at $1,000,000, based on the market value of the Company's stock at the date of the settlement agreement, to settle past due research and development obligations. In addition, the Company committed to funding at least $1,000,000 of research and development activity through December 31, 2001. Finally, the Amendment defined a milestone payment of Common Stock with a value of $1,000,000 due to M.D. Anderson upon the enrollment of the first patient in the first FDA Phase I human trial of any product that utilizes licensed subject matter.

Under the amended M.D. Anderson License Agreement, the Company has the right to a royalty-bearing, exclusive license to manufacture, have manufactured, and use and/or sell licensed products. M.D. Anderson's retained interest consists of royalties on net sales of licensed products and a share of consideration received by the Company from all sublicenses and assignments. No royalties were paid under this agreement during the years ended December 31, 2004 and 2003, respectively. The M.D. Anderson License Agreement continues in effect until all patent rights have expired.

Also, we currently plan to renegotiate the terms of our license agreement with MD Anderson. We have no guarantee that we will be able to negotiate terms, including the royalty and milestone payment terms, which would be mutually acceptable to both MD Anderson and the Company.

USC

Under an Option and License Agreement with USC dated January 23, 1998, amended August 16, 2000, the Company acquired license rights to a total of three patents, two relating to the Company's CoFactor product and one relating to Selone, both of which are intended for use in connection with cancer chemotherapy. In addition, under a second Option and License Agreement dated August 17, 2000, the Company acquired rights under four patents related to its Thiovir anti-viral technologies. These agreements with USC (the USC License Agreements) grant the Company exclusive worldwide licenses to study, use, manufacture and market drug products covered by the subject patents. Under the USC License Agreements, the Company is obligated to pay USC for out-of-pocket expenses incurred in filing, prosecuting, enforcing, and maintaining the licensed patent rights and all future patent-related expenses paid by USC as long as the USC License Agreements remain in effect and until the patent rights have expired. USC's retained interest consists of royalties on net sales of licensed products and a share of consideration received by the Company from all sublicenses and assignments. No royalties have been paid under this agreement. The USC License Agreements continue in effect until all patent rights have expired.

In May 2003, the Option and License Agreement dated August 17, 2000 was amended to eliminate minimum royalty payments and instead require payments upon the achievement of certain milestones. These milestones include a payment due following market approval from the FDA, and is it unlikely that we will reach this milestone in 2005.

NIH Agreement

During December 2002, the Company entered into a worldwide exclusive patent license agreement with the Public Health Service National Institutes of Health (NIH) concerning composition of matter for our drug, BlockAide/CR. Under the terms of the agreement, the Company agrees to pay minimum royalty payments during the first year of the license and minimum annual royalties thereafter or the higher amount based upon a percentage of net sales. In addition, there are benchmark royalties based upon: initiation of Phase I trials, initiation of Phase II trials, initiation of Phase III trials, and upon first approval of a Product License Application for an HIV therapeutic or vaccine in the U.S. and for first approval in Europe. No material amount has been paid under this agreement to date.

(9) Commitments and Contingencies

Operating Leases

The Company is obligated under operating leases for office space and equipment. In July 2004, the Company leased office space in San Diego, California. Based on a straight-line basis, the lease requires a monthly payment of $15,532 and expires in August 2009. Rent expense was $118,966 and $40,648 during the years ended December 31, 2004 and 2003, respectively.

Future rental commitments under all operating leases amounts are as follows:

Year Ending December 31,	
2005	$ 183,437
2006	188,756
2007	194,238
2008	193,721
2009	131,705

Total	$ 891,857

Litigation

In the normal course of business, the Company may become subject to lawsuits and other claims and proceedings. Such matters are subject to uncertainty and outcomes are often not predictable with assurance. On March 28, 2005, the Company received a letter from counsel to a former executive in which the former executive claims that the Company constructively terminated him, discriminated against him on the basis of age and committed various torts against him. No settlement demand was specifically made by the former executive in this letter and the letter otherwise did not state any specific monetary damages that this former executive has purportedly sustained. The Company believes that these claims lack merit and intends to vigorously defend against them. Management is not aware of any other pending or threatened lawsuit or proceeding that would have a material adverse effect on the Company's financial position, results of operations or cash flows.

(10) Subsequent Events

Company 401(k) Plan

Effective January 1, 2005, the Company adopted a deferred savings and profit sharing plan under Section 401(k) of the Internal Revenue Code. Substantially all of its employees may participate in and make voluntary contributions to this defined contribution plan after they meet certain eligibility requirements. The Company makes a percentage match of employee contributions subject to the Safe Harbor provision of the 401(k) Plan.