

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-KSB

(Mark one)

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

For the Fiscal Year December 31, 2003, or

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

Commission file number: 000-33219

ADVENTRX PHARMACEUTICALS, INC.

(Name of Small Business Issuer in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

84-1318182

(I.R.S. Employer Identification No.)

9948 Hibert Street, Suite 100, San Diego, California 92131

(Address of principal executive offices)

(858) 271-9671

(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 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: \$12,872

The aggregate market value of the Common Stock held by non-affiliates of the issuer, as of February 29, 2004 was approximately \$52,863,246 based upon the closing price of the issuer's Common Stock reported for such date on the OTC Bulletin Board. 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 February 29, 2004, 42,491,708 shares of the issuer's Common Stock were outstanding.

No documents are incorporated by reference into this Form 10-KSB.

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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

CoFactorÔ, BlockAideÔ, ThiovirÔ, EradicAideÔ and SeloneÔ 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. The term “Common Stock ” refers to the Company’s Common Stock, par value \$0.001 per share.

Business Development

We were initially organized as a corporation under the Delaware General Corporation Law in December 1995. In October 2000, we closed the merger of our wholly owned subsidiary, Biokeys Acquisition Corp., with and into Biokeys, Inc. In consideration of the merger, we issued an aggregate of 6,999,990 shares of Common Stock to the holders of capital stock of Biokeys, Inc.

On May 30, 2003, the Company merged its 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.

Business of Issuer

We are a biomedical research and development business focused on treatments for viral infections and cancer. Our business is in the development stage; we have not generated any significant revenues or any operating revenues and we have not yet commercialized or marketed any products. Pursuant to license agreements with the University of Texas M.D. Anderson Cancer Center (“M.D. Anderson”), the National Institutes of Health (the “NIH”) and the University of Southern California (“USC”), we have been granted development, commercialization, manufacturing and marketing rights to a number of drug candidates in the fields of antiviral and anticancer therapy, which are in varying stages of development. Our goal is to become a leading developer of drug therapies for the treatment of the Human Immunodeficiency Virus (“HIV”), Acquired Immune Deficiency Syndrome (“AIDS”) and cancer.

Principal Products

General information regarding each of our products is listed below.

Product/Description	Development Stage	Indication	Intellectual Property
CoFactorTM 5-FU Biomodulator	Phase I/II trials completed in Europe Phase II first-line US trial began in Q1 2004	Metastatic GI and Breast cancers Metastatic Colorectal Cancer	Worldwide license to use patents and other intellectual property from USC.
	File for Phase II first-line UK trial in QII 2004	Metastatic Colorectal Cancer	
	File for Phase II second-line trials in QIII/QIV 2004 for US and UK	Metastatic Colorectal Cancer	
	File for Phase II first-line trials in QIII 2004 for US and EU	Metastatic Pancreatic Cancer	
BlockAide/CRTM Viral Entry Inhibitor	Phase Ib/IIa IND filed Q1 2004	HIV/AIDS	Worldwide licenses to use patents and other intellectual property from MD Anderson Cancer Center and NIH.
ThiovirTM Pyrophosphate Analogue	Pre Clinical preparation for IND filing in QIII 2004	HIV/AIDS	Worldwide license to use patents and other intellectual property from USC.
EradicAideTM Therapeutic Vaccine	Phase Ib/IIa IND targeted to file QIII 2004	HIV/AIDS	Worldwide license to use patents and other intellectual property from MD Anderson.
BlockAide/VPTM Viral Entry Inhibitor	Pre Clinical	HIV/AIDS	Worldwide license to use patents and other intellectual property from MD Anderson.
SeloneTM Alkylating Agent	Pre Clinical	Drug Resistant Cancers	Worldwide license to use patents and other intellectual property from USC.

CoFactor

CoFactor[®] is a folate-based chemotherapy drug designed for use with 5-FU, the world's most frequently used cancer drug. Clinical data in previous clinical trials in Europe have demonstrated that CoFactor can block cancer cell growth by creating more stable binding of the target enzyme TS (compared to Leucovorin). CoFactor bypasses the chemical pathway required by Leucovorin to deliver the correct form of folate to cancer cells to allow 5-FU to work more effectively. This improves 5-FU performance and lowers toxicity. Because Leucovorin is a precursor to CoFactor in the folate biochemical pathway, we expect CoFactor to gain more rapid approval by FDA because it is chemically similar to Leucovorin, but works more effectively in 5-FU-based therapies. The Company is the exclusive licensee of this compound.

Based upon previous and ongoing results, we will target replacement of 5-FU/Leucovorin therapy with 5-FU/CoFactor therapy, as well as targeting 5-FU/Leucovorin/CPT-11 (CamptosarTM, irinotecan) therapy and 5-FU/Leucovorin/Oxaliplatin (Eloxatin[®]) therapy, which are more toxic and only marginally more effective than 5-FU/Leucovorin. There is also an opportunity for 5-FU/CoFactor to be used in conjunction with the newer less toxic regimens that incorporate the use of ErbituxTM (cetuximab) or AvastinTM (bevacizumab).

We began the trial for metastatic colorectal cancer patients with 5-FU and our drug CoFactor in QI 2004, based upon an approved IND Application in the United States to treat metastatic colorectal cancer patients in conjunction with 5-FU. This Phase II trial is a Simon II Phase design consisting of an open-label single arm trial of 48 patients to test 5-FU/CoFactor. While the first-line trial is being conducted, we intend to file in QII 2004 for approval to begin a two arm first-line metastatic colorectal cancer trial in the United Kingdom. We also intend to file in QIII and QIV 2004 for approval to begin second-line therapy trials for metastatic colorectal cancer in both the U.S. and Europe in order to qualify for accelerated approval and to later achieve registration as a second-line therapy for patients who have failed the current first-line 5-FU-based therapy. We also intend to follow with regulatory filings in QIII 2004 to begin trials for treatment of patients with advanced pancreatic cancer in both the U.S. and Europe. This will include application for orphan drug status.

BlockAide/CR[®] is a peptide-based drug that is representative of the new "fourth modality" of HIV therapeutics that is intended to work by blocking viral entry and infection of human immune system cells. In non-human primate studies, BlockAide/CR demonstrated the ability to reduce viral load by nearly one hundred fold in only two weeks of daily treatments. This compound also inhibits syncytia formation that causes the progression to AIDS. The Company is the exclusive licensee of this compound.

We filed an IND in Q1 2004 to gain clearance to begin a Phase Ib/IIa human clinical trial in the United States during the first half of 2004 to treat HIV infected patients who have rising viral load and may have developed resistance to HAART therapy. We believe BlockAide/CR could be used effectively in conjunction with HAART therapy for patients who have already developed problems with drug resistance and eventually with HAART naive patients to delay the onset of HAART therapy to reduce toxicity.

Thiovir

Thiovir, and other Thiovir-analogues under development, are parts of a new class of compounds known as thiophosphonoforates, which have demonstrated powerful antiviral properties. Thiovir is an oral replacement for the IV-administered antiviral drug, foscarnet, which is FDA-approved for treatment of cytomegalovirus (CMV) infection in HIV patients. Clinical observations of patients treated with Thiovir have documented the broad-spectrum efficacy of this drug, which includes inhibition of HIV and HSV (herpes simplex virus) and the hyper sensitization of previously AZT resistant patients to AZT therapy. The Company is the exclusive licensee of this compound.

Although foscarnet is a highly effective, broad-spectrum antiviral, it has limitations from a commercial perspective. Foscarnet is a small molecule whose parent structure restricts modification, which could lead to improved oral bioavailability or effectiveness. Therefore, there is a need for a new class of broad-spectrum antiviral compounds that might address the limitations of foscarnet while still offering the antiviral advantages.

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. Preliminary animal studies, with enteric-coated capsules of Thiovir, demonstrated up to 44% oral bioavailability, delivering three times more drug than orally-dosed foscarnet.

We plan to complete preclinical development of Thiovir during the first half of 2004 in order to file an IND during QIII 2004 to begin human clinical trials of Thiovir, as part of AZT-based HAART therapy, before the end of 2004 under an accelerated approval program for treatment of HIV infection.

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 infection. Merck's DNA vaccine, now in human trials, demonstrated the ability to stimulate killer-T cells in some patients, indicating that this is a viable approach, but needs to be improved significantly to achieve more universal results. The Company is the exclusive licensee of this compound.

EradicAide is a therapeutic vaccine with a formulation that does not stimulate the production of antibodies, which have been shown to enhance HIV infection in studies designed to observe how HIV spreads. Antibody-based vaccines have achieved only mixed results in human testing, such as the poor results reported by VaxGen in February 2003, which caused VaxGen to discontinue this effort in early 2004.

Feasibility of the EradicAide vaccine approach has been demonstrated in multiple primate studies where rhesus monkeys, after a single series of vaccinations, have been infected with SHIV virus and have been able to keep infection under control for up to three years. We believe that this may translate to superior results in human trials, since our animal testing has been both successful and extensive compared to animal testing of DNA vaccines that have been reported in the literature.

We are working on completion of preclinical testing of EradicAide, including toxicology and pharmacology, while preparing clinical trial materials for human dosing. Pre-IND discussions with the FDA will begin during QII 2004. We intend to file an IND during the second half of 2004. The first testing in humans will be a Phase Ib/IIa clinical trial designed to demonstrate the safety and efficacy of EradicAide vaccine therapy for HIV infected individuals which we currently plan to begin in QIV 2004.

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. We intend to complete preclinical development and assessment of this drug during 2004 to determine whether to move forward into clinical development in 2005 and beyond. The Company is the exclusive licensee of this compound.

Selone

Selone™ is the lead compound in a new 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, and 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, and in a variety of human tumor cell lines in laboratory testing. We intend to undertake further preclinical testing of Selone during QIV 2004 and into 2005 in order to determine the potential for this drug to be moved into human testing in the future. The Company is the exclusive licensee of this compound.

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 predicts that there will be more than 1.3 million new cases of cancer diagnosed in the U.S. and over 563,000 deaths due to cancer in 2004.

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 the single most commonly used cancer drug among all chemotherapy agents. 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.

Today's 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, Leucovorin must be properly metabolized, which often does not occur. When Leucovorin fails, the overall 5-FU-based therapy is less effective and generally fails and is more toxic to the patient.

Our drug, CoFactor, bypasses the chemical pathway required for Leucovorin metabolism. This biochemical strategy delivers the correct form of folate that 5-FU requires 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.

In addition to 5-FU-based therapies, alkylating agents, as a class, are the most broadly used anticancer agents in the world, collectively surpassing the use of 5-FU as a 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. However, approximately one-half of all cancers can become resistant to therapy with current drugs so there is a need for new compounds to address drug-resistant cancer therapy.

We believe that the total annual market potential for CoFactor is related to new cases of cancer, which will be treated by 5-FU-based therapy. 5-FU doses vary based upon the cancer being treated. In order to estimate the total market potential for CoFactor, dose calculations must be determined for each type of cancer before total 5-FU doses can be determined. As an example, approximately 36 doses of 5-FU are administered to 70% of colorectal cancer patients annually vs. 12 doses of 5-FU to 33% of breast cancer patients.

Based upon current treatment criteria, the cancer population represents over 4 million doses of 5-FU annually. However, the majority of doses are used for colorectal cancer patients. Initial emphasis for CoFactor will therefore be focused on combination therapy with 5-FU for metastatic colorectal cancer. Assuming treatment of 70% of the 131,200 new cases per year in the U.S., there is a potential need for 3.3 million doses of 5-FU and 3.3 million doses of CoFactor. It should be noted that these estimates do not take into account additional market opportunities to enhance other drugs, which are similar to 5-FU, such as floxuridine (FUDR), florafur (tegafur) and Doxifluridine (5'-deoxyfluorouridine) or new agents such as Camptosar® (CPT-11, irinotecan), Eloxatin® (oxaliplatin), Avastin™ (bevacizumab) and Erbitux™ (cetuximab).

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 which 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 US and Europe where the vast majority of HIV drugs are used. However, according to a 2002 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 14,000 new infections are occurring 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 push HIV viral load to below "detectable levels." However, recent studies have shown that poor patient adherence, due to toxic side effects, will continue to cause problems of viral resistance, rendering many drugs ineffective. There is no conclusive evidence that current drugs can eradicate HIV from the body over the long term. The reason is that these drugs do not block the HIV virus before it enters human cells to begin its replication process. Once inside, the virus 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 a Legg Mason and Company report, Infectious Diseases Spring 2004, anti-HIV drug sales amounted to approximately \$6.2 billion in 2003 and have demonstrated double-digit growth rates during the last few years. 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.

The average annual drug cost for HAART treatment in the US is \$13,000 to \$23,000 per patient according to the New England Journal of Medicine. This translates to over \$15 billion in HAART costs per year. We believe that our understanding of viral inhibition and resistance, as well as our broad technology base for treatment of HIV infection, will provide new options in the treatment of HIV/AIDS with therapies that enhance the performance of current drugs, while reducing side effects and improving quality of life for patients who are being treated for HIV/AIDS.

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 do not presently have a marketing and sales staff, although the experience and background of Nicholas Jon Virca, our Chief Executive Officer, includes pharmaceutical marketing and sales 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. At that point, we would also likely seek to add marketing personnel for liaison, support and administrative purposes. 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.

For further information on the requirements for clinical trials and future commercialization, see the discussion below under "Government Regulation and Clinical Testing for New Drugs." See also the discussion under "Risk Factors" in Item 6 below.

Manufacturing

We do not have our own manufacturing facilities, and do not currently intend to establish them. However, the Company has entered into a manufacturing agreement with Merck Eprova AG, of Schaffhausen, Switzerland, under which Merck Eprova will produce CoFactor for clinical trial requirements and if approved, future product sales. We have also used the services of Multiple Peptide Systems, Inc., of San Diego, California, to produce the BlockAide/CR peptide and we are using Peptisyntha, Inc. of Torrance, California to produce the EradicAide peptides in order to obtain clinical trial materials for initial human trials in 2004. We have also contracted MediChem/decode Genetics of Woodridge, Illinois to produce clinical trial materials for Thiovir. (See "Risk Factors" in Item 6 below.)

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, the Company believes that it will need to be selective with its choice of manufacturers who have expertise in the cGMP production of either chemical or biological formulations, such as those required for the Company's products.

Number	Assignee	Patent Title	Product	Royalty	Expiration Date
5,376,658	USC	5,10-Methylene-Tetrahydrofolate as a Modulator of a Chemotherapeutic Agent.	CoFactor	3% of North American sales	12-23-13
5,534,519	USC	5,10-Methylene-Tetrahydrofolate as a Modulator of a Chemotherapeutic Agent.	CoFactor	3% of North American sales	10-20-14
5,562,905	NIH	Human immunodeficiency virus (HIV) ENV-coded Peptide Capable of Eliciting HIV Inhibition.	BlockAide	1.5% on sales up to \$200 million and 2% on sales in excess of \$200 million.	10-08-13
5,072,032	USC	Preparation and use of Thiophos-phonates and Thioanalogues of Phosphonoformic Acid.	Thiovir	1% of worldwide sales	06-21-09
5,183,812	USC	Preparation and use of Thiophosphonates and Thioanalogues of Phosphonoformic Acid.	Thiovir	1% of worldwide sales	09-30-11
6,147,245	USC	Preparation and Use of Alpha-Keto Bisphosphonates.	Thiovir	1% of worldwide sales	05-03-19
6,147,244	USC	Preparations of Thiophosphites and Thiophosphates.	Thiovir	1% of worldwide sales	07-13-19
6,284,909	USC	Preparations of thiophosphites and thiophosphonates.	Thiovir	1% of worldwide sales	11-01-20
5,128,319	M.D. Anderson	Prophylaxis and Therapy of Acquired Immunodeficiency Syndrome.	EradicAide	1.5% of worldwide sales	09-20-09
EP 0400076	M.D. Anderson	Synthetic Antigen Evoking Anti-HIV Response.	EradicAide	1.5% of worldwide sales	01-17-09
5,603,933	M.D. Anderson	CD-4 Peptides for Binding to Viral Envelope Proteins.	EradicAide	1.5% of worldwide sales	02-18-14
EP 0671947	M.D. Anderson	Compositions for Eliciting Cytotoxic T-Lymphocyte Responses Against Viruses. Royalty of 1.5% of sales.	EradicAide	1.5% of worldwide sales	02-12-12
6,210,873	M.D. Anderson	Methods and compositions for the priming of specific cytotoxic T-lymphocyte response.	EradicAide	1.5% of s worldwide ales	04-03-18
6,265,539	M.D. Anderson	Prophylaxis and Therapy of Acquired Immunodeficiency Syndrome.	EradicAide	1.5% of worldwide sales	07-24-18
6,645,471	M.D. Anderson	HIV Specific T-Cell Induction.	EradicAide	1.5% of worldwide sales	11-16-19
5,614,562	USC	Method of Treating Drug Resistant Tumor Cells using Organoselenones.	Selone	3% of North American sales	03-25-14

Patents, Licensing and Research Agreements

Patents

Listed below are patents that have been issued to USC, M.D. Anderson, and NIH. The Company has certain exclusive rights under the patents listed below, as more fully described below:

License Agreements
M.D. Anderson Agreements

In June 1996, the Company entered into an exclusive worldwide Patent and Technology License Agreement with M.D. Anderson (the “M.D. Anderson Agreement”) pursuant to which M.D. Anderson granted to the Company development, manufacturing and marketing rights, relating to the commercialization of technologies described in seven patents and patent applications developed by scientists at M.D. Anderson in the field of HIV therapy and preventions. The M.D. Anderson Agreement continues in effect for the life of the subject patents (including any extensions or renewals), and requires payment of royalties based on percentages of sales and a share of sub-licensing revenues from products developed under the M.D. Anderson Agreement. Our exclusive license rights are subject to any non-exclusive rights that the U.S. government may have as a result of any agreement between it and M.D. Anderson by which government-funded research was provided in connection with the licensed technology. The M.D. Anderson Agreement requires the Company to reimburse M.D. Anderson for the cost of preparing, filing, prosecuting and maintaining the licensed patents. No royalties were paid under this agreement during the years ended December 31, 2003 and 2002.

The M.D. Anderson 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. Pursuant to the Amendment, the Company is required to issue shares of Common Stock with a value of \$1,000,000 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.

USC Agreements

Under an Option and License Agreement with USC dated January 23, 1998, amended August 16, 2000, we hold exclusive license rights to three patents, two relating to our 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 with USC dated August 17, 2000, we acquired exclusive rights under five patents related to Thiovir antiviral technologies. Under a third Amendment to Option and License Agreement, dated April 21, 2003, the field of use of our agreement was expanded to include drugs to treat HPV (human papillomavirus) infections, HIV infections, HIV/HPV coinfections and drug delivery for other human therapeutic uses. Minimum royalties were excluded from the agreement and replaced with future milestones to be based upon entry into human trials and regulatory approvals. (\$75,000 at Phase I, \$100,000 at Phase II, \$125,000 at Phase III and \$250,000 at market approval for each drug candidate developed under the agreement) These agreements with USC (the “USC License Agreements”) grant us exclusive worldwide licenses to study, use, manufacture and market drug products covered by the subject patents. Under the USC License Agreements, we must pay USC for out-of-pocket expenses incurred in filing, prosecuting, enforcing and maintaining the licensed patents 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. In consideration of these licenses the Company must pay USC 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 these agreements.

NIH Agreement

During December 2002, the Company entered into a worldwide exclusive patent license agreement with the NIH concerning composition of matter for its drug, BlockAide/CR. Under the terms of the agreement, the Company agrees to pay annual royalty payments or, if higher, a minimum annual royalty of \$25,000. In addition, we must pay NIH benchmark royalties based upon: initiation of Phase I trials (\$25,000), initiation of Phase II trials (\$75,000), initiation of Phase III trials (\$150,000), and upon first approval of a Product License Application for an HIV therapeutic or vaccine in the US (\$750,000) and for first approval in Europe(\$750,000),

We periodically enter into sponsored research agreements pursuant to which an institution will provide research service to the Company on a fee for services basis. The Company currently has no obligation to make any 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 and pharmaceutical divisions of chemical companies as well as 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 do. 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.

BlockAide/CR

According to the Pharmaceutical Research and Manufacturers of America, there are a total of 54 approved medications used to treat AIDS. The currently approved antiviral medications are designed to inhibit HIV after it has already infected cells, with the single exception of T-20 (Fuzeon[®]), a viral fusion inhibitor co-marketed by Trimeris, Inc. and F. Hoffman-La Roche Ltd. ("Roche").

We believe that BlockAide/CR, if approved, could prove to be a significant competitor to T-20. The FDA approved T-20 for sale in March 2003. T-20 is the first product that works to inhibit HIV from outside the cell. However, T-20 seems to presently have many difficulties associated with its manufacture, pricing and therapy, which the Company believes BlockAide/CR may be able to overcome because of simpler manufacturing, easier administration and lower patient costs. T-20 is priced at \$20,000 per year in the US and \$25,000 per year in Europe. Because the manufacture of BlockAide/CR presently is relatively simpler than the manufacture of T-20, we believe we can price BlockAide/CR competitively with T-20 and other current drugs. In addition, BlockAide/CR is expected to be dosed once a day while T-20 requires two large doses a day by injection. Initially BlockAide/CR will be injected, but independent assessments of the structure of this drug make it a viable candidate for non-injectable delivery. Finally, BlockAide/CR is intended to protect immune system cells to prevent viral entry, whereas T-20 binds to HIV to inhibit a final and rapid step in the infection process. As a result, BlockAide/CR may be less susceptible to problems with viral resistance that have already been observed in the clinical setting with T-20.

According to Legg Mason and Company, of new medications under development for the treatment or prevention of AIDS/HIV, 37 are antivirals (including other fusion inhibitors), several are second-generation protease inhibitors, 47 are vaccines (as of mid 2003); 60 Phase I/II trials of 30 vaccine candidates were being conducted worldwide), 16 are anti-infectives and antifungals to fight opportunistic infections, 10 are immunomodulators designed to boost the immune system, 24 are anticancer medications to treat AIDS-related cancers such as lymphoma and KS (Kaposi's Sarcoma) and five are gene therapies.

On the vaccine front, EradicAide is a therapeutic drug with a formulation that does not stimulate the production of antibodies, which have been shown to enhance HIV infection in studies designed to observe how HIV spreads. Antibody-based vaccines have achieved only mixed results in human testing, such as the relatively disappointing results reported by VaxGen in February 2003, a potential competitor for EradicAide that discontinued its vaccine program in Q1 2004. EradicAide is based upon a cell-mediated immunity approach to controlling HIV, by stimulating disease-fighting cells, called killer-T cells whose job it is to clear infection. Merck & Co., Inc.'s DNA vaccine, now in human trials, demonstrated the ability to stimulate killer-T cells in some patients, indicating that this is a viable approach, but needs to be improved to achieve more universal results. Success of the EradicAide approach has been demonstrated in multiple primate studies following a series of vaccinations where rhesus monkeys were challenged with SHIV virus and have been able to keep infection under control for up to three years. The Company believes that this will translate to promising results in human trials, since its animal testing has been both successful and extensive compared to animal testing of DNA vaccines. Currently, HIV vaccines in clinical trials are injected. Animal studies now being conducted by the Company have already shown the feasibility for oral delivery of the EradicAide vaccine, which would make it a viable candidate for use with current oral HIV drugs and for oral delivery in third-world countries. Thus oral EradicAide could prove to be strong competition for injectable vaccines.

CoFactor

The Company intends to target replacement of 5-FU/leucovorin therapy, as well as 5-FU/leucovorin/CPT-11 (Camptosar[®], irinotecan) therapy for various cancers, which are toxic and less effective than the results the Company achieved in Phase I/II trials in Sweden. With an ongoing need for significant improvement in the clinical response of tens of thousands of cancer patients, especially those with colorectal cancer where leucovorin performs poorly, the Company currently believes CoFactor could successfully compete against current therapies.

There are approximately 40 different companies marketing 5-FU-related drugs that are generic. One exception is Roche, which markets the prodrug (drug that activates in vivo) Xeloda[®], which is an oral formulation that converts to 5-FU. Since CoFactor is intended to be used with 5-FU, but is only in IV form, generic forms of leucovorin that are oral represent competition for CoFactor, which in its current form must be administered by IV. 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.

The Company believes that if the 5-FU/CoFactor cocktail can limit the need for addition of CPT-11 to cancer treatment therapy, then overall toxicity of that regimen can be lowered significantly to improve the quality of life of patients being treated. If CoFactor is shown to be an effective part of cancer treatment regimen, we believe it will lower the overall cost of therapy by reducing the number of drugs administered, lengthening remissions and reducing toxicity.

Thiovir

The Company intends 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 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 a few additional drugs under development.

Because Thiovir is an oral replacement for foscarnet, an IV-administered drug that is already FDA approved for use in treatment of HIV-infected patients for CMV (cytomegalovirus) infection that can cause blindness, the Company believes it can gain acceptance based upon the resistance profile of foscarnet, once this is verified in clinical testing. Also, because foscarnet re-enables the use of AZT in AZT resistant patients, and AZT-based therapy is the most common therapy for HIV patients, there should be significant demand for Thiovir as an oral replacement for foscarnet and as a component of AZT-based HAART.

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 current Good Manufacturing Practices (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.

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. This would include our HIV/AIDS drugs as well as the Company's anticancer agents.

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 the Company cannot predict whether legislative or regulatory proposals will be adopted or the effect such proposals or managed care efforts may have on its business, the announcement or adoption of such proposals or efforts could have a material adverse effect on the Company. 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.

Research and Development Outlays

During fiscal year 2003 and 2002, the Company expended \$748,997 and \$282,966, 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, 2003, the Company had five employees all of whom were employed on a full-time basis.

Item 2. Description of Property.

The Company's principal office is located at 9948 Hibert St., Suite 100, San Diego, California. Our principal office consists of 1,553 square feet of office space which we use pursuant to a lease which will expire on July 14, 2004. The lease rate for this space is currently \$36,456 per year, which amount includes incremental operating cost adjustments.

Our research and development activities during 2003 were conducted mainly on the premises of M.D. Anderson, and USC.

We believe our facilities are in good operating condition and that the real property leased by the Company 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 have begun looking for new space to accommodate our planned expansion of in-house drug testing.

The Company does not have any investments in and does 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. The Company does not own or have an interest in any real property the book value of which amounts to 10% or more of the total assets of the Company and its consolidated subsidiaries.

Item 3. Legal Proceedings.

In September 2003, the Company filed a complaint in the Superior Court of California in and for the County of San Diego, alleging claims against Louis R. Reif, a former officer and director of the Company, for breach of fiduciary duty, negligent misrepresentation, and aiding and abetting breach of fiduciary duty, and seeking damages and injunctive relief. Later in September 2003, the Company named an additional defendant, Robert D. Whitworth, who is also a former officer and director of the Company. In October 2003, Mr. Reif filed a Notice of Removal of Action in the U.S. District Court in and for the Southern District of California, joined by Mr. Whitworth. In November 2003, Messrs. Reif and Whitworth filed motions with the federal court to dismiss the lawsuit based on an alleged lack of personal jurisdiction. On December 31, 2003, the Company filed papers opposing the motion to dismiss, and the parties filed related papers shortly thereafter. In February 2004, the Court denied Messrs. Reif and Whitworth's motion to dismiss. Later in February 2004, Messrs. Reif and Whitworth filed answers denying the material allegations of the Company's amended complaint. In March 2004, the Company received letters from Messrs. Reif and Whitworth demanding that the Company advance payment for expenses incurred by them in defending against the lawsuit filed by the Company. The Company has reserved its rights in respect of those demands. In late March 2004, pursuant to mandatory court mediation all parties agreed to dismiss the case without prejudice, with all parties reserving their rights.

In December 2003, the Company filed a complaint in the Superior Court of California in and for the County of San Diego, alleging claims against Bengt G. Gustavsson and Biofol AB, who are former consultants of the Company, for misappropriation of trade secrets, breach of written contracts, breach of the implied covenant of good faith and fair dealing, breach of fiduciary duty, breach of duty of confidence, aiding and abetting breach of fiduciary duty and breach of duty of confidence, unfair competition, intentional interference with prospective economic relations, and seeking damages, declaratory and injunctive relief. In January 2004, Dr. Gustavsson and Biofol filed a Notice of Removal of Action in the U.S. District Court in and for the Southern District of California. In February 2004, the federal court adopted a stipulation of the Company, Dr. Gustavsson and Biofol pursuant to which Dr. Gustavsson and Biofol accepted service of the lawsuit effective as of January 14, 2004 and agreed to file their response to the Company's complaint by March 1, 2004. On March 1, 2004, Dr. Gustavsson and Biofol filed an answer denying the material allegations of the Company's complaint. To the Company's knowledge, as of the date of this report, no other substantive filings have been made by the Company, Dr. Gustavsson or Biofol regarding this lawsuit. The outcome of and the amount of any damages that may be recovered in this lawsuit is uncertain.

On February 26, 2004, the Company received a letter from a stockholder in which the stockholder demanded to inspect certain books and records of the Company. One stated purpose for the stockholder's demand is to determine whether corporate wrongdoing occurred in connection with certain private placements of the Company's securities. On March 2, 2004, the Company timely responded to this stockholder's demand and agreed to make documents available for inspection on or after March 15, 2004. Since March 2, 2004, the Company has not had any communication with this stockholder and the inspection has neither taken place nor been scheduled by the stockholder. The Company believes that there is no reasonable basis for any claim by this stockholder. The Company will vigorously defend any such claim, if asserted.

From time to time we may be subject to additional 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. We are not aware of any legal proceedings or claims that we believe could harm our business or cause our stock price to fall.

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

In October 2003, the Company received the written consent, in lieu of a meeting of stockholders, from the holders of 22,396,793 shares of Common Stock, representing approximately 53.7% of our then outstanding shares of voting capital stock, authorizing the Company to increase the authorized number of shares of capital stock of the Company from 51,000,000 shares to 101,000,000 shares, 100,000,000 of which are designated as Common Stock, by filing an amendment to the Company's Certificate of Incorporation (the "Stockholder Consent"). On November 3, 2003, we filed a preliminary information statement on Schedule 14C with the Securities and Exchange Commission regarding the Stockholder Consent and the increase in our authorized capital stock. On November 24, 2003, we filed a definitive information statement on Schedule 14C with respect to these matters. On January 4, 2004, we filed the amendment to our certificate of incorporation with the Secretary of State of the State of Delaware to increase the authorized number of shares of capital stock of the Company from 51,000,000 to 101,000,000. No other matters were submitted to a vote of the holders of the Company's securities, through solicitation of proxies or otherwise, during 2003.

Part II

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

Market Information.

Our Common Stock is quoted on the National Association of Securities Dealers' OTC Bulletin Board under the symbol AVRX.

The following table lists the high and low closing price information for our Common Stock for each quarter for the fiscal years 2002 and 2003. All prices listed herein reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions.

<u>Quarter Ending</u>	<u>High</u>	<u>Low</u>
March 31, 2002	\$2.00	\$1.55
June 30, 2002	\$4.00	\$1.11
September 30, 2002	\$1.85	\$0.46
December 31, 2002	\$0.51	\$0.15
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

Holders.

As of December 31, 2003 the number of record holders of Common Stock was approximately 1,126 and the number of holders of preferred stock was 3.

Dividends.

The Company has never paid cash dividends on shares of its Common Stock or Preferred Stock and does not currently expect to pay any cash dividends on its shares of Common Stock or Preferred Stock in the foreseeable future. Pursuant to the terms of our Certificate of Designations, Preferences, Rights and Limitations of Series A 8% Convertible Preferred Stock filed with the Secretary of State of the State of Delaware in September 2000, so long as any shares of our Series A 8% Convertible Preferred Stock ("Series A Preferred Stock") remain outstanding, we may not declare or pay any dividend or other distribution upon our Common Stock, unless all amounts then due to the holders of Series A Preferred Stock have been paid. As of February 29, 2004, 473 shares of Series A Preferred Stock were outstanding. Pursuant to the terms of our Certificate of Designation of Series B Convertible Preferred Stock and Series C Convertible Preferred Stock filed with the Secretary of State of the State of Delaware in September 2002, so long as any shares of our Series C Convertible Preferred Stock ("Series C Preferred Stock") remain outstanding, we may not declare or pay any dividend or other distribution upon our Common Stock, unless all accrued dividends then due to the holders of Series C Preferred Stock have been paid. As of February 29, 2004, no shares of Series C Preferred Stock were outstanding. As of December 31, 2003, the Company accrued unpaid dividends on the Series A 8% Convertible Preferred Stock of \$72,800

Securities Authorized for Issuance Under Equity Compensation Plans.

As of February 29, 2004, other than the individual compensation arrangements set forth in the table below, the Company 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	3,160,000	\$0.45	0
Total	3,160,000	\$0.45	0

In October 2002, the Compensation Committee of the Board of Directors of the Company granted three stock options to Nicholas J. Virca, our Chief Executive Officer. One of the stock options granted to Mr. Virca represents the right to purchase up to 1,000,000 shares of Common Stock at an exercise price of \$0.20 per share, which right was completely vested on the date of grant. Another of the stock options granted to Mr. Virca represents the right to purchase up to 500,000 shares of Common Stock at an exercise price of \$0.20 per share, which right vested with respect to 125,000 shares in July 2003 and continues to vest with respect to 125,000 shares each quarterly anniversary thereafter until fully-vested. The third stock option granted to Mr. Virca represents the right to purchase up to 165,000 shares of Common Stock at an exercise price of \$0.50 per share, which right was completely vested on the date of grant. The Compensation Committee also granted a stock option to an employee of the Company to purchase up to 25,000 shares of Common Stock at an exercise price of \$0.20 per share, which right was vested with respect to 12,500 shares on the date of grant and vested with respect to the remaining 12,500 shares in December 2003. The Compensation Committee also granted stock options to employees of the Company to purchase up to 400,000 shares of Common Stock at an exercise price of \$0.50 per share, which rights were vested with respect to 112,500 shares on the date of grant and will vest with respect to all of the remaining 387,500 shares by April 2005.

In March 2003, the Compensation Committee granted non-statutory stock options to purchase 1,000,000 and 500,000 shares of Common Stock at an exercise price of \$0.50 per share, which rights will vest by April 2006, to Evan Levine, our Chief Operation Officer, and Ross Johnson, our Chairman of the Board, respectively. In April and June 2003, the Company and four of its 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 Mr. Levine's non-statutory stock option was modified such that the 750,000 shares of Common Stock subject to his option that were not vested as of July 1, 2003 were cancelled in consideration of the Company's agreement to begin paying Mr. Levine a salary. Each of the foregoing options will expire in December 2008 and each of the foregoing options provides that the optionholder may exercise the option on a "net issue" or "cashless" basis.

In January and February 2004, the Company appointed three new independent members to the board of directors. Each director was granted an option to purchase 50,000 shares of Common Stock at a purchase price of \$1.50 per share.

In February 2004, the Company added a member to its 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.

Recent Sales of Unregistered Securities.

In January 2003, the Company issued an aggregate of 119,454 shares of Common Stock to holders of certain promissory notes issued by the Company in October and December 2001 to the holders of such notes in payment of accrued interest that was due under such notes.

On March 4, 2003, the Board of Directors of the Company granted an option to Evan M. Levine, our Chief Operating Officer, to purchase up to 1,000,000 shares of Common Stock at an exercise price of \$0.50 per share, which right vested with respect to 125,000 shares on April 1, 2003 and will continue to vest with respect to 125,000 shares each quarterly anniversary thereafter until fully-vested. The Board of Directors also granted an option to Joan Robbins, our Chief Technical Officer, to purchase up to 300,000 shares of Common Stock at an exercise price of \$0.50 per share, which right vested with respect to 100,000 shares on the date of grant, will vest with respect to 100,000 shares on March 4, 2004 and will vest with respect to 100,000 shares on March 4, 2005. Each of the foregoing options will expire on December 30, 2008 and each of the foregoing options provide that the optionholder may exercise the option on a "net issue" or "cashless" basis.

On March 25, 2003, the Company issued three warrants to three individuals in consideration of certain investment banking advice. The three warrants represent the right to purchase an aggregate of 110,000 shares of Common Stock at an exercise price of \$0.50 per share.

On March 25, 2003, the Company issued 125,000 shares of Common Stock and two warrants to two entities in consideration of each such entity's introduction of the Company to investors that purchased shares of Common Stock between January 2003 and March 2003. The two warrants represent the right to purchase an aggregate of 75,000 shares of Common Stock at an exercise price of \$0.50 per share.

On March 26, 2003, the Board of Directors of the Company granted an option to M. Ross Johnson, Ph.D., our Chairman of the Board, to purchase up to 500,000 shares of Common Stock at an exercise price of \$0.50 per share, which right vested with respect to 62,500 shares on April 1, 2003 and will continue to vest with respect to 62,500 shares each quarterly anniversary thereafter until fully-vested. The Board of Directors also granted an option to Steven M. Plumb, CPA, our Chief Financial Officer, to purchase up to 100,000 shares of Common Stock at an exercise price of \$0.50 per share, which right vested with respect to 12,500 shares on April 1, 2003 and will continue to vest with respect to 12,500 shares each quarterly anniversary thereafter until fully-vested. Each of the foregoing options will expire on December 30, 2008 and each of the foregoing options provides that the optionholder may exercise the option on a "net issue" or "cashless" basis.

Between January 9, 2003 and March 31, 2003, the Company closed sales of an aggregate of 1,589,856 shares of Common Stock to eight accredited investors for gross proceeds of \$635,949 in cash. These purchasers of Common Stock represented their intention to acquire the shares for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the share certificates representing the shares.

In March 2003, all of the holders of Series C Preferred Stock converted all of their shares of Series C Preferred Stock into an aggregate of 14,021,860 shares of Common Stock pursuant to the terms of our Certificate of Designation of Series B Convertible Preferred Stock and Series C Convertible Preferred Stock filed with the Secretary of State of the State of Delaware on September 23, 2002.

In April 2003, pursuant to the terms of promissory notes issued by the Company in October and December 2001, the Company issued an aggregate of 46,376 shares of Common Stock to the holders of such notes in payment of accrued interest that was due such holders.

In June 2003, the Company completed a private placement of 5,027,328 shares of common stock and warrants to purchase an aggregate of 1,508,199 shares of common stock at \$0.60 per share to accredited investors for gross proceeds of \$2,010,931 in cash. The Company paid cash commissions of \$49,400 in connection with this private placement.

In June 2003, the Company issued 59,535 shares of Common Stock, 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 \$0.10 per share as commissions on the private placement.

In June 2003, the Company paid a consulting firm for public relations services with 75,000 shares of Common Stock.

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 aggregate of 834,600 shares of Common Stock at \$1.25 per share to accredited 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.

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 December 2003, the Company paid a consulting firm for public relations services with 30,000 shares of Common Stock.

Between October 2003 and December 2003, the Company completed a private placement of 849,561 shares of Common Stock and warrants to purchase an aggregate of 435,000 shares of Common Stock at \$1.25 per share to accredited investors for gross proceeds of \$1,489,961 in cash. In connection with the private placement the Company reissued 649,797 shares of Common Stock previously held as treasury stock. The Company issued warrants to purchase 124,200 shares of Common Stock at \$1.25 per share and paid cash commissions of \$188,596 in connection with the private placement.

In December 2003, warrants to purchase 175,100 shares of Common Stock were exercised for gross proceeds of \$49,721 and warrants to purchase 69,426 shares of Common Stock were exercised on a cashless basis for 37,026 shares of Common Stock.

In March 2004, two Series A 8% Convertible Stock shareholders agreed to convert 200 shares of Series A 8% Convertible Stock into 100,000 shares of Common Stock. In addition, accrued, but unpaid dividends, of \$56,800 on these converted shares were extinguished upon conversion.

In March 2004, the sole holder of shares of Series B Convertible Preferred agreed to convert all of its 200,000 shares of Series B Convertible Preferred Stock into 200,000 shares of Common Stock.

Except as otherwise noted above, no commission was paid or given, directly or indirectly in connection with any of the above sales, amendments, issuances, exchanges or conversions.

The issuances of the above securities were 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 or Regulation D promulgated under the Securities Act, as transactions by an issuer not involving a public offering or, in the case of the conversion of shares of Series C Preferred Stock and the cashless exercise of warrants, in reliance on 3(a)(9) of the Securities Act, as an exchange by the Company with one of its security holders where no commission or other remuneration is paid or given directly or indirectly for soliciting such exchange.

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 revenues from any of our products. We have had no earnings since inception, and have an accumulated deficit of \$(28,481,146) as of December 31, 2003. 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 and HIV 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 the Company establish agreements with other parties for the clinical testing, manufacturing, commercialization and sale of its products.

Since inception, the Company has generally funded itself 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 private placements of our capital stock primarily to expand our preclinical and clinical efforts for CoFactor, BlockAide/CR and EradicAide as well as for general working capital. At this time we are beginning to commit additional resources to the development of Thiovir and are committing significantly fewer resources to the development of BlockAide/VP and Selone.

We began the trial for metastatic colorectal cancer patients with 5-FU and our drug CoFactor in Q1 2004, based upon an approved IND Application in the United States to treat metastatic colorectal cancer patients in conjunction with 5-FU. We also intend to file for approval for a Phase II trial for CoFactor for metastatic colorectal cancer patients in the United Kingdom during QIII 2004 and also file in QIII 2004 for approvals to begin treatment of pancreatic cancer patients with 5-U and CoFactor in two separate Phase II trials in the United States and Europe. We will also file for approval during QIII 2004 and QIV 2004, respectively, to begin second-line therapy trials for CoFactor use with 5-FU for metastatic colorectal cancer for the United States and United Kingdom. We have filed an IND Application in Q1 2004 for approval to treat HIV patients with BlockAide/CR during 2004 and also intend to file an IND application in QIII 2004 to treat HIV patients with Thiovir, beginning in QIV 2004 and file an IND application in QIII 2004 to treat HIV patients with the initial formulation of EradicAide vaccine later in 2004. Additional detail regarding the human trials and INDs that the Company plans to file are discussed in Part I, Item 1, Description of Business, of this annual report. We expect the foregoing to require the expenditures set forth below:

Expenditure	Estimated Cost
CoFactor trials	\$4,900,000
BlockAide/CR trials	900,000
First Thiovir Trial	400,000
First EradicAide trial	300,000
Total estimated research and development	6,500,000
Estimated general and administrative	1,581,000
Total estimated costs	<u>\$8,081,000</u>

The Company's current cash position of \$4,226,397 is not sufficient to meet the Company's goals as set forth above. We are continuing efforts to raise additional capital and execute our research and development plans. Even if we are successful in raising sufficient money to carry out these plans, additional clinical development, necessary to bring our products to market, will require significant additional capital.

In February 2004, the Company purchased 18 Rhesus monkeys for use in future research at M.D. Anderson in Houston, Texas for \$118,000. We purchased laboratory equipment totaling approximately \$40,000 during the first quarter of 2004. We do not currently believe we will need any additional equipment involving significant expenditures for the rest of 2004.

Our facility lease expires in July 2004. We are currently undergoing a search for new office and laboratory space that would meet our forecast research and administrative needs for several years to come. In conjunction with this anticipated move to a new location we expect to spend \$50,000 on telephone and computer equipment and increased rent on the newly leased space beginning in the third quarter of 2004.

In conjunction with the additional research and development activities we expect to conduct, we anticipate adding two administrative staff and four research and development support personnel in the next 12 months. In March 2004, we hired a Vice President of Clinical and Medical Affairs at an annual salary of \$160,000.

Liquidity and Capital Resources

The Company has incurred negative cash flows since its inception, and has funded its activities primarily through short-term loans and sales of equity securities. As of December 31, 2003 and 2002, the Company had cash and equivalents of \$4,226,397 and \$103,928 respectively. 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.

The Company does not have any bank or any other commercial financing arrangements. The Company's operations over the last 12 months have been funded by the proceeds from private equity placements.

The Company's dependence on raising additional capital will continue at least until the Company is able to commercially market one of its products at significant sales level. Depending on profit margins and other factors, the Company may still need additional funding to continue research and development efforts. The Company's future capital requirements and the adequacy of its financing depend upon numerous factors, including the successful commercialization of the Company's drug candidates, progress in its 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 its products.

The Company 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. The Company does 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, the Company will be required to delay, scale-back or eliminate certain aspects of its operations or attempt to obtain funds through arrangements with collaborative partners or others that may require the Company to relinquish rights to certain of its 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 United States of America 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 its 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 the Company's common stock until the options are vested. The Company values 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. Series A and Series B preferred stock are valued at the liquidation value of \$1,000 and \$10 per share, respectively.

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.

The Company accounts 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 the Company's common stock until the options are vested. The Company values 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. Series A and Series B preferred stock are valued at the liquidation value of \$1,000 and \$10 per share, respectively.

Revenue Recognition

The Company recognizes revenue at the time service is performed on commercial contracts and collectability is 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 the reimbursement request is submitted.

New Accounting Pronouncements

In December 2002, the FASB issued Statement of Financial Accounting Standards No. 148, *Accounting for Stock-Based Compensation - Transition and Disclosure - an amendment of FASB Statement No. 123* (SFAS No. 148). SFAS No. 148 amends FASB Statement No. 123 to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of FASB Statement No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. SFAS No. 148 is effective for the fiscal years beginning after December 15, 2002.

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

In May 2003, the FASB issued Statement of Financial Accounting Standards No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* (SFAS No. 150), which establishes standards for how a company classifies and measures certain financial instruments with characteristics of both liabilities and equity. SFAS No. 150 is generally effective for interim periods beginning after June 15, 2003.

The adoption of these new pronouncements did not have, or are not expected to have, a material effect on the Company's consolidated 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.

The Company had an accumulated deficit of \$(28,481,146) as of December 31, 2003. Since the Company presently has no source of revenues and is committed to continuing its 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 and successfully marketed. In addition, the Company has funded its operations primarily through the sale of Company securities, and has had limited working capital for its 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.

The Company has devoted its 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 the Company's present activities, and no revenues will likely be available until, and unless the new products are clinically tested, approved by the FDA and successfully marketed, either by the Company or a marketing partner, an outcome which the Company is not able to guarantee.

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

It is not expected that the Company 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 and/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 which preclude the Company from making distributions to stockholders and taking other actions beneficial to stockholders. If adequate funds are not available, the Company may be required to delay or reduce the scope of its drug development program or attempt to continue development by entering into arrangements with collaborative partners or others that may require the Company to relinquish some or all of its rights to proprietary drugs. The inability to fund its capital requirements would have a material adverse effect on the Company.

The Company is not certain that it will be successful in the development of its 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 the Company from marketing a drug product. There can be no assurance that the development of drug candidates will demonstrate the efficacy and safety of a drug candidate as a therapeutic drug, or, even if demonstrated, that there will be sufficient advantages to its use over other drugs or treatments so as to render the drug product commercially viable. In the event that the Company is 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.

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

The Company is engaged in a segment of the pharmaceutical industry that is highly competitive and rapidly changing. If successfully developed and approved, any of the Company's 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 the Company. The Company anticipates that it 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 by the Company. Competitive products may render the Company's drugs obsolete or noncompetitive prior to the Company's recovery of development and commercialization expenses.

Many of the Company's 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 the Company, which would have a material adverse effect on the Company.

There is no assurance that the Company's products will have market acceptance.

The success of the Company 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 drug product of the Company.

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.

The Company's ability to commercialize its 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. The Company cannot guarantee that adequate third-party insurance coverage will be available for the Company to establish and maintain price levels sufficient for realization of an appropriate return on its 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 uses of the Company's products, the market acceptance of these products would be adversely affected if the amount of reimbursement available for the use of the Company's therapies proved to be unprofitable for health care providers.

Uncertainties related to health care reform measures may affect the Company's 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. The Company cannot predict the effect health care reforms may have on its business, and there is no guarantee that any such reforms will not have a material adverse effect on the Company.

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 the Company's activities, and provide an advantage to larger companies that compete with the Company. There can be no assurance that FDA or other regulatory approval for any products developed by the Company 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 the Company's ability to utilize any of its technologies, thereby adversely affecting the Company's 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.

The Company's success will be dependent on licenses and proprietary rights it receives from other parties, and on any patents it may obtain.

Our success will depend in large part on the ability of the Company and its licensors 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 (v) 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. The Company has obtained licenses to patents and other proprietary rights from M.D. Anderson, USC and the NIH.

The patent positions of pharmaceutical companies, including those of the Company, are uncertain and involve complex legal and factual questions. There is no guarantee that the Company or its 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 the Company. In addition, we cannot be certain that any patents issued to or licensed by the Company will not be challenged, invalidated, infringed or circumvented, or that the rights granted thereunder will provide competitive disadvantages to the Company.

Litigation, which could result in substantial cost, may also be necessary to enforce any patents to which the Company has rights, or to determine the scope, validity and unenforceability of other parties' proprietary rights, which may affect the rights of the Company. 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 the Company's 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 the Company pending resolution of the disputed matters.

The Company may also rely on unpatented trade secrets and know-how to maintain its competitive position, which it seeks 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 the Company will have adequate remedies for any breach, or that trade secrets will not otherwise become known or be independently discovered by competitors.

The Company's license agreements can be terminated in the event of a breach.

The license agreements pursuant to which the Company has licensed its core technologies for its potential drug products permit the licensors, respectively M.D. Anderson, NIH and USC, to terminate the agreement under certain circumstances, such as the failure by the licensee to use its reasonable best efforts to commercialize the subject drug or the occurrence of any other uncured material breach by the licensee. The license agreements also provide that the licensor is primarily responsible for obtaining patent protection for the technology licensed, and the licensee is required to reimburse it 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 the Company.

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 the Company 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.

The Company's success is dependent on its key personnel.

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

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 the Company 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 the Company.

We currently have no sales or marketing capability.

The Company does not have marketing or sales personnel. The Company 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 the Company will be able to establish marketing, distribution or sales capabilities or make arrangements with third parties to perform those activities on terms satisfactory to the Company, or that any internal capabilities or third party arrangements will be cost-effective.

In addition, any third parties with which the Company 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 the Company will be able to control the amount and timing of resources that any third party may devote to the products of the Company or prevent any third party from pursuing alternative technologies or products that could result in the development of products that compete with, and/or the withdrawal of support for, the products of the Company.

The Company does 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.

The Company will not have any manufacturing capacity. When required, the Company will seek to establish relationships with third-party manufacturers for the manufacture of clinical trial material and the commercial production of a drug product just as it has with Merck Eprova AG and Multiple Peptide Systems, Inc. There can be no assurance that the Company 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 the drug product 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 its manufacturing requirements on commercially acceptable terms would have a material adverse effect on the Company.

The Company does not have its own research facilities and will be dependent on third parties for drug development.

The Company does not have its own research and development facilities and engages consultants and independent contract research organizations to design and conduct clinical trials in connection with the development of a drug. As a result, these important aspects of a drug's development will be outside the direct control of the Company. In addition, there can be no assurance that such third parties will perform all of their obligations under arrangements with the Company 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.

The business of the Company will expose it 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 the Company. The Company intends to obtain additional limited product liability insurance for its clinical trials, directly or through its marketing development partners or CRO (contract research organization) partners, when they begin in the U.S. and to expand its insurance coverage if and when the Company begins marketing commercial products. However, there can be no assurance that the Company will be able to obtain product liability insurance on commercially acceptable terms or that the Company 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 the Company could have a material adverse effect on the Company.

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 share that risk in excess of our insurance limits. 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 Company's 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 the Company or its 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.

The Company has never paid cash dividends on Common Stock, and does not intend to do so in the foreseeable future.

The issuance of shares of our preferred stock may adversely affect our Common Stock.

The 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 of the Company from occurring, among other possibilities.

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

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 the Certificate of Incorporation and the 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 the Common Stock.

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

Pursuant to the Company's 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. The Certificate of Incorporation and by-laws provide that the Company must indemnify its 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.

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

On February 10, 2003, we filed a current report on Form 8-K to report a change in independent accountants. There were no disagreements with our preceding independent accountants on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure.

Item 8A. Controls and Procedures.

Evaluation of disclosure controls and procedures

The Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness, as of December 31, 2003, of the design and operation of the Company's disclosure controls and procedures pursuant to Rule 13a-14 of the Securities Exchange Act of 1934 (the "Exchange Act"). Based upon that evaluation, the Company's principal executive and financial officers concluded that the Company's disclosure controls and procedures were effective, as of December 31, 2003, in timely providing them with material information relating to the Company, as required to be disclosed by the Company in the reports that it files or submits under the Exchange Act, within the time periods specified in the Securities and Exchange Commission's rules and forms.

Changes in internal controls

There were no significant changes in the Company's internal controls or other factors that could significantly affect those controls subsequent to the date of the Company's evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

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 the Company's directors and executive officers, including those persons nominated or chosen to become such, and significant employees as of February 29, 2004 and certain information about each them are set forth below:

Name	Age	Position(s) with the Company
Nicholas J. Virca	57	Chief Executive Officer, President, Secretary and Director
M. Ross Johnson, Ph.D.	59	Chairman of the Board
Evan Levine	38	Chief Operating Officer and Director
Steven M. Plumb, CPA	44	Chief Financial Officer
Joan M. Robbins	43	Chief Technical Officer
Michael M. Goldberg, M.D. (1)(2)	45	Director (3)
Mark J. Pykett, V.M.D., Ph.D (1)(2)	39	Director (3)
Mark Bagnall, CPA (1)(2)	47	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. Since October 2000, Dr. Johnson has also served as a Director for Biokeys, Inc., our wholly owned subsidiary. 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 Berkeley 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 United States. 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.

Nicholas J. Virca. Mr. Virca has served as our Chief Executive Officer and a Director since October 2002. From 1997 to the present, Mr. Virca served as the President and Chief Executive Officer and a Director of Biokeys, Inc., our wholly owned subsidiary. In 1991 Mr. Virca co-founded and from 1991 to 1997 Mr. Virca served as the Vice President of Operations and a Director of Diametrix Detectors, Inc., a privately held immunosensor company which was focused on the airborne vapor detection of narcotics using monoclonal antibodies. From 1994 to 1997, Mr. Virca served as Business Unit Manager, Security Products, for Nicolet Imaging Systems, a company that purchased substantially all of IRT Corporation's assets in 1994. From 1991 to 1994, Mr. Virca served as Vice President, Business Operations, of IRT Corporation, a publicly held company that specialized in x-ray inspection and imaging systems for industrial and security applications. Earlier employment includes key marketing and general management positions with Fisher Scientific, Damon Biotech, Promega Corporation, the Ortho Division of Johnson & Johnson and the Ross Division of Abbott Laboratories. Mr. Virca received a B.A. in Biology from Youngstown State University.

Evan M. Levine. Mr. Levine has served as our Chief Operating Officer 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 his MBA at New York University's Stern School of Business.

Steven M. Plumb, CPA. Mr. Plumb has served as our Chief Financial Officer since February 2003. Prior to joining the Company as its Chief Financial Officer, Mr. Plumb provided financial consulting services to the Company. Mr. Plumb is President of Steven M. Plumb, P.C., a business consulting firm. Mr. Plumb has over 20 years experience in accounting and consulting in a diverse array of industries, including biotechnology, healthcare, and telecommunications. Prior to founding Steven M. Plumb, P.C. in 1992, Mr. Plumb served as the Chief Financial Officer of DePelchin Children's Center and as a controller of Memorial City Rehabilitation Hospital. He is also a former auditor for and consultant with KPMG. Mr. Plumb earned his B.B.A. in accounting from the University of Texas in Austin, Texas. He is a Certified Public Accountant and a member of the American Institute of Certified Public Accountants and a member of the Information Technology section of the American Institute of CPAs.

Joan M. Robbins, Ph.D. Dr. Robbins has served as our Chief Technical Officer since April 1, 2003. From 1996 through March 2003, Dr. Robbins served in multiple roles at Immusol, Inc., a biopharmaceutical company specializing in cancer therapeutics, including Vice President, Product Development, Senior Director, Product Development, and Director, Therapeutics. From 1994 to 1995, Dr. Robbins was a Research Scientist and Project Leader for Cancer Research at Immusol. From 1992 to 1993, Dr. Robbins was a Post Graduate Researcher at University of California, San Diego. From 1990 to 1991, Dr. Robbins was a Research Fellow at the Garvin Institute for Medical Research, Centre for Immunology in Sydney, Australia. From 1981 to 1989, Dr. Robbins was a Microbiologist at the Laboratory of Tumor Immunology and Biology at National Cancer Institute, Bethesda, Maryland. Dr. Robbins received her B.S. in genetics the University of California, Davis and a Ph.D. in genetics from George Washington University.

Michael M. Goldberg, M.D. Dr. Goldberg is Chairman and Chief Executive Officer of Emisphere Technologies, Inc. (NASDAQ: EMIS). 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 his M.D. from Albany Medical College of Union University and his M.B.A. from Columbia University Graduate School of Business.

Mark J. Pykett, V.M.D., Ph.D. Dr. Pykett is Co-Founder, President, Chief Executive Officer and a member of the Board of Directors of Cytomatrix, LLC, and President of Cordlife, Pte Ltd., of Singapore, which acquired Cytomatrix in 2003. Cytomatrix is focused on the research, development and commercialization of novel cell-based therapies. 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 currently serves as Senior Vice President and Chief Business Officer of Metabolex, Inc. 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 the Company's Directors and officers, and persons who own more than 10% of a registered class of the Company's 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 Common Stock and other equity securities of the Company. Section 16 Persons are required by SEC regulation to furnish the Company with copies of all Section 16(a) reports they file. Based on the Company's review of the forms it has received, on other reports filed by Section 16 Persons with the SEC and on the Company's records, the Company believes that during 2003 (1) Nicholas J. Virca failed to timely file a Form 4 to report the acquisition of 15,698 shares of Common Stock pursuant to the cashless exercise of a warrant; and (2) Joan M. Robbins failed to timely file a Form 4 to report the acquisition of 125,000 shares of Common Stock by her husband.

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 its 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, 9948 Hibert Street, Suite 100, San Diego, California 92131.

Item 10. Executive Compensation.

Summary Compensation Table

The following Summary Compensation Table sets forth summary information as to compensation received by the Company's Chief Executive Officer and each of the other most highly compensated persons who were serving as executive officers of the Company as of December 31, 2003.

Name and Principal Position	Year	Annual Salary (1)	Securities underlying Options	All Other Compensation
Nicholas J. Virca <i>Chief Executive Officer, President and Secretary</i>	2003	\$157,789	—	\$15,000
	2002	\$120,192	1,665,000	—
	2001	\$124,000	—	—
Evan Levine (2) <i>Chief Operating Officer</i>	2003	\$ 85,000	250,000	—
	2002	\$ —	—	—
	2001	\$ —	—	—
Steven M. Plumb, CPA (3) <i>Chief Financial Officer</i>	2003	\$ 75,391	100,000	—
	2002	\$ —	—	—
	2001	\$ —	—	—
Joan M. Robbins (4) <i>Chief Technical Officer</i>	2003	\$127,497	300,000	—
	2002	\$ —	—	—
	2001	\$ —	—	—

- (1) Only one of the named executives received any bonus or other annual compensation in any of the years listed. Mr. Virca received a bonus of \$15,000 in 2003.
- (2) Mr. Levine became an executive of the Company in October 2002. Mr. Levine did not receive any salary or other compensation from the Company in 2002. Mr. Levine began receiving an annual salary of \$170,000 in July 2003.
- (3) Mr. Plumb was hired as Chief Financial Officer, on a part-time basis, on January 1, 2003. From July 1, 2001 to December 31, 2002, Mr. Plumb served as a consultant to the Company. In 2001, 2002, and 2003 Mr. Plumb received an aggregate of \$21,618, \$55,150, and \$75,391 respectively, for services rendered to the Company as a consultant. Mr. Plumb's base annual salary as Chief Financial Officer is \$60,000.
- (4) Dr. Robbins began her employment with the Company on April 1, 2003. Dr. Robbins annual salary is \$170,000.

Option Grants.

	Number of shares of Common Stock underlying options granted	Percent of total options granted to employees in the fiscal year ended December 31, 2003	Exercise Price	Expiration Date
Nicholas J. Virca	1,665,000	71.9%	\$0.23 (1)	12/30/2008
Evan Levine	250,000	10.8%	\$0.50	12/30/2008
Steven M. Plumb	100,000	4.3%	\$0.50	12/30/2008
Joan M. Robbins	300,000	12.9%	\$0.50	12/30/2008

(1) This is a weighted-average exercise price.

Aggregated Option Exercises in Last Fiscal Year and Fiscal Year-End Values

No executive officer or Director of the Company exercised any options during the fiscal year ended December 31, 2003.

The following table provides information regarding the number of shares covered by both exercisable and unexercisable stock options held by the named executive officers as of December 31, 2003, and the value of "in-the-money" options, which values represent the positive spread between the exercise price of any such options and the fiscal year-end value of the Common Stock.

	Number of Securities Underlying Unexercised Options At December 31, 2003		Value of in-the-Money Options At December 31, 2003 (1)	
	Exercisable	Unexercisable	Exercisable	Unexercisable
Nicholas J. Virca	1,290,000	375,000	\$1,109,400	\$322,500
Evan Levine	250,000	-	215,000	-
Steven M. Plumb	37,500	62,500	32,250	53,750
Joan M. Robbins	100,000	200,000	86,000	172,000

(1) Value based on the closing price of Common Stock of \$0.86 on December 31, 2003, less the option exercise price.

Long-Term Incentive Plans

The Company does not have a long-term incentive plan and no shares or other rights were awarded to any executive officer or Director of the Company under any long-term incentive plan during the fiscal year ended December 31, 2003.

Compensation of Directors

Michael Goldberg, Mark Pykett and Mark Bagnall, as members of our Board of Directors, each receives a quarterly payment of \$5,000 in consideration of such member's services as a director. In addition the Company has issued options to purchase shares of Common Stock to directors as compensation for their services as directors.

Employment Contracts

The Company and Steven M. Plumb, P.C., a professional corporation wholly-owned by Steven M. Plumb, CPA (the "Plumb Company"), entered into a letter agreement dated January 20, 2003, retroactively effective as of January 1, 2003, pursuant to which the Company agreed to pay the Plumb Company a monthly fee of \$5,000 for up to 30 hours of Mr. Plumb's services each month. Any additional services in a given month will be billed at the rate of \$165 per hour. The Plumb Company agreed that Mr. Plumb would provide services to the Company as the Company's Chief Financial Officer. The letter agreement with the Plumb Company has a term of one year that will automatically renew for additional one-year terms unless either the Company or the Plumb Company gives notice to the other party at least 60 days prior to the end of then-current term of such party's termination of the letter agreement.

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

The following table sets forth certain information as of February 29, 2004, concerning the ownership of Common Stock by (i) each stockholder of the Company known by the Company to be the beneficial owner of more than 5% of the outstanding shares of Common Stock or Preferred Stock, (ii) each current member of the Board of Directors of the Company and (iii) each executive officer of the Company named in the Summary Compensation Table appearing under "Executive Compensation" above.

Beneficial ownership is determined in accordance with Rule 13d-3 of the Securities Exchange Act of 1934, as amended, and includes all shares over which the beneficial owner exercises voting or investment power. Options and warrants to purchase Common Stock or Preferred Stock of the Company that are presently exercisable or exercisable within 60 days of February 29, 2004 and shares of Preferred Stock of the Company that are presently convertible or convertible within 60 days of February 29, 2004 that are held by the persons listed below are included in the total number of shares beneficially owned for such person and are considered outstanding for the purpose of calculating the percentage ownership of such holder. The Company has relied on information supplied by its officers, directors and certain stockholders and on information contained in filings with the SEC in completing the table below. Except as otherwise indicated, and subject to community property laws where applicable, we believe, based on information provided by these persons, that the persons named in the table have sole voting and investment power with respect to all shares of Common Stock or Preferred Stock of the Company shown as beneficially owned by them.

Title or Class	Name and Address of Beneficial Owner (1)	Amount and Nature of Beneficial Ownership as of February 29, 2004	Percent of Class (2)
Common Stock	Mark Capital LLC 300 Felton Drive Menlo Park, CA 94025	4,194,399	9.40%
Common Stock	Matthew Balk (3) 570 Lexington Ave. New York, NY 10022	3,945,624	8.74%
Preferred Stock	Emisphere Technologies, Inc. (6)	200,000	99.76%
Current Directors			
Common Stock	Nicholas J. Virca	1,762,956	3.95%
Common Stock	M. Ross Johnson, Ph.D.	1,215,064	2.72%
Common Stock	Evan M. Levine (4)	4,624,399	10.36%
Common Stock	Mark Pykett	4,500	0.01%
Executive Officers who are not Directors			
Common Stock	Steven M Plumb, CPA	62,500	0.14%
Common Stock	Joan M. Robbins, Ph.D.(5)	362,500	0.81%

- (1) Unless indicated otherwise, the address of each person listed in the table is c/o ADVENTRX Pharmaceuticals, Inc.; 9948 Hibert Street, Suite 100; San Diego, California 92131
- (2) The percentage of beneficial ownership of Common Stock is based on 42,491,708 shares of Common Stock outstanding as of February 29, 2004 and excludes all shares of Common Stock issuable upon the exercise of outstanding options or warrants to purchase Common Stock or conversion of any outstanding preferred stock of the Company, other than the shares of Common Stock issuable upon the exercise of options or warrants to purchase Common Stock held by the named person to the extent such options or warrants are exercisable within 60 days of February 29, 2004. The percentage of beneficial ownership of preferred stock of the Company is based on 200,473 shares of preferred stock of the Company outstanding as of February 29, 2004.
- (3) Includes 250,763 shares of Common Stock held by Mr. Balk's wife; 400,000 shares of Common Stock held by Mr. Balk's wife's retirement plan; 703,650 shares of Common Stock held by Mr. Balk as custodian for his two children; and 200,000 shares of Common Stock held by Mr. Balk's retirement plan.
- (4) Includes 4,194,399 shares of Common Stock held by Mark Capital LLC. Mr. Levine is the managing member of Mark Capital LLC.
- (5) Dr. Robbins is deemed to be the beneficial holder of 125,000 shares of Common Stock held by her husband.
- (6) In March 2004, Emisphere Technologies, Inc. converted its 200,000 shares of Series B Convertible Preferred Stock into 200,000 shares of Common Stock.

Item 12. Certain Relationships and Related Transactions.

In October 2002, (a) Dr. Ross Johnson, the Company's Chairman of the Board, purchased 6,000 shares of Series C Preferred Stock for \$60,000 in cash; (b) Matthew Balk, a beneficial owner of more than 5% of the outstanding shares of Common Stock, and entities related to or under the control of Matthew Balk purchased an aggregate of 15,600 shares of Series C Preferred Stock for \$106,000 cash and cancellation of \$50,000 of indebtedness; and (c) Evan Levine, the Company's Chief Operating Officer and a member of the Board of Directors of the Company, purchased 20,000 shares of Series C Preferred Stock for \$100,000 in cash and cancellation of \$100,000 of indebtedness pursuant to the terms of the Series C Convertible Preferred Stock Purchase Agreement, dated September 27, 2002, among the Company and the purchasers of Series C Preferred Stock (the "Series C Purchase Agreement"). Prior to the foregoing purchases of shares of Series C Preferred Stock, neither Dr. Johnson, Mr. Balk nor Mr. Levine were either officers, directors or the beneficial holders of more than 10% of the outstanding shares of Common Stock. Dr. Johnson, however, had been a member of the Board of Directors of Biokeys, Inc., our then wholly-owned subsidiary, at that time. In connection with the foregoing purchases of shares of Series C Preferred Stock and pursuant to the terms of the Series C Purchase Agreement, Dr. Johnson was appointed as Chairman of the Board of the Company and Mr. Levine was appointed as a member of the Board of Directors of the Company. Mr. Levine was also appointed to serve the Company as its Chief Operating Officer in October 2002.

Item 13. Exhibits and Reports on Form 8-K.

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 on pages F-1 through F-17 of this report are filed as part of this report.

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Report of J.H. Cohn LLP	F-1
Consolidated Balance Sheets	F-2
Consolidated Statements of Operations	F-3
Consolidated Statements of Stockholders' Equity (Deficit)	F-4/5
Consolidated Statements of Cash Flows	F-6
Notes to Consolidated Financial Statements	F-7

Exhibits.

Exhibit Number	Description
2.1*	Agreement and Plan of Merger dated May 19, 2000 among BioQuest, Inc.; BioQuest Acquisition Corp.; and Biokeys, Inc.
3.1*	Certificate of Amendment of Certificate of Incorporation of BioQuest, Inc.
3.2*	Certificate of Amendment of Certificate of Incorporation of BioQuest, Inc.
3.3*	Certificate of Merger of BioQuest Acquisition Corp. into Biokeys, Inc.
3.4*	Certificate of Incorporation of BioQuest Acquisition Corp.
3.6*	Amended and Restated Bylaws of Biokeys Pharmaceuticals, Inc.
4.1*	Certificate of Designation of BioQuest, Inc.
4.2	Certificate of Designation of Series B Convertible Preferred Stock and Series C Convertible Preferred Stock of Biokeys Pharmaceuticals, Inc. effective September 23, 2002

- 10.1** Patent and Technology License Agreement with M.D. Anderson - June, 1996 (Request for confidential treatment of certain data)
- 10.2** Amendment to M.D. Anderson Licensing Agreement June 15, 2000 (Request for confidential treatment of certain data)
- 10.3** Option and License Agreement with USC - June 23, 1998 (Co Factor and Selone) (Request for confidential treatment of certain data)
- 10.4* Amendment to Option and License Agreement with USC dated August 16, 2000 (Co Factor and Selone) (Request for confidential treatment of certain data)
- 10.5** Option and License Agreement with USC dated August 17, 2000 (Thiovir) (Request for confidential treatment of certain data)
- 10.6 Not currently in use
- 10.7*** Patent License Agreement, effective August 1, 2002, between Biokeys, Inc. and the National Institutes of Health
- 10.8 Letter Agreement, effective January 1, 2003, between Biokeys Pharmaceuticals, Inc. and Steven M. Plumb, P.C.
- 10.9 Offer Letter, dated March 5, 2003, from Biokeys Pharmaceuticals, Inc. to Joan M. Robbins, Ph.D.
- 11.1* Statement Regarding Computation of Per Share Earnings
- 21.1 Subsidiaries of Biokeys Pharmaceuticals, Inc. as of December 31, 2002
- 24.1* Powers of Attorney (included on signature pages)
- 31.1 Certificate Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certificate Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32 Certificate Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350

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

** Incorporated by reference to the same-numbered exhibit to the Company's Registration Statement on Form 10-SB/A, filed January 11, 2002.

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

Reports on Form 8-K.

On February 10, 2003, we filed a current report on Form 8-K to report a change in independent accountants.

Item 14. Principal Accountant Fees and Services.

Audit Fees.

The aggregate fees billed for professional services rendered by J.H. Cohn LLP and KPMG, LLP for the audit of our annual financial statements and review of financial statements included in our Forms 10-QSB for fiscal years 2003 and 2002 are set forth in the table below.

	2003	2002
J.H. Cohn LLP	\$50,386	-
KPMG, LLP	-	\$158,000

Audit-Related Fees.

During the fiscal years ended December 31, 2003 and 2002, no assurance or related services were performed by either J.H. Cohn LLP or KPMG, LLP that were reasonably related to the performance of the audit or review of our financial statements.

Tax Fees.

During the fiscal years ended December 31, 2003 and 2002, no fees were billed by either J.H. Cohn LLP or KPMG, LLP for tax compliance, tax advice or tax planning services.

All Other Fees.

During the fiscal years ended December 31, 2003 and 2002, no fees were billed by either J.H. Cohn LLP or KPMG, LLP other than the fees set forth under the caption "Audit Fees" 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.

ADVENTRX Pharmaceuticals, Inc.
Index to Consolidated Financial Statements

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Report of Independent Public Accountants

To the Board of Directors
ADVENTRX Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheet of ADVENTRX Pharmaceuticals, Inc. and Subsidiary (a development stage enterprise) as of December 31, 2003 and 2002, and the related consolidated statements of operations, shareholders' equity (deficit) and cash flows for the years then ended and for the period from June 12, 1996 (date of inception) through December 31, 2003. 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) through 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 (deficit) and cash flows for the period from June 12, 1996 (date of inception) through December 31, 2003, insofar as it relates to amounts for the period for June 12, 1996 (date of inception) through December 31, 2001, is based solely on the report of the other auditors.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. 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 and the reports of other auditors 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, 2003 and 2002, and their results of operations and cash flows for the years then ended and for the period from June 12, 1996 (date of inception) through December 31, 2003, in conformity with accounting principles generally accepted in the United States of America.

/s/J. H. COHN LLP

San Diego, California
February 13, 2004

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

	December 31, 2003	December 31 2002
Assets		
Current assets:		
Cash and cash equivalents	\$ 4,226,397	\$ 103,928
Prepaid insurance	28,376	—
Total current assets	4,254,773	103,928
Property and equipment, net	20,840	13,434
Other assets	7,743	12,983
Total assets	4,283,356	130,345
Liabilities and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable and accrued liabilities	90,243	579,146
Accrued salary and related taxes	—	115,021
Accrued dividends payable	72,800	34,960
Current portion of notes payable	—	197,075
Total current liabilities	163,043	926,202
Notes payable, net of current portion	—	56,873
Total liabilities	163,043	983,075
Commitments and contingencies		
Shareholders' equity / (deficit):		
Series A cumulative convertible preferred stock, \$0.01 par value; Authorized 8,000 shares; issued and outstanding, 473 shares (aggregate involuntary liquidation preference \$473,000 at December 31, 2003 and 2002)	4	4
Series B convertible preferred series stock, \$0.01 par value; Authorized 200,000 shares; issued and outstanding, 200,000 shares (no liquidation preference)	2,000	2,000
Series C convertible preferred stock, \$0.01 par value; Authorized 125,000 shares; issued and outstanding, 70,109 shares at December 31, 2002	—	701
Common stock, \$0.001 par value; Authorized 100,000,000 shares; issued and outstanding 42,491,708 in 2003 and 17,496,275 shares in 2002	42,492	17,496
Additional paid-in capital	32,556,963	25,276,138
Deficit accumulated during the development stage	(28,481,146)	(26,149,069)
Total shareholders' equity / (deficit)	4,120,313	(852,730)
Total liabilities and shareholders' equity / (deficit)	4,283,356	130,345

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,
	2003	2002	2003
Net sales	\$ —	\$ —	\$ 174,830
Cost of goods sold	—	—	51,094
Gross margin	—	—	123,736
Grant revenue	3,603	45,792	129,733
Interest income	9,269	1,272	99,236
	<u>12,872</u>	<u>47,064</u>	<u>352,705</u>
Operating expenses:			
Research and development	748,997	282,966	4,729,926
General and administrative	1,585,596	1,388,020	8,414,844
Depreciation and amortization	8,970	428,109	10,098,707
Impairment loss - write off of goodwill	—	—	5,702,130
Interest expense	1,386	53,696	179,090
Equity in loss of investee	—	—	178,936
Total operating expenses	2,344,949	2,152,791	29,303,633
Loss before cumulative effect of change in accounting principal	(2,332,077)	(2,105,727)	(28,950,928)
Cumulative effect of change in accounting principal	—	—	(25,821)
Net loss	(2,332,077)	(2,105,727)	(28,976,749)
Preferred stock dividends	(37,840)	(242,200)	(621,240)
Net loss applicable to common stock	\$ (2,369,917)	\$ (2,347,927)	\$ (29,597,989)
Loss per common share - basic and diluted	\$ (0.07)	\$ (0.15)	

ADVENTRX PHARMACEUTICALS, INC. AND SUBSIDIARY

(A Development Stage Enterprise)

Consolidated Statements of Shareholders' Equity (Deficit)

Inception (June 12, 1996) through December 31, 2003

	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	—	—	—	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	—	—	—	—	—	—
Detachable warrants issued with notes payable	—	—	—	—	—	—
Issuance of warrants to pay operating expenses	—	—	—	—	—	—
Issuance of common stock to pay operating expenses	137	1	—	—	—	—
Issuance of preferred stock to pay operating expense	—	—	—	—	—	—
Net loss	3,337	33	—	—	—	—
Balances at December 31, 2001	—	—	—	—	—	—
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	—	—	—	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	—	\$ —

ADVENTRX PHARMACEUTICALS, INC. AND SUBSIDIARY

(A Development Stage Enterprise)

Consolidated Statements of Shareholders' Equity (Deficit)

Inception (June 12, 1996) through December 31, 2003

CONTINUED FROM PREVIOUS PAGE

	Common Stock		Additional paid-in capital	Deficit accumulated during the development stage	Total stockholders' equity (deficit)
	Shares	Amount	Capital		
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)	—	—
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	—	—	998,392	—	1,001,093
Sale of preferred stock at \$10.00 per share	—	—	298,000	—	—
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)	—	—
Issuance of common stock to pay interest on Bridge Notes	165,830	165	53,326	—	53,491
Sale of common stock at \$0.40 per share, net of issuance costs	6,640,737	6,676	2,590,656	—	6,590,182
Sale of common stock at \$1.00 per share, net of issuance costs	3,701,733	3,668	3,989,131	—	49,721
Exchange of warrants	235,291	235	49,486	—	206,799
Issuance of common stock to pay operating expenses (note 6)	230,000	230	206,569	—	156,734
Issuance of warrants to pay operating expenses (note 6)	—	—	156,735	—	286,033
Issuance of stock options to employees (note 6)	—	—	286,033	—	(2,332,077)
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

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,
	2003	2002	2003
Cash flows from operating activities:			
Net loss	\$ (2,332,077)	\$ (2,105,727)	\$(28,976,749)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	8,970	32,548	9,648,707
Amortization of debt discount	–	395,561	450,000
Forgiveness of employee advance	–	30,036	30,036
Impairment loss – write off of goodwill	–	–	5,702,130
Expenses paid by warrants	156,735	163,109	486,982
Expenses paid by preferred stock	–	6,001	142,501
Expenses related to stock warrants issued	–	–	612,000
Expenses related to employee stock options issued	286,033	329,296	615,329
Expenses paid by issuance of common stock	206,799	12,269	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 assets	(28,376)	–	(28,376)
(Increase) decrease in other assets	5,240	(9,094)	(147,111)
Increase (decrease) in accounts payable and accrued liabilities	(550,433)	44,062	(431,028)
Increase in sponsored research payable and license obligation	–	–	924,318
Net cash used in operating activities	(2,247,109)	(1,101,939)	(9,796,090)
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	(16,376)	(2,370)	(122,469)
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	–	35,993	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	(16,376)	33,623	326,557
Cash flows from financing activities:			
Proceeds from sale of preferred stock	–	1,001,093	4,200,993
Proceeds from sale of common stock	6,590,181	–	8,526,146
Proceeds from sale or exercise of warrants	49,721	286,675	384,237
Repurchase of warrants	–	–	(55,279)
Payment of financing and offering costs	–	–	(98,976)
Payments of notes payable and long-term debt	(253,948)	(280,000)	(605,909)
Proceeds from issuance of notes payable and detachable warrants	–	–	1,344,718
Net cash provided by financing activities	6,385,954	1,007,768	13,695,930
Net increase (decrease) in cash and cash equivalents	4,122,469	(60,548)	4,226,397
Cash and cash equivalents at beginning of period	103,928	164,476	–
Cash and cash equivalents at end of period	\$ 4,226,397	\$ 103,928	\$ 4,226,397

See accompanying notes to consolidated financial statements.

(1) Description of the Company

ADVENTRX Pharmaceuticals, Inc., a Delaware corporation, (the Company), is a development stage enterprise, that conducts biomedical research and development focused on treatments for cancer and certain viral infections, including HIV. The Company currently does not manufacture, market, sell or distribute any product. Through its 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 its 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.

(2) Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the 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. Series A 8% convertible preferred stock is valued at the liquidation value of \$1,000 per share. Series B preferred stock is valued at the purchase price of \$1 per share.

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 fair value of notes payable at the date of issuance and at December 31, 2003 and 2002 was not determinable.

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, 2003, cash and cash equivalents with banks exceeded federally insured limits by approximately \$4,258,000.

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.

Deferred Financing Costs

Costs associated with arranging debt financing are deferred and amortized using the effective interest method over the terms of the notes payable.

Debt Discount

The discount on notes payable is being amortized using the effective interest method through the stated due dates of each note.

Revenue Recognition

The Company recognizes revenue at the time service is performed on commercial contracts and collectability 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.

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 \$1,386 and \$7,425 was paid during the years ended December 31, 2003 and 2002, respectively. No income taxes were paid during 2003 and 2002.

Noncash investing and financing transactions excluded from the consolidated statements of cash flows for the years ended December 31, 2003 and 2002 and for the period from Inception (June 12, 1996) through December 31, 2003 are as follows:

	2003	2002	Inception (June 12, 1996) through December 31, 2003
Issuance of warrants, common stock and preferred stock for:			
Conversion of notes payable and accrued interest	\$ 53,491	\$ 220,000	\$ 1,213,988
Payment of operating expenses	—	181,372	1,224,281
Conversion of preferred stock	701,093	—	701,093
Acquisitions	—	—	14,617,603
Payment of dividends	—	—	213,000
Assumptions of liabilities in acquisitions	—	—	1,009,567
Acquisition of license agreement for long-term debt			161,180
Cashless exercise of warrants	2,360	100	3,278
Dividends accrued	37,840	242,200	621,040
Dividends forgiven	—	335,440	335,440
Trade payable converted to note payable	—	83,948	83,948
Issuance of warrants for return of common stock	0,852	—	50,852
Detachable warrants issued with notes payable	—	—	450,000

New Accounting Pronouncements

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

In May 2003, the FASB issued Statement of Financial Accounting Standards No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* (SFAS No. 150), which establishes standards for how a company classifies and measures certain financial instruments with characteristics of both liabilities and equity. SFAS No. 150 is generally effective for interim periods beginning after June 15, 2003.

The adoption of these new pronouncements did not have, or are not expected to have, a material effect on the Company's consolidated financial position or results of operations.

(3) **Property and Equipment**

Property and equipment at December 31, 2003 and December 31, 2002 were as follows:

	Useful lives	2003	2002
Office furniture and equipment	5 years	\$ 48,259	\$ 31,883
Computer software and equipment	3 years	11,845	11,845
		60,104	43,728
Less accumulated depreciation and amortization		(39,264)	(30,294)
		\$ 20,840	\$ 13,434

(4) **Notes Payable**

In October and December 2001, the Company issued notes payable totaling \$300,000 and \$150,000, respectively. The notes bore interest at 12% and were originally due on the earlier of November 1, 2002 or the date of receipt by the Company of gross proceeds of at least \$600,000 from private placement offerings. Interest accrued at 12% annually and was paid in shares of common stock when the notes were repaid, based on the five-day average closing price of common stock preceding the date when interest was paid. The notes were issued with detachable warrants to purchase a total of 450,000 shares of common stock through November 2006 at an exercise price of \$4.00 per share through December 31, 2002, and thereafter at an exercise price that will be fixed at the higher of \$2.50 or the average closing price of the Company's common stock during the 20 trading days prior to December 31, 2002, not to exceed \$4.00 per share.

The entire proceeds of \$450,000 were allocated to the warrants and debt discount. The fair value of the warrants, calculated using the Black-Scholes pricing model, was greater than the proceeds. The fair value of the notes payable was not determinable at the dates of issuance.

Between October and December 2002, some of the notes and warrants were amended and \$220,000 in notes were converted to Series C preferred stock of the Company. \$60,000 in notes were repaid and the due date of the \$170,000 in remaining notes were extended to April 1, 2003. The exercise price of nine warrants to purchase an aggregate of 420,000 shares of common stock was amended to \$.50 per share. The outstanding balance on the notes was \$170,000 at December 31, 2002. The notes were repaid in full in April 2003.

In April 2003, the Company converted a trade payable into a note payable in the amount of \$83,948. The note carried interest at 10% per year and called for eighteen monthly payments of \$5,000 per month beginning July 1, 2003. The trade payable was reclassified as of December 31, 2002 with current and long term portions of \$27,075 and \$56,873. The note was repaid in full in June 2003.

(5) **Income Taxes**

Components of income tax expense for the years ended December 31, 2003 and 2002 are as follows:

	2003	2002
Deferred tax asset	\$ 637,283	\$ 601,110
Increase in valuation allowance for deferred tax assets	(637,283)	(601,110)
Income tax expense	\$ —	\$ —

The tax effects of temporary differences that give rise to deferred tax assets at December 31, 2003 and December 31, 2002 are as follows:

	2003	2002
Net operating loss carryforwards	\$ 4,691,417	\$ 4,051,425
Organization costs and license agreement, due to differences in amortization	27,825	30,534
Total deferred tax assets	4,719,242	4,081,959
Less valuation allowance	(4,719,242)	(4,081,959)
Net deferred tax assets	\$ —	\$ —

At December 31, 2003, the Company had unused net operating loss carryforwards of approximately \$13,800,000 for tax reporting purposes, which expire from 2012 through 2014 and from 2019 through 2023.

(6) Equity Transactions

In February 2002, the Company issued 200,000 shares of Series B Preferred Stock at \$1.50 per share for proceeds of \$300,000. The par value of the Series B Preferred Stock is \$0.01 and there is no liquidation preference.

In March 2002, the Company transferred warrants which had previously been held in escrow to three investors who immediately exercised the warrants for the purchase of a total of 229,573 shares of common stock at \$0.49 per share for \$112,491 in proceeds to the Company.

In April 2002, warrants to purchase a total of 240,000 shares of common stock at \$0.49 per share were exercised for \$117,853 in proceeds to the Company.

In June 2002, a warrant holder exercised warrants through a cashless exercise. Warrants to purchase a total of 144,435 shares of common stock were exchanged for a total of 100,201 shares of common stock.

In July 2002, warrants to purchase a total of 115,000 shares of common stock at \$0.49 per share were exercised for \$56,331 in proceeds to the Company.

In October and December 2002, the Company issued an aggregate of 70,109.3 shares of Series C Convertible Preferred Stock with a par value of \$0.01 per share. The Series C preferred stock is convertible into common stock at \$0.05 per share and has a liquidation preference of \$10 per share plus accrued and unpaid dividends. The purchase price of 22,000 shares of Series C preferred stock was paid by the conversion of \$220,000 of notes payable. In addition, warrants that were issued in conjunction with the converted notes payable were amended to modify the purchase price of the common stock to \$0.50 per share.

On November 21, 2002, the Company exchanged 3,000 shares of Series A preferred stock for 1,800,000 shares of common stock. In conjunction with this transaction the Company purchased 375,000 warrants from the preferred stockholder for \$100. In conjunction with the exchange, accumulated preferred dividends in the amount of \$335,440, which had been accrued through the date of the exchange, were extinguished upon conversion.

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 share of common stock at \$0.40 per share to private 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 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 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 \$0.10 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.

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 2003 and 2002: no dividend yield for either year; expected volatility of 125% to 199%; risk-free interest rates 2.78% to 6.8%; and expected lives of three and seven years, respectively.

At December 31, 2003, there were outstanding warrants to purchase a total of 5,474,987 shares of common stock as follows:

Warrants	Exercise price	Expiration date
620,622	\$0.49	September 2005
440,000	0.50	October 2005
110,000	0.50	March 2006
100,000	3.00	April 2006
2,094,287	0.60	May 2006
502,528	0.49	June 2006
914,175	1.25	October 2006
150,000	0.50	December 2006
543,375	1.25	December 2006

(7) Stock Compensation Plans

In October 2002, the Company granted three non-statutory stock options to purchase an aggregate of 1,525,000 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 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 its 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 were 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.

The Company recognized compensation expense of \$286,033 in the year ended December 31, 2003, related to the portion of the options which vested in that period.

	December 31, 2003		December 31, 2002	
<u>Non-statutory Stock Options</u>	Shares (000)	Weighted- Average Exercise Price	Shares (000)	Weighted Average Exercise Price
Outstanding at beginning of period	1,690	\$0.23	—	—
Granted	2,040	\$0.58	1,690	\$0.23
Exercised	—	—	—	—
Forfeited	(750)	\$0.50	—	—
Outstanding at end of period	2,980	\$0.38	1,690	\$0.23
Options exercisable at year end	1,808		1,177	
Weighted-average fair value of options granted during the year		\$0.54		\$0.19

Options Outstanding			Options Exercisable		
Range of Exercise Price	Number Outstanding at 12/31/03	Weighted Average Remaining Contractual Life	Weighted- Average Exercise Price	Number Exercisable at 12/31/03	Weighted- Average Exercise Price
\$0.20 to \$1.25	2,980,000	5.0 years	\$.382	1,808,300	\$.319

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
1,012,500	\$ 0.20	October 2002
165,000	0.50	October 2002
100,000	0.50	March 2003
137,500	0.50	April 2003
62,500	0.20	July 2003
179,167	0.50	July 2003
11,250	1.25	July 2003
62,500	0.20	October 2003
54,167	0.50	October 2003
11,250	1.25	October 2003
12,500	0.20	December 2003
62,500	0.20	January 2004
54,167	0.50	January 2004
11,250	1.25	January 2004
62,500	0.20	April 2004
154,167	0.50	April 2004
11,250	1.25	April 2004
62,500	0.20	July 2004
54,167	0.50	July 2004
11,250	1.25	July 2004
62,500	0.20	October 2004
54,167	0.50	October 2004
11,250	1.25	October 2004
25,000	1.25	November 2004
62,500	0.20	January 2005
54,167	0.50	January 2005
11,250	1.25	January 2005

Options	Exercise price	Vesting date
62,500	0.20	April 2005
141,667	0.50	April 2005
11,250	1.25	April 2005
41,667	0.50	July 2005
41,667	0.50	October 2005
25,000	1.25	November 2005
41,667	0.50	January 2006
41,663	0.50	April 2006

(8) Net Loss per Common Share

The computation of basic and diluted net loss per share for the years ended December 31, 2003 and 2002 is as follows:

	2003	2002
Numerator:		
Net loss	\$ (2,332,077)	\$ (2,105,727)
Preferred stock dividends	(37,840)	(242,400)
Numerator for basic and diluted loss per share		
	\$ (2,369,917)	\$ (2,348,127)
Denominator for basic and diluted loss per share – weighted average common shares outstanding		
	31,797,986	15,681,743
Loss per common share—basic and diluted		
	\$ (0.07)	\$ (0.15)

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. At December 31, 2003 and 2002, 4,462,473 and 2,827,238 potentially dilutive shares, respectively, 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 incurred in 2003 and 2002.

(9) 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, 2003 and 2002, respectively. The M.D. Anderson License Agreement continues in effect until all patent rights have expired.

USC

Under an Option and License Agreement with USC dated January 23, 1998, amended August 16, 2000, Biokeys acquired license rights to a total of three patents, two relating to Biokeys' 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, Biokeys acquired rights under four patents related to its Thiovir antiviral technologies. These agreements with USC (the USC License Agreements) grant Biokeys exclusive worldwide licenses to study, use, manufacture and market drug products covered by the subject patents. Under the USC License Agreements, Biokeys 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 Biokeys 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.

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 its 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 US and for first approval in Europe.

(10) Commitments and Contingencies

Employment Contracts

Effective January 1, 2003, the Company entered into a letter agreement with its Chief Financial Officer to retain his services for a period of one year at a monthly cost of \$5,000. The letter agreement will automatically renew for additional one-year terms unless either the Company or the Chief Financial Officer gives notice to the other party at least 60 days prior to the end of the then current term of such party's termination of the letter agreement.

Effective April 1, 2003, the Company entered into a contract to retain the services of a Chief Technical Officer to oversee the Company's research and development efforts and FDA trials at an annual salary of \$170,000 per year, plus benefits.

Effective July 1, 2003, the Company retained a Chief Operating Officer at an annual salary of \$170,000.

On July 1, 2003, the Company formed a Scientific Advisory Board (the SAB). Members of the SAB have been granted options to purchase 30,000 shares of the Company's common stock at a purchase price of \$1.25 per share. The options vest over the subsequent eight quarters, beginning July 1, 2003, and expire on December 30, 2008. The value of the options on the date of grant, July 1, 2003, is \$97,086 and is expensed over the terms of the agreements.

Operating Leases

The Company is obligated under operating leases for office space and equipment. In February 2001, the Company leased office space in San Diego, California. The lease requires a monthly payment of \$3,038 and expires in July 2004. Rent expense was \$40,648 and \$57,996 during the years ended December 31, 2003 and 2002, respectively.

Future rental commitments under all operating leases amounts to \$18,941 in 2004.

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. Management is not aware of any 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.

(11) Subsequent Events

In January and February 2004, the Company appointed three new independent members to the board of directors. Each director was granted options to purchase 50,000 shares of the Company's 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 is \$223,826.

In February 2004, the Company added a member to the SAB. The new member was granted an option to purchase 30,000 shares of the Company's common stock at a purchase price of \$1.50 per share. The option will vest in equal installments over the next eight quarters, starting March 1, 2004. The option will expire on December 30, 2008. The value of the option on the date of grant is \$45,350.

ADVENTRX Pharmaceuticals, Inc.
CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Nicholas Jon Virca, Chief Executive Officer of ADVENTRX Pharmaceuticals, Inc. certify that:

1. I have reviewed this annual report on Form 10-KSB of ADVENTRX Pharmaceuticals, Inc.
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this annual report is being prepared;
 - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;
 - c) Disclosed in this annual report any change in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The Registrant's other certifying officer and I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 26, 2004

By: /s/ Nicholas Jon Virca
Nicholas Jon Virca
Chief Executive Officer

ADVENTRX Pharmaceuticals, Inc.
CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Steven M. Plumb, CPA, Chief Financial Officer of ADVENTRX Pharmaceuticals, Inc. certify that:

1. I have reviewed this annual report on Form 10-KSB of ADVENTRX Pharmaceuticals, Inc.
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this annual report is being prepared;
 - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation;
 - c) Disclosed in this annual report any change in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The Registrant's other certifying officer and I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 26, 2004

By: /s/ Steven M. Plumb
Steven M. Plumb
Chief Financial Officer

CERTIFICATION OF CEO AND CFO PURSUANT TO
18 U.S.C. Section 1350,
AS ADOPTED PURSUANT TO
Section 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-KSB of ADVENTRX Pharmaceuticals, Inc. (the "Company") for the fiscal year ended December 31, 2003 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of Nicholas J. Virca, Chief Executive Officer of the Company, and Steven M. Plumb, CPA, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Nicholas J. Virca
Nicholas J. Virca
Chief Executive Officer
March 26, 2004

/s/ Steven M. Plumb
Steven M. Plumb, CPA
Chief Financial Officer

March 26, 2004

This certification accompanies this Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, or otherwise required, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.