

ADVENTRX PHARMACEUTICALS INC

Form 10-K

March 16, 2006

**Table of Contents**

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549  
FORM 10-K**

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

**For the fiscal year ended December 31, 2005**

**OR**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission File No. 1-15803**

**ADVENTRX PHARMACEUTICALS, INC**

*(Exact name of registrant as specified in its charter)*

**Delaware**

*(State or other jurisdiction of incorporation or  
organization)*

**84-1318182**

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

**6725 Mesa Ridge Road, Ste 100 San Diego CA**

*(Address of principal executive offices)*

**92121**

*(Zip Code)*

**(858) 552-0866**

*(Registrant's telephone number, including area code)*

Securities registered pursuant to Section 12(b) of the Act:

Common Stock, par value \$0.001 per share

Securities registered pursuant to Section 12(g) of the Act:

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

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

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

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

Large accelerated filer  Accelerated filer  Non-accelerated filer

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2005 was approximately \$106,604,071, based upon the closing price on the American Stock Exchange reported for such date. Shares of common stock held by each officer and director and by each person who is known to own 5% or more of the outstanding Common Stock have been excluded in that such persons may be deemed to be affiliates of the Company. This determination of affiliate status is not necessarily a conclusive determination for other

purposes.

68,796,978 shares of the registrant's Common Stock were issued and outstanding as of March 13, 2006.

**DOCUMENTS INCORPORATED BY REFERENCE**

Certain information required to be disclosed in Part III of this report is incorporated by reference from the registrant's definitive Proxy Statement, which will be filed with the Securities and Exchange Commission in connection with the registrant's Annual Meeting of Shareholders to be held on May 15, 2006.

---

**Table of Contents**

	<b>Page</b>
<u>PART</u>	
<u>I</u>	1
<u>Item</u>	
<u>1. Business</u>	1
<u>Item</u>	
<u>1A. Risk Factors</u>	13
<u>Item</u>	
<u>1B. Unresolved Staff Comments</u>	19
<u>Item</u>	
<u>2. Properties</u>	20
<u>Item</u>	
<u>3. Legal Proceedings</u>	20
<u>Item</u>	
<u>4. Submission of Matters to a Vote of Security Holders</u>	20
<u>PART</u>	
<u>II</u>	21
<u>Item</u>	
<u>5. Market For Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	21
<u>Item</u>	
<u>6. Selected Financial Data</u>	22
<u>Item</u>	
<u>7. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	23
<u>Item</u>	
<u>7A. Quantitative and Qualitative Disclosures About Market Risk</u>	27
<u>Item</u>	
<u>8. Financial Statements and Supplementary Data</u>	27
<u>Item</u>	
<u>9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	27
<u>Item</u>	
<u>9A. Controls and Procedures</u>	27
<u>Item</u>	
<u>9B. Other Information</u>	28
<u>PART</u>	
<u>III</u>	
<u>Item</u>	
<u>10. Directors and Executive Officers of the Registrant</u>	28
<u>Item</u>	
<u>11. Executive Compensation</u>	28
<u>Item</u>	
<u>12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	28
<u>Item</u>	
<u>13. Certain Relationships and Related Transactions</u>	29
<u>Item</u>	
<u>14. Principal Accountant Fees and Services</u>	29
<u>PART</u>	
<u>IV</u>	30

Item

15. Exhibits, Financial Statements and Schedules  
SIGNATURES

30  
31

EXHIBIT INDEX

EXHIBIT 3.1  
EXHIBIT 10.10  
EXHIBIT 10.11  
EXHIBIT 10.13  
EXHIBIT 10.17  
EXHIBIT 10.19  
EXHIBIT 21.1  
EXHIBIT 23.1  
EXHIBIT 31.1  
EXHIBIT 31.2  
EXHIBIT 32.1  
EXHIBIT 32.2

---

**Table of Contents**

**PART I**

**Forward-Looking Statements**

*This Annual Report on Form 10-K 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 I, Item 1A, Business Risk Factors, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates 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.*

**ITEM 1. BUSINESS**

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

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

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

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

CoFactor<sup>®</sup>, Selone<sup>®</sup> and Thiovir<sup>®</sup> are our trademarks, and we have an additional product, vinorelbine emulsion (ANX-530), for which we do not yet have registered trademark. Product names, trade names and trademarks of other entities are also referred to in this report.

**Business of Issuer**

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

**Table of Contents****Principal Products**

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

<b>Product/Description</b>	<b>Development Stage</b>	<b>Indication</b>	<b>Status</b>
<b>CoFactor</b> (ANX-510) 5-FU Biomodulator	Phase II US and Europe	Metastatic Colorectal Cancer	Patient dosing completed. Complete clinical trial results currently expected in 2006.
	Phase IIb Europe and India	Metastatic Colorectal Cancer	Over 50% of patients enrolled. Clinical trial results currently expected in 2007.
	Phase III US	Metastatic Colorectal Cancer	Dosing currently expected to begin in Q2 2006.
<b>Vinorelbine emulsion</b> (ANX-530)	505(b)(2)	Non-small cell lung and other solid tumors	Currently plan to File IND in Q3 2006
<b>Selone</b> Alkylating Agent	Preclinical	Drug Resistant Cancers	Continue preclinical testing in 2006
<b>Thiovir</b> Pyrophosphate Analogue	Preclinical	HIV/AIDS and Avian Influenza	Currently plan to File INDs in Q2 2006
	Preclinical	Herpes	Preclinical testing during 2006.

**CoFactor (ANX-510)**

CoFactor (ANX-510) is a folate-based biomodulator drug being developed to enhance the activity and reduce associated toxicity of the widely used cancer chemotherapeutic agent 5-fluorouracil (5-FU). CoFactor creates more stable binding of the active form of 5-FU, 5-fluorodeoxyuracil monophosphate (FdUMP) to the target enzyme, thymidylate synthase (TS), improving 5-FU performance. We have an exclusive license to use certain patents and other intellectual property related to CoFactor from the University of Southern California which permits us to develop and commercialize CoFactor. We also have additional patents pending.

**Preclinical studies**

We have presented results from preclinical studies using *in vivo* human tumor xenotransplant mouse models for colorectal and pancreatic cancer that demonstrated the antitumor efficacy of CoFactor/5-FU in combination with irinotecan, oxaliplatin, anti-VEGF antibody, and gemcitabine. CoFactor-containing combination regimens induced either equivalent or better antitumor responses, as noted by slower tumor growth and increased mouse survival, compared with leucovorin-containing combinations for all drug types tested. Furthermore, in an *in vivo* immunocompetent mouse model, CoFactor/5-FU induced less systemic toxicity than 5-FU/leucovorin either alone or in combination drug regimens. Lower hematological toxicity was observed including less thrombocytopenia, leukopenia, neutropenia and lymphopenia. Furthermore, weight loss was quantitatively less severe with drug treatments containing CoFactor. For example, while 5-FU/leucovorin/gemcitabine induced greater than 25% weight loss in 91% of mice, significantly less ( $p < 0.05$ , Fisher's exact test) mice treated with 5-FU/CoFactor/gemcitabine (33% of mice) had this level of weight loss. Additional preclinical studies are planned for CoFactor during 2006.

**Phase I/II single site clinical trial in gastrointestinal and breast cancers**

A Phase I/II single-arm clinical trial in 62 patients conducted at a single site in Sweden between November 1989 and March 1993 demonstrated increased clinical benefit, improved time to tumor progression, overall median survival and reduced toxicity in advanced colorectal, pancreatic, stomach and breast cancer patients treated with CoFactor plus 5-FU when compared historically with multiple studies using leucovorin plus 5-FU. In this clinical trial, treatment with CoFactor and 5-FU demonstrated the following rates of clinical benefit, defined as stable disease or tumor response: pancreatic (40%), colorectal (57%), gastric (66%) and breast (89%).



**Table of Contents**

**Phase II multi-center clinical trial in first-line metastatic colorectal cancer**

We are evaluating CoFactor use with 5-FU in a 50-patient Phase II clinical trial for first line treatment of metastatic colorectal cancer at nine sites in the US and Serbia. The Phase II clinical trial is a single-arm, multi-center study to evaluate tumor response as the primary endpoint, and safety, time-to-tumor-progression and overall survival, as secondary endpoints, in patients treated with CoFactor and 5-FU in a weekly bolus regimen. We completed patient enrollment in the first quarter 2005. We reported preliminary Phase II results from an independent radiological assessment that found an overall clinical benefit of 85% and objective response of 35% in metastatic colorectal cancer patients treated with CoFactor and 5-FU. We also reported time to tumor progression (TTP) of 163 days. The response rate and time to tumor progression values from our Phase II clinical trial have surpassed previous published values from multiple institutional studies using Leucovorin and 5-FU, including the registration trials for irinotecan and capecitabine, for which the CoFactor Phase II time to tumor progression was approximately 25% longer. There were no drug-related grade 3 or grade 4 gastrointestinal or hematological toxicities. Median survival has not yet been reached but is expected to be announced during 2006. The study database was closed March 8, 2006 and a final study report is in preparation for submission to the FDA. Long-term follow-up and survival data will continue to be captured and analyzed.

**Phase IIb multi-center clinical trial in first-line metastatic colorectal cancer**

We initiated a multi-national 300-patient Phase IIb randomized controlled clinical trial in the second quarter 2005 using CoFactor in first-line treatment of metastatic colorectal cancer. Patients are being randomized to one of two arms containing either CoFactor or leucovorin, each in combination with infusional 5-FU. We reported in the first quarter 2006 that we had enrolled more than 50% of the total patients in this clinical trial. The trial's primary endpoint is a reduction in the frequency of grade 3 or grade 4 hematological or gastrointestinal toxicities. Secondary endpoints are response rate, time to tumor progression, and survival. We are conducting the study at 30 sites in Europe and India. We currently plan to have initial results from the clinical trial during 2007.

**Phase III multi-center clinical trial in first-line metastatic colorectal cancer**

In the second quarter of 2005, we reported that the FDA granted clearance under a special protocol assessment (SPA) to initiate a 600-patient Phase III pivotal clinical trial using CoFactor in first-line treatment of metastatic colorectal cancer. Patients will be equally randomized to two arms containing either CoFactor or leucovorin, each in combination with 5-FU and bevacizumab (Avastin®). The primary endpoint is progression-free survival. Secondary endpoints include response rate, duration of response, overall survival and incidence and severity of adverse events. In February 2006, following extensive consultations with thought-leading oncologists, we requested certain adjustments with the FDA with respect to certain revisions we would like to make to our protocol for this Phase III clinical trial, including increasing the trial size to 1,200 patients. We previously announced that we would begin dosing patients in this trial in the first quarter of 2006. We now plan to wait until after we receive the response to these adjustments from the FDA and expect that we will begin patient dosing for this clinical trial in the second quarter of 2006.

**Proposed Phase III clinical trial in third-line breast cancer**

In addition to the clinical trials listed above, we announced in the first quarter 2006 that we plan to conduct a Phase III clinical trial in patients with advanced breast cancer who have completed taxane and doxorubicin treatment. Patients would be equally randomized to two arms containing either CoFactor in combination with 5-FU or capecitabine (Xeloda®). We currently anticipate that we would enroll approximately 450 patients in this proposed Phase III clinical trial. This proposed Phase III clinical trial would require clearance regarding the clinical design from the FDA which we have not yet sought. We currently plan to seek clearance from the FDA regarding the clinical design in the fourth quarter 2006 and initiate the clinical trial in 2007.

## **Table of Contents**

### *Vinorelbine emulsion (ANX-530)*

In the fourth quarter 2005 we announced that we obtained an exclusive license of certain rights to ANX-530, a novel emulsion formulation of vinorelbine tartrate. This new formulation emulsifies vinorelbine into a homogeneous suspension of nanoparticles, and is designed to protect the venous endothelium during administration into a peripheral vein, and therefore reduce associated vein irritation caused by the drug. Vinorelbine is a chemotherapeutic agent indicated as a single agent or in combination with cisplatin for treatment of advanced non-small cell lung cancer (NSCLC).

### Preclinical studies

In preclinical testing, ANX-530 demonstrated markedly reduced vein irritation following repeated IV injections compared with Navelbine<sup>®</sup>, GlaxoSmithKline's FDA-approved form of vinorelbine. Vein irritation was examined in rabbits following repeated IV injections in the marginal ear vein. In parallel studies in rodents ANX-530 demonstrated comparable efficiency to Navelbine.

### Proposed 505(b)(2) clinical trial

We had a pre-IND meeting with the FDA in the fourth quarter 2005, regarding our proposed 505(b)(2) New Drug Application (NDA) regulatory path for ANX-530. Section 505(b)(2) of the US Food, Drug & Cosmetic Act allows the FDA to approve a follow-on drug on the basis of data in the scientific literature or data used by the FDA in the approval of other drugs. This procedure potentially makes it easier for drug manufacturers to obtain rapid approval of new forms of drugs based on proprietary data of the original drug manufacturer. The FDA affirmed our proposal to conduct a single bioequivalency study of ANX-530 as a marketing-enabling clinical trial.

We currently plan to file an IND for ANX-530 and begin dosing patients in the third quarter of 2006. The proposed protocol would be open-label, with a two-period crossover and would assess bioequivalence and pharmacokinetics of ANX-530 and Navelbine. If our planned marketing-enabling clinical trial is successful, we currently expect that we would file a new drug application (NDA) in the first quarter of 2007.

### *Selone*

Selone is a compound in a class of drugs known as organoselenones, consisting of carbon, oxygen and selenium. Selone and its analogues have shown effectiveness, at even relatively low concentrations, against human ovarian, breast, lung and head/neck cancers, and against leukemias and lymphomas, based upon current in vitro screening methods. Their potency is high for their rate of alkylating activity, suggesting an increased specificity of action. Preclinical efforts have demonstrated effectiveness of Selone in treatment of leukemia in mice at doses predicted to easily achieve effective blood concentrations, as well as in a variety of human tumor cell lines in laboratory testing. We intend to undertake further preclinical testing of Selone during 2006 in order to determine the potential for this drug to be moved into human testing in the future. We have an exclusive license to patents from the University of Southern California to develop and commercialize Selone.

## **Infectious Diseases**

### *Thiovir for HIV/AIDS*

Thiovir is a broad spectrum anti-viral compound that has been shown to inhibit HIV, herpes and influenza A viruses. Thiovir is being developed as a non-nucleoside reverse transcriptase inhibitor (NNRTI) designed for oral delivery and as a component of highly active antiretroviral therapy (HAART) for HIV/AIDS. Thiovir is a prodrug for foscarnet, an FDA-approved intravenously-delivered therapy for opportunistic infections in HIV patients. Thiovir delivers both the active drug TPFA (thiophosphonoformate) and the active metabolite PFA (foscarnet) in an oral formulation. We have an exclusive license to patents from the University of Southern California to develop and commercialize Thiovir, and additional patents pending.

## **Table of Contents**

Foscarnet is an effective, broad-spectrum antiviral but we believe it has limitations from a commercial perspective because it must be delivered by protracted infusion. We believe that Thiovir can serve as an effective oral antiviral drug as part of HAART for HIV/AIDS. Preclinical studies have demonstrated that Thiovir is equivalent to foscarnet as a reverse transcriptase inhibitor and has a dosage profile similar to foscarnet to inhibit HIV polymerase, with less affect on human DNA polymerases.

### **Thiovir preclinical studies for HIV/AIDS**

In the third quarter 2005, we announced results from an *in vitro* study indicating that Thiovir demonstrated effectiveness against HIV-1 which is resistant to other NNRTIs and NRTIs. Thiovir also exhibited a slightly higher level of antiviral activity against HIV-1 than foscarnet. In combination testing with zidovudine (AZT), an NRTI, Thiovir was highly synergistic while foscarnet was only slightly synergistic to antagonistic. A poster of the study data was presented at the 3rd International AIDS Society Conference on HIV Pathogenesis and Treatment in Rio de Janeiro. We have demonstrated synergy of Thiovir with Tenofovir (an NRTI in Truvada® and Viread®) in preclinical studies, and we are planning additional preclinical studies testing synergy with Thiovir in combination with other NRTIs in 2006.

### **Proposed Phase I/II clinical trial for HIV/AIDS**

We currently plan to file an IND with the US Food and Drug Administration in the first half of 2006 for testing of Thiovir in patients with HIV/AIDS who have resistance to nucleoside reverse transcriptase inhibitors (NRTIs). The clinical trial is proposed to enroll patients who are resistant to one or more NRTIs. We currently plan to file an IND in the second quarter and initiate the clinical trial in the second half 2006.

### ***Thiovir preclinical studies for Influenza A and avian flu***

We announced in the first quarter 2006 that a series of independent preclinical tests confirmed inhibition of influenza A virus by Thiovir. We conducted preliminary preclinical research on strains of influenza A, which includes the H5N1 avian flu strain. We filed a provisional patent application with the US Patent and Trademark Office on January 27, 2006 in connection with these findings. Additional preclinical studies are planned during 2006 to study Thiovir against strains of influenza A, including the H5N1 avian flu.

## **Markets for our Products**

### **Cancer Chemotherapy Market**

On a worldwide basis, more than 11 million people each year are diagnosed with cancer and over 7 million people die each year from cancer, according to statistics published by the World Health Organization. In the U.S., cancer is responsible for approximately 25% of all deaths according to recent statistics. The American Cancer Society estimates that more than 1.3 million new cases of cancer were diagnosed and over 570,000 people died due to cancer in 2005 in the U.S.

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.

### **Market for CoFactor**

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-fluorouracil (5-FU) is a widely used chemotherapeutic agent. 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.

**Table of Contents**

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, antibody-based drugs, such as Erbitux® (cetuximab) and Avastin® (bevacizumab) may also be added to 5-FU and Leucovorin or be used as a monotherapy (as in the case of Erbitux).

In order for 5-FU to work more effectively, the folate-based compound Leucovorin, is often administered to the cancer patient. Results from multiple clinical trials have shown that Leucovorin in combination with 5-FU is only modestly effective in improving clinical outcomes in cancer patients. Leucovorin efficiency is reduced since the drug must undergo several metabolic steps to the active form of folate. Our drug, CoFactor, bypasses the chemical pathway required for Leucovorin metabolism. This biochemical strategy delivers the correct form of folate that allows 5-FU to kill cancer cells more effectively while reducing 5-FU-associated toxicity. We believe that CoFactor overcomes the limitations of Leucovorin and will lead to developments that will increase patient survival, while reducing side effects and improving the quality of life of patients on chemotherapy.

Worldwide sales of Leucovorin in 2005 were over \$320M according to IMS Health. We believe that if CoFactor shows improved clinical benefit and patient survival, it may be widely used as a replacement for Leucovorin in 5-FU based cancer therapies.

Market for ANX-530 (vinorelbine emulsion)

Our drug ANX-530 is a novel, emulsion formulation of vinorelbine tartrate that is designed to reduce vein irritation associated with the drug's intravenous administration. Vinorelbine is a marketed chemotherapeutic agent indicated as a single agent or in combination with cisplatin for treatment of advanced non-small cell lung cancer (NSCLC). Vinorelbine also shows activity in breast, ovarian and other cancers. Data from IMS Health show annual generic vinorelbine sales in 2005 of approximately \$60 million in the United States and approximately \$120 million outside the U.S. and annual unit sales growth of greater than 10% worldwide. Two NSCLC clinical studies published in 2005 (ANITA trial results, presented by J. Douillard at 2005 ASCO Annual Meeting and Winton, et al, published in NEJM, June 23, 2005) showed an improvement in survival in patients treated with vinorelbine plus cisplatin following tumor resection. Based on these two studies, we believe that adjuvant use of vinorelbine could increase. We believe we could capture an increasing share of the total vinorelbine market following additional post-marketing clinical trials demonstrating the benefits to patients and clinicians from reduced vein irritation from ANX-530.

Market for Selone

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

**HIV Drug Therapy Market**

The World Health Organization and the Centers for Disease Control report that there are 1.5 million HIV positive individuals in the U.S. and Europe where the vast majority of HIV drugs are used. According to a report by the United Nations Program on HIV/AIDS (UNAIDS), more than 40 million adults and children in the world are living with HIV and there are thousands of new infections each day.

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

**Table of Contents**

According to Datamonitor, the global commercial market for HIV treatments is expected to grow to almost \$12 billion by 2012. The current HIV market consists of 5 different classes of drugs: nucleoside reverse transcriptase inhibitors (NRTI), non-nucleoside reverse transcriptase inhibitors (NNRTI), nucleotide reverse transcriptase inhibitors (NtRTIs) and protease inhibitors (PI), which are dosed orally in various forms, as well as one entry inhibitor, which was approved in March 2003 and is dosed by injection. HIV entry inhibitors and maturation inhibitors are also currently under development by various pharmaceutical companies. NNRTI sales were approximately \$972M in 2004 (NDC Health).

**Market for Thiovir**

HIV replicates rapidly and can readily mutate to eventually evade inhibitor drugs and drug cocktails. Therefore, new drugs that target novel areas of the virus or overcome drug resistance are needed. We believe there is opportunity for Thiovir since its mechanism of action is different from other NNRTIs on the market or in development. Thiovir does not bind reverse transcriptase in the manner as currently-approved NNRTIs.

**Competition**

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

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

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

***CoFactor***

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

We know of no other company that is developing a metabolite of Leucovorin to enhance 5-FU activity. Leucovorin is 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.

Another source of competition for us is a branded prodrug (drug that activates *in vivo*) called Xeloda<sup>®</sup> (marketed by Roche), which is an oral formulation that converts to 5-FU. Xeloda may be used with or without oral leucovorin. Since CoFactor is being currently developed as an IV drug, generic forms of oral Leucovorin represent competition for CoFactor. To address this threat, we are evaluating the development of an oral form for CoFactor. We have performed preclinical studies that show benefit of CoFactor use with Xeloda over that of Xeloda alone.

Clinical studies in metastatic colorectal cancer are in progress or in the planning stages worldwide. In the clinical development for CoFactor, we will face competition from other groups for the pool of metastatic colorectal cancer patients that are eligible to enroll in our Phase III pivotal clinical trial. We may not finish the clinical trial in a timely fashion if we cannot readily recruit patients for this clinical trial.

## **Table of Contents**

### *ANX-530*

We intend to develop ANX-530 via a 505(b)(2) registration strategy to demonstrate bioequivalency of ANX-530 and vinorelbine in patients with advanced solid tumors. While we intend to further develop ANX-530 as a form of vinorelbine that reduces vein irritation, we initially will market the drug as an equivalent or generic form of vinorelbine. There are approximately five manufacturers of generic vinorelbine in addition to GlaxoSmithKline which markets Navelbine, the branded version of vinorelbine. We will face price competition based on the generic status of vinorelbine. Our 505(b)(2) registration strategy will only allow us to market the drug as bioequivalent upon FDA marketing approval. In addition to generic competitors, there are companies that have developed novel formulation technologies such as those utilizing liposomal carriers that could develop or resume development of a novel formulation of vinorelbine. There is also an oral formulation of vinorelbine approved for use in Europe against which we would compete if ANX-530 were approved for use in Europe.

### *Thiovir*

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

We are also investigating the use of Thiovir as a treatment for avian flu. There are numerous biotechnology and pharmaceutical companies also developing treatments for avian flu, representing potential competition for Thiovir in this indication.

### **Marketing, Distribution and Sales**

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

### **Manufacturing**

We do not have our own manufacturing facilities, and do not currently intend to establish them. We contract with outside manufacturers in order to produce our clinical trial materials.

### **Raw Materials**

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

### **Patents, Licensing and Research Agreements**

#### Patents

Listed below are all of the issued patents which we have the exclusive right to use pursuant to license agreements with the University of Southern California (USC). Our rights under these patents are more fully described below.

**Table of Contents**

<b>Where Filed</b>	<b>Patent Title</b>	<b>Expiration Date</b>
CoFactor Patents		
US	5,10-Methylene-Tetrahydrofolate as a Modulator of a Chemotherapeutic Agent	12-23-13
US	5,10-Methylene-Tetrahydrofolate as a Modulator of a Chemotherapeutic Agent	10-20-14
CA	5,10-Methylene-Tetrahydrofolate as a Modulator of a Chemotherapeutic Agent	05-13-11
Thiovir Patents		
US	Preparation and use of Thiophosphonates and Thio-analogues of Phosphonoformic Acid	06-21-09
US	Preparation and use of Thiophosphonates and Thio-analogues of Phosphonoformic Acid	09-30-11
US	Preparations of Thiophosphites and Thiophosphonates	05-03-19
US	Preparations of Thiophosphites and Thiophosphonates	11-01-20
EP	Preparation of Thiophosphonoformate Esters	05-03-20
US	Derivatives and Analogs	07-13-19
EP	Sulfur-containing Phosphonoformate Derivatives and their Uses	07-13-19
US	Synthesis and Antiviral Activity of a Series of Pyrophosphate Analogs	03-23-20
Selone Patent		
US	Method of Treating Drug Resistant Tumor Cells using Organoselenones	03-25-14
Other Patent		
US	Preparation and Use of Alpha-Keto Bisphosphonates	07-13-19

**Table of Contents**

In addition, we have filed three patent applications covering technology developed pursuant to our research and development activities and have licensed the right to use certain intellectual property from SD Pharmaceuticals, Inc which is covered in part by a pending patent application (the SD Pharma Application ).

We cannot assure that the claims in our pending patent applications or the SD Pharma Application will be issued as patents, that any issued patents will provide us with significant competitive advantages, or that the validity or enforceability of any of the patents we have the right to practice will not be challenged or, if instituted, that these challenges will not be successful. The cost of litigation to uphold the validity and prevent infringement of the patents we have the right to practice could be substantial. Furthermore, we cannot assure that others will not independently develop similar technologies or duplicate our technologies or design around the patented aspects of our technologies. We can provide no assurance that our proposed technologies will not infringe patents or rights owned by others, the licenses to which might not be available to us.

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

Information regarding the status of our various research and development programs, and the amounts spent on major programs through the last two fiscal years, can be found under the caption Management's Discussion and Analysis of Financial Condition and Results of Operations.

**License Agreements**

*USC Agreements*

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

The first license from USC provides for the payment to USC of a 3% royalty (on net sales of products made or sold in a country in which a patent has issued or is pending), while the second license provides for the payment of a 1% royalty. Both require the Company to pay USC a share of consideration received by the Company from any sublicensee as well as the cost of filing, prosecuting and maintaining the licensed patents. Under the second license (as amended), milestone payments will also be due based upon entry into human trials and regulatory approval for each drug candidate developed (\$75,000 at Phase I, \$100,000 at Phase II, \$125,000 at Phase III and \$250,000 at market approval). No royalties have been paid to date under these licenses.

*SD Pharmaceuticals Agreement*

Under a License Agreement with SD Pharmaceuticals, Inc., dated April 29, 2005, we acquired an exclusive license to commercially develop, use and sell within the United States an invention relating to an emulsion composition for delivering highly water-soluble drugs, such as vinca alkaloids. Based upon this license, we are currently developing ANX-530, a vinorelbine emulsion, for use in the treatment of cancer. In consideration for the rights to develop this invention, we agreed to pay SD Pharmaceuticals license fees, milestone payments and royalties. No milestone payments or royalties have been paid to date.



**Table of Contents**

**Sponsored Research Agreements**

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

**Government Regulations**

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

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

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

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

Clinical trials are typically conducted in three sequential phases that may or may not 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 clinical trials for cancer indications, Phase II typically denotes an uncontrolled study which addresses primary response rate. Phase IIB studies are generally larger, and controlled, and serve to finalize dosing regimens for Phase III trials.

In serious diseases such as HIV/AIDS, patients suffering from the disease rather than healthy volunteers are included 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.

**Table of Contents**

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 sponsor of a clinical trial may request a special protocol assessment (SPA) from the FDA. If an SPA is requested, the FDA will evaluate within 45 days certain protocols, including Phase III clinical trial protocols, and issues relating to the protocols to assess whether they are adequate to meet scientific and regulatory requirements identified by the sponsor. In a Phase III clinical protocol SPA request, the sponsor requests that data used in a Phase III clinical trial form the primary basis for an efficacy claim. The clinical protocols for Phase III trials can relate to efficacy claims that will be part of an original new drug application (NDA) or biologics license application (BLA) or that will be part of an efficacy supplement to an approved NDA or BLA.

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.

Section 505(b)(2) of the US Food, Drug & Cosmetic Act allows the FDA to approve a follow-on drug on the basis of data in the scientific literature or data used by the FDA in the approval of other drugs. This procedure potentially makes it easier for drug manufacturers to obtain rapid approval of new forms of drugs based on proprietary data of the original drug manufacturer. Some examples of products that may be allowed to follow a 505(b)(2) path to approval are drugs which have a new dosage form, strength, route of administration, formulation or indication.

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 CoFactor, Thiovir and Selone may be candidates for accelerated development or approval under these procedures.

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

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

**Health Care Reform Measures and Third Party Reimbursement**

Pharmaceutical companies are affected by the efforts of governments and third party payors to contain or reduce the cost of health care through various means. A number of legislative and regulatory proposals aimed at changing the health care system have been proposed in recent years including the Medicare Modernization Act of 2003 (MMA). In addition, increasing emphasis on managed care in the U.S. has and will continue to increase pressures on pharmaceutical pricing. While we cannot predict whether legislative or regulatory proposals will be

**Table of Contents**

adopted or the effect such proposals or managed care efforts may have on our business, the announcement or adoption of such proposals or efforts could have a material adverse effect on us. In the U.S. and elsewhere, sales of prescription pharmaceuticals are dependent in large part on the availability of reimbursement to the consumer from third party payors, such as government and private insurance plans that mandate predetermined discounts from list prices.

**Employees**

As of March 10, 2006 we employed 20 persons, including 12 engaged in research and development activities, including preclinical research, clinical development, and regulatory affairs, and eight in general and administrative functions such as marketing, accounting, purchasing and investor relations. Our staff includes four employees with Ph.D. or M.D. degrees. None of our employees are unionized and we believe that our relationship with our employees is good.

**Available Information**

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available free of charge on our website (www.adventrx.com) as soon as reasonably practicable after they are filed with, or furnished to, the Securities and Exchange Commission.

**ITEM 1A. RISK FACTORS**

**Risks Relating to Our Business**

*Readers and prospective investors in our securities should carefully consider the following risk factors as well as the other information contained or incorporated by reference in this report.*

*The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties that management is not aware of or focused on or that management currently deems immaterial may also impair our business operations. This report is qualified in its entirety by these risk factors.*

*If any of the following risks actually occur, the Company's financial condition and results of operations could be materially and adversely affected. If this were to happen, the value of the Company's securities could decline significantly, and you could lose all or part of your investment.*

**We have a substantial accumulated deficit and limited working capital.**

We had an accumulated deficit of \$59,964,840 as of December 31, 2005. Since we presently have no source of revenues and are committed to continuing our product research and development program, significant expenditures and losses will continue until development of new products is completed and such products have been clinically tested, approved by the FDA or other regulatory agencies and successfully marketed. In addition, we fund our operations primarily through the sale of equity securities, and have had limited working capital for our product development and other activities. We do not believe that debt financing from financial institutions will be available until at least the time that one of our products is approved for commercial production.

**We have no current product sales revenues or profits.**

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

**Table of Contents**

**It is uncertain that we will have access to future capital.**

We do not expect to generate positive cash flow from operations for at least the next several years. As a result, substantial additional equity or debt financing for research and development or clinical development will be required to fund our activities. Although we have raised equity financing in the past, including in April 2004 and July 2005, we cannot be certain that we will be able to continue to obtain such financing on favorable or satisfactory terms, if at all, or that it will be sufficient to meet our cash requirements. Any additional equity financing could result in substantial dilution to stockholders, and debt financing, if available, would likely involve restrictive covenants that preclude us from making distributions to stockholders and taking other actions beneficial to stockholders. If adequate funds are not available, we may be required to delay or reduce the scope of our drug development program or attempt to continue development by entering into arrangements with collaborative partners or others that may require us to relinquish some or all of our rights to proprietary drugs. The inability to adequately and timely fund our capital requirements would have a material adverse effect on us.

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

The successful development of any new drug is highly uncertain and is subject to a number of significant risks. Our drug candidates, all of which are in a development stage, require significant, time-consuming and costly development, testing and regulatory clearance. This process typically takes several years and can require substantially more time. Risks include, among others, the possibility that a drug candidate will (i) be found to be ineffective or unacceptably toxic, (ii) have unacceptable side effects, (iii) fail to receive necessary regulatory clearances, (iv) not achieve broad market acceptance, (v) be subject to competition from third parties who may market equivalent or superior products, (vi) be affected by third parties holding proprietary rights that will preclude us from marketing a drug product, or (vii) not be able to be manufactured by manufacturers in a timely manner in accordance with required standards of quality. There can be no assurance that the development of our drug candidates will demonstrate the efficacy and safety of our drug candidates as therapeutic drugs, or, even if demonstrated, that there will be sufficient advantages to their use over other drugs or treatments so as to render the drug product commercially viable. In the past, we have been faced with limiting the scope and/or delaying the launch of preclinical and clinical drug trials due to limited cash and personnel resources. We have also chosen to terminate licenses of some drug candidates that were not showing sufficient promise to justify continued expense and development. In the event that we are not successful in developing and commercializing one or more drug candidates, investors are likely to realize a loss of their entire investment.

We have been delayed at certain times in the past in the development of our drug products by limited funding. In addition, if certain of our scientific and technical personnel resigned at or about the same time, the development of our drug products would probably be delayed until new personnel were hired and became familiar with the development programs.

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

Success in preclinical and 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. In the past, we have terminated licenses of drug candidates when our preclinical trials did not support or verify earlier preclinical data. There is a significant risk that any of our drug candidates could fail to show satisfactory results in continued trials, and would not justify further development.

**Table of Contents****We will face intense competition from other companies in the pharmaceutical industry.**

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

Many of our likely competitors, such as Merck and Pfizer, 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. Companies such as Gilead, Roche and GlaxoSmithKline all have drugs in various stages of development that could become competitors. Accordingly, competitors may succeed in commercializing products more rapidly or effectively than us, which would have a material adverse effect on us.

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

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

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

Our ability to commercialize our technology successfully will depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, private health insurers and other third-party payors. Significant uncertainty exists as to the reimbursement status of newly approved medical products. We cannot guarantee that adequate third-party insurance coverage will be available for us to establish and maintain price levels sufficient for realization of an appropriate return on our investments in developing new therapies. If we are successful in getting FDA approval for CoFactor, we will be competing against a generic drug, leucovorin, which has a lower cost and a long, established history of reimbursement. Receiving sufficient reimbursement for purchase costs of CoFactor will be necessary to make it cost effective and competitive versus the established drug, leucovorin. Government, private health insurers, and other third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new therapeutic products approved for marketing by the FDA. Accordingly, even if coverage and reimbursement are provided by government, private health insurers, and third-party payors for use of our products, the market acceptance of these products would be adversely affected if the amount of reimbursement available for the use of our therapies proved to be unprofitable for health care providers.



**Table of Contents**

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

There have been some federal and state proposals in the past to subject the pricing of health care goods and services, including prescription drugs, to government control and to make other changes to the U.S. health care system. None of the proposals seems to have affected any of the drugs in our programs. However, it is uncertain if future legislative proposals would be adopted that might affect the drugs in our programs or what actions federal, state, or private payors for health care treatment and services may take in response to any such health care reform proposals or legislation. Any such health care reforms could have a material adverse effect on the marketability of any drugs for which we ultimately require FDA approval.

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

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

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

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

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

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

Our success will depend in large part on our ability and our licensors' ability to (i) maintain license and patent protection with respect to their drug products, (ii) defend patents and licenses once obtained, (iii) maintain trade secrets, (iv) operate without infringing upon the patents and proprietary rights of others and (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. We have obtained licenses to patents and other proprietary rights from the University of Southern California and SD Pharmaceuticals, Inc.

The patent positions of pharmaceutical companies, including ours, are uncertain and involve complex legal and factual questions. There is no guarantee that we or our licensors have or will develop or obtain the rights to products or processes that are patentable, that patents will issue from any of the pending applications or that claims





**Table of Contents**

allowed will be sufficient to protect the technology licensed to us. In addition, we cannot be certain that any patents issued to or licensed by us will not be challenged, invalidated, infringed or circumvented, or that the rights granted thereunder will provide competitive disadvantages to us.

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

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

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

The license agreements pursuant to which we license our core technologies for our potential drug products permit the licensors, respectively the University of Southern California and SD Pharmaceuticals, Inc., to terminate the agreement under certain circumstances, such as the failure by us to use our reasonable best efforts to commercialize the subject drug or the occurrence of any other uncured material breach by us. The license agreements also provide that the licensor is primarily responsible for obtaining patent protection for the technology licensed, and we are required to reimburse the licensor for the costs it incurs in performing these activities. The license agreements also require the payment of specified royalties. Any inability or failure to observe these terms or pay these costs or royalties could result in the termination of the applicable license agreement in certain cases. In the past, we have let lapse certain licenses for drug candidates when we determined that the expense and risk of continued development outweighed the likely benefits of that continued development. The termination of any license agreement could have a material adverse effect on us.

**Protecting our proprietary rights is difficult and costly.**

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. Accordingly, we cannot predict the breadth of claims allowed in these companies' patents or whether we may infringe or be infringing these claims. Although we have not been notified of any patent infringement, nor notified others of patent infringement, such 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.

**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. We are currently dependent upon our scientific staff, which has a deep background in our drug candidates and the ongoing preclinical and clinical trials. Recruiting and retaining senior employees with relevant drug development experience in oncology and anti-viral therapeutics is costly and time-consuming. There can be no assurance that we will be able to attract and retain such individuals on an uninterrupted basis and on commercially acceptable terms, and the failure to do so could have a material adverse effect on us by significantly delaying one or more of our drug development programs. The loss of any of our senior executive officers, including our chief executive officer and chief financial officer, in particular, could have a material adverse effect on the company and the market for our common stock, particularly if such loss was abrupt or unexpected. All of our employees are employed on an at-will basis under offer letters. We do not have non-competition agreements with any of our employees.



**Table of Contents**

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

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

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

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

We do not have any manufacturing capacity. When and if required, we will seek to establish relationships with third-party manufacturers for the manufacture of clinical trial material and the commercial production of drug products as we have with our current manufacturing partners. There can be no assurance that we will be able to establish relationships with third-party manufacturers on commercially acceptable terms or that third-party manufacturers will be able to manufacture a drug product on a cost-effective basis in commercial quantities under good manufacturing practices mandated by the FDA or other regulatory matters.

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

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

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

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

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

**Table of Contents**

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

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

**If we cannot satisfy AMEX's listing requirements, it may delist our common stock and we may not have an active public market for our common stock. The absence of an active trading market would likely make the common stock an illiquid investment.**

Our common stock is quoted on the American Stock Exchange. To continue to be listed, we are required to maintain shareholders equity of \$6,000,000 among other requirements. We do not satisfy that requirement as of December 31, 2005. The AMEX may consider delisting our common stock and suspend trading in the common stock in which case our common stock would likely trade in the over-the-counter market in the so-called pink sheets or, if available, the OTC Bulletin Board Service. As a result, an investor would likely find it significantly more difficult to dispose of, or to obtain accurate quotations as to the value of, our shares. Our ability to raise capital would most likely also be impaired due to our ineligibility to file resale registration statements under the Securities Act.

**If our common stock is delisted, it may become subject to the SEC's penny stock rules and more difficult to sell.**

SEC rules require brokers to provide information to purchasers of securities traded at less than \$5.00 and not traded on a national securities exchange or quoted on the Nasdaq Stock Market. If our common stock becomes a penny stock that is not exempt from these SEC rules, these disclosure requirements may have the effect of reducing trading activity in our common stock and making it more difficult for investors to sell. The rules require a broker-dealer to deliver a standardized risk disclosure document prepared by the SEC that provides information about penny stocks and the nature and level of risks in the penny market. The broker must also give bid and offer quotations and broker and salesperson compensation information to the customer orally or in writing before or with the confirmation. The SEC rules also require a broker to make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction before a transaction in a penny stock.

**Changes in laws and regulations that affect the governance of public companies has increased our operating expenses and will continue to do so.**

Recently enacted changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and the listing requirements for American Stock Exchange have imposed new duties on us and on our executives, directors, attorneys and independent accountants. In order to comply with these new rules, we have hired and expect to hire additional personnel and use additional outside legal, accounting and advisory services, which have increased and are likely to continue increasing our operating expenses. In particular, we expect to incur additional administrative expenses as we implement Section 404 of the Sarbanes-Oxley Act, which requires management to extensively evaluate and report on, and our independent registered public accounting firm to attest to, our internal controls. For example, we have incurred significant expenses, and expect to incur additional expenses, in connection with the evaluation, implementation, documentation and testing of our existing and newly implemented control systems. Management time associated with these compliance efforts necessarily reduces time available for other operating activities, which could adversely affect operating results. If we are unable to achieve full and timely compliance with these regulatory requirements, we could be required to incur additional costs, expend additional money and management time on additional remedial efforts which could adversely affect our results of operations.

**Failure to implement effective control systems, or failure to complete our assessment of the effectiveness of our internal control over financial reporting, may subject us to regulatory sanctions and could result in a loss of public confidence, which could harm our operating results.**

Pursuant to Section 404 of the Sarbanes-Oxley Act, beginning with our fiscal year ending December 31, 2005, we are required to include in our annual report our assessment of the effectiveness of our internal control over financial reporting. Furthermore, our independent registered public accounting firm is required to issue an opinion on whether our assessment of the effectiveness of our internal control over financial reporting is fairly stated in all material respects and separately report on whether it believes we maintained, in all material respects, effective internal control

over financial reporting as of December 31, 2005.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

Not applicable.

**Table of Contents****ITEM 2. PROPERTIES**

Our principal offices are located at 6725 Mesa Ridge Road, San Diego, California 92121. Our principal offices consist of 12,038 square feet of office and lab space, which we use pursuant to a lease which will expire on August 31, 2009. The base rent for this space is currently \$242,209 annually, with incremental operating cost adjustments.

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

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

**ITEM 3. LEGAL PROCEEDINGS**

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

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

A special meeting of the stockholders of the Company was held on November 15, 2005. At the meeting, the stockholders approved (i) an amendment to our Certificate of Incorporation to prohibit us from establishing a classified board; (ii) an amendment to our Certificate of Incorporation to prohibit us from adopting or approving any rights plan, poison pill or other similar plan, agreement or device; and (iii) an amendment and restatement of our Certificate of Incorporation that, among other things, increased the number of shares of common stock we are authorized to issue to 200,000,000. Each of the foregoing matters approved by the stockholders are described in further detail in our Proxy Statement filed with the Securities and Exchange Commission on October 18, 2005.

The following table shows the tabulation of the votes cast in connection with these matters:

<b>Proposal</b>	<b>Votes</b>		<b>Votes Abstained</b>
	<b>Votes For</b>	<b>Against/Withheld</b>	
Amendment to Certificate of Incorporation regarding classified board prohibition	47,268,567	392,146	1,062,676
Amendment to Certificate of Incorporation regarding poison pill prohibition	47,453,882	204,481	1,065,026
Amendment and restatement of Certificate of Incorporation to increase authorized shares of common stock, among other things	46,437,170	1,287,043	999,176

**Table of Contents****PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

Our common stock trades under the symbol ANX on the American Stock Exchange (the AMEX). The following table sets forth the high and low closing sales prices for our common stock in each of the quarters over the past two fiscal years, as quoted on the AMEX.

	Common Stock Price			
	Fiscal 2005		Fiscal 2004	
	High	Low	High	Low
First Quarter	\$1.69	\$0.90	\$2.40	\$0.87
Second Quarter	\$3.12	\$1.61	\$2.30	\$1.55
Third Quarter	\$4.13	\$2.18	\$1.74	\$0.99
Fourth Quarter	\$3.65	\$2.68	\$1.19	\$0.82

On March 13, 2006, the closing sales price of Common Stock was \$4.22 per share.

As of March 10, 2006, we had approximately 7,021 stockholders, including 246 holders of record and an estimated 6,775 beneficial owners. We have not paid any dividends on our common stock since our inception and do not expect to pay dividends on our common stock in the foreseeable future.

**Dividend Policy**

We have not declared or paid cash dividends on our common stock and do not anticipate paying any cash dividends in the foreseeable future. We expect to retain future earnings, if any, to fund the development and growth of our business. Our board of directors will determine future dividends, if any.

**Equity Compensation Plan Information**

The following table provides information as of December 31, 2005 regarding equity compensation plans approved by the Company's securityholders. The Company does not have any equity compensation plans that have not been approved by our securityholders.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in second column)
2005 Equity Incentive Plan	2,457,000	\$ 1.45	3,258,000
2005 Employee Stock Purchase Plan	0	\$ 0	2,000,000

**Recent Sales of Unregistered Securities**

From February 24, 2006 through March 13, 2006, we issued 509,124 shares of common stock to six of our warrant holders in connection with their exercise of outstanding warrants. We received gross proceeds of \$683,979 upon exercise of these warrants. The issuances of shares of common stock upon exercise of these warrants were not

registered under the Securities Act of 1933 in reliance upon Section 4(2) of such Act.

Pursuant to the terms of an agreement we entered into with Burnham Hill Partners, a division of Pali Capital, Inc., in March 2004, we are obligated to pay a 4% cash commission on each cash exercise of warrants issued in a financing that we consummated in April 2004. In accordance with this obligation, we owe Burnham Hill Partners approximately \$16,353 in connection with the exercises of warrants from February 24, 2006 through March 13, 2006. No other commission or other remuneration was paid or given directly or indirectly in connection with these warrant exercises.



**Table of Contents****Item 6. SELECTED CONSOLIDATED FINANCIAL DATA**

The selected consolidated financial data set forth below at December 31, 2005 and 2004, and for the fiscal years ended December 31, 2005, 2004 and 2003, are derived from our audited consolidated financial statements included elsewhere in this report. This information should be read in conjunction with those consolidated financial statements, the notes thereto, and the report of independent registered public accounting firm thereon, and with Management's Discussion and Analysis of Financial Condition and Results of Operations. The selected consolidated financial data set forth below at December 31, 2003, 2002 and 2001, and for the years ended December 30, 2002 and 2001, are derived from our audited consolidated financial statements that are contained in reports previously filed with the SEC. The quarterly consolidated financial data are derived from unaudited financial statements included in our Quarterly Reports on Form 10-Q.

**Summary Financial Information**

	<b>Fiscal Years Ended December 31,</b>				
<b>Statement of operations data:</b>	<b>2005</b>	<b>2004</b>	<b>2003</b>	<b>2002</b>	<b>2001</b>
Loss from operations	\$ (13,202,986)	\$ (6,701,048)	\$ (2,332,077)	\$ (2,105,727)	\$ (16,339,120)
Net loss	\$ (24,782,646)	\$ (6,701,048)	\$ (2,369,917)	\$ (2,347,927)	\$ (16,595,120)
Basic and diluted net loss per share	\$ (0.41)	\$ (0.13)	\$ (0.07)	\$ (0.15)	\$ (1.12)
Weighted average number of shares of common stock outstanding:					
Basic and diluted	59,828,357	50,720,180	31,797,986	15,681,743	14,805,150
Cash dividends declared per share	\$	\$	\$	\$	\$

	<b>December 31,</b>				
<b>Balance sheet data:</b>	<b>2005</b>	<b>2004</b>	<b>2003</b>	<b>2002</b>	<b>2001</b>
Cash and cash equivalents	\$ 14,634,618	\$ 13,032,263	\$ 4,226,397	\$ 103,928	\$ 164,476
Short-term investments	7,958,458				
Total cash, cash equivalents and short-term investments	22,593,076	13,032,263	4,226,397	103,928	164,476
Working capital	(8,534,219)	12,047,819	4,091,730	(822,274)	(686,151)
Total assets	23,621,773	13,608,787	4,283,356	130,345	278,006
Long-term obligations	57,078			56,873	
Total liabilities	31,450,389	1,218,396	163,043	983,075	916,492
Shareholders' equity/(deficit)	(7,828,616)	12,390,391	4,120,313	(852,730)	(638,486)

	<b>Fiscal Quarters Ended</b>			
<b>Quarterly statement of operations data</b>	<b>September 30,</b>			<b>December 31,</b>
<b>for fiscal 2005:</b>	<b>March 31, 2005</b>	<b>June 30, 2005</b>	<b>2005</b>	<b>2005</b>
Loss from operations	\$ (2,844,934)	\$ (3,330,554)	\$ (3,482,475)	\$ (3,545,023)
Net loss	\$ (2,844,934)	\$ (3,330,554)	\$ (16,454,867)	\$ (2,152,291)
Basic and diluted net loss per share	\$ (0.05)	\$ (0.26)	\$ (0.26)	\$ (0.03)
Basic and diluted weighted average number of shares of common stock outstanding	53,967,933	54,821,480	63,255,407	67,194,366

	<b>Fiscal Quarters Ended</b>	
<b>Quarterly statement of operations data</b>	<b>September 30,</b>	
<b>for fiscal 2004:</b>	<b>June 30, 2005</b>	<b>2004</b>

Edgar Filing: ADVENTRX PHARMACEUTICALS INC - Form 10-K

	<b>March 31,</b>			<b>December 31,</b>
	<b>2005</b>			<b>2004</b>
Net loss	\$ (710,463)	\$ (1,509,254)	\$ (2,123,807)	\$ (2,357,524)
Basic and diluted net loss per share	\$ (0.02)	\$ (0.03)	\$ (0.04)	\$ (0.04)
Basic and diluted weighted average number of shares of common stock outstanding	42,886,237	52,560,875	53,811,072	53,811,072

---

**Table of Contents**

**ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*This annual report on Form 10-K contains forward-looking statements concerning future events and performance of our company. When used in this report, the words intend, estimate, anticipate, believe, plan and expect and similar expressions as they relate to Adventrx are included to identify forward-looking statements. You should not rely on these forward-looking statements, because they are only predictions based on our current expectations and assumptions. Many factors could cause our actual results to differ materially from those indicated in these forward-looking statements. You should review carefully the factors identified in this report in Part I., Item 1A, Business Risk Factors, those set forth below under Critical Accounting Policies and Estimates and elsewhere in this report.. We disclaim any obligation to update or announce revisions to any forward-looking statements to reflect actual events or developments.*

**Overview**

**CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

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

Our critical accounting policies are those that affect our financial statements materially and involve a significant level of judgment by management. Our critical accounting policies regarding revenue recognition are in the following areas: license and research contracts, royalty revenues, sale of rights to future royalties, grant revenues and product sales, however, since inception we have not recognized a material amount of revenue. Our critical accounting policies also include recognition of expenses in research contracts and research and development expenses.

***Recognition of Expenses in Research Contracts***

Pursuant to management's assessment of the services that have been performed on clinical trials and other contracts, we recognize expenses as the services are provided. Such management assessments generally consist of, but are not limited to, an evaluation by the project manager of the work that has been completed during the period, measurement of progress prepared internally and/or provided by the third-party service provider, analysis of data that justifies the progress, and finally, management's judgment. Several of our contracts extend across multiple reporting periods.

***Research and Development Expenses***

Research and development expenses consist of expenses incurred in performing research and development activities including salaries and benefits, facilities and other overhead expenses, clinical trials, contract services and other outside expenses. Research and development expenses are charged to operations as they are incurred.

*Acquired contractual rights.* Payments to acquire contractual rights to a licensed technology or drug candidate are expensed as incurred when there is uncertainty in receiving future economic benefits from the acquired contractual rights. We consider the future economic benefits from the acquired contractual rights to a drug candidate to be uncertain until such drug candidate is approved by the FDA or when other significant risk factors are abated. To date, for expense accounting purposes management has viewed future economic benefits for all of our drug candidates to be uncertain.

**Table of Contents****NATURE OF OPERATING EXPENSES**

Our total operating expenses are influenced substantially by the amount of spending devoted to research and development. During the past two years, we have expanded our drug development pipeline, which requires that we allocate significant amounts of our resources to such programs, including increased spending on clinical trials as those programs advance in their development. We expect research and development expenses will represent approximately 65% to 70% of our operating expenses for fiscal 2006. We expect that general and administrative expenses for fiscal 2006 will represent approximately 35% of our operating expenses.

Our business is exposed to significant risks, as discussed in the section entitled *Risk Factors*, which may result in additional expenses, delays and lost opportunities that could have a material adverse effect on our results of operations and financial condition.

**RESULTS OF OPERATIONS**

We operate our business on the basis of a single reportable segment — discovery, development and commercialization of novel therapeutics for chronic diseases.

**Comparison of Fiscal 2005 and 2004****Operating Expenses 2005 vs. 2004**

Total operating expenses amounted to \$13.7 million in fiscal 2005, compared to \$6.8 million in fiscal 2004. The \$6.9 million or 101% increase in operating expenses was due to a \$5.9 million or 216% increase in research and development expenses, a \$900,000 or 22% increase in general and administrative expenses and a \$74,000 or 180% increase in depreciation and amortization expense. Explanations of operating expenses in both fiscal 2005 and fiscal 2004 are described more fully in the paragraphs that follow.

	<b>Operating Expenses</b>		
	<b>Years Ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Research and development	63%	40%	32%
General and administrative	36%	59%	68%
Depreciation and amortization	1%	1%	0%
Total operating expenses	100%	100%	100%

**Research and development (R&D) expenses.** R&D expenses increased to \$8.7 million in fiscal 2005 from \$2.7 million in fiscal 2004. The increase is primarily due to \$3.5 million of expenses incurred for our Phase II and Phase IIB CoFactor clinical trials, an increase in preclinical expenditures of \$1.2 million related to CoFactor, ANX-530 (vinorelbine emulsion) and Thiovir, an increase in wages and related employee expenses of \$500,000 due to the hiring of additional clinical personnel, an increase in outside services expense of \$225,000 related to clinical support efforts and an increase in stock compensation expense related to employee options of \$584,000.

**General and administrative (G&A) expenses.** G&A expenses increased to \$4.9 million in fiscal 2005 from \$4.0 million in fiscal 2004. The increase is primarily due to an increase of \$300,000 in wages and related employee expenses due to the hiring of finance and development personnel, an increase in outside consulting of \$280,000 related to efforts to comply with the Sarbanes-Oxley Act of 2002 and related system implementation efforts, and an increase in facilities cost of \$115,000 due to an increase in the amount of space leased.

**Table of Contents**

**Interest Income.** Interest income increased by \$393,000, or 381%, to \$496,000 in fiscal 2005 from \$103,000 in fiscal 2004. The increase is primarily due to the investment of the proceeds of an equity financing which occurred in July 2005 with net proceeds of \$19 million which resulted in an increase in the average balance of investments in fiscal 2005, compared to fiscal 2004. In addition, we experienced a rise in interest rates in the second half of 2005.

**Loss from Operations.** Loss from operations was \$13.2 million in fiscal 2005 compared to a net loss of \$6.7 million in fiscal 2004. The increase in net loss was due to a large increase in R&D expenses related to our Phase II trial of CoFactor and increased preclinical expenses related to CoFactor and other drugs in development.

We expect to continue to pursue our drug development strategy focused on the development of CoFactor, ANX-530 (vinorelbine emulsion) and Thiovir followed by other programs in earlier stages of development. To help fund and develop our product development efforts, we may elect to license certain of our technologies and drug candidates to third parties. These potential license arrangements could materially change our outlook for future revenues and costs. However, the timing of such potential arrangements is unpredictable.

**Net Loss.** Net loss was \$24.8 million or \$(0.41) per share in fiscal 2005 compared to a net loss of \$6.7 million or \$0.13 per share in fiscal 2004. The increase was due to reasons discussed above under Loss from Operations and an \$11.6 million loss booked in the fourth quarter to book warrants issued in conjunction with financing at fair market value.

**Comparison of Fiscal 2004 and 2003**

**Operating Expenses 2004 vs. 2003**

Total operating expenses amounted to \$6.8 million in fiscal 2004, compared to \$2.3 million in fiscal 2003. The \$4.5 million, or 190%, increase in operating expenses is discussed in the paragraphs below.

**Research and development expenses.** R&D expenses totaled \$2.7 million in fiscal 2004 compared to \$749,000 in fiscal 2003. The increase of \$2.0 million or 266% was primarily related to costs incurred for our Phase II CoFactor trial which commenced in May 2004 as well as additional personnel costs due to the hiring of clinical and preclinical personnel in 2004.

**General and administrative expenses.** Our general and administrative expenses increased to \$4.0 million in fiscal 2004, compared to \$1.6 million in fiscal 2003. The increase of \$2.4 million or 153% is primarily related to the hiring of a significant number of personnel including two executive level positions. In addition, occupancy, insurance and related costs all increased in 2004 as we leased more office and lab space and ramped up for our clinical trials.

**Interest Income.** Interest income increased to \$103,000 in 2004 as compared to \$9,000 in 2003. The increase of \$94,000 was due to an increase in our cash balances due to the investment of the proceeds of an equity financing which closed in April 2004.

**Net Loss.** Net loss was \$6.7 million, or \$0.13 per share, in fiscal 2004 compared to a net loss of \$2.4 million, or \$0.07 per share, in fiscal 2003. The increase of \$4.3 million or 183% in net loss was due to large increases in research and development and general and administrative costs which included the hiring of ten people including two executive level positions.

**Table of Contents****Liquidity and Capital Resources**

Historically, we have funded our operations primarily through sales of our equity securities. As of December 31, 2005, we had cash, cash equivalents and short-term investments in securities totaling \$22.6 million, including cash and cash equivalents of \$14.6 million and short-term investments of \$8.0 million. Our net working capital balance as of December 31, 2005 was (\$8.5) million. As of December 31, 2004, we had cash and cash equivalents totaling \$13.0 million. Our net working capital balance as of December 31, 2004 was \$12.0 million. Explanations of net cash provided by or used in operating, investing and financing activities are provided below.

	<b>December 31, 2005</b>	<b>Increase (Decrease) During Period</b>	<b>December 31, 2004</b>
Cash, cash equivalents and investments	\$22,593,076	\$9,560,813	\$13,032,263
Cash and cash equivalents	14,634,618	1,602,355	13,032,263
Net working capital	\$ (8,534,219)	9,114,373	12,047,819

  

	<b>Year Ended December 31, 2005</b>	<b>Change Between Periods</b>	<b>Year Ended December 31, 2004</b>
Net cash used in operating activities	\$ (11,646,829)	\$ (6,471,439)	\$ (5,175,390)
Net cash used in investing activities	(8,086,005)	(7,780,232)	(305,773)
Net cash provided by financing activities	21,335,189	7,048,160	14,287,029
Net increase in cash and cash equivalents	\$ 1,602,355	\$ (7,203,511)	\$ 8,805,866

*Operating activities.* Net cash used for operating activities was \$11.6 million in fiscal 2005, compared to \$5.2 million in fiscal 2004. The increase in cash used for operating activities was mainly due to the increase in our research and development and general and administrative expenses.

Net cash used for operating activities in fiscal 2004 was \$5.2 million, compared to net cash provided by operating activities of \$2.2 million in fiscal 2003. The increase in cash used for operating activities was mainly due to our increased research and development and general and administrative expenses.

*Investing activities.* Net cash used by investing activities was \$8.1 million in fiscal 2005, compared to \$300,000 in fiscal 2004 and \$16,000 in fiscal 2003. The increase in fiscal 2005 was mainly due to net purchases of short-term investments of \$7.8 million. The increase in fiscal 2004 was due to purchases of fixed assets (office furniture and computer hardware).

*Financing activities.* Net cash provided by financing activities was \$21.3 million in fiscal 2005, consisting primarily of \$18.1 million in net proceeds from sales of our common stock through private placements and \$3.0 million from exercises of warrants to purchase our common stock. Net cash provided by financing activities amounted to \$14.3 million in the fiscal 2004, consisting of \$14.3 million received from the sale of our common stock.

As of December 31, 2005, we have contractual obligations for operating leases and purchase obligations, as summarized in the table that follows. We anticipate being able to satisfy the obligations described below out of cash, cash equivalents and investments in securities held by the Company as of December 31, 2005. We do not have any off balance sheet arrangements and no commitments for any significant additional capital expenditures.

	<b>Payments Due by Period</b>			
	<b>Less than 1 Year</b>	<b>1-3 Years</b>	<b>3-5 Years</b>	<b>More than 5 years</b>
<b>Total</b>				

Edgar Filing: ADVENTRX PHARMACEUTICALS INC - Form 10-K

Operating lease obligations	\$ 935,651	\$ 248,364	\$ 687,287	\$ 0	\$ 0
Purchase obligations	\$ 423,934	\$ 423,934	\$ 0	\$ 0	\$ 0
Total	\$ 1,359,585	\$ 672,298	\$ 687,287	\$ 0	\$ 0

**Table of Contents**

**Management Outlook**

We believe that cash, cash equivalents, and short-term investments of approximately \$22.6 million at December 31, 2005, should be sufficient to sustain our planned level of operations for at least the next 12 months.

If we are unable to raise capital as needed to fund our operations then we may need to slow the rate of development of some of our programs or sell the rights to one or more of our drug candidates. For information regarding the risks associated with our need to raise capital to fund our ongoing and planned operations, please see Risk Factors.

**Recent Accounting Pronouncements**

See Note 2, Summary of Significant Accounting Policies Recent Accounting Pronouncements, in the Notes to Consolidated Financial Statements for a discussion of recent accounting pronouncements and their effect, if any, on the Company.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

As described below, we are exposed to market risk related to changes in interest rates. Because substantially all our expenses, and capital purchasing activities are transacted in U.S. dollars, our exposure to foreign currency exchange rates is immaterial. Until such time as we are faced with material amounts of foreign currency exchange rate risks, we do not plan to use derivative financial instruments, which can be used to hedge such risks. We will evaluate the use of derivative financial instruments to hedge our exposures as the needs and risks should arise.

**Interest Rate Sensitivity**

Our investment portfolio consists primarily of government or investment grade fixed income instruments with an average duration of under 60 days. The primary objective of our investments in debt securities is to preserve principal while achieving attractive yields, without significantly increasing risk. We classify our investments in securities as of December 31, 2005 as available-for-sale. These available-for-sale securities are subject to interest rate risk. Due to the short average duration as of December 31, 2005 the interest rate risks were not significant.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

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

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

**ITEM 9A. CONTROLS AND PROCEDURES**

**Disclosure Controls and Procedures**

With the supervision and with the participation of our management, including the principal executive officer and principal financial officer, we have evaluated the effectiveness of our disclosure controls and procedures (as defined under Exchange Act Rules 13a-15(e) and 15(d)-15(e)), as of the end of the period covered by this report. Based on that evaluation, the principal executive officer and principal financial officer have concluded that these disclosure controls and procedures were effective as of the end of the period covered by this report. Additionally, there was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that occurred during the fiscal quarter ended December 31, 2005 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.



**Table of Contents**

**Management's Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control - Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2005.

Our assessment of the effectiveness of our internal control over financial reporting as of December 31, 2005 has been audited by J.H. Cohn LLP, an independent registered public accounting firm, as stated in their report, which is set forth below in this Item 9A.

**Report of Independent Registered Public Accounting Firm**

To Board of Directors and Shareholders  
Adventrx Pharmaceuticals, Inc.

We have audited management's assessment, included in Item 9A, Management's Report on Internal Control over Financial Reporting, that ADVENTRX Pharmaceuticals, Inc. and Subsidiary maintained effective internal control over financial reporting as of December 31, 2005 based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. ADVENTRX Pharmaceuticals, Inc. and Subsidiary's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

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

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America, and receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements. Because of inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that ADVENTRX Pharmaceuticals, Inc. and Subsidiary maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of the Sponsoring Organizations of the Treadway Commission. Also, in our opinion, ADVENTRX Pharmaceuticals, Inc. and Subsidiary maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on such criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of ADVENTRX Pharmaceuticals, Inc. and Subsidiary as of December 31, 2005, and the related consolidated statements of operations, shareholders' equity and cash flows for the year then ended, and our report dated March 10, 2006 expressed an unqualified opinion thereon.

/s/ J. H. Cohn LLP

San Diego, California

March 10, 2006

**ITEM 9B. OTHER INFORMATION**

None.

**PART III**

**ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS**

Information relating to our executive officers and directors will be presented under the caption "Executive Officers and Directors" in our definitive proxy statement in connection with our 2006 Annual Meeting of Stockholders to be held on or about May 15, 2006. That information is incorporated into this report by reference.

**Code of Ethics**

We have adopted a code of business conduct and ethics for employees, executive officers and directors. This code of business conduct and ethics is available on the investors section of our website at [www.adventrx.com](http://www.adventrx.com). Any waivers from or amendments to the code of ethics will be filed with the SEC on Form 8-K.

**ITEM 11. EXECUTIVE COMPENSATION**

The information required by this item is incorporated by reference to the information under the caption "Executive Compensation" contained in the Proxy Statement.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREHOLDER MATTERS**

The information required by this item is incorporated by reference to the information under the caption "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" contained in the Proxy Statement.

**Table of Contents**

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

The information required by this item is incorporated by reference to the information under the caption Certain Relationships and Related Transactions contained in the Proxy Statement.

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The information required by this item is incorporated by reference to the information under the caption Fees for Independent Registered Public Accounting Firm contained in the Proxy Statement.

**Table of Contents**

**PART IV**

**Item 15. EXHIBITS, FINANCIAL STATEMENTS AND SCHEDULES**

(a) Financial Statements and Schedules

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

The list of exhibits required by this Item is incorporated by reference to the Exhibit Index filed as part of this report.

30

---

**Table of Contents**

**SIGNATURES**

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

ADVENTRX Pharmaceuticals

By: /s/ Evan M. Levine

Evan M. Levine  
President and Chief Executive Officer

Date: March 16, 2006

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Evan M. Levine	President and Chief Executive Officer	March 16, 2006
Evan M. Levine	(Principal Executive Officer)	
/s/ Carrie Carlander	Chief Financial Officer, Senior Vice President, Finance, Secretary and Treasurer	March 16, 2006
Carrie Carlander	(Principal Financial and Accounting Officer)	
/s/ Robert A. Daniel	Controller	March 16, 2006
Robert A. Daniel	(Principal Accounting Officer)	
/s/ M. Ross Johnson	Chairman of the Board	March 16, 2006
M. Ross Johnson		
/s/ Michael M. Goldberg	Director	March 16, 2006
Michael M. Goldberg		

Edgar Filing: ADVENTRX PHARMACEUTICALS INC - Form 10-K

/s/ Mark J. Pykett	Director	March 16, 2006
Mark J. Pykett		
/s/ Mark Bagnall	Director	March 16, 2006
Mark Bagnall		
/s/ Keith Meister	Director	March 16, 2006
Keith Meister		

Index to Consolidated Financial Statements

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Balance Sheets</u>	F-3
<u>Consolidated Statements of Operations</u>	F-4
<u>Consolidated Statements of Shareholders' Equity</u>	F-5 F-6
<u>Consolidated Statements of Cash Flows</u>	F-7 F-8
<u>Notes to Consolidated Financial Statements</u>	F-9 F-24

F-1

---

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

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

We have audited the accompanying consolidated balance sheets of ADVENTRX Pharmaceuticals, Inc. and Subsidiary (a development stage enterprise) as of December 31, 2005 and 2004, and the related consolidated statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2005 and for the period from June 12, 1996 (date of inception) to December 31, 2005. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. The consolidated financial statements for the period from June 12, 1996 (date of inception) to December 31, 2001 were audited by other auditors whose report, dated April 10, 2003, expressed an unqualified opinion and included an explanatory paragraph concerning the Company's ability to continue as a going concern. Our opinion on the consolidated statements of operations, shareholders' equity and cash flows for the period from June 12, 1996 (date of inception) to December 31, 2005, insofar as it relates to amounts for the period for June 12, 1996 (date of inception) to December 31, 2001, is based solely on the report of the other auditors.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, based on our audits and the report of the other auditors, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of ADVENTRX Pharmaceuticals, Inc. and Subsidiary (a development stage enterprise) as of December 31, 2005 and 2004, and their results of operations and cash flows for each of the three years in the period ended December 31, 2005 and for the period from June 12, 1996 (date of inception) to December 31, 2005, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of ADVENTRX Pharmaceuticals, Inc. and subsidiary's internal control over financial reporting as of December 31, 2005, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 10, 2006 expressed an unqualified opinion thereon.

/s/ J.H. Cohn LLP  
San Diego, California  
March 10, 2006



**Table of Contents**

**ADVENTRX PHARMACEUTICALS, INC. AND SUBSIDIARY**  
**Consolidated Balance Sheets**

	<b>December 31,</b>	
	<b>2005</b>	<b>2004</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 14,634,618	\$ 13,032,263
Accrued interest income	10,214	10,808
Prepaid expenses	255,802	115,144
Short-term investments	7,958,458	
Assets available for sale		108,000
Total current assets	22,859,092	13,266,215
Property and equipment, net	407,544	285,304
Other assets	355,137	57,268
Total assets	\$ 23,621,773	\$ 13,608,787
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities:		
Accounts payable	593,228	532,327
Accrued liabilities	930,274	628,754
Accrued salary and related taxes	173,398	57,315
Warrant liability	29,696,411	
Total current liabilities	31,393,311	1,218,396
Other long-term liabilities	57,078	
Total liabilities	31,450,389	1,218,396
Commitments and contingencies		
Temporary equity:		
Common stock subject to continuing registration, \$.001 par value; 10,810,809 shares issued and outstanding		
Shareholders' equity/(deficit):		
Common stock, \$.001 par value; authorized 200,000,000, issued and outstanding 56,529,388 and 53,834,237 shares in 2005 and 2004	67,364	53,835
Additional paid-in capital	52,105,329	47,553,497
Deficit accumulated during the development stage	(59,964,840)	(35,182,194)
Accumulated other comprehensive gains (losses)	(1,722)	
Treasury stock, at cost	(34,747)	(34,747)
Total shareholders' equity	(7,828,616)	12,390,391
Total liabilities and shareholders' equity	\$ 23,621,773	\$ 13,608,787

See accompanying notes to consolidated financial statements.



**Table of Contents****ADVENTRX PHARMACEUTICALS, INC. AND SUBSIDIARY**

(Formerly Biokeys Pharmaceuticals, Inc.)

(A Development Stage Enterprise)

Consolidated Statements of Operations

	<i>Years Ended December 31,</i>			<i>Inception</i>
	<i>2005</i>	<i>2004</i>	<i>2003</i>	<i>(June 12,</i>
				<i>1996)</i>
				<i>through</i>
				<i>December 31,</i>
				<i>2005</i>
Net sales	\$	\$	\$	\$ 174,830
Cost of goods sold				51,094
Gross margin				123,736
Grant revenue			3,603	129,733
Interest income	496,059	103,042	9,269	698,337
Total revenue	496,059	103,042	12,872	951,806
Operating expenses:				
Research and development	8,682,498	2,744,328	748,997	16,156,752
General and administrative	4,901,002	4,018,453	1,585,596	17,334,299
Depreciation and amortization	115,545	41,309	8,970	10,255,561
Impairment loss write off of goodwill				5,702,130
Interest expense			1,386	179,090
Equity in loss of investee				178,936
Total operating expenses	13,699,045	6,804,090	2,344,949	49,806,768
Loss from operations	(13,202,986)	(6,701,048)	(2,332,077)	(48,854,962)
Loss on fair value of warrants	(11,579,660)			(11,579,660)
Loss before cumulative effect of change in accounting principle	(24,782,646)	(6,701,048)	(2,332,077)	(60,434,622)
Cumulative effect of change in accounting principle				(25,821)
Net loss	(24,782,646)	(6,701,048)	(2,332,077)	(60,460,443)
Preferred stock dividends			(37,840)	(621,240)
Net loss applicable to common stock	(24,782,646)	(6,701,048)	(2,369,917)	\$ (61,081,683)
Loss per common share- basic and diluted	\$ (0.41)	\$ (0.13)	\$ (0.07)	

Weighted average shares outstanding- basic and diluted	59,828,357	50,720,180	31,797,986
---	------------	------------	------------

See accompanying notes to consolidated financial statements.

F-4

---

**Table of Contents****ADVENTRX PHARMACEUTICALS, INC. AND SUBSIDIARY**

(A Development Stage Enterprise)

Consolidated Statements of Shareholders' Equity

Inception (June 12, 1996) through December 31, 2005

	Cumulative convertible preferred stock, series A			Cumulative convertible stock, series B		Cumulative convertible stock, series C		Common stock		Deficit Accumulated			Total Shareholders' equity (deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	paid-up capital	comprehensive loss	development stage	Treasurer's stock, at cost	
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											(45,003)		(45,003)

deficiency at acquisition charged to the Company					
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	3,200	32	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	70,354	70	83,930		84,000

payable							
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	3,200	32	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 dividends			93,421	93	212,907		213,000
Detachable warrants issued with notes payable					450,000		450,000
Issuance of warrants to pay operating					167,138		167,138

expenses							
Issuance of common stock to pay operating expenses			106,293	106	387,165		387,271
Issuance of preferred stock to pay operating expenses	137	1			136,499		136,500
Net loss						(16,339,120)	(16,339,120)
Balances at December 31, 2001	3,337	33	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							

F-5



**Table of Contents**

Cumulative convertible preferred stock, series A		Cumulative convertible preferred stock, series B		Cumulative convertible preferred stock, series C		Common stock		Deficit Accumulated			Treasury
Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Additional paid-in capital	other comprehensive loss	during the development stage	stock, at cost
						240,000	240	117,613			
						100,201	100	(100)			
						344,573	345	168,477			
		200,000	2,000					298,000			
				70,109	701			700,392			
(3,000)	(30)					1,800,000	1,800	(1,770)			
								335,440			
								163,109			
						6,292	6	12,263			
136	1							6,000			
								329,296			
										(2,105,727)	

473	4	200,000	2,000	70,109	701	17,496,257	17,496	25,276,138	(26,149,069)
								(37,840)	
				(70,109)	(701)	14,021,860	14,022	(13,321)	
						165,830	165	53,326	
						6,640,737	6,676	2,590,656	
						3,701,733	3,668	3,989,181	
						235,291	235	49,486	
						230,000	230	206,569	
								156,735	
								286,033	(2,332,077)
473	4	200,000	2,000			42,491,708	42,492	32,556,963	(28,481,146)
(473)	(4)					236,500	236	72,800 (232)	

(200,000)	(2,000)	200,000	200	1,800		
		464,573	465	(465)		
		23,832	23	27,330		
				86,375		
		10,417,624	10,419	15,616,031		
				(1,366,774)		
				524,922		
				34,747		(34,747)
					(6,701,048)	
		53,834,237	53,835	47,553,497	(35,182,194)	(34,747)
					(24,782,646)	
					(1,722)	
		10,810,809	10,811	(10,811)		
		2,408,316	2,408	3,071,030		

185,000      185      144,815

994,874

93,549

125,000      125      258,375

\$                      \$                      \$      67,363,362    \$ 67,364    \$ 52,105,329    \$ (1,722)    \$ (59,964,840)    \$ (34,747)

See accompanying notes to consolidated financial statements.

F-6

---

**Table of Contents**

**ADVENTRX PHARMACEUTICALS, INC. AND SUBSIDIARY**  
(Formerly Biokeys Pharmaceuticals, Inc.)  
(A Development Stage Enterprise)  
Consolidated Statements of Cash Flows

	Years ended December 31,			Inception (June 12, 1996) through December 31, 2005
	2005	2004	2003	
<b>Cash flows from operating activities:</b>				
Net loss	\$ (24,782,646)	\$ (6,701,048)	\$ (2,332,077)	\$ (60,460,443)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	115,545	41,309	8,970	9,805,561
Fair value of warrant liability	11,579,660			11,578,971
Amortization of debt discount				450,000
Forgiveness of employee receivable				30,036
Impairment loss write off of goodwill				5,702,130
Expenses paid by warrants		86,375	156,735	573,357
Expenses paid by preferred stock				142,501
Expenses related to stock warrants issued				612,000
Expenses related to employee stock options issued	994,874	524,922	286,033	2,135,125
Expenses related to options issued to non-employees	93,549			93,549
Expenses paid by issuance of common stock	101,833		206,799	919,381
Equity in loss of investee				178,936
Write-off of license agreement				152,866
Write-off assets available for sale	108,000			108,000

Cumulative effect of change in accounting principle				25,821
Accretion of discount	(111,960)			(111,960)
Changes in assets and liabilities, net of effect of acquisitions:				
Increase in prepaid and other assets	(281,266)	(255,101)	(23,136)	(711,854)
Increase (decrease) in accounts payable and accrued liabilities	478,504	1,128,153	(550,433)	1,175,629
Increase in long-term liabilities	57,078			57,078
	F-7			

---

**Table of Contents**

	Years ended December 31,			Inception (June 12, 1996) through December 31, 2005
	2005	2004	2003	
Increase in sponsored research payable and license obligation				924,318
Net cash used in operating activities	(11,646,829)	(5,175,390)	(2,247,109)	(26,618,309)
<b>Cash flows from investing activities:</b>				
Purchase of certificate of deposit				(1,016,330)
Maturity of certificate of deposit				1,016,330
Purchases of property and equipment	(237,785)	(305,773)	(16,376)	(666,027)
Purchase of short-term investments	(13,123,220)			(13,123,220)
Proceeds from sales of short-term investments	5,275,000			5,275,000
Payment on obligation under license agreement				(106,250)
Cash acquired in acquisition of subsidiary				64,233
Issuance of note receivable - related party				(35,000)
Payments on note receivable				405,993
Advance to investee				(90,475)
Cash transferred in rescission of acquisition				(19,475)
Cash received in rescission of acquisition				230,000
Net cash used in investing activities	(8,086,005)	(305,773)	(16,376)	(8,065,221)
<b>Cash flows from financing activities:</b>				

Edgar Filing: ADVENTRX PHARMACEUTICALS INC - Form 10-K

Proceeds from sale of preferred stock				4,200,993
Proceeds from sale of common stock	19,999,997	15,626,450	6,590,181	44,152,593
Proceeds from exercise of stock options	145,000			145,000
Proceeds from sale or exercise of warrants	3,073,438	27,353		3,485,028
Repurchase of warrants			49,721	(55,279)
Payment of financing and offering costs	(1,883,246)	(1,366,774)		(3,348,996)
Payments of notes payable and long-term debt			(253,948)	(605,909)
Proceeds from issuance of notes payable and detachable warrants				1,344,718
Net cash provided by financing activities	21,335,189	14,287,029	6,385,954	49,318,148
Net increase in cash and cash equivalents	1,602,355	8,805,866	4,122,469	14,634,618
Cash and cash equivalents at beginning of period	13,032,263	4,226,397	103,928	
Cash and cash equivalents at end of period	\$ 14,634,618	\$ 13,032,263	\$ 4,226,397	\$ 14,634,618

See accompanying notes to consolidated financial statements.

F-8



**Table of Contents**

**ADVENTRX Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements**  
**December 31, 2005**

**(1) Description of the Company**

ADVENTRX Pharmaceuticals, Inc., a Delaware corporation, (the Company), is a biopharmaceutical research and development company focused on introducing new technologies for anticancer and antiviral treatments that surpass the performance and safety of existing drugs and address significant problems such as drug metabolism, toxicity, bioavailability and resistance. The Company currently does not manufacture, market, sell or distribute any product. Through our license agreements with the University of Southern California (USC) and SD Pharmaceuticals, Inc., 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.

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

**(2) Summary of Significant Accounting Policies**

*Use of Estimates*

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

*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.

*Short-term Investments*

We account for and report our investments in accordance with Statement of Financial Accounting Standards No. 115, Accounting for Certain Investments in Debt and Equity Securities. Investments are comprised of marketable

**Table of Contents**

**ADVENTRX Pharmaceuticals, Inc.  
Notes to Consolidated Financial Statements (Continued)  
December 31, 2005**

securities consisting primarily of certificates of deposit, federal, state and municipal government obligations and corporate bonds. All marketable securities are held in our name and primarily under the custodianship of two major financial institutions. Our policy is to protect the principal value of our investment portfolio and minimize principal risk. Our marketable securities are classified as available-for-sale and stated at fair value, with net unrealized gains or losses recorded as a component of accumulated other comprehensive loss. Short-term investments are marketable securities with maturities of less than one year from the balance sheet date. Marketable securities are evaluated periodically for impairment. If it is determined that a decline of any investment is other than temporary, then the investment basis would be written down to fair value and the write-down would be included in earnings as a loss.

***Concentrations***

Substantially all of our cash and cash equivalents are maintained with two major financial institutions in the United States. Deposits held with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk. At December 31, 2005, cash and cash equivalents with banks exceeded federally insured limits by approximately \$14,714,000.

Financial instruments that potentially subject us to concentrations of credit risk consist principally of marketable securities and interest rate instruments. The counterparties to our investment securities and interest rate instruments are various major corporations and financial institutions of high credit standing.

During 2005, approximately 20% of our total vendor payments were made to a contract research organization that is assisting us in our clinical trial administration and data management. In the event we lost this vendor, we could experience delays in continuing our trial efforts which would result in increased costs as well as delays in obtaining FDA approvals.

***Fair Value of Financial Instruments***

At December 31, 2005 and 2004, our financial instruments included cash and cash equivalents, short-term investments, accounts payable, accrued expenses, and accrued compensation and payroll taxes. The carrying amount of cash and cash equivalents, accounts payable, accrued expenses and accrued compensation and payroll taxes approximates fair value due to the short-term maturities of these instruments. Our short-term investments in securities are carried at fair value based on quoted market prices.

***Property and Equipment***

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

***Revenue Recognition***

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

F-10

---

**Table of Contents**

**ADVENTRX Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2005**

***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.

***Marketing Expenses***

Marketing costs are expensed as incurred. Marketing costs charged to operations for the years ended December 31, 2005, 2004 and 2003 totaled \$33,064, \$67,782 and \$88,221 respectively.

***Income Taxes***

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

***Supplementary Cash Flow Information***

No interest was paid during the years ended December 31, 2005 and 2004. Interest of \$1,386 was paid during the year ended December 31, 2003. No income taxes were paid during 2005, 2004 or 2003.

Noncash investing and financing transactions excluded from the consolidated statements of cash flows for the years ended December 31, 2005, 2004, and 2003 and for the period from Inception (June 12, 1996) to December 31, 2005 are as follows:

F-11

---

**Table of Contents**

	Years ended December 31,			Inception (June 12, 1996) through December 31, 2005
	2005	2004	2003	
Issuance of warrants, common stock and preferred stock for:				
Conversion of notes payable and accrued interest	\$	\$	\$ 53,491	\$ 1,213,988
Payment of operating expenses	258,500			1,482,781
Conversion of preferred stock		2,004	701	2,705
Acquisitions				14,617,603
Payment of dividends				213,000
Financial advisor services in conjunction with private placement		1,137,456		1,137,456
Settlement of claim		86,375		86,375
Acquisition of treasury stock in settlement of a claim		34,747		34,747
Assumptions of liabilities in acquisitions				1,009,567
Acquisition of license agreement for long-term debt				161,180
Cashless exercise of warrants	150	465	2,360	3,892
Dividends accrued			37,840	621,040
Trade asset converted to available for sale asset		108,000		108,000
Dividends extinguished		72,800	0	408,240
Trade payable converted to note payable				83,948
Issuance of warrants for return of common stock			50,852	50,852
Detachable warrants issued with notes payable				450,000
Unrealized loss on short-term investments	1,722			1,722

F-12

**Table of Contents**

**ADVENTRX Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2005**

***New Accounting Pronouncements***

In December 2004, the FASB issued SFAS No. 123 (R), *Share-Based Payment*. SFAS No. 123 (R) establishes standards for the accounting for transactions in which an entity exchanges its equity instruments for goods or services. SFAS No. 123 (R) focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions. SFAS No. 123 (R) requires that the fair value of such equity instruments be recognized as expense in the historical financial statements as services are performed. Prior to SFAS No. 123 (R), only certain pro forma disclosures of fair value were required. SFAS No. 123 (R) shall be effective for all of the Company's interim and annual reporting periods commencing on January 1, 2006 and is not expected to have a material impact on the financial statements of the Company during the fiscal year 2007 and thereafter as the Company has already adopted SFAS No. 123.

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs*. SFAS No. 151 clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage) that previously stated that "... under some circumstances, items such as idle facility expense, excessive spoilage, double freight, and rehandling costs may be so abnormal as to require treatment as current period charges. . . . SFAS No. 151 requires that those items be recognized as current-period charges regardless of whether they meet the criterion of so abnormal. In addition, SFAS No. 151 requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The adoption of this new accounting pronouncement did not have a material impact on the Company's financial statements.

In December 2004, the FASB issued SFAS No. 153, *Exchanges of Nonmonetary Assets*. SFAS No. 153 is based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. The guidance in APB Opinion 29, however, included certain exceptions to that principle. SFAS No. 153 amends Opinion 29 to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. The adoption of this new accounting pronouncement did not have a material impact on the Company's financial statements.

In May 2005, the FASB issued SFAS No. 154 *Accounting Changes and Error Corrections* for the accounting for and reporting of a change in accounting principles. SFAS No. 154 applies to all voluntary changes in accounting principles. It also applies to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. Under the provisions of APB Opinion 20, most accounting changes were recognized by including in net income of the period of the change the cumulative effect of changing to the newly adopted accounting principle. SFAS No. 154 improves financial reporting because its requirement to report voluntary changes in accounting principles via retrospective application, unless impractical, enhances the consistency of financial information between periods. That improved consistency enhances the usefulness of the financial information, especially by facilitating analysis and understanding of comparative accounting data. Also, in instances in which full retrospective application is impracticable, SFAS No. 154 improves consistency of financial information between periods by requiring that a new accounting principle be applied as of the earliest date practicable. The adoption of this new accounting principle did not have a material impact on the Company's financial statements.

**Table of Contents**

**ADVENTRX Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2005**

SFAS No. 154 also requires that a change in depreciation, amortization or depletion methods for long-lived, nonfinancial assets be accounted for as a change in accounting estimate that is effected by a change in accounting principles. The provisions of SFAS No. 154 better reflect the fact that an entity should change its depreciation, amortization or depletion methods only in recognition of changes in estimated future benefits of an asset, in the pattern of consumption of those benefits, or in the information available to the entity about those benefits. The adoption of this new accounting pronouncement did not have a material impact on the Company's financial statements.

**(3) Short-term investments**

The following table summarizes our investments in securities, all of which are classified as available for sale.

	<b>Cost</b>	<b>2005 Gross Unrealized Gains (Losses)</b>	<b>Fair Value</b>
Government debt securities	\$ 1,443,845	\$ 165	\$ 1,444,010
Commercial paper	6,215,397	(1,690)	6,213,707
Corporate bonds	300,938	(197)	300,741
	<b>\$ 7,960,180</b>	<b>\$ (1,722)</b>	<b>\$ 7,958,458</b>

**(4) Property and Equipment**

Property and equipment at December 31, 2005 and 2004 were as follows:

	<b>Useful lives</b>	<b>2005</b>	<b>2004</b>
Office furniture, computer and lab equipment	3 - 5 years	\$ 513,222	\$ 333,286
Computer software	3 years	64,559	11,845
		577,781	345,131
Less accumulated depreciation and amortization		(170,237)	(59,827)
		<b>\$ 407,544</b>	<b>\$ 285,304</b>

**Table of Contents****(5) Income Taxes**

Due to the Company's net loss position for the years ended December 31, 2005, 2004 and 2003, and as the Company has recorded a full valuation allowance against deferred tax assets, there was no provision or benefit for income taxes recorded. There were no components of current or deferred federal, state or foreign tax provisions for the years ended December 31, 2005, 2004 and 2003.

The income tax provision is different from that which would be obtained by applying the statutory Federal income tax rate (34%) to income before income tax expense. The items causing this difference for the period are as follows:

	<b>2005</b>	<b>2004</b>	<b>2003</b>
Income tax expense at federal statutory rate	\$ 4,489,000	\$ 2,278,000	\$ 793,000
State tax on continuing operations	1,000	1,000	1,000
Other	371,000	(19,000)	3,000
Change in federal valuation allowance	(4,861,000)	(1,778,000)	(797,000)
Stock options previously expensed		(112,000)	
	\$	\$	\$

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities at December 31, 2005 and 2004 are as follows:

	<b>December 31,</b>	
	<b>2005</b>	<b>2004</b>
Deferred tax assets:		
Accrued expenses	\$ 47,028	\$ 231,000
Stock options expense under SFAS No. 123	772,919	292,000
Net operating loss carryforwards	11,068,149	6,864,000
Income tax credit carryforwards	844,509	
Property, plant and equipment	5,628	2,000
Intangibles	600,162	
Other	577	1,000
Total deferred tax assets	13,338,972	7,390,000
Less: valuation allowance	(13,338,972)	(7,390,000)
Total deferred tax assets, net of valuation allowance	\$	\$

The Company has established a valuation allowance against its deferred tax asset due to the uncertainty surrounding the realization of such assets. Management periodically evaluates the recoverability of the deferred



tax asset. At such time as it is determined that it is more likely than not that the deferred tax assets are realizable, the valuation allowance will be reduced. The Company has recorded a valuation allowance of \$13,338,972 as of December 31, 2005 to reflect the estimated amount of deferred taxes that may not be realized. The Company increased its valuation allowance by \$5,948,972 for the year ended December 31, 2005. The valuation allowance includes approximately \$50,000 related to stock option deductions, the benefit of which may eventually be credited to equity.

F-15

---

**Table of Contents**

**ADVENTRX Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2005**

At December 31, 2005 the Company had federal and California tax loss carryforwards of approximately \$29,263,000 and \$19,113,000 respectively. The federal net operating loss carryforwards begin to expire in 2011 and 2013 respectively, if unused. At December 31, 2005, the Company had federal and state tax credit carryforwards of approximately \$565,000 and \$424,000 respectively. The federal credits will begin to expire in 2024.

The utilization of net operating loss carryforwards and tax credit carryforwards is dependent on the future profitability of the Company. Furthermore, the Internal Revenue Code imposes a substantial restriction on the utilization of net operating loss and tax credit carryforwards in the event of an ownership change of more than 50 percentage points during any three year period. As a result of the change in ownership provisions, utilization of net operating loss and tax credit carryforwards may be subject to an annual limitation in future periods. As a result of an annual limitation, a portion of these carryforwards may expire before ultimately becoming available to reduce future taxable income or income tax. The extent of such limitations, if any, are not known.

**(6) Financing Activities**

On July 21, 2005, the Company entered into a Securities Purchase Agreement with Icahn Partners LP, Icahn Partners Master Fund LP, High River Limited Partnership, Viking Global Equities LP, VGE III Portfolio Ltd., North Sound Legacy Institutional Fund LLC, North Sound Legacy International Ltd. and the Royal Bank of Canada for the sale of 10,810,809 shares of Common Stock at a purchase price of \$1.85 per share for aggregate gross proceeds of \$19,999,996.65, and the issuance of 7-year warrants to purchase 10,810,809 shares of Common Stock at an exercise price of \$2.26 per share. The Company received net proceeds of \$18,116,751 as of July 21, 2005, which increased by \$197,000 to \$18,313,751 the fourth quarter. The private placement consisted of accredited institutional investors.

Pursuant to the terms of the Securities Purchase Agreement entered into in connection with the transaction, if (i) a Registration Statement covering (A) all of the Shares and the Warrant Shares and (B) any other shares of Common Stock issued or issuable in respect to the Shares and the Warrant Shares because of stock splits, stock dividends, reclassifications, recapitalizations or similar events (together, the Registrable Shares ) required to be covered thereby and required to be filed by the Company is (A) not filed with the SEC on or before forty-five (45) days after the Closing Date (a Filing Failure ) or (B) if such Registration Statement is not declared effective by the SEC on or before (1) ninety (90) days after the Closing Date (an Effectiveness Failure ) or (ii) on any day after the effective date of the Registration Statement sales of all the Registrable Shares required to be included on such Registration Statement cannot be made (other than as permitted during a suspension pursuant to this Agreement) pursuant to such Registration Statement (including, without limitation, because of a failure to keep such Registration Statement effective, to disclose such information as is necessary for sales to be made pursuant to such Registration Statement or to register sufficient shares of Shares) (a Maintenance Failure ), then, the Company shall pay as liquidated damages (the Liquidated Damages ) for such failure and not as a penalty to any Purchaser an amount in cash determined in accordance with the formula set forth below:

For each 30-day period that a Filing Failure, Effectiveness Failure or Maintenance Failure remains uncured, the Company shall pay an amount equal to the purchase price paid to the Company for all Shares then held by such Purchaser multiplied by 1% for the first 30-day period or any portion thereof and increasing by an additional 1% with regard to each additional 30-day period until such Filing Failure, Effectiveness Failure or Maintenance Failure is cured. For any partial 30-day period in which a Filing Failure, Effectiveness Failure or Maintenance Failure exists but is cured prior to the end of the 30-day period, the Company shall pay the Purchasers a pro rata

portion of the amount which would be due if the failure continued for the entire 30-day period. For example, if the purchase price paid for all Shares then held by a Purchaser is \$5,000,000, then, (a) at the end of the 30th day, the Liquidated Damages would be 1% or \$50,000, (b) at the end of the 60th day, the Liquidated Damages for the first 30-day period would have been 1% or \$50,000 and for the second 30-day period would be 2% or \$100,000, and (c) at the end of the 105th day, the Liquidated Damages for the first 30-day period would have been 1% or \$50,000, for the second 30-day period 2% or \$100,000, for the third 30-day period 3% or \$150,000, and for the final 15-day period, 4% applied pro rata to such 15 days, or \$100,000.

Payments to be made pursuant to this Agreement shall be due and payable to the Purchasers at the end of each calendar month during which Liquidated Damages shall have accrued. No Liquidated Damages shall be due or payable to a Purchaser in any event if as of the date of the Filing Failure, Effectiveness Failure or Maintenance Failure such Purchaser could sell all of the Registrable Shares such Purchaser then holds without registration by reason of Rule 144(k) of the Securities Act.

The registration statement was filed and declared effective by the SEC within the allowed time. The Company has not yet been required to pay any liquidated damages in connection with the filing or effectiveness of the registration.

In accordance with Emerging Issues Task Force (EITF) Issue No. 00-19, Accounting for Derivative Financial Instruments Indexed To, and Potentially Settled In a Company's Own Stock, and the SEC's December 2005 interpretation the terms of the warrants and the transaction documents, the fair value of the warrants was accounted for as a liability, with an offsetting reduction to additional paid-in capital at the closing date (July 21, 2005). At the end of each reporting period, the value of the warrants will be remeasured based on the fair market value of the underlying shares, and changes to the warrant liability and related gain or loss will be made appropriately. The warrant liability will be reclassified to equity when the registration statement is no longer subject to risk for Maintenance Failures.

The fair value of the warrants was estimated using the Black-Scholes option-pricing model with the following assumptions: no dividends; risk-free (10-year Treasury yield) interest rate of 4.39%; the contractual life of 7 years and volatility of 90%. The fair value of the warrants was estimated to be \$19,439,185 on the closing date of the transaction. The difference between the fair value of the warrants of \$19,439,185 and the gross proceeds from the offering was classified as Loss on fair value of warrants in the Company's statement of operations, and included in Warrant liability on the Company's balance sheet. The fair value of the warrants was then re-measured at December 31, 2005 and estimated to be \$29,695,722 with the increase in fair value due to the increase in the market value of the Company's common stock. The increase in fair value of the warrants of \$10,256,537 from the transaction date to December 31, 2005 was recorded as Loss on fair value of warrants in the Company's statement of operations, and included in Warrant liability on the Company's balance sheet.

The Company paid the placement agents \$1,600,000 in cash as fees for services performed in conjunction with the private placement. The Company also incurred \$283,246 in other legal and accounting fees. In the fourth quarter, \$197,000 of the placement agent fees was refunded to the Company, reducing our fees for placement services to \$1,403,000.

The adjustments required by EITF Issue No. 00-19 as interpreted by the SEC in December 2005 were triggered by the terms of the Company's agreements for the private placement it completed in July 2005, specifically related to the potential penalties if the Company did not timely register the common stock underlying the warrants issued in the transaction, and remain effective during the registration period. The adjustments for EITF Issue No. 00-19 had no impact on the Company's cash flow, liquidity, or business operations.

The Company intends to utilize the net proceeds of \$18,313,751 to fund pivotal clinical trials for its various compounds, and meet working capital needs through December 31, 2005.

**(7) Equity Transactions**

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

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

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

In March 2003, the Company paid two consulting firms for services rendered with 125,000 shares of Common Stock with a fair market value on the date of issuance of \$68,750, and two warrants to purchase 37,500 shares of Common Stock at an exercise price of \$0.50 per share. The fair market value of the warrants on the date of issuance was \$33,777.

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

In March 2003, the Company issued a warrant to a former executive in consideration of certain covenants related to his separation from the Company. The warrant represents the right to purchase 150,000 shares of Common Stock at an exercise price of \$1.25 per share. The 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.

**Table of Contents**

**ADVENTRX Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2005**

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

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

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

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

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

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

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

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

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

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

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

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

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

Edgar Filing: ADVENTRX PHARMACEUTICALS INC - Form 10-K

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

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

F-17

---

**Table of Contents**

**ADVENTRX Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2005**

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

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

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

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

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

In April 2005, the Company issued 25,000 shares of Common Stock as partial payment for services rendered by a consulting firm. Those shares were recognized at fair market value as of the date of obligation and resulted in compensation expense of \$23,500 in the first quarter of 2005, when the services were performed.

In July 2005, the Company issued 100,000 shares of Common Stock pursuant to a consulting agreement entered into in January 2005. Those shares were recognized at fair market value as of the date of issuance and resulted in compensation expense of \$78,333 for the year ended December 31, 2005.

In July 2005, the Company issued 10,810,809 shares in conjunction with a private placement which resulted in net proceeds of \$18,116,751. The net proceeds increased by \$197,000 in the fourth quarter of 2005 due to a partial refund of commissions paid. The Company also issued warrants to purchase 10,810,809 shares of Common Stock at an exercise price of \$2.26 per share with this placement.

In 2005, Company employees exercised vested stock options for total proceeds of \$145,000 and were issued 185,000 shares of Common Stock. Over the same period, investors exercised warrants for total proceeds of \$3,073,438 and were issued 2,408,316 shares of Common Stock. There were also 125,000 shares of Common Stock issued to vendors and consultants in 2005.

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 2005, 2004 and 2003: no dividend yield for either year; expected volatility of 81% to 199%; risk-free interest rates 2.78% to 4.74%; and expected lives of three and seven years, respectively.

**Table of Contents**

**ADVENTRX Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2005**

At December 31, 2005, there were outstanding warrants to purchase a total of 19,629,933 shares of Common Stock as follows:

Warrants	Exercise price	Expiration date
1,305,025	\$ 0.60	May-06
502,528	\$ 0.49	Jun-06
49,118	\$ 10.00	Jun-06
811,693	\$ 1.25	Oct-06
165,601	\$ 0.50	Nov-06
250,000	\$ 0.50	Dec-06
309,750	\$ 1.25	Dec-06
100,000	\$ 3.00	Dec-06
50,000	\$ 2.50	Apr-07
300,000	\$ 2.50	Oct-07
2,689,536	\$ 1.98	Apr-09
1,705,826	\$ 2.38	Apr-09
580,047	\$ 1.98	Jun-09
10,810,809	\$ 2.26	Jul-12
19,629,933		

**(8) Stock Compensation Plans**

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

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

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

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

In January and February 2004, three individuals became members of the Company's board of directors. Each new director was granted an option to purchase 50,000 shares of Common Stock at a purchase price of \$1.50 per share. The options expire on December 30, 2008. The value of the options on the dates of grant was \$223,826.



**Table of Contents**

**ADVENTRX Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2005**

In February 2004, an individual became a member of the SAB. The new SAB member was granted an option to purchase 30,000 shares of Common Stock at a purchase price of \$1.50 per share. The option will vest in equal installments over eight quarters, starting March 1, 2004. The value of the option on the date of grant was \$45,350. In March 2004, the Company granted an option to purchase 100,000 shares of Common Stock at a purchase price of \$1.50 per share to the Company's Vice President of Clinical and Medical Affairs. The option will vest in three installments over three years starting March 2004. The value of the option on the date of grant was \$88,627. In April 2004, the Company granted an option to purchase 30,000 shares of Common Stock at a purchase price of \$1.50 per share to the Director of Antiviral Research. The option will vest in three installments over three years starting April 2004. The value of the option on the date of grant was \$37,600. In the period May 2004 through August 2004, the Company granted options to purchase an aggregate of 66,000 shares of Common Stock at purchase prices of \$1.20 to \$1.80 per share to employees. AMEX listing requirements prohibit granting equity without a shareholder vote or an approved stock option plan; therefore, the options were rescinded in February 2005. Accordingly, the financial statement effect of the options granted has been reversed in 2004. On May 24, 2005, at the Company's annual meeting of stockholders, the Company's stockholders approved the 2005 Equity Incentive Plan (the 2005 Plan) and the 2005 Employee Stock Purchase Plan. The 2005 Plan is intended to encourage ownership of shares of common stock by directors, officers, employees, consultants and advisors of the Company and its affiliates and to provide additional incentive for them to promote the success of the Company's business through the grant of equity-based awards. The 2005 Plan permits the Company to issue options, share appreciation rights, restricted shares, restricted share units, performance awards, annual incentive awards and other share-based awards and cash-based awards. The maximum aggregate number of shares of Common Stock which may be issued pursuant to or subject to the foregoing types of awards granted under the 2005 Plan at the time of adoption was 6,000,000. This maximum number is subject to an annual automatic increase beginning on January 1, 2006 equal to the lesser of (i) 1% number of outstanding shares of common stock on such day, (ii) 750,000 and (iii) such other amount as the Company's board of directors may specify. The 2005 Plan is intended to comply with applicable securities law requirements, permit performance-based awards that qualify for deductibility under Section 162(m) of the Internal Revenue Code and allow for the issuance of incentive stock options. In July 2005, the Company granted 1,625,000 options to employees under the 2005 Plan to replace pre-existing options that were not issued under the 2005 Plan or any other incentive plan approved by the Company's stockholders. In addition in July 2005, the Company granted 1,103,000 new options to employees and board members under the 2005 Plan. In December 2005, the exercise prices on 743,000 of the 1,103,000 options were increased to equal the fair market value of Common Stock on the date of grant in July 2005. In addition, the exercise prices on 730,000 of the pre-existing options were increased to equal the fair market value of Common Stock on the original grant dates. There was no material impact to the compensation expense as a result of this change. The Company has acknowledged that this increase in exercise prices could adversely impact affected employees' morale and the Company's ability to retain these employees. However, the Company has not yet taken any action to remedy any such impact. For purposes of Black-Scholes pricing model the following assumptions were used to estimate a fair value for these option grants: no dividend yield, expected volatility 81% to 90%, risk-free interest rates 3.30% to 4.74% and expected lives of 3 to 5 years. The Company cancelled 200,000 options in the year ended December 31, 2005 related to terminated employees. The Company recognized compensation expense of \$994,874, \$524,922 and \$286,033 in the years ended December 31, 2005 and 2004, respectively, related to the portion of the options that vested in that period. In July 2005, the Company granted 114,000 options to consultants. These option grants were valued as of December 31, 2005 using the Black-Scholes pricing model with the following assumptions: no dividend yield, expected volatility of 90%, risk-free interest rate 4% and expected life of 3 or 5 years. The Company recognized \$93,549 in compensation expense for these options in the year ended December 31, 2005.

**Table of Contents**

**ADVENTRX Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2005**

There were 1,557,503 options exercisable at year end. The weighted average fair value of options granted during the year was \$2.34.

	Shares (000)	Weighted Average Exercise Price
Stock Options		
Outstanding at January 1, 2003	1,690	\$ 0.23
Granted	2,040	\$ 0.58
Forfeited	(750)	\$ 0.50
Outstanding at December 31, 2003	2,980	\$ 0.38
Granted	310	\$ 1.50
Exercised		
Forfeited	(1,665)	\$ 0.23
Outstanding at December 31, 2004	1,625	\$ 0.75
Granted	1,217	\$ 2.34
Exercised	(185)	\$ 0.78
Forfeited	(200)	\$ 1.41
Outstanding at December 31, 2005	2,457	\$ 1.45

	Options Outstanding			Options Exercisable	
	Number Outstanding at 12/31/05 (000)	Weighted- Average Remaining Contractual Life	Weighted- Average Exercise Price	Number Exercisable at 12/31/05 (000)	Weighted- Average Exercise Price
Range of Exercise Price					
\$0.50 to \$2.04	1,400	2.96	\$ 0.77	1,307	\$ 0.78
\$2.30	757	8.68	\$ 2.30	168	\$ 2.30
\$2.42 to \$2.50	300	7.86	\$ 2.45	83	\$ 2.42
	2,457	5.32	\$ 1.45	1,558	\$ 1.03

**Table of Contents**

**ADVENTRX Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2005**

**(9) Net Loss per Common Share**

	2005	2004	2003
Numerator:			
Net loss	\$ (24,782,646)	\$ (6,701,048)	\$ (2,332,077)
Preferred Stock dividends			(37,840)
Numerator for basic and diluted loss per common share	\$ (24,782,646)	\$ (6,701,048)	(2,369,917)
Denominator for basic and and diluted loss per share-weighted average common shares outstanding	59,828,357	50,720,180	31,797,986
Loss per common share- basic and diluted	\$ (0.41)	\$ (0.13)	\$ (0.07)

Net loss per common share is calculated according to Statement of Financial Accounting No. 128, *Earnings per Share*, using the weighted average number of shares of Common Stock outstanding during the period. The following potentially dilutive shares were not included in the computation of net loss per common share diluted, as their effect would have been anti-dilutive due to the Company's net losses in 2005, 2004 and 2003:

	<b>2005</b>	<b>2004</b>	<b>2003</b>
Preferred stock			318,250
Warrants	19,629,933	11,154,964	5,474,987
Options	2,457,000	1,625,000	2,980,000
	22,086,933	12,779,964	8,773,237

**Table of Contents**

**ADVENTRX Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2005**

**(10) 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 was 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 remained in effect. In 2005, the Company terminated this agreement.

***USC Agreement***

Under an Option and License Agreement with the University of Southern California (USC) dated January 23, 1998 (as amended August 16, 2000), the Company holds exclusive rights to a number of patents that have issued in the United States and Canada covering products (CoFactor<sup>®</sup> and Selone) and methods intended for use in connection with cancer chemotherapy. Under another Option and License Agreement with USC dated August 17, 2000 (as amended April 21, 2003), the Company holds exclusive rights to a number of additional patents that have issued in the United States and Europe relating to the antiviral product Thiovir and drugs useful for the treatment of HPV (human papillomavirus) infections, HIV infections, HIV/HPV coinfections and other human therapeutic uses. Additional patent applications relating to Thiovir are pending in Europe, Canada and Australia.

The first license from USC provides for the payment to USC of a 3% royalty (on net sales of products made or sold in a country in which a patent has issued or is pending), while the second license provides for the payment of a 1% royalty. Both require the Company to pay USC a share of consideration received by the Company from any sublicensee as well as the cost of filing, prosecuting and maintaining the licensed patents. Under the second license (as amended), milestone payments will also be due based upon entry into human trials and regulatory approval for each drug candidate developed (\$75,000 at Phase I, \$100,000 at Phase II, \$125,000 at Phase III and \$250,000 at market approval). No royalties have been paid to date under these licenses.

***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 BlockAide/CR, a drug we were previously developing. Under the terms of the agreement, the Company agreed 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 were benchmark royalties based upon: initiation of Phase I trials, initiation of Phase II trials, initiation of Phase III trials, and upon first approval of a Product License Application for an HIV therapeutic or vaccine in the U.S. and for first approval in Europe. No material amount was paid under this agreement. In 2005, the Company terminated this agreement.

***SD Pharma Agreement***

We signed an exclusive license agreement in the third quarter of 2005 with SD Pharmaceuticals, Inc. (SD Pharma) for rights to a patent application which describes an invention relating to an emulsion composition for delivering highly water-soluble vinca alkaloid drugs (the Invention). The rights include the right to commercial development, use, and sale of the Invention. ANX-530 (vinorelbine emulsion) is included in the license agreement and is the drug which we currently plan to develop. In consideration for these rights, we agreed to pay SD Pharma a license fee, milestone payments and royalties.

**Table of Contents**

**ADVENTRX Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements (Continued)**  
**December 31, 2005**

**(11) Commitments and Contingencies*****Operating Leases***

The Company is obligated under operating leases for office space and equipment. In July 2004, the Company entered into a lease for its current office space in San Diego, California. In June 2005, the Company leased additional space in the same facility. Based on a straight-line basis, the lease requires a monthly payment of \$20,798. The lease expires in August 2009. Rent expense was \$220,517, \$118,966 and \$40,648 during the years ended December 31, 2005, 2004 and 2003, respectively.

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

Year Ending	
December 31,	
2006	\$ 248,364
2007	255,630
2008	256,959
2009	174,698
Total	\$ 935,651

**(12) 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. 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.

**(13) 401(k) Plan**

In January 2005, the Company adopted a plan intended to qualify as a qualified cash or deferred arrangement under Section 401(k) of the Internal Revenue Code of 1986, as amended (the 401(k) Plan). Under the provisions of the 401(k) Plan, the Company is required to make matching contributions in the amount of 100% of salary deferrals up to 3% and 50% of salary deferrals between 3% and 5% of the annual salary of the contributing employee. During 2005, the Company incurred a total charge of \$61,354 in employer matching contributions.

**(14) Preferred Stock**

In November 2005, at a special meeting of the Company's stockholders, the stockholders approved a proposal to increase the number of shares of Common Stock the Company is authorized to issue to 200,000,000 shares. The number of authorized shares of Preferred Stock remains unchanged at 1,000,000 shares. The Series A, Series B and Series C Preferred Stock were eliminated, and the Company is no longer authorized to issue any such series of Preferred Stock as previously designated. We have no present plans to issue any new shares or designate any series of Preferred Stock.

**Table of Contents**

**Exhibit Index**

Exhibit	Description
3.1	Amended and Restated Certificate of Incorporation
3.2 (1)	Amended and Restated Bylaws of Biokeys Pharmaceuticals, Inc.
4.1 (2)	Common Stock and Warrant Purchase Agreement, dated as of April 5, 2004, among the Company and the Investors named therein
4.2 (2)	A-1 Warrant to Purchase Common Stock issued to Investors pursuant to the Common Stock and Warrant Purchase Agreement with the Investors
4.3 (2)	A-2 Warrant to Purchase Common Stock issued to Investors pursuant to the Common Stock and Warrant Purchase Agreement with the Investors
4.4 (3)	Common Stock and Warrant Purchase Agreement, dated April 8, 2004, between the Company and CD Investment Partners, Ltd.
4.5 (3)	A-1 Warrant to Purchase Common Stock issued to CD Investment Partners, Ltd.
4.6 (3)	A-2 Warrant to Purchase Common Stock issued to CD Investment Partners, Ltd.
4.7 (3)	Warrant to Purchase Common Stock issued on April 8, 2004 to Burnham Hill Partners
4.8 (3)	Warrant to Purchase Common Stock issued on April 8, 2004 to Ernest Pernet
4.9 (3)	Warrant to Purchase Common Stock issued on April 8, 2004 to W.R. Hambrecht + Co., LLC
4.10 (2)	Registration Rights Agreement, dated as of April 5, 2004, among the Company and the Investors named therein
4.11 (3)	Registration Rights Agreement, dated as of April 8, 2004, between the Company and CD Investment Partners, Ltd.
4.14 (4)	Common Stock and Warrant Purchase Agreement, dated April 19, 2004, between the Company and Franklin Berger
4.15 (4)	A-1 Warrant to Purchase Common Stock issued to Franklin Berger
4.16 (4)	A-2 Warrant to Purchase Common Stock issued to Franklin Berger
4.17 (4)	Registration Rights Agreement, dated as of April 19, 2004, between the Company and Franklin Berger
4.18 (2)	Registration Rights Agreement, dated ____, 2001, between the Company and certain stockholders
4.19 (2)	Warrant to Purchase Common Stock issued by the Company
4.20 (2)	Stock Subscription Agreement
4.21 (2)	Warrant to Purchase Common Stock issued by the Company
4.22 (2)	Warrant for the Purchase of Shares of Common Stock No. WA-2A issued June 14, 2001 to Robert J. Neborsky and Sandra S. Neborsky, JTWROS
4.23 (5)	Securities Purchase Agreement, dated July 21, 2005, among the Registrant and the Purchasers named therein
4.24 (5)	Rights Agreement, dated July 27, 2005, among the Registrant and the Purchasers named therein
4.25 (5)	Common Stock Warrants Nos. WP-1 to WP-5 and WP-8
4.26 (5)	Common Stock Warrants Nos. WP-6 and WP-7
4.31 (6)	Warrant to Purchase Common Stock, No. WC-290, issued to Robert J. Neborsky MD Inc Combination Retirement Trust
4.32 (6)	Warrant to Purchase Common Stock, No. WC-291, issued to S. Neborsky and R Neborsky TTEE Robert J. Neborsky MD Inc Comb Retirement Trust
4.33 (6)	Warrant to Purchase Common Stock, No. WC-292, issued to S. Neborsky and R Neborsky TTEE Robert J. Neborsky MD Inc Comb Retirement Trust
4.34 (6)	Warrant to Purchase Common Stock, No. WC-287, issued to Thomas J. DePetrillo
10.1 (7)	2005 Equity Incentive Plan
10.2 (7)	Form of Stock Option Agreement under the 2005 Equity Incentive Plan
10.3 (7)	2005 Employee Stock Purchase Plan

Edgar Filing: ADVENTRX PHARMACEUTICALS INC - Form 10-K

- 10.4 (7) Form of Subscription Agreement under the 2005 Employee Stock Purchase Plan
  - 10.5 (8) Option and License Agreement, dated January 23, 1998, between the Company and the University of Southern California (Request for confidential treatment of certain data)
  - 10.6 (1) First Amendment to License Agreement, dated August 16, 2000, between the Company and the University of Southern California (Request for confidential treatment of certain data)
  - 10.7 (8) Option and License Agreement, dated August 17, 2000, between the Company and the University of Southern California (Request for confidential treatment of certain data)
  - 10.8 (9) Amendment to Option and License Agreement, dated April 21, 2003, the Company and the University of Southern California
-

**Table of Contents**

10.9 (10) License Agreement, effective April 29, 2005, between the Company and SD Pharmaceuticals, Inc  
 10.10 Agreement, effective as of May 1, 2005, between the Company and Pharm-Olam International Ltd.  
 10.11 Amendment dated July 19, 2005 to the Agreement between the Company and Pharm-Olam International Ltd.  
 10.12 Standard Multi-Tenant Office Lease Gross, dated June 3, 2004, between the Company and George V. Casey & Ellen M. Casey, Trustees of the Casey Family Trust dated June 22, 1998  
 (11)  
 10.13 First Amendment to the Standard Multi-Tenant Office Lease Gross, dated June 3, 2004 between the Company and George V. & Ellen M. Casey, Trustees of the Casey Family Trust dated June 22, 1998  
 10.14 Offer Letter, dated March 5, 2003, from the Company to Joan M. Robbins, Ph.D.  
 (12)  
 10.15 Offer Letter, dated November 15, 2004, from the Company to Brian Culley  
 (13)  
 10.16 Offer Letter, dated November 17, 2004, from the Company to Carrie Carlander  
 (14)  
 10.17 Offer Letter, dated October 30, 2003, from the Company to Mark Cantwell  
 10.19 Form of Restricted Share Award Agreement under the 2005 Equity Incentive Plan  
 21.1 List of Subsidiaries  
 23.1 Consent of JH Cohn LLP, Independent Registered Public Accounting Firm  
 31.1 Rule 13a-14(a)/15d-14(a) Certification  
 31.2 Rule 13a-14(a)/15d-14(a) Certification  
 32.1 Section 1350 Certification  
 32.2 Section 1350 Certification

- (1) Incorporated by reference to the same-numbered exhibit to the Company's Registration Statement on Form 10-SB, filed October 2, 2001.
- (2) Incorporated by reference to the same-numbered exhibit to the Company's Registration Statement on Form S-3, filed June 30, 2004.
- (3) Incorporated by reference to the same-numbered exhibit to the Company's Current Report on Form 8-K, filed April 13, 2004.
- (4) Incorporated by reference to the same-numbered exhibit to the Company's Quarterly Report on Form 10-QSB, filed May 12, 2004.
- (5) Incorporated by reference to the same-numbered exhibit to the Company's Quarterly Report on Form 10-QSB, filed August 12, 2005.
- (6) Incorporated by reference to the same-numbered exhibit to the Company's Registration Statement on Form S-3, filed August 26, 2005.
- (7) Incorporated by reference to the same-numbered exhibit to the Company's Registration Statement on Form S-8, filed August 26, 2005.
- (8) Incorporated by reference to the same-numbered exhibit to the Company's Registration Statement on Form 10-SB/A, filed January 14, 2002.
- (9)



Edgar Filing: ADVENTRX PHARMACEUTICALS INC - Form 10-K

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

- (10) Incorporated by reference to Exhibit 10.14 to the Company's Quarterly Report on Form 10-QSB, filed November 14, 2005.
- (11) Incorporated by reference to the same-numbered exhibit to the Company's Quarterly Report on Form 10-QSB, filed August 10, 2004.
- (12) Incorporated by reference to the same-numbered exhibit to the Company's Annual Report on Form 10-KSB, filed April 16, 2003
- (13) Incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-KSB, filed March 31, 2005.
- (14) Incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-KSB, filed March 31, 2005.