SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-KSB

(Mark one)
[X] ANNUAL REPORT UNDER SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year December 31, 2002, or

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 000-33219

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

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

9948 HIBERT STREET, SUITE 100, SAN DIEGO, CALIFORNIA 92131
(Address of principal executive offices)

(858) 271-9671
(Issuer's telephone number, including area code)

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

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

COMMON STOCK, PAR VALUE $0.001 PER SHARE

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

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

State issuer's revenues for its most recent fiscal year: $47,064

The aggregate market value of the Common Stock held by non-affiliates of the issuer, as of March 31, 2003 was approximately $11,319,973 based upon the closing price of the issuer's Common Stock reported for such date on the OTC Bulletin Board. For purposes of this disclosure, shares of Common Stock held by persons who beneficially own more than 5% of the outstanding shares of Common Stock and shares held by officers and directors of the issuer have been excluded because such persons may be deemed to be affiliates of the issuer. This determination is not necessarily conclusive.

As of March 31, 2003, 32,652,630 shares of the issuer's Common Stock were outstanding.

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

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PART I

PART I

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

ITEM 1. DESCRIPTION OF BUSINESS.

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

BUSINESS DEVELOPMENT

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

BUSINESS OF ISSUER

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

Principal Products

We have three products moving toward clinical development and three products in preclinical research:

| Product Line | Focus | Application | Stage of Development |
|---|---|---|---|
| CoFactorTM | colorectal cancer | 5-FU biomodulator | approved to begin Phase II trials in the US |
| BlockAide/CRTM | HIV/AIDS | viral entry inhibitor | preclinical; planning for Phase I trials |
| EradicAideTM | HIV/AIDS | therapeutic vaccine | preclinical; planning for Phase I trials |
| ThiovirTM | HIV/AIDS, HPV viral infections | viral replication inhibitor | preclinical |
| BlockAide/VPTM | HIV/AIDS | viral entry inhibitor | preclinical |
| SeloneTM | drug-resistant cancer | alkylating agent | preclinical |

CoFactor

CoFactor (5,10-methylenetetrahydrofolate) is a patented new drug which in clinical trials has significantly improved the performance of 5-FU (5-Fluorouracil) and other fluoropyrimidines commonly used in cancer chemotherapy. CoFactor was developed by researchers at USC in Los Angeles and at the Sahlgrenska University Hospital, University of Goteborg, Sweden, who discovered its ability to significantly enhance 5-FU's inhibition of a key enzyme, thymidylate synthase, necessary for cancer cell growth. Because 5-FU is one of the most extensively used cancer chemotherapy drugs in the world, including in the United States, the European Union and Japan, and CoFactor could significantly improve the performance of 5-FU, we believe that the 5-FU/CoFactor combination therapy drug for the treatment of cancer has significant market potential.

Between November 1989 and March 1993, a Phase I/II clinical study of the use of CoFactor in combination with 5-FU was performed at Sahlgrenska University Hospital, under the direction of Dr. Bengt Gustavsson, in close collaboration with Dr. Colin Paul Spears at USC. Dr. Gustavsson and Dr. Spears are the co-inventors of this technology. Results of their work with humans were published in The Cancer Journal, vol. 10, no. 5 September-October 1997.

In human clinical trials conducted at Sahlgrenska University Hospital, CoFactor was administered to 62 cancer patients receiving 5-FU therapy. Reductions in the size of tumors were observed in 21% to 55% of colorectal, pancreas, stomach, gallbladder and breast cancer patients. The magnitude of reduction was dependent on the type of cancer and the dosage of 5-FU and CoFactor given to separate groups of those patients. The reductions we observed demonstrate that CoFactor is highly effective under different conditions and different dosages. The average duration of cancer remission in patients who received CoFactor in combination with 5-FU in our clinical trial was nine to 15 months. The average duration of cancer remission in these patients is more than 100% longer than the average duration of cancer remission in patients receiving 5-FU in combination with leucovorin, a drug commonly administered in combination with 5-FU in an effort to improve the performance of 5-FU. In clinical trials, the toxicity of the 5-FU/CoFactor drug combination was less than the toxicity of 5-FU alone and less than the 5-FU/leucovorin drug combination. No toxicities of CoFactor have been observed. We believe these results represent a significant improvement over the standard 5-FU/leucovorin therapy for cancer patients.

Several articles regarding the use of CoFactor in the treatment of cancer were published during late 1997 and early 1998 in leading medical journals, including Cancer Investigations, Cancer Treatment, Anticancer Research, and The Cancer Journal. Such articles discussed the:

- curative results with 5-FU therapy in combination with CoFactor for liver cancer in animal studies compared to 5-FU alone or to 5-FU/leucovorin therapy;
- significant response to 5-FU/CoFactor in animal colon cancer studies;
- human pharmacokinetic (drug action/metabolism) data documenting high blood levels of CoFactor for several hours after administration; and
- the achievement of stabilizing the CoFactor compound for routine administration to patients.

Subsequent to completing our Phase I/II human clinical trials of CoFactor, we analyzed tissue samples from the 62 patients treated in that trial using newly developed methods for determining relative human enzyme levels by analyzing genes. Our further analysis has enhanced our understanding of why patients responded to the 5-FU/CoFactor combination therapy and will be useful in studying responses in future trials of CoFactor.

On December 19, 2001, we received approval from the United States Food and Drug Administration (the "FDA") to conduct Phase II trials of CoFactor in the United States for initial therapy of patients who are newly diagnosed with metastatic colorectal cancer. We plan to conduct this Phase II human trial once we receive adequate funding. We further intend to apply for Phase II trials of CoFactor in Sweden during 2003 and Phase III trials in both the United States and Sweden thereafter.

BlockAide/CR

BlockAide/CR is a viral entry inhibitor first identified at the National Institutes of Health and subsequently developed by scientists at M.D. Anderson Cancer Center for its antiviral properties. This product is licensed to the Company by both NIH and M.D. Anderson. It represents a new approach to combating HIV, based on a synthetic peptide (a sequence of amino acids that is part of a protein), which appears to be able to block the ability of HIV to infect human immune cells. During in vitro experiments in human cell cultures, and in preclinical animal tests, BlockAide/CR was able to significantly depress the level of viral infection (as indicated in blood samples).

Studies from several laboratories, including M.D. Anderson and the NIH, indicate that at least two cell surface receptors are involved in the mechanism for HIV binding and immune cell penetration. One is the CD4 receptor, largely found on T helper cells. Members of a family of chemokine receptors represent the second receptor, which has only recently been described. HIV researchers have found that a molecular component called the V3 Loop, which is part of the gp-120 surface protein on the outer coat of the HIV virus, plays a critical role in interacting with chemokine receptors, thus initiating the infection process.

Recent research at M.D. Anderson Cancer Center and the Institute of Mediterranean Research and Nutrition in Marseilles has described a further mechanism for HIV infection regarding the CD4 and chemokine receptors. HIV boards a lipid raft that keeps it afloat as it searches for a way into the cell. The raft is made up of glycosphingolipids ("GSL"), a group of carbohydrate-containing fatty acid derivatives. HIV binds to the CD4 receptor and then to the GSL in the lipid rafts and floats on the lipid rafts until it finds an appropriate chemokine receptor. The coreceptor then displaces the lipid raft and begins the membrane fusion process whereby HIV gains entry to the cell. The lipid raft interacts with the HIV gp-120 envelope glycoprotein in the presence of CD4.

M.D. Anderson researchers believe that BlockAide/CR, which is structurally similar to a portion of the V3 Loop present in the outer coat protein of HIV, mimics the V3 Loop and, by interacting with the lipid raft on immune system cells, prevents the virus from binding to chemokine receptors and subsequently penetrating the cell. M.D. Anderson is credited with discovering the inhibitory effects of BlockAide/CR and likens the V3 Loop to a hook. When HIV, using the V3 Loop as a hook, tries to hook onto a human immune cell via the lipid raft, the virus is unsuccessful because its V3 Loop is competitively inhibited by BlockAide/CR.

In addition to blocking infection, it is believed that BlockAide/CR can effectively block syncytium formation and prevent or limit the T-cell loss that invariably occurs with a progressive HIV infection. Syncytium formation is a very important step in the spread of HIV infection and the destruction of T-cells. In this process, an HIV infected cell combines with a number of healthy T-cells to form a large multinuclear mass or syncytium. The syncytia quickly die, killing the incorporated T-cells and reducing the disease-fighting capacity of the human immune system. Published studies suggest that, at the time of transmission, and for a variable period afterwards, HIV exists largely in nonsyncytial form and is relatively harmless to the body's natural immune system. It is believed that, during this phase, T-cells generated by the immune system keep the virus in check. As the virus evolves, however, it acquires the ability to infect T-cells and the immune system becomes less able to combat the virus. The result is the emergence of the syncytial form of HIV and the onset of the illness phase; the point at which the patient begins to develop AIDS.

In an animal trial at M.D. Anderson Cancer Center, rhesus monkeys were treated with a daily injection of BlockAide/CR to determine effectiveness of the drug against an acute infection with Simian (monkey)/Human Immunodeficiency Virus ("SHIV"), a chimeric virus which consists of the core proteins and genetic material of SIV, or Simian Immunodeficiency Virus, and the outer envelope proteins and viral binding proteins of HIV. Viral load decreased by almost 100-fold after approximately two weeks of treatment. The Company believes that positive results in that testing warrant additional studies in human clinical trials. It is believed that the injection of BlockAide/CR into an HIV-infected individual would block the spread of infection from outside the cell in a way that would be much less toxic to the patient than the use of current HAART (Highly Active Antiretroviral Therapy) therapy. The Company intends to proceed with preparations for human testing under the FDA's Fast Track Program, under a Corporate Investigational New Drug application, in 2003, utilizing the FDA's current Good Manufacturing Practices ("cGMP") materials, which have already been prepared for human use.

EradicAide

EradicAide is an antiviral drug, which is based upon cell-mediated immunity technology, a patented immunotherapeutic and vaccine strategy, developed by M.D. Anderson Cancer Center, in Houston, Texas. It consists of a cocktail of six synthetic peptides and a carrier system. The technology relies on eliciting a cell-mediated immunity response to treat individuals already infected with HIV and to protect against new HIV infections. A unique feature of this new treatment is that it is designed to not elicit an antibody response. It is antibody-negative. The Company has licensed the exclusive right to commercialize this technology from M.D. Anderson.

The survival of the HIV virus in the human body is dependant on its ability to penetrate special target cells, take over genetic material in those cells, and use that genetic material to make millions and billions of copies which then propagate from the surface of the cell, killing the cell in the process. In cell-mediated immunity, after a virus has penetrated the cell and released its genetic material, its viral proteins are broken into fragments by the infected cell. The resulting viral protein fragments are then transported within the infected cell through a mechanism called the MHC (Major Histocompatibility Complex) Class I pathway to special sites on the surface of the infected cell. Here the viral protein fragments are displayed to the body's immune system as evidence that the cell is infected and should be destroyed before it can produce new virus particles. Killer T-cells, circulating in the body, recognize the presence of these displayed viral proteins as a signal to kill the infected cells and also as a signal to the immune system to produce more Killer T-cells preprogrammed to seek out and specifically kill off the HIV infected cells.

A research model system incorporating a special version of HIV has recently been developed. A form of SHIV has proven to be an invaluable research tool in the quest for effective approaches to HIV control. Monkeys to whom SHIV was administered showed rapidly induced immunodeficiency (profound reduction in CD-4 positive cell counts within three to four weeks after infection), progressing to an AIDS state nearly identical to that seen in humans infected with HIV.

Preliminary trials were conducted at the University of Texas animal research facility in Bastrop, Texas under the supervision of Dr. Jagan Sastry. Rhesus monkeys were used along with SHIV developed by a group of research labs, including M.D. Anderson. In an initial trial, test animals were vaccinated with the antibody-negative immunity-inducing agent, EradicAide, consisting of a peptide cocktail with complete Freund's adjuvant (mixture of oil, chemicals and bacteria) followed by two booster immunizations with incomplete Freund's adjuvant (mixture of oil and chemicals) and the peptide cocktail. Animals were then infected with live SHIV. Compared to control animals, viral levels in plasma in treated animals were reduced more than 1,000-fold three weeks after infection with SHIV. In non-treated control animals, the CD-4 positive T-cell counts dropped at least 90%, while in treated animals the change in CD-4 positive T-cell counts ranged from 0 to 10% with one animal showing a maximum 30% reduction. Results of the study were published in Vaccine (Vol. 20; 2002, pages 813-825).

A subsequent trial of EradicAide was conducted during 2001 and 2002, consisting of a larger number of monkeys divided into a control group, a group treated with EradicAide peptides delivered with incomplete Freunds adjuvant and a group treated with EradicAide peptides delivered with autologous dendritic cells. All the animals were then infected with SHIV. Both groups of treated animals began showing a drop in viral load four weeks after infection with SHIV and were maintaining viral control for approximately one year, verifying previous data in the earlier trial, with all but one of the treated animals continuing to suppress viral load to undetectable levels.

These data demonstrate scientific proof of principle for the cell-mediated immunity strategy. We expect that the Company may be able to qualify for the FDA's Fast Track Program for human trials, which provides for an accelerated FDA review process of HIV therapeutic drugs, during the second half of 2003.

In September 2002, the Company, along with a collaborating partner, BioDelivery Sciences International of Newark, New Jersey, announced that the NIH awarded a research grant, totaling $600,000, to conduct work on the development of an oral form of EradicAide. Payments under the grant will begin in January 2003 and be shared equally over a period of two years between BioDelivery Sciences and the Company's HIV scientists at M.D. Anderson Cancer Center in Houston, Texas.

Thiovir

Thiovir is a sulfur-containing compound synthesized using technology developed at USC and exclusively licensed to the Company by USC.

Thiovir, and other Thiovir-analogues under development, are parts of a new class of compounds known as thiophosphonoformates (sulfur/phosphorous compounds), which have demonstrated powerful antiviral properties. As a result, Thiovir was designed to be a replacement for the broad-spectrum antiviral drug, foscarnet. Foscarnet is dosed by central line IV catheter administration and is FDA-approved for treatment of viral infections, such as HIV, Herpes and CMV (cytomegalovirus). Although foscarnet is a highly effective, broad-spectrum antiviral, it has disappointing limitations from a commercial perspective. Foscarnet is a small molecule whose parent structure restricts modification, which could lead to improved oral bioavailability or effectiveness. Therefore, there is a need for a new class of broad-spectrum antiviral compounds that might address the limitations of foscarnet while still offering the antiviral advantages.

Thiovir (Thiophosphonoformic acid) can serve as a highly effective oral replacement for foscarnet as part of HAART (highly active antiretroviral therapy) where foscarnet is not currently used since it is too difficult to administer. Thiovir is a NNRTI (non-nucleoside reverse transcriptase inhibitor), which can be used with NRTIs (nucleoside reverse transcriptase inhibitors) and protease inhibitors (based upon prior experience with the prior use of foscarnet). Thiovir has a different mode of action toward HIV, which is complimentary to NRTIs and protease inhibitors, with the added benefit of effectiveness against CMV and HSV-6-8, associated with Kaposi's sarcoma.

Preclinical studies on human cells have demonstrated that Thiovir is equivalent to foscarnet as a reverse transcriptase inhibitor and has a dosage profile similar to foscarnet to direct HIV inhibition, with lower toxicity toward human DNA. Preliminary animal studies, with enteric-coated capsules of Thiovir, demonstrated up to 44% oral bioavailability, delivering three times more drug than orally dosed foscarnet.

An in vitro test of a group of Thiovir analogues was conducted at the National Cancer Institute. Results reported to USC between 2001 and 2002 revealed several compounds with better therapeutic values than foscarnet for HHV-8, a herpes virus linked to Kaposi's sarcoma, the cancer that causes lesions on the skin of AIDS patients. In addition, studies conducted by the Company on Thiovir efficacy against papillomaviruses (a viral infection directly related to genital warts and cervical cancer) between 1999 and 2002, showed that Thiovir had potential as an antiviral treatment for papillomavirus infection. However, during 2002, the technical difficulties in testing Thiovir efficacy in animal models, as well as results obtained during in vitro testing on analogues of Thiovir, under a US government grant, have led the Company to change its strategy for HPV testing during 2003. Current research and development efforts for Thiovir are supported by the Company and by U.S. government funding, which the Company intends to continue during 2003 to identify the most effective Thiovir analogues for HPV treatment..

BlockAide/VP

The BlockAide/VP compound was also created and patented by M.D. Anderson and is licensed to the Company. It works to prevent HIV infection in human cells in a different way from BlockAide/CR.

HIV depends on its ability to enter and infect host cells in order to multiply and survive. In the case of HIV, the binding protein gp-120 on the surface of the HIV particle interacts with a receptor site known as CD4, which is present on the surface of certain human cells. Interaction of the HIV virus with CD4 causes a change in the shape of gp-120, uncovering the actual binding region of gp-120, which then fuses with a second, chemokine receptor.

The BlockAide/VP compound mimics a section of the CD4 receptor. When BlockAide/VP comes into contact with the gp-120 protein present on the surface of HIV, it appears to cause a change in the protein-folding configuration of gp-120, rendering the gp-120 unable to initiate the infection process.

Early tests indicate that HIV virus treated with BlockAide/VP and exposed to human cells is unable to bind to and infect such cells. The Company does not know of any other available antiviral agent which can render HIV unable to infect cells in this manner.

BlockAide/VP has progressed through in vitro testing with encouraging results and must still be tested in animals to gauge effectiveness and toxicity before progressing to human trials, in the same manner as described above for BlockAide/CR. BlockAide/VP has demonstrated synergistic and additive effect to BlockAide/CR in in vitro testing as well. If proven safe and effective in preclinical testing, and if approved by the FDA through its Fast Track Program, BlockAide/VP could be used for HIV infected individuals as an adjunct to their HAART or as a primary therapy for newly infected individuals.

Selone

Selone is the Company's leading compound in a new class of compounds which are potential new cancer drugs for drug resistant cancer, discovered through USC research focused on the use of the element selenium, an anti-oxidant. We are the exclusive licensee of a patent from USC, which encompasses the use of Selone and other oxygen-carbon-selenium compounds as anticancer agents, as well as the method for their synthesis.

Selone acts, in part, as a highly nitrogen-specific alkylating agent (a drug that kills cancer cells by directly attacking their DNA) found to be effective against cancer cell lines that exhibit drug resistance to currently available alkylating and platinating (alkylating compounds which contain platinum) agents. Alkylating agents, as a class, are the most broadly used anticancer agents in the world, collectively surpassing the use of 5-FU. In recent years, alkylating agents have been increasingly used, in dose intensification strategies such as bone marrow transplant, and have exhibited further promise when used with compounds known as thiophosphate protection agents. However, a majority of cancers develop resistance to currently available alkylating and platinating agents, usually through a thiol (sulfur metabolism) mechanism. Selone was developed to address this problem, through increased targeting to guanine nitrogen contained in DNA, without increased susceptibility to the thiol mechanisms connected with drug resistance.

Based upon current in vitro screening methods, Selone shows promise of being broadly effective, at even very low concentrations, against human ovarian, breast, lung and head/neck cancers, and against leukemias and lymphomas. Its potency is remarkably high for its rate of alkylating activity, suggesting an increased specificity of action. Demonstrated effectiveness in central nervous system cell lines, in addition to the extraordinarily high solubility of Selone in watery and fatty tissues, suggests potential activity in brain tumors. Selone shows full activity in human cell lines resistant to other cancer drugs, including antitumor antibiotics, and in nitrosourea-resistant colon cancer. It has also demonstrated significant activity against leukemia in mice at doses predicted to readily achieve effective blood concentrations.

The Company intends to support further research for Selone through government grants, for which it intends to apply during 2003, to determine the future course of action for taking this drug toward human testing.

Markets for our Products

Anticancer Agents

On a worldwide basis, cancer killed over 6 million people in 1998, according to statistics published by the World Health Organization. After cardiovascular disease, cancer is the second most frequent cause of death in developing countries, accounting for 21% of all deaths. In the U.S., cancer is responsible for approximately 23% of all deaths according to recent statistics. The American Cancer Society reported in 1998 that there were more than 1.4 million new cases of cancer diagnosed in the U.S. and over 560,000 deaths due to cancer in the previous year.

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 US of approximately $9 billion ($15 billion worldwide), according to Frost & Sullivan Market Research and IMS Market Research.

Traditional cancer chemotherapy poisons all body cells to some extent, but particularly targets rapidly dividing cells such as cancer cells. Its effect on

other rapidly dividing cells, such as hair follicles, cells lining the stomach and red blood cells, accounts for some of the more common negative side effects of cancer chemotherapy. Current approaches often use several drugs in combination, aimed at minimizing side effects while attacking the rapidly proliferating cells at vulnerable times.

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. Chemotherapy drugs such as 5-FU, Ancobon, Methotrexate, Alkeran and Cyloxan, are commonly used to treat patients.

We believe that the total annual market potential for CoFactor is related to new cases of cancer, which are often treated by 5-FU therapy, the single most widely used cancer drug in the world, according to industry experts. Doses of 5-FU vary widely based upon the cancer being treated. As an example, in U.S. therapy regimens, approximately 36 doses of 5-FU are administered to approximately two-thirds of colorectal cancer patients annually, compared with 12 doses of 5-FU to about one-third of breast cancer patients.

Based upon statistics for cancer incidence and cancer treatment reported by the American Cancer Society, we estimate that the annual potential for CoFactor use can be based on an assumed annual use of over 4 million doses of 5-FU, with initial emphasis focused on combination therapy with 5-FU for colorectal cancer. There are approximately 131,000 new cases of colorectal cancer per year in the US alone. It should be noted that these estimates do not take into account additional market opportunities to enhance other drugs similar to 5-FU, such as floxuridine (FUDR), florafur (tegafur), Doxifluridine(R) (5'deoxyfluorouridine) and Xeloda(R) (capecitiabine).

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

HIV/AIDS Therapy

Significant advancements have been made in the treatment of asymptomatic HIV positive patients. It is now understood that early combination therapy with a three or four drug "cocktail" can push HIV viral load to below "detectable levels." This therapy is often referred to as HAART (highly active antiretroviral therapy). It is widely reported that the average annual drug cost for such combination therapy in the U.S. is $11,000 per patient.

However, recent studies have shown that, whether or not patients adhere to the strict therapy regimens required for HAART treatment, antiretroviral therapy will continue to lead to problems of viral resistance, rendering many drugs ineffective over time. There is no conclusive evidence that current drugs can eradicate HIV from the body over the long term. As long as HIV is present in the body, the opportunity exists for the evolution of HIV escape mutants resistant to HAART. These mutant strains can reproduce unchecked by HAART, subsequently becoming the predominant strain and re-establishing high viral loads in patients. This can lead to permanently damaged immune systems, opportunistic infections, and the advance to AIDS even if HAART therapy continues. Currently, no one combination of drugs is effective for all patients, and therapies are continually modified based upon patient progress. Therefore, new drugs and new drug approaches continue to be needed for HIV therapy.

In a recent study reported by the University of California-San Francisco, based upon treatment of HIV positive patients at San Francisco General Hospital, 53% of patients had evidence of treatment failure after at least six months of therapy. Based on these facts, we believe that the demand for new types of HIV drugs, designed to block infection or to clear HIV-infected cells, will therefore increase. Additional new therapy is on the horizon, with the first HIV viral entry inhibitor approved in early 2003, with an annual cost of $20,000 per patient for therapy. The Company believes therefore, that its efforts concerning the development of its viral entry inhibitors are well-founded, since this new mode of HIV treatment is medically valid based upon clinical trial data and the recent FDA approval, and also because it is believed that the Company's viral entry inhibitors can be produced and sold at much lower costs.

According to NIAID (National Institute of Allergy and Infectious Disease), at the end of 2002, there were 42 million people infected with HIV on a worldwide basis, with 14,000 new infections occurring each day. An estimated 5 million new infections occurred worldwide in 2002. HIV infections are not being treated in the third world, to even the smallest extent, since cost is prohibitive and the ability to administer complex therapy is nearly impossible. Thus, simple, inexpensive new therapies are required.

Thiovir and HPV

According to the Center for Disease Control and the American Cancer Society, the most prevalent sexually transmitted disease in the U.S. is human papillomavirus (HPV) infection, which is extremely contagious, with approximately two-thirds of all people exposed to the virus becoming infected within a three-month period. The virus exists in over 80 different subtypes, 40 of which affect the urogenital region.

Transmission of HPV usually occurs through direct skin contact during vaginal, anal or oral sex with an infected individual, and warts (called genital warts or condylomas) may or may not begin to appear on the skin surrounding the entrance to infection, depending on the length of the latency period. Because one of the consequences of HPV infection is the introduction of abnormal cells, the infection may lead to cancerous growths, particularly on the cervix. Although HPV and genital warts are treatable, there is currently no known cure for the infection.

HPV is highly prevalent in women under 30 years of age, and studies indicate that the majority of college age women are HPV positive without clinical or cytological evidence. According to American Cancer Society, the lifetime risk of invasive cancer is 5-10% for untreated HPV infection, and, if infected with a high-oncogenic form of HPV, there is a 70% risk of having an abnormal papsmear. Approximately 5.5 million new cases of sexually transmitted HPV occur in the U.S. each year, with at least 20 million people currently infected according to pharmaceutical industry estimates. Of special importance is the link between HPV and cancer, particularly cervical cancer. The role of HPV as a principal agent in the etiology of cervical cancer has been clearly established by the American Cancer Society and the American Association of Obstetrics and Gynecology.

Marketing, Distribution and Sales

We have not received the necessary regulatory approval from the FDA or any other similar government agency to commercially market, distribute or sell any of our products. We do not presently have a marketing and sales staff, although the experience and background of Nicholas Jon Virca, Chief Executive Officer, includes pharmaceutical marketing and sales functions. If we approach the point at which we anticipate receiving regulatory approval to commercially market, distribute or sell any of our products, we will likely arrange with third parties, such as pharmaceutical companies, to market, distribute and sell our products. At that point, we would also likely seek to add marketing personnel for liaison, support and administrative purposes. While we have held preliminary discussions on a number of occasions with potential commercialization and marketing partners, we have not yet entered into any binding agreements regarding the commercialization or marketing of any of our products.

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

Manufacturing

We do not have our own manufacturing facilities, and do not intend to establish them. However, the Company has entered into a manufacturing agreement with Merck Eprova AG, of Schaffhausen, Switzerland, under which Merck Eprova will produce CoFactor for clinical trial requirements and future product sales. We have also used the services of Multiple Peptide Systems, Inc., of San Diego, California, to produce its BlockAide/CR peptide and also intend to use Multiple Peptide Systems to produce the peptides for EradicAide testing, beginning in

the first half of 2003. In the future, we will have to establish one or more relationships with additional manufacturers as new drug candidates progress through development, testing and commercialization stages. Consequently, the Company will be dependent upon various manufacturers for a reliable supply of its drug products. (See "Risk Factors" in Item 6 below.)

Raw Materials

Raw materials and supplies required for the production of our products for clinical trials are generally available from various suppliers in quantities adequate to meet our needs. However, the Company believes that it will need to be selective with its choice of manufacturers who have expertise in the cGMP production of either chemical or biological formulations, such as those required for the Company's products.

Licensing and Research Agreements

M.D. Anderson Agreements

In June 1996, the Company entered into an exclusive worldwide Patent and Technology License Agreement with M.D. Anderson (the "M.D. Anderson Agreement") granting development, manufacturing and marketing rights, relating to the commercialization of technologies described in seven patents and patent applications developed by scientists at M.D. Anderson in the field of HIV therapy and preventions. The M.D. Anderson Agreement continues in effect for the life of the subject patents (including any extensions or renewals), and requires payment of royalties based on percentages of sales and a share of sub-licensing revenues from products developed under the Agreement. Our exclusive license rights are subject to any non-exclusive rights that the U.S. government may have as a result of any agreement between it and M.D. Anderson by which government-funded research was provided in connection with the licensed technology. The M.D. Anderson Agreement requires the Company to reimburse M.D. Anderson for the cost of preparing, filing, prosecuting and maintaining the licensed patents.

Pursuant to the terms of the M.D. Anderson Agreement, the Company has the right to a royalty-bearing, exclusive license to manufacture, have manufactured and use or sell licensed products. M.D. Anderson's retained interest consists of royalties on net sales of licensed products and a share of consideration received by the Company from all sublicenses and assignments. No royalties were paid under this agreement during the years ended December 31, 2002 and 2001. The M.D. Anderson License Agreement continues in effect until all patent rights have expired.

The M.D. Anderson Agreement was amended effective June 15, 2000 (the "Amendment"). The Amendment incorporated additional licensed subject matter, revised certain royalty rates due to M.D. Anderson upon commercialization, and settled past due patent and research and development amounts from the Company to M.D. Anderson. The Company gave consideration valued at approximately $172,000 through the issuance of 71,555 shares of common stock to reimburse M.D. Anderson for patent costs incurred through June 15, 2000. The Company also issued 414,829 shares of common stock to M.D. Anderson valued at $1,000,000, based on the market value of the Company's stock at the date of the settlement agreement, to settle past due research and development obligations. In addition, the Company committed to funding at least $1,000,000 of research and development activity through December 31, 2001, including the amounts referred to in note 7. Finally, the Amendment defined a milestone payment of common stock with a value of $1,000,000 due to M.D. Anderson upon the enrollment of the first patient in the first FDA Phase I human trial of any product that utilizes licensed subject matter.

USC Agreements

Under an Option and License Agreement with USC dated January 23, 1998, amended August 16, 2000, we hold exclusive license rights to a total of three patents, two relating to Biokeys Pharmaceuticals' CoFactor product and one relating to Selone, both of which are intended for use in connection with cancer chemotherapy. In addition, under a second Option and License Agreement dated August 17, 2000, we acquired exclusive rights under the five patents related to Thiovir antiviral technologies. These agreements with USC (the USC License Agreements) grant us exclusive worldwide licenses to study, use, manufacture and market drug products covered by the subject patents. Under the

USC License Agreements, we are obligated to pay USC for out-of-pocket expenses incurred in filing, prosecuting, enforcing and maintaining the licensed patent rights and all future patent-related expenses paid by USC, as long as the USC License Agreements remain in effect and until the patent rights have expired. USC's retained interest consists of a running royalty on net sales of licensed products and a share of consideration received by Biokeys Pharmaceuticals from all sublicenses and assignments. No royalties have been paid under these agreements.

NIH Agreement

During December 2002, the Company entered into a worldwide exclusive patent license agreement with the NIH concerning composition of matter for its drug, BlockAide/CR. Under the terms of the agreement, the Company agrees to pay minimum royalty payments during the first year of the license and minimum annual royalties thereafter or the higher amount based upon a percentage of net sales. In addition, there are benchmark royalties based upon: initiation of Phase I trials, initiation of Phase II trials, initiation of Phase III trials, and upon first approval of a Product License Application for an HIV therapeutic or vaccine in the US and for first approval in Europe.

Sponsored Research Agreements

We entered into a sponsored research agreement with M.D. Anderson on September 7, 2000, which provided for studies to test the ability of a mixture of synthetic HIV-derived peptides to elicit an antibody-negative cell-mediated immune response. The testing was undertaken to determine if this immune response can protect against new HIV infection and if the preparation can be administered after HIV infection as a therapeutic. This required a total of $814,490 payable in two equal installments for research conducted through 2001 and 2002.

We also have sponsored research arrangements with USC, under which USC will continue studies in the therapeutic potential of Thiovir and its analogues as antiviral agents. The Company entered into a grant agreement with USC effective November 1, 2000, under which USC performed research into Thiovir and its analogues as inhibitors for HPV and other pathogenic viruses. The budgeted research costs for this study were approximately $217,000, which have been paid by the Company and are still under use by USC. The Company and USC also applied for additional research grants near the end of 2002 for which they might receive funding in 2003.

In September 2002, the Company, along with a collaborating partner, BioDelivery Sciences International of Newark, New Jersey, announced that the NIH awarded a research grant, totaling $600,000, to conduct work on the development of an oral form of EradicAide. Payments from the grant will begin in January 2003 and be shared equally over a period of two years between BioDelivery Sciences and the Company's HIV scientists at the M.D. Anderson Cancer Center in Houston, Texas.

Competition

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

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

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

BlockAide/CR

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

BlockAide/CR should prove to be a formidable competitor to T-20. The FDA approved T-20 for sale on March 13, 2003. T-20 is the first product that works to inhibit HIV from outside the cell. However, T-20 has many difficulties associated with its manufacture, pricing and therapy, which the Company believes BlockAide/CR may be able to overcome because of simpler manufacturing, easier administration and lower patient costs.

Of new medications under development for the treatment or prevention of AIDS/HIV, 37 are antivirals (including other fusion inhibitors), several are second-generation protease inhibitors, 12 are vaccines (as of mid 2000; 60 Phase I/II trials of 30 vaccine candidates were being conducted worldwide), 16 are antiinfectives and antifungals to fight opportunistic infections, 10 are immunomodulators designed to boost the immune system, 24 are anticancer medications to treat AIDS-related cancers such as lymphoma and KS (Kaposi's Sarcoma) and five are gene therapies.

EradicAide

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

CoFactor

The Company intends to target replacement of 5-FU/leucovorin therapy, as well as 5-FU/leucovorin/CPT-11 (Camptosar(, irinotecan) therapy, which are toxic and less effective than the results the Company achieved in Phase I/II trials in Sweden. With an ongoing need for significant improvement in the clinical response of tens of thousands of cancer patients, especially those with colorectal cancer where leucovorin performs very poorly, the Company believes there will be great demand for CoFactor.

There are approximately 40 different companies marketing 5-FU-related drugs that are generic. One exception is Roche, which markets the prodrug (drug that activates in vivo) Xeloda(, which is an oral formulation that converts to 5-FU. Since CoFactor is intended to be used with 5-FU, but is only in IV form, generic forms of leucovorin that are oral represent competition for CoFactor, which in its current form must be administered by IV. Leucovorin is also marketed by more than a dozen companies as a generic drug for IV dosing in conjunction with 5-FU. As an IV drug, leucovorin represents competition to CoFactor based upon generic pricing.

The Company believes that if it continues to demonstrate superior results in human trials to 5-FU/leucovorin or 5-FU/leucovorin/CPT-11 performance, it will be able to command branded pharmaceutical pricing (be sold a much higher prices due to improved therapy). Further, if the 5-FU/CoFactor can limit the

need for addition of CPT-11 to the therapy, than overall toxicity of that regimen can be lowered significantly to improve the quality of life of patients being treated, and CoFactor acceptance will be driven by lowering the overall cost of therapy, measured by the number of drugs administered, the length of remissions and the need to treat toxicity.

Government Regulation and Clinical Testing for New Drugs

The manufacture and sale of therapeutic drugs are subject to government regulation in the U.S. and in certain foreign countries. 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.

Safety and effectiveness standards are required in certain other countries as well. The Company believes that only a limited number of foreign countries have extensive regulatory requirements for new drugs, especially Japan and the countries comprising the European Union.

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 Investigational New Drug ("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 and/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, and unless the FDA objects, the IND 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 that detail the objectives of the trial, the parameters used to monitor safety and the efficacy criteria that are being evaluated. Each clinical trial is conducted under the auspices of an Institutional Review Board ("IRB") at the institution at which the trial is conducted. The IRB considers, among other things, ethical factors, the safety of the human subjects and the possible liability risk for the institution.

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

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

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

The results of the preclinical tests and clinical trials are submitted to the FDA in the form of an NDA for marketing approval. The testing and approval

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

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

The FDA has developed several regulatory procedures to accelerate the clinical testing and approval of drugs intended to treat serious or life-threatening illnesses under certain circumstances. For example, in l988, the FDA issued regulations to expedite the development, evaluation and marketing of drugs for life-threatening and severely debilitating illnesses, especially where no alternative therapy exists (the "l988 Regulations"). These procedures encourage early consultation between the IND sponsors and the FDA in the preclinical testing and clinical trial phases to determine what evidence will be necessary for marketing approval and to assist the sponsors in designing clinical trials. Under this program, the FDA works closely with the IND sponsors to accelerate and condense Phase II clinical trials, which may, in some cases, eliminate the need to conduct Phase III trials or limit the scope of Phase III trials. Under the l988 Regulations, the FDA may require post-marketing clinical trials (Phase IV trials) to obtain additional information on the drug's risks, benefits and optimal use.

In l992, the FDA issued regulations establishing an accelerated NDA approval procedure for certain drugs under Subpart H of the agency's NDA approval regulations ("Subpart H Regulations"). The Subpart H Regulations provide for accelerated NDA approval for new drugs intended to treat serious or life-threatening diseases where the drugs provide a meaningful therapeutic advantage over existing treatment. Under this accelerated approval procedure, the FDA may approve a drug based on evidence from adequate and well-controlled studies of the drug's effects. This approval is conditional on the favorable completion of trials to establish and define the degree of clinical benefits to the patient. In this case, post-marketing clinical trials would usually be underway when the product obtains accelerated approval. If, after approval, a post-marketing clinical study establishes that the drug does not perform as expected, or if post-marketing restrictions are not adhered to or are not adequate to ensure the safe use of the drug, or other evidence demonstrates that the product is not safe and/or effective under its conditions of use, the FDA may withdraw approval. The Subpart H Regulations can complement the l988 Regulations for expediting the development, evaluation and marketing of drugs. These two procedures for expediting the clinical evaluation and approval of certain drugs may shorten the drug development process by as much as two to three years.

We believe that several of our drugs may be candidates for accelerated development and/or approval under the l988 Regulations and/or the Subpart H Regulations. This would include our HIV/AIDS drugs as well as the Company's anticancer agents.

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

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

Health Care Reform Measures and Third Party Reimbursement

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

Research and Development Outlays

During fiscal year 2002 and 2001, the Company expended $282,966 and $946,419, respectively, on research and development activities.

Environment

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

Employees

At December 31, 2002, the Company had three employees all of whom were employed on a full-time basis.

ITEM 2. DESCRIPTION OF PROPERTY.

The Company's principal office is located at 9948 Hibert St., Suite 100 in San Diego, California. Our principal office consists of 1,553 square feet of office space which we use pursuant to a lease which will expire on January 14, 2004. The lease rate for this space is currently $32,458 per year, which amount includes incremental operating cost adjustments.

Our research and development activities during 2002 were conducted mainly on the premises of M.D. Anderson, USC, and Sahlgrenska University Hospital, pursuant to the terms of sponsored research arrangements.

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

Until December 2002, the Company leased approximately 800 square feet of office space at 333 N. Sam Houston Parkway, Suite 1035, Houston, Texas pursuant to a month to month lease at a cost of $1,860.75 per month. The office in Houston was closed in December 2002, at which time we terminated the lease for our Houston office and consolidated operations at our San Diego office.

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

ITEM 3. LEGAL PROCEEDINGS.

The Company was a defendant in the action entitled Karo Bio USA, Inc. v. Biokeys Pharmaceuticals, Inc. (Case No. 01-455), commenced in the United States

District Court for the District of Delaware on July 3, 2001 (the "Trademark Lawsuit"). In the Trademark Lawsuit, Karo Bio asserted among other things that the Company was infringing the trademark BIOKEY(R) that Karo Bio registered with the United States Patent and Trademark Office. Karo Bio sought to prevent us from continuing to use "Biokeys" as part of our name, as well as an unspecified amount of damages. Pursuant to the terms of the Settlement Agreement, dated March 14, 2002, between Karo Bio USA, Inc. and the Company (the "Settlement Agreement"), the Company agreed to cease using the "Biokeys" mark, with certain permitted excepted uses by us. The Company retains the right to use the name "Biokeys Pharmaceuticals, Inc." The Settlement Agreement also required that Karo Bio and the Company dismiss all claims and counterclaims in the Trademark Lawsuit and to file a stipulated dismissal with the United States District Court for the District of Delaware. The settlement with Karo Bio has not had and we believe it will not have a material adverse effect on the Company or our business.

From time to time we may be subject to additional legal proceedings and claims in the ordinary course of business. These claims, even if not meritorious, could result in the expenditure of significant financial and managerial resources. We are not aware of any legal proceedings or claims that we believe could harm our business or cause our stock price to fall.

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

No matter was submitted to a vote of securities holders, through solicitation of proxies or otherwise, during the fourth quarter of 2002. We did not hold an annual meeting of stockholders in 2002 and have not scheduled an annual meeting for 2003.

## PART II

ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

MARKET INFORMATION.

Our Common Stock is quoted on the National Association of Securities Dealers' OTC Bulletin Board under the symbol BKYS. From December 7, 1999 until June 11, 2002, our Common Stock was quoted on Pink Sheets LLC's Electronic Quotation Service under the symbol HIVX.

The following table lists the high and low bid information for our Common Stock for each quarter for the fiscal years 2001 and 2002. All prices listed herein reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions.

| QUARTER ENDING | HIGH | LOW |
|---|---|---|
| March 31, 2001 | $5.25 | $2.75 |
| June 30, 2001 | $2.90 | $2.10 |
| September 30, 2001 | $3.10 | $2.00 |
| December 31, 2001 | $3.30 | $1.40 |
| March 31, 2002 | $2.00 | $1.55 |
| June 30, 2002 | $4.00 | $1.11 |
| September 30, 2002 | $1.85 | $0.46 |
| December 31, 2002 | $0.51 | $0.15 |

HOLDERS.

The number of record holders of Common Stock as of December 31, 2002 was approximately 178.

DIVIDENDS.

The Company has never paid cash dividends on its Common Stock and does not expect to pay any cash dividends on its Common Stock in the foreseeable future. Pursuant to the terms of our Certificate of Designations, Preferences, Rights and Limitations of Series A 8% Convertible Preferred Stock filed with the

Secretary of State of the state of Delaware on September 11, 2000, so long as any shares of our Series A 8% Convertible Preferred Stock ("Series A Preferred Stock") remain outstanding, we may not declare or pay any dividend or other distribution upon our Common Stock, unless all amounts then due to the holders of Series A Preferred Stock have been paid. As of March 31, 2003, 473 shares of Series A Preferred Stock were outstanding. Pursuant to the terms of our Certificate of Designation of Series B Convertible Preferred Stock and Series C Convertible Preferred Stock filed with the Secretary of State of the state of Delaware on September 23, 2002, so long as any shares of our Series C Convertible Preferred Stock ("Series C Preferred Stock") remain outstanding, we may not declare or pay any dividend or other distribution upon our Common Stock, unless all amounts then due to the holders of Series C Preferred Stock have been paid. As of March 31, 2003, no shares of Series C Preferred Stock were outstanding.

SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS.

As of December 31, 2002, other than the individual compensation arrangements set forth in the table below, the Company did not have any compensation plans under which our equity securities are authorized for issuance.

| | NUMBER OF SHARES OF COMMON STOCK TO BE ISSUED UPON EXERCISE OF OUTSTANDING OPTIONS | WEIGHTED-AVERAGE EXERCISE PRICE OF OUTSTANDING OPTIONS, WARRANTS AND RIGHTS | NUMBER OF SECURITIES REMAINING AVAILABLE FOR FUTURE ISSUANCE UNDER EQUITY COMPENSATION PLANS |
|---|---|---|---|
| EQUITY COMPENSATION PLANS APPROVED BY SECURITY HOLDERS | 0 | $0.00 | 0 |
| EQUITY COMPENSATION PLANS NOT APPROVED BY SECURITY HOLDERS | 1,690,000 | $0.23 | 0 |
| TOTAL | 1,690,000 | $0.23 | 0 |

On October 28, 2002, the Compensation Committee of the Board of Directors of the Company granted three stock options to Nicholas J. Virca, our Chief Executive Officer. One of the stock options granted to Mr. Virca represents the right to purchase up to 1,000,000 shares of Common Stock at an exercise price of $0.20 per share, which right was completely vested on the date of grant. Another of the stock options granted to Mr. Virca represents the right to purchase up to 500,000 shares of Common Stock at an exercise price of $0.20 per share, which right will vest with respect to 125,000 shares on July 1, 2003 and will continue to vest with respect to 125,000 shares each quarterly anniversary thereafter until fully-vested. The last stock option granted to Mr. Virca represents the right to purchase up to 165,000 shares of Common Stock at an exercise price of $0.50 per share, which right was completely vested on the date of grant. The Compensation Committee also granted a stock option to an employee of the Company to purchase up to 25,000 shares of Common Stock at an exercise price of $0.20 per share, which right was vested with respect to 12,500 shares on the date of grant and will vest with respect to the remaining 12,500 shares on December 30, 2003. Each of the foregoing options will expire on December 30, 2008 and each of the foregoing options provide that the optionholder may exercise the option on a "net issue" or "cashless" basis.

RECENT SALES OF UNREGISTERED SECURITIES.

As described in detail immediately above, on October 28, 2002, the Compensation Committee of the Board of Directors of the Company granted three stock options to Nicholas J. Virca, our Chief Executive Officer, to purchase up to an aggregate of 1,665,000 shares of Common Stock and one stock option to an employee of the Company to purchase up to 25,000 shares of Common Stock.

On October 31, 2002, the Company offered each holder of its Series A Preferred Stock the right to exchange their shares of Series A Preferred Stock for shares of Common Stock at an exchange rate of 600 shares of Common Stock for each share of Series A Preferred Stock. The exchange offer expired on November 27, 2002. On November 26, 2002, one of the holders of Series A Preferred Stock accepted the exchange offer and exchanged 3,000 shares of Series A Preferred Stock for 1,800,000 shares of Common Stock. The Company received no remuneration for this exchange.

In December 2002, the Company closed sales of an aggregate of 8,809.3 shares of its Series C Preferred Stock to 7 investors for gross proceeds of $88,093 in cash. Shares of Series C Preferred Stock are convertible at any time after March 1, 2003 by the holders thereof into shares of Common Stock at the initial conversion rate of 200 shares of Common Stock per share of Series C Preferred Stock (an effective initial conversion price of $0.05 per share). Each purchaser of Series C Preferred Stock represented their intention to acquire shares of Series C Preferred Stock for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the share certificates to issued to each purchaser of Series C Preferred Stock.

In connection with the purchases and sales of Series C Preferred Stock in December 2002, the Company and one of the purchasers of Series C Preferred Stock executed amendments to two warrants to purchase a total of 45,000 shares of Common Stock held by such purchaser. Pursuant to the amendments, the per share exercise price of each warrant was reduced to $0.50. Prior to the execution of the amendments, each of these warrants had a per share exercise price of $4.00 through December 31, 2002, and thereafter a per share exercise price equal to the higher of $2.50 or the average closing price of the Common Stock during the 20 trading days prior to December 31, 2002, not to exceed $4.00. The Company received no remuneration for the amendment of the warrants.

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

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

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

On March 25, 2003, the Company issued 75,000 shares of Common Stock and two warrants to one entity in consideration of such entity's introduction of the Company to investors that purchased shares of Common Stock between January 2003 and March 2003. Each of the two warrants represents the right to purchase 37,500 shares of Common Stock at an exercise price of $0.50 per share. Each warrant will expire on March 25, 2006.

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

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

In March 2003, all of the holders of Series C Preferred Stock converted all of their shares of Series C Preferred Stock into an aggregate of 14,021,860 shares of Common Stock pursuant to the terms of our Certificate of Designation of Series B Convertible Preferred Stock and Series C Convertible Preferred Stock filed with the Secretary of State of the state of Delaware on September 23, 2002. As of March 31, 2003, no shares of Series C Preferred Stock were outstanding.

On April 11, 2003, the Company issued 25,785 shares of Common Stock to an entity in consideration of such entity's introduction of the Company to investors that purchased shares of Common Stock in January 2003.

In April 2003, pursuant to the terms of promissory notes issued by the Company in October and December 2001, the Company issued an aggregate of 23,411 shares of Common Stock to the holders of such notes in payment of accrued interest that was due such holders.

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

The issuances of the above securities were deemed to be exempt from registration under the Securities Act of 1933, as amended (the "Securities Act"), in reliance on Section 4(2) of the Securities Act or Regulation D promulgated under the Securities Act, as transactions by an issuer not involving a public offering or, in the case of the exchange offer and the conversion of all of the outstanding shares of Series C Preferred Stock, in reliance on 3(a)(9) of the Securities Act, as an exchange by the Company with one of its security holders where no commission or other remuneration is paid or given directly or indirectly for soliciting such exchange.

ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION.

This Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the accompanying consolidated financial statements and notes included in this report.

GENERAL

As a development-stage biomedical research company, we have not yet generated any revenues from any of our products. We have had no earnings since inception, and have an accumulated deficit of $26,149,069 as of December 31, 2002. Our expenses have related mainly to costs incurred in research activities for the development of our drug candidates and from administrative expenses required to support these efforts. We expect losses to continue for the near future, and such losses will likely increase as human clinical trials are undertaken in the U.S. and Europe for our cancer and HIV drugs. Future profitability will be dependent upon our ability to complete the development of our pharmaceutical products, obtain necessary regulatory approvals and effectively market such products. Also, future profitability will require that the Company establish agreements with other parties for the clinical testing, manufacturing, commercialization and sale of its products.

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

RESULTS OF OPERATIONS

Year Ended December 31, 2002 compared with year ended December 31, 2001.

We used the proceeds of our August 2000 equity financing to significantly expand our research and development efforts in connection with our EradicAide and BlockAide/CR products for HIV/AIDS. Results in preliminary, small-scale non-human primate trials warranted an expansion of the Company's research program into larger scale non-human primate trials conducted through researchers at M.D. Anderson. In addition, we continued to fund research and development efforts in connection with CoFactor and Thiovir. However as these

funds were expended our research efforts have been reduced. Recent successful capital acquisition efforts will enable the Company to again expand its research and development efforts. Accordingly, our research and development expenses decreased from $946,419 in the year ended December 31, 2001 to $282,966 in the year ending December 31, 2002.

General and administrative expenses decreased by approximately 32%, from $2,038,130 in 2001 to $1,388,020 in 2002 primarily due to efforts to streamline operations and reduce overhead.

Depreciation and amortization decreased by approximately 94%, from $7,672,112 in 2001 to $428,109 in 2002 due to amortization of goodwill that was recorded in 2001 and not recorded in 2002 due to the write-off of all goodwill at December 31, 2001 due to the impairment of the goodwill at that time. Amortization of goodwill in 2001 was $7,602,836.

Impairment loss - write off of goodwill decreased from $5,702,130 in 2001 to zero in 2002. Through December 31, 2001, the Company had not been able to raise sufficient capital to ensure future funding of its research and development; consequently, the Company reviewed the carrying value of goodwill for impairment and reduced its carrying value to zero through a noncash charge of $5,702,130 at December 31, 2001.

Interest expense increased by 347%, from $12,019 in 2001 to $53,696 in 2002 due to interest expense incurred in relation to the Bridge Financing Notes Payable issued in October and December 2001.

As a result of the factors described above, the Company's net loss decreased from $(16,339,120) in 2001 to $(2,105,727) in 2002 and the loss per share decreased from $(1.12) in 2001 to $(0.15) in 2002.

LIQUIDITY AND CAPITAL RESOURCES

The Company has incurred negative cash flows since its inception, and has funded its activities primarily through short-term loans and sales of equity securities. As of December 31, 2002 and 2001, the Company had cash and equivalents of $103,928 and $164,476, respectively.

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

To continue operations as a going concern through at least December 31, 2003, the Company will need to raise a total of approximately $2,000,000 for the second half of calendar 2003 and will require approximately $1,000,000 for overhead expenses and another $2,000,000 to fund expanded testing of its drug candidates in 2003. (See "Risk Factors," below.)

In December 2001, we obtained FDA approval to commence a Phase II clinical trial of our CoFactor product. In March 2002, we completed planning for a Phase I clinical trial of our BlockAide/CR product in affiliation with Paraxel, Inc., a contract research organization, at a hospital in Berlin, Germany. At that time, we did not have the resources to conduct these two trials and are seeking a strategic partner to finance and conduct the CoFactor trial or to raise the necessary money on our own for the CoFactor trial. We intend to finance the BlockAide/CR trial as well as an EradicAide trial on our own at this time. While the Company has had discussions with a number of potential CoFactor development partners, it has not yet entered into any agreement for the conduct and financing of clinical trials. If we are unable to enter into such an agreement on acceptable terms, we will have to delay such clinical trials or seek an outright sale of our CoFactor rights. The Company has not had discussions with potential development partners for its HIV drugs.

The Company's dependence on raising additional capital will continue at least until the Company is able to begin marketing its new technologies. The Company's future capital requirements and the adequacy of its financing depend upon numerous factors, including the successful commercialization of the Company's drug candidates, progress in its product development efforts, progress with preclinical studies and clinical trials, the cost and timing of production arrangements, the development of effective sales and marketing activities, the cost of filing, prosecuting, defending and enforcing intellectual property rights, competing technological and market developments, and the development of strategic alliances for the marketing of its products.

The Company will be required to obtain such funding through equity or debt financing, strategic alliances with corporate partners and others, or through

other sources not yet identified. The Company does not have any committed sources of additional financing, and cannot guarantee that additional funding will be available on acceptable terms, if at all. If adequate funds are not available, the Company may be required to delay, scale-back or eliminate certain aspects of its operations or attempt to obtain funds through arrangements with collaborative partners or others that may require the Company to relinquish rights to certain of its technologies, product candidates, products or potential markets.

QUANTITATIVE AND QUALITATIVE INFORMATION ABOUT MARKET RISK

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

CRITICAL ACCOUNTING POLICIES

USE OF ESTIMATES

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

The most significant accounting estimates relate to valuing equity transactions as described below.

ACCOUNTING FOR STOCK-BASED COMPENSATION

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

The Company accounts for nonemployee stock-based compensation in accordance with EITF 96-18. Amounts are based on the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measurable.

The value assigned to stock warrants granted to non-employees are accounted for in accordance with SFAS No. 123 and Emerging Issues Task Force (EITF) 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services, which require that such costs be measured at the end of each reporting period to account for changes in the fair value of the Company's

common stock until the options are vested. The Company values warrants using the Black-Scholes pricing model. Common stock is valued using the market price of common stock on the measurement date as defined in EITF 96-18. Series A and Series B preferred stock are valued at the liquidation value of $1,000 and $10 per share, respectively.

REVENUE RECOGNITION

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

RESEARCH AND DEVELOPMENT COSTS

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

IMPAIRMENT OF LONG-LIVED ASSETS

In the event that facts and circumstances indicate that property and equipment and intangible or other long-lived assets with definitive lives

may be impaired, an evaluation of the recoverability of currently recorded costs will be made. If an evaluation is required, the estimated value of undiscounted future net cash flows associated with the asset is compared to the asset's carrying value to determine if impairment exists. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets.

INCOME TAXES

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

NEW ACCOUNTING PRONOUNCEMENTS

The FASB issued Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets ("SFAS No. 142"), which was effective for the Company as of January 1, 2002. SFAS No. 142 requires that goodwill and other intangible assets with indefinite lives no longer be amortized. SFAS No. 142 further requires that the fair value of goodwill and other intangible assets with indefinite lives be tested for impairment upon adoption of this statement, annually and upon the occurrence of certain events and be written down to fair value if considered impaired. SFAS No. 142 eliminates the annual amortization expense related to goodwill. The adoption of SFAS No. 142 did not have a material impact on the Company's financial statements because, as of December 31, 2002 and 2001, the Company had no goodwill or other intangible assets with indefinite lives.

The FASB issued Statement of Financial Accounting Standards No. 143, Accounting for Asset Retirement Obligations ("SFAS No. 143"), which addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. This statement applies to all entities that have legal obligations associated with the retirement of long-lived assets that result from the acquisition, construction, development, or normal use of the assets. SFAS No. 143 will be effective for the Company as of January 1, 2003. The Company does not expect the adoption of SFAS No. 143 to have a significant impact on its financial condition or results of operations.

The FASB issued Statement of Financial Accounting Standards No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets ("SFAS No. 144"), which addresses financial accounting and reporting for the impairment or disposal of long-lived assets. While SFAS No. 144 supersedes SFAS No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of, it retains many of the fundamental provisions of that statement. SFAS No. 144 also supersedes the accounting and reporting provisions of APB Opinion No. 30, Reporting the Results of Operations - Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual, and Infrequently Occurring Events and Transactions, for the disposal of a segment of a business. SFAS No. 144 was effective for the Company as of January 1, 2002. The adoption of SFAS No. 144 did not have a significant impact on its financial condition or results of operations.

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

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

RISK FACTORS

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

WE HAVE CERTAIN FINANCIAL STATEMENT ITEMS THAT RAISE SUBSTANTIAL DOUBT AS TO OUR ABILITY TO CONTINUE AS A GOING CONCERN.

The Company has suffered recurrig losses from operations resulting in an accumulated deficit of $26,149,069 as of December 31, 2002. Since the Company presently has no source of revenues and is committed to continuing its product research and development program, significant expenditures and losses will continue until development of new products is completed and such products have been clinically tested, approved by the FDA and successfully marketed. In addition, the Company has funded its operations primarily through the sale of Company securities, and has had limited working capital for its product development and other activities.

WE HAVE NO CURRENT PRODUCT SALES REVENUES OR PROFITS.

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

IT IS UNCERTAIN THAT THE COMPANY WILL HAVE ACCESS TO FUTURE CAPITAL OR GOVERNMENT GRANTS.

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

THE COMPANY IS NOT CERTAIN THAT IT WILL BE SUCCESSFUL IN THE DEVELOPMENT OF ITS DRUG CANDIDATES.

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

POSITIVE RESULTS IN PRECLINICAL AND EARLY CLINICAL TRIALS DO NOT ENSURE THAT FUTURE CLINICAL TRIALS WILL BE SUCCESSFUL OR THAT DRUG CANDIDATES WILL RECEIVE ANY NECESSARY REGULATORY APPROVALS FOR THE MARKETING, DISTRIBUTION OR SALE OF SUCH DRUG CANDIDATES.

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

THE COMPANY WILL FACE INTENSE COMPETITION FROM OTHER COMPANIES IN THE PHARMACEUTICAL INDUSTRY.

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

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

THERE IS NO ASSURANCE THAT THE COMPANY'S PRODUCTS WILL HAVE MARKET ACCEPTANCE.

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

THE UNAVAILABILITY OF HEALTH CARE REIMBURSEMENT FOR ANY OF OUR PRODUCTS WILL LIKELY ADVERSELY IMPACT OUR ABILITY TO EFFECTIVELY MARKET SUCH PRODUCTS AND WHETHER HEALTH CARE REIMBURSEMENT WILL BE AVAILABLE FOR ANY OF OUR PRODUCTS IS UNCERTAIN.

The Company's ability to commercialize its technology successfully will depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, private health insurers and other third-party payors. Significant uncertainty exists as to the reimbursement status of newly-approved medical products. The Company cannot guarantee that adequate third-party insurance coverage will be available for the Company to establish and maintain price levels sufficient for realization of an appropriate return on its investments in developing new therapies. Government, private health insurers, and other third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new therapeutic products approved for marketing by the FDA. Accordingly, even if coverage and reimbursement are provided by government, private health insurers, and third-party payors for uses of the Company's products, the market acceptance of these products would be adversely affected if the amount of reimbursement available for the use of the Company's therapies proved to be unprofitable for health care providers.

UNCERTAINTIES RELATED TO HEALTH CARE REFORM MEASURES MAY AFFECT THE COMPANY'S SUCCESS.

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

FURTHER TESTING OF OUR DRUG CANDIDATES WILL BE REQUIRED AND THERE IS NO ASSURANCE OF FDA APPROVAL.

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

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

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

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

THE COMPANY'S SUCCESS WILL BE DEPENDENT ON LICENSES AND PROPRIETARY RIGHTS IT RECEIVES FROM OTHER PARTIES, AND ON ANY PATENTS IT MAY OBTAIN.

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

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

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

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

THE COMPANY'S LICENSE AGREEMENTS CAN BE TERMINATED IN THE EVENT OF A BREACH.

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

PROTECTING OUR PROPRIETARY RIGHTS IS DIFFICULT AND COSTLY.

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

THE COMPANY'S SUCCESS IS DEPENDENT ON ITS KEY PERSONNEL.

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

WE MAY BE UNABLE TO RETAIN SKILLED PERSONNEL AND MAINTAIN KEY RELATIONSHIPS.

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

WE CURRENTLY HAVE NO SALES OR MARKETING CAPABILITY.

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

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

THE COMPANY DOES NOT HAVE MANUFACTURING CAPABILITIES AND MAY NOT BE ABLE TO EFFICIENTLY DEVELOP MANUFACTURING CAPABILITIES OR CONTRACT FOR SUCH SERVICES FROM THIRD PARTIES ON COMMERCIALLY ACCEPTABLE TERMS.

The Company will not have any manufacturing capacity. When required, the Company will seek to establish relationships with third-party manufacturers for the manufacture of clinical trial material and the commercial production of a drug product just as it has with Merck Eprova AG and Multiple Peptide Systems, Inc. There can be no assurance that the Company will be able to establish relationships with third-party manufacturers on commercially acceptable terms or that third-party manufacturers will be able to manufacture a drug product on a cost-effective basis in commercial quantities under good manufacturing practices mandated by the FDA.

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

THE COMPANY DOES NOT HAVE ITS OWN RESEARCH FACILITIES AND WILL BE DEPENDENT ON THIRD PARTIES FOR DRUG DEVELOPMENT.

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

IN THE FUTURE, WE ANTICIPATE THAT WE WILL NEED TO OBTAIN ADDITIONAL OR INCREASED PRODUCT LIABILITY INSURANCE COVERAGE AND IT IS UNCERTAIN THAT SUCH INCREASED OR ADDITIONAL INSURANCE COVERAGE CAN BE OBTAINED ON COMMERCIALLY REASONABLE TERMS.

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

INSURANCE COVERAGE IS INCREASINGLY MORE DIFFICULT TO OBTAIN OR MAINTAIN.

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

THE MARKET PRICE OF OUR SHARES, LIKE THAT OF MANY BIOTECHNOLOGY COMPANIES, IS HIGHLY VOLATILE.

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

WE ARE NOT PAYING DIVIDENDS ON OUR COMMON STOCK.

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

THE ISSUANCE OF SHARES OF OUR PREFERRED STOCK MAY ADVERSELY AFFECT OUR COMMON STOCK.

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

UNDER PROVISIONS OF THE COMPANY'S CERTIFICATE OF INCORPORATION, BYLAWS AND DELAWARE LAW, THE COMPANY'S MANAGEMENT MAY BE ABLE TO BLOCK OR IMPEDE A CHANGE IN CONTROL.

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

OFFICERS' AND DIRECTORS' LIABILITIES ARE LIMITED UNDER DELAWARE LAW.

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

ITEM 7. FINANCIAL STATEMENTS.

See the Financial Statements and Reports of J.H. Cohn LLP and KPMG LLP set forth in Item 13, which are incorporated herein by reference.

ITEM 8. CHANGE IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

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

PART III

ITEM 9. DIRECTOR, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(A) OF THE EXCHANGE ACT.

DIRECTORS, EXECUTIVE OFFICERS AND SIGNIFICANT EMPLOYEES.

The names of the Company's Directors and executive officers, including those persons nominated or chosen to become such, and significant employees as of April 1, 2003 and certain information about each them are set forth below:

| NAME | AGE | POSITION(S) WITH THE COMPANY |
|---|---|---|
| Nicholas J. Virca | 56 | Chief Executive Officer, President, Secretary and Director |
| M. Ross Johnson, Ph.D. (1)(2) | 58 | Chairman of the Board |
| Evan Levine (1)(2) | 37 | Chief Operating Officer and Director |
| Steven M. Plumb, CPA | 43 | Chief Financial Officer |
| Joan M. Robbins | 42 | Chief Technical Officer |

(1) Member of the Audit Committee of the Board of Directors.
(2) Member of the Compensation Committee of the Board of Directors.

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

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

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

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

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

Section 16(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), requires the Company's Directors and officers, and persons who own more than 10% of a registered class of the Company's equity securities ("Section 16 Persons"), to file with the Securities and Exchange Commission (the "SEC") initial reports of ownership and reports of changes in ownership of Common Stock and other equity securities of the Company. Section 16 Persons are required by SEC regulation to furnish the Company with copies of all Section

16(a) reports they file. Based on the Company's review of the forms it has received, on other reports filed by Section 16 Persons with the SEC and on the Company's records, the Company believes that during the fiscal years preceding and including 2002: (1) Warren C. Lau, the former Chief Financial Officer and President and a former Director of the Company, failed to timely file a Form 3 and failed to timely file a Form 4 to report certain changes in his beneficial ownership of Common Stock; (2) Loius R. Reif, the former Chief Executive Officer and Chairman of the Board of the Company, failed to timely file a Form 3; (3) Robert Whitworth, the former Secretary and a former Director of the Company failed to timely file a Form 3, (4) M. Ross Johnson failed to timely file a Form 3 when the Company became subject to the periodic filing requirements of the Exchange Act and failed to timely file a Form 4 to report certain changes in his beneficial ownership of Common Stock; and (5) Nicholas J. Virca failed to timely file a Form 3 when the Company became subject to the periodic filing requirements of the Exchange Act and failed to timely file a Form 4 to report certain changes in his beneficial ownership of Common Stock.

ITEM 10. EXECUTIVE COMPENSATION.

SUMMARY COMPENSATION TABLE

The following Summary Compensation Table sets forth summary information as to compensation received by the Company's Chief Executive Officer and each of the other most highly compensated persons who were serving as executive officers of the Company as of December 31, 2002, one former executive who would have been among the four most highly compensated persons but for the fact that he was not employed by the Company as of December 31, 2002 and two executives of the Company who would have been among the four most highly compensated persons but for the fact they were not employed by the Company as of December 31, 2002 (collectively, the "named executive officers") for services rendered to the Company in all capacities during the three fiscal years ended December 31, 2002. The table below does not list Louis R. Reif, the former Chief Executive Officer and Chairman of the Board of the Company. Mr. Reif was Chief Executive Officer and Chairman of the Board of the Company until October 7, 2002, at which time the Board of Directors of the Company appointed Nicholas J. Virca as Chief Executive Officer of the Company and appointed M. Ross Johnson, Ph.D. as Chairman of the Board. Mr. Reif resigned his position as a member of the Board of Directors of the Company effective January 10, 2003. Mr. Reif did not receive any annual salary, other compensation or options or warrants to purchase Common Stock in fiscal years 2002, 2001 and 2000.

| NAME AND PRINCIPAL POSITION | YEAR | ANNUAL SALARY (1) | SECURITIES UNDERLYING OPTIONS | ALL OTHER COMPENSATION |
|---|---|---|---|---|
| Nicholas J. Virca | 2002 | $120,192 | 1,665,000 | -- |
| Chief Executive Officer, President and Secretary | 2001 | $124,000 | -- | -- |
| | 2000 | $30,000 (2) | -- | -- |
| Evan Levine (3) | 2002 | $-- | -- | -- |
| Chief Operating Officer | 2001 | $-- | -- | -- |
| | 2000 | $-- | -- | -- |
| Steven M. Plumb, CPA (4) | 2002 | $-- | -- | -- |
| Chief Financial Officer | 2001 | $-- | -- | -- |
| | 2000 | $-- | -- | -- |
| Joan M. Robbins (5) | 2002 | $-- | -- | -- |
| Chief Technical Officer | 2001 | $-- | -- | -- |
| | 2000 | $-- | -- | -- |
| Warren C. Lau (6) | 2002 | $105,818 | -- | $35,036 (7) |
| Former Chief Financial Officer and President | 2001 | $114,000 | -- | -- |
| | 2000 | $114,000 | -- | -- |

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(1) None of the named executives received any bonus or other annual compensation in any of the years listed.

(2) Mr. Virca became an executive of Biokeys, Inc. in March 1997. Biokeys, Inc. became a wholly-owned subsidiary of the Company in October 2000. The $30,000 listed represents that portion of Mr. Virca's salary that he received as an executive of Biokeys, Inc. while Biokeys, Inc. was a wholly-owned subsidiary of the Company. Mr. Virca started serving as an executive of the Company in October 2002.

(3) Mr. Levine became an executive of the Company in October 2002. Mr. Levine did not receive any salary or other compensation from the Company in any of the years listed and has not yet been reimbursed for any actual expenses in connection with his position as an executive of the Company.
(4) Mr. Plumb was hired as Chief Financial Officer, on a part-time basis, on February 10, 2003. From July 1, 2001 to February 10, 2003, Mr. Plumb served as a consultant to the Company. In 2001 and 2002, Mr. Plumb received an aggregate of $21,618 and $55,150, respectively, for services rendered to the Company as a consultant. Mr. Plumb's annual salary as Chief Financial Officer is $60,000.
(5) Dr. Robbins began her employment with the Company on April 1, 2003. Dr. Robbins annual salary is $170,000.
(6) Mr. Lau resigned from his position as Chief Financial Officer and President of the Company as of December 12, 2002.
(7) This amount reflects a $5,000 separation payment to Mr. Lau and the forgiveness of $30,036 of debt Mr. Lau owed the Company.

OPTION GRANTS.

| | NUMBER OF SHARES OF COMMON STOCK UNDERLYING OPTIONS GRANTED | PERCENT OF TOTAL OPTIONS GRANTED TO EMPLOYEES IN THE FISCAL YEAR ENDED DECEMBER 31, 2002 | EXERCISE PRICE | EXPIRATION DATE |
|---|---|---|---|---|
| Nicholas J. Virca | 1,665,000 | 98.5% | $0.23 (4) | 12/30/2008 |
| Evan Levine | - | - | - | - |
| Steven M. Plumb, CPA (1) | - | - | - | - |
| Joan M. Robbins (2) | - | - | - | - |
| Warren C. Lau (3) | - | - | - | - |

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(1) Mr. Plumb started as Chief Financial Officer of the Company on February 10, 2003.
(2) Dr. Robbins started as Chief Technical Officer of the Company on April 1, 2003.
(3) Mr. Lau resigned from his position as Chief Financial Officer and President of the Company as of December 12, 2002.
(4) This is a weighted-average exercise price.

AGGREGATED OPTION EXERCISES IN LAST FISCAL YEAR AND FISCAL YEAR-END VALUES

No executive officer or Director of the Company exercised any options during the fiscal year ended December 31, 2002.

The following table provides information regarding the number of shares covered by both exercisable and unexercisable stock options held by the named executive officers as of December 31, 2002, and the value of "in-the-money" options, which values represent the positive spread between the exercise price of any such options and the fiscal year-end value of the Common Stock.

| | NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS AT DECEMBER 31, 2002 | | VALUE OF IN-THE-MONEY OPTIONS AT DECEMBER 31, 2002 (1) | |
|---|---|---|---|---|
| | EXERCISABLE | UNEXERCISABLE | EXERCISABLE | UNEXERCISABLE |
| Nicholas J. Virca | 1,165,000 (2) | 500,000 | $190,000 | $95,000 |
| Evan Levine | - | - | - | - |
| Steven M. Plumb, CPA | - | - | - | - |
| Joan M. Robbins | - | - | - | - |
| Warren C. Lau | - | - | - | - |

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(1) Value based on the closing price of Common Stock of $0.39 on December 31, 2002, less the option exercise price.

(2) Does not include a warrant to purchase 29,435 shares of Common Stock at $0.49 per share held by Mr. Virca.

LONG-TERM INCENTIVE PLANS

The Company does not have a long-term incentive plan and no shares or other rights were awarded to any executive officer or Director of the Company under any long-term incentive plan during the fiscal year ended December 31, 2002.

COMPENSATION OF DIRECTORS

Members of our Board of Directors do not receive compensation for their services as Directors.

EMPLOYMENT CONTRACTS

Warren C. Lau, the Company's former Chief Financial Officer and President, and the Company entered into an Employment Agreement dated December 1, 1999. Pursuant to the terms of the Employment Agreement, if a "Change of Control" of the Company, as defined in the Employment Agreement, occurs and Mr. Lau's working condition or status materially and adversely changes without his consent, then Mr. Lau could terminate the Employment Agreement and the Company would be obligated to pay Mr. Lau a severance payment equal to one year's salary. Mr. Lau terminated his Employment Agreement effective November 30, 2002, however, no "Change of Control" of the Company had occurred pursuant to the terms of the Employment Agreement and Mr. Lau did not receive a severance payment pursuant to the terms of the Employment Agreement.

On December 12, 2002, the Company entered into a Separation Agreement and Release with Warren C. Lau pursuant to which Mr. Lau resigned from the Company's Board of Directors and specifically waived and released any claims Mr. Lau may have under the Employment Agreement. Pursuant to the terms of the Separation Agreement and Release, in consideration of Mr. Lau's resignation, surrender of shares of the Company's Common Stock held by Mr. Lau and waiver and release of claims, the Company paid Mr. Lau $5,000 and agreed to reimburse Mr. Lau for certain premiums for medical insurance coverage until June 10, 2003.

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

Pursuant to an offer letter dated March 5, 2003, the Company offered Joan M. Robbins, Ph.D. the position of Chief Technical Officer of the Company which offer Dr. Robbins accepted. To provide an incentive to Dr. Robbins to secure government grants to the Company and to introduce or refer the Company to potential investors, the Company agreed to issue to Dr. Robbins an option to purchase shares of Common Stock for each government grant the Company receives and each investment in the Company made by an investor that is introduced or referred by Dr. Robbins; each option so granted will be for a number of shares of Common Stock equal to 5% of the dollar amount of the relevant grant or investment.

ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The following table sets forth certain information as of March 31, 2003, concerning the ownership of Common Stock by (i) each stockholder of the Company known by the Company to be the beneficial owner of more than 5% of the outstanding shares of Common Stock or Preferred Stock, (ii) each current member of the Board of Directors of the Company and (iii) each executive officer of the Company named in the Summary Compensation Table appearing under "Executive Compensation" above other than Warren C. Lau, our former Chief Financial Officer and President.

Beneficial ownership is determined in accordance with Rule 13d-3 of the Securities Exchange Act of 1934, as amended, and includes all shares over which the beneficial owner exercises voting or investment power. Options and warrants to purchase Common Stock or Preferred Stock of the Company that are presently exercisable or exercisable within 60 days of March 31, 2003 and shares of Preferred Stock of the Company that are presently convertible or convertible within 60 days of March 31, 2003 that are held by the persons listed below are included in the total number of shares beneficially owned for such person and are considered outstanding for the purpose of calculating the percentage ownership of such holder. The Company has relied on information supplied by its officers, directors and certain stockholders and on information contained in filings with the SEC in completing the table below. Except as otherwise indicated, and subject to community property laws where applicable, we believe, based on information provided by these persons, that the persons named in the table have sole voting and investment power with respect to all shares of Common Stock or Preferred Stock of the Company shown as beneficially owned by them.

| TITLE OR CLASS | NAME AND ADDRESS OF BENEFICIAL OWNER (1) | AMOUNT AND NATURE OF BENEFICIAL OWNERSHIP AS OF MARCH 31, 2003 | PERCENT OF CLASS (2) |
|---|---|---|---|
| Common Stock | Mark Capital LLC<br>300 Felton Drive<br>Menlo Park, CA 94025 | 4,268,792 | 13.03% |
| Common Stock | Matthew Balk (3)<br>245 Park Avenue, 44th Floor<br>New York, NY 10167 | 3,884,531 | 11.88% |
| Preferred Stock | Emisphere Technologies, Inc. | 200,000 | 99.76% |
| | CURRENT DIRECTORS | | |
| Common Stock | Nicholas J. Virca | 1,526,693 | 4.51% |
| Common Stock | M. Ross Johnson, Ph.D. | 1,810,092 | 5.44% |
| Common Stock | Evan M. Levine (4) | 4,473,792 | 13.57% |
| | EXECUTIVE OFFICERS WHO ARE NOT DIRECTORS | | |
| Common Stock | Steven M Plumb, CPA | 12,500 | 0.04% |
| Common Stock | Joan M. Robbins, Ph.D.(5) | 100,000 | 0.31% |

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(1) Unless indicated otherwise, the address of each person listed in the table is c/o Biokeys Pharmaceuticals, Inc.; 9948 Hibert Street, Suite 100; San Diego, California 92131

(2) The percentage of beneficial ownership of Common Stock is based on 32,652,630 shares of Common Stock outstanding as of March 31, 2003 and excludes all shares of Common Stock issuable upon the exercise of outstanding options or warrants to purchase Common Stock or conversion of any outstanding preferred stock of the Company, other than the shares of Common Stock issuable upon the exercise of options or warrants to purchase Common Stock held by the named person to the extent such options or warrants are exercisable within 60 days of March 31, 2003. The percentage of beneficial ownership of preferred stock of the Company is based on 201,473 shares of preferred stock of the Company outstanding as of March 31, 2003.

(3) Includes 251,263 shares of Common Stock held by Mr. Balk's wife; 400,000 shares of Common Stock held by Mr. Balk's wife's retirement plan; 706,650 shares of Common Stock held by Mr. Balk as custodian for his two children; and 200,000 shares of Common Stock held by Mr. Balk's retirement plan.

(4) Includes 4,268,792 shares of Common Stock beneficially held by Mark Capital LLC. Mr. Levine is the managing member of Mark Capital LLC.

(5) Dr. Robbins started as the Company's Chief Technical Officer on April 1, 2003. Dr. Robbin's beneficial interest is shown as she may have been deemed to hold an option to purchase 300,000 shares of Common Stock of the Company as of March 31, 2003 which option was vested as to 100,000 shares as of the date of grant.

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

On October 3, 2002, Dr. Johnson purchased 6,000 shares of Series C Preferred Stock for $60,000 in cash and Matthew Balk, currently the beneficial holder of more than 10% of the outstanding shares of Common Stock, and entities related to or under the control of Matthew Balk purchased an aggregate of 15,600 shares of Series C Preferred Stock for $106,000 cash and cancellation of $50,000 of indebtedness pursuant to the terms of the Series C Convertible Preferred Stock Purchase Agreement, dated September 27, 2002, among the Company and the purchasers of Series C Preferred Stock (the "Series C Purchase Agreement"). On October 4, 2003, Evan Levine, the Company's Chief Operating Officer and a member of the Board of Directors of the Company, purchased 20,000 shares of Series C Preferred Stock for $100,000 in cash and cancellation of $100,000 of indebtedness. Prior to the foregoing purchases of shares of Series C Preferred Stock, neither Dr. Johnson, Mr. Balk nor Mr. Levine were either officers, directors or the beneficial holders of more than 10% of the outstanding shares of Common Stock. Dr. Johnson, however, has been a member of the Board of Directors of Biokeys, Inc., our wholly-owned subsidiary, since October 2000. In connection with the foregoing purchases of shares of Series C Preferred Stock and pursuant to the terms of the Series C Purchase Agreement, Dr. Johnson was appointed as Chairman of the Board of the Company and Mr. Levine was appointed as a member of the Board of Directors of the Company. Mr. Levine was also appointed to serve the Company as its Chief Operating Officer on October 7, 2002.

ITEM 13. EXHIBITS AND REPORTS ON FORM 8-K.

FINANCIAL STATEMENTS INCORPORATED BY REFERENCE

The Financial Statements and Reports of J.H. Cohn LLP and KPMG LLP which are set forth in the index to Consolidated Financial Statements on pages F-1 through F-16 of this report are filed as part of this report.



EXHIBITS.

| EXHIBIT NUMBER | DESCRIPTION |
|---|---|
| 2.1* | Agreement and Plan of Merger dated May 19, 2000 among BioQuest, Inc.; BioQuest Acquisition Corp.; and Biokeys, Inc. |
| 3.1* | Certificate of Amendment of Certificate of Incorporation of BioQuest, Inc. |
| 3.2* | Certificate of Amendment of Certificate of Incorporation of BioQuest, Inc. |
| 3.3* | Certificate of Merger of BioQuest Acquisition Corp. into Biokeys, Inc. |
| 3.4* | Certificate of Incorporation of BioQuest Acquisition Corp. |
| 3.6* | Amended and Restated Bylaws of Biokeys Pharmaceuticals, Inc. |
| 4.1* | Certificate of Designation of BioQuest, Inc. |
| 4.2 | Certificate of Designation of Series B Convertible Preferred Stock and Series C Convertible Preferred Stock of Biokeys Pharmaceuticals, Inc. effective September 23, 2002 |
| 10.1** | Patent and Technology License Agreement with M.D. Anderson - June, 1996 (Request for confidential treatment of certain data) |
| 10.2** | Amendment to M.D. Anderson Licensing Agreement June 15, 2000 (Request for confidential treatment of certain data) |
| 10.3** | Option and License Agreement with USC - June 23, 1998 (Co Factor and Selone) (Request for confidential treatment of certain data) |
| 10.4* | Amendment to Option and License Agreement with USC dated August 16, 2000 (Co Factor and Selone) (Request for confidential treatment of certain data) |

| | |
|---|---|
| 10.5** | Option and License Agreement with USC dated August 17, 2000 (Thiovir) (Request for confidential treatment of certain data) |
| 10.6 | Not currently in use |
| 10.7*** | Patent License Agreement, effective August 1, 2002, between Biokeys, Inc. and the National Institutes of Health |
| 10.8 | Letter Agreement, effective January 1, 2003, between Biokeys Pharmaceuticals, Inc. and Steven M. Plumb, P.C. |
| 10.9 | Offer Letter, dated March 5, 2003, from Biokeys Pharmaceuticals, Inc. to Joan M. Robbins, Ph.D. |
| 11.1* | Statement Regarding Computation of Per Share Earnings |
| 21.1 | Subsidiaries of Biokeys Pharmaceuticals, Inc. as of December 31, 2002 |
| 24.1* | Powers of Attorney (included on signature pages) |
| 99.1 | Certificate Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350 |

* Incorporated by reference to the same-numbered exhibit to the Company's Registration Statement on Form 10-SB, filed October 2, 2001.
** Incorporated by reference to the same-numbered exhibit to the Company's Registration Statement on Form 10-SB/A, filed January 11, 2002.
*** Incorporated by reference to the same-numbered exhibit to the Company's Quarterly Report on Form 10-QSB, filed November 26, 2002.

REPORTS ON FORM 8-K.

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

ITEM 14. CONTROLS AND PROCEDURES.

EVALUATION OF DISCLOSURE CONTROLS AND PROCEDURES

Within the 90-day period prior to the date of this report, the Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures pursuant to Rule 13a-14 of the Securities Exchange Act of 1934 (the "Exchange Act"). Based upon that evaluation, the Company's principal executive and financial officers concluded that the Company's disclosure controls and procedures are effective in timely providing them with material information relating to the Company, as required to be disclosed by the Company in the reports that it files or submits under the Exchange Act, within the time periods specified in the Securities and Exchange Commission's rules and forms.

CHANGES IN INTERNAL CONTROLS

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

SIGNATURES

Pursuant to the requirements of the Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on the 15th day of April 2003.

Biokeys Pharmaceuticals, Inc.

By:/s/ Nicholas J. Virca
---
Nicholas J. Virca
Chief Executive Officer, President and Secretary

By:/s/ Steven M. Plumb
---
Steven M. Plumb, CPA
Chief Financial Officer

POWER OF ATTORNEY

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

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

| SIGNATURE | TITLE | DATE |
|---|---|---|
| /s/ Nicholas J. Virca<br>- ---<br>Nicholas J. Virca | Chief Executive Officer, President and Secretary | April 15, 2003 |
| /s/ Steven M. Plumb<br>- ---<br>Steven M. Plumb, CPA | Chief Financial Officer | April 15, 2003 |
| /s/ M. Ross Johnson<br>- ---<br>M. Ross Johnson | Chairman of the Board | April 15, 2003 |
| /s/ Evan Levine<br>- ---<br>Evan Levine | Director | April 15, 2003 |

BIOKEYS PHARMACEUTICALS, INC.
CERTIFICATE PURSUANT TO
RULE 13A-14 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Nicholas J. Virca, Chief Executive Officer of Biokeys Pharmaceuticals, Inc., certify that:

1. I have reviewed this annual report on Form 10-KSB of Biokeys Pharmaceuticals, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this annual report;

4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the Registrant and we have:

   a) designed such disclosure controls and procedures to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   b) evaluatedthe effectiveness of the Registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

   c) presentedin this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the Registrant's auditors and the audit committee of Registrant's board of directors (or persons performing the equivalent function):

   a) all significant deficiencies in the design or operation of internal controls which could adversely affect the Registrant's ability to record, process, summarize and report financial data and have identified for the Registrant's auditors any material weaknesses in internal controls; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal controls; and

6. The Registrant's other certifying officer and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

April 15, 2003

/s/ Nicholas J. Virca
---
Nicholas J. Virca
Chief Executive Officer

BIOKEYS PHARMACEUTICALS, INC.
CERTIFICATE PURSUANT TO
RULE 13A-14 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

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

1. I have reviewed this annual report on Form 10-KSB of Biokeys Pharmaceuticals, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this annual report;

4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the Registrant and we have:

   a. designed such disclosure controls and procedures to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   b. evaluatedthe effectiveness of the Registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

   c. presentedin this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the Registrant's auditors and the audit committee of Registrant's board of directors (or persons performing the equivalent function):

   a. all significant deficiencies in the design or operation of internal controls which could adversely affect the Registrant's ability to record, process, summarize and report financial data and have identified for the Registrant's auditors any material weaknesses in internal controls; and

   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal controls; and

6. The Registrant's other certifying officer and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

April 15, 2003

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

BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To The Board of Directors
Biokeys Pharmaceuticals, Inc.:

We have audited the accompanying consolidated balance sheet of Biokeys Pharmaceuticals, Inc. and Subsidiary (a development stage enterprise) as of December 31, 2002, and the related consolidated statements of operations, shareholders' equity (deficit) and cash flows for the year then ended and for the period from June 12, 1996 (date of inception) through December 31, 2002. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit. The consolidated financial statements for the period from June 12, 1996 (date of inception) through December 31, 2001 were audited by other auditors whose report, dated April 10, 2002, expressed an unqualified opinion and included an explanatory paragraph concerning the uncertainty as to the Company's ability to continue as a going concern. Our opinion on the consolidated statements of operations, shareholders' equity (deficit) and cash flows for the period from June 12, 1996 (date of inception) through December 31, 2002, insofar as it relates to amounts for the period for June 12, 1996 (date of inception) through December 31, 2001, is based solely on the report of the other auditors.

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

In our opinion, based on our audit and the report of the other auditors, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Biokeys Pharmaceuticals, Inc. and Subsidiary (a development stage enterprise) as of December 31, 2002, and their results of operations and cash flows for the year then ended and for the period from June 12, 1996 (date of inception) through December 31, 2002, in conformity with accounting principles generally accepted in the United States of America.

The consolidated financial statements referred to above have been prepared assuming that the Company will continue as a going concern. As discussed in Note 12 to the consolidated financial statements, the Company has suffered recurring losses from operations and had a working capital deficiency and an accumulated deficit at December 31, 2002. These matters raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 12. The consolidated financial statements referred to above do not include any adjustments that might result from the outcome of this uncertainty.

J. H. COHN LLP

/s/ J.H. Cohn LLP

San Diego, California
March 18, 2003, except for Note 5
the date for which is April 1, 2003

INDEPENDENT AUDITORS' REPORT

The Board of Directors
Biokeys Pharmaceuticals, Inc.:

We have audited the accompanying consolidated balance sheet of Biokeys Pharmaceuticals, Inc. and subsidiary (a development stage enterprise) (the Company) as of December 31, 2001, and the related consolidated statements of operations, shareholders' equity (deficit), and cash flows for the year then ended. 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 audit.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Biokeys Pharmaceuticals, Inc. and subsidiary (a development stage enterprise) as of December 31, 2001, and the results of their operations and their cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in note 12 to the consolidated financial statements, the Company has suffered recurring losses from operations; this fact raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in note 12. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KPMG LLP

Houston, Texas
April 10, 2002

BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY
(A Development Stage Enterprise)
Consolidated Balance Sheets

| ASSETS | DECEMBER 31, 2002 | 2001 |
|---|---|---|
| Current assets: | | |
| Cash and cash equivalents | $ 103,928 | $ 164,476 |
| Advances to employees | -- | 29,872 |
| Note receivable - related party | -- | 35,993 |
| Total current assets | 103,928 | 230,341 |
| Property and equipment, net | 13,434 | 13,612 |
| Other assets | 12,983 | 34,053 |
| Total assets | $ 130,345 | $ 278,006 |
| LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT) | | |
| Current liabilities: | | |
| Accounts payable and accrued liabilities | $ 579,146 | $ 430,216 |
| Accrued salary and related taxes | 115,021 | 303,837 |
| Accrued dividends payable | 34,960 | 128,000 |
| Current portion of notes payable | 197,075 | 54,439 |
| Total current liabilities | 926,202 | 916,492 |
| Notes payable, net of current portion | 56,873 | -- |
| Total liabilities | 983,075 | 916,492 |
| Commitments and contingencies | -- | -- |
| Shareholders' equity (deficit): | | |
| Series A cumulative convertible preferred stock, $0.01 par value. Authorized 8,000 shares; issued and outstanding, 473 shares in 2002 and 3,337 shares in 2001 (aggregate involuntary liquidation preference $337,000 at December 31, 2002) | 4 | 33 |
| Series B convertible preferred series stock, $0.01 par value. Authorized 200,000 shares; issued and outstanding, 200,000 shares in 2002 | 2,000 | -- |
| Series C convertible preferred stock, $0.01 par value. Authorized 125,000 shares; issued and outstanding, 70,109 shares in 2002 (aggregate involuntary liquidation preference $701,093 at December 31, 2002) | 701 | -- |
| Common stock, $0.001 par value. Authorized 50,000,000 shares; issued and outstanding, 17,496,257 shares in 2002 and 15,005,191 shares in 2001 | 17,496 | 15,005 |
| Additional paid-in capital | 25,276,138 | 23,389,818 |
| Deficit accumulated during the development stage | (26,149,069) | (24,043,342) |
| Total shareholders' equity (deficit) | (852,730) | (638,486) |
| Total liabilities and shareholders' equity (deficit) | $ 130,345 | $ 278,006 |

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS.

BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY
(A Development Stage Enterprise)
Consolidated Statements of Operations

| | YEAR ENDED DECEMBER 31, | | INCEPTION (JUNE 12, 1996) THROUGH DECEMBER 31, |
|---|---|---|---|
| | 2002 | 2001 | 2002 |
| Net sales | $ -- | $ -- | $ 174,830 |
| Cost of goods sold | -- | -- | 51,094 |
| Gross margin | -- | -- | 123,736 |
| Grant revenue | 45,792 | -- | 126,130 |
| Interest income | 1,272 | 31,690 | 89,967 |
| | 47,064 | 31,690 | 339,833 |
| Operating expenses: | | | |
| Research and development | 282,966 | 946,419 | 3,980,929 |
| General and administrative | 1,388,020 | 2,038,130 | 6,829,248 |
| Depreciation and amortization | 428,109 | 7,672,112 | 10,089,737 |
| Impairment loss - write off of goodwill (note 2) | -- | 5,702,130 | 5,702,130 |
| Interest expense | 53,696 | 12,019 | 177,704 |
| Equity in loss of investee | -- | -- | 178,936 |
| Total operating expenses | 2,152,791 | 16,370,810 | 26,958,684 |
| Loss before cumulative effect of change in accounting principle | (2,105,727) | (16,339,120) | (26,618,851) |
| Cumulative effect of change in accounting principle | -- | -- | (25,821) |
| Net loss | (2,105,727) | (16,339,120) | (26,644,672) |
| Preferred stock dividends | (242,200) | (256,000) | (583,400) |
| Net loss applicable to common stock | $(2,347,927) | $(16,595,120) | $ (27,228,072) |
| Loss per common share - basic and diluted (note 9) | $ (.15) | $ (1.12) | |

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS.

BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY
(A Development Stage Enterprise)
Consolidated Statements of Shareholders' Equity (Deficit)
Inception (June 12, 1996) through December 31, 2002

| | CUMULATIVE CONVERTIBLE PREFERRED STOCK, SERIES A | | CONVERTIBLE PREFERRED STOCK, SERIES B | | CONVERTIBLE PREFERRED STOCK, SERIES C | |
|---|---|---|---|---|---|---|
| | SHARES | AMOUNT | SHARES | AMOUNT | SHARES | AMOUNT |
| Balances at June 12, 1996 (date of incorporation) | -- | $ -- | -- | $ -- | -- | $ -- |
| Sale of common stock without par value | -- | -- | -- | -- | -- | -- |
| Change in par value of common stock | -- | -- | -- | -- | -- | -- |
| Issuance of common stock and net liabilities assumed in acquisition | -- | -- | -- | -- | -- | -- |
| Issuance of common stock | -- | -- | -- | -- | -- | -- |
| Net loss | -- | -- | -- | -- | -- | -- |
| Balances at December 31, 1996 | -- | -- | -- | -- | -- | -- |
| Sale of common stock, net of offering costs of $9,976 | -- | -- | -- | -- | -- | -- |
| Issuance of common stock in acquisition | -- | -- | -- | -- | -- | -- |
| Minority interest deficiency at acquisition charged to the Company | -- | -- | -- | -- | -- | -- |
| Net loss | -- | -- | -- | -- | -- | -- |
| Balances at December 31, 1997 | -- | -- | -- | -- | -- | -- |
| Rescission of acquisition | -- | -- | -- | -- | -- | -- |
| Issuance of common stock at conversion of notes payable | -- | -- | -- | -- | -- | -- |
| Expense related to stock warrants issued | -- | -- | -- | -- | -- | -- |
| Net loss | -- | -- | -- | -- | -- | -- |
| Balances at December 31, 1998 | -- | -- | -- | -- | -- | -- |
| Sale of common stock | -- | -- | -- | -- | -- | -- |
| Expense related to stock warrants issued | -- | -- | -- | -- | -- | -- |
| Net loss | -- | -- | -- | -- | -- | -- |
| Balances at December 31, 1999 | -- | -- | -- | -- | -- | -- |
| Sale of preferred stock, net of offering costs of $76,500 | 3,200 | 32 | -- | -- | -- | -- |
| Issuance of common stock at conversion of notes and interest payable | -- | -- | -- | -- | -- | -- |
| Issuance of common stock at conversion of notes payable | -- | -- | -- | -- | -- | -- |
| Issuance of common stock to settle obligations | -- | -- | -- | -- | -- | -- |
| Issuance of common stock for acquisition | -- | -- | -- | -- | -- | -- |
| Issuance of warrants for acquisition | -- | -- | -- | -- | -- | -- |
| Stock issued for acquisition costs | -- | -- | -- | -- | -- | -- |
| Expense related to stock warrants issued | -- | -- | -- | -- | -- | -- |
| Dividends payable on preferred stock | -- | -- | -- | -- | -- | -- |
| Cashless exercise of warrants | -- | -- | -- | -- | -- | -- |
| Net loss | -- | -- | -- | -- | -- | -- |
| Balances at December 31, 2000 | 3,200 | 32 | -- | -- | -- | -- |
| Dividends payable on preferred stock | -- | -- | -- | -- | -- | -- |
| Repurchase of warrants | -- | -- | -- | -- | -- | -- |
| Sale of warrants | -- | -- | -- | -- | -- | -- |
| Cashless exercise of warrants | -- | -- | -- | -- | -- | -- |
| Issuance of common stock to pay preferred dividends | -- | -- | -- | -- | -- | -- |
| Detachable warrants issued with notes payable | -- | -- | -- | -- | -- | -- |
| Issuance of warrants to pay operating expenses | -- | -- | -- | -- | -- | -- |
| Issuance of common stock to pay operating expenses | -- | -- | -- | -- | -- | -- |
| Issuance of preferred stock to pay operating expenses | 137 | 1 | -- | -- | -- | -- |
| Net loss | -- | -- | -- | -- | -- | -- |
| Balances at December 31, 2001 | 3,337 | 33 | -- | -- | -- | -- |
| Dividends payable on preferred stock | -- | -- | -- | -- | -- | -- |
| Repurchase of warrants | -- | -- | -- | -- | -- | -- |
| Sale of warrants | -- | -- | -- | -- | -- | -- |
| Cashless exercise of warrants | -- | -- | -- | -- | -- | -- |
| Exercise of warrants | -- | -- | -- | -- | -- | -- |
| Sale of preferred stock | -- | -- | 200,000 | 2,000 | 70,109 | 701 |
| Conversion of preferred stock into common stock | (3,000) | (30) | -- | -- | -- | -- |
| Preferred stock dividends forgiven | -- | -- | -- | -- | -- | -- |
| Issuance of warrants to pay operating expenses | -- | -- | -- | -- | -- | -- |
| Issuance of common stock to pay operating expenses | -- | -- | -- | -- | -- | -- |
| Issuance of preferred stock to pay operating expenses | 136 | 1 | -- | -- | -- | -- |
| Issuance of stock options to employees | -- | -- | -- | -- | -- | -- |
| Net loss | -- | -- | -- | -- | -- | -- |
| Balances at December 31, 2002 | 473 | $ 4 | 200,000 | $ 2,000 | 70,109 | $ 701 |

THE TABLE ABOVE IS CONTINUED ON THE FOLLOWING PAGE.

THE TABLE BELOW IS A CONTINUATION OF THE TABLE ON THE PRECEDING PAGE.
THE TABLE ON THE PRECEDING PAGE CONTINUES FROM LEFT TO RIGHT
BEGINNING WITH THE COLUMN "COMMON STOCK"

| | COMMON STOCK | | ADDITIONAL PAID-IN | DEFICIT ACCUMULATED DURING THE DEVELOPMENT | TOTAL SHAREHOLDERS' EQUITY |
|---|---|---|---|---|---|
| | SHARES | AMOUNT | CAPITAL | STAGE | (DEFICIT) |
| Balances at June 12, 1996 (date of incorporation) | -- | $ -- | $ -- | $ -- | $ -- |
| Sale of common stock without par value | 503 | 5 | 5 | -- | 10 |
| Change in par value of common stock | -- | (4) | 4 | -- | -- |
| Issuance of common stock and net liabilities assumed in acquisition | 1,716,132 | 1,716 | 3,224 | (18,094) | (13,154) |
| Issuance of common stock | 2,010,111 | 2,010 | 456 | (2,466) | -- |
| Net loss | -- | -- | -- | (259,476) | (259,476) |
| Balances at December 31, 1996 | 3,726,746 | 3,727 | 3,689 | (280,036) | (272,620) |
| Sale of common stock, net of offering costs of $9,976 | 1,004,554 | 1,004 | 1,789,975 | -- | 1,790,979 |
| Issuance of common stock in acquisition | 375,891 | 376 | 887,874 | -- | 888,250 |
| Minority interest deficiency at acquisition charged to the Company | -- | -- | -- | (45,003) | (45,003) |
| Net loss | -- | -- | -- | (1,979,400) | (1,979,400) |
| Balances at December 31, 1997 | 5,107,191 | 5,107 | 2,681,538 | (2,304,439) | 382,206 |
| Rescission of acquisition | (375,891) | (376) | (887,874) | 561,166 | (327,084) |
| Issuance of common stock at conversion of notes payable | 450,264 | 451 | 363,549 | -- | 364,000 |
| Expense related to stock warrants issued | -- | -- | 260,000 | -- | 260,000 |
| Net loss | -- | -- | -- | (1,204,380) | (1,204,380) |
| Balances at December 31, 1998 | 5,181,564 | 5,182 | 2,417,213 | (2,947,653) | (525,258) |
| Sale of common stock | 678,412 | 678 | 134,322 | -- | 135,000 |
| Expense related to stock warrants issued | -- | -- | 212,000 | -- | 212,000 |
| Net loss | -- | -- | -- | (1,055,485) | (1,055,485) |
| Balances at December 31, 1999 | 5,859,976 | 5,860 | 2,763,535 | (4,003,138) | (1,233,743) |
| Sale of preferred stock, net of offering costs of $76,500 | -- | -- | 3,123,468 | -- | 3,123,500 |
| Issuance of common stock at conversion of notes and interest payable | 412,487 | 412 | 492,085 | -- | 492,497 |
| Issuance of common stock at conversion of notes payable | 70,354 | 70 | 83,930 | -- | 84,000 |
| Issuance of common stock to settle obligations | 495,111 | 496 | 1,201,664 | -- | 1,202,160 |
| Issuance of common stock for acquisition | 6,999,990 | 7,000 | 9,325,769 | -- | 9,332,769 |
| Issuance of warrants for acquisition | -- | -- | 4,767,664 | -- | 4,767,664 |
| Stock issued for acquisition costs | 150,000 | 150 | 487,350 | -- | 487,500 |
| Expense related to stock warrants issued | -- | -- | 140,000 | -- | 140,000 |
| Dividends payable on preferred stock | -- | -- | (85,000) | -- | (85,000) |
| Cashless exercise of warrants | 599,066 | 599 | (599) | -- | -- |
| Net loss | -- | -- | -- | (3,701,084) | (3,701,084) |
| Balances at December 31, 2000 | 14,586,984 | 14,587 | 22,299,866 | (7,704,222) | 14,610,263 |
| Dividends payable on preferred stock | -- | -- | (256,000) | -- | (256,000) |
| Repurchase of warrants | -- | -- | (55,279) | -- | (55,279) |
| Sale of warrants | -- | -- | 47,741 | -- | 47,741 |
| Cashless exercise of warrants | 218,493 | 219 | (219) | -- | -- |
| 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 expenses | -- | -- | 167,138 | -- | 167,138 |
| Issuance of common stock to pay operating expenses | 106,293 | 106 | 387,165 | -- | 387,271 |
| Issuance of preferred stock to pay operating expenses | -- | -- | 136,499 | -- | 136,500 |
| Net loss | -- | -- | -- | (16,339,120) | (16,339,120) |
| Balances at December 31, 2001 | 15,005,191 | 15,005 | 23,389,818 | (24,043,342) | (638,486) |
| Dividends payable on preferred stock | -- | -- | (242,400) | -- | (242,400) |
| Repurchase of warrants | -- | -- | -- | -- | -- |
| Sale of warrants | 240,000 | 240 | 117,613 | -- | 117,853 |
| Cashless exercise of warrants | 100,201 | 100 | (100) | -- | -- |
| Exercise of warrants | 344,573 | 345 | 168,477 | -- | 168,822 |
| Sale of preferred stock | -- | -- | 998,392 | -- | 1,001,093 |
| Conversion of preferred stock into common stock | 1,800,000 | 1,800 | (1,770) | -- | -- |
| Preferred stock dividends forgiven | -- | -- | 335,440 | -- | 335,440 |
| Issuance of warrants to pay operating expenses | -- | -- | 163,109 | -- | 163,109 |
| Issuance of common stock to pay operating expenses | 6,292 | 6 | 12,263 | -- | 12,269 |
| Issuance of preferred stock to pay operating expenses | | | 6,000 | -- | 6,001 |
| Issuance of stock options to employees | -- | -- | 329,296 | -- | 329,296 |
| Net loss | -- | -- | -- | (2,105,727) | (2,105,727) |
| Balances at December 31, 2002 | 17,496,257 | $17,496 | $25,276,138 | $(26,149,069) | $ (852,730) |

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS.

BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY
(A Development Stage Enterprise)
Consolidated Statements of Cash Flows

| | YEAR ENDED DECEMBER 31, | | INCEPTION (JUNE 12, 1996) THROUGH DECEMBER 31, |
|---|---|---|---|
| | 2002 | 2001 | 2002 |
| Cash flows from operating activities: | | | |
| Net loss | $ (2,105,727) | $ (16,339,120) | $ (26,644,672) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation and amortization | 32,548 | 7,617,673 | 9,639,737 |
| Amortization of debt discount | 395,561 | 54,439 | 450,000 |
| Forgiveness of employee advance | 30,036 | -- | 30,036 |
| Impairment loss - write off of goodwill | -- | 5,702,130 | 5,702,130 |
| Expenses paid by warrants | 163,109 | 167,138 | 330,247 |
| Expenses paid by preferred stock | 6,001 | 136,500 | 142,501 |
| Expenses related to stock warrants issued | -- | -- | 612,000 |
| Expenses related to employee stock options issued | 329,296 | -- | 329,296 |
| Expenses paid by issuance of common stock | 12,269 | 387,271 | 610,749 |
| Equity in loss of investee | -- | -- | 178,936 |
| Write-off of license agreement | -- | -- | 152,866 |
| Cumulative effect of change in accounting principle | -- | -- | 25,821 |
| Changes in assets and liabilities, net of effect of acquisitions: | | | |
| (Increase) decrease in other assets | (9,094) | 12,386 | (152,351) |
| Increase in accounts payable and accrued liabilities | 44,062 | 550,482 | 119,405 |
| Increase in sponsored research payable and license obligation | -- | -- | 924,318 |
| Net cash used in operating activities | (1,101,939) | (1,711,101) | (7,548,981) |
| Cash flows from investing activities: | | | |
| Purchase of certificate of deposit | -- | -- | (1,016,330) |
| Maturity of certificate of deposit | -- | 1,016,330 | 1,016,330 |
| Purchases of property and equipment | (2,370) | (16,093) | (106,093) |
| Payment on obligation under license agreement | -- | -- | (106,250) |
| Cash acquired in acquisition of subsidiary | -- | -- | 64,233 |
| Issuance of note receivable - related party | -- | (35,000) | (35,000) |
| Payments on note receivable | 35,993 | -- | 405,993 |
| Advance to subsidiary | -- | -- | (90,475) |
| Cash transferred in rescission of acquisition | -- | -- | (19,475) |
| Cash received in rescission of acquisition | -- | -- | 230,000 |
| Net cash provided by investing activities | 33,623 | 965,237 | 342,933 |
| Cash flows from financing activities: | | | |
| Proceeds from sale of preferred stock | 1,001,093 | -- | 4,200,993 |
| Proceeds from sale of common stock | -- | -- | 1,935,965 |
| Proceeds from sale or excersice of warrants | 286,675 | 47,741 | 334,516 |
| Repurchase of warrants | -- | (55,279) | (55,279) |
| Payment of financing and offering costs | -- | -- | (98,976) |
| Payments of notes payable and long-term debt | (280,000) | -- | (351,961) |
| Proceeds from issuance of notes payable and detachable warrants | -- | 450,000 | 1,344,718 |
| Net cash provided by financing activities | 1,007,768 | 442,462 | 7,309,976 |
| Net increase (decrease) in cash and cash equivalents | (60,548) | (303,402) | 103,928 |
| Cash and cash equivalents at beginning of period | 164,476 | 467,878 | -- |
| Cash and cash equivalents at end of period | $ 103,928 | $ 164,476 | $ 103,928 |

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS.

BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY

(A Development Stage Enterprise)

Notes to Consolidated Financial Statements

December 31, 2002 and 2001

(1) DESCRIPTION OF THE COMPANY

Biokeys Pharmaceuticals, Inc., a Delaware corporation, (the Company), is a development stage enterprise, which conducts biomedical research and development focused on treatments for cancer and certain viral infections, including HIV. The Company currently does not market any product. Through its license agreements with University of Texas M.D. Anderson Cancer Center (M.D. Anderson), University of Southern California (USC) and National Institutes of Health (NIH), the Company has rights to drug candidates in varying early stages of development.

The Company's shares trade in the over-the-counter market under the symbol BKYS.

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

PRINCIPLES OF CONSOLIDATION

The consolidated financial statements of the Company include the accounts of Biokeys Pharmaceuticals, Inc. and its wholly owned subsidiary, Biokeys, Inc. All intercompany balances and transactions have been eliminated in consolidation.

USE OF ESTIMATES

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

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.

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

The value assigned to stock warrants granted to non-employees are accounted for in accordance with SFAS No. 123 and EITF 96-18, which require that such

costs be measured at the end of each reporting period to account for changes in the fair value of the Company's common stock until the options are vested. The Company values warrants using the Black-Scholes pricing model. Common stock is valued using the market price of common stock on the measurement date as defined in EITF 96-18. Series A and Series B preferred stock are valued at the liquidation value of $1,000 and $10 per share, respectively.

CASH EQUIVALENTS

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

FINANCIAL INSTRUMENTS

The carrying amounts of cash and cash equivalents, certificateS of deposit, advances to employees, note receivable, and accounts payable are a reasonable estimate of their fair values at the balance sheet dates due to the short-term nature of these instruments. The fair value of notes payable at the date of issuance and at December 31, 2002 was not determinable.

The Company maintains cash and cash equivalents with banks, which from time to time may exceed federally insured limits. The Company periodically assesses the financial condition of the institutions and believes that the risk of any loss is minimal.

GOODWILL

Goodwill (excess of purchase price over fair value of net assets acquired) was being amortized using the straight-line method over two years. The Company recorded amortization of goodwill of $7,602,836 during the year ended December 31, 2001. Through December 31, 2001, the Company had not been able to raise sufficient capital to ensure future funding of its research and development; consequently, the Company reviewed the carrying value of goodwill for impairment and reduced its carrying value to zero through a noncash charge of $5,702,130 at December 31, 2001.

PROPERTY AND EQUIPMENT

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

DEFERRED FINANCING COSTS

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

DEBT DISCOUNT

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

REVENUE RECOGNITION

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

government grants is a reimbursement for expenditures associated with the research. The Company submits bills to the grant agency and revenue is recognized at the time the expenses are reimbursed.

RESEARCH AND DEVELOPMENT COSTS

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

IMPAIRMENT OF LONG-LIVED ASSETS

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

INCOME TAXES

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

SUPPLEMENTARY CASH FLOW INFORMATION

Interest of $7,425 and $3,000 was paid during 2002 and 2001, respectively. No income taxes were paid during 2002 and 2001.

Noncash investing and financing transactions excluded from the statements of cash flows for the years ended December 31, 2002 and 2001 are as follows:

| | 2002 | 2001 |
|---|---|---|
| Issuance of common stock to pay preferred dividends | $ -- | $ 213,000 |
| Detachable warrants issued with notes payable | -- | 450,000 |
| Issuance of warrants, common stock, and preferred stock to pay operating expenses | 181,372 | 690,909 |
| Dividends payable | 242,400 | 256,000 |
| Cashless exercise of warrants | 100 | 219 |

| | | |
|---|---|---|
| Conversion of notes payable and accrued interest into common stock | 220,000 | -- |
| Dividends forgiven | 335,440 | -- |
| Trade payable converted to note payable | 83,948 | -- |

NEW ACCOUNTING PRONOUNCEMENTS

The FASB issued Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets (SFAS No. 142), which was effective for the Company as of January 1, 2002. SFAS No. 142 requires that goodwill and other intangible assets with indefinite lives no longer be amortized. SFAS No. 142 further requires that the fair value of goodwill and other intangible assets with indefinite lives be tested for impairment upon adoption of this statement, annually and upon the occurrence of certain events and be written down to fair value if considered impaired. SFAS No. 142 eliminates the annual amortization expense related to goodwill. The adoption of SFAS No. 142 did not have a material impact on the Company's financial statements because, as of December 31, 2002 and 2001, the Company had no goodwill or other intangible assets with indefinite lives.

The FASB issued Statement of Financial Accounting Standards No. 143, Accounting for Asset Retirement Obligations (SFAS No. 143), which addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. This statement applies to all entities that have legal obligations associated with the retirement of long-lived assets that result from the acquisition, construction, development, or normal use of the assets. SFAS No. 143 will be effective for the Company as of January 1, 2003. The Company does not expect the adoption of SFAS No. 143 to have a significant impact on its financial condition or results of operations.

The FASB issued Statement of Financial Accounting Standards No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets (SFAS No. 144), which addresses financial accounting and reporting for the impairment or disposal of long-lived assets. While SFAS No. 144 supersedes SFAS No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of, it retains many of the fundamental provisions of that statement. SFAS No. 144 also supersedes the accounting and reporting provisions of APB Opinion No. 30, Reporting the Results of Operations - Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual, and Infrequently Occurring Events and Transactions, for the disposal of a segment of a business. SFAS No. 144 was effective for the Company as of January 1, 2002. The adoption of SFAS No. 144 did not have a significant impact on its financial condition or results of operations.

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

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

(3) NOTE RECEIVABLE - RELATED PARTY

In August 2001, the Company loaned $35,000 to a company whose owner is also the co-founder of Biokeys, Inc., the Company's wholly-owned subsidiary. The note accrues interest at prime plus 1% (4.25% at December 31, 2002). The note receivable on the 2001 consolidated balance sheet included accrued interest. The note was repaid with interest in July 2002.

(4) PROPERTY AND EQUIPMENT

Property and equipment at December 31, 2002 and 2001 were as follows:

| | Useful lives | 2002 | 2001 |
|---|---|---|---|
| Office furniture and equipment | 5 years | $ 31,883 | $ 32,198 |
| Computer software and equipment | 3 years | 11,845 | 9,160 |
| | | 43,728 | 41,358 |
| Less accumulated depreciation and amortization | | (30,294) | (27,746) |
| | | $ 13,434 | $ 13,612 |

(5) NOTES PAYABLE

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

The entire proceeds of $450,000 were allocated to the warrants and debt discount. The fair value of the warrants, calculated using the Black-Scholes pricing model, is greater than the proceeds. The fair value of the notes payable was not determinable at the dates of issuance. The original debt discount of $450,000 is being amortized to the redemption value of the debt through the initial stated due date of the notes payable; $395,561 and $54,439 was amortized during 2002 and 2001, respectively.

In October 2002, the notes and warrants were amended and $220,000 in notes were converted to preferred stock in the Company. $60,000 in notes was repaid and the due date of the $170,000 in remaining notes were extended to April 1, 2003. The exercise price of the warrants was amended to $.50 per share. The outstanding balance on the notes was $170,000 and $54,439 at December 31, 2002 and 2001, respectively.

Subsequent to year end the Company converted a trade payable into a note payable in the amount of $83,948. The note carries interest at 10% per year and calls for eighteen monthly payments of $5,000 per month beginning July 1, 2003. The trade payable was reclassified as of December 31, 2002 with current and long term portions of $27,075 and $56,873, respectively.

The maturities of notes payable in years subsequent to December 31, 2002 are as follows:

| Year Ended December 31, | Amount |
|---|---|
| 2003 | $ 197,075 |
| 2004 | 56,873 |
| Total | $ 253,948 |

(6) INCOME TAXES

Significant components of income tax expense for the years ended December 31, 2002 and 2001 are as follows:

| | 2002 | 2001 |
|---|---|---|
| Deferred tax benefit | $ 601,110 | $ 799,623 |
| Increase in valuation allowance for deferred tax assets | (601,110) | (799,623) |
| Income tax expense | $ -- | $ -- |

The tax effects of temporary differences that give rise to deferred tax assets at December 31, 2002 and 2001 are as follows:

| | 2002 | 2001 |
|---|---|---|
| Net operating loss carryforward | $ 4,051,425 | 3,436,311 |
| Organization costs and license agreement, due to differences in amortization | 30,534 | 44,538 |
| Total deferred tax assets | 4,081,959 | 3,480,849 |
| Less valuation allowance | (4,081,959) | (3,480,849) |
| Net deferred tax assets | $ -- | -- |

At December 31, 2002, the Company had an unused net operating loss carryforwards of approximately $11,900,000 for tax reporting purposes, which expire from 2112 through 2113 and 2119 through 2122.

(7) EQUITY TRANSACTIONS

In a private placement offering to European investors pursuant to Regulation S of the Securities and Exchange Commission, the Company sold a total of 3,200 shares of its Series A 8% Convertible Preferred Stock for gross proceeds of $3,200,000 between August and September 2000. In addition to the shares of Series A Convertible Preferred Stock, which are convertible into common stock at $4.00 per share, the offering included warrants to purchase a total of 400,000 shares of common stock at $5.00 per share. The preferred stock has a liquidation preference of $1,000 per share plus accrued and unpaid dividends, carries cumulative dividends at 8% per annum payable semi-annually, and provides for future adjustments in conversion price if specified dilutive events take place. The preferred stock is redeemable at the option of the Company at any time the closing price of common stock remains at a level of at least $8 per share for 20 consecutive days if the Company is listed on the American Stock Exchange or NASDAQ at such time, with the redemption price being equal to the liquidation preference. In addition, at any time after July 1, 2003, the Company may call all of any portion of the outstanding preferred stock for redemption on at least 30 days' notice, at a redemption price equal to 105% of the liquidation preference plus all accrued and unpaid dividends. The Company incurred consulting fees totaling $76,500, paid to a stockholder who acted as a finder and agent in this transaction.

In February 2001, the Company granted 100,000 shares of common stock to a consulting firm for financial consulting services to be provided in 2001. The Company recognized the value of these shares, $375,000, as a noncash charge to expense during 2001.

In May 2001, the Company repurchased warrants to purchase 50,254 shares of common stock for $55,279 and sold the same warrants in June 2001 for $47,741. The warrants have an exercise price of $0.49 per share.

In August 2001, two warrant holders exercised warrants through a cashless exercise. Warrants to purchase a total of 271,758 shares of common stock were exchanged for a total of 218,493 shares of common stock.

In October 2001, the Company issued 93,421 shares of common stock valued at $213,000 to pay dividends on preferred stock through June 30, 2001.

In December 2001, the Company entered into a consulting agreement with a third party for financial consulting services. The services are being paid through the issuance of 273 shares of Series A Preferred Stock with a fair value of $273,000, 12,585 shares of common stock with a fair value of $24,541, and five-year warrants to purchase 34,125 shares of common stock at an exercise price of $5.00 per share with a fair value of $62,280. The compensation vests 50% in December 2001 and 50% in December 2002. The Company recognized the value of 50% of these equity instruments in 2002 and 2001 and recorded a noncash charge to expense of $154,769 and $315,909, respectively. The warrants were valued using the Black-Scholes pricing model. Common stock was valued using the market price of common stock as defined in EITF 96-18. Preferred stock was valued at the liquidation value of $1,000 per share.

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

In April 2002, warrants to purchase a total of 240,000 shares of common stock at $.49 per share were exercised.

In April 2002, the Company entered into a preliminary agreement (the "Preliminary Agreement") with a corporate investor under which the investor agreed to subscribe for 200,000 shares of a new class of Series B Convertible Preferred Stock to be authorized and issued by the Company. The Preliminary Agreement contemplated an initial subscription payment of $300,000, which was received by the Company in April 2002, with an option to purchase additional shares of Series B Preferred Stock. The Company also granted the investor a right of first refusal to serve as a provider of an oral delivery system for future company products, which expired in June 2002.

In December 2002, the Company issued 200,000 shares of Series B Convertible Preferred Stock to the corporate investor pursuant to the terms of the Preliminary Agreement.

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

In July 2002, warrants to purchase a total of 115,000 shares of common stock at $0.49 per share were exercised for $56,350.

In October and December 2002, the Company issued an aggregate of 70,109.3 shares of Series C Convertible Preferred Stock with a par value of $0.01 per share. The Series C preferred stock is convertible into common stock at $0.05 per share and has a liquidation preference of $10 per share plus accrued and unpaid dividends. In conjunction with the issuance of 45,000 shares of the Series C preferred stock, $220,000 in Bridge Financing loans were forgiven and related warrants to purchase common stock issued with the Bridge Loans were amended to modify the purchase price of the common stock to $0.50 per share.

On November 21, 2002 the Company exchanged 3,000 Series A preferred stock for 1,800,000 shares of common stock. In conjunction with this transaction the Company purchased 400,000 warrants from the preferred stockholder for

$100. In conjunction with the exchange, accumulated preferred dividends in the amount of $335,440, which had been accrued through the date of the exchange, were forgiven by the shareholder.

Nonemployee stock-based compensation is valued, as of the grant date, using the Black-Scholes pricing model with the following assumptions for grants in 2002 and 2001: no dividend yield for either year; expected volatility of 125% to 170%; risk-free interest rates 4.25% to 6.8%; and expected lives of three and seven years, respectively.

At December 31, 2002, there were outstanding warrants to purchase a total of 2,537,804 shares of common stock as follows:

| WARRANTS | EXERCISE PRICE | EXPIRATION DATE |
|---|---|---|
| 100,506 | $ 0.49 | May 2003 |
| 50,000 | 4.00 | August 2003 |
| 25,000 | 5.00 | August 2003 |
| 689,148 | 0.49 | December 2003 |
| 620,622 | 0.49 | September 2005 |
| 450,000 | 0.50 | October 2005 |
| 100,000 | 3.00 | April 2006 |
| 502,528 | 0.49 | June 2006 |

(8) STOCK COMPENSATION PLANS

In October 2002 the Company granted to employees three non-statutory stock options to purchase an aggregate of 1,525,000 and one non-statutory stock option to purchase 165,000 shares of common stock at $.20 and $.50 per share, respectively. The fair value of the options was $329,296, based on the Black-Scholes model using the assumptions given in Note 7. None of the foregoing options were issued pursuant to a stock option plan. The options expire on December 30, 2008 and additional information regarding the options follows:

| | 2002 | |
|---|---|---|
| | SHARES (000) | WEIGHTED-AVERAGE EXERCISE PRICE |
| Outstanding at beginning of year | -- | -- |
| Granted | 1,690 | $0.23 |
| Exercised | -- | -- |
| Forfeited | -- | -- |
| Outstanding at end of year | 1,690 | $0.23 |
| Options exercisable at year-end | 1,177 | |
| Weighted-average fair value of options granted during the year | $0.19 | |

| | OPTIONS OUTSTANDING | | | OPTIONS EXERCISABLE | |
|---|---|---|---|---|---|
| RANGE OF EXERCISE PRICE | NUMBER OUTSTANDING AT 12/31/02 | WEIGHTED-AVERAGE REMAINING CONTRACTUAL LIFE | WEIGHTED-AVERAGE EXERCISE PRICE | NUMBER EXERCISABLE AT 12/31/02 | WEIGHTED-AVERAGE EXERCISE PRICE |
| $0.20 to $0.50 | 1,690,000 | 6.23 years | $0.23 | 1,177,000 | $0.24 |

(9) NET LOSS PER COMMON SHARE

The computation of basic and diluted net loss per share for the years ended December 31, 2002 and 2001 is as follows:

| | 2002 | 2001 |
|---|---|---|
| Numerator: | | |
| Net loss | $ (2,105,727) | $ (16,335,346) |
| Preferred stock dividends | (242,400) | (256,000) |
| Numerator for basic and diluted loss per share | $ (2,348,127) | $ (16,591,346) |
| Denominator for basic and diluted loss per share - weighted average common shares outstanding | 15,681,743 | 14,805,150 |
| Loss per common share - basic and diluted | $ (0.15) | $ (1.12) |

Net loss per common share is calculated according to Statement of Financial Accounting No. 128, Earnings per Share, using the weighted average number of shares of common stock outstanding during the period. At December 31, 2002 and 2001, 2,537,803 and 3,826,409 potentially dilutive shares, respectively, were not included in the computation of net loss per common share - diluted, as their effect would have been antidilutive due to the Company's net loss incurred in 2002 and 2001.

(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 is obligated to pay M.D. Anderson for all out-of-pocket expenses incurred in filing, prosecuting, enforcing, and maintaining the licensed patent rights and all future patent-related expenses paid by M.D. Anderson as long as the M.D. Anderson License Agreement remains in effect.

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

Under the amended M.D. Anderson License Agreement, the Company has the right to a royalty-bearing, exclusive license to manufacture, have

manufactured, and use and/or sell licensed products. M.D. Anderson's retained interest consists of royalties on net sales of licensed products and a share of consideration received by the Company from all sublicenses and assignments. No royalties were paid under this agreement during the years ended December 31, 2002 and 2001. The M.D. Anderson License Agreement continues in effect until all patent rights have expired.

USC

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

NIH AGREEMENT

During December 2002, the Company entered into a worldwide exclusive patent license agreement with NIH concerning composition of matter for its drug, BlockAide/CR. Under the terms of the agreement, the Company agrees to pay minimum royalty payments during the first year of the license and minimum annual royalties thereafter or the higher amount based upon a percentage of net sales. In addition, there are benchmark royalties based upon: initiation of Phase I trials, initiation of Phase II trials, initiation of Phase III trials, and upon first approval of a Product License Application for an HIV therapeutic or vaccine in the US and for first approval in Europe.

(11) SPONSORED RESEARCH

Since September 1996, the Company has entered into a total of four Sponsored Research Agreements (SRAs) with M.D. Anderson. Under the SRAs, M.D. Anderson agreed to conduct specific research activities for the Company, at the expense of the Company, into various aspects of treating HIV infections using technologies made available under the M.D. Anderson License Agreement. All amounts due to M.D. Anderson under the first three SRAs were paid or settled as of December 31, 2000, and such SRAs have been terminated. The most recent SRA with M.D. Anderson, entered into September 7, 2000, provides for studies to test the ability of a mixture of synthetic HIV derived peptides to elicit an antibody-negative cell mediated immune response. The testing will seek to determine if this immune response can protect against new infection and if the preparation can be administered after HIV infection as a therapeutic. This SRA requires a total of $814,490 payable in two equal installments for research to be conducted through 2001 and into 2002. The first installment was paid by the Company in 2000 and the second in 2001.

(12) OPERATIONAL STATUS

The accompanying consolidated financial statements have been prepared on a going-concern basis which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of

business. The Company has incurred losses since inception and had net losses of $2,105,727 and $16,339,120 for the years ended December 31, 2002 and 2001, respectively. In addition the Company had a working capital deficiency and an accumulated deficit at December 31, 2002.

Through December 31, 2002 the Company has been principally engaged in licensing and research and development efforts. The Company has no current revenues, is not marketing any products, and projects a loss from operations for 2003. The Company will require additional capital, which it intends to obtain through equity and debt offerings and/or strategic partnership in order to continue to operate its business. The Company's ability to meet its obligations as they become due and to continue as a going concern must be considered in light of the expenses, difficulties and delays frequently encountered in operating a new business, particularly since the Company will focus on research, development and unproven technology which may require a lengthy period of time and substantial expenditures to complete. Even if the Company is able to successfully develop new products or technologies, there can be no assurance that the Company will generate sufficient revenues from the sale or licensing of such products and technologies to be profitable. Management believes that the Company's ability to meet its obligations as they become due and to continue as a going concern through at least December 31, 2003 is dependent upon obtaining additional financing. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

(13) COMMITMENTS AND CONTINGENCIES

LITIGATION

In the normal course of business, the Company may become subject to lawsuits and other claims and proceedings. Such matters are subject to uncertainty and outcomes are not predictable with assurance. Management is not aware of any pending or threatened lawsuit or proceeding that would have a material adverse effect on the Company's financial position, liquidity or results of operations.

EMPLOYMENT CONTRACTS

Effective January 1, 2002 the Company entered into a letter agreement with its Chief Financial Officer to retain his services for a period of one year at a monthly cost of $5,000. The letter agreement will automatically renew for additional one-year terms unless either the Company or the Chief Financial Officer gives notice to the other party at least 60 days prior to the end of the then current term of such party's termination of the letter agreement.

OPERATING LEASES

The Company is obligated under operating leases for office space and equipment. A lease for office space expired in November 2000 and was continued on a month to month basis through October 31, 2002. Rent expense was $57,996 and $51,609 during the years ended December 31, 2002 and 2001, respectively.

In February 2001, the Company leased office facilities in San Diego, California. The lease requires a monthly payment of $2,900 and expires in January 2004.

The following table summarizes the future rental commitments under all operating leases for years subsequent to December 31, 2002:

| YEAR ENDED DECEMBER 31, | AMOUNT |
|---|---|
| 2003 | $ 38,493 |
| 2004 | 2,951 |
| Total | 41,444 |

(14) SUBSEQUENT EVENTS

In January 2003 the Company initiated a private placement offering in an effort to raise $1,200,000 in additional capital. Through March 18, 2003, the Company has raised $635,949 in connection with this offering.

In March 2003 the Company converted 70,109.3 shares of Series C convertible preferred stock into 14,021,860 shares of common stock.

In March 2003 the Company granted options under a non-statutory stock option plan to purchase 2,412,500 shares of the Company's stock at .50 price 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. The options expire on December 30, 2008 and vest on varying dates from March 2003 to April 2005.

EXHIBIT 10.8

20, January 2003

Mr. Nicholas J. Virca
Biokeys Pharmaceuticals, Inc.
9948 Hibert Street, Suite 100
San Diego, CA

Dear Nick:

This contract is between Biokeys Pharmaceuticals, Inc. (Biokeys) and Steven M. Plumb, P.C. (Firm). This is an employee leasing contract. The Firm will provide a Chief Financial Officer (CFO) for Biokeys. The Firm has identified the following employee to provide this service for Biokeys:

Steven M. Plumb, CPA

The Firm will be responsible for all benefits, taxes and other costs related to Mr. Plumb's employment. The Firm will provide 30 hours per month of Mr. Plumb's time for a monthly fee of $5,000. If the amount of time Mr. Plumb spends on Biokeys activities exceeds 30 hours per month, the excess time will be billed at $165 per hour. Our standard billing rate is $175 per hour. A no interest bearing retainer will be due upon execution of this contract.

Biokeys is required to maintain Directors and Officers insurance (Insurance) during the term of this contract. The CFO will be under the control of the management of Biokeys. The CFO will sign SEC reports filed by Biokeys. However, if Insurance is not in force during any portion of this contract, CFO will not sign any SEC documents during that period of time. CFO retains the right to modify the SEC disclosure requirements mandated by the Sarbanes-Oxley Act.

The Firm has not been engaged to provide, nor will it provide, any attestation services, such as auditing, review or compilation services under this contract.

The effective date of this contract is retroactive to January 1, 2003 and is for a period of one year. If Biokeys cancels the contract or fails to perform for any reason, then it shall pay the Firm damages equal to the balance that it would have paid had the contract been fully performed. Unless canceled by either party with written notice sixty (60) days prior to the end of the contract, the contract will automatically renew for another twelve (12) month period with a 5% fee increase. The contract will roll over automatically until canceled in writing by either party within sixty (60) days notice prior to the end of the contract. The retainer will be applied to the last months billing. Should the contract be renewed, the retainer shall be rolled forward and will apply to the last billing of the renewed contract. If Steven M. Plumb becomes disabled or unable to perform due to circumstances beyond his control, then the Firm is released from this contract and the Firm has no liability under this agreement. Biokeys may cancel this contract with 60 days written notice.

Payment will be due on the 15th of each month via wire transfer. Payment for the month of January 2003 is due immediately. Funds will be wired to the account of Steven M. Plumb, P.C. at Compass Bank, Routing Number 113040547, Account Number 71392791. Interest of 1.5% per month will be charged on all outstanding balances. The payment due upon execution of this contract is $10,000, which consists of $5,000 for January and the $5,000 retainer. If Biokeys becomes 60 days or more in arrears on payments to the Firm, the Firm has the right to stop performing services under this contract.

All outstanding invoices, for services previously billed by the Firm, will be paid by February 15, 2003. Any outstanding invoices that are still outstanding after this date will be subject to a finance charge of 1.5% per month. It is the intent of both parties to resolve the outstanding balance before the next SEC filing deadline, March 31, 2003. If the SEC deadline is extended, then this data shall also be extended.

Biokeys will reimburse Firm for reasonable expenses such as travel, mileage, photocopies, long distance, postage and supplies. Biokeys will pay for a subscription to SEC practice procedures. The cost of this subscription is estimated to be $900 per year.

This contract does not cover any services rendered prior to January 1, 2003. Fees for these services will be billed separately and are due upon receipt. Late payment of these fees will result in an interest charge of 1.5% per month on the unpaid balance.

All agreements between the parties are contained in this document. There are no oral agreements between the parties.

This agreement is governed exclusively by Texas substantive law without reference to Texas choice of law rules. The parties agree that all disputes arising out of or related to this agreement must be litigated in the state district courts of Harris County, Texas, which the parties agree shall be the exclusive forum for any and all litigation between them. Biokeys expressly agrees that it is subject to personal jurisdiction in Texas for any and all disputes between the parties. Biokeys further agrees that subject matter jurisdiction for any and all disputes between the parties lies exclusively in the Texas state courts.

Please indicate your acceptance of the above understanding by signing below. A copy is enclosed for your records. If your needs change during the year, the nature of our services can be adjusted appropriately. Likewise, if you have special projects with which we can assist, please let us know.

Sincerely,
Steven M. Plumb, P.C.

Steven Plumb, CPA

The undersigned represents that he is authorized by Biokeys Pharmaceuticals, Inc. to sign on behalf of Biokeys Pharmaceuticals, Inc. and hereby accepts this contract.

Accepted by: _____ Date _____

Nicholas J. Virca
President

March 5, 2003

Joan M. Robbins, Ph.D.
10265 Pinetree Drive
San Diego, CA 92131

Dear Joan:

Biokeys Pharmaceuticals, Inc. is pleased to offer you the position of Chief Technical Officer, reporting directly to me. Responsibilities will encompass all aspects of moving our product portfolio from the research lab through clinical development and regulatory authorities. This is a key position in the Company, intended to take full advantage of your experience base, while offering you an opportunity to grow in responsibility and be rewarded through a lucrative compensation package as follows:

COMPENSATION PACKAGE

1. Annual Salary of $170,000, paid every two weeks (You will be entitled to a compensation review at the one year anniversary of employment.)
2. 300,000 Incentive Stock Options struck at 50 cents per share that expire on 12/30/08. 100,000 will vest upon acceptance of this offer, 100,000 will vest at the one year anniversary of your employment and 100,000 will vest at the two year anniversary of your employment.
3. A Bonus Schedule of 5% for all government grants received by the Company to be paid in incentive stock options. (For example, if the Company receives a grant for $1,000,000, then we will reserve 50,000 additional incentive options priced at the close of business on the day that the Company is notified of the grant. When the grant is received, you will receive the options.)
4. A Bonus Schedule of 5% paid in incentive stock options for all capital received by the Company that is a direct result of your introduction, which does not require that you consummate the investment, but rather you only need refer the new party. (For example, if the Company receives an investment for $2,000,000 from an Investor that you introduce or refer to the Company, then we will issue to you 100,000 additional incentive stock options priced at the close of business on the day that the investment is received.)
5. You will receive four weeks paid vacation per year, which will begin to accrue at one week per quarter, plus paid holidays.
6. You will be offered a paid healthcare benefits package if you do not have coverage.
7. The Company will pre-pay or reimburse you for all pre-approved job related expenses for performance of your duties.

We believe you can contribute significantly to the success of our Company, grow with us, and be rewarded appropriately for your accomplishments. Please let us know if you want to join our team.

Sincerely,

Nicholas J. Virca
Chief Executive Officer

EXHIBIT 21.1

LIST OF SUBSIDIARIES

Biokeys, Inc., a corporation incorporated under the laws of the state of Delaware, is a wholly-owned subsidiary of Biokeys Pharmaceuticals, Inc. Biokeys, Inc. does business only under the name Biokeys, Inc.

EXHIBIT 99.1

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

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

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

/s/ Nicholas J. Virca
- ----------
Nicholas J. Virca
Chief Executive Officer
April 15, 2003

/s/ Steven M. Plumb
- ----------
Steven M. Plumb, CPA
Chief Financial Officer
April 15, 2003

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