

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

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FORM 10-K/SB

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

FOR THE FISCAL YEAR ENDING DECEMBER 31, 2001

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

FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_

COMMISSION FILE NO. 0 - 33219

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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 ST., SUITE 100  
SAN DIEGO, CALIFORNIA

92131

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number: (858) 271-9671  
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SECURITIES TO BE REGISTERED PURSUANT TO SECTION 12(B) OF THE ACT: None

SECURITIES TO BE REGISTERED PURSUANT TO SECTION 12(G) OF THE ACT:  
Common Stock, par value \$0.001  
(Title of Class)

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

Check if there is no disclosure of delinquent filers in response to ITEM 405 OF REGULATION S-B is not contained in this form, and no disclosure will be contained, to the best of registrant's knowledge, in definite proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. [ ]

The aggregate market value of the voting stock held by non-affiliates of the Registrant based upon the closing price of the Common Stock listed in the "Pink Sheets" on December 31, 2001, is \$21,118,720.

The total number of shares outstanding of each of the Registrants common stock, as of December 31, 2001 is 15,005,191.

DOCUMENTS INCORPORATED BY REFERENCE

Certain Exhibits filed with the Registrant's prior registration statement under the Securities Exchange Act of 1933 are incorporated herein by reference into

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## FORWARD LOOKING STATEMENTS AND RISK FACTORS

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created by those sections. These forward-looking statements include but are not limited to statements about our strategy, our research and development efforts, our potential products, our license rights and the sufficiency and anticipated sources of our cash and other resources.

These forward-looking statements are generally identified by words such as "expect," "anticipate," "intend," "believe," "hope," "assume," "estimate," "plan," "will" and other similar words and expressions. Discussions containing these forward-looking statements may be found in "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as at other locations in this report. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those contemplated in the forward-looking statements. We undertake no obligation to publicly release any revisions to the forward-looking statements or to reflect events or circumstances after the date of this document. The risks set forth under "Risk Factors" in Item 6, among other things, should be considered in evaluating our prospects and future financial performance.

## ITEM 1. DESCRIPTION OF BUSINESS

## COMPANY BACKGROUND

Biokeys Pharmaceuticals, Inc. (formerly known as BioQuest, Inc.) and its wholly owned subsidiary, Biokeys, Inc. (which we refer to collectively as the "Company" or "we") are a biomedical research and development business focused on treatments for cancer and viral infections. Our business is in the development stage, meaning that we have not generated any significant revenues and we have not yet marketed any product. Through a merger transaction completed on October 10, 2000, Biokeys, Inc. became a wholly-owned subsidiary of BioQuest, Inc., and BioQuest, Inc. changed its name to Biokeys Pharmaceuticals, Inc.

Through our license agreements with the University of Texas M.D. Anderson Cancer Center (referred to as "M.D. Anderson") and the University of Southern California (referred to as "USC"), we have 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 HIV/AIDS, HPV (human papillomavirus) and cancer.

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COMPANY TECHNOLOGIES UNDER DEVELOPMENT  
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We have six potential drug products in development:

PRODUCT LINE
FOCUS
APPLICATION ---
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CoFactor(TM)
Anticancer 5-FU biomodulator Selone(TM) Anticancer alkylating agent for drug- resistant cancers
EradicAide(TM)
Antiviral HIV/AIDS prophylactic and therapeutic agent
BlockAide/CR(TM)
Antiviral HIV/AIDS therapeutic agent
BlockAide/VP(TM)
Antiviral HIV/AIDS therapeutic agent
Thiovir(TM)
Antiviral broad- spectrum agent for human papillomaviruses and other viral infections

COFACTOR

CoFactor (5,10-methylenetetrahydrofolate) is a patented new drug which affects the performance of 5-FU (5-Fluorouracil) and other fluoropyrimidines commonly used in cancer chemotherapy. It was developed by researchers at USC in Los Angeles and at the Sahlgrenska University Hospital, University of Goteborg, Sweden, who discovered its ability to greatly enhance 5-FU's inhibition of a key enzyme, thymidylate synthase (TS), necessary for cancer cell growth. Since 5-FU is probably the most extensively used cancer chemotherapy drug in the world, this enhanced performance makes CoFactor a promising new combination therapy drug for the treatment of cancer.

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. Results of Drs. Gustavsson's and Spear's work with humans were published in THE CANCER JOURNAL, vol. 10, no. 5 September-October 1997.

Dr. Gustavsson and Dr. Spears, who are the co-inventors of CoFactor technology, are currently medical/clinical consultants to the Company. Dr. Bengt Gustavsson has an annual consulting contract. In 2001, he earned \$70,000; in

2002 he will receive \$100,000. Dr. Colin Paul Spears is compensated for his services as needed, at a rate of approximately \$1,000 per day, but also provides basic consultation from time to time without per diem remuneration. Both Dr. Gustavsson and Dr. Spears are reimbursed for some of their expenses, including Company-related travel.

In the human clinical trials at Sahlgrenska University Hospital, CoFactor was administered to 62 cancer patients receiving 5-FU therapy. Partial responses in the range of 21%-55% were noted in colorectal, pancreas, stomach, gallbladder and breast cancer patients. The average duration of remissions was 9-15 months, which is at least a two-fold increase over 5-FU/leucovorin therapy. Toxicity was milder than expected for 5-FU or 5-FU/leucovorin, and no toxicities of CoFactor have been observed. We consider that these results represent a significant improvement over 5-FU/leucovorin standard traditional therapy for cancer patients.

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Several publications appeared during late 1997 and early 1998 in leading medical journals, including CANCER INVESTIGATIONS, CANCER TREATMENT, ANTICANCER RESEARCH, and THE CANCER JOURNAL, concerning the use of CoFactor. Such publications discussed:

- o 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;
- o significant response to 5-FU/CoFactor in animal colon cancer studies;
- o human pharmacokinetic (drug action/metabolism) data documenting high blood levels of CoFactor for several hours after administration; and
- o the achievement of stabilizing the CoFactor compound for routine administration to patients.

Since the time when the clinical trials were conducted and reported, technology for analyzing human enzyme levels has progressed. As a result, in January 2001, the Company undertook a study on tissue samples from the 62 patients who were treated in the earlier trials, by retrieving paraffin-embedded tissues of those patients from the Sahlgrenska University Hospital's medical archives. Analyses were based upon a RT-PCR (Reverse Transcriptase - Polymerase Chain Reaction), a technique first described in Goteborg, Sweden in 1977 for detection of TS gene expression, but now dramatically improved by technology developed at USC. This advancement permitted retrospective analyses from paraffin-fixed tissues, using micro-dissection technology, which enabled the Company to better understand why patients responded to 5-FU/CoFactor therapy.

An IND (Investigational New Drug) application has been submitted to the U.S. Food and Drug Administration, or FDA, and approved in December 2001 for Phase II trials for front-line metastatic colorectal cancer therapy, in order to test CoFactor in conjunction with 5-FU. We also intend to file an IND with the Swedish FDA in 2002. For further discussion of intended clinical trials for CoFactor, see Management's Discussion and Analysis of Financial Condition and Results of Operations.

#### SELONE

Selone is the Company's 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,

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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 effective, at even very low concentrations, against human ovarian, breast, lung and head/neck cancers, and against leukemias and lymphomas. Its potency is 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 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.

Now that chemical, kinetic and tissue toxicity relationships have been established for Selone, we are planning further IN VIVO testing and pre-clinical optimization and toxicity studies to determine recommended dose/schedules for later Phase I-II human clinical trials.

#### ERADICAIDE

We have licensed the exclusive right to commercialize a patented immunotherapeutic and vaccine strategy, developed by M.D. Anderson, that 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 technology is that it is designed to not elicit an antibody response.

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. Cruising 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 or Simian (monkey)/Human Immunodeficiency Virus, a chimeric virus, which contains the inner core proteins and genetic material from SHIV and the outer envelope proteins and viral binding proteins of HIV, has proven to be an invaluable research tool in the quest for effective approaches to HIV control. Monkeys to whom SHIV was administered

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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 research collaborators, Dr. Bill Narayan in Kansas and Dr. Norm Letvin in Massachusetts. (M.D. Anderson's SHIV research work was supported in part by the Company.)

In the first trial, five test animals were vaccinated with the antibody-negative immunity inducing agent, EradicAide, consisting of a peptide cocktail with complete Freund's adjuvant (primary immunization) followed by two booster immunizations with incomplete Freund's adjuvant and peptide cocktail. Animals were then challenged with live SHIV. Compared with control animals, viral levels in plasma in treated animals were reduced more than 1,000-fold three weeks after challenge with virus. 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.

Four of the animals from the first trial have been followed for over three years. At 180 weeks, the treated monkeys have undetectable levels of virus.

A subsequent trial of EradicAide was conducted during 2001, consisting of a larger number of monkeys (18 total) divided into a control group, a group treated with EradicAide peptides delivered with incomplete Freund's adjuvant (IV) and a group treated with EradicAid peptides delivered with autologous dendrite cells. The animals were challenged with SHIV virus. Both groups of treated animals began showing a drop in viral load at four weeks post challenge and were maintaining viral control at 29 weeks, verifying previous data in the five-monkey trial.

These data demonstrate scientific proof of principle for the cell-mediated immunity strategy. 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, upon completion of toxicology and pharmacokinetic files and a manufacturing file as part of its IND submission.

#### BLOCKAIDE/CR

Scientists at M.D. Anderson have developed another approach to combating HIV, based on the BlockAide/CR compound, 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 preliminary animal tests conducted at M.D. Anderson and sponsored by the Company, BlockAide/CR was able to significantly depress the level of HIV infection indicated in blood samples.

Studies from several laboratories, including M.D. Anderson and the United States National Institutes of Health (NIH), indicate that at least two cell surface receptors are involved in the mechanism for HIV binding and immune cell penetration. One is the CD-4 receptor,

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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 gp120 envelope glycoprotein in the presence of CD4.

M.D. Anderson researchers believe that the 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 key. When HIV, using the V3 Loop as a key, tries to enter a human immune cell via the lipid raft (the keyhole), the virus is unsuccessful because BlockAide/CR already blocks the entrance keyhole.

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 inevitably 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 syncytia. 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 its initial

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 SHIV virus. Viral load reached undetectable levels at approximately two weeks of treatment.

The Company believes that positive results in current 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. Assuming adequate funding, the Company intends to proceed with preparations from

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human testing under the FDA's Fast Track Program, under a physician sponsored IND, or Corporate IND, utilizing cGMP materials, which have already been prepared for human use.

#### 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 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. If proven safe and effective in pre-clinical 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.

#### THIOVIR

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

Thiovir and Thiovir-analogues under development are part of a new class of compounds known as thiophosphonates (sulfur/phosphorous compounds), which have demonstrated powerful antiviral properties. Thiovir was designed to be a replacement for the broad-spectrum antiviral drug, foscarnet. Foscarnet is administered by intravenous catheter (IV drip) and is FDA-approved for treatment of HIV, herpes and CMV (cytomegalovirus) infections. Although foscarnet is a highly effective, broad-spectrum antiviral, it has limitations from a commercial perspective because it must be administered by IV catheter with medical supervision. Also, foscarnet is a small molecule whose parent chemical structure restricts modifications that could lead to the future development of an oral form of the drug.

In contrast to foscarnet, the creation of thiophosphonates (such as Thiovir) makes possible an entirely new class of compounds, of which there can

These derivatives can lead to additional improvements in antiviral effectiveness, oral drug forms and reduced toxicity. The thiophosphonate is delivered as an active prodrug (an initial form of a drug which converts in the body through normal metabolic processes), and may also metabolize to additional active compounds. In the case of Thiovir, a dual action antiviral effect is achieved through delivery of an active prodrug and an active metabolite, which is foscarnet.

An IN VITRO test of a group of Thiovir analogues was conducted at the National Cancer Institute. Results reported to USC in early 2000 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, preliminary studies conducted by the Company on Thiovir efficacy against papillomaviruses (a viral infection directly related to genital warts and cervical cancer) between 1999 and 2001, with collaborators at the Gittlen Cancer Research Institute and Hershey Medical Center, Penn State University, showed that Thiovir had potential as an antiviral treatment for papillomavirus infection. Current research and development efforts for Thiovir are supported by the Company and by U.S. government funding. If positive research results continue, the Company would intend to file an IND for a form of Thiovir for testing in humans infected with genital warts caused by HPV.

#### MEDICAL MARKETS

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#### 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 U.S. of approximately \$9 billion, 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 U.S. 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) (capecitabine).

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 a need 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 aggressive 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 combination 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

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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.

The World Health Organization and the U.S. Centers for Disease Control report that there are 1.5 million HIV positive individuals in the U.S. and Europe, where the vast majority of anti- HIV drugs are used. However, according to a November 1999 report by the United Nations Program on HIV/AIDS, more than 33 million adults and children in the world are living with HIV and 16,000 new infections are occurring each day. As current transmission rates hold steady, the number of people with HIV/AIDS will increase to 40 million in 2001. HIV infections are not being treated in the third world, to even the smallest extent, because of the cost and the ability to administer complex therapy is difficult outside a medical sitting. 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.

Preliminary studies sponsored by the Company on Thiovir efficacy against HPV, with collaborators at the Gittlen Cancer Research Institute and Hershey Medical Center, Penn State University, showed that Thiovir had potential as an antiviral treatment for papillomavirus infection. These studies along with animal toxicology data, could provide the basis for an IND to test a topical form of Thiovir for genital warts in humans.

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#### MARKETING AND SALES

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We do not presently have a marketing and sales staff, although the experience and background of Nicholas Jon Virca, President of Biokeys, Inc., includes pharmaceutical marketing and sales functions. As one or more Company products approach commercialization, we intend to seek arrangements with third parties, such as pharmaceutical companies, for the marketing and distribution of our products. At that point, we would also 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 with a commercialization or marketing partner.

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 6A below.

#### MANUFACTURING

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We do not have our own manufacturing facilities, and do not intend to establish them. Instead, the Company has entered into a clinical supply agreement with Eprova AG, of Schaffhausen, Switzerland, and Clinalfa AG of Laufelfingen, Switzerland, under which Eprova and Clinalfa will produce CoFactor in limited quantities for clinical testing requirements. At present, this contract is terminable at will, and, assuming eventual approval of CoFactor for sale in the U.S. and other parts of the world, we intend to negotiate a long-term manufacturing contract for the commercial supply of CoFactor with Eprova. Eprova is a leading manufacturer of compounds with chemical structures comparable to CoFactor, and we therefore believe it has the aptitude and capability for large-scale production of CoFactor. In addition, the Company anticipates developing additional manufacturing sources for CoFactor so that there will not be a single source. There are a number of contract manufacturers available for such work in the U.S. and abroad. The Company has also begun to explore manufacturing capabilities with several different contract manufacturers for other potential products now under development, including initial clinical trial supply of BlockAide/CR by multiple peptide systems, located in San Diego, California.

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

#### LICENSING AND RESEARCH AGREEMENTS

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## 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

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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 prevention. 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.

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. In accordance with the Amendment, we issued 414,829 shares of our Common Stock to M.D. Anderson, valued at \$1,000,000 based on the then market price of the shares. 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 Phase I 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 our CoFactor product and one relating to Selone, both of which are intended for use in connection with cancer chemotherapy. In addition, under a second Option and License Agreement dated August 17, 2000, we acquired exclusive rights under the four 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 from all sublicenses and assignments. A prepaid royalty of \$100,000 is due upon market approval of a New Drug Application (NDA) by the FDA. There is also an annual minimum royalty on each product: \$25,000 on the first anniversary of the Agreement; \$75,000 on the second anniversary; and \$125,000 for each succeeding year up to the date of expiration of the last patent. An additional licence fee of \$100,000 is also payable upon the first Company's public offering.

## SPONSORED RESEARCH AGREEMENTS

We entered into a sponsored research agreement with M.D. Anderson on September 7, 2000, which 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 HIV infection and if the preparation can be

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administered after HIV infection as a therapeutic. This required 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.

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 has entered into a grant agreement with USC effective November 1, 2000, under which USC will perform research into Thiovir and its analogues as inhibitors for HPV and other pathogenic viruses. The budgeted research costs for this study are approximately \$217,000, which amount has been paid by the Company.

LICENSED PATENT RIGHTS  
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As summarized above, the Company has license rights under 13 issued patents as of December 2001. Our license rights under these patents remain valid for the life of the various patents. The following chart summarizes those patents and indicates the currently estimated expiration dates of such patents.

PATENT #	PATENT DESCRIPTION	APPLICATION	ISSUE DATE	Expiration /FOCUS Date
5,072,032	Preparation and use of thiophos- Antiviral	6/21/1989	12/10/1991	6/21/2009
5,128,319	phonates and thio-analogues of /Anticancer phosphonoformic acid	5,128,319	Prophylaxis and therapy of Antiviral	9/20/1989 7/7/1992 9/20/2009
5,183,812	acquired immunodeficiency syndrome	5,183,812	Preparation and use of thiophos- Antiviral	09/30/1991 2/2/1993 9/30/2011
5,376,658	phonates and thio-analogues /Anticancer of phosphonoformic acid	5,376,658	5,10-methylene-tetrahydrofolate Anticancer	12/23/1993 12/27/1994 12/23/2013 as a modulator of a chemotherapeutic agent
5,534,519	5,10-methylene-tetrahydrofolate Anticancer	5,534,519	5,10-methylene-tetrahydrofolate Anticancer	10/20/1994 7/9/1996 10/20/2014 as a modulator of a chemotherapeutic agent
5,603,933	peptides for binding to	5,603,933	CD4	

viral Antiviral  
8/31/1993  
2/18/1997  
2/18/2014  
envelope  
proteins  
5,614,562  
Method of  
treating drug  
resistant  
Anticancer  
12/16/1992  
3/25/1997  
3/25/2014 tumor  
cells using  
organoselenones  
-16- EP 0 671  
947  
Compositions  
for eliciting  
cytotoxic  
Antiviral  
2/12/1992  
8/3/2000  
2/12/2012 T-  
lymphocyte  
responses  
against viruses  
6,147,244  
Preparations of  
thiophosphites  
and Antiviral  
5/3/1999  
11/14/2000  
5/3/2019  
Thiophosphonates  
/Anticancer  
6,147,245  
Preparation and  
use of Alpha-  
Keto Antiviral  
7/13/1999  
11/14/2000  
7/13/2019  
Bisphosphonates  
6,210,873  
Methods and  
compositions  
for the  
Antiviral  
12/2/1991  
4/3/2001  
4/3/2018  
priming of  
specific  
cytotoxic T-  
lymphocyte  
response  
6,265,539  
Prophylaxis and  
therapy of  
Antiviral  
2/13/1992  
7/24/2001  
7/24/2018  
acquired  
immunodeficiency  
syndrome  
6,284,909  
Preparations of  
thiophosphites  
and Antiviral  
11/1/2000  
9/4/2001  
11/1/2020  
thiophosphonates

Other than those listed above, the Company does not have any patent license or royalty agreements. However, as a biomedical research and development company, we expect that the Company will continue to seek new patent and license

opportunities related to its business.

#### GOVERNMENT REGULATION AND CLINICAL TESTING FOR NEW DRUGS

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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 the FDA's current Good Manufacturing Practices (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 IND, 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 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.

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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 1988, 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 "1988 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 1988 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 1992, 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 1988 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 1988 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

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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

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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

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During 2000, the Company incurred expenses of \$1,017,198, on research and development activities. The Company has incurred expenses of \$946,419 for research and development during the twelve months ending December 31, 2001.

#### ITEM 2. DESCRIPTION OF PROPERTIES

The Company's principal office is located at 9948 Hibert St., Suite 100 in San Diego, California, and consists of 1,553 square feet. The office is occupied under a three-year lease expiring on January 14, 2004, at an annual rental of \$34,800 per year.

The Company also has an office handling administrative and finance matters, at 333 N. Sam Houston Parkway, Suite 1035, Houston, Texas, which consists of approximately 800 square feet. The lease on this office expired as of October 31, 2001, and the Company presently has a month-to-month lease arrangement at \$19.00 per square foot. We believe the Company will easily be able to find comparable space should the Company need or want to vacate this office.

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

#### ITEM 3. LEGAL PROCEEDINGS

The Company was a defendant in an action entitled KARO BIO USA, INC. VS. BIOKEYS PHARMACEUTICALS, INC., commenced in the United States District Court for the District of

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Delaware on July 3, 2001. The action alleged infringement of Karo Bio's federal trademark registration for the name "Biokey," based upon a claimed prior use in connection with a particular Karo Bio product, and the use of "Biokeys" in our Company's name. The plaintiff sought to prevent us from continuing to use "Biokeys" as part of our name, as well as an unspecified amount of damages.

The action was settled and discontinued in March, 2002 without monetary liability by either party. The Company agreed to a cessation of the commercial use of "Biokeys", with certain permitted exceptions through a period of transition. However, the Company will retain the use of its corporate name, "Biokeys Pharmaceuticals, Inc. " We believe that the settlement with Karo Bio will not have a material adverse effect on the Company.

#### 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 2001.

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ITEM 5. MARKET FOR THE REGISTRANT'S COMMON STOCK AND RELATED STOCKHOLDER MATTERS

MARKET INFORMATION

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Until December 7, 1999, the Common Stock of Biokeys Pharmaceuticals, Inc. (then known as BioQuest, Inc.) was quoted on the National Association of Securities Dealers (NASD) OTC Bulletin Board under the symbol "HIVX". Since that time, our Common Stock has been quoted in the "Pink Sheets". Trading in the "Pink Sheets" takes place on an irregular basis, and liquidity in this trading market may be variable or extremely limited. All prices shown have been adjusted to reflect a 1 for 1.989949857 reverse stock split in 2000. The Company is presently in the process of reapplying for quotation privileges on the OTC Bulletin Board.

The following represents high and low prices in the Pink Sheets during the last 24 months:

QUARTER	HIGH	LOW
ENDING		
HIGH LOW		
-----		
-----		
-----		
March		
31, 2000		
\$3.48		
\$0.299		
June 30,		
2000		
\$3.18		
\$0.995		
September		
30, 2000		
\$3.90		
\$2.25		
December		
31, 2000		
\$3.85		
\$2.80		
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		

HOLDERS

The number of record and beneficial holders of our Common Stock as of December 31, 2001 is approximately 600.

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.

TRANSFER AGENT

GENERAL

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As a development-stage biomedical research company, we have not yet generated any revenues from our anti-cancer and anti-viral products. We have had no earnings since inception, and have an accumulated deficit of \$24,043,342 as of December 31, 2001. Our expenses from inception have related to costs incurred in research activities for the development of our drug candidates, administrative expenses required to support these efforts and, more recently, substantial charges for amortization of goodwill and an impairment loss resulting in a write off of goodwill totalling \$15,205,675. The goodwill resulted from the October 2000 merger with Biokeys, Inc. We expect losses to continue for the near future, and such losses will likely increase as we approach human clinical trials for our CoFactor drug. 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."

CRITICAL ACCOUNTING POLICIES

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The most significant accounting estimates relate to valuing equity transactions. 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.

Preferred stock is valued at the liquidation value of \$1,000 per share. Common Stock is valued using the market price of common stock on the measurement date as defined in EITF 96-18. Common stock is valued using the market price of common stock on the measurement date as defined in EITF 96-18. The Company values warrants using the Black-Scholes pricing model. The model considers a number of factors, including the market price and expected volatility of our common stock at the date of measurement or re-measurement. The expense related to all equity transactions is amortized over the vesting period of the related equity instruments.

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The amount of compensation expense we record in future periods could fluctuate significantly from period to period as a result of: (a) the period re-measurement of equity instruments from non-employees principally as a result of fluctuations in the market price of our common stock; (b) the method and period over which the value is amortized as charges to operations; (c) additional equity instruments granted; and (d) subsequent forfeitures or cancellations of unvested instruments.

RESEARCH AND DEVELOPMENT COSTS

Research and development costs consist of costs incurred for company-sponsored as well as collaborative research and development activities. These costs include direct and research-related overhead expenses and are expensed as incurred. Patent costs and technology license fees for technologies that are utilized in research and development and have no alternative future use are expensed when incurred.

YEAR ENDED DECEMBER 31, 2001 COMPARED WITH YEAR ENDED DECEMBER 31, 2000

The Company continued its research and development efforts in the year ended December 31, 2001, and no revenues were received. The Company earned interest income of \$31,690 in 2001, which is a decrease from \$40,922 earned in the prior year, as interest-earning funds received in the Company's 2000 overseas private placement were applied to operations.

During 2001, we intensified our research and development efforts in

connection with our EradicAide and BlockAide products for HIV/AIDS. We also funded research and development efforts in connection with CoFactor and Thiovir, and have obtained FDA approval of our IND application for undertaking U.S. clinical trials for CoFactor. We incurred total research and development expenses of \$946,419 in 2001, down slightly from \$1,017,198 incurred in 2000, reflecting research grants made by the Company in late 2000 which provided for "front-loaded" payments for ongoing research projects extending into 2001 and beyond.

General and Administrative expenses increased from \$793,970 in 2000 to \$2,308,130 in 2001, primarily as a result of additional costs and expenses related to fees paid to the Company's accountants, investment and financial advisers, attorneys and other consultants. A significant portion of the increase related to expanded activities after the merger and to the Company's efforts to register as a reporting company under the Securities Exchange Act of 1934.

Depreciation and amortization amounted to \$7,672,112 in 2001, primarily reflecting amortization of goodwill resulting from the October 2000 merger with Biokeys, Inc., at the rate of \$1,900,709 for each of the four calendar quarters during the year. This compares with a goodwill amortization charge of only \$1,900,709 for the last quarter of 2000, following the merger in October 2000.

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 the goodwill associated with the acquisition of Biokeys, Inc. for impairment. The

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Company reduced its carrying value to zero through a noncash charge of \$5,702,130 on December 31, 2001, eliminating further amortization for goodwill in 2002.

Interest expense decreased to \$12,019 in 2001 from \$23,497 in 2000, due to the conversion into Common Stock of the Company's Subordinated Convertible Notes issued in 2000, and the resulting reduction in interest.

As a result of the substantial increase in amortization of goodwill and the non-cash impairment loss, as well as the other factors described above, the Company's net loss increased from \$(3,701,084) in 2000 to \$(16,339,120) in 2001, and the loss per share increased from \$(0.44) per share in 2000 to \$(1.12) per share in 2001.

#### YEAR ENDED DECEMBER 31, 2000 COMPARED WITH YEAR ENDED DECEMBER 31, 1999

The Company continued its research and development efforts in both 1999 and 2000, and no revenues were received during the period. However, the Company earned interest income which increased to \$40,922 in 2000 from \$14,234 in 1999, as a result of interest earned on funds received from the Company's overseas private placement offering.

Using the proceeds of our overseas private placement offering, we were able to significantly expand our research and development efforts in connection with our EradicAide and BlockAide 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, after the consummation of the merger with Biokeys, Inc., we began to fund research and development efforts in connection with CoFactor and Thiovir. Accordingly, our research and development expenses increased substantially from \$351,446 in 1999 to \$1,017,198 in 2000.

General and Administrative expenses increased by approximately 12% from \$708,562 in 1999 to \$793,970 in 2000, primarily as a result of additional costs and expenses related to the merger.

Depreciation and amortization increased from \$5,385 in 1999 to \$1,907,341 in 2000. Such increases are due primarily to the merger, which resulted in \$15,205,675 of goodwill being recorded on the Company's balance sheet based on allocation of the purchase price to net assets acquired. Such amount was being amortized over a two-year period, beginning in the last quarter of 2000, at which time a goodwill amortization charge of \$1,900,709 for the quarter was recorded.

Interest expense increased from \$4,326 in 1999 to \$23,497 in 2000.

As a result of the factors described above, the Company's net loss increased from \$(1,055,485) in 1999 to \$(3,701,084) in 2000, and the loss per share increased from \$(0.20) per share in 1999 to \$(0.44) per share in 2000.

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, 2001, cash and cash equivalents totaled \$164,476, compared with \$467,878 plus a \$1,016,320 certificate of deposit on December 31, 2000.

The Company does not have any bank or any other commercial financing arrangements. The Company's operations since the merger have been funded primarily from the proceeds of its overseas private placement offering consummated in August and September 2000, by which the Company raised a total of \$3.2 million through the issuance of its Series A 8% Convertible Preferred Stock.

We intend to move our CoFactor product into human clinical trials in the U.S. during 2002, since the FDA has approved our IND. The Company will need adequate funding to conduct the trials, either through a commercial partnership, additional financing, or a combination of both. The clinical trials for 2002 are expected to cost between \$3 and \$4 million, based upon estimates obtained from three different contract research organizations capable of running clinical trials for CoFactor.

The Company also plans further development of its HIV products, EradicAide and BlockAide, in 2002 if funding is available through a marketing partnership, government grant (for which the Company has applied during 2001) or additional financing. Expenditures on research and development for EradicAide are expected to range between \$250,000 and \$1,000,000, and will require an additional \$2 million if initial human trials are undertaken.

We raised approximately \$450,000 through the issuance of short-term notes and warrants in October and December, 2001. We believe our current resources are sufficient to fund our general and administrative overhead until the end of May 2002, at which time we will need to obtain additional financing of approximately \$1,000,000 to cover corporate overhead and working capital needs until early 2003. In addition, we are seeking additional resources to fund the research projects described above. If sufficient funding is available, we may add up to two additional employees in 2002.

We are currently formulating plans for the additional financing which will be required for 2002 and beyond, but we have not yet obtained commitments for such financing. The Company's dependence on obtaining 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 will 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, government grants, 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 presently 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.

Financial Accounting Standards No. 141, BUSINESS COMBINATIONS (SFAS No. 141). SFAS No. 141 eliminates the pooling of interests method of accounting and requires that all business combinations initiated after June 30, 2001 be accounted for under the purchase method. Adoption of SFAS No. 141 had no material impact on the Company.

The FASB has also issued Statement of Financial Accounting Standards No. 142, GOODWILL AND OTHER INTANGIBLE ASSETS (SFAS No. 142), which will be 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. Adoption of SFAS No. 142 will result in the elimination of annual amortization expense related to goodwill. The Company does not expect the adoption of SFAS No. 142 will have a material impact on its business because, as of December 31, 2001, it has 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 will 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 will be effective for the Company as of January 1, 2002. The Company does not expect the adoption of SFAS No. 144 will have a significant impact on its financial condition or results of operations.

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#### ITEM 6A. 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 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.

#### RISK FACTORS

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THERE IS A SUBSTANTIAL ACCUMULATED DEFICIT AND A WORKING CAPITAL DEFICIENCY; THE COMPANY'S AUDITED FINANCIAL STATEMENTS ARE SUBJECT TO A GOING CONCERN UNCERTAINTY.

The Company had an accumulated deficit of \$24,043,342 as of December 31, 2001. 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. The Company has had limited working capital for its product development and other activities, and had a working capital deficiency of \$(686,151) as of December 31, 2001. The Company's audited financial statements have been prepared on the assumption that the Company will continue as a going concern, and are presented subject to the uncertainty, expressed in the report of the Company's auditors, that the Company's recurring losses from operations raise substantial doubt as to the Company's ability to continue as a going concern. (See the Company's Consolidated Financial Statements, included with this Annual Report.)

WE HAVE NO CURRENT REVENUES OR PROFITS.

The Company has devoted its resources in recent years 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 be available until, and unless the new products are clinically tested, approved by the FDA and successfully marketed, an outcome which the Company is not able to guarantee.

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

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 may be required to fund our activities. The Company has funded its operations primarily through the sale of Company Securities. We cannot assure you that we will be able to consummate any future financing

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on favorable terms, if at all, or that such financing will be adequate to meet 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 severely limit the Company's ability to continue its research and development projects.

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.

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

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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.

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 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 you 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.

Potential competition for CoFactor is difficult to quantify at this time. CoFactor is designed to enhance the performance of the Cancer Chemotherapy drug 5-FU (as described under Item 1 above). For colorectal cancer applications, which is our intended target market for CoFactor at this

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time, there are products which could be considered indirect competition, and we know of no direct competition to CoFactor as of the present time. Such indirect competition would come from leucovorin manufacturers, such as Astra Pharmaceuticals, Inc. and GlaxoSmithKline, which are large pharmaceutical companies, Xanodyne, which is a new biotech company which acquired rights to leucovorin from Immuney corporation and generic manufacturers such as Roxane Laboratories and Elkins-Sin, Inc. Since CoFactor will work synergistically with other key drugs such as CPT-11, manufactured by Pharmacia & Upjohn, and because CoFactor has a different mode of action than CPT-11, we believe CoFactor will be

useful with 5-FU drugs that are now manufactured by approximately 40 different branded or generic pharmaceutical manufacturers. However, we cannot rule out the possibility that there may be other directly competitive drugs available by the time CoFactor is able to obtain market approval.

Competition for Selone, the Company's other anticancer agent, could arise from anticancer agents that are manufactured by pharmaceutical companies such as Bristol Myers Squibb, with its Cisplatin and carboplatin drugs, which are platinating agents, other anti-cancer drugs, such as Vinblastine, and Vincristine from Eli Lilly or Methotrexate from Lederle.

Competition in the HIV/AIDS area is focused on drugs that are used in combination regimens to fight HIV progression to AIDS by suppressing the viral load. These drugs, such as Abacavir, Acyclovir, Amprenavir, 3TC, AZT and Valcyclovir, marketed by GlaxoSmithKline, or d4T and ddI marketed by Bristol Myers Squibb, are only a few of the approximately 20 different drugs approved by the FDA for HIV therapy. They are all sold by large pharmaceutical companies.

Competition for Thiovir for treatment of HPV infection consists of topical creams, made from plant extracts, or surgical methods for removal of genital warts caused by HPV.

Many of our competitors have significantly greater financial, technical and human resources and will likely be better equipped to develop, manufacture and market products. In addition than the Company, 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 could drastically reduce the extent of the market for our products.

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.

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The Company has obtained licenses to patents and other proprietary rights from M.D. Anderson and from USC.

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 you 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 hinder future financing efforts and delay clinical development efforts by 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, M.D. Anderson 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 a significant license agreement would require the Company to adjust and/or change its business plan.

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

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Company or will perform those obligations satisfactorily.

THERE IS NO SALES AND MARKETING CAPABILITY AT THE PRESENT TIME.

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'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.

In addition, to develop and commercialize future drug products, the Company may need to hire and retain a number of additional highly qualified and experienced management, scientific personnel, consultants and advisors. The ability to attract and retain qualified personnel will be critical to the success of the Company. Competition for qualified individuals is intense, and the Company will face competition 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 acceptable terms or at all, and the failure to do so would have a material

adverse effect on the Company.

If the Company were to lose the services of its current biomedical researchers, we believe such services could be replaced by other independent researchers available in the San Diego and Houston areas, which have substantial biomedical research facilities and personnel. In addition, much of the research already conducted on CoFactor has been published in peer-review scientific journals and is therefore available to successor research personnel. However, the replacement process, if necessary, could cause delays in development and clinical trial work.

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THERE IS UNCERTAINTY AS TO THE AVAILABILITY AND AMOUNTS OF HEALTH CARE REIMBURSEMENT.

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 which any future health care reforms may have on its business, and such reforms could limit coverage or reimbursement for claims of patients receiving therapies based on the Company's products.

THE COMPANY HAS NO MANUFACTURING FACILITIES.

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 Eprova, AG and Clinalfa AG. 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.

THERE IS NO PRODUCT LIABILITY INSURANCE AND IT IS UNCERTAIN THAT SUCH INSURANCE CAN BE OBTAINED.

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 limited product liability insurance for its clinical trials 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 impact both the reputation and the financial resources of the Company.

THE MARKET PRICE OF OUR SHARES IS VOLATILE.

Market prices for the Company's Common Stock and the securities of other medical and biomedical technology companies have been volatile. 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 PREFERRED STOCK IN THE FUTURE MAY AFFECT THE COMMON STOCK.

The Company has previously issued shares of Series A Convertible Preferred Stock to overseas investors. In addition, the Board of Directors is authorized, without action by the stockholders, to issue other shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. Although no such issuance is currently planned, the effect of such issuance in the future may be to (i) restrict future dividends on Common Stock, (ii) dilute the voting power of Common Stock, (iii) impair the liquidation rights of the Common Stock, and (iv) delay or prevent a change in control without further action by the stockholders.

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.

THE EFFECT OF ADDITIONAL OPTIONS, WARRANTS AND CONVERTIBLE SECURITIES COULD DEPRESS THE PRICE OF OUR STOCK.

As of December 31, 2001, there were outstanding options and warrants for the purchase of an aggregate of 3,468,094 shares of Common Stock at various exercise prices. In addition, the Company's Series A Convertible Preferred Stock is convertible into a total of 800,000 shares of Common Stock at the election of the holders. Assuming that all options and warrants were exercised and that all of the Series A Preferred Stock was converted, a total of 4,268,094 additional shares of Common Stock would be issued, for which the Company would receive aggregate cash proceeds of approximately \$4,903,595. After various holding period requirements under Rule 144 of the Securities and Exchange Commission are satisfied, the holders of such shares would be entitled to sell such shares in the public market, assuming a public market for the Company's shares were then available. The public sale of such significant amounts of shares could adversely affect the prevailing price of Common Stock in the market and could seriously impair the Company's ability to raise capital through subsequent securities offerings.

A SUBSTANTIAL PORTION OF THE COMPANY'S OUTSTANDING COMMON STOCK MAY BECOME AVAILABLE FOR PUBLIC SALE UNDER RULE 144 IN THE FUTURE.

A substantial portion of the Company's outstanding shares of Common Stock, including certain shares issues in the merger with Biokeys, Inc. may become available for public sale in the future under Rule 144 of the Securities and Exchange Commission, after the owners of such shares satisfy the holding period and other requirements of Rule 144. Future sales of significant numbers of shares of Common Stock could adversely affect the prevailing market price of the Common Stock and could also impair the Company's ability to raise capital through subsequent offerings of securities.

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ITEM 7. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The Company's Consolidated Financial Statements for the years ended December 31, 2001 and 2000 are incorporated into this report and are attached in a separate section following Part IV of this document. They include:

- o Independent Auditor's Report dated April 10, 2002
- o Consolidated Balance Sheets
- o Consolidated Statements of Operations
- o Consolidated Statements of Shareholders' Equity (Deficit)
- o Consolidated Statements of Cash Flow
- o Notes to Consolidated Financial Statements

ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS

None

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PART III

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ITEM 9. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The Board of Directors of Biokeys Pharmaceuticals, Inc. is presently composed of Louis R. Reif, Warren C. Lau, and Robert D. Whitworth. Directors generally serve for one-year terms and until successors are duly elected and qualified.

The Board of Directors of our subsidiary, Biokeys, Inc., is comprised of M. Ross Johnson, Ph.D., Nicholas Jon Virca, Francis E. O'Donnell, Jr., M.D., and Louis R. Reif.

The members of the board of directors and executive officers of each of Biokeys Pharmaceuticals, Inc. and Biokeys, Inc., and their respective positions and ages as of December 31, 2001, are as follows:

NAME AGE  
POSITION - ----  
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Officer and a Director of Delaware North Companies, a large privately-held company operating food concession businesses at major sports arenas in the U.S. He has served as past Chairman of the American Gas Association and Chairman of the 17th World Gas Conference of the International Gas Union. He is a Trustee-emeritus of the State University of New York. Mr. Reif received a B.A. degree from the University of Buffalo and a J.D. degree from the University of Michigan.

NICHOLAS JON VIRCA has served as President, and a Director of Biokeys, Inc., the Company's wholly-owned subsidiary, since March 1997, becoming Chief Executive Officer in March 2000. From 1991 to 1997, he served as Vice President of Operations, and as a director from 1997 to 1998, of Diametrix Detectors, Inc., a privately-held immunosensor company which he co-founded and which focused on detection of narcotics using monoclonal antibodies. From 1991 to 1994, Mr. Virca also served as Vice President, Business Operations, of IRT Corporation, a publicly-traded company that specialized in x-ray inspection and imaging systems for industrial and security applications. In addition, 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's assets in 1994. His 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, during which he participated in the commercialization of numerous prescription and OTC pharmaceuticals and biotherapeutic and diagnostic reagents. Mr. Virca received a B.A. degree in biology from Youngstown State University.

WARREN C. LAU is the co-founder of Biokeys Pharmaceuticals, Inc. and has served as its President and as a member of its Board of Directors from June 1996, and Chief Financial Officer of Biokeys, Inc., the Company's wholly-owned subsidiary, since the merger. From November 1997 to September 1998, Mr. Lau served as a director of Immune Complex Corporation and Synthetic Genetics, Inc., privately-held biotechnology companies with which the Company was affiliated during such period. From 1986 to 1996, Mr. Lau was a registered representative of Josephthal, Lyons and Ross, an investment banking and brokerage firm, where he was involved with the underwriting of biotechnology issues.

M. ROSS JOHNSON, PH.D. serves as Chairman and a Director of Biokeys, Inc. From 1996 to 1999, he was President, Chief Executive Officer and member of the Board of Directors of Trimeris, Inc., and, from 1995 to 1996, served as its Chief Scientific Officer and Vice President of Research and Development. Trimeris is engaged in the development of fusion inhibitor technology for antivirals to treat HIV infection. Prior to his service with Trimeris, Dr. Johnson was President and CEO of Parnassus Pharmaceuticals and Vice President of Chemistry at the Glaxo, Inc. Research Institute in North Carolina, where he was part of the original scientific founding team. Earlier, he served in key scientific and research management positions with Pfizer Central Research. He is Adjunct Professor of Chemistry and Adjunct Professor of Medicinal Chemistry at the University of North Carolina at Chapel Hill. He has authorized or participated in numerous patents, scientific publications and scientific and medical presentations. Dr. Johnson received his B.S. degree in chemistry from the University of California at Berkeley and a Ph.D. degree in organic chemistry from the University of California at Santa Barbara.

FRANCIS E. O'DONNELL, JR., M.D. has served as a director of Biokeys, Inc. (including its predecessor) since 1996. He is founder and Managing Partner of Hopkins Capital Group, LLC, a biotech business development company. In his role as Managing Partner for the Hopkins Capital Group, he is actively

involved in the management of the portfolio companies: APP Specialty Pharmacy, Photo Vision Pharmaceuticals, BioDelivery Sciences International, Inc., RetinaPharma, Inc., Pen2Net, Inc. and Sublase, Inc. Dr. O'Donnell is the Founder and Managing Partner of Hopkins Biotech Development Corporate (HBDC) which provides biotech company advertising. Dr. O'Donnell has published over 30 peer-reviewed scientific articles and he has been awarded 22 U.S. patents. He is a 1975 graduate of the Johns Hopkins School of Medicine and former a Professor and Chairman, Department of Ophthalmology at the St. Louis University School of Medicine in St. Louis, Missouri.

ROBERT D. WHITWORTH has served as a director of Biokeys Pharmaceuticals, Inc. since August, 1998. Mr. Whitworth began his business career in 1976 with Charles Martin, Inc., a petroleum inspection company, and ultimately served as Chief Chemist for Europe, Africa, and the Middle East. In 1979, Mr. Whitworth became Vice President, Logistics and Quality Control, at Hydrocarbon Trading and Transport, Inc., a Houston, Texas, company, which at the time was the largest private supplier of jet fuel in the U.S. From 1989 to 1994, Mr. Whitworth was a Vice President of Croydon Resources, Inc., a provider of crude oil and refined

petroleum products for refinery processing. From 1994 to the present, Mr. Whitworth has served as Manager of International Fuel Sales and Operations for Mercury Group, Inc., a jet fuel supplier for the airline industry. Mr. Whitworth is the holder of 22 U.S. and international patents in chemical and petroleum engineering, and is a member of the American Chemical Society, the American Society for Testing and Materials and the International Standards Association. Mr. Whitworth holds a B.S. degree in Chemistry from Southern Methodist University.

KEY CONSULTANT

The Company also utilizes the consulting services of Chris Chapman, M.D., who advises the Company on planning, preparation and implementation of the Company's clinical trials.

CHRIS CHAPMAN, M.D. (MEDICAL DIRECTOR) is a consultant to the pharmaceutical industry; he is President of Chapman Pharmaceutical Consulting. Prior to starting his consulting practice, Dr. Chapman was Executive Director, Medical Affairs, Quintiles Consulting and a founding Co-Director of Quintiles BRI (QBRI) Medical Affairs, Drug Safety and Medical Writing Departments, where he served from 1995 to 1999. At Quintiles, he developed a team of medical professionals, including Board-certified physicians in Infectious Disease, Internal Medicine, Cardiology, Allergy- Immunology, and Neurology to spearhead clinical activities with a focus toward FDA drug approvals. Dr. Chapman was responsible for overseeing the work of other physicians on clinical trials, the domestic and international Serious Adverse Event Database, and the departments performing adverse event coding and medical writing for a wide range of clinical trial documents. Prior to Quintiles, Dr. Chapman served as Medical Director/Safety Officer for Regeneration Pharmaceuticals, Inc. Dr. Chapman received his M.D. degree from Georgetown University in Washington, D.C., where he completed his internship in Internal Medicine, a residency in Anesthesiology, and a fellowship in cardiovascular and Obstetric Anesthesiology. He is currently a critical care physician on the staff at Doctor's Community Hospital, Lanham, Maryland. As a consultant to the pharmaceutical industry, Dr. Chapman has been instrumental in achieving FDA approval of many drugs including Corolopam(R), Agrylin(TM), Zyvox(R), Arava(TM), and Integrilin(R). He is a Diplomat, National Board of Medical Examiners, and a member of the American Medical Association, American Society of Anesthesiologists and Academy of Pharmaceutical Physicians.

ITEM 10. EXECUTIVE COMPENSATION

The following table sets forth the compensation paid to each executive officer of Biokeys Pharmaceuticals, Inc. and Biokeys, Inc., for each of the three fiscal years ended December 31, 2001:

(i)	(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	Annual Compensation				
									Salary	Bonus	Other		
									Restricted Securities	LTIP	All and	(\$)	(\$)
									Annual Stock	Underlying	Payouts	Other	Principal Compe
									Award(s)	Options/	(\$)	Compen-	Position
									nsation	(\$)	SARS (#)	sation	(\$)
									(\$)	(\$)	Nicholas Jon	Virca	2001
									124,000	-0-	-0-	-0-	-0-
									-0-	-0-	-0-	-0-	-0-
									President and	CEO	2000	30,000	(1)
									Biokeys, Inc.	1999	Warren C.		

Lau 2001  
 114,000 -0- -0-  
 -0- -0- -0-  
 President 2000  
 114,000 Biokeys  
 1999 114,000  
 5,000  
 Pharmaceuticals,  
 Inc., CFO,  
 Biokeys  
 Pharmaceuticals,  
 Inc. Louis R.  
 Reif (2) -0-  
 -0- -0- -0- -0-  
 -0- -0- -0- CEO  
 and Chairman,  
 Biokeys  
 Pharmaceuticals,  
 Inc.

Notes: (1) Includes salary only for the last quarter of 2000, during which Biokeys, Inc. was a subsidiary.  
 (2) Mr. Reif has not been paid compensation, but is reimbursed for actual expenses.

The Company has an employment agreement with Warren C. Lau, President of Biokeys Pharmaceuticals, Inc., expiring November 30, 2002. The agreement provides for an annual salary of \$114,000, plus cost-of-living increases based on percentage changes in the Consumer Price Index among other things. In the event of a change of control of the Company and a related termination of the employment agreement, Mr. Lau will be entitled to a severance payment equal to one year's salary.

Nicholas Jon Virca, the President and Chief Executive Officer of Biokeys, Inc., does not presently have an employment agreement. He receives a salary of \$124,000 per year.

ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information known to the Company regarding beneficial ownership of the Common Stock of the Company as of December 31, 2001, of (i) each person who is known to the Company to own of record or beneficially more than five percent (5%) of such Common Stock, (ii) each director and executive officer of the Company (including Biokeys, Inc.)

and (iii) all directors and executive officers of the Company (including Biokeys, Inc.) as a group. All share amounts shown here and elsewhere in this registration have been adjusted to reflect a reverse stock split of approximately one for 1.9899 in 2000.

Name and Address of Beneficial Owners Number of Shares Percent of Class - ----- ----- ----- ----- -----
--- Louis R. Reif 201,0101 1.35% c/o Biokeys Pharmaceuticals, Inc. 333 N. Sam Houston Pkwy, Suite 1035 Houston, Texas 77060 Warren C. Lau 885,7972 5.94% c/o Biokeys



Pharmaceuticals,  
Inc. 333 N. Sam  
Houston Pkwy,  
Suite 1035  
Houston, Texas  
77060 Nicholas  
Jon Virca  
476,6933 3.20%  
c/o Biokeys

Pharmaceuticals,  
Inc. 9948  
Hibert Street,  
Suite 100 San  
Diego, CA 92131  
Robert D.  
Whitworth  
50,205 0.34%  
c/o Biokeys

Pharmaceuticals,  
Inc. 333 N. Sam  
Houston Pkwy,  
Suite 1035  
Houston, Texas  
77060 Francis  
E. O'Donnell,  
Jr., M.D.  
1,323,6464  
8.88% 709 The  
Hamptons Lane  
Town & Country,  
Missouri 63017  
Thomas  
DePetrillo  
957,9225 6.57%  
988 Centerville  
Road Warwick,  
Rhode Island  
02886 Matthew  
Balk 976,2756  
6.69% 245 Park  
Avenue, 44th  
Floor New York,  
NY 10167

- - - - -

(1) Does not include a total of 703,536 shares held by the adult children of Mr. Reif, as trustees of family trusts, as to which Mr.Reif disclaims any voting power or beneficial ownership.

(2) Includes 6,000 shares held by Mr. Lau as custodian for his minor children, as to which he has voting power but disclaims any beneficial ownership.

(3) Includes currently exercisable warrants for the purchase of 144,435 shares.

(4) Includes shares held by family trust and children, as to which Dr. O'Donnell has voting power but disclaims any beneficial interest.

(5) Includes warrants held by Mr. DePetrillo to purchase 366,430 shares, currently exercisable, and shares held by family members. Mr. DePetrillo has voting power but disclaims any beneficial interest as to such family-owned shares.

(6) Does not include other shares held by certain adult relatives of Mr. Balk, as to which he disclaims any voting power or beneficial ownership.

Name and  
Address of  
Beneficial  
Owners  
Number of  
Shares  
Percent of  
Class - -  
-----



Common Stock at an exercise price of \$0.49 per share. These Incentive Warrants constituted a portion of the total number of warrants which were permitted to be outstanding for the combined companies under the terms of the Merger

(7) Represents currently exercisable warrants.

Agreement. The Incentive Warrants were not initially assigned to specific individuals, but were issued to the Company's directors, and held by its counsel under the terms of an Escrow Agreement which provided for the directors to designate, from time to time, employees, officers, consultants, directors and others whose present or future services were deemed to be of substantial benefit to the Company and who would become recipients of the Incentive Warrants. As of December 31, 2001, none of such Incentive Warrants had been assigned to any individuals. Because the Incentive Warrants had not been so assigned by the directors, they were not recorded in the Company's financial statements through December 31, 2001. In late March 2002, the Board of Directors determined that the Incentive Warrants should not be granted to any individuals for services, but should instead be assigned to several investors who had offered to exercise such warrants for cash, as a means of generating additional working capital for the Company. All of the Incentive Warrants were exercised in March 2002 and are no longer outstanding.

PART IV

ITEM 13. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 10-KSB

(a) The following documents are filed as part of this report of Form 10-KSB:

- 1. Financial Statements - See Financial Statements and Supplementary Data in Item 7 of this report on Form 10KSB.
- 2. Financial Statement Schedules - None
- 3. The following Exhibits are incorporated by reference pursuant to Rule 12b-23 of the Securities and Exchange Commission:

Exhibit DESCRIPTION Number - -----
-----
-----
-----
-----
-----
-----
2.1 o Agreement and Plan of Merger dated May 19, 2000 among BioQuest, Inc.; BioQuest Acquisition Corp.; and Biokeys, Inc.
3.1 o Certificate of Amendment of Certificate of Incorporation of BioQuest, Inc. - October 12, 2000
3.2 o Certificate of Amendment of Certificate of Incorporation of BioQuest, Inc. - October 12, 2000
3.3 o Certificate of Merger of BioQuest Acquisition

Corp. into  
Biokeys, Inc. -  
October 12,  
2000 3.4 o  
Certificate of  
Incorporation  
of BioQuest  
Acquisition  
Corp. - May 19,  
2000 3.6 o  
Amended and  
Restated Bylaws  
of Biokeys  
Pharmaceuticals,  
Inc. 4.1 o  
Certificate of  
Designation of  
BioQuest, Inc.  
- September 11,  
2000 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 o  
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)  
-45- 10.6 o  
Employment  
Agreement with  
Warren C. Lau  
11.1 o  
Statement  
Regarding  
Computation of

Per Share  
Earnings 21.1 o  
Subsidiaries of  
the Registrant  
24.1 o Powers  
of Attorney  
(included on  
signature  
pages)

o Filed with Form 10-SB (October 2, 2001)

\* Refiled with amendment on Form 10-SB/A (January 11, 2002)

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SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BIOKEYS PHARMACEUTICALS, INC.

By: /s/ LOUIS R. REIF

-----  
Louis R. Reif, Chairman and Chief Executive Officer

By: /s/ WARREN C. LAU

-----  
Warren C. Lau, President and Chief Financial Officer

In accordance with the Exchange Act, 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/ LOUIS R. REIF ----- Louis R. Reif	Director	April 15, 2002
/s/ ROBERT D. WHITWORTH ----- Robert D. Whitworth	Director	April 15, 2002
/s/ WARREN C. LAU ----- Warren C. Lau	Director	April 15, 2002

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BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY  
(A Development Stage Enterprise)  
Consolidated Financial Statements  
December 31, 2001 and 2000  
(With Independent Auditors' Report Thereon)

INDEPENDENT AUDITORS' REPORT

The Board of Directors  
Biokeys Pharmaceuticals, Inc.:

We have audited the accompanying consolidated balance sheets of Biokeys Pharmaceuticals, Inc. and subsidiary (a development stage enterprise) (the Company) as of December 31, 2001 and 2000, and the related consolidated statements of operations, shareholders' equity (deficit), and cash flows for the years then ended, and for the period from inception (June 12, 1996) through December 31, 2001. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide 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 2000, and the results of their operations and their cash flows for the years then ended, and for the period from inception (June 12, 1996) through December 31, 2001, 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.

Houston, Texas  
April 10, 2002

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

DECEMBER 31,  
-----  
-----  
----- 2001  
2000 -----  
-----

-----  
Assets  
Current  
assets: Cash  
and cash  
equivalents  
\$ 164,476  
467,878  
Certificate  
of deposit -  
- 1,016,330  
Advances to  
employees  
29,872  
10,500  
Prepaid  
expenses --  
71,624 Note  
receivable -  
related  
party (note  
9) 35,993 --

-----  
-----  
Total  
current  
assets  
230,341  
1,566,332  
Property and  
equipment,  
net (note 4)  
13,612 6,356  
Goodwill,  
net of  
accumulated  
amortization  
of  
\$1,900,709  
in 2000 --  
13,304,966  
Other assets  
34,053 1,180  
-----

-----  
Total assets  
\$ 278,006  
14,878,834  
=====

=====

LIABILITIES  
AND

SHAREHOLDERS'  
EQUITY  
(DEFICIT)  
Current  
liabilities:  
Accounts  
payable and  
accrued  
liabilities  
\$ 430,216  
67,537  
Accrued  
salary and  
related  
taxes  
303,837  
116,034  
Accrued  
dividends  
payable  
128,000  
85,000 Notes  
payable  
(note 5)  
54,439 -- --  
-----

-----  
Total  
current  
liabilities  
916,492  
268,571 ----  
-----

-----  
Shareholders'  
equity  
(deficit)  
(notes 1 and  
8):  
Cumulative  
convertible  
preferred  
stock, \$0.01  
par value  
Authorized  
1,000,000  
shares;  
issued and  
outstanding,  
3,337 shares  
in 2001 and

3,200 shares  
 in 2000  
 (aggregate  
 involuntary  
 liquidation  
 preference  
 \$3,337,000  
 at December  
 31, 2001) 33  
 32 Common  
 stock,  
 \$0.001 par  
 value.  
 Authorized  
 50,000,000  
 shares;  
 issued and  
 outstanding,  
 15,005,191  
 shares in  
 2001 and  
 14,586,984  
 shares in  
 2000 15,005  
 14,587  
 Additional  
 paid-in  
 capital  
 23,389,818  
 22,299,866  
 Deficit  
 accumulated  
 during the  
 development  
 stage  
 (24,043,342)  
 (7,704,222)  
 -----  
 -----  
 Total  
 shareholders'  
 equity  
 (deficit)  
 (638,486)  
 14,610,263  
 Commitments  
 and  
 contingencies  
 (notes 5, 6,  
 8, 12, and  
 13) -----  
 -----  
 ----- Total  
 liabilities  
 and  
 shareholders'  
 equity  
 (deficit) \$  
 278,006  
 14,878,834  
 =====  
 =====

See accompanying notes to consolidated financial statements.

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

INCEPTION  
 (JUNE 12,  
 1996) YEAR  
 ENDED  
 DECEMBER 31,  
 THROUGH -----  
 -----



-----  
DECEMBER 31,  
2001 2000  
2001 -----  
-----

-----  
---- Net  
sales \$ -- --  
174,830 Cost  
of goods sold  
-- -- 51,094  
-----  
-----

-----  
Gross margin  
-- -- 123,736  
Grant revenue  
-- -- 80,338  
Interest  
income 31,690  
40,922 88,695  
-----  
-----

-----  
31,690 40,922  
292,769 -----  
-----  
-----

-----  
Operating  
expenses:  
Research and  
development  
946,419  
1,017,198  
3,697,963  
General and  
administrative  
2,038,130  
793,970  
5,441,228  
Depreciation  
and  
amortization  
7,672,112  
1,907,341  
9,661,628  
Impairment  
loss - write  
off of  
goodwill  
(note 2)  
5,702,130 --  
5,702,130  
Interest  
expense  
12,019 23,497  
124,008  
Equity in  
loss of  
subsidiary --  
-- 178,936 --  
-----  
-----

-----  
Total  
operating  
expenses  
16,370,810  
3,742,006  
24,805,893 --  
-----  
-----

-----  
Loss before  
cumulative  
effect of  
change in  
accounting  
principle  
(16,339,120)

(3,701,084)  
(24,513,124)  
Cumulative  
effect of  
change in  
accounting  
principle --  
-- (25,821) -  
-----  
-----  
-----  
Net loss  
\$(16,339,120)  
(3,701,084)  
(24,538,945)  
=====

Loss per  
common share  
- basic and  
diluted (note  
11) \$ (1.12)  
(0.44)  
=====

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, 2001

CUMULATIVE  
CONVERTIBLE  
PREFERRED  
STOCK COMMON  
STOCK -----  
-----  
-----  
-----  
----- SHARES  
AMOUNT SHARES  
AMOUNT -----  
-----  
-----  
-- Balances  
at June 12,  
1996 (date of  
incorporation)  
-- \$ -- -- \$  
-- Sale of  
common stock  
without par  
value -- --  
503 5 Change  
in par value  
of common  
stock -- -- -  
- (4)  
Issuance of  
common stock  
and net  
liabilities  
assumed in  
acquisition -  
- --  
1,716,132  
1,716  
Issuance of  
common stock  
-- --  
2,010,111  
2,010 Net

loss -- -- --  
 -----  
 -----  
 -----  
 -----  
 Balances at  
 December 31,  
 1996 -- --  
 3,726,746  
 3,727 Sale of  
 common stock,  
 net of  
 offering  
 costs of  
 \$9,976 -- --  
 1,004,554  
 1,004  
 Issuance of  
 common stock  
 in  
 acquisition -  
 - -- 375,891  
 376 Minority  
 interest  
 deficiency at  
 acquisition  
 charged to  
 the Company -  
 - -- -- --  
 Net loss -- --  
 -----  
 -----  
 -----  
 --- Balances  
 at December  
 31, 1997 -- --  
 - 5,107,190  
 5,107  
 Rescission of  
 acquisition -  
 - --  
 (375,891)  
 (376)  
 Issuance of  
 common stock  
 at conversion  
 of notes  
 payable -- --  
 450,264 451  
 Expense  
 related to  
 stock  
 warrants  
 issued -- --  
 -- -- Net  
 loss -- -- --  
 -----  
 -----  
 -----  
 -----  
 Balances at  
 December 31,  
 1998 -- --  
 5,181,564  
 5,182 Sale of  
 common stock  
 -- -- 678,412  
 678 Expense  
 related to  
 stock  
 warrants  
 issued -- --  
 -- -- Net  
 loss -- -- --  
 -----  
 -----  
 -----  
 -----  
 Balances at  
 December 31,

1999	--	--
5,859,976		
5,860 Sale of preferred stock, net of offering costs of \$76,500 (note 8)	3,200	32
- - - Issuance of common stock at conversion of notes and interest payable (note 8)	--	--
412,487	412	
Issuance of common stock at conversion of notes payable (note 8)	--	--
70,354	70	
Issuance of common stock to settle obligations (notes 1 and 6)	--	--
495,111	496	
Issuance of common stock for acquisition (note 1)	--	-
- 6,999,990		7,000
Issuance of warrants for acquisition (note 1)	--	-
- - - - - Stock issued for acquisition costs (note 1)	--	--
150,000	150	
Expense related to stock warrants issued (note 8)	--	--
- Dividends payable on preferred stock	--	--
- - - Cashless exercise of warrants (note 8)	--	-
- 599,066	599	
Net loss	--	-
- - - - -		
- - - - -		
- - - - -		
--- Balances at December 31, 2000		
3,200	32	
14,586,984		
14,587		
Dividends payable on preferred stock	--	--
- - -		
Repurchase of		

warrants  
 (note 8) -- -  
 - - - - - Sale  
 of warrants  
 (note 8) -- -  
 - - - - -  
 Cashless  
 exercise of  
 warrants  
 (note 8) -- -  
 - 218,493 219  
 Issuance of  
 common stock  
 to pay  
 preferred  
 dividends  
 (note 8) -- -  
 - 93,421 93  
 Detachable  
 warrants  
 issued with  
 notes payable  
 (note 6) -- -  
 - - - - -  
 Issuance of  
 warrants to  
 pay operating  
 expenses  
 (note 8) -- -  
 - - - - -  
 Issuance of  
 common stock  
 to pay  
 operating  
 expenses  
 (note 8) -- -  
 - 106,293 106  
 Issuance of  
 preferred  
 stock to pay  
 operating  
 expenses  
 (note 8) 137  
 1 -- -- Net  
 loss -- -- --  
 -- -----  
 - -----  
 -----

Balances at  
 December 31,  
 2001 3,337 \$  
 33 15,005,191  
 \$ 15,005

=====  
 =====  
 =====  
 =====

DEFICIT  
 ACCUMULATED  
 TOTAL  
 ADDITIONAL  
 DURING THE  
 SHAREHOLDERS'  
 PAID-IN  
 DEVELOPMENT  
 EQUITY  
 CAPITAL STAGE  
 (DEFICIT) ---  
 -----  
 -----  
 -----

Balances at  
 June 12, 1996  
 (date of  
 incorporation)  
 -- -- -- Sale  
 of common  
 stock without  
 par value 5 -  
 - 10 Change

in par value  
of common  
stock 4 -- --  
Issuance of  
common stock  
and net  
liabilities  
assumed in  
acquisition  
3,224  
(18,094)  
(13,154)  
Issuance of  
common stock  
456 (2,466) -  
- Net loss --  
(259,476)  
(259,476) ---  
-----

-----  
Balances at  
December 31,  
1996 3,689  
(280,036)  
(272,620)  
Sale of  
common stock,  
net of  
offering  
costs of  
\$9,976  
1,789,975 --  
1,790,979  
Issuance of  
common stock  
in  
acquisition  
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  
2,681,538  
(2,304,439)  
382,206  
Rescission of  
acquisition  
(887,874)  
561,166  
(327,084)  
Issuance of  
common stock  
at conversion  
of notes  
payable  
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

2,417,213

(2,947,653)

(525,258)

Sale of

common stock

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

2,763,535

(4,003,138)

(1,233,743)

Sale of

preferred

stock, net of

offering

costs of

\$76,500 (note

8) 3,123,468

-- 3,123,500

Issuance of

common stock

at conversion

of notes and

interest

payable (note

8) 492,085 --

492,497

Issuance of

common stock

at conversion

of notes

payable (note

8) 83,930 --

84,000

Issuance of

common stock

to settle

obligations

(notes 1 and

6) 1,201,664

-- 1,202,160

Issuance of

common stock

for

acquisition

(note 1)

9,325,769 --

9,332,769

Issuance of

warrants for

acquisition

(note 1)

4,767,664 --

4,767,664

Stock issued

for

acquisition

costs (note

1) 487,350 --

487,500  
 Expense  
 related to  
 stock  
 warrants  
 issued (note  
 8) 140,000 --  
 140,000  
 Dividends  
 payable on  
 preferred  
 stock  
 (85,000) --  
 (85,000)  
 Cashless  
 exercise of  
 warrants  
 (note 8)  
 (599) -- --  
 Net loss --  
 (3,701,084)  
 (3,701,084) -  
 -----  
 -----

-----  
 Balances at  
 December 31,  
 2000  
 22,299,866  
 (7,704,222)  
 14,610,263  
 Dividends  
 payable on  
 preferred  
 stock  
 (256,000) --  
 (256,000)  
 Repurchase of  
 warrants  
 (note 8)  
 (55,279) --  
 (55,279) Sale  
 of warrants  
 (note 8)  
 47,741 --  
 47,741  
 Cashless  
 exercise of  
 warrants  
 (note 8)  
 (219) -- --  
 Issuance of  
 common stock  
 to pay  
 preferred  
 dividends  
 (note 8)  
 212,907 --  
 213,000  
 Detachable  
 warrants  
 issued with  
 notes payable  
 (note 6)  
 450,000 --  
 450,000  
 Issuance of  
 warrants to  
 pay operating  
 expenses  
 (note 8)  
 167,138 --  
 167,138  
 Issuance of  
 common stock  
 to pay  
 operating  
 expenses  
 (note 8)  
 387,165 --  
 387,271



Issuance of  
 preferred  
 stock to pay  
 operating  
 expenses  
 (note 8)  
 136,499 --  
 136,500 Net  
 loss --  
 (16,339,120)  
 (16,339,120)

-----  
 -----  
 -----  
 Balances at  
 December 31,  
 2001  
 23,389,818  
 (24,043,342)  
 (638,486)  
 =====  
 =====  
 =====

See accompanying notes to consolidated financial statements.

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

INCEPTION  
 (JUNE 12,  
 1996) YEAR  
 ENDED  
 DECEMBER 31,  
 THROUGH ----  
 -----  
 -----  
 -- DECEMBER  
 31, 2001  
 2000 2001 --  
 -----  
 -----  
 -- Cash  
 flows from  
 operating  
 activities:  
 Net loss  
 \$(16,339,120)  
 (3,701,084)  
 (24,538,945)  
 Adjustments  
 to reconcile  
 net loss to  
 net cash  
 used in  
 operating  
 activities:  
 Depreciation  
 and  
 amortization  
 7,617,673  
 1,907,341  
 9,607,189  
 Amortization  
 of debt  
 discount  
 54,439 --  
 54,439  
 Impairment  
 loss - write  
 off of  
 goodwill  
 5,702,130 --  
 5,702,130

Expenses paid by warrants	167,138	--	167,138
Expenses paid by preferred stock	136,500		136,500
Expenses related to stock warrants issued	140,000	--	612,000
Expenses paid by issuance of common stock	387,271		211,209
	598,480		
Equity in loss of subsidiary	-	--	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	12,386		(81,382)
	(81,382)		(143,257)
Increase (decrease) in accounts payable and accrued liabilities	550,482		(624,376)
	(624,376)		75,343
Increase in sponsored research payable and license obligation	-	--	924,318
-----			
-----			
Net cash used in operating activities	(1,711,101)		(2,148,292)
	(2,148,292)		(6,447,042)
-----			
-----			
Cash flows			

from  
 investing  
 activities:  
 Purchase of  
 certificate  
 of deposit -  
 -  
 (1,016,330)  
 (1,016,330)  
 Maturity of  
 certificate  
 of deposit  
 1,016,330 --  
 1,016,330  
 Purchases of  
 property and  
 equipment  
 (16,093)  
 (3,745)  
 (103,723)  
 Payment on  
 obligation  
 under  
 license  
 agreement --  
 -- (106,250)  
 Cash  
 acquired in  
 acquisition  
 of  
 subsidiary -  
 - -- 64,233  
 Issuance of  
 notes  
 receivable -  
 related  
 party  
 (35,000) --  
 (35,000)  
 Payments on  
 note  
 receivable -  
 - -- 370,000  
 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  
 (used in)  
 investing  
 activities  
 965,237  
 (1,020,075)  
 309,310 ----  
 -----  
 -----  
 -----  
 Cash flows  
 from  
 financing  
 activities:  
 Proceeds

from sale of preferred stock --	3,200,000
Proceeds from sale of common stock --	1,935,965
Proceeds from sale of warrants	47,741
Repurchase of warrants (55,279) --	(55,279)
Payment of financing and offering costs --	(76,500)
Payments of notes payable and long-term debt --	(17,718)
Proceeds from issuance of notes payable and detachable warrants	450,000
	472,000
	1,344,718
	-----
	-----
Net cash provided by financing activities	442,462
	3,577,782
	6,302,208
	-----
	-----
Net increase (decrease) in cash and cash equivalents	(303,402)
	409,415
164,476 Cash and cash equivalents at beginning of period	467,878
	58,463
	-----
	-----
Cash and cash equivalents at end of period \$	164,476
	467,878
	164,476
	=====

=====  
=====  
See accompanying notes to consolidated financial statements.

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BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY

(A Development Stage Enterprise)

Notes to Consolidated Financial Statements

December 31, 2001 and 2000

(1) DESCRIPTION OF THE COMPANY

Biokeys Pharmaceuticals, Inc., a Delaware corporation, formerly known as BioQuest, Inc. (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) and University of Southern California (USC), the Company has rights to drug candidates in varying early stages of development.

On October 10, 2000, a wholly owned subsidiary of BioQuest, Inc. merged with Biokeys, Inc. (Biokeys) of San Diego, California (see note 3). BioQuest, Inc. (BioQuest) changed its name to Biokeys Pharmaceuticals Inc. Pursuant to the merger, Biokeys shareholders received 6,999,990 shares of BioQuest common stock, representing 49.9999% of the total common stock of BioQuest outstanding upon consummation of the merger. Shareholders of BioQuest maintained 50.0001% of the shares of the combined entity and the combined entity retained the management of BioQuest. All previously outstanding Biokeys shares were canceled, and all outstanding Biokeys warrants were replaced with warrants to purchase a total of 1,468,018 shares of Company common stock at \$0.49 per share expiring December 15, 2003, representing 50% of the outstanding warrants to purchase common stock upon consummation of the merger. A Biokeys liability was settled through the issuance of 8,727 shares of Company common stock. The Company issued 150,000 shares of common stock in payment of certain direct acquisition costs. The officers and directors of BioQuest have continued as the officers and directors of the Company after consummation of the merger. For financial reporting purposes, the merger was accounted for as a purchase and BioQuest was considered the acquirer for accounting purposes. Biokeys operating activity is included in the Company's consolidated financial statements from the date of the merger.

The Company's shares trade in the over-the-counter market and are quoted in the so-called "pink sheets" 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. 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.

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(Continued)

BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY

(A Development Stage Enterprise)

Notes to Consolidated Financial Statements

December 31, 2001 and 2000

The most significant accounting estimates relate to valuing equity transactions. 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. Preferred stock is valued at the liquidation value of \$1,000 per share.

ACCOUNTING FOR STOCK-BASED COMPENSATION

The Company applies Accounting Principles Board Opinion No. 25 and related interpretations in accounting for employee stock-based compensation, and includes the required footnote disclosures of Statement of Financial Accounting Standards No. 123.

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.

CASH EQUIVALENTS

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

FINANCIAL INSTRUMENTS

The carrying amounts of cash and cash equivalents, certificate 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, 2001 was not determinable. The Company maintains cash, cash equivalents, and certificates of deposit 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 and \$1,900,709 during the years ended December 31, 2001 and 2000, respectively. 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.

BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY

(A Development Stage Enterprise)

Notes to Consolidated Financial Statements

December 31, 2001 and 2000

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 date.

#### RESEARCH AND DEVELOPMENT COSTS

All research and development costs are expensed as incurred and include Company-sponsored research and development.

#### LICENSE AGREEMENTS

Costs of license agreements for patent rights and technology rights that currently have no alternative future uses are expensed as research and development costs.

#### IMPAIRMENT OF LONG-LIVED ASSETS

In the event that facts and circumstances indicate that property and equipment and intangible or other noncurrent assets 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 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.

### BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY

(A Development Stage Enterprise)

Notes to Consolidated Financial Statements

December 31, 2001 and 2000

#### COMMON STOCK

On June 20, 2000, the Company effected a reverse stock split of its common stock of approximately 1.9899 to 1. All share and per-share information included in the accompanying consolidated financial statements and related notes has been adjusted to reflect the stock split.

#### RECLASSIFICATIONS

Certain amounts presented in the accompanying consolidated financial statements for 2000 have been reclassified to conform with the presentation used for 2001.

SUPPLEMENTARY CASH FLOW INFORMATION

Interest of \$0 and \$3,000 was paid during 2001 and 2000, respectively. No income taxes were paid during 2001 and 2000.

Noncash investing and financing transactions excluded from the statements of cash flows for the years ended December 31, 2001 and 2000 are as follows:

2001	2000
-----	
-----	
Issuance of common stock to pay preferred dividends (note 8) \$ 213,000 --	
Detachable warrants issued with notes payable (note 5) 450,000 --	
Issuance of warrants, common stock, and preferred stock to pay operating expenses (note 8) 690,909 140,000	
Dividends payable (note 8) 256,000 85,000	
Cashless exercise of warrants (note 8) 219 599	
Conversion of notes payable and accrued interest into common stock (note 8) - 84,000	
Issuance of common stock to settle obligations (note 6) - -	
1,172,490	
Issuance of common stock for acquisition (note 1) - -	
9,332,769	
Issuance of warrants	



for  
acquisition  
(note 1) -  
-  
4,767,664  
Acquisition  
liability  
settled  
with stock  
(note 1) -  
- 29,670  
Issuance  
of common  
stock for  
direct  
costs of  
acquisition  
(note 1) -  
- 487,500  
Issuance  
of common  
stock at  
conversion  
of notes  
and  
interest  
payable  
(note 8) -  
- 492,497  
Acquisition  
of  
Biokeys,  
Inc.:  
Other  
assets --  
5,812  
Current  
liabilities  
-- 582,260

BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY

(A Development Stage Enterprise)

Notes to Consolidated Financial Statements

December 31, 2001 and 2000

NEW ACCOUNTING PRONOUNCEMENTS

The Financial Accounting Standards Board (FASB) has issued Statement of Financial Accounting Standards No. 141, BUSINESS COMBINATIONS (SFAS No. 141). SFAS No. 141 eliminates the pooling of interests method of accounting and requires that all business combinations initiated after June 30, 2001 be accounted for under the purchase method. Adoption of SFAS No. 141 had no material impact on the Company.

The FASB has also issued Statement of Financial Accounting Standards No. 142, GOODWILL AND OTHER INTANGIBLE ASSETS (SFAS No. 142), which will be 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. Adoption of SFAS No. 142 will result in the elimination of annual amortization expense related to goodwill. The Company does not expect the adoption of SFAS No. 142 will have a material impact on its business because, as of December 31, 2001, it has 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 will 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 will be effective for the Company as of January 1, 2002. The Company does not expect the adoption of SFAS No. 144 will have a significant impact on its financial condition or results of operations.

BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY

(A Development Stage Enterprise)

Notes to Consolidated Financial Statements

December 31, 2001 and 2000

(3) ACQUISITION OF BIOKEYS, INC.

On October 10, 2000, the Company merged with Biokeys, Inc. (see note 1). The cost of the acquisition follows:

Value of 6,999,990 shares of common stock	\$ 9,332,769
Value of warrants to purchase 1,468,018 shares of common stock, including warrants to purchase 103,904 shares of common stock to settle Biokeys, Inc. obligations at closing	4,767,664
Value of common stock issued to settle Biokeys, Inc. liability at closing	29,670
Direct costs of acquisition	580,850
	-----
	\$14,710,953
	=====

The value of the 6,999,990 shares of common stock is based on the average closing price of BioQuest's common stock between the dates the acquisition was agreed to and announced. The value of the warrants to purchase 1,468,018 shares of common stock was based on the Black-Scholes pricing model with assumptions of expected life of 3.2 years, risk-free interest rate of 5.91%, volatility of 160%, and no dividends.

The cost of the acquisition has been allocated on the basis of the estimated fair value of the assets acquired and liabilities assumed. This allocation resulted in goodwill of \$15,205,675, which was being amortized using the straight-line method over two years. In connection with the acquisition, net liabilities were assumed by the Company as follows:

Other assets	\$ 5,812
Current liabilities	(500,534)
	-----
	\$(494,722)
	=====

## BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY

(A Development Stage Enterprise)

## Notes to Consolidated Financial Statements

December 31, 2001 and 2000

The following unaudited pro forma results of operations for the year ended December 31, 2000 have been prepared as though the merger occurred January 1, 2000. The pro forma results include amortization of goodwill arising from the merger of \$1,900,709 per quarter. This pro forma information is not necessarily indicative of any future results of the Company.

Interest income	\$ 40,922
Operating expenses	(11,706,535)
	-----
Net loss	\$(11,665,613)
	=====
Loss per common share	\$ (0.83)
	=====
Weighted average number of common shares outstanding	14,027,144
	=====

## (4) PROPERTY AND EQUIPMENT

Property and equipment at December 31, 2001 and 2000 were as follows:

USEFUL LIVES 2001 2000 ----- ----- -- ----- -- ---- Office furniture and equipment 5 years \$ 32,198 13,420 Computer software and equipment 3 years 9,160 11,845 ---- ---- ----- -- 41,358 25,265 Less accumulated depreciation and amortization (27,746) (18,909) -- ----- ---- \$ 13,612 6,356 =====
---

## (5) NOTES PAYABLE

At December 31, 1999, the Company had overdue unsecured promissory notes payable to investors in the principal amounts of \$80,000 and \$17,718, bearing interest at 8% and 12% per annum, respectively. The notes had

original maturity dates of November 30, 1999 and July 31, 1999, respectively, but the investors agreed to forbear any action to collect the notes in 1999. The two notes were paid in full, including accrued interest, during 2000. The \$80,000 note and accrued interest were converted to common stock (see note 8). The \$17,718 note and accrued interest were repaid with cash.

## BIOKEYS PHARMACEUTICALS, INC. AND SUBSIDIARY

(A Development Stage Enterprise)

## Notes to Consolidated Financial Statements

December 31, 2001 and 2000

In October and December 2001, the Company issued notes payable totaling \$300,000 and \$150,000 respectively. The notes bear interest at 12% and are 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 will be paid in shares of common stock when the notes are 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. 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. Of the original debt discount of \$450,000, \$54,439 was amortized during 2001. The discount is being amortized to the redemption value of the debt through the stated due date of the notes payable.

## (6) 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, 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.

December 31, 2001 and 2000

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, 2001 and 2000. 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.

(7) 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.

Biokeys has entered into an SRA with USC under which USC will continue studies in the therapeutic potential of Thiovir and its analogues as anti-viral agents. The Company has entered into a grant agreement with USC effective November 1, 2000, under which USC will perform research into Thiovir and its analogues as inhibitors for HPV and other pathogenic viruses. The budgeted research costs for this study are approximately \$217,000, which sum has been paid and expensed by the Company in 2000.

(8) EQUITY TRANSACTIONS

In August 1999, the Company borrowed \$80,000 from two investors who had previously purchased common stock. The notes issued to the investors were due in November 1999 and carried interest at an annual rate of 8%. The Company issued warrants to purchase 40,202 shares of common stock at \$0.49 per share to the investors as part of the same transaction. The notes, which were due November 30, 1999, were repaid in March 2000 through the conversion of principal and interest into common stock at \$1.19 per share and the issuance of additional warrants to purchase 40,202 shares of common stock at \$0.49 per share.

In November and December 1999, the Company agreed to sell to four investors a total of 678,412 shares of its common stock at a price of approximately \$0.20 per share for a total of \$135,000. Each share was accompanied by a warrant to purchase shares of common stock at an exercise price of \$0.40 cents per share. The warrants were exercised in March 2000 under a provision permitting cashless exercise, with 599,066 shares being issued to the holders as a result of such exercise.

Beginning in April 2000, the Company sold an aggregate of \$472,000 principal amount of 8.5% subordinated convertible promissory notes in a private placement offering to accredited investors. The principal amounts of the notes, together with accrued interest of \$20,497, was converted into shares of common stock at a conversion price of \$1.19 per share, effective as of the consummation of the merger between the Company and Biokeys.

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 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 May 2000, the Company issued warrants to two of its research scientists for the purchase of a total of 100,506 shares of common stock. The fair value of the warrants on the date of issue, \$140,000, has been recorded as a noncash research and development expense. The warrants are exercisable at \$0.49 per share and expire in May 2003. No such warrants have been exercised as of December 31, 2001.

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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 and sold the same warrants in June 2001. The warrants



0.49  
September  
2005  
33,333  
3.00 April  
2006  
502,528  
0.49 June  
2006  
450,000  
4.00\*  
November  
2006  
17,063  
5.00  
December  
2006

\*Subject to repricing, see note 5.

(9) NOTE RECEIVABLE - RELATED PARTY

In August 2001, the Company loaned \$35,000 to a company whose owner is also the co-founder of Biokeys. The note accrues interest at prime plus one percent (5.75% at December 31, 2001). The note receivable on the consolidated balance sheet includes accrued interest.

(10) INCOME TAXES

Significant components of income tax expense for the years ended December 31, 2001 and 2000 are as follows:

2001	
2000	---
-----	-
-----	-
Deferred	
tax	
benefit	
\$	
799,623	
487,617	
Increase	
in	
valuation	
allowance	
for	
deferred	
tax	
assets	
(799,623)	
(487,617)	
-----	
-	-----
---	
Income	
tax	
expense	
\$	---
=====	
=====	

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The tax effects of temporary differences that give rise to deferred tax



assets at December 31, 2001 and 2000 are as follows:

2001	2000	-
		-----
		-----
		Net
		operating
		loss
		carryforward
\$ 3,436,311		
2,642,171		
		Organization
		costs and
		license
		agreement,
		due to
		differences
		in
		amortization
44,538		
39,055		----
		-----
		-----
		Total
		deferred
		tax assets
3,480,849		
2,681,226		
		Less
		valuation
		allowance
(3,480,849)		
(2,681,226)		
		-----
		-----
		Net
		deferred
		tax assets
\$ --		--
		=====
		=====

At December 31, 2001, the Company had an unused net operating loss carryforward of approximately \$10,107,000 for tax reporting purposes, which expires in 2111 through 2112 and 2118 through 2121. Included in the 2000 carryforward is a net operating loss carryforward acquired from Biokeys, Inc. of approximately \$3,475,000.

(11) NET LOSS PER COMMON SHARE

The computation of basic and diluted net loss per share for the years ended December 31, 2001 and 2000 is as follows:

2001	2000	--
		-----
		-----
		Numerator:
		Net loss
\$(16,335,346)		
(3,701,084)		
		Less
		preferred
		stock
		dividends
(256,000)		
(85,000)		----
		-----
		-----
		Numerator
		for basic
		and diluted
		loss per
		share
(16,591,346)		
(3,786,084)		
		=====
		=====
		Denominator
		for basic

and diluted  
loss per  
share -  
weighted  
average  
shares  
14,805,150  
8,582,707  
=====

=====

Loss per  
common share  
- basic and  
diluted \$  
(1.12)  
(0.44)  
=====

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, 2001 and 2000, 3,826,409 and 4,022,331 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 2001 and 2000.

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Notes to Consolidated Financial Statements

December 31, 2001 and 2000

(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 \$16,335,346 and \$3,701,084 for the years ended December 31, 2001 and 2000, respectively.

To date, 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 2002. 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 December 2002 are dependent upon obtaining additional financing.

(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.

## OPERATING LEASES

The Company has operating leases for office space and equipment. A lease for office space expired in November 2000 and is currently being paid on a month by month basis. Rent expense was \$51,609 and \$23,500 during the years ended December 31, 2001 and 2000, respectively.

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